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Oral Presentations

OP001 Cross Border Cooperation On High-Cost-Capital Investments In Health

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ABSTRACT SUMMARY:
The provision of capital investment goods such as medical scanners and radiotherapy units in the European Union (EU) shows a high variability in provision and utilization rates as well as a large share of health budgets. The objective for this study was to contribute to effective cross-border cooperation between EU-Member States by pooling resources for high-cost medical equipment investments.

INTRODUCTION:
The medical equipment sector is characterized by a large share of overall health budgets spent for the provision of capital investment goods such as medical scanners and radiotherapy units. A high variability in provision and utilization rates of medical equipment can be observed too.

METHODS:
Potential cost-intensive and highly specialized medical equipment, where cross-border investment resource pooling may be recommended, were identified by a combined evidence search and expert consultation. An efficiency assessment of medical equipment potential savings for EU-countries was done by a benchmark-approach and a best-practice-approach. Furthermore six examples for cross-border cooperation were investigated and two surveys have been conducted.

RESULTS:
The following medical equipment can be considered as cost-intensive and highly specialized across EU-Member States: Magnetic Resonance Imaging (MRI) scanners, Computed Tomography (CT) scanners, Stereotactic systems and Surgical robots.

The efficiency assessment using the benchmark approach was performed for MRI, CT scanners, Positron Emission Tomography (PET) scanners, Angiography units, Gamma cameras and Lithotriptors. The results of the best-practice approach showed potential cost savings due to under- or overutilization per device group and EU-Member State. However, as this analysis offers a view on health systems on a very macro level it was not possible to give detailed insights at the country-level.

The six selected cross-border examples demonstrated a wide variety of options regarding the structure, extent and organization of cross-border cooperation: Five of six cross-border examples were cooperation close to the border, in four of six examples EU funds played an important role.

CONCLUSIONS:
The study highlighted that cross-border cooperation in the field of cost-intensive/highly specialized medical equipment could bring economic advantages for many EU-Member States.
States. Despite this, still only little is done by EU-Member States in terms of cooperation. Reasons are diverse and can be ascribed to lacking information, differences of national health systems, organizational and administrative hurdles, differences of national health systems, organizational and administrative hurdles and lacking political support.

REFERENCES:

INTRODUCTION:
The changing regulatory landscape brings new challenges to health technology assessment (HTA). Marketing authorizations are being granted as the evidence base evolves to facilitate timely patient access to promising health technologies. Consequently, some products come to HTA bodies sooner in their development cycles with less evidence, which ultimately leads to greater uncertainty in decision making. A key challenge for payer and HTA bodies is providing access to promising medicines while the evidence is still emerging, in a financially sustainable way.

METHODS:
Changes to the Cancer Drugs Fund (CDF) have resulted in a managed access fund for cancer medicines in England. The National Institute for Health and Care Excellence (NICE) can now recommend a treatment for use within the CDF if there is plausible potential to satisfy the criteria for routine use in the National Health Service (NHS) at its current price, but the evidence is not robust enough and associated with significant uncertainty. Further evidence is then generated in clinical trials, through observational data collection, or a combination of the two, while the drug’s price reflects the decision uncertainty. At the end of the managed access period, NICE reviews the guidance to determine if the treatment can be recommended for routine commissioning.

RESULTS:
The first treatment recommended for use within the new CDF was osimertinib for non-small cell lung cancer (1). At the time of NICE appraisal, there was considerable uncertainty in osimertinib’s clinical and cost effectiveness because only short-term phase II trial results were available. NICE’s independent appraisal committee considered there was plausible potential for osimertinib to be cost effective and identified that an ongoing phase III trial would provide longer-term data addressing the key uncertainties.
OP003 Trends In The National Institute for Health and Care Excellence (NICE) Cancer Drugs Fund Reconsiderations

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ABSTRACT SUMMARY:
As of July 2016, funding from England’s Cancer Drugs Fund (CDF) (1) is dispensed based on the results of National Institute for Health and Care Excellence (NICE) technology appraisal guidances (2) instead of independent CDF appraisals. This study looked at trends in NICE’s reconsiderations of drugs previously funded through the CDF.

INTRODUCTION:
As of July 2016, funding from England’s Cancer Drugs Fund (CDF) is dispensed based on the results of National Institute for Health and Care Excellence (NICE) technology appraisal guidances instead of independent CDF appraisals (1). As part of this transition, NICE is reconsidering drugs previously funded through the CDF (2). This analysis examines CDF reconsiderations conducted between the inception of the new process in July and the end of 2016 to identify any possible trends.

METHODS:
We collected all NICE final technology appraisal guidances (3) completed before the end of 2016 and noted whether each drug was a CDF reconsideration, what the final decision was, and which factors impacted the decisions.

RESULTS:
We identified twenty-one NICE oncology reviews competed between July 2016 and the end of 2016. Of these reviews, eight were reconsiderations of drugs previously funded through the old CDF; the rest were new reviews. Only one drug evaluated in the reconsiderations received a negative decision. All the reconsiderations included confidential manufacturer discounts and all noted updated clinical data. End of life (EOL) criteria expanded the acceptable incremental cost-effectiveness ratio (ICER) range for some of the CDF reconsiderations.

CONCLUSIONS:
All the reconsiderations included updated clinical data and analyses, though it does not appear that updated clinical data were sufficient to bring ICERs to acceptable levels. This is to be expected as the old CDF process served as an alternate funding source for many drugs that did not or were unlikely to fare well under NICE’s evaluations. The updated clinical data may have at least increased NICE’s confidence in the accuracy of the ICERs. All of the reconsiderations included confidential manufacturer discounts to reach acceptable ICER ranges. The results of this first round of reconsiderations suggest that manufacturers prefer offering their drugs at lower prices to potentially losing National Health Service (NHS) reimbursement entirely.
OP004 Lessons Learnt When Implementing A Health Technology Assessment Institution In Costa Rica

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ABSTRACT SUMMARY:
There are no experiences of HTA organised initiatives in Central American countries. The present abstract explores the methods, challenges, enablers and barriers to the implementation of a structured and organized HTA national body in Costa Rica. The initiative took into account the voices of different stakeholders including the ministry for health, providers, purchasers, citizens, health professionals and industry.

INTRODUCTION:
Faced with increasing financial challenges to the single-payer social security system and constitutional challenges supporting all citizen’s right to health, Costa Rica has endeavored to introduce Health Technology Assessment (HTA) to ensure sustainability and promote the timely introduction of technology innovations in the health system. The Ministry of Health initiated a process to establish an independent, external institution providing leadership in the process of HTA.

METHODS:
Based on a survey developed by REDETSA/PAHO (HTA Network of the Americas/Pan American Health Organization), an inclusive method of stakeholders participation was used to analyze the strengths, weaknesses, opportunities and threats regarding the implementation of an HTA entity. This was combined with qualitative research methods, market access situation analysis and the review of coverage and provision processes to define the elements for the new HTA institution. The “in-depth” interviews extended to manufacturers, ministry representatives, services providers, purchasers, patients and citizens representatives, judiciary court, professional colleges, academia and non-governmental organizations (NGOs). Analysis of the professional competencies required for the HTA institution was carried out based on best practice analysis of international HTA institutions.

RESULTS:
The implementation of an HTA unit in Costa Rica was identified by all the actors as crucial to ensuring the health system’s sustainability. Costa Rica’s health system is based on all citizens right to health and all inputs required delivering health services, judicialization and access to health care have become a big issue. Two main issues were identified as essential to implement an HTA

REFERENCES:
institution: the establishment of a clear framework to provide legal and financial support and the need to have sufficient independence from the Ministry and the Social Security, including maximum transparency and methodological robustness.

CONCLUSIONS:
The business model for the new HTA institution should consider the participation of all the interested actors. The HTA institution should bridge the gap between technology regulation and health technology management and aim to improve both processes. It should also provide third party independent evidence to inform the constitutional court around health care claims.

OP005 Non Invasive Prenatal Test (NIPT) For Identification Of Trisomy 21, 18 And 13 In Norway

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ABSTRACT SUMMARY:
We summarize research of diagnostic test accuracy of a Non Invasive Prenatal Test (NIPT) compared with the current screening with ultrasound (CUB). In addition, we analyze health economic implications and highlight ethical consequences related to the national introduction of NIPT for detection of trisomy in pregnant women.

INTRODUCTION:
Currently, screening for trisomy 21,18 and 13 in Norway is based on a combination of blood tests and ultrasound (CUB) offered to all pregnant women 38 years of age or older. Genetic verification via an invasive diagnostic test is offered either through chorionic villus sampling or amniocentesis. Non-Invasive Prenatal Testing (NIPT) (1) measures the underlying genetic pathology of trisomies directly by analyzing fetal genetic material in the maternal circulation (cell-free fetal DNA, cfDNA). Diagnostic sensitivity and specificity are technical characteristics of a test, which specify the ability of the test to identify healthy and diseased individuals in a group.

METHODS:
We searched for systematic reviews. Search strategies were designed for selected relevant databases, and were based on a combination of subject headings and text words for NIPT. Searches were limited to the period of 2010 to 2015. Two reviewers critically appraised the selected publications. We investigated the outcomes diagnostic test accuracy, predictive values and inconclusive results, and compared the combined test with NIPT in a clinical setting. We performed a cost-effectiveness analysis (CEA) to estimate health economic consequences of different scenarios and look at ethical consequences.

RESULTS:
NIPT is a more accurate test for detecting trisomy than the CUB that is in use in Norway today. A program with NIPT as a secondary test after CUB will result in fewer invasive tests and be more expensive than the current screening in Norway. A program with NIPT as a primary test instead of CUB will also result in fewer invasive tests, but will be more expensive than both the current screening and if NIPT is used as secondary screening test. NIPT is a test that challenges the underlying rationale for why and how we as a community and health service want to organize the fetal diagnostic services in Norway.
CONCLUSIONS:
The number of invasive tests is considerably reduced in all alternative health economic scenarios involving NIPT compared with current CUB screening practice. The scenario with NIPT as a secondary screening test, offered to the intermediate risk group of pregnant women is more effective than the current CUB screening.

REFERENCES:

INTRODUCTION:
Rapid technological innovation is leading to new health technologies and interventions becoming available to healthcare markets at increasing speed; these often cost more than current alternatives and significantly affect the cost of healthcare services and delivery (1). Identifying future technologies supports service preparedness, long-term planning, and strategic decision making. The aim of this study was to describe and classify health technologies predicted in fifteen forecasting studies according to their type, purpose and clinical use, and relate these to the original purpose and timing of the forecasting studies.

METHODS:
This was a descriptive study of predicted healthcare technologies identified in fifteen forecasting studies included in a previously published systematic review (2). Outcomes related to (i) each forecast study including country, year, intent and forecasting methods used, and (ii) the predicted technology type, purpose, targeted clinical area and forecast timeframe.

RESULTS:
We identified 896 predicted health-related topics, of which 685 were health technologies. Of these, 19.1 percent were diagnostic or imaging tests and 14.3 percent devices or biomaterials; 38.1 percent were intended to treat or manage disease and 21.6 percent to diagnose or monitor disease. The most frequent targeted clinical areas were infectious diseases followed by cancer, circulatory and nervous system disorders. The mean timeframe for technology forecast was 11.6 years (Standard Deviation, SD = 6.6). The forecasting timeframe significantly differed by technology type (p = .002), the intent of the forecasting group (p < .0001), and the methods used (p < .0001).

CONCLUSIONS:
Our description and classification of predicted health-related technologies from prior forecasting studies provides an overview of the technological
and clinical frontiers of innovation in health and healthcare provision.

REFERENCES:


OP007 Towards Better Outcomes: New Standard For Placing A Value On Health

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ABSTRACT SUMMARY:
There are major issues related to current economic evaluations, in particular the measurement of health effects. New health measurement methods that address the violations and biases associated with the existing methods are needed. We present the first generic health preference-based measurement system that is fully based on the perception and reporting from patients (experienced based).

INTRODUCTION:
Cost-effectiveness analysis is probably the most often applied analysis in the field of Health Technology Assessment. Yet, there are major issues related to this analytical approach. Apart from the discussions about discounting, and which type of costs should be included in the analysis, there is discussion about the measurement of the health effects. The dominant economic and decision-making research paradigm that underpins present protocols to value health show flaws and limitations.

METHODS:
All existing generic health instruments (e.g. EuroQol five dimensions questionnaire, EQ-5D; Health Utilities Index, HUI; Short Form, SF-6D) used to collect values for health states use a small, fixed set of health domains. Descriptions of health states are created based on these domains and their levels. Subsequently, these descriptions are valued with special preference-based methods (measuring the quality or importance of something). When developing those instruments, patients’ opinions were not actively incorporated in the choice of domains, nor have patients’ preferences been considered in assessing weights to the domains and their levels.

RESULTS:
We developed a novel preference-based health measurement methodology that combines the strength of two existing measurement models for subjective phenomena: the discrete choice model and Rasch item response theory (1-3). This new approach is referred to as the multi-attribute preference response (MAPR) model. This is the first generic health preference-based model that is fully based on the perception and reporting from patients (experienced based) and is insensitive to adaptation mechanisms. Apart from being grounded on measurement theory, the valuation tasks are easy and attractive to perform in a self-completion setting. A first application based on this novel model has been worked out in a mobile app to measure the overall health condition of infants (reported by mothers) (1-3).

CONCLUSIONS:
Our recently introduced and informative health measurement model overcomes many problems associated with the conventional methods.

REFERENCES:
OP008 National Institute for Health Research HTA Programme Research Funding And UK Burden Of Disease

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ABSTRACT SUMMARY:
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme regularly compares its active funded portfolio against Disability-Adjusted Life Years (DALYs) during the prioritisation and funding of research within the programme’s remit. This ensures the NIHR HTA programme funded research portfolio, approximately GBP400m within a five-year period, broadly reflects the disease burden in the UK.

INTRODUCTION:
This study compared the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme portfolio of research with the UK burden of disease, as measured by Disability-Adjusted Life Years (DALYs).

METHODS:
Design: Cross-sectional study.

Setting: The HTA Programme cohort included all funded applications (n=363) received by the HTA Programme during the period 1 April 2011 to 31 March 2016. The sample contained primary research and evidence syntheses, all purely methodological studies were excluded since these are not comparable to the other study types.

Main Outcome Measure: Proportion of spend for each of the twenty-one Health Research Classification System (HRCS) health categories were compared with burden of disease in the UK calculated using 2015 DALY data from the Institute for Health Metrics and Evaluation (IHME) Global Health Data Exchange (GHDx).

RESULTS:
The funded HTA Programme projects totalled about GBP397m research spend, which broadly reflected the UK DALY burden. Overall, there was less than 5 percent difference between the actual and predicted programme spend based on the burden of disease in the UK in most instances (seventeen out of the twenty-one HRCS Health Categories).

The largest categories of apportioned spend were Cancer (accounting for 12.1 percent of portfolio), and Mental Health (11.8 percent of portfolio) which particularly reflected the 9.8 percent burden of disease to the UK. Most notable deviations from DALY, where spend was lower than disease burden, were in the Cancer, Cardiovascular and Musculoskeletal categories; which may reflect the importance of other, notably charity, funding.

CONCLUSIONS:
The HTA Programme spend broadly aligns with burden of disease as measured using DALYs. Discrepancies were expected owing to the programme remit and its approach to commissioning research to address market failure particularly in areas that are not already well
supported by research charities or industry. Regular review of DALY data during research prioritisation and commissioning allows the HTA Programme to identify and address shortfalls in disease areas and to balance its portfolio.

OP009 Quantifying Bias Of Existing Human Immunodeficiency Virus (HIV) Models Using Empirical Cascade Data

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ABSTRACT SUMMARY:
Optimism towards eliminating HIV through ambitious policies and its cost-effectiveness was emboldened by the promise of the test-and-treat model and health benefit projections produced by several mathematical models. This paper quantifies the magnitude of overestimation of health benefits from policy changes when models do not incorporate real-life barriers of care delivery in modeling HIV epidemics.

INTRODUCTION:
Current optimism regarding prospects for eliminating Human Immunodeficiency Virus (HIV) by expanding antiretroviral treatment has been emboldened in part by projections from several mathematical modeling studies. Drawing from a detailed empirical assessment of rates of progression through the HIV care cascade, this paper aims to quantify the extent to which models may overestimate health benefits from policy changes when they fail to incorporate a realistic understanding of the cascade.

METHODS:
We estimated rates of progression through stages of the HIV treatment cascade using data from a longitudinal population-based HIV surveillance system in rural KwaZulu-Natal, South Africa. Incorporating empirical estimates in a mathematical model of HIV progression, infection transmission, and care, we estimated mortality and secondary infections averted under a range of treatment scale-up scenarios, reflecting expanding treatment eligibility thresholds from CD4 200 to 350, 350 to 500, and 500 cells/mm3 to treating all HIV-positives irrespective of their CD4 count, and compared the results to those implied by the conventional assumptions that have been commonly adopted by existing models.

RESULTS:
Health benefits, namely years of life gained and HIV transmission averted, from expanding the treatment eligibility threshold from CD4 200 to 350 and 350 to 500 cells/mm3 may be overestimated by two to five-fold in models that fail to capture realities of the care cascade. In the case of raising the HIV treatment eligibility threshold from CD4 500 cells/mm3 to treating everyone irrespective of their CD4 count, which is the current WHO recommendation, health benefits gained from this policy change may be overestimated by approximately 15 to 21-fold.

CONCLUSIONS:
Health benefits projected from existing HIV models using conventional assumptions may be largely overestimated. As implementation of treatment scale-up proceeds, it is important to assess the effects of required scale-up efforts in a way that incorporates empirical realities of how people move through the HIV cascade.
**OP010 Myeloma Patient Value Mapping**  

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**ABSTRACT SUMMARY:**  
The purpose of this study was to evaluate myeloma patient preferences using a discrete choice experiment. Patients were invited to participate by Myeloma UK using email, social media, and support groups. The model revealed two classes of patients (segments) with different preferences for treatment attributes. Results were presented as an interactive dashboard.

**INTRODUCTION:**  
Myeloma is a life threatening hematological cancer. Although myeloma is responsive to treatments, there remains no cure. In recent years, there have been improvements in survival due to the use of high dose therapies, stem cell transplant, and other novel therapies. However, while myeloma patients are living longer, they are also living with symptoms and treatment side-effects. Therefore, myeloma patients face difficult decisions about the benefits and risks of treatment. The purpose of this study was to assess myeloma patient preferences for treatment.

**METHODS:**  
Participants were 475 myeloma patients in the United Kingdom. Data were collected using discrete choice experiments (DCEs) through an online survey. The DCEs presented patients with a traditional treatment choice experiment (for example, treatment A vs treatment B), focusing on the clinical benefits of treatments and the associated risks. The attributes and levels of the attributes were selected based on previous research, literature review, and expert opinion. The DCE data were modelled using a Latent Class Model (LCM), and the effect of demographic characteristics were also examined.

**RESULTS:**  
The LCM revealed two classes of patients (segments) with different preferences for treatment attributes. Patients in class 1 placed greater importance on overall survival and mild-to-moderate side effects, whereas patients in class 2 placed greater importance on how the treatment was administered and the average out-of-pocket costs. Patients living with others and those diagnosed in the last 5 years were more likely to be in class 1 than class 2.

**CONCLUSIONS:**  
This study demonstrated that not all myeloma patients valued the same treatment features equally. This has important implications for healthcare policy decisions and could be used to guide decisions around the value of new myeloma medicines. For example, to establish more patient-aligned endpoints in clinical trials or as evidence which is incorporated into the health technology assessment process.

**OP011 Structural Uncertainty In Economic Modelling For Smoking Cessation**  

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ABSTRACT SUMMARY:
We built a cohort state-transition and individual-level discrete event simulation to explore structural uncertainty in smoking cessation. The results show that the choice of model makes relatively little difference to the incremental cost-effectiveness ratio (ICER) but adding in relapse dramatically increases the ICER.

INTRODUCTION:
Guidance for developing economic models recommend that model structure is carefully considered, and assumptions varied in sensitivity analysis (1). Models in smoking cessation have typically used cohort-level approaches, although recently discrete event simulations (DESs) have been developed (2). DESs allow additional flexibility such as modelling changing risk over time, and recurrent events. Our aim was to explore the impact of varying model structure and assumptions on the cost-effectiveness of smoking cessation programs.

METHODS:
We built a cohort state-transition model which related mortality to smoking status and considered the prevalence (based on smoking status) of five comorbidities associated with smoking, each of which has an associated cost and quality of life decrement. We additionally built a patient-level DES, using the Discretely Integrated Condition Event framework (3). The DES used the same data as the cohort model, except considering incidence for comorbidities rather than prevalence. We considered a population of smokers aged 16 years old and an intervention costing GBP827 on which 27 percent of people quit, compared with no treatment. We produced results using the two models for comparable scenarios, and ran additional scenarios considering different assumptions.

RESULTS:
In the cohort model, the incremental cost-effectiveness ratio (ICER) for intervention versus no treatment was GBP4,000/quality-adjusted life year (QALY). In the DES, modelling mortality linked to smoker status produced an ICER of GBP1,000/QALY and modelling mortality linked to comorbidities produced an ICER of GBP6,000/QALY. In the DES with mortality linked to comorbidities, varying the relative risk of comorbidities with time since quitting gave an ICER of GBP3,000/QALY. Including relapse increased the ICER to GBP21,000/QALY.

CONCLUSIONS:
The ICER for the smoking cessation program changes when model assumptions are varied, although the choice of DES versus cohort model appears to make a relatively small difference. Inclusion of relapse substantially changes the ICER, demonstrating the importance of long-term effects in economic models.

REFERENCES:
OP012 Activity-Based Costing Methodologies And Time-Driven Activity-Based Costing Methods: A Systematic Review Of The Literature

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ABSTRACT SUMMARY:
Describe how Activity-Based Costing methodologies (ABC) and Time-Driven Activity-Based Costing (TDABC) have been applied to measurement and cost management in the cancer environment (prevention, diagnosis and treatment) in healthcare facilities. The use of costing methods for improving knowledge of financial information, correct guidance and management decision-making process is presented in the literature as essential for the institutions that target prospect value.

INTRODUCTION:
The objective of this research is to describe how Activity-Based Costing methodologies (ABC) and Time-Driven Activity-Based Costing (TDABC) have been applied to measurement and cost management in the cancer environment (prevention, diagnosis and treatment) in healthcare facilities.

METHODS:
It was included studies that used the method of Activity-Based Costing and/or Time-Driven Activity-Based Costing to estimate the costs related to cancer in studies of prevention, diagnosis and treatment of cancer.

The search for published articles was held in bases: Medline, ScieLO and Lilacs, Embase, using the following keywords: “cancer”, “Activity-Based Costing” and “Time-Driven Activity-Based Costing”.

There was no restriction as to the year of publication, but only have been accepted articles in Portuguese and/or in English.

RESULTS:
A total of 420 studies were evaluated. Only 26 studies fulfilled the eligibility criteria. The publications began in the year 2000, but the largest number of publications occurred in the year 2016 (n = 9). Regarding the country of origin of the studies, United States and Belgium are the ones that have the largest number of publications (five each).

The main focus of the publications was the cancer treatment (n = 19), followed by reviews of programmes (prevention) and diagnosis with 4 and 3 publications respectively. Among the treatments, radiation therapy and its different modalities was factor in more frequent study noted. Those results to can be explained by the presence of many equipment radiation environment, facilitating the collection of financial data by activity. In 57.6 percent of the studies, the clinical data has been extracted from retrospective studies. More than 50 percent of the studies did not specify the type of pharmacoeconomic analysis. The perspective adopted was of the hospital.

CONCLUSIONS:
The use of economic evaluations using the ABC methods and in the oncological setting TDABC, is emerging and presents opportunity to be exploited in the academic and practical environment.

The use of costing methods for improving knowledge of financial information, correct guidance and management decision-making process is presented in the literature as essential for the institutions that target prospect value through effective
OP013 Cost-effectiveness Analysis Of Non-invasive Prenatal Testing For Down Syndrome In China

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
This study aimed to evaluate the cost-effectiveness of non-invasive prenatal testing (NIPT) and provide evidence-based information for decision-makers in China. We concluded that implementing NIPT as an optional secondary screening test for those high risk women by maternal serum screening is the preferred option for prenatal screening of women with pregnancies affected by Down syndrome in China.

INTRODUCTION:
In China, prenatal screening of non-invasive prenatal testing (NIPT) for Down syndrome (DS) is used in some hospitals as a pilot. There is little evidence regarding to cost-effectiveness between NIPT and maternal serum screening (MSS). This study aimed to evaluate NIPT’s cost-effectiveness and provide evidence-based information for decision makers in China.

METHODS:
The cost-effectiveness analysis of NIPT for DS from a societal perspective was conducted, compared with current clinical practice. Cost of NIPT, MSS, genetic counseling, diagnostic testing and second trimester termination were considered. All variables were based on field surveys in four selected cities in China and a literature review using both an English and Chinese database. A decision-analytic model was developed to compare five different strategies with (i) No screening; (ii) Current clinical practice using MSS only; (iii) Implementing NIPT as an optional secondary screening test for those high risk women by MSS (the contingent screening strategy); and (iv) NIPT as primary screening test, replacing MSS.

RESULTS:
In current clinical practice, for a cohort of 10,000 pregnant women, NIPT as primary strategy can detect 10.39 DS births which was found to be the most effective. The contingent screening strategy dominated all other screening strategies however: it had the best cost effectiveness ratio ($56,434.06 per case averted of DS) with fewest procedure-related miscarriages (0.02 per 10,000 pregnancies) and can detect 9.15 DS births. Sensitivity analysis showed that if the price of NIPT decreases to $44.20 (current price is $552.49), NIPT as primary strategy would be the most cost effective.

CONCLUSIONS:
Implementing NIPT as an optional secondary screening test is the preferred option for prenatal screening of women with pregnancies affected by Down syndrome in China.

OP014 Health Utility Scores For Breast Cancer In China: A Multicenter Survey

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ABSTRACT SUMMARY:
High-level evidence on quality of life, especially utility scores, of breast cancer are still quite limited from both China and worldwide. This study estimated multi-state related utility scores of breast cancer and pre-cancer through a large-number (n=3,097) multicenter survey across China (twelve provinces). The results are expected to support quality of life improving in certain sub-groups and further cost-utility analysis.

INTRODUCTION:
Health related quality of life and utility score of female breast cancer was sparse in China. The objective of this study was to investigate the health utility scores associated with breast cancer and precancerous lesion in China.

METHODS:
A interviewer-administered, face-to-face, cross-sectional survey was conducted to female patients with breast cancer and precancerous lesion in twelve provinces across China during 2013–2014. The three-level EuroQol-5-Dimension (EQ-5D-3L) instrument was used and utility scores were generated using the Chinese value set. The influence of socio-demographic and clinical variables on utility scores was analyzed in the multiple linear regression.

RESULTS:
In total, 3,097 patients were included in this study (breast cancer: 2,626; precancerous lesion: 471), and the mean±standard deviation age was 48.7±10.6 years. Mean (95 percent Confidence Interval) utility scores for breast cancer and precancerous lesion were .89 (.87-.90) and .78 (.77-.79). The utility scores for clinical stage I, II, III, and IV of breast cancer were .79 (.77-.81), .79 (.78-.80), .77 (.76-.79), and .69 (.65-.72), respectively. In the multiple regression, shorter duration of education, lower annual household income, advanced clinical stage, under surgery therapy, and in the period of undergoing treatment were independently significant with lower utility scores of breast cancer.

CONCLUSIONS:
This study provides detailed utility scores for breast precancerous lesion and all stages of breast cancer in China, and scores varied by socio-demographic and clinical parameters, which are fundamental for further cost-utility analysis.

OP015 The Incremental Cost Of Delirium Following Aortic Valve Replacement

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ABSTRACT SUMMARY:
This analysis attempts to quantify the frequency and resource use implications of post-operative delirium following TAVR and SAVR procedures performed in the United States.

INTRODUCTION:
Postoperative delirium has been associated with poorer long term survival in Transcatheter aortic valve replacement (TAVR) and Surgical aortic valve replacement (SAVR) patients. However, its effect...
on hospitalization costs and length of stay in these populations has not been formally assessed.

**METHODS:**

Using the Medicare Provider Analysis and Review File, we retrospectively analyzed elderly (80 years of age and older) Medicare patients receiving TAVR and SAVR in the United States during the 2015 fiscal year. ICD-9-CM codes were used to identify post-operative delirium diagnoses. The incremental hospital resource consumption, measured as hospital cost and length of stay, was estimated for patients with post-operative delirium during their TAVR or SAVR index hospitalization. Multivariate regression models were used for the adjusted cost estimates controlling for patient demographics, comorbidities, and complications.

**RESULTS:**

A total of 21,088 claims were available for analysis (12,114 TAVR and 8,974 SAVR). The mean age of the TAVR group was older compared to the SAVR group (87 versus 84; p<.001) and TAVR patients presented with a higher comorbidity burden (Charlson Index score 3.0 versus 2.1; p<.0001). 1.6 percent of TAVR patients experienced post-operative delirium during the index hospitalization compared to 3.6 percent of surgical patients (p<.0001). For the overall cohort, the regression adjusted incremental cost of post-operative delirium was (USD15,592; p<.0001). Patients experiencing delirium also had significantly longer hospital length of stay (4.16 days; p<.0001). When stratified by treatment approach, the adjusted incremental cost was USD13,862 for TAVR (p<.0001) and USD16,656 for SAVR (p<.0001).

**CONCLUSIONS:**

While infrequent, post-operative delirium significantly increased hospital cost and length of stay following transcatheter or surgical aortic valve replacement (AVR). Despite a significantly higher comorbidity burden, TAVR was associated with lower post-operative delirium rates compared to SAVR. Moreover, post-TAVR delirium may be associated with less resource consumption than post-SAVR delirium. Future studies should seek to determine whether general anesthesia avoidance in appropriately selected transfemoral TAVR patients can further decrease rates of delirium.

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**OP016 A Patient-centered Value Framework For Healthcare In Hemophilia**

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**ABSTRACT SUMMARY:**

How can Health Technology Assessment (HTA) adapt to rare conditions? Hemophilia is a rare bleeding disorder requiring lifelong care, subject to growing budget constraints that could compromise health care. This three-tiered value framework was developed to shift focus to the value of interventions to patients. It identifies and organizes hemophilia-specific outcomes, including those overlooked by clinicians/policymakers, and supports value assessment in HTA.

**INTRODUCTION:**

Hemophilia is a rare, inherited bleeding disorder affecting an estimated 400,000 people worldwide (1). Characterized by spontaneous bleeding and long-term, irreversible joint damage, persons with hemophilia are often limited in normal day-to-day activities, including work/school, and require comprehensive care at specialized treatment centers. With replacement therapies extending survival by decades and vastly improving quality of life (QoL), routine prophylaxis is considered the standard-of-care in developed countries. However, due to the cost of replacement factor, access to
treatment remains a challenge, and increased scrutiny over funding has been augmented by growing demands on healthcare budgets (2). Thus, the hemophilia community shares a unified goal of objectively defining patient-centered value in hemophilia care.

METHODS:
Using a three-tiered outcomes hierarchy model initially described by Porter (3), an international, multidisciplinary panel of health economics outcomes researchers and hemophilia experts developed a value framework for decision makers to assess value of various healthcare interventions in hemophilia.

RESULTS:
The three tiers for assessing value are: (i) Health status achieved/retained; (ii) Process of recovery; and (iii) Sustainability of health. Tier one measures survival, quality of life (QoL), and hemophilia-specific outcomes of bleeding frequency, musculoskeletal complications, and severe bleeds, as well as function/activity (that is, lifestyle impairment). Tier two measures time to initial treatment or recovery and time missed at education/work, as well as disutility of care (that is, inhibitor development, pathogen transmission/infections, orthopedic intervention, and venous access). Tier three measures avoidance of bleeds, maintenance of productive lives, and long-term health, while capturing long-term consequences of insufficient therapy or age-related complications. Applicability of the framework can be demonstrated in areas of healthcare delivery, treatment regimen, and innovation for new therapies.

CONCLUSIONS:
This value framework represents an initial collaboration with stakeholders to define and organize an array of patient-centric outcomes of importance in hemophilia into a practical tool that can influence treatment and funding decisions in hemophilia care.

REFERENCES:

OP017 Health Technology Assessment And Disinvestment In Australia

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Informed policy making, especially decisions to disinvest in services of contested value, must rely on the sound application of Health Technology Assessment (HTA) methods. A number of medical services funded under Australia’s universal healthcare program, Medicare, have been subject to review, leading to disinvestment of varying degrees. Consistent application of HTA gives policy makers the basis for authoritative, evidence-based decisions about Medicare funding.

INTRODUCTION:
A key component of Medicare, the Australian Government’s universal health care program, is the payment of patient benefits for privately rendered professional services listed on the Medicare Benefits Schedule (MBS). Each year these payments total AUD20 billion (EUR14.2 billion) and rising.

Informed policy making for the MBS, especially decisions to disinvest in services of contested
value, must rely on the sound application of Health Technology Assessment (HTA) methods. Such a framework enables policy makers to assess the evidence regarding services’ safety, clinical- and cost-effectiveness, and then to make defensible choices about the Government’s investment in them.

With this awareness, ad hoc review of MBS services has gradually transformed into systematic processes, culminating in the MBS Review Taskforce, which has begun reviewing all MBS services through a clinician-led, coordinated assessment.

**METHODS:**
The MBS lists more than 5,700 services, but many do not reflect contemporary clinical best practice, and few have undergone HTA.

Certain MBS services requiring review were identified before the Taskforce began, through numerous sources including advice from the medical profession. Review of the evidence for these services led to disinvestment of varying degrees. They were:
- bariatric surgery
- lipectomy
- hyperbaric oxygen therapy (HBOT)
- hip arthroscopy
- rhinoplasty

**RESULTS:**
The Taskforce has just begun, but previous MBS reviews have resulted in redirection of Medicare funding to services with demonstrated evidence of effectiveness. As an example, HBOT for the treatment of chronic non-diabetic wounds was removed from the MBS after the treatment was found to be no more clinically effective than conventional wound care. Utilization of the amended MBS item fell by 25 percent in the year following disinvestment.

**CONCLUSIONS:**
Disinvestment in MBS services must be systematic and supported by the medical profession. The consistent application of HTA gives policy makers the basis for authoritative, evidence-based decisions about Medicare funding.

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**OP019 Unlocking The Potential Of Established Products: Need For Incentives**

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**ABSTRACT SUMMARY:**
Re-purposing of established products (EPs – marketed for 8 years or more) may represent a high value for patients and society. However, it is perceived that no financial incentives exist for the pharmaceutical industry to invest in new indications for EPs. The objective of this research was to review current European regulations and propose strategies stimulating development in this field.

**INTRODUCTION:**
Re-purposing of established products (EPs) – defined as marketed for 8 years or more –
may represent a high value for patients and society. It has been recognized by the European Commission as an important factor contributing to greater access to new therapies. Due to a lower development cost, it could also represent a cost-effective alternative and help to reduce pressure on healthcare budgets. However, it is perceived that no financial incentives exist for the pharmaceutical industry to invest in new indications for EPs. The objective of this research was to review current European regulations and propose strategies stimulating development in this field.

METHODS:
We performed a targeted literature review and held two international expert panel workshops to discuss current policies and their implications, and issue recommendations for changes.

RESULTS:
Within the current regulatory framework EPs face price cuts due to generic competition, reference pricing (RP), price re-negotiations or systematic price cuts, after a period of marketing presence. Extension of indications does not permit to increase or maintain the price. Generic substitution regardless of indication poses another challenge. Limited incentives in the form of an additional year of market protection exists only for new indication(s) registered within the first 8 years following initial approval. The expert panel proposed several strategies to stimulate development in this field, including: (i) extending the period in which registering a new indication results in additional market protection beyond 8 years and extending the duration of additional market protection; (ii) delaying inclusion in RP for EPs with a new value adding indication; (iii) establishing a differential pricing by indication; (iv) preventing temporarily generic substitution when an EP is prescribed for a new indication.

CONCLUSIONS:
Current regulations represent a serious disincentive to develop new indications for EPs. Regulatory and pricing policy changes are needed to stimulate development in this important field.

OP020 Innovations in Payment and Medical Care: How Do Poor and Mentally Ill

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Health care financing in the United States is shifting rapidly away from fee-for-service to shared risk contracts, e.g., Accountable Care Organizations. We investigate how these changes might influence care or investments, particularly for vulnerable populations.

INTRODUCTION:
Health care financing in the United States is shifting rapidly away from fee-for-service payments and towards shared risk contracts or Accountable Care Organizations (ACOs). There is limited information on how these payment changes might impact treatment intensity or clinical innovation, particularly for more vulnerable beneficiaries. If ACOs optimize their care delivery for and target investments towards a typical beneficiary, it is unclear how beneficiaries with less typical clinical conditions or less common needs might fare. Using 2009-14 Medicare claims for one of the largest Pioneer ACOs, we examined the impact of ACO entry on poor and severely mentally ill beneficiaries.

METHODS:
We defined poor beneficiaries as those dually eligible for Medicare and Medicaid (duals), and defined the severely mentally ill, for example, schizophrenia. Beneficiaries could join the ACO between 2012-14. We compared ACO-entrants with those who had yet to join (difference-in-difference design exploiting the staggered ACO entry.
entry). We then examined changes in within-person visit rates over time for earlier versus later entrants, using negative binomial or linear regression models with individual-level fixed effects, and adjusted for changes in risk scores, calendar month, and year.

RESULTS:
Among all ACO beneficiaries, 20 percent were duals, and 14 percent had a severe mental illness. In adjusted models among duals and the mentally ill, ACO entry was associated with reductions in ED visit and hospitalization rates, for example, 17 percent decrease in ED visit rates among duals (95 percent Confidence Interval, CI: 13–20 percent), and 18 percent decrease in ED visit rates among the mentally ill (95 percent CI: 14–22 percent). ACO entry also was associated with lower monthly spending versus non-entry: $110 less among duals (95 percent CI: $69–151) and $160 less among the mentally ill (95 percent CI: $104–216).

CONCLUSIONS:
ACOs are associated with decreases in unfavorable clinical event rates and spending for poor and mentally ill beneficiaries. Additional work will examine how these changes impact ACO investments and treatment intensity.

OP021 Involving Clinical Experts In Prioritising Topics For Health Technology Assessment: A Randomized Controlled Trial

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ABSTRACT SUMMARY:
We conducted a factorial randomized controlled trial within the UK’s National Institute for Health Research Health Technology Assessment (NIHR HTA) Program, to establish the best way to engage with remote clinical referees to identify the most important research questions for the National Health Service. We demonstrated that the choice of material sent was unimportant, but showed a significant and important difference between two modes of response.

INTRODUCTION:
The National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme commissions research to inform health services in the UK. The program prioritises research ideas from literature, guidelines, patients, and clinicians, to decide which research should be funded. We get clinical input on these ideas through (i) committees of clinicians and patients and (ii) seeking written advice from multiple clinicians — a refereeing process. Chairs of our committees suggested that the material we sent to clinicians was too extensive and the method of response too burdensome. We set out to determine whether reducing the information provided or burden of response would improve the engagement of clinicians with our processes, and hence improve the quality of advice provided, and the research available to health services.

METHODS:
We undertook a factorial randomized controlled trial (University of Southampton Faculty of Medicine Ethics Committee #8192, Trial registration: ACTRN12614000167662). Each participant was randomized to receive one of two types of material to comment on, and one of two means to respond. In the first allocation participants were randomized in a 1:1 ratio between receiving a ‘vignette’ (a briefing paper of up to ten pages discussing possible research = usual practice), or a ‘commissioning brief’ (a single page summarising the proposed research). In the second allocation,
the method of response was randomized, between a structured form and free text email.

RESULTS:
We randomized 460 clinical experts, and 356 (77.4 percent) responded. The responses were graded for quality on a scale of 0 to 4 (higher scores better). Non-response was scored as 0. Analysis using ANOVA gave results of a structured response scoring .34 points (SD .36) over a freeform response (p = .02); and the commissioning brief as .04 points over a vignette (p = .81).

CONCLUSIONS:
This was the first randomised trial to take place inside the secretariat of the HTA program. The difference in quality score between the brief and the vignette allocations was neither statistically nor practically important. The difference between the structured and freeform response was statistically significant, and sufficiently large to be important in practice. While the choice of material to share with clinicians seems unimportant we have shown that it is worth sending a structured response form to experts.

OP022 Societal Perspective On Cost Drivers For Health Technology Assessment

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ABSTRACT SUMMARY:
This study reports on a societal perspective of cost drivers that are relevant to stakeholders who are considering health technologies. We have demonstrated that real-world costs from public and private health sectors [including those representing out-of-pocket (OOP) and productively-loss to family] are essential to Health Technology Assessment (HTA) in low-and-middle-income countries (LMICs).

INTRODUCTION:
Understanding cost drivers and estimating societal costs are important challenges for economic evaluation of health technologies in low-and-middle-income countries (LMICs) (1). This study assessed community experiences of health resource utilization and perceived cost-drivers from a societal perspective to inform the design of an economic model for the Community Level Interventions for Pre-eclampsia (CLIP) trials (2).

METHODS:
Qualitative research was undertaken alongside the CLIP trial in two districts of Sindh province, Pakistan. Nine focus groups were conducted with a wide range of stakeholders, including pregnant women, mothers-in-law, husbands, fathers-in-law, healthcare providers at community and health facility-levels, and health decision-/policy-makers at the district-level. The societal perspective included out-of-pocket (OOP), health system, and program implementation costs related to CLIP. Thematic analysis was performed using NVivo software.

RESULTS:
Most pregnant women and male decision makers reported a large burden of OOP costs for in- and out-patient care, informal care from traditional healers, self-medication, childbirth, newborn care, transport to health facility, and missed wages by caretakers. Many healthcare providers identified health system costs associated with human resources for hypertension risk.
assessment, transport, and communication about patient referrals. Health decision-/policy-makers recognized program implementation costs (such as the mobile health infrastructure, staff training, and monitoring/supervision) as major investments for the health system.

CONCLUSIONS:

Our investigation of care-seeking practices revealed financial implications for families of pregnant women, and program implementation costs for the health system. The societal perspective provided comprehensive knowledge of cost drivers to guide an economic appraisal of the CLIP trial in Sindh, Pakistan.

REFERENCES:


OP023 Multi-criteria Decision Analysis To Elicit Stakeholders’ Preferences In Italy: Obinutuzumab Case

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ABSTRACT SUMMARY:

This study applied an MCDA approach (EVIDEM) to obtain preferences on decision criteria across three stakeholder groups (patients, clinicians, and payers) in Italy and to assess the value of obinutuzumab for rituximab-refractory iNHL. This study provides an example of how stakeholders’ views can be quantified and captured in decision making in an explicit way.

INTRODUCTION:

Health decision makers need to understand what matters most to stakeholders, such as patients, when allocating resources across the health system. Stakeholders need to know to what extent and how their input affects allocation decisions. The purpose of this study was to use multi-criteria decision analysis (MCDA) to obtain preferences on criteria across three stakeholder groups (patients, clinicians and payers) in Italy and to use these to assess the value of obinutuzumab for rituximab-refractory indolent non-Hodgkin lymphoma (iNHL).

METHODS:

An MCDA framework (EVIDEM V3.0) was used to obtain stakeholders’ preferences about the relative importance of criteria (weights) and to assess the degree of achievement of obinutuzumab for rituximab-refractory iNHL in each criteria (scores) via an online survey and structured meetings. The normalised weights and scores from each group were combined with a linear function to calculate the intervention value score.

RESULTS:

Patients and clinicians expressed a preference for interventions targeting severe conditions and ranked the economic criteria among the five least important criteria. Payers expressed preference for treatments targeting populations in which there is an unmet need, which are less expensive than the comparator, and which are underpinned by high quality evidence.

Obinutuzumab received high scores for the criteria
“disease severity” and “type of therapeutic benefit” by all three groups. Against the economic-related criteria obinutuzumab obtained a negative score compared to its comparator bendamustine, according to all stakeholder groups.

CONCLUSIONS:
This study shows that MCDA (and in particular EVIDEM) can be used to elicit stakeholders’ views.

Decision-makers in Italy already consider some of the EVIDEM criteria, such as disease severity, but with no systematic approach. We conclude that MCDA studies provide useful evidence to decision makers on what constitutes value of interventions according to different stakeholder perspectives, and can ensure that this is captured consistently across different decisions.

OP024 A Framework For Improved Systems Of Care In Myocardial Infarction

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ABSTRACT SUMMARY:
Our cardiovascular evaluation unit found persistent gaps in care for patients with acute myocardial infarction in Québec. We developed a more comprehensive quality improvement framework that further engaged healthcare professionals. We combined evidence from the literature and ‘real world’ data to establish standards, quality-of-care indicators and an implementation plan, in collaboration with key stakeholders.

INTRODUCTION:
In the past decade numerous efforts have been made to enhance quality of care in the province of Québec for patients with ST-elevation myocardial infarction (STEMI). Despite two prior field evaluations and diffusion of a systematic review as well as recommendations, a third audit revealed persistent gaps in care, specifically excessive treatment delays. Our cardiovascular evaluation unit thus aimed to develop a more comprehensive quality improvement framework that further engaged healthcare professionals.

METHODS:
A literature update identified best practices and ways to reduce treatment delays and improve outcomes. This review, combined with the latest evaluation results, was used to establish structural and process quality standards adapted to the Québec context, via a consensus process with a panel of clinical experts. The standards identified quality-of-care targets and key elements of a governance structure to guide the improvement process. Quality indicators to monitor change were also developed. An implementation plan was then created, likewise based on literature and evaluation results.

RESULTS:
For the first time, the unit publicly disseminated the results of the third evaluation according to region, in addition to standard individual hospital “report cards”. A summit conference was held during which the standards and indicators were presented to clinicians and other stakeholders, in collaboration with the health ministry and a panel of cardiovascular experts. Site visits are planned to facilitate change and establishment of local improvement plans and committees. A “tool kit” was developed containing a treatment algorithm, a drug protocol, five quality indicators each for
Conclusions:
A comprehensive framework aimed at improving quality of care for STEMI patients and monitoring change was created by combining evidence from the literature and “real world” data and mobilizing key stakeholders.

**OP025 Evidence Gathering Across Key Stakeholders Involved In Early Health Technology Assessment**

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**Abstract Summary:**
This study empirically investigates the value of early Health Technology Assessment (HTA), which remains a relatively unexplored topic in the field of innovative medical devices, by collecting evidence across academia and medical device firms in the UK and Italy. The preliminary findings shed light on how early HTA might be effectively conducted to support the development and adoption/reimbursement of new medical devices.

**Introduction:**
The adoption and reimbursement of a new or novel medical device frequently occurs after an economic evaluation of the innovation. One important factor for reimbursement rejections by the English National Institute for Health and and Care Excellence (NICE) Medical Technologies Evaluation Programme (MTEP) appears to be the little or no attention to early assessment (1).

The aim of this study is to achieve a more in-depth and comprehensive understanding of the value of early Health Technology Assessment (HTA) for new medical devices.

**Methods:**
This study employs a mixed methods research strategy. Our informant interviews involved two types of key stakeholders: health economists in academia and professionals in medical devices firms with a professional role in research and development or market access departments. Our qualitative analysis focused on two samples from six universities (five in the United Kingdom, UK, and one in Italy) and six small to medium-sized enterprises (five in the UK, and one in Italy). Insights from field work interviews helped to design our complementary quantitative analysis.

**Results:**
During thematic analysis, barriers to adoption of early HTA emerged across three domains. First, educational barriers (that is, what HTA/early HTA is and how to conduct it) influenced the foundation for the reimbursement strategy. Second, interviewees highlighted the presence of intrinsic barriers (e.g. resources for translational and early preclinical research, reliability and reproducibility, evidence, and dissemination of sensitive information) within existing practices and knowledge. Third, several research gaps (i.e. medical device classification, standardization of methods, guidelines for developers, and alignment of stakeholders perspectives) were identified. Finally, academics adopted early HTA to assess different aspects of a medical device early in development; however, developers were focused on the assessment of investment and safety/usability factors, especially for in-house evaluations.
CONCLUSIONS:
If decision makers expect developers to produce better quality evidence and society aims to optimise resources i.e. not investing in non-cost-effective technologies, then the incorporation of a more robust analytical framework including a societal perspective is necessary to understand how early HTA can be embedded into all aspects of the development process.

REFERENCES:

OP026 Priority Setting: Being Accountable To The Adversely Affected

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ABSTRACT SUMMARY:
Health authorities are required to legitimize their decisions to members of society. First, key principles of being accountable to adversely affected stakeholders are presented. Second, based on careful reflection, a checklist is presented in the form of twenty-seven reflective questions. Health authorities are advised to use the checklist to identify shortcomings of current processes and to install mechanisms for improval.

INTRODUCTION:
Priority setting in health inevitably results in some people ending up adversely affected. We argue there is a strong ethical demand to arrange the decision-making process in such a way that it aims to provide people who are adversely affected by priority setting decisions with well-justified reasons for conferring legitimacy to the decision that they do not get the wanted care (1,2). The aim of this paper is two-fold. One aim is to spell out key principles of being accountable to adversely affected stakeholders. The second is to provide a practical checklist for health authorities who want to improve their decision-making practices on this aspect.

METHODS:
The discussion is based on normative theory and philosophical reflection. First, we define the key principles of being accountable to adversely affected stakeholders. Second, based on careful reflection on how to pay adequate attention to these key principles, we developed a checklist in the form of twenty-seven reflective questions.

RESULTS:
Practical lead ways are provided to authorities on how they can be accountable to stakeholders who are adversely affected by decisions. First, key principles are defined – relating to the identification of the adversely affected, their comprehensive inclusion, ensuring meaningful participation, considerate communication of recommendations or decisions, and the organization of evaluation and appeal mechanisms. Second, a checklist is presented in the form of twenty-seven reflective questions that health authorities can use to rethink and improve the legitimacy of their current priority setting processes.

CONCLUSIONS:
Accountable decision makers are required to legitimize their decisions to members of society. Health authorities are advised to use the checklist to identify shortcomings of current processes and to install mechanisms for improval.
OP027 Patient-Reported Outcome Measures In Carotid Artery Revascularisation

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ABSTRACT SUMMARY:
Currently, there are no recommended patient-reported outcome measures (PROMs) for use in patients undergoing carotid artery revascularisation. This review was undertaken to identify PROMs that have been developed and/or validated in this patient population, assess their psychometric properties and examine suitability for clinical and research use.

INTRODUCTION:
Patient-reported outcome measures (PROMs) provide a way to measure the impact of a disease and its associated treatments on the quality of life from the patients’ perspective. The aim of this review was to identify PROMs that have been developed and/or validated in patients with carotid artery disease (CAD) undergoing revascularisation, and to assess their psychometric properties and examine suitability for research and clinical use.

METHODS:
Eight electronic databases including MEDLINE and CINAHL were searched from inception to May 2015 and updated in the MEDLINE database to February 2017. A two-stage search approach was used to identify studies reporting the development and/or validation of relevant PROMs in patients with CAD undergoing revascularisation. Supplementary citation searching and hand-searching reference lists of included studies were also undertaken. The Consensus-based standards for the selection of health measurement instruments (COSMIN) and Oxford criteria were used to assess the methodological quality of the included studies, and the psychometric properties of the PROMs were evaluated using established assessment criteria.

RESULTS:
Six PROMs, reported in five studies, were identified: 36-Item Short Form Health Survey (SF-36), Euro-QoL-5-Dimension Scale (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Dizziness Handicap Inventory (DHI), Quality of life for CAD scale by Ivanova 2015 and a disease-specific PROM designed by Stolker 2010. The rigour of the psychometric assessment of the PROMs were variable with most only attempting to assess a single psychometric criterion. No study reported evidence on criterion validity and test-retest reliability. The overall psychometric evaluation of all included PROMs was rated as poor.

CONCLUSIONS:
This review highlighted a lack of evidence in validated PROMs used for patients undergoing carotid artery revascularisation. As a result, the development and validation of a new PROM for this...
OP028 Health Apps: A Proposed Framework To Guide Clinical Risk Assessment

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ABSTRACT SUMMARY:
We developed a clinical risk framework that helps app users, developers, commissioners and other stakeholders worldwide to deal with the large quantity of health apps, manage risks and improve patient safety. We aimed to identify criteria for assessing clinical risks of different health apps and propose questions that should be answered to assess whether risks have been addressed.

INTRODUCTION:
Globally, health systems are struggling with reliably appraising the safety and efficacy of rapidly changing digital health interventions whilst allowing useful innovations to be rapidly adopted. Assessment and regulation of the large number of health apps should be proportional to their clinical risk, but there is large uncertainty about suitable criteria to assess risk (1). We aimed to identify criteria for assessing clinical risks associated with different types of health apps.

METHODS:
Our work builds on previous studies that identified some of the risks that health apps can pose and contextual factors that can moderate these risks (2,3). This work is grounded in a review of existing literature; wide consultation of stakeholders; participation in multiagency policy discussion; and sense-checking successive versions of the framework that evolved over time. We combined different risk domains for apps (technical safety, usability, intervention quality, and engagement) with their functions (learning, behaviour and cognition change, communication, record keeping, and clinical decision support).

RESULTS:
We developed a comprehensive generic risk framework that app users, developers, commissioners, regulators and other stakeholders worldwide can use to guide assessment of the likely risks posed by a specified health app in a specific context. We also propose questions that should help determine whether these risks have been addressed.

CONCLUSIONS:
Apps are very promising in health care but are very numerous, complex, rapidly evolving and with overlapping functions. A rigorous risk framework should help stakeholders to deal with the large quantity of health apps, classify and manage clinical risks, and improve patient safety by applying generic risk assessment criteria. Further work is needed to test and develop the criteria we propose, especially as apps that integrate different functions are emerging, which will make risk assessment more complex.

REFERENCES:
OP029 Efficacy And Safety Of Radiofrequency Ablation Combined With Transcatheter Arterial Chemoembolization For Primary Liver Cancer

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ABSTRACT SUMMARY:
This study systematically reviewed and meta-analyzed the efficacy and safety of radiofrequency ablation (RFA) combined with transcatheter arterial chemoembolization (TACE) in the treatment of PLC in China. The combination therapy of TACE and RFA significantly improved the efficacy for the patients with PHC without increasing the postoperative risks. But its economic implications should be explored before being widely used.

INTRODUCTION:
Thermal ablation therapy of primary liver cancer (PLC) becomes widely used because of its potential to accurately destroy tumor cells. This study was to compare the efficacy and safety of radiofrequency ablation (RFA) combined with transcatheter arterial chemoembolization (TACE) to those of TACE or RFA alone in the treatment of the patients with PLC in China.

METHODS:
All eligible literature related to the above comparison and which involved randomized controlled trials in China were collected from three databases (PubMed, CBM, and CNKI) and reviewed. The tumor response rate (RR) based on RECIST criterion, overall survival (OS) rate, and major complications were analyzed in the study, using M-H fixed or D-L random meta models. The Egger’s tests and Begg’s tests indicated no publication bias were involved in the studies.

RESULTS:
Thirty-one studies, with 1,400 patients in the TACE+RFA group, 841 patients in the TACE group, and 434 patients in the RFA group, were included in the analyzes. The tumor response rate of the TACE+RFA group was higher than those of the TACE group (Odds Ratio, OR=3.52, 95 percent Confidence Interval, CI was 2.59,4.78) and the RFA group (OR =3.11, 95 percent CI was 1.64,5.90). The OS rates for 1 year, 2 years, and 3 years in the TACE+RFA group was significantly higher than those in the TACE group (OR₁ =3.83, OR₂ =3.26, and OR₃ =4.62) and those in the RFA group (OR₁=2.38, OR₂=2.68, and OR₃=1.68). However, the major complications in the TACE+RFA group were not significantly different from those in the TACE group and RFA group, respectively.

CONCLUSIONS:
The combination therapy of TACE and RFA significantly improves the efficacy for patients with PLC without increasing the postoperative risks, compared to TACE therapy or RFA therapy alone. But its economic implications should be explored before being widely used for patients with PLC.
OP030 Health Technology Assessment And The Decision-Making Process Of New Drug Listing In Hong Kong

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ABSTRACT SUMMARY:
This review summarized the decision-making trajectory from submission to final outcome in the Hong Kong context in comparison to existing policies of overseas countries adopting Health Technology Assessment (HTA) for new drug reimbursement submissions. Despite identifying several major challenges, this review provided suggestions for establishing a more transparent, credible, evidence-based decision-making process in Hong Kong.

INTRODUCTION:
In Hong Kong, the Drug Advisory Committee (DAC) has had the role of evaluating and advising new drugs to be included in the listing of the Hospital Authority Drug Formulary since July 2005. The drug review process was subject to challenge due to a lack of transparency to members of the public and documentation of the scientific basis for decision making. The purpose of this review was to describe the process, evaluation criteria and possible outcomes of decision making for new drugs listed in the Hong Kong Hospital Authority Drug Formulary in comparison to Health Technology Assessment (HTA) policies in overseas countries.

METHODS:
Details of the decision-making processes including new drug listing submissions, the DAC meeting, procedures before and after the meeting, were extracted from the official Hong Kong Hospital Authority drug formulary management website and manual. Publicly available information related to new drug decision making processes for four HTA agencies (National Institute for Health and Clinical Excellence (NICE), Scottish Medicines Consortium (SMC), Australian Pharmaceutical Benefits Advisory Committee (PBAC), and Canadian Agency for Drugs and Technologies in Health (CADTH)) were reviewed and retrieved from official documents on their public domains.

RESULTS:
The DAC is in charge of the systematical and critical appraisal of new drugs for listing on the formulary, reviewing submitted applications, and making decisions of drug listing based on scientific evidence in which safety, efficacy and cost-effectiveness are primary considerations. When compared to other HTA agencies, transparency of decision-making processes of the DAC, relevance of clinical and health economic evidence, and lack of health economic and methodological input to submissions were major challenges of the new drug listing policy in Hong Kong.

CONCLUSIONS:
Despite the challenges identified, this review provided suggestions for establishing a more transparent, credible, evidence-based decision-making process for the Hong Kong Hospital Authority Drug Formulary. Proposals for improvement in the listing of new drugs in the formulary should be a priority in healthcare reform.

OP031 Mapping Of Health Technology Assessment In China: Preliminary Analysis And Comparison

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) in China is still not formally integrated in the policy-making processes, although HTA has been introduced into China for 30 years. There is a lack of quantifiable information on HTA researchers and research institutions in China. This study aimed to measure the development of HTA in the context of international comparison.

INTRODUCTION:
Health Technology Assessment (HTA) was introduced into China back in 1980s and made some progresses, but still faces many bottlenecks. Since the evaluation of HTA development was lacking, the study aimed to map and compare the level of HTA in China with other countries, in order to promote the development of HTA in China.

METHODS:
A Mapping Instrument, which was developed and applied in ten countries (1), was used to map the level of HTA in China. The instrument measured two key elements of HTA (institutionalization of HTA and HTA process itself), which were further scored into eight domains. We launched an on-line nationwide survey, supplemented with snowball sampling by emails. Three types of respondents were targeted: policy-makers, researchers, and industry representatives, to complete the on-line survey. One-sample T test was used to describe the differences.

RESULTS:
We collected 222 questionnaires, 33 from policy-makers, 158 from researchers and 31 from the industry. The total HTA development score of China was 76.4 (out of a maximum score of 146), including eight domain scores: level of institutionalization (score 15.1 out of 28), identification (score 3.4 out of 19), priority setting (score 10.4 out of 18), assessment (score 25.3 out of 39), appraisal (score 4.6 out of 9), reporting (score 6.5 out of 11), dissemination (score 6.8 out of 12), and implementation (score 4.4 out of 10). Although the total score in China was comparable to the average score of 75.6 among the ten selected countries, China was significantly lower than the average score of 117.0 among the three developed countries. As a result, China was significantly higher than the total score of other seven middle-income countries, but China was significantly lower in the domain of institutionalization.

CONCLUSIONS:
As the foundation of development, institutionalization was the significant gap between China and other countries. Future government initiatives to address need of institutionalizing national HTA system or agency will improve the development of HTA in China.

REFERENCES:

OP033 Developing A Public Version Of A Health Technology Assessment Report

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ABSTRACT SUMMARY:
We adapted the principles from the European collaborative project DECIDE, on the communication of clinical guidelines to the public, to develop a public version of a Health Technology Assessment (HTA). It was well received and the Scottish government is using this work to develop educational materials for the public. However, some challenges in communicating with the public about evidence remain.

INTRODUCTION:
As the Health Technology Assessment (HTA) community moves towards greater levels of Patient and Public Involvement (PPI), the need to communicate with the public about the results and impact of HTA, and of PPI itself, is also increasing. DECIDE was a European Commission funded collaborative project arising from the GRADE working group, which developed and evaluated strategies for effectively communicating the recommendations from clinical guidelines to a multiple stakeholders. The Scottish Intercollegiate Guidelines Network (SIGN) led the work stream on patients and the public (1, 2). We extended the findings to develop a patient/public version of an HTA on Antimicrobial Wound Dressings (AWDs). The clinical and cost effectiveness evidence was inconclusive (3) which increased the importance of engagement with clinical and patient/public stakeholders.

METHODS:
A literature review, and a series of focus groups and user testing informed the development of a set of principles for designing patient versions of guidelines (1,2). Using these principles developed by the DECIDE collaboration, a patient version of the HTA was developed, in partnership with public volunteers and a standing public communications advisory group.

RESULTS:
We incorporated key facilitators of usability, such as distinct branding as material for the public, a clearly communicated purpose, and the layering of information. Other facilitators included a “friendly” and accessible tone which was achieved by the use of colour, icons, simple language and charts, and brief chunked text. While feedback about clarity, design and usefulness was generally positive, some public reviewers were concerned by the level of uncertainty and complexity in the findings.

CONCLUSIONS:
Using the principles from the DECIDE project, it is feasible and useful to develop a public versions of an HTA report. The patient version is currently informing the development of educational material for patients/public about chronic wounds and AWDs by the Scottish Government. However, it remains a challenge to balance the complexity and uncertainty underlying evidence-based recommendations, with the need to provide accessible, understandable, and yet accurate information about them for the public.

REFERENCES:
OP034 United Kingdom Stakeholders’ Preferences For Novel M-Health Sexually Transmitted Infection Testing And Treatment

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ABSTRACT SUMMARY:
Chlamydia, the most common sexually transmitted infection, is frequently asymptomatic. A range of new technologies could revolutionize future screening and treatment pathways. A national discrete choice experiment (DCE) has been undertaken in England. Responses from 1,230 young people aged 16-24 years will be presented. Expressed preferences have been integrated into an economic model for new digital chlamydia pathway options.

INTRODUCTION:
Chlamydia is the most common sexually transmitted infection (STI) among young people (1). Technological advances offer the opportunity to redesign existing asymptomatic chlamydia screening/testing and treatment pathways, potentially improving uptake and the percentage of identified infections currently treated (56 percent-100 percent). Innovations underway include self-tests networked through mobile phones, combined with online clinical care and other non-face-to-face care pathways (2). Evidence of young people’s preferences for these will be required to inform optimal service re-design.

METHODS:
Factors influencing young people’s preferences have been quantified in a large-scale discrete choice experiment (DCE). Methods used to select key pathway attributes included: (i) systematic literature reviews of stated preference studies for STI testing/treatment in OECD high income countries; (ii) focus groups with young stakeholder aged 16-24 years with range of socio-economic characteristics; and (iii) expert groups, including clinicians and researchers. Following questionnaire piloting, the final questionnaire was completed online by a panel of 16-24 year olds across England. Analysis used multinomial logit models and included validity checks (3).

RESULTS:
There were 1,230 respondents (response rate 73 percent). Main attribute influencing preferences was test accuracy (Odds Ratio [OR] 3.24, 95 percent Confidence Interval [CI] 3.13 – 3.36), followed by time-to-result (OR 1.81, 95 percent CI 1.71-1.91). Clear preference shown for remote testing (self-testing, self-sampling, postal testing) over attendance at testing location. For accessing antibiotic treatment, slight preference exhibited for online versus traditional General Practitioner/ pharmacy/clinics. Little difference in consultation preferences between face-to-face, telephone, instant messaging, or email. No significant difference in treatment preferences, for example, pharmacy/post.

CONCLUSIONS:
DCE coefficients have been integrated into an economic model to estimate costs and consequences for re-designed chlamydia pathways (3). Findings should assist technology developers, policy makers, commissioners, and service providers to optimise technology adoption and service re-design. The DCE was completed by an online population, so generalisability to other populations may be limited.
REFERENCES:
2. Electronic Self-Testing Instruments for Sexually Transmitted Infection (eSTI2) Consortium (www.esti2.org.uk)

OP035 Involving Members Of The Public In A National Screening Programme Health Technology Assessment

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ABSTRACT SUMMARY:
This research explores how different groups of public contributors, with various prior experience of involvement, participated in the Health Technology Assessment (HTA) consultation process. Early analysis suggests that Prior involvement in research or specific research methods training may not be necessary for public involvement in HTA. This has implications for involving diverse or “hard to reach” groups, without high levels of associated cost.

INTRODUCTION:
Involving members of the public in the development of Health Technology Assessments (HTAs) has scientific and public value (1) but the most common form of involvement in HTA remains collection of people’s views in the form of data (2). Involving members of the public in shaping the research is rare due to perceived time or resource constraints (3). Our research aimed to; (i) develop tailored meeting formats for public involvement in a lung cancer screening HTA , (ii) capture views on lung cancer screening using a community drop in format (iii) explore how different groups of public contributors, with various prior experience of involvement, participated in the HTA consultation process.

METHODS:
The involvement included three separate public meetings and a drop-in session at a community centre. Meeting formats were specifically tailored to meet the needs of the lung cancer screening HTA while drawing on previous patient and public involvement (PPI) work in relevant disciplines. All meetings were audio recorded and observed using a structured form. This data is currently being analysed using a combination of inductive and thematic analysis.

RESULTS:
The qualitative research data on PPI processes was collected in November 2016. The paper will present results from our full analysis. At present, we note that while limited time was available to explain HTA to participants, this did not hamper the discussions’ relevance to the HTA work. Participants shared personal stories irrespective of whether they knew each other from before. People drew on own and others’ experiences when discussing outcomes of importance to this HTA.

CONCLUSIONS:
Prior involvement in research or specific research methods training may not be necessary for public involvement in HTA. This has implications for involving diverse or “hard to reach” groups, without high levels of associated cost.
REFERENCES:

OP036 The Mosaic Of Patient Participation In Health Technology Assessment

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ABSTRACT SUMMARY:
This presentation will review the main frameworks for public participation in policy making and consider how they apply to HTA. Reflecting on barriers and enablers, a new framework (mosaic) is developed to support patient participation at any stage of HTA. This will help HTA bodies establish optimal processes for patient participation in their own setting.

INTRODUCTION:
Public participation in policy making is imprecisely defined, has different aims and can take many forms. Often hierarchies of participation range from tokenistic participation to full empowerment. Questions arise as to whether these hierarchies are relevant for Health Technology Assessment (HTA) and how patients can be supported to contribute to HTA.

METHODS:
A literature review of existing participation structures and barriers and enablers to patient participation in HTA led to development of an HTA framework for patient participation. This was consulted on with a range of HTA bodies in Europe, North and South America and Asia/Australia.

RESULTS:
The way patients participate in an HTA process depends on the context of the HTA system, the technology being assessed and the goals of participation. Hence, a framework has been developed that offers mechanisms by which patients and their representatives can participate in every stage of HTA, both for individual HTAs and in developing HTA processes and policy. The mechanism of participation and who should participate depends on the goal and context and thus creates a multi-dimensional framework that we call a mosaic, following the work of Tritter (1). This mosaic includes activities that are being used commonly by HTA bodies such as patient participation in expert groups, patient group submissions and patient expert comment on draft documents. It suggests other activities such as focus groups to elicit topic proposals and using patient groups as a ‘safe harbour’ for Managed Entry Agreements. It also stresses the importance of capacity building.
CONCLUSIONS:
Participation processes need to be designed to elicit the unique knowledge that patients have in the most efficient way possible so that patient insights can inform individual HTAs and improve HTA processes. The mosaic of patient participation in HTA is a tool that can be used by HTA bodies to help them construct such processes (2).

REFERENCES:

OP037 Can Local Ultra-Orphan Patient Evidence Shape Global Understanding?

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ABSTRACT SUMMARY:
Patient evidence is provided to the National Institute for Health and Care Excellence (NICE) by patient organizations and patient experts. We reviewed the impact that patient evidence has on the committee’s decision making for ultra-orphan HTAs. The findings will inform an updated patient submission template and guide. These will be available on the NICE website and offered to the Health Technology Assessment International (HTAi) Patient/Citizen Involvement Interest Group for sharing globally.

INTRODUCTION:
Written patient evidence is submitted to the National Institute for Health and Care Excellence (NICE) by patient organizations and their nominated patient experts. We reviewed the impact that patient evidence had on the committee’s decision making. This local learning can help generate global opportunities for Health Technology Assessment (HTA) bodies and patient groups to further develop their understanding and methodology about how patient evidence can support HTA decision making for ultra-orphan conditions.

METHODS:
There were two phases.

Phase 1 was an online questionnaire about the impact of patient evidence on the committee’s decision making for ultra-orphan HTA evaluations. It was sent to the committee chair, lay committee members and selected other committee members.

Phase 2 developed the initial questionnaire findings using in-depth interviews with the committee chair and the lay members. These gained further understanding of the impact of patient evidence and the themes raised.

RESULTS:
Key findings showed patient evidence was helpful to understand the:

- Burden of disease
- Patient population
- Likely uptake of new medicines
- Impact on carers.

For ultra-orphan conditions, where other forms of evidence are scarcer, patient evidence is fundamental to understanding patient needs, the impact of the disease, patient population and preferences.
CONCLUSIONS:
Patient evidence was useful for the committee in different ways; it provided the committee with new evidence and it helped the committee understand and interpret the evidence submitted by others. Both are key to committee decision making. It was clear that due to the very small patient population, patient groups knew the patient population, their stage of disease, and their preferences in detail.

The findings will be used to inform an updated patient submission template for ultra-orphan HTAs, and supporting guide. These will be available on the NICE website and offered to the HTAi Interest Group on Patient and Citizen Involvement so they can be shared globally.

INTRODUCTION:
Value frameworks, analogous to Health Technology Assessment (HTA) internationally, have emerged in the United States to aid stakeholders in assessing the value of new treatments. Since patient perspectives on value may differ significantly from other stakeholders, formalized procedures to involve patients in their work have been created. Despite these efforts, concerns persist that patient involvement is insufficient or "rhetoric." To assist in this effort, the National Health Council (NHC) created a rubric to aid decision makers in improving the patient centricity of their value assessments.

METHODS:
A convenience sample of twenty-eight organizations was invited to participate in a roundtable discussion. Participants discussed experiences with value frameworks; debated and thematically grouped hallmark patient-centeredness characteristics; and developed illustrative examples of the characteristics. These materials were organized into the rubric, and subsequently vetted via multi-stakeholder peer review.

RESULTS:
Participants agreed upon six key domains of patient centeredness: partnership (patients are involved in every step of development/dissemination processes), transparency (assumptions/inputs are disclosed in an understandable, timely way), inclusiveness (perspectives drawn from broad range of stakeholders), diversity (differences in subpopulations, trajectory of disease, and stage of a life should be accounted for), outcomes (includes those that patients have identified as important), and data (variety of credible data sources are used allowing for timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes). The Rubric describes each domain and includes illustrative examples of how patient engagement/centeredness can be operationalized through direct and indirect pathways.

OP038 Improving The Patient Centricity Of Value Assessments: A Rubric

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ABSTRACT SUMMARY:
Understanding and defining the value of healthcare treatments and interventions has become a national priority. To help incorporate the patient perspective in the debate over value, the National Health Council (NHC) released a Patient-Centered Value Model Rubric. This presentation will describe methods used to create the Rubric and the results.
CONCLUSIONS:
The NHC Rubric is a first step toward creating patient-centered value assessments patients and their families can rely on. It is intended to assist all stakeholders, especially the patient community, in assessing the level of patient centeredness and engagement in a given framework or model. It can be a guide to support developers in conceptualizing plans for meaningfully engaging patients.

OP039 Reporting Clinical Outcomes In Transcatheter Aortic Valve Implantation (TAVI) Registries

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ABSTRACT SUMMARY:
A systematic review was performed to assess endpoints reporting status in twenty Transcatheter Aortic Valve Implantation (TAVI) registries, who reported clinical outcomes based on the Valve Academic Research Consortium (VARC-2) definitions. We extracted and analyzed data of patients characteristics, procedure characteristics, 30-day and 1-year mortality, 30-day major complications, and composite endpoints from each registry’s publications. The comparability and quality of VARC-2 reporting within the identified TAVI registries was reviewed.

INTRODUCTION:
Transcatheter aortic valve implantation (TAVI) has been demonstrated to be an alternative treatment for high surgical risk patients with severe aortic stenosis. However, the fast growth of TAVI has created difficulties in cross-study result comparison. In 2011 and 2013, the Valve Academic Research Consortium (VARC) published standardized definitions on reporting endpoints in TAVI studies. The objective of this study was to provide an overview of TAVI registries and the reporting of clinical outcomes based on VARC-2 definitions.

METHODS:
A systematic review of TAVI registries reporting VARC-2 definitions was performed in line with PRISMA guidelines in PubMed, ScienceDirect, Scopus databases and EMBASE. Based on VARC-2, patient characteristics and procedure characteristics, 30-day clinical outcomes, 1-year mortality and composite endpoints were extracted from each registry’s publications. No publication time restriction was used.

RESULTS:
Twenty TAVI registries were identified in our review with an overall sample size of 12,583 patients. The 30-day all-cause mortality ranged from 0 to 12.7 percent. Fourteen registries reported 30-day cardiovascular mortality, which ranged from 0 to 8.8 percent. Nine registries reported myocardial infarction rates, ranging from 0.5 to 2 percent. The majority of registries reported complications such as bleeding, vascular complications and new pacemaker implantation. The transapical (TA) approach has been associated with lower rates of vascular complications than the transfemoral (TF) route, but higher myocardial infarction rates. Additionally, the self-expandable Medtronic CoreValve requires a higher rate of new pacemaker implantation than the Edwards valve, which ranged from 3.8 to 17.0 percent, and 23.6 percent in the pure CoreValve registry, respectively.

CONCLUSIONS:
VARC original and VARC-2 definitions are more and more widely used by TAVI registries. Reporting VARC-2 definitions makes cross-registry comparisons more feasible. This transparency will provide better evidence to patients and decision-makers.
OP040 First Case Of Disinvestment Using Real-World Evidence In Brazil

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ABSTRACT SUMMARY:
Using data linkage of the Unified Health System information databases, we developed a nationwide registry study of 12,154 multiple sclerosis (MS) patients and showed that those using intramuscular beta-interferon were more likely to present treatment failure in a 11-year follow-up than patients using subcutaneous beta-interferons. This result led to disinvestment in this technology in Brazil.

INTRODUCTION:
Beta-interferons are used as first-line therapy for relapsing-remitting multiple sclerosis in Brazil. In order to evaluate the possible inferiority of one of the beta-interferons available and support a guideline update, we conducted an eleven-year (January 2000 to December 2010) nationwide real-world performance assessment using the Unified Health System (SUS) databases.

METHODS:
We assessed whether patients using subcutaneous beta-interferon switched treatment, relapsed or died (composite event) earlier than patients using intramuscular beta-interferons. Patients without a dispensing registry longer than three months were censored. We used the Kaplan-Meier method to estimate the cumulative probability of persistence on initial treatment, and compared groups with the Log-rank test. The influence of the drug on the occurrence of event was assessed with Cox proportional hazards analysis.

RESULTS:
The number of patients included was 12,154, and the majority started treatment with subcutaneous beta-interferon-1a (45.7 percent), followed by subcutaneous beta-interferon-1b (27.7 percent) and by intramuscular beta-interferon (26.6 percent). Women represented 73.1 percent and the mean age was 38.93±11.34 years old. The group of patients who used intramuscular beta-interferon switched treatment, relapsed or died earlier (median 47 months; 95 percent Confidence Interval, CI 44-52) than patients using the subcutaneous beta-interferons, (69 months (95 percent CI 64-76) for beta-interferon 1a and 73 (95 percent CI 66-84) months for beta-interferon 1b) (p< .0001 for both comparisons). Accordingly, the use of intramuscular beta-interferon was associated with a higher probability of event (Hazard ratio - HR 1.38; 95 percent CI 1.29-1.48), while the use of the other beta-interferons had a protective effect (1a: HR .86; 95 percent CI .81-.92; 1b: HR .89; 95 percent CI .83-.95).

CONCLUSIONS:
The inferiority of intramuscular beta-interferon found in the real-world corroborates findings from head-to-head studies and systematic reviews conducted by Cochrane and the National Commission for Technology Incorporation in SUS
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(OP041) This result led to disinvestment in intramuscular beta-interferon and was the first case of clinical guideline update using real-world evidence in Brazil.

**OP041 Real-World Evidence Navigator To Support Evaluation Of Relative Effect**

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**ABSTRACT SUMMARY:**
The web-based Real-World Evidence (RWE) Navigator (https://rwe-navigator.eu) is a shared platform created to address the lack of clarity on what is meant by RWE, and about what methods should be used to synthesize and analyze the data. The tool is an educational resource, a source of guidance, and a directory of resources related to RWE in medicines development.

**INTRODUCTION:**
The use of real-world evidence (RWE) to estimate relative effectiveness could provide payers and health technology assessment (HTA) agencies with the evidence they need to make reimbursement or access decisions. However, there is misunderstanding and confusion about what is meant by RWE and about what methods should be used to synthesize and analyze these data. IMI GetReal (1) Work Package 1 was tasked with seeking this clarity and communicating this to stakeholders.

**METHODS:**
Stakeholder engagement with patient organizations, clinicians, clinical trialists, pharmaceutical companies, regulators, HTA bodies and payers confirmed that clarity around RWE is needed. Case study workshops in multiple disease areas were used to examine different analytical methods and study designs using real-world data (RWD) to provide estimates of relative effectiveness, and to elicit stakeholders views on the usefulness and acceptability of each option. Feedback from stakeholders confirmed what information would be useful to provide clarity.

**RESULTS:**
A web-based tool called the Real-World Evidence (or RWE) Navigator (https://rwe-navigator.eu) was developed. The tool is an educational resource on potential issues in demonstrating relative effectiveness (‘effectiveness issues’), a source of guidance on methods using RWE, and a directory of resources related to RWE in medicines development. The tool includes a two-step process to explore potential effectiveness issues and potential options using RWE to address these issues. Other components include overviews of and links to authoritative sources on RWD/RWE, data governance, synthesis, quality assessment, and adjustment of RWD/RWE; summaries of case studies examined in GetReal; and overviews of current policies and perspectives, and related initiatives.

**CONCLUSIONS:**
The RWE Navigator is a valuable shared platform for stakeholders and the broader clinical and patient community to address the inclusion of alternative study designs and analyses in medicines development using RWE but further work is needed. This work has supported engagement and dialogue between all stakeholders, such as industry and decision makers, and has driven forward the scientific and policy agenda.
OP042 Cost-Benefit Of Computed Tomography In Secondary Hospitals In China

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ABSTRACT SUMMARY:
This study analyzed the cost-benefit of computed tomography in secondary hospitals of China in the past 5 years by using real-world panel data, with a view to providing information for overall economic management in hospitals as well as for regional planning of medical equipment in different areas.

INTRODUCTION:
With the promotion of a tiered medical service system, secondary hospitals will play a more important role in the future. This study aims to explore the cost-benefit of computed tomography (CT) in secondary hospitals in China, with a view to providing information for overall economic management in hospitals as well as for regional planning of medical equipment in different areas.

METHODS:
Fifty-eight secondary hospitals from six provinces located in the eastern, central, and western regions of China were selected as the study sample. Questionnaires were used to collect information on the cost structure, efficiency, and benefits of CT in the secondary hospitals in the past 5 years. Cost analysis was conducted from the perspective of the hospitals, which mainly referred to direct fixed costs and variable costs. We analyzed the investment recovery years a, cost recovery rate b, and benefit-cost ratio to evaluate the economic benefits of CT. We also analyzed the technological benefits of CT based on its effective utilization rate c and positive detection rate.

RESULTS:
Depreciation costs (36.3 percent) were the largest proportion of all costs over the 5-year period, followed by material costs (22.2 percent), maintenance costs (18.2 percent), labor costs (17.1 percent), and electricity consumption (1.2 percent). The investment recovery periods of CT in the eastern, central, and western regions were 2.5, 2.8, and 3.1 years, respectively; the cost recovery rates were 186.5 percent, 172.0 percent, and 174.1 percent, respectively; the benefit-cost ratios were 1.9, 1.7, and 1.7, respectively; the effective utilization rates were 46.1 percent, 58.3 percent, and 71.2 percent, respectively; and the positive detection rates were 52.3 percent, 60.5 percent, and 73.3 percent, respectively.

CONCLUSIONS:
The current study indicates that the cost-benefit of CT is good in secondary hospitals, especially in terms of economic benefits. But to achieve greater technological benefits in all three regions, more appropriate utilization of CT is needed.
OP043 Unconventional Health Technology Assessment Use: Diagnosis Of Likely Emerging Tropical Diseases

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ABSTRACT SUMMARY:
The increase in travelers, refugees combined with global warming may soon lead to the development of tropical diseases such as Schistosoma or Strongyloides infections in some European countries. Our aim was to assess the clinical relevance of tests used in schistosomiasis’ or strongyloidiasis’ diagnosis and include the most relevant in the national list of reimbursed tests.

INTRODUCTION:
The increase in travelers, refugees combined with global warming may soon lead to the development of tropical diseases such as Schistosoma or Strongyloides infections in some European countries. Those intestinal parasites may persist for decades with subclinical infections or low-grade disease with nonspecific manifestations. In the presence of immunosuppression, strongyloidiasis can rapidly evolve into life-threatening disseminated disease, whereas chronic schistosomiasis can lead to complications causing future morbidity and death.

Currently in France, an update of diagnostic tests reimbursed for those tropical diseases is ongoing to fully cover diagnostic needs.

Our aim was to assess the clinical relevance of tests used in schistosomiasis’ or strongyloidiasis’ diagnosis and include the most relevant in the national list of reimbursed tests.

METHODS:
The assessment involves a critical analysis of national and international guidelines identified by a systematic literature search, and stakeholders’ views.

RESULTS:
This work identifies several autochthonous outbreaks of those diseases in France; such as urogenital schistosomiasis that occurred in Corsica, in summer 2013. Also it enlightens the increase of strongyloides serological tests performed in the past years. Those facts prove the potential development of those infections in Europe.

It underlines that, serology is the first diagnostic test line for most cases and is more sensitive than stool microscopy which represents however the final diagnostic investigation to confirm the intestinal infection.

It confirms the main indications of those two diagnostic tools.

It relies on a tropical infectious disease expert network including the French army health service. They have brought further clarification of diagnostic tests clinical relevance for travelers or autochthonous cases.

CONCLUSIONS:
This new use of Health Technology Assessment has allowed updating and listing the relevant diagnostic tools which might be crucial to better follow those diseases and it may help the health system to face the increase of tropical infections.

OP044 Cost-Effectiveness Of Hepatitis C Virus Screening In Swiss Prisons Using Rapid Tests

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ABSTRACT SUMMARY:
Hepatitis C virus (HCV) prevalence amongst prisoners is typically high due to the large proportion of high-risk groups. An economic model investigated screening and treatment of prisoners in Switzerland, based on recent diagnostic and therapeutic advances such as rapid antibody saliva and dried blood spot testing. Results showed that screening all prisoners was cost effective compared to testing only high-risk groups.

INTRODUCTION:
This study explored the cost effectiveness of expanding Hepatitis C Virus (HCV) screening and subsequent treatment in Swiss custodial settings, given the availability of rapid antibody saliva tests (Oraquick®) and dried blood spot tests (semi-quantitative viremia and viral genotype), and recent therapeutic advances which have higher cure rates and shorter treatment courses (1).

METHODS:
A comprehensive strategy offering screening to all detainees was compared to the current setup of screening high-risk individuals (for example, from endemic countries, active or former injecting drug users). A decision tree simulated the diagnosis pathway, and results from a Markov model were included to predict treatment effects and natural progression over a lifetime time-horizon. Input data were derived from clinical studies, literature reviews, custodial health services and expert opinion (2). The net monetary benefit (NMB) and incremental cost-effectiveness ratio (ICER) of comprehensive compared to current screening were calculated. Deterministic and probabilistic sensitivity analyses were performed to explore parameter uncertainty and whether variations informed by expert opinion changed the cost-effectiveness of comprehensive screening.

RESULTS:
At a willingness-to-pay threshold of CHF100,000 (USD99,500) per Quality-Adjusted Life-Year (QALY), comprehensive screening had an 83 percent probability of being cost-effective, with a corresponding NMB of CHF33,451,972 (USD33,284,712) and ICER of CHF7,168/QALY (USD7,132/QALY). Results were most sensitive to the QALYs gained from the treatment model (both treatment and no treatment arms), respective HCV prevalence in the current and comprehensive screening populations, treatment initiation rates, and screening offer acceptance rates. Compared to the current practice of screening high-risk individuals, comprehensive screening is likely to be cost effective due to the increase in testing rates, which were conservatively estimated in this study. Furthermore, comprehensive HCV screening of prisoners may prove more cost-effective in countries where prisoners are not routinely screened.

CONCLUSIONS:
Comprehensive screening programs could be considered in prison units with a large proportion of high-risk individuals and where detainees are incarcerated for enough time to complete a treatment course during their sentence.

REFERENCES:
**OP045 Study On Effects Of CAP Clinical Pathway On Antibiotics’ Utilization**

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**ABSTRACT SUMMARY:**
This study aimed to determine if the clinical pathway of community-acquired pneumonia (CAP) had effects on the antibiotic use in patients with CAP. The results showed that adoption of the CAP clinical pathway in hospitals can improve antibiotics’ utilization.

**INTRODUCTION:**
Drug overuse in healthcare settings is common in China. Clinical pathways are tools that provide the link between the best available evidence and clinical practice. This study aimed to determine if the clinical pathway of community-acquired pneumonia (CAP) had effects on the antibiotic use in patients with CAP.

**METHODS:**
The study was conducted in Shanghai, Hubei Province, and Gansu Province to represent high, middle, and low levels of socioeconomic status in 2015. In each region, three public tertiary general hospitals and three public secondary general hospitals were selected for chart review of antibiotics’ utilization in the patients with CAP during 2014. A multilevel logistic regression model was used in the study, with a dependent variable of appropriate utilization of antibiotics (right time, right type, and right combined use) and independent variables of hospital adoption of clinical pathway and patient characteristics (sex, age, severity of disease, and number of comorbidities).

**RESULTS:**
Twelve surveyed hospitals (66.67 percent) adopted CAP clinical pathways and 354 cases (66.29 percent) were from these twelve hospitals (CP group). Among the total utilization of antibiotics (796 times) in 18 types of antibiotics used in patients with CAP, the 5 recommended types of antibiotics accounted for 82.16 percent.

The percentages of cases that got initial antibiotics in time were 90.60 percent in the CP group and 76.11 percent in the non-CP group. The compliance rate for appropriate types of antibiotic utilization was 88.36 percent in CP group, much higher than that in non-CP group (70.22 percent). For 244 cases that used combined antibiotics, the compliance rate for the recommended combinations of antibiotics was 20.12 percent in the CP group, but 1.25 percent in the non-CP group. After controlling patients’ characteristics, the patients in the CP group got more appropriate antibiotics than those in the non-CP group.

**CONCLUSIONS:**
Adoption of the CAP clinical pathway in hospitals can improve antibiotics’ utilization.

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**OP046 Addressing National Health Service (NHS) Priorities: Medtech Innovation Briefings**

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**ABSTRACT SUMMARY:**
National Institute for Health and Care Excellence (NICE) medtech innovation briefings (MiBs) are
INTRODUCTION:
Medtech innovation briefings (MIBs) are intended to support National Health Service (NHS) decision makers and staff who are considering using new innovative medical devices and in-vitro diagnostics. MIBs are produced in support of the NHS 5-Year Forward View, specifically to accelerate innovation in new treatments and diagnostics. This project aimed to evaluate the extent to which published MIBs address national priorities set by NHS England, including in six clinical areas: cancer, mental health, dementia, diabetes, learning disabilities, and maternity.

METHODS:
Data was extracted from eighty-seven MIBs downloaded from the National Institute for Health and Care Excellence (NICE) website including: study design, amount of evidence, date of CE mark, population, cost, manufacturer, device class, publication date, and category of conditions and disease (as prescribed by NICE). Descriptive analysis was done for each variable and frequency tables were produced for MIBs by disease category.

RESULTS:
Cardiovascular disease (n=19) and cancer (n=12) were the two most common conditions addressed by MIB-evaluated devices. The four medical conditions with the fewest MIBs (n=1 each) were: diabetes, liver conditions, neurological conditions, and fertility, pregnancy and childbirth. Of the eighty-five MIBs with stated device classifications, just over half were Class IIa and IIb devices and 18 percent were in-vitro diagnostics. The earliest original CE mark was 1997, and approximately half of the devices obtained or updated their CE mark after 2010.

CONCLUSIONS:
Chronic conditions such as cancer, cardiovascular disease, and diabetes accounted for 89 percent of total deaths in the UK in 2014, thus, the most commonly published MIBs aptly address these issues. However, MIBs are lacking in five out of six NHS priority areas. There is opportunity for innovative technologies to be reviewed via MIBs and alternative NICE pathways in the areas of diabetes, maternity, mental health, and learning disabilities and dementia.

OP047 National Drug Policy In Ukraine: Use Of Health Technology Assessment In The Decision-Making

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) implementation for the development of the National list of essential medicines took place in Ukraine in 2016 in the context of National Drug Policy for the time period until 2025. In line with the international requirements HTA use will provide transparent, consistent decision-making process in assessing the health technologies for inclusion on regulatory lists and reimbursement programs.

INTRODUCTION:
Health Technology Assessment (HTA) introduction and implementation for the development of the National list of essential medicines (NLEM) took place in Ukraine in 2016 in the context of National Drug Policy for the time period until 2025. The regulation states that the selection of
medicines should be based on HTA approaches. Consequently, HTA and pharmacoeconomic analysis is highly relevant currently in the decision-making process in line with the international requirements. The study aimed to outline the main steps in HTA development in Ukraine in 2016 and future directions.

METHODS:
Systematic review, expert interviews within deliberative process with main stakeholders were conducted. A legislation, scientific publications on the study question were analyzed and presented.

RESULTS:
In Ukraine a legal framework was developed in 2016 for the elaboration of the NLEM. HTA should be used for the inclusion of medicines based on the applied evidence of quality, efficacy, effectiveness, safety and economic evaluations adhering to the Order of Ministry of Health (MOH) No. 84 dated 11 February 2016 and Order of MOH No. 1050 dated 7 October 2016. HTA implementation in 2016 consisted of legislation, capacity building regarding HTA training for members of Expert committee of MOH and development of NLEM. Reimbursement programs for cardiovascular disease, type 2 diabetes, asthma are going to be started in April 2017 due to the adopted regulations.

CONCLUSIONS:
HTA use in the decision making in Ukraine will provide an access to innovative treatments for patients and transparent, consistent decision-making process in assessing the health technologies for inclusion on regulatory lists and reimbursement programs.

OP048 Allocation Equity As A Result Of CON In China: An Impact Analysis

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ABSTRACT SUMMARY:
To evaluate the equity impact of the Certificate of Need policy (CON) in China, analysis was done based on the data of CT and MRI distribution in three provinces from 2006 to 2013. The results show that the CON policy improves the equity of major medical equipment overall.

INTRODUCTION:
Equity analysis is an important aspect of policy evaluation in relation to patients’ access to medical equipment. However, very little research has been done on equitable allocation of major medical equipment, especially the equity impact of the Certificate of Need policy (CON) in China.

METHODS:
Using data on CT and MRI distribution in three provinces (A, B, and C from the eastern, central, and western regions of China, respectively) from 2006 to 2013, we performed analyses, using Gini coefficients based on population and geographic distribution, and concentration indices to measure inequalities and map the changing trends during the study period.

RESULTS:
The Gini coefficients of CT and MRI based on population distribution shows a general decreasing
trend over time in the 3 provinces. Between 2006 and 2013, The Gini coefficients of CT based on population distribution changed from .289 to .212 for province A, from .047 to .054 for province B, and from .088 to .007 for province C. As to MRIs, similar changes could be observed: from .334 to .300, from .227 to .089, and from .194 to .008 for province A, B, and C respectively.

The Gini coefficients based on geographic distribution shows different trends by types of equipment and province. For CTs, it changed from .559 to .536, from .088 to .109, and from .386 to .303 respectively. And it varied from .582 to .640, from .272 to .127, and from .420 to .302 for MRIs respectively.

The concentration indices of CT and MRI are all above 0 and show a downward trend, except CT in province B and MRI in province A. The concentration indices for CTs changed from .250 to .207, from .047 to .061, and from .137 to .070 separately. For MRIs, it varied from .253 to .277, from .193 to .069, and from .096 to .073 separately.

CONCLUSIONS:

The equity status of CT and MRI based on population distribution is relatively fair while it’s less fair on geographical distribution. The CT and MRI are gathering in populations with good economic condition, but the situation has improved. The CON policy improves the equity of major medical equipment overall, but some measures shall be taken to enhance the equity on geographical distribution and in the eastern province.

ABSTRACT SUMMARY:

The main aim of this research is to model the impact of drug reimbursement decisions on health outcomes. In particular, this study is looking at countries that have different acceptance, restriction and rejection rates for drug reimbursement decisions. The results show that a more restrictive drug reimbursement system is not related with a worse health outcome.

INTRODUCTION:

Existing literature shows evidence on the differences in drug reimbursement decisions across countries. These differences are the reason for this study. The main aim of this research is to model the impact of drug reimbursement decisions on health outcomes (that is, life expectancy, healthy life years and mortality rates). In particular, this study is looking at countries that have different acceptance, restriction and rejection rates for drug reimbursement decisions.

METHODS:

The current study is based on a longitudinal dataset with data from nine European countries from 2002 to 2014. This dataset is formed of primary data on drug reimbursement decisions (that is, cancer drugs) collected in the Advancing and strengthening the methodological tools and practices relating to the application and implementation of Health Technology Assessment (ADVANCE-HTA) project and secondary data on life tables and indicators of health and socioeconomic status (from Eurostat and World Bank). Following the longevity model defined by Lichtenberg (1), a panel data model with country and year fixed-effects is run on this dataset in order to model the impact of the level of access to drugs on health outcomes.

RESULTS:

The results show that the rate of adoption of new drugs into national health system does not have any significant effect on life expectancy. However, more restrictive systems are positively and significantly related with healthy life years.
Finally, for mortality rates, higher rejection rates are associated with lower deaths.

CONCLUSIONS:
To conclude, contrary to the public opinion, results show that a more restrictive drug reimbursement system is not related with a worse health outcome, it is either associated with a positive outcome or it is not related.

REFERENCES:

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OP050 European Assessments Of Medical Devices: Avenues For Improvement

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ABSTRACT SUMMARY:
This study analyzed the amount of overlap in the assessment of medical devices in Europe. The findings revealed a redundancy of reports, ranging from one to six assessments for one technology per year, and overall five to twenty-two within the time span of 12 years. These results suggest that there is room for improvement regarding the collaboration of health technology assessment institutes in Europe.

INTRODUCTION:
European collaboration in Health Technology Assessments (HTAs) has gained increasing recognition in recent years, not only on pharmaceutical products but also on high-risk medical devices. For medical devices, quality assessments of efficacy and safety are particularly important due to the weak market authorization in Europe. Strengthening efforts towards better collaboration thus plays a pivotal role to reduce overlap and save resources. This study explored the level of redundancy in HTA assessments of medical devices in Europe in order to identify areas for better collaboration.

METHODS:
We performed an analysis of European HTA reports of medical devices regarding their timing in relation to market authorization, the respective level of evidence used and the overlaps in topics. The ADVANCE HTA database from 2014 was used to select a cohort group of ten high-risk medical devices. A systematic search was conducted to identify all relevant, European HTA reports investigating the ten devices within a time span of 12 years (2003-2015). We analysed the number of annual assessments per technology and evaluated activity patterns, late and early assessors, and minimum evidence requirements.

RESULTS:
The results revealed the amount of redundancies in European HTA production: the number of reports per technology ranged from a minimum of five to a maximum of twenty-two over a time-span of 12 years. Within a single year, one technology was assessed up to six times by different HTA institutes in Europe. Out of fourteen countries included in the evaluation, two countries assessed each technology, and seven countries assessed more than seven out of the ten technologies.

CONCLUSIONS:
The findings indicate that more efficient collaboration is needed to save scarce resources and time of HTA institutes. Efficient collaboration as such needs to shift the focus beyond the time span of one year, and start building on each others work from previous assessments.

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OP051 Thrombectomy In France: A National Use Of European Network for Health Technology Assessment (EUnetHTA) Joint Assessment

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ABSTRACT SUMMARY:
This work illustrates the use of a European assessment in the French context. It has facilitated and shortened the assessment of the clinical benefit of this technology, confirming the relevance of EUnetHTA cooperation.

INTRODUCTION:
Mechanical thrombectomy (MT) is used in patients with acute ischaemic stroke due to occlusion of a proximal cerebral artery. Over the years endovascular techniques have been used to re-canalise blocked vessels, but are not currently reimbursed by National Health Insurance in France.

The aim was to assess the efficacy and safety of MT in combination with intravenous tissue plasminogen activator (IV t-PA), or as an alternative to it, in adults with an acute ischaemic stroke who are not eligible for thrombolysis or in whom thrombolysis has failed; to support the reimbursement decision by National Health Insurance.

METHODS:
Within the scope of The European Network for Health Technology Assessment (EUnetHTA), a rapid assessment of “Endovascular therapy using devices for acute ischaemic stroke” was jointly produced with Haute Autorité de santé (HAS) as a reviewer.

RESULTS:
The EUnetHTA report provided a systematic review based on eight randomised controlled trials (RCT) for effectiveness and all available published data for safety.

To produce its assessment, HAS has adapted the EUnetHTA report by:
1. Updating the systematic literature review including the latest published trials
2. Retaining the subgroup analysis of the five most recent trials considered more relevant in the EUnetHTA report for the assessment of effectiveness
3. Analysing specifically the different endovascular interventions studied in the five RCTs
4. Taking into account contributions from stakeholders.

CONCLUSIONS:
This horizontal collaboration among European HTA doers has facilitated and shortened the assessment of the clinical benefit of this technology, confirming the relevance of EUnetHTA cooperation.

This clinical assessment of thrombectomy is to be completed by the evaluation of its organizational impact in the management of acute ischemic stroke.

OP052 The Health Technology Assessment Cooperation Model In Andalusian Public Health System

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**ABSTRACT SUMMARY:**
Andalusia, with a public health system consisting of 1,518 primary care centres and 40 hospitals has established a system of Health Technology Assessment (HTA) provincial committees. In this presentation, we describe the procedure to establish a cooperative network model for HTA among these committees along with AETSA, the regional agency. The working plan and the main actions already in place are presented.

**INTRODUCTION:**
Andalusia - a Spanish region, 8.5 million inhabitants, 8 provinces - has a public health system consisting of a network of 1,518 primary care centres and 40 hospitals. Under an instruction from the Health Technology Assessment (HTA) provincial committees have been set up with a mission to decide which new technologies, indications or products that are requested by the clinical services should be added to the centres’ portfolio. This presentation describes the procedure to establish a model of networking cooperation among HTA provincial commissions and AETSA (the agency responsible for HTA at regional level).

**METHODS:**
Networking models in HTA were identified through a systematic review of available scientific literature. A comparative analysis of these models was carried out, based on methodology and work organization. A working group was then set up to define the model in Andalusia, composed of the coordinators of provincial committees, representatives of the Andalusian Health Service and AETSA. This group identified the needs and expectations of those involved in the HTA process and objectives, critical points and a work plan were established.

**RESULTS:**
Models identified and analyzed were the Spanish Network for HTA, the European Network for HTA (EUnetHTA), HTA units in the university hospitals of Quebec and the AdopHTA project. Actions developed up to the present time were: definition of the network and its members; establishment of the network coordination point; implementation of procedures and workflow algorithms; a website platform to share information; the elaboration of a joint short report model; implementation of a procedure for HTA information retrieval and methodological support by AETSA.

**CONCLUSIONS:**
This work model implemented in Andalusia indicates that it is possible to carry out a collaborative and productive working relationship within HTA by integrating resources from provincial commissions together with the Andalusian Health Service and the regional agency AETSA.

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**OP053 Tuberculosis Treatment Adherence In Homeless: An Overview Of Reviews**

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**ABSTRACT SUMMARY:**
We aimed to systematically overview published systematic reviews (SR) that evaluate interventions purposed to increase adherence to tuberculosis treatment for homeless. Four interventions were effective to increase the adherence: (i) financial
incentives and enablers to improve adherence (two SR); (ii) housing and support (five SR); (iii) case management programs; (iv) assertive community treatment and peer education (four SR).

INTRODUCTION:
Tuberculosis’ prevalence in homeless people is exacerbated by interruptions in a complex and long-term therapy. We aimed to systematically overview published systematic reviews (SR) that evaluate interventions purposed to increase adherence to tuberculosis treatment by this population.

METHODS:
We conducted electronic searches in the Cochrane Library, PubMed MEDLINE, Web of Science, Health System evidence, Center of Review Dissemination-CRD, and Latin American and Caribbean Health Science Literature- LILACS databases, without language restrictions. The last search was in April 2016, for all databases. The MESH terms utilized were: (i) “homeless,” “homeless person,” “Homelessness,” “Street People;” (ii) “treatment,” “medication adherence.” Searches were limited to SR. The eligibility criteria were studies that: included homeless people and incentives, related the type of incentive to treatment adherence, and evaluated the effect. Two authors independently performed the studies selection, data collection, and analysis. The variables of analysis were: intervention’s elements, benefits, and damages, and costs and uncertainties regarding the intervention. The overall quality of studies was assessed according to the AMSTAR.

RESULTS:
Sixteen reviews, from 239, met the inclusion criteria. Four interventions were effective to increase adherence: (i) financial incentives and enablers to improve adherence (two SR); (ii) housing and support (five SR); (iii) case management programs; (iv) assertive community treatment and peer education (four SR). Most of the interventions found were conducted in high-income countries. Adaptations to the local context in low and middle-income country might be necessary. The uncertainties of implementation should consider the participation of health professionals, policy makers, and patients.

CONCLUSIONS:
The effective interventions that increase adherence to treatment in homeless persons may allow the reduction of inequity in health care of patients in extreme poverty.

OP054 Health Technology Assessment And Chronic Hepatitis C: Coverage Decisions In Eight Countries

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ABSTRACT SUMMARY:
Despite Chronic Hepatitis C (HCV) being a relatively common infection in OECD countries, access to new high-cost therapies across countries remains fragmented. This paper analyses Health Technology Assessment recommendations for HCV in eight countries and offers insights on the key parameters and the rationale driving different coverage decisions across different countries.

INTRODUCTION:
Despite Chronic Hepatitis C (HCV) being a relatively common infection in OECD countries, access to new life saving therapies across countries remains fragmented. This paper analyses the reimbursement situation for HCV treatments across eight countries (Australia, Canada, England, France, Germany, Italy, Scotland, and Sweden) that use Health Technology Assessment.
Assessment (HTA) and other tools informing coverage decisions.

METHODS:

Data on HTA appraisals were collected in 2016 from eight HTA agencies. A database capturing ninety-six unique data points grouped under six areas (clinical and economic evidence, clinical and economic uncertainties, social values judgements, and real-world evidence) was constructed. The data collected qualitatively were quantitatively analyzed with the software Nvivo10 to identify the influence of the criteria on the final outcomes and to measure the extent of differences across cases and how these contributed to explaining different outcomes.

RESULTS:

Around 75 percent of HTA recommendations on new hepatitis treatments have been favorable or favorable with restrictions, with the exception of IQWIG where “Added benefit not proven” is the most common outcome. Thirty-five percent of all recommendations were restricted to specific sub-populations particularly related to advanced fibrosis stage, liver cirrhosis, or previous treatments. The disparities in recommendations recorded were stemming often from different inclusion of clinical trials (35 percent of the time) or economic model (56 percent of the time). A high variability in the economic analysis was noted leading in some cases to restrictions put in place by the HTA agencies for improving the cost-effectiveness of these treatments.

CONCLUSIONS:

This research showed a high degree of discordance in methods used to assess different genotypes of HCV across the countries studied, driven by several factors including the complex epidemiology of hepatitis C disease, the large number of treatment regimen available, and the different ways of accounting evidence across agencies. On one hand, this could be seen generally good due to the high heterogeneity in the global distribution of the genotypes, on the other there is a need to standardize methods to guarantee a fairer access to life saving medicines.

OP055 Health Technology Assessment In Children And Adolescents: Adolescent Preferences For Child Health Utility 9D Health States

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ABSTRACT SUMMARY:

This study provides important cross-country insights into the use of choice methods to elicit health state values with young people for application in health technology assessment (HTA) in children and adolescents. The differential preferences identified between Australia and China highlights the necessity to derive country-specific adolescent scoring algorithms for preference based health related quality of life measures in this context.

INTRODUCTION:

Preference-based measures of health-related quality of life play a key role in the calculation of Quality-Adjusted Life Years (QALYs) for Health Technology Assessment (HTA). The Child Health Utility 9D (CHU9D) is a new preference-based instrument designed specifically for application in children and adolescents (aged 7 to 17 years). This study aimed to compare Chinese and Australian...
adolescent population preferences for CHU9D health states using profile case best worst scaling (BWS) methods.

METHODS:
Fifty CHU9D health states (blocked into five survey versions) were generated for valuation using a fractional factorial design. Study participants were recruited through an online panel company in Australia, and through primary and secondary schools in China. A latent class modelling framework was adopted for econometric analysis.

RESULTS:
A total of 1,982 respondents (51 percent female) in Australia and 902 respondents (43 percent female) in China provided useable survey responses. Latent class analysis indicated the existence of preference heterogeneity for both population groups. In the Australian sample, respondents in Class I placed the most importance on the mental health dimensions of the CHU9D (for example, Worried and Annoyed) and the least importance on daily activities (for example, Activities, Daily routine, Sleep), whilst respondents in Class II placed equal weights on all attributes. In the Chinese sample, respondents in Class I placed the most importance on the Activities dimension of the CHU9D and the least importance on the Annoyed dimension, whilst Class II placed the most importance on the Schoolwork dimension and the least importance on Pain.

CONCLUSIONS:
This study has provided important cross-country insights into the use of profile case BWS methods to elicit health state preferences with young people for application in HTA in children and adolescents. The differential latent classes identified between Australia and China highlights the necessity to derive country-specific adolescent scoring algorithms for the CHU9D instrument for application in HTA.

OP056 Advancing Research In Hernia Repair: A Value Of Information Analysis

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ABSTRACT SUMMARY:
Value of information analysis (VOI) is an important tool to guide future research to decrease or eliminate uncertainty surrounding cost-effectiveness. In the comparison of the two Markov models (baseline model and updated model), there was clear evidence that updating model parameters greatly reduced expected value of perfect parameter information (EVPPI) as hypothesized, leading to a reduction in uncertainty surrounding cost-effectiveness.

INTRODUCTION:
Inguinal hernia repair is one of the most common surgical procedures carried out in the United Kingdom and consumes significant scarce healthcare resources. Value of information analysis (VOI) is an important tool to guide future research to decrease or eliminate uncertainty surrounding cost-effectiveness. This study applies VOI analysis to an evolving evidence base for surgical repair of primary inguinal hernia, testing the hypothesis that new evidence actually reduces the need for future research.

METHODS:
VOI was conducted on two different Markov cohort models to enable the comparison. The most recent model with updated parameters evaluated the cost-effectiveness of Lichtenstein, open pre-peritoneal, and laparoscopic repair strategies. The older, baseline model compared Lichtenstein to laparoscopic repair. VOI was conducted using only
the comparable strategies. The expected value of perfect information (EVPI) was calculated for both models as well as the expected value of perfect parameter information (EVPPI) for ten comparable parameters between the models.

RESULTS:
Expanding the evidence base did not change the most cost-effective treatment strategy (open pre-peritoneal repair). The population EVPI for the old model was GBP16,725,410 and the EVPI for the new model was GBP7,853,116 (a decrease of 53 percent). The EVPPI for three parameters (relative risks of chronic pain and recurrence as well as utility associated with chronic pain) were positive in the old model but turned zero in the updated model.

CONCLUSIONS:
There was clear evidence that updating model parameters greatly reduced EVPI as hypothesised, leading to a reduction in uncertainty surrounding cost-effectiveness. The greatest uncertainty lies between open pre-peritoneal and laparoscopic repair, meaning more research is required to compare these two strategies. Whilst the use of VOI analysis is growing, there remains a requirement to make decision makers aware of its benefits and potential for use in applied research funding decisions.

OP057 ‘Beyond The Mean’ in Biomarkers Modelling For Economic Evaluations

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ABSTRACT SUMMARY:
In Gestational Diabetes Mellitus (GDM), treatment is recommended for women whose 2-hours post-load and/or fasting glucose levels exceed extreme values. We apply flexible parametric distributions to model the biomarkers and predict the likelihood of extreme values. We incorporate the optimal distributions in a decision analytic framework and estimate the cost-effective diagnostic thresholds and the cost-effectiveness of the alternative strategies.

INTRODUCTION:
Economic evaluations often rely on individual-patient data (IPD) to calculate the probabilities of events based on observed proportions (1). This approach is limited when interest is in the likelihood of extreme biomarker values, which vary by observable characteristics (such as high blood glucose levels in Gestational Diabetes Mellitus (GDM)). As an alternative, we utilise flexible parametric models that estimate the full conditional distribution (2), capturing the non-normal characteristics of biomarkers. This enables tail probabilities for particular populations to be derived (3). Overall, this approach improves generalisability of conclusions and disengages decision models from direct use of IPD.

METHODS:
Data was sourced from the Born in Bradford study (n=10,353). We use a two-step approach. Firstly, we applied fully parametric maximum-likelihood to estimate the alternative models, and Information Criteria and tail probability goodness-of-fit measures to choose the optimal distributions for each glucose marker. Secondly, we integrated the chosen distributions in a probabilistic decision analytic model that estimates the cost-effective diagnostic thresholds and the expected costs and Quality-Adjusted Life Years (QALYs) of the alternative strategies. Main strategies include:

RESULTS:

Log-Logistic (Fisk) and Singh-Maddala distributions provide optimal fit for the 2-hours post-load and fasting glucose biomarkers, respectively. At GBP13,000 per QALY, maximum NMB with ‘Test and Treat’ (-GBP330) was achieved for a diagnostic threshold of Fasting glucose > 6.6mmol/L, 2-hours Post-load glucose > 9mmol/L, identifying 2.9 percent of women as GDM positive. However, ‘Do Nothing’ is the cost-effective strategy (-GBP285NMB) for all analyses. Results are robust to scenario analyses.

CONCLUSIONS:

Fully parametric approaches (2,3) can be implemented in healthcare modelling when interest is in extreme biomarker values. Although ‘Do Nothing’ is the optimal strategy for GDM, accurate estimation of longer-term benefits for mothers and offspring may change that decision and the optimal diagnostic thresholds.

REFERENCES:


OP058 Testing Of A Multiple Criteria Decision Analysis Value Framework With Decision Makers Across Europe

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ABSTRACT SUMMARY:

The application of an MCDA value framework was tested in practice for a set of hormone-relapsed metastatic prostate cancer treatments through a series of experimental case studies with different HTA agencies. A disease-specific value tree was constructed and the MACBETH approach was adopted to elicit decision-makers preferences based on which overall weighted value scores were produced and treatments were ranked.

INTRODUCTION:

We test in practice a Multiple Criteria Decision Analysis (MCDA) framework for the value assessment of a set of therapeutic options for the indication of hormone relapsed metastatic prostate cancer (mPC) through a series of simulation exercises with the participation of decision makers from different Health Technology Assessment (HTA)/insurance agencies across Europe, including TLV (Sweden), AETSA (Andalusia-Spain), INAMI-RIZIV (Belgium) and AOTMIT (Poland). The drugs evaluated were abiraterone, cabazitaxel and enzalutamide.
METHODS:
Using a multi-attribute value theory framework, past research outcomes and literature findings, an mPC-specific value tree was constructed incorporating relevant concerns as criteria. By adopting the MACBETH approach the different drugs were scored against the criteria through the development of value functions, relative weights were assigned to the criteria using a swing weighting technique, scores and weights were combined using an additive aggregation technique, and sensitivity analysis of results was conducted. All stages were informed through the participation of a small group of experts from each HTA/insurance agency at a series of decision conferences taking place in each country.

RESULTS:
Value parameters considered spanned the dimensions of therapeutic impact, safety profile, innovation level and socioeconomic impact. Overall weighted preference value scores were produced reflecting the performance of the treatments against the criteria while considering their relative importance. Order of treatments’ rankings was identical across all agencies, with enzalutamide scoring highest and cabazitaxel lowest. Therapeutic impact criteria always produced the greatest relative weight. Hypothetical priority setting decisions were made based on “value-for-money” grounds through the use of “cost per unit of value” metrics by incorporating purchasing costs.

CONCLUSIONS:
The MCDA framework tested possesses a number of characteristics that could facilitate decision making, including the systematic and explicit incorporation of value trade-offs as part of model assessment and the transparency throughout all its stages. Therefore, it has the prospects to act as a practical evaluation tool for value assessment and communication during the HTA process.

OP059 Decision Uncertainty And Incentives For Conducting Further Research

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ABSTRACT SUMMARY:
fEVAR is an example of a typical dilemma facing healthcare decision makers: early decision based on poor evidence and high risk of error, or delayed decision based on more evidence but at the expense of current patients? A framework to characterize the sources of uncertainty and to identify the most appropriate decision option for health technologies is tested.

INTRODUCTION:
A typical dilemma that has proved challenging for healthcare decision makers is whether making an early decision based on poor evidence and high risk of error, or delaying a decision until more evidence becomes available but leave current patients without effective treatment. Fenestrated endovascular aneurysm repair (fEVAR) is a new endovascular approach that is used as an example of such dilemma. We assess the clinical and cost-effectiveness of fEVAR compared to open surgical repair (OSR), characterize relevant sources of uncertainty and quantify their impact on cost-effectiveness to discuss how this would influence the decision and need for further research.

METHODS:
A systematic review, meta-analysis and a four state Markov model were developed to estimate the cost-effectiveness of fEVAR versus OSR in patients.
with complex abdominal aortic aneurysms (cAAAs). We refer to a recently developed framework to characterize the relevant sources of uncertainty for this device-based intervention and inform decisions about the type of further research that would be most worthwhile and feasible.

RESULTS:
Seven observational comparative studies were identified, with a central estimate of the odds ratio of .54 (95 percent Confidence Interval, CI: .05 to 6.24) for mortality in favour of fEVAR. With current evidence, the incremental cost-per-Quality Adjusted Life Year (QALY) was estimated to GBP75,528/QALY, with low probability that fEVAR would be cost-effective at standard threshold.

CONCLUSIONS:
Based on current evidence, fEVAR is not a cost-effective option at standard acceptable cost-effectiveness thresholds in the United Kingdom but the Only in Research (OIR) decision might be warranted in jurisdictions with higher thresholds. More research might plausibly reduce decision uncertainty, particularly around operative mortality. Coverage with evidence development recommendations may be warranted.

**OP060 Ramucirumab In Gastric Cancer Treatment: An Economic Evaluation**

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**ABSTRACT SUMMARY:**
Gastric cancer (GC) is the third leading cause of cancer mortality worldwide. We performed a cost-effectiveness analysis of the Ramucirumab plus paclitaxel doublet versus paclitaxel alone in patients with previously treated GC, based on results of the RAINBOW trial. This is the first study from an Italian-payer perspective and the first worldwide to examine ramucirumab as a 2nd-line treatment.

**INTRODUCTION:**
Gastric cancer (GC) is one of the most common malignancy and the third leading cause of cancer mortality worldwide. Currently, platinum-based and fluoropyrimidine-based combinations represent the milestone of front-line drug regimens. Unfortunately, there are few treatment options after failure of first-line therapy. Ramucirumab, a human IgG1 monoclonal antibody to VEGFR-2, has been recently approved in the European Union (EU) for use as monotherapy or in combination with paclitaxel as second-line treatment in patients with advanced GC with progressed disease. We performed a cost-effectiveness analysis of the Ramucirumab plus paclitaxel doublet versus paclitaxel alone in patients with previously treated advanced GC, based on results of the RAINBOW trial (1).

**METHODS:**
A Markov model has been developed in order to estimate the Life Years Gained (LYGs) and the incremental cost-effectiveness ratio (ICER) for both treatments. The model adopted the Italian healthcare system perspective and the time horizon is that of the lifetime of a patient with an advanced GC. The model considered three distinct health states: stable, progression or death. Transition probabilities were extracted from the Kaplan-Meier curves provided in the trial and cubic/spline function was used to approximate the extrapolation of survival curves for each treatment cycle. An internal model validation was performed to validate the Overall Survival (OS) curves generated by our model simulation. We based our economic analysis
on clinical data and resource consumption (drugs, drug administration, supportive care medications, disease monitoring and graded 3 or 4 adverse events) on the Italian setting (2,3). All costs were expressed in euros. Sensitivity analysis also have been performed.

RESULTS:
This cost-effectiveness study demonstrated that, in 2nd-line therapy, the combination of ramucirumab with paclitaxel provides an incremental benefit (+1.54) at high incremental cost (EUR41,616) per LYGs.

CONCLUSIONS:
At a threshold of EUR5,000 for LYGs, based on Italian perspective, ramucirumab plus paclitaxel had less probability of being cost-effective. To our knowledge, our study is the first modeling study from an Italian payer perspective and the first worldwide to examine ramucirumab as a 2nd-line treatment.

REFERENCES:

OP061 Cost-Utility Analyses Of Biologics For Refractory Ulcerative Colitis

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ABSTRACT SUMMARY:
Using a 10-year time horizon, a 3-health state transition model was developed to determine the cost-utility of biologics in patients with refractory moderate-to-severe Ulcerative Colitis from a National and Regional perspective in Italy. The results of our analysis suggest that local analyses are needed to evaluate the real economic impact of these treatments in the Italian Healthcare systems.

INTRODUCTION:
Although many biologics (Bs) have been approved for the treatment of moderate-to-severe Ulcerative Colitis (UC) in patients who have responded inadequately to conventional therapy, the selection of Bs is controversial due to the lack of head-to-head trials. Indirect economic comparisons of these costly drugs are available from National Healthcare perspectives that are not the Italian ones. Therefore, the objective is to evaluate cost-utility of Bs for the treatment of refractory moderate-to-severe UC both in Italy and in the Lombardy Region.
METHODS:
A Markov model (considering three transition states: remission, clinical response, relapse) was constructed using the software R 3.3.1 markovchain-package to evaluate incremental cost-utility ratios (ICUR) of adalimumab (ADA), infliximab (IFX), infliximab biosimilar (IFX-B), golimumab (GOL) and vedolizumab (VED) treatments of patients over a 10-year time horizon from the perspective of the Italian (N) and Lombardy Region (R) healthcare system. Clinical parameters were derived from clinical trials. Costs (actualized by – 1.5 percent) were obtained from the National database and Regional public tender. Utility was expressed as QALY (Quality-Adjusted Life Years).

RESULTS:
Costs per treatment were different from a N and R perspective (ADA -55 percent; IFX -16.7 percent; IFX-B -29.6 percent; GOL -9.6 percent; VED -10 percent). Direct healthcare costs (treatment cost, visits, laboratory tests, hospital admissions) were calculated over 10 years of treatment per patient: ADA (N: EUR114,227, R: EUR68,314, -40.2 percent), IFX (N: EUR130,595, R: EUR103,081, -21 percent), IFX-B (N: EUR110,438, R: EUR78,852, -28.6 percent), GOL (N: EUR118,602, R: EUR96,922, -18.3 percent), VED (N: EUR113,852, R: EUR102,932, -9.6 percent) with associated QALY respectively of 6.68, 6.66, 6.66, 7.02. From a N perspective, IFX-B was dominating compared to all other treatments. The ICUR of VED/IFX-B was EUR9,483 for 10 years (willingness to pay EUR948/QALY). From a R perspective, ADA was dominating compared to all other treatments. The ICUR of VED/ADA was EUR101,818 for 10 years (Willingness to Pay, WTP EUR10,182/QALY).

CONCLUSIONS:
National and Regional cost-utility analyses produced different results. As Regional price discounts can occur, local analysis is needed to estimate the economic impact of therapies to ensure optimal choice.

OP062 Cost-Effectiveness Of Mechanical Thrombectomy For Endovascular Therapy

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ABSTRACT SUMMARY:
The addition of endovascular treatment with second-generation mechanical thrombectomy devices to intravenous thrombolysis significantly improves functional outcomes for eligible patients experiencing an acute ischaemic stroke. The cost-effectiveness is contingent on the infrastructure and ability to deliver the service within existing capacity.

INTRODUCTION:
There is Randomized Controlled Trial (RCT) evidence that the addition of endovascular treatment with second-generation mechanical thrombectomy devices to intravenous thrombolysis significantly improves functional outcomes for eligible patients experiencing an acute ischaemic stroke. This study estimated the cost-effectiveness of adding mechanical thrombectomy to established standard-of-care.

METHODS:
A decision-tree model with Markov component was populated with clinical effectiveness data derived from a systematic review and meta-analysis of published RCTs and other parameter estimates derived from the literature and local cost databases. The main outcome was the incremental cost-effectiveness ratios (ICER) at five years. The base
case analysis assumed that an additional dedicated bi-planed angiography suite would be required to provide sufficient capacity for a national service. The cost of transferring patients from stroke units to one of two national endovascular treatment centers was also included.

RESULTS:
A national endovascular treatment service would lead to an incremental cost and benefit of EUR2,626 and 0.19 quality-adjusted life years (QALYs) per eligible patient. The ICER was EUR14,016 per QALY with a probability of being cost-effective of 70 percent and 99 percent at thresholds of EUR20,000 and EUR45,000 per QALY gained, respectively. The parameter with most influence on the ICER was the proportion of patients achieving functional independence. A national service would have substantial organizational implications, particularly for the timely transport of patients to treatment centers.

CONCLUSIONS:
Assuming clinical outcomes achieved in RCTs can be replicated by a national service, the addition of mechanical thrombectomy to standard-of-care would deliver a substantial clinical benefit and be cost-effective. Provision of such a service would have a number of organizational implications in terms of patient transfer and staffing. The finding that mechanical thrombectomy is cost-effective is contingent on the infrastructure and ability to deliver the service within existing capacity.

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ABSTRACT SUMMARY:
This work describes the experience of rationalization of the hospital medical devices (MDs) list in a disinvestment viewpoint conducted in an university hospital. We present two different pilots in two fields of hospital applications: surgery (advanced energy devices to seal and cut tissue) and orthopedic (ankle and knee prosthesis).

INTRODUCTION:
This work describes the experience of rationalization of the hospital medical devices (MDs) list in a disinvestment viewpoint conducted in an university hospital. We present two different pilots in two fields of hospital applications: surgery (advanced energy devices to seal and cut tissue) and orthopedic (ankle and knee prosthesis). The two pilots were coordinated by the Health Technology Assessment (HTA) unit of the hospital. We performed a review of all MDs available in the hospital list to simplify the overloaded list, to guarantee the appropriate use of MDs, and to obtain savings in the annual spending.

METHODS:
Through the involvement of all relevant stakeholders, we follow common methods: hospital list analysis, clustering of the devices into the two areas, negotiation of referred MDs with all the suppliers, proposal to users to modify the list with the introduction of the cost-effective MDs, and contemporarily the removal of obsolete, not cost-effective, and overlapping MDs.

OP063 Lights And Shadows Of Health Technology Assessment Disinvestment In A Hospital Context

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RESULTS:
The results of the pilots were different and opposing: (i) a success for the area of ankle and knee prosthesis with a potential annual cost saving of around EUR300,000 (-20 percent) and a definition of a light and simpler hospital list with a logistics benefit, (ii) an ongoing project in the advanced energy device that in the mid-term implicated an increase into use of more complex MDs that determined an increase in the annual spending (+20 percent). Now we are considering a corrective action. There are several explanations for these so different results. In the case of advanced energy, there are more users and more applications (laparoscopic and open surgery in different surgical areas: abdominal, urologic, gynecologic, neurosurgical, bariatric, thyroid) so it is more complex to introduce changes first of all from a cultural point of view. Meanwhile in the orthopedic field in our hospital there are only two head physicians characterized by influential personalities who decide on all the equipment.

CONCLUSIONS:
The lesson learned from these two projects is that the definition of transparent methods is the starting point of every work, but this method has to complete with the consideration of all variables in context.

OP064 Economic Impact Of Cardiac Device Remote Monitoring In South Korea

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ABSTRACT SUMMARY:
This work provides an estimation of the potential economic benefit of remote monitoring in cardiac implantable electronic devices in South Korea, providing additional substance to the ongoing societal debate about the value of telemedicine. Remote monitoring could result in a 53 percent of saving in annual healthcare costs.

INTRODUCTION:
The reduction of healthcare costs and societal cost due to remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) has been demonstrated in several countries; however, to the best of our knowledge it does not exist for South Korea. This work aims at providing an estimation of the potential benefit of RM versus standard care (SC) of CIEDs in term of healthcare costs in South Korea, in order to provide additional substance to the currently ongoing societal debate about the value of telemedicine.

METHODS:
Healthcare resource consumption was taken from the results of the TARIFF study, a prospective, non-randomized, multicenter clinical trial designed in Italy to assess the economic benefits of RM follow-up in comparison with standard follow-up in 209 patients (107 SC, 102 RM). The main results demonstrated that RM reduced healthcare resource consumption by 54 percent from a healthcare services perspective (SC: EUR1,044.89±1,990.47 vs RM: EUR482.87±2488.10, p<.0001 (1).

In order to perform a cost analysis from the perspective of the South Korean healthcare payer, the following unit costs were assigned to resources collected in TARIFF (hospitalizations, visits, examinations): fee-for-service tariffs, emergency tariffs and outpatient tariffs. Remote follow-up costs were considered as zero.
RESULTS:
From the perspective of the South Korean healthcare payer, the overall mean annual cost/patient in the RM group is 53 percent lower than in SC group (SC: EUR405,439±40,135 vs RM: EUR189,96±725,52, p<.0001) (SC: KRW 497,145±49,213 vs RM: KRW 232,936±890,181, p<.0001). This is mainly due to a significant cost reduction in device-related hospitalizations, examination tests and visits in the follow-up period.

CONCLUSIONS:
RM of CIED patients is cost-saving from the perspective of the South Korean healthcare system. Introducing appropriate reimbursement for remote monitoring of CIED is not likely to change this result and should make RM sustainable for the provider and encourage widespread adoption of RM.

REFERENCES:

OP065 Lung Cancer Screening: Microsimulation Analysis Based On NLST & NELSON

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ABSTRACT SUMMARY:
LDCT based lung cancer screening (LCS) still leaves many questions unanswered. Ongoing clinical trials, NELSON in Europe and NLST in the USA, are investigating impact of LCS on cancer mortality. Eligibility criteria and nodule managements are different. We compare benefits and harms of both approaches using a stochastic microsimulation model for LCS that is designed to simulate individual life histories.

INTRODUCTION:
Two major ongoing randomized control clinical trials examine efficacy of screening with low-dose Computed Tomography (LDCT) in reduction of lung cancer mortality: NLST in the United States and NELSON in Europe. NELSON and NSLT apply different eligibility criteria and protocols for the nodule assessment and management. The current results show reduction of lung cancer mortality, however, the screening has negative outcomes, for example false positive findings and overdiaognoses. A screening program requires a trade-off between its benefits and harms.

We aim to investigate the impact of the nodule management strategies used in NLST and NELSON on the outcomes of lung cancer screening, and to assess the benefits and harms of varying scenarios for a screening program in Germany.

METHODS:
The study is based on a microsimulation model for lung cancer screening which is of modular design and comprises of population, natural history, clinical detection and survival, and screening modules. Five histological classes of lung cancer are simulated. Five years of six different screening scenarios are evaluated. Main health outcomes are life years saved and averted lung cancer specific deaths. The main comparator is no screening scenario. Sensitivity analysis is performed.

RESULTS:
The NELSON nodule management protocol leads to inconsiderably higher values of the benefits than the NLST. The NELSON protocol leads to an insignificantly higher percent of overdiagnosis cases than the NLST. The NLST nodule management, leads to 60 percent more follow-up examinations of malignant and benign nodules than NELSON.
The five-year annual screening yields gains of 352,096 life years (LY) at a cost of 11,552.85 EUR/LY and over 24,000 averted deaths due to the cancer and results in 11.7 percent reduction of lung cancer mortality.

CONCLUSIONS:
The favourable scenario for Germany is age range from 55 to 74 years, 30 pack-years and 15 years since quitting smoking and the NELSON approach to the nodule management.

OP066 Optical Coherence Tomography For Neovascular Age-related Macular Degeneration: Economic Evaluation

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ABSTRACT SUMMARY:
Age-related macular degeneration (AMD) is the commonest cause of sight impairment in elderly people in the UK. In neovascular AMD (nAMD), vision worsens rapidly; close monitoring and treatment (anti-Vascular Endothelial Growth Factor, anti-VEGF) are needed. Optical coherence tomography (OCT), a non-invasive imaging test widely used in the National Health Service (NHS), often alongside others, can detect nAMD. The aim of this study was to assess the relative efficiency of OCT in diagnosing and monitoring people newly presenting with suspected nAMD.

INTRODUCTION:
Age-related macular degeneration (AMD) is the commonest cause of sight impairment in elderly people in the UK. In neovascular AMD (nAMD), vision worsens rapidly due to the growth of abnormal blood vessels that leak fluid and blood at the macula. Close monitoring and treatment (anti-Vascular Endothelial Growth Factor, anti-VEGF) are needed. Optical coherence tomography (OCT), a non-invasive imaging test widely used in the National Health Service (NHS), often alongside others, can detect nAMD. The aim of this study was to assess the relative efficiency of OCT in diagnosing and monitoring people newly presenting with suspected nAMD.

METHODS:
A Markov model was developed (65 year old cohort, nAMD-prevalence 70 percent) with nine strategies for diagnosis and/or monitoring (ophthalmologist or nurse/technician led visits; OCT combined or not with other tests). Data to populate the model were obtained from systematic (sensitivities and specificities) as well as structured reviews. NHS and Personal Social Services perspective was adopted. Costs and quality-adjusted life years (QALYs) were discounted (3.5 percent). Deterministic and probabilistic sensitivity analyses were performed.

RESULTS:
In pooled estimates of diagnostic studies (all Time domain-OCT), sensitivity and specificity (95 percent Confidence Interval, CI) was 88 percent (46 to 98 percent), and 78 percent (64 to 88 percent), respectively. For monitoring (TD-OCT and Spectral Domain-OCT), the pooled sensitivity and specificity was 85 percent (72 to 93 percent) and 48 percent (30 to 67 percent), respectively.

Fundus fluorescein angiography (FFA) for diagnosis and nurse/technician-led monitoring (OCT & visual acuity) strategy had the lowest cost (GBP39,769; QALYs 10.473) and dominated all others except FFA for diagnosis and ophthalmologist-led monitoring.
(GBP44,649; QALYs 10.575; ICER GBP47,768). The least costly strategy had a 46.5 percent probability of being cost-effective at GBP30,000 willingness to pay threshold.

CONCLUSIONS:
OCT had high sensitivity and moderate specificity for diagnosis, and relatively high sensitivity but low specificity for monitoring. OCT alone for diagnosis and/or monitoring is unlikely to be cost-effective. Further research is required on: (i) the performance of SD-OCT (monitoring and diagnosis) (ii) the likelihood of active/inactive nAMD becoming inactive/active, and (iii) treatment-associated utility weights.

INTRODUCTION:
The cost-effectiveness of Human papillomavirus (HPV)-based primary cervical screening in the Irish healthcare setting is assessed using a decision-analysis approach to inform a decision around changes to the national screening program. Current practices comprises primary screening with liquid-based cytology (LBC) followed by HPV triage, at 3-yearly intervals for ages 25 to 45 years and 5-yearly until age 60 years.

METHODS:
This study assessed changing the primary screening test from LBC to HPV testing, in both an unvaccinated and a vaccinated (against HPV 16/18) cohort. It considered extending the screening interval (to 5-yearly for all), the upper age limit (from 60 to 65 years) and different test sequences (four possible tests were included: HPV, LBC, partial genotyping for HPV16 or HPV 18 and the molecular biomarker p16INK4a/Ki67). A Markov-model for HPV-infection and cervical cancer was developed based on a German cervical screening model (1). The perspective of the healthcare system was adopted and a 5 percent discount rate used.

RESULTS:
Strategies using HPV as the primary screening test are more effective than LBC-based strategies. The optimal strategy, at a willingness-to-pay threshold of EUR45,000 per quality-adjusted life year (QALY), for the unvaccinated cohort was HPV-based primary screening with a LBC triage test, at five-yearly intervals from age 25 to 60 years. This strategy is cost saving compared with current practice) and cost effective when compared to no screening, with an Incremental cost-effectiveness ratio (ICER) of EUR18,164 per QALY. The optimal strategy for the vaccinated cohort was also HPV primary screening with a LBC triage test, at five-yearly intervals from age 25 to 60 years. While more effective and cost saving compared with current practice, it would not be considered cost effective compared with no screening (ICER of EUR58,745/QALY).
CONCLUSIONS:
Based on our analyses, HPV-based cervical screening is more effective and cost saving compared with LBC-based screening for both vaccinated and unvaccinated cohorts in an Irish setting.

REFERENCES:

OP068 An Evidence-Based Clinical Pathways Program Reduces Low-Value Care

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ABSTRACT SUMMARY:
This presentation shows how a hospital-based Health Technology Assessment (HTA) center can influence clinical decision making by presenting clinical pathways in a website and mobile app.

INTRODUCTION:
Misdiagnosis of asymptomatic bacteriuria as catheter-associated urinary tract infection (CAUTI) leads to unnecessary tests and other low-value care. We used this topic as the prototype to develop a clinical pathways program to promote evidence-based decision making in a multi-hospital system.

METHODS:
We convened a task force including hospital and critical care physicians, nurses, laboratory staff, and informatics specialists. Our Health Technology Assessment (HTA) center completed a rapid systematic review on guidelines and algorithms for diagnosing CAUTI. Additional rapid reviews were completed as necessary to address specific follow-up questions. A draft pathway based on the guidelines was developed, and then the task force edited it in an iterative process.

We used the Dorsata platform (Dorsata Inc., Washington, DC) to create, distribute and maintain the pathway. Dorsata has both desktop and mobile interfaces that guide clinicians through decision algorithms. Individual pathways include links to references and a portal for direct user feedback. Pathway owners have access to a real-time pathway utilization dashboard.

A standardized order set with the pathway was added to our electronic health record system. We also held educational meetings for residents and provided “huddle sheets” to nurse educators at each hospital. Posters and computer screen savers were also used to raise awareness of the new pathway.

RESULTS:
We now have a total of 111 pathways on Dorsata, developed following the same model as the CAUTI evaluation pathway. Some topics, like breast cancer, have as many as sixteen pathways, addressing different clinical questions like first- and second-line therapy. Over 600 individuals have registered for the mobile app, including attending and resident physicians, nurses, and medical students. The pathway site had 1,619 views in December 2016, the most recent month for which complete records are available. The pathways are proving to have an effect on clinical decision making. For example, the annualized number of unnecessary urine cultures avoided as a result of the pathway is 4,474; resulting in estimated direct cost savings of USD67,110.
OP069 Hospital-Based Health Technology Assessment Is Applicable To Investment Decision-Making Process

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ABSTRACT SUMMARY:
Hospital-based Health Technology Assessment (HTA) was tested out in the budget planning of investments for a new diagnostic and teaching center at a publicly funded university hospital. Proposals over EUR250,000 were evaluated by expert groups using multi-domain assessment adapting Hospital-based HTA-principles; Proposals between EUR50,000 and EUR250,000 were returned to the units for miniHTA-assessments by clinicians who submitted the initial proposals and (iii) All proposals below EUR50,000 were prioritized by the units to cut the expenditure by at least 25 percent, with a special emphasis on synergistic use of devices and equipment among the units.

METHODS:
Depending on the level of expenditure, all proposals were assessed by one of the following processes: (i) Proposals over EUR250,000 were evaluated by three to five person expert groups using multi-domain assessment adapting Hospital-based HTA-principles; (ii) Proposals between EUR50,000 and EUR250,000 were returned to the units for miniHTA-assessments by clinicians who submitted the initial proposals and (iii) All proposals below EUR50,000 were prioritized by the units to cut the expenditure by at least 25 percent, with a special emphasis on synergistic use of devices and equipment among the units.

RESULTS:
The expert groups suggested significant reductions to the proposals, including the withdrawal of a Magnetic Resonance Imaging (MRI)-unit considered to be suboptimally located. Furthermore, the need for a new scanner was declined by promoting adherence to evidence-based diagnostic guidelines and more efficient utilization of existing scanners. Self-assessed MiniHTAs revealed proposals that were unnecessary or the specifications for devices needed re-adjustments. Prioritization revealed excess numbers of devices, for instance the number of cold storage appliances could be reduced. Altogether, the investment proposals were cut by over EUR3.8 million to reach the initial budgetary allocation.

CONCLUSIONS:
INnovative and flexible usage of hospital-based HTA methodology can be applied to budget planning and evaluation of investment proposals to support decision making. Based on encouraging results, hospital-based HTA was accepted to become a part of hospital strategy as a tool for the annual investment planning.
REFERENCES:

OP070 Economic Impact Of Macular Edema Diseases: A Retrospective Study

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ABSTRACT SUMMARY:
This is a retrospective study aimed at quantifying direct medical costs related to Retinal Vascular Diseases (RVD) from the perspective of five hospitals in Italy.

INTRODUCTION:
Inhibitors of Vascular Endothelial Growth Factor (VEGF) have made possible the treatment of the Retinal Vascular Diseases (RVD) for which there were limited therapeutic resources. The aim of this work was to estimate annual direct costs of major macular edema diseases in Italy in particular Choroidal Neovascularization (CNV), Diabetic Macular Edema (DME) and Retinal Vein Occlusions (RVO) from the hospital perspectives.

METHODS:
This descriptive study was aimed at quantifying direct costs incurred by five hospitals in Italy. Administrative and clinical databases of Policlinico Tor Vergata in Rome were analyzed for a 6-year period. In this context, it was possible to stratify patients depending on the disease and number of eyes treated. From these results, a survey with structured questionnaires was developed involving four other hospitals in Italy. Thanks to that, direct costs (drugs and specialist) were estimated from the hospitals perspective in 2016.

RESULTS:
Interviews included 7,356 individuals of which 1,860 were treated in both eyes. Within the considered five hospitals, 64 percent of treated patients had CNV, 21 percent DME, and 15 percent RVOs. The average annual administration rate of anti-VEGF treatment resulted in 4.03 (Standard Deviation, SD 3.46) per patient eye: 4.69 (SD 1.75) for cases enrolled for less than one year (naïve) and 3.38 (SD 0.82) per patients treated for more than one year (experienced). Naïve patients had a mean per capita annual cost of EUR2,368 per eye (EUR2,536 for CNV; EUR2,280 RVO; EUR1,986 DME) of which EUR2,952 was related to the administration of on-label drugs mainly Eylea, Lucentis, Macugen, Ozurdex and EUR49 due to off-labels such as Avastin. Experienced patients average annual cost per eye was EUR1,689: EUR2.179 for the on-label drugs, EUR34 due to off-labels (EUR1,839 for CNV; EUR1,327 RVO; EUR1,399 DME). The average rate of the specialist annual visit was four times; the most frequent types were Optical Coherence Tomography (OCT), Angiography, and Fundus Photography (FP).

CONCLUSIONS:
This is a first attempt to study direct costs incurred from the hospital perspective associated with RVD with overexpression of VEGF in Italy. This might represent a first step for further analysis assessing the burden of RVD diseases from the Italian National Health System perspective globally.
OP071 Evidence-Based Searching For Health Technology Assessment: Keeping Up-to-Date With Summarized Research In Information Retrieval (SuRe Info)

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ABSTRACT SUMMARY:
Increasing numbers of research papers about information retrieval for health technology assessments, systematic reviews and other evidence syntheses are being published. It is time-consuming and demanding for searchers to keep up-to-date with the latest developments. To help decide how best to approach searching, Summarized Research in Information Retrieval (SuRe) Info offers research-based advice on evidence identification processes for Health Technology Assessment (HTA) organizations.

INTRODUCTION:
Increasing numbers of research papers about information retrieval for Health Technology Assessments (HTA), systematic reviews and other evidence syntheses are being published. It is time-consuming for information specialists to keep up-to-date with the latest developments in the field. To help searchers with this challenge, the Interest Group on Information Retrieval (IRG) of Health Technology Assessment International (HTAi) has compiled the best available research evidence on information retrieval aspects into an open-access web resource: Summarized Research in Information Retrieval for HTA (SuRe Info). The resource can be accessed at http://www.sure-info.org

METHODS:
The SuRe Info team run topic-specific search strategies in selected relevant databases to identify information retrieval methods publications that fulfill the SuRe Info inclusion criteria. Eligible publications receive a structured abstract containing a brief critical appraisal. Key messages for search practice based on the appraisals and accepted best practice are summarized into topic-specific chapters.

RESULTS:
SuRe Info currently offers fourteen chapters, with more in development. SuRe Info chapters fall into two categories: (i) chapters about general search methods that are used across all types of research, such as how to develop search strategies and the availability and use of search filters, and (ii) chapters summarizing the methods to use when searching for specific aspects of HTA (as defined in the European Network for HTA (EUnetHTA) HTA Core Model®), including searching for evidence on clinical effectiveness and safety, and identifying economic evaluations. References at the end of each chapter are linked to appraisals of publications that have been used to develop each chapter. Links to the full-text of the publications are provided when freely available. The SuRe Info chapters are reviewed every six months and updated if new evidence is identified or if resources change.

CONCLUSIONS:
SuRe Info is a unique resource, identifying and summarizing current best research evidence on information retrieval aspects for HTA. It supports the timely uptake of potential efficiencies arising from new evidence that may be incorporated into the evidence identification processes of HTA organizations.
OP072 Adherence Of Budget Impact Analyses To Principles Of Good Practice

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ABSTRACT SUMMARY:
Budget Impact Analysis (BIA) is integral to a comprehensive Health Technology Assessment. Compared to the ISPOR Principles of Good Practice, the BIAs included in this systematic review were overcomplicated and deterministic, ignoring possible scenarios relevant to budget holders. The research advocates a wider use of scenario planning as a tool to link uncertainty to the base-case economic assessment.

INTRODUCTION:
Budget Impact Analysis (BIA) is an integral element of a comprehensive Health Technology Assessment. Prior systematic reviews showed significant methodological dissimilarities in BIAs published from 2002 to 2015 (1,2). Aimed to improve the generalisability and transferability of outcomes, a guidance on methods was updated in 2014 (3). The objective of this study was to measure the adherence to Principles of Good Practice of BIAs published after the release of the updated guidelines.

METHODS:
Fifteen features representative of methodological appropriateness were identified from the Principles of Good Practice. A systematic review of the extant literature was conducted to identify BIAs published from January 2015 to December 2016. The adherence of each BIA to the Principles of Good Practice was defined by the number of representative characteristics taken into consideration as a percent of the total. The full study protocol is available online: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016049287.

RESULTS:
A sample of thirty-nine published BIAs were included in the analysis. The mean adherence of BIAs to the Principles of Good Practice was 69 percent (10.4 representative features out of 15). The highest adherence was 87 percent, while the lowest was 33 percent. The distribution of the scores was highly concentrated around the mean value, with thirty-four BIAs (87 percent of total sample) showing a level of adherence ≥ 60 percent. Only two BIAs reported an adherence < 50 percent (5 percent of total sample). Six representative features showed a level of adherence < 50 percent: off-label use (0 percent); uncertainty (26 percent); validation (33 percent); choice of computing framework (44 percent); eligible population (44 percent) and relevant features of healthcare system (49 percent).

CONCLUSIONS:
Compared to the Principles of Good Practice, the BIAs included in the systematic review were overcomplicated and deterministic, ignoring the impact of possible scenarios relevant to budget holders. The research advocates a wider use of scenario planning as a tool to link uncertainty to the economic assessment of new interventions.

REFERENCES:
OP073 Using Visualization In Scoping The Literature For A Prognostic Health Technology Assessment

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ABSTRACT SUMMARY:
A case study of how data visualisation (with VOS Viewer) was used to explore an over-sized corpus of retrieved papers and identify potential markers in a large-scale prognostic Health Technology Assessment (HTA) study.

INTRODUCTION:
One of the challenges of large scale Health Technology Assessment (HTA) projects is managing the large volume of studies retrieved by the requisite comprehensive literature searches. At the scoping stage of the project, a pragmatic judgement needs to be made as to how sensitive the search strategy should be in order to find all the relevant papers without returning an overwhelming volume of irrelevant studies.

METHODS:
For this HTA (evaluating prognostic and predictive markers in rheumatoid arthritis), the research team already had prior knowledge of several key markers of interest, but wanted to ensure that no others had been missed. Advice from practising clinicians was obtained, but for additional validation, a broad scoping search was conducted for ‘rheumatoid arthritis’ using the sensitive Haynes filters for prognostic (1) and clinical prediction (2) studies. Unsurprisingly, this initial search retrieved too many studies for them all to be admitted to the full review; but once those dealing with known markers had been removed, a sample of the remaining records was loaded into a software visualisation tool (3) to display “heat maps” of frequently occurring terms and phrases.

RESULTS:
On this occasion, no additional markers were identified, however this provided reassurance that the advice obtained from clinicians was comprehensive, enabling the HTA team to proceed confidently with its evaluation of the selected markers.

CONCLUSIONS:
Visualization offers an alternative means of exploring and interrogating large text archives, and has the potential to complement the role of traditional search methods in identifying literature for systematic reviews and health technology assessments. As processing power increases and more and more full-text papers become available open access, it may provide a solution to some of the limitations associated with comprehensive searching.

REFERENCES:
OP074 Healthcare Inequity In Asia Despite High Universal Health Coverage

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ABSTRACT SUMMARY:
This pragmatic literature review investigated whether there is inequity in access to inpatient and outpatient health care under universal health coverage (UHC) schemes in Asia. Concentration indices were identified for China, Korea, Thailand, and Taiwan. After UHC implementation in all countries, higher levels of UHC and government healthcare expenditure corresponded to increased healthcare distribution towards the poor.

INTRODUCTION:
Many Asian countries have implemented universal health coverage (UHC) schemes. This study aimed to investigate whether there is inequity in access to inpatient and outpatient health care under these schemes.

METHODS:
A pragmatic literature review was conducted using PubMed and Google Scholar. The most frequently reported measure of inequity was the concentration index (CIs). This index demonstrates the concentration of healthcare resource distribution; CI=0 indicates equal distribution, while CI>0 indicates resource is disproportionately concentrated on the rich and CI<0 on the poor. Comparisons of CIs before and after implementation of UHC and between rural and urban areas were conducted along with analysis of the relationship between CIs, UHC levels, and government expenditure on health care (GEH).

RESULTS:
Data were available for China, Korea, Thailand, and Taiwan. Before and after UHC implementation in Korea and Thailand, CIs for inpatient and outpatient care were marginally pro-poor. In China, healthcare was generally concentrated on the rich, although CIs reduced after UHC. Data for urban versus rural areas were available for Thailand, where the CI (CI=-.14) was pro-poor for inpatient care in urban areas but there was almost equal healthcare distribution (CI=-.04) in rural areas. Across all four countries, higher levels of UHC and GEH (2013 Purchasing Power Parity) corresponded to lower CIs for outpatient care and, to a lesser extent, inpatient care.

CONCLUSIONS:
Despite reportedly high levels of UHC in all four countries, inequities in access to inpatient and outpatient care were identified, and increased UHC and GEH corresponded with increasing distribution of health care towards the poor. Countries with reportedly high UHC should therefore consider sources of inequality within their schemes. This study primarily considered CI so investigation of further measures could verify these results.

OP075 Implementing Risk Stratification In Primary Care: A Qualitative Study

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ABSTRACT SUMMARY:
A predictive risk stratification tool (PRISM) to estimate a patient’s risk of an emergency hospital admission was trialled in general practice in an area of the UK. We report on an embedded qualitative study which examined implementation and adoption of the tool.

INTRODUCTION:
A predictive risk stratification tool (PRISM) to estimate a patient’s risk of an emergency hospital admission in the following year was trialled in general practice in an area of the United Kingdom. PRISM’s introduction coincided with a new incentive payment (‘QOF’) in the regional contract for family doctors to identify and manage the care of people at high risk of emergency hospital admission.

METHODS:
Alongside the trial, we carried out a complementary qualitative study of processes of change associated with PRISM’s implementation. We aimed to describe how PRISM was understood, communicated, adopted, and used by practitioners, managers, local commissioners and policy makers. We gathered data through focus groups, interviews and questionnaires at three time points (baseline, mid-trial and end-trial). We analysed data thematically, informed by Normalisation Process Theory (1).

RESULTS:
All groups showed high awareness of PRISM, but raised concerns about whether it could identify patients not yet known, and about whether there were sufficient community-based services to respond to care needs identified. All practices reported using PRISM to fulfil their QOF targets, but after the QOF reporting period ended, only two practices continued to use it. Family doctors said PRISM changed their awareness of patients and focused them on targeting the highest-risk patients, though they were uncertain about the potential for positive impact on this group.

CONCLUSIONS:
Though external factors supported its uptake in the short term, with a focus on the highest risk patients, PRISM did not become a sustained part of normal practice for primary care practitioners.

REFERENCES:

OP076 Economic Contributions Of Older Adults In Europe

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ABSTRACT SUMMARY:
This study focuses on the market and non-market
productive activities of older adults to determine the nature and magnitude of the contributions they make across Europe. Particular attention is paid to how these contributions vary by country, time, and age, and the influence policy, institutions, behavior, and health may have on the economic effects of population aging.

INTRODUCTION:
Europe’s population is aging rapidly. Europeans aged 60 years and over formed only 16 percent of Europe’s total population in 1980, but they now constitute 24 percent and will grow to 34 percent by 2050 (1). This aging population will create economic challenges in the form of tighter labor markets, lower savings rates, slower economic growth, and fiscal stress from lower earnings taxes and increased pension and healthcare spending.

We may, however, overestimate the magnitude of these challenges and make poorer policy choices if we underestimate the productive contributions that older adults make to society. The literature measuring these productive contributions is regrettably underdeveloped, as is the literature on what policies can enhance such contributions.

This study focuses on the market and non-market productive contributions of older adults in Europe and addresses three questions:

(i) What is the nature and magnitude of the contributions made by older adults in Europe?

(ii) How do those contributions vary by country, time, and age, and how are they likely to evolve as the relative size of older cohorts swells?

(iii) How might changes in policy, institutions, behavior, and health likely influence the economic effects of population aging in Europe?

METHODS:
These research questions are explored using multivariate statistical tools to analyze rich data from multiple countries and waves of the Survey of Health, Ageing, and Retirement in Europe (SHARE) and the English Longitudinal Study of Ageing (ELSA).

RESULTS:
Older adults in Europe make significant productive contributions in the form of labor force participation, caregiving for family and friends, and volunteering. These contributions vary widely by country and are correlated with age, health status, official retirement age, and population age structure.

CONCLUSIONS:
The economic effects of population aging in Europe can be significantly moderated by effective retirement and healthcare policy.

REFERENCES:

OP077 Identifying Topics For Health Technology Assessment: The German “ThemenCheck Medizin”

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ABSTRACT SUMMARY:
A new process of topic selection for Health Technology Assessment (HTA) reports from proposals by patients and the general public has recently been established in Germany,
“ThemenCheck Medizin” (Topic Check Medicine). Proposals for HTA topics are submitted via an easy-to-use online form. A selection committee of patient representatives choose fifteen suitable topics from these proposals. HTA reports are produced for up to five topics per year.

**INTRODUCTION:**
Clinicians, epidemiologists, economists and other non-medical professions are involved in the production of Health Technology Assessment (HTA) reports. In addition, patients or representatives from patient organizations, as well as the general public, are increasingly involved. In 2015 a new proposal process of topic selection for HTA reports was initiated by German legislation with the aim of more closely involving patients and the general public. The new process has been implemented by the Institute for Quality and Efficiency in Health Care (IQWiG) under the project title “ThemenCheck Medizin” (Topic Check Medicine).

**METHODS:**
Since July 2016, patients and the general public can propose topics for HTA reports to IQWiG, excluding topics on the assessment of drugs. The proposals are submitted via the IQWiG website www.themencheck-medizin.iqwig.de (available only in German). No specific expertise is required for the submission of a topic. On the basis of the proposals a selection committee (patient representatives appointed by patient organizations legitimized in Germany) choose up to fifteen topics deemed suitable for HTA reports. In 2017 the committee will be extended to include members of the general public. IQWiG makes the final decision on the selection of up to five topics per year for HTA reports.

**RESULTS:**
In the first proposal phase thirty proposals were submitted. The topics were allocated to the following categories: two for diagnostics; four for teeth; one for skin and hair; four for head and nerves; three for muscles, bones and joints; two for heart and circulation; four for cancer; two for children and adolescents; one for reproductive health and birth; and three for mental and emotional wellbeing. Four topics could not be considered because they either addressed the assessment of drugs or could not be transferred into an HTA question.

**CONCLUSIONS:**
Through “ThemenCheck Medizin” patients and the general public in Germany can actively be involved in the process of collecting proposals for HTA reports as well as in topic prioritization. The prerequisites for successful implementation were in particular the easy-to-use online form and IQWiG’s support of persons submitting topics in their formulation of an HTA question. The integration of a selection committee of patient representatives was shown to be constructive and productive.

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**OP078 Patient Involvement In European Health Technology Assessment Focus Group With Cardiac Patients**

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**ABSTRACT SUMMARY:**
Involving patients in defining the scope of health technology assessments is recognized as a valuable strategy. Within the EUnetHTA project, we conducted a focus group with five heart transplant participants to help us evaluate the wearable cardioverter-defibrillator therapy. Gathered results informed the inclusion of outcomes relevant to the
target group and revealed patients views on health-related quality of life.

**INTRODUCTION:**
Involving patients in defining the scope of health technology assessments is recognized as a valuable strategy that ensures that patient-relevant outcomes are considered.

The aim of this project was to pilot the focus group approach with cardiac patients in a European rapid assessment on the wearable cardioverter defibrillator, to improve involvement processes, to identify neglected outcomes, and to explore the potential of this methodology for eliciting the patients views on their disease and the wearable cardioverter defibrillator therapy.

**METHODS:**
An e-mail was sent to members of the nine regional associations of the Austrian Organization for Heart and Lung Transplant Patients to identify eligible participants. Guiding questions for the discussion were developed based upon a hand search of patient involvement initiatives and a review of appropriate literature. The 4-hour meeting was moderated by a patient support expert and recorded upon approval of participants. The anonymized transcript was analyzed using framework analysis.

**RESULTS:**
Ten eligible patients responded, of which five men, aged between 55 and 73 years (mean 65 years) from Austria and Germany, were able to participate. All respondents experienced heart transplantation, and four had received an implantable cardioverter defibrillator before.

Participants reported that experiencing a sense of security was crucial to them and that they expected to do sports and live a life with few limitations, despite receiving a therapy. A wearable cardioverter defibrillator was hence not considered a long-term solution due to expected restrictions in living a ‘normal’ life.

Challenges included the identification of participants representative of this patient group and the complexity of patient histories.

**CONCLUSIONS:**
The focus group approach proved useful in the wearable cardioverter defibrillator assessment. Gathered results informed the inclusion of outcomes relevant to the target group and revealed patients views on health-related quality of life. Lessons learned guide us in further improving patient involvement processes within the European Network for HTA (EUnetHTA) project.

**OP079 Experimenting HTAi Patient Group Submission Template To Involve Patients**

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**ABSTRACT SUMMARY:**
Agenas’ procedure to involve patients via the HTAi’s Patient Group Submission Template for Health Technology ASsessment (HTA) within HTA report on Dialysis Modalities in Italy is described. An account of the procedure is given and pros and cons of using the Template are outlined. Main findings obtained via this collection and pros and cons of tool and procedure are described.

**INTRODUCTION:**
The Health Technology Assessment International
The HTAi (HTAi) community recognizes the importance of including patients’ views from published research and systematically obtaining input from patient organizations (POs). The HTAi’s Patients and Public Involvement Subgroup has elaborated the Patient Group Submission Template for HTA (HTA Template) to facilitate the collection of evidence from patients via POs involvement. In 2015 AGENAS outlined a procedure to involve POs and tested the HTA Template within a Health Technology Assessment (HTA) report on dialysis.

**METHODS:**
The HTAi template was translated into Italian and adapted to the HTA report’s specific information needs: to understand patients’ experiences with different dialysis modalities and any delivery problems at the regional level. Some questions were reformulated, others were cut and two different versions of the template were used. One was tailored to POs representatives and the other to individual patients selected with a purposive sampling procedure. We provided the HTA Template to POs appointed by an umbrella organization, Cittadinanzattiva, for their input and to identify other relevant POs to be involved. We identified a list of four associations, based on geographical location and typology of patients. Each POs representative completed the first template and administered the second one to, at least one patient for each five dialysis modalities. AGENAS staff provided support on a cascade basis POs collected and returned all templates.

**RESULTS:**
Researchers performed a thematic analysis of the answers received and this input was introduced in the HTA report within the chapter on Patients Aspects. Patients’ experiences closely corresponded to the ones in our qualitative literature’s systematic review. However, PO representatives templates revealed an important problem of equity in access to different dialysis modalities across regions that we highlighted in the HTA report’s recommendations.

**CONCLUSIONS:**
One of the template’s limitations was related to self-administration. In some cases, a lack of familiarity with communicating one’s views in writing may have affected the survey’s informative power. This pilot also demonstrated the need for a more inclusive involvement procedure, as some important POs were not initially represented by the umbrella organization.

**OP080 Public Involvement In Health Technology Assessment: Which Publics For Which Technologies?**

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**ABSTRACT SUMMARY:**
This presentation will explore the question of which publics should be involved in the assessment of which technologies and health conditions, drawing on interviews with expert advisory committee members and clinical epidemiologists responsible for reviewing the evidence and making recommendations about the public funding of healthcare services and medical devices in Ontario, Canada.

**INTRODUCTION:**
Health Technology Assessment (HTA) agencies have made much progress in addressing the who and how of patient and citizen involvement at a general level. Less attention has been given to the rationales for engaging with different publics for different technologies and health conditions. As HTA organizations become more active in...
the patient and citizen involvement arena, more consideration to these issues may promote more effective involvement of publics and use of organizational resources. We explored this topic in the context of the process for reviewing the evidence and making recommendations for the public funding of health care services and medical devices in Ontario, Canada, which is overseen by Health Quality Ontario (HQO).

METHODS:
We conducted interviews with sixteen expert advisory committee members and five clinical epidemiologists on staff at HQO. A common set of interview questions was used across both groups to explore views about the rationales and perceived values of involving various publics in the HTA process. Interviews were transcribed and data were managed using QSR NVivo. Our analysis followed a constant comparative method: iterative coding and analysis of transcripts until emerging themes were identified.

RESULTS:
Interviewees identified a range of rationales for patient and citizen involvement in the HTA process – democratic and scientific rationales were most commonly cited. Perceived value was discussed in relation to which publics are involved and for which technologies and health conditions. For example, patient input about experiences with health conditions contributes to a more comprehensive review process, while broader citizen involvement should address societal questions about resource allocation and transparency. Selected technologies were used as illustrative examples to highlight key dimensions that should inform which publics should be involved and for what purpose, for example, media-hyped and economically driven technologies versus population interventions.

CONCLUSIONS:
Patient and citizen involvement is perceived as a valuable addition to the Ontario HTA process. Careful mapping of rationales in relation to the publics involved and the technologies assessed may promote more effective involvement and resource use within HTA organizations.

OP081 Public Involvement In Modelling For Vaccination Evaluation

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ABSTRACT SUMMARY:
A key aim of the MEMVIE (Mathematical & Economic Modelling for Vaccination and Immunisation Evaluation) study is to develop the first framework for public involvement in modelling for immunization programmes. This paper will present the MEMVIE Public Involvement Framework (PIF) which identifies areas where the public can contribute to modelling in Health Technology Assessment.

INTRODUCTION:
Immunization is a key tool against a range of infectious diseases, but has a considerable cost, with the United Kingdom (UK) spending over GBP200 million per year on vaccines. Mathematical and health economic models are necessary to assess whether changes in the immunization programme are cost-effective. Mathematical & Economic Modelling for Vaccination and Immunisation Evaluation (MEMVIE) is a five-year programme funded by the Department of Health in England, providing input on likely costs and benefits of vaccination programmes through the development of mathematical and cost-effectiveness models.

Such mathematical modelling has not routinely
included the public as collaborators in the creation of models. This paper will present the MEMVIE Public Involvement Framework (PIF), a public involvement framework, which identifies key areas of public contribution for modelling.

METHODS:
A public reference group has been developed. The Group includes eight individuals recruited through the Warwick Medical School User Involvement Network. The reference group is providing input into a modelling study assessing alternative vaccination strategies for pneumococcal disease in the UK. Each meeting is recorded, transcribed, and thematic analysis undertaken to identify the contribution of the PPI Reference Group in order to develop the framework.

RESULTS:
Key areas of contribution have been identified including critique of individual variables selected for the model, how variables relate to each other, the assumptions underpinning the model, critique of data utilized in the model, identification of limitations or missing data, and quality criteria for modelling.

CONCLUSIONS:
MEMVIE is the first modelling study to conceptualize public involvement in the development of a model. In addition to identifying key areas of contribution, the public involvement Reference Group has contributed to broader discussion about the nature of public involvement in model development. We expect our findings to have international transferability to agencies and policy makers developing their public involvement in mathematical and economic modelling.

OP083 Value Assessment Framework: Evidence-Informed Deliberative Processes

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ABSTRACT SUMMARY:
Priority setting is an intrinsically complex and value-laden process. ‘Evidence-informed deliberative processes’ recognise this and enhance the legitimacy of Health Technology Assessment (HTA) agencies recommendations by integrating the virtues of accountability for reasonableness, that is, deliberation between stakeholders to incorporate relevant social values, and multi-criteria decision analysis, that is structured and rational decision making informed by evidence on multiple criteria.

INTRODUCTION:
Priority setting in health care has been long recognized as an intrinsically complex and value-laden process. Yet, Health Technology Assessment (HTA) agencies presently employ value assessment frameworks that are ill-fitted to capture the range and diversity of stakeholder values, and thereby risk to compromise the legitimacy of their recommendations. We propose ‘evidence-informed deliberative processes’ as an alternative framework with the aim to enhance this legitimacy.

METHODS:
The framework is based on an integration of
two increasingly popular and complementary frameworks for priority setting: multi-criteria decision analysis (MCDA) and accountability for reasonableness (A4R). Evidence-informed deliberative processes are, on the one hand, based on early, continued stakeholder deliberation to learn about the importance of relevant social values. On the other hand, they are based on rational decision-making – through evidence-informed evaluation of the identified values.

RESULTS:
The framework has important implications for how HTA agencies should ideally organize their processes. Firstly, HTA agencies should take the responsibility to organize stakeholder involvement. Second, agencies are advised to integrate their assessment and appraisal phase, allowing for the timely collection of evidence on values that are considered relevant. Third, HTA agencies should subject their specification of decision-making criteria to public scrutiny. Fourth, agencies are advised to use a checklist of potentially relevant criteria, and to provide argumentation how each criterion affected the recommendation. Fifth, HTA agencies must publish their argumentation and install options for appeal.

CONCLUSIONS:
Adopting `evidence-informed deliberative processes` as a value assessment framework could be an important step forward for HTA agencies to optimize the legitimacy of their priority setting decisions. Agencies can incorporate elements according to their needs and affordances.

OP084 Health Technology Assessment (HTA) Impact: Stories From The Front-Lines Of HTA Production And Use

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ABSTRACT SUMMARY:
Around the world, the International Network of Agencies for Health Technology Assessment (INAHTA) member agencies produce Health Technology Assessments (HTAs) with impact. The highly successful INAHTA Impact Story Sharing activity will be described in this session, along with the main themes of six stories from INAHTA members in Uruguay, Germany, Ireland, Finland, Australia, and Canada: a truly international and diverse collection of stories, soon to appear in a mini-theme in IJTAHC.

INTRODUCTION:
The International Network of Agencies for Health Technology Assessment (INAHTA) is a network of publicly-funded Health Technology Assessment (HTA) agencies that support health system decision making that affects over 1 billion people around the globe. Member agencies produce reports that influence policy and decision making to achieve value and support appropriate technology use, equitable access, and health system sustainability. INAHTA has developed an innovative program called Impact Story Sharing to enable member agencies to continue to build capacity and knowledge through sharing front-line experiences in achieving HTA impact.

METHODS:
The impact story sharing occurs in-person at the annual INAHTA Congress following a guideline and
The six manuscripts of the mini-theme tell very different stories about HTA impact that reflect different health system contexts around the globe. From Canada, we learn about an early example of health technology management for continuous improvement of trauma services. From Australia, we learn about the application of rapid review methods to provide an accurate and timely review of legislative accreditation policies. From Finland, we learn about the impact of a long standing HTA program to deliver evidence-based recommendations to hospital districts. From Ireland, we learn about the engagement of stakeholders to maximize the acceptance of legislative decision making based on HTA report findings. From Germany, we learn about the reactions of surgical societies to changes in reimbursement status of knee arthroscopy based results of an HTA. From Uruguay, we learn about the impact of HTA on the reimbursement of high cost drugs in the context of the judicialization of health.

CONCLUSIONS:
The INAHTA Impact Story Sharing program allows sharing of experiences in narrative format that increases knowledge and also build relationships among INAHTA members, thus creating the conditions for stronger network connections.
METHODS:
A decision-model comparing two scenarios ("current clinical practice" and "with PBM implementation") was used to estimate the PBM impact including hospital-assisted patients from the following therapeutic areas: surgery (orthopaedic, cardiac and urologic), cardiology, oncology, gastrointestinal bleeding, abnormal uterine bleeding, hemodialysis, inflammatory bowel disease and pregnancy. Model inputs were obtained from Portuguese national health databases and literature review. The public health impact was measured in life years (LY) gained, disability-adjusted life years (DALY) reduction, hospital length of stay (LOS) and 30-day readmission rate reduction. The economic value was expressed in total and hospitalization costs savings.

RESULTS:
A total of 384,704 patients were eligible for PBM strategies. We estimated that a one year nationwide PBM implementation could avoid 594 premature deaths, representing a gain of 1,481 LY and a reduction of 3,660 DALYs relative to the current paradigm. An 8.4 percent and 37.3 percent reduction in length of stay and 30-day readmission rate are expected, respectively. This corresponds to EUR70.4 million savings in hospitalization costs. Although PBM closer monitoring would imply additional physician visits and medicines use, leading to EUR24.1 million in additional expenditure, in this population the overall PBM implementation can generate net savings of more than EUR67.7 million per year (6.3 percent reduction of public expenditure).

CONCLUSIONS:
The implementation of a nationwide PBM in Portugal may represent a great public health impact, especially in decreased mortality and disability, with substantial public expenditure reduction.

OP086 Identifying Surgical Procedures Of Low Or No-Added Value In Spain

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ABSTRACT SUMMARY:
Disinvestment of health procedures is a complex task for health care systems in which lack of evidence could be a barrier. This research explores the basis of evidence based and context tailored divestment activities for health procedures on the basis of existing lists of obsolete technologies and variability in practice.

INTRODUCTION:
There is an increasing interest in divesting activities, giving rise to several initiatives both academic and governmental to identify and address one of the problems of health systems. In 2013 the Spanish Atlas of variability in Clinical Practice (VPM) in collaboration with the Spanish Network of Health Technology Assessment (HTA) Agencies started a project with the purpose of providing elements to support a national strategy aimed at minimizing the use of doubtful procedures in the Spanish National Health System (1).
METHODS:
The identification, selection and definition of low added value procedures and the determination of the most cost-effective alternatives were carried out jointly between the AtlasVPM group and the HTA agencies of Andalusia (AETSA), Catalonia (AQUAS), Galicia (Avalia-t), Basque Country (Osteba), Madrid (UETS) and Aragon (IACS). The process consisted of the following phases: (i) Literature review; (ii) Preliminary list of procedures of dubious value; (iii) Analysis of feasibility and construction of the indicators (variability); and (iv) Empirical validation of the defined indicators. Different lists and sources of evidence were used to identify the procedures and evidence that support their low-value.

RESULTS:
The synthesis of the evidence gave rise to an initial list of fifty-nine procedures of doubtful value that could be classified as: obsolete or outdated procedures in comparison to more effective / cost-effective alternatives (n=31), procedures of doubtful value when used outside their main indication (n=17) and procedures for which the evidence around effectiveness was still insufficient (n=11). With the advice of clinical experts and coders, the original list was reduced to seventeen procedures and after some adjustments to thirteen.

CONCLUSIONS:
Identifying procedures of low-added value is a complex task and is context dependent. Literature could be useful to identify a preliminary list but the analysis of the clinical practice, its variability and reasons that justify it are required to determine which procedures are good candidates for disinvestment.

REFERENCES:
framework. Coverage and funding options based on HTA recommendations as well as on criteria or policies other than HTA (for example, risk-sharing agreements) were also considered.

RESULTS:
There is huge heterogeneity in coverage recommendations depending on setting, despite evidence submitted to HTA bodies being almost identical. In general, there seems to be a higher willingness to pay for orphan drugs, either through a higher ICER threshold, or only when costs are not exceeding the budget. Additional criteria related to the rarity of diseases or special considerations, particularly centered on unmet need and severity, seem to play an important and increasing role beyond strict cost-effectiveness criteria. Decisions about purchasing may be influenced by factors beyond HTA (for example, early access schemes), which may be relevant to orphan drugs. Little uniformity exists in the time taken to assess a drug following MA, leading to inequities in access.

CONCLUSIONS:
Despite the extensive and ever increasing use of HTA for orphan drugs, the variations in HTA recommendation outcomes across jurisdictions and the—often—very significant time lapses between the date of MA, the final HTA recommendation and the eventual funding decision, imply variations in access and highlight the importance of establishing specific policies for orphan drugs to ensure fair assessment and equitable access to treatment for rare diseases.

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ABSTRACT SUMMARY:
We developed and tested a procedure for the acquisition of implantable medical devices in which the clinical benefit of the device is incorporated into the tendering administrative pathway. The algorithm of net monetary benefit is the basis of the tender. Two devices for percutaneous mitral valve repair (Watchman, Carillon) and three for endovascular thrombectomy (Solitaire, Trevo, Merci) were evaluated.

INTRODUCTION:
To manage the in-hospital acquisition of implantable medical devices, procurement procedures can be optimized by incorporating an assessment of clinical benefits. We describe the experience conducted in 2016 by ESTAR (the regional institution of NHS responsible for purchasing medicines and medical devices). We developed and tested an acquisition procedure in which the clinical benefit of the device is incorporated into the administrative pathway for purchasing the device.

METHODS:
A detailed description of our procedure is given along with two real-life examples presented below. These examples deal with two competitive tenders aimed at the two following implantable devices: (i) devices for percutaneous mitral valve repair (PMVR) in inoperable patients; (ii) endovascular thrombectomy (ET) devices employed in patients with acute ischemic stroke. For participating in the tender, manufacturers were requested to present the following information: (a) a measure of the clinical benefit (expressed in quality-adjusted life years); (b) an estimate of the “accessory” costs (that
is, short-term costs generated by implantation and those on the long-term related to outcomes; (c) the price of the device (that is, the price offered by the manufacturer). The willingness-to-pay threshold was assumed to be at €60,000 per quality-adjusted life year gained. In the tenders, offers made by different manufacturers were ranked according to the algorithm of net monetary benefit (NMB) (1); in particular, parameter (a) was assigned a positive sign whereas parameters (b) and (c) were negative. Then, the higher the NMB, the better the rank.

RESULTS:
Three devices were evaluated for ET (Solitaire, Trevo, Merci), and two for PMVR (Watchman, Carillon). In both cases, application of the NMB algorithm generated a series of ranks that differentiated the devices according to (a), (b), and (c).

CONCLUSIONS:
The preliminary experience described herein indicates that our NHS can benefit from tenders in which an appropriate quantitative weight is assigned to the benefit generated by individual devices. This experience has been focused on a few devices, but is applicable to other implantable devices employed for other disease conditions.

REFERENCES:

OP089 Using Economic Evidence to Set Priorities in Ghana: The Case of Malaria

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ABSTRACT SUMMARY:
Malaria is the number one cause of morbidity and mortality in Ghana. Priority setting using evidence from economic evaluation studies ensures efficient use of resources in a cost-effective manner. This study sought to assess the use and influence of economic evaluation studies directly related to malaria in Ghana on priority setting, specifically, the formulation of malaria control policies.

INTRODUCTION:
Malaria remains the number one cause of morbidity and mortality in Ghana. Since 1961, several malaria control strategies have been adopted, some of which were discontinued due to funding. In spite of the numerous malaria control strategies in place, its prevalence continues to rise. Priority setting using economic evidence has been proven to ensure efficient use of resources in a cost-effective manner (1). This study, therefore, sought to examine economic evaluation studies conducted on malaria in Ghana and their influence on malaria control policies.

METHODS:
A systematic search was conducted in databases including Medline and Embase to identify relevant malaria economic evaluation studies conducted in Ghana up to December 2016. Malaria control policies formulated in Ghana over the years were also reviewed. The economic studies were examined alongside the policies to establish their influence on them.

RESULTS:
A total of eight studies were identified, all of which were conducted in response to a global directive on malaria control and funded by international agencies. All studies were cost-effective; five
evaluating preventive measures and the remaining evaluating treatment. The studies used different methodological approaches, rendering the comparison between alternatives impossible.

Most malaria control initiatives are funded by international agencies, hence its abandonment when funding ceases. Although the majority of economic studies addressed some of these policies, none of them directly influenced their adoption. These policies were rather influenced by global malaria control initiatives. Also, malaria chemoprophylaxis; demonstrated as cost-effective by three studies, is not on the Ghana malaria control policy (2,3).

CONCLUSIONS:
To ensure sustainability of malaria control strategies and subsequently reduce its prevalence, Ghana must invest financially into economic analysis for formulating and implementation of these policies. Also, the use of economic evidence by policy makers can be promoted, should researchers adopt a methodological guideline for its conduct that ensures comparability of results.

REFERENCES:

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**OP090 Comprehensive Application Of Health Technology Reassessment (HTR)**

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**ABSTRACT SUMMARY:**
Health policy makers need more concrete evidence due to variations of values in health technology perspectives on life cycle. Also, there is uncertainty in regards to confidence about health technology safety and effectiveness once evaluated. Therefore, a health technology re-assessment (HTR) system should be used in real healthcare environments. We intended to recommend appropriate HTR systems in the Republic of Korea.

**INTRODUCTION:**
The market coverage of new health-related technologies is expanding, while the value of health technology is deteriorating with regard to its life cycle. There is uncertainty in regards to confidence about health technology safety and effectiveness once evaluated. Therefore, a health technology re-assessment (HTR) system should be used in domestic healthcare environments. We aimed to develop appropriate HTR systems in the Republic of Korea, for steroid intradiscal therapy (SIDT) using the Korean HTR model.

**METHODS:**
The Korean HTR model application consisted of four steps. First, expert panels selected a target technology after which priority setting was performed. In the re-assessment step, a systematic review was performed to review the
existing evidence of the safety and effectiveness regarding the SIDT for lower back pain (LBP), and health insurance claims-related data analysis was conducted to identify the current trend and domestic safety and effectiveness. Finally, the expert panels made recommendations according to the ETD (evidence to decision) framework.

RESULTS:
The SIDT obtained the highest priority and availability score to HTR application, among the 4 nominated health technologies. A total of twenty-nine studies (nine randomized controlled trials, one NRT, nineteen case series) were selected and included in the systematic review. The systematic review and claims data analysis showed that it was difficult to make a definite conclusion on the safety and efficacy of SIDT. We investigated additional data such as clinical guidelines, medical policy, or coverage report in other countries. Almost all panels recommended against the SIDT in LBP patients than comparators using EtD framework.

CONCLUSIONS:
The steroid intradiscal therapy for LBP was recommended as against the use of the technology using Korean HTR model. The HTR model was useful as a decision-making tool, but there is still a need to cumulate the experiences in real-world healthcare systems.

OP091 Health Technology Assessment On The Da Vinci Surgical System Using Real World Data In China

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ABSTRACT SUMMARY:
In order to strengthen the life cycle evaluation of high technology and expensive medical devices, our center was authorized by the National Health and Family Planning Commission to conduct this Health Technology Assessment (HTA) project using real world data to generate evidence for supporting the next procurement plan in the thirteenth 5-year plan.

INTRODUCTION:
The Da Vinci surgical system is classified as a type “A” medical device in China; the procurement plan of which is regulated by the National Health and Family Planning Commission (NHFP). Between 2010 to 2015, there were thirty-four Da Vinci surgical robots purchased, and installed in thirty tertiary public hospitals across the country. In order to generate context-specific evidence and support further capital funding decisions, the NHFP commissioned a Health Technology Assessment (HTA) of Da Vinci surgical robots, with a focus on real use of the technology in those tertiary public hospitals.

METHODS:
Nine hospitals were selected to collect real word data between 2013 to 2015. Using a cross-sectional survey, data of all robotic surgical cases were collected and described. The unit costs of the robotic surgery were estimated from activity based costing. We also collected cases of prostatectomy (427 versus 421) and hysterectomy (247 versus 105) using the robotic system and laparoscope respectively, and then compared hospital fees and effectiveness during hospitalization. Simulation of the budget impact on health insurance in Shanghai City over the next 5 years was also performed.
RESULTS:
A full HTA was conducted based on real data from nine public hospitals in the central and eastern region. Based on a systematic review methodology, we appraised evidence on safety, effectiveness and cost-effectiveness of the Da Vinci surgical robot. Data on technology use, clinical management, and pricing and payment were collected through a cross-sectional survey and interviews of hospital managers, surgeons and nurses. We designed a cohort study on cost-effectiveness of Da Vinci-assisted prostatectomy and hysterectomy, comparing Da Vinci-assisted and laparoscopic prostatectomy (427 vs 421) and Da Vinci-assisted and laparoscopic hysterectomy (247 versus 105). Ethics and inequity issues were discussed based on patient interviews. A budget impact analysis was performed based on scenario mapping of promoting Da Vinci-assisted prostatectomy in Shanghai City over a 5-year timeline.

CONCLUSIONS:
Due to a lack of evidence on long-term clinical effectiveness and high impact on public finances, the Da Vinci robotic robot should not be procured in large numbers in China. For equipment purchasing the government should strengthen regulations and require the public hospitals to collect more evidence.

INTRODUCTION:
South Africa is in the process of providing comprehensive health insurance to all its citizens, thus paving the pathway for Health Technology Assessment (HTA) to play a significant role in provision of safe and effective healthcare. The National Department of Health (DoH) has a published framework and Health Technology Act and strategies since the 1990s to improve health outcomes, and service and delivery of care. The purpose of this study is to explore challenges faced in the implementation of the framework and policies.

METHODS:
The study will be based on review and analysis of health technology policies and legislations introduced in South Africa since the 1990s. These documents are available from the DoH archive. The review from this grey literature was supplemented by information collected from a self-completion questionnaire, which was distributed to key stakeholders. Respondents were identified by direct contact with ministries of health and professional bodies, and included health professionals from the public and private healthcare sector, for example, practitioners, experts from hospitals, and industry representatives. The questionnaire addressed issues pertaining to decision making regarding health service delivery and the status of HTA in the country.

RESULTS:
The framework lays out the strategy to facilitate appropriate utilization of health technologies and includes among others, an HTA section. Fragmented use of HTA or parts thereof has been observed in the public and private healthcare sector. Furthermore, the respondents pointed out that decisions on health technology...
can be political, institutional or professionally driven whereas they all agreed that a formal and institutional implementation of HTA would improve healthcare service.

CONCLUSIONS:
The goal to achieve universal health care provides an excellent window of opportunity for formal use of HTA in policy- and decision-making. However, (i) the inadequate number of trained professionals and education and training opportunities (ii) lack of awareness and understanding of the principles of HTA and its impact on the improvement of healthcare are among the many challenges faced by the system. It has also been observed that national and regional champions can act as change agents and would have a snowball effect.

OP093 Conditional Financing In Health Technology Assessment Practice: The Dutch Experience

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ABSTRACT SUMMARY:
From 2006 to 2012, the Dutch National Healthcare Institute implemented conditional financing (CF) of expensive hospital drugs. Dossiers for drugs that underwent the full CF procedure were reviewed to assess procedural, methodological and decision-making aspects relating to CF. Although theoretically a valuable option, considerations related to scheme design and implementation may have affected the value of CF in decision-making practice.

INTRODUCTION:
In 2007, the National Healthcare Institute (ZIN) initiated conditional financing (CF) of expensive hospital drugs as an example of conditional reimbursement schemes (CRS). CF is a 4-year procedure encompassing initial HTA assessment (T=0) followed by additional data collection via outcomes research (separately assessing appropriate use & cost-effectiveness in routine practice) and re-assessment (T=4). This study aims to review performance and experiences with CF in the Netherlands to date.

METHODS:
All dossiers for drugs that underwent the full CF procedure were reviewed. Using a standardized data abstraction form, two researchers independently extracted information on procedural, methodological and decision-making aspects (that is, related to implemented outcomes research, evidence assessment and appraisal). A scoring algorithm was used to assess all three aspects.

RESULTS:
Fourty-seven candidates were nominated for CF; fourty-four underwent T=0 assessments and eleven T=4 assessments. The procedure extended beyond 4 years for 10/11 candidates. For the eleven candidates, applicants clearly defined study designs and data collection methods for outcomes research proposals addressing 16/22 research questions posed in T=0 reports. ZIN provided discussion points and recommendations regarding research proposals for 18/22 research questions. Applicants implemented recommendations fully in 8/22 cases and partially in 12/22. Sufficient data was available at T=4 to answer 15/22 research questions posed at T=0. However, discussion points remained regarding implemented outcomes research for all eleven candidates at T=4. ZIN
advise to continue reimbursement for nine candidates and to stop reimbursement for two. For six of the nine candidates, reimbursement was continued on the basis of conditions relating to additional evidence generation beyond T=4.

CONCLUSIONS:
Theoretically, CF provides a valuable option for enabling quick but conditional access to medicines in the Netherlands. However, procedural, methodological and decision-making considerations related to scheme design and implementation may affect its value in decision-making practice.

INTRODUCTION:
Whereas Health Technology Assessments (HTAs) by the National Institute for Health and Care Excellence (NICE) rely heavily on cost utility analysis, HTAs by the German Institute for Quality and Efficiency in Health Care (IQWiG) and the Federal Joint Committee (GBA) focus on an assessment of comparative effectiveness, rejecting a cost per quality-adjusted life year benchmark. The present study aimed to explore the differential impact of methodological choices by NICE and IQWiG/GBA on HTA outcomes.

METHODS:
We extracted data from all GBA decisions between January 2011 (when early benefit assessments were implemented) and April 2015 (cut-off date for the present study), as well as all single technology appraisals (STAs) by NICE published during the same period. We compared early benefit assessment results by IQWiG/GBA and by NICE overall, and by additional criteria including therapeutic area, clinical and incremental cost effectiveness, and patient-relevant endpoints.

RESULTS:
During the study period, NICE issued guidance for 88 technologies (with 125 subgroups). GBA completed 105 appraisals (with 226 subgroups). We identified thirty-seven matched condition-intervention pairs; of these, twenty-four were evaluated differently by NICE and GBA. NICE recommended twenty-nine of thirty-seven interventions (78 percent), whereas GBA confirmed additional benefit for 21/37 only (57 percent; p< .05, two-tailed chi-square test). By therapeutic area, NICE was more likely to evaluate interventions for metabolic and cardiovascular disorders favorably, whereas IQWiG/GBA appraisals were more favorable for treatments of hematological and oncological diseases. Results including all HTAs were consistent with those for matched pairs.
CONCLUSIONS:
Our results suggest that, overall, NICE tends to evaluate new inter-ventions more favorably than IQWiG/GBA. However, our analysis revealed conspicuous differences by therapeutic area. The results are consistent with the hypothesis that different methodological choices may lead to systematic differences in decision making. It seems plausible that the observed differences reflect, at least in part, differences in underlying value judgments.

OP095 An Update On The Economic Value Of A Statistical Life Year In Europe

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ABSTRACT SUMMARY:
By means of a systematic literature search, we identified forty-one European studies reporting original data, yielding a total of forty-eight average estimates for the value of a statistical life (VSL, or fatality prevented). We classified studies by methodology, for example, revealed preference (RP) or stated preference (contingent valuation, CV; discrete choice experiment, DCE) approach. We transformed VSL estimates into VSLY expressed in year 2014 Euros, using the life expectancy of the populations studied, a real discount rate of 3 percent, the national Consumer Price Index (CPI) for inflating, and purchasing power parities for currency conversion. We calculated confidence intervals by means of nonparametric bootstrapping.

METHODS:
Our literature search (using the EconBiz and EconLit databases, supplemented by an analysis of relevant reviews) identified forty-one European studies providing original data, yielding a total of forty-eight average estimates for the value of a statistical life (VSL, or fatality prevented). We classified studies by methodology, for example, revealed preference (RP) or stated preference (contingent valuation, CV; discrete choice experiment, DCE) approach. We transformed VSL estimates into VSLY expressed in year 2014 Euros, using the life expectancy of the populations studied, a real discount rate of 3 percent, the national Consumer Price Index (CPI) for inflating, and purchasing power parities for currency conversion. We calculated confidence intervals by means of nonparametric bootstrapping.

RESULTS:
The median VSLY was EUR158,000 (for RP studies, EUR218,000; DCE, EUR188,000; CV; EUR143,000); we did not identify studies using the human capital approach. Our VSLY estimates showed large heterogeneity, both by methodology and regional origin; thus the differences that we observed did not reach statistical significance.

CONCLUSIONS:
Our results suggest that the empirical willingness-to-pay for a statistical life year might be substantially higher than benchmarks currently used by the international HTA community.
OP096 A Framework To Develop The Structure Of Public Health Economic Models

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ABSTRACT SUMMARY:
A conceptual modelling framework is presented to assist modellers through the process of developing the structure of public health economic models. The framework was informed by: literature reviews; qualitative research with modellers; and piloting a draft version. It provides the first systematic and transparent approach for public health economic model development, having the potential to increase resource allocation efficiency.

INTRODUCTION:
Formal methods for the development of health economic model structures are relatively underdeveloped (1,2). The lack of formal conceptual modelling approaches is particularly problematic for economic models of public health interventions, which tend to operate within complex systems and require broader considerations than clinical interventions. Inappropriately simple models may lead to poor validity and credibility, resulting in suboptimal allocation of resources. The aim of this work is to offer the first conceptual modelling framework for public health economic evaluation, to assist modellers through the process of developing the model structure.

METHODS:
The framework was informed by: literature reviews of (i) the key challenges in public health economic modelling (3) and (ii) existing conceptual modelling frameworks; interviews, focus groups, and observation with modellers from different United Kingdom (UK) centers to understand their experiences when developing public health economic models and their views about using a conceptual modelling framework; and piloting a draft version of the framework.

RESULTS:
The framework comprises four key principles of good practice and a proposed methodology. The key principles are that: (i) a systems approach to modelling should be taken; (ii) a documented understanding of the problem is imperative prior to and alongside developing and justifying the model structure; (iii) strong communication with stakeholders and members of the team throughout model development is essential; and (iv) a systematic consideration of the determinants of health is central to identifying the key impacts of public health interventions. An overview of the methodology will be described.

CONCLUSIONS:
The conceptual modelling framework provides the first systematic and transparent approach for public health economic model development, having the potential to increase resource allocation efficiency. The framework should be tested within diverse case studies, including outside of the UK context, to evaluate and develop it further. Future research should involve development of methods for modelling individual and social behaviour.

REFERENCES:
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OP097 Program Budgeting Marginal Analysis for the Real World

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
A real world example of piloting and implementation of program budgeting marginal analysis (PBMA) for two different service areas and development of a lean PBMA process.

INTRODUCTION:
Program budgeting marginal analysis (PBMA) accommodates economic analysis, multi-stakeholder inputs, values, needs and perspectives within one framework in order to determine optimal use of available resources to deliver the highest ‘health value’. Two pilot PBMA projects in two different services were conceived and completed in a Welsh Health Board (HB) as ‘proof of concept’ methodology for robust prioritization decisions and for improving quality of patient care, outcomes and experience. The pilots were essential to enable development of a ‘bespoke’ PBMA process for the HB to implement.

METHODS:
The PBMA methods were based on methods and criteria for successful PBMAs reported in the literature. Project teams and stakeholder communities supported the PBMAs which were executed over a 12 -18 month period between 2013-15. Group decision support methods were used to facilitate meetings and decision making. Formal interviews with project team members and informal feedback informed development of the final PBMA framework.

RESULTS:
Identifying the costs and resources attributable to services and those that could be moved around services was challenging. Evidence of outcomes and ‘health value’ was more easily available. One PBMA pilot recommended that some modest service reorganization and quality improvement could be made within budget but no substantial improvement/decommissioning could be undertaken. The other pilot agreed a disinvestment decision on the basis of evidence and reallocated the resources to a higher value service. The HB commissioning team found the information from the PBMA ‘journey’ as useful as the recommendations. A PBMA framework for the HB was devised.

CONCLUSIONS:
A ‘Prudent PBMA’ framework trimmed back to the critical essentials enables success criteria to be met. PBMA is to be adopted as a ‘way of working’ to operationalize resource reallocation and disinvestment in the ‘real world’ of Welsh healthcare commissioning.
OP098 The Impact Of Nondivisibility And Diminishing Returns On The Threshold

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ABSTRACT SUMMARY:
We consider the implications of departures from the assumptions underlying the standard model of the cost-effectiveness threshold, including the possibility of diminishing marginal returns to scale or non-divisibility of technologies. We also consider if the optimal threshold is dependent upon a new technology’s budget impact and whether the new technology constitutes a net investment or net disinvestment.

INTRODUCTION:
The optimal cost-effectiveness threshold has been subject to much debate. In the standard model, technologies are assumed to be divisible and exhibit constant returns to scale. We consider the implications of departures from the assumptions underlying the standard model, including the possibility of diminishing marginal returns to scale or non-divisibility of technologies. We also consider if the optimal threshold is dependent upon a new technology’s budget impact and whether the new technology constitutes a net investment or net disinvestment.

METHODS:
We conducted simulations using a de novo model of a hypothetical health care system. The model comprises three stages: allocation of a budget among a pool of initial technologies, consideration of a new technology, and reallocation of resources if the new technology is adopted. The optimal threshold ensures that new technologies are adopted only if the net incremental benefit of adoption and reallocation is positive. Three scenarios were considered: divisible technologies exhibiting constant returns; divisible technologies exhibiting diminishing returns; and non-divisible technologies. For each scenario we estimated optimal thresholds across a range of possible budget impacts for different initial budgets.

RESULTS:
The standard exposition of the threshold holds only if: (a) initial technologies are divisible and exhibit constant returns to scale; (b) one technology remains partially adopted following initial allocation; and (c) the budget impact of each new technology is sufficiently small that reallocation involves expanding or contracting only the partially adopted technology. In all other cases, the threshold depends upon whether the new technology is a net investment or net disinvestment and the magnitude of the budget impact. The threshold curve is a piecewise linear function under divisibility and constant returns, a concave function under divisibility and diminishing returns, or a step function under non-divisibility.

CONCLUSIONS:
The standard exposition of the cost-effectiveness threshold is a special case that holds only under specific conditions. Under other conditions, threshold curves take a different functional form that reduces the scope for new technologies to be cost-effective.

OP099 Micro-Costing Study Of Breast Cancer Intervention In China

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ABSTRACT SUMMARY:
Micro-costing is known as the most precise costing approach, and it’s never been applied in breast cancer screening, diagnosis, and treatment in China. From a societal perspective, our study was conducted in two sites and costing data were aggregated. Combined with existing expenditure data, we explored cost-expenditure-ratio approach to estimate the costs in broader regions in China.

INTRODUCTION:
To estimate cost of breast cancer screening, diagnosis, and treatment in China for further economic evaluation on various breast cancer screening strategies, and to evaluate the feasibility of a cost-expenditure-ratio approach in broader regions in this population.

METHODS:
During 2014–2015, from a societal perspective, the study was conducted in one municipal hospital in Gansu and one provincial one in Hunan. Direct medical cost (DMC) was measured using a micro-costing approach combined with clinical pathway. The aggregated cost (AC) also included direct non-medical and indirect costs via face-to-face interview. Cost-expenditure ratios were calculated to estimate costs in other regions. All the cost data are presented in USD in 2015.

RESULTS:
A total of 59 professionals and 815 individuals received screening, diagnosis, or treatment were interviewed. The ranges of AC for ultrasound, mammography screening, and histologic diagnosis were USD13–USD15, USD18–USD46 (the DMC accounted >88.1 percent), and USD69–USD106 (DMC >98.1 percent), respectively. Treatment costs varied: (i) municipal hospital, the DMC of pre-cancer treatment was USD349 and the AC for cancer treatment was USD6,929 (DMC=73.6 percent); (ii) provincial hospital, the DMC of pre-cancer treatment was USD2,708 and the AC for cancer treatment was USD17,690 (DMC=91.4 percent). The cost-expenditure ratios of ultrasound screening, mammography screening, diagnosis, pre-cancer, and cancer treatment in the municipal hospital were .94, .76, .69, .54, and .51, respectively; while those in the provincial hospital were .91, 1.60, 1.12, .92, and 2.43, respectively. Furthermore, cost of screening, diagnosis, pre-cancer, and cancer treatment for other regions were estimated at USD10–USD82, USD14–USD180, USD591–USD2,719, and USD1,608–USD17,643, respectively.

CONCLUSIONS:
All the aggregated costs and cost-expenditure-ratios for breast cancer screening, diagnosis, and treatment were higher in the provincial hospital, suggesting that inputs were supposed to decrease if service providing were shifted down to a lower-level hospital. The cost-expenditure-ratio approach might be an alternative method for cost estimation if accurate expenditure data is available.
OP100 How Health Technology Assessment Is Adapting To Orphan Drugs In Canada – Not!

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ABSTRACT SUMMARY:
Canada has no separate Health Technology Assessment (HTA) pathway for rare disease drugs (DRDs), and rejection is much higher than for common drugs. The Canadian Agency for Technologies in Health introduced two revisions to accommodate DRDs. Using methods of review synthesis, primary analysis and case studies, this study concluded revisions notwithstanding, HTA for all drugs does not result in equitable assessment.

INTRODUCTION:
Some countries have distinct pathways for drugs for rare diseases (DRDs) (1). In May 2014, the Canadian Agency for Technologies in Health (CADTH) rejected the option of a separate review pathway for DRDs, reiterating that “pharmacoeconomic analyses are critical for all types of drugs”. While the gap between positive recommendations for common and rare drugs may have narrowed, the rejection for DRDs is still proportionally much higher (2). The default has been to provincially negotiate drug access, for patient populations, subgroups or individuals. Still not wishing to create a separate pathway, in March 2016, CADTH produced a revised evaluation framework for “uncertain clinical and pharmacoeconomic evidence” and other considerations representing “significant unmet need” including rarity and difficulty to study because of small patient population”(3). This study analyzes recommendations for DRDs following the two CADTH revisions.

METHODS:
Methods used were: synthesis of previously conducted analyses of CADTH recommendations for rare and non-rare drugs, primary comparative analysis of CADTH recommendations for DRDs from 2004 to 2016, and qualitative analysis of two drugs submitted for both rare and non-rare conditions: everolimus (breast cancer, pancreatic neuroendocrine tumours, and tuberous sclerosis complex) and ibrutinib (chronic lymphocytic leukemia, small lymphocytic lymphoma, and Waldenström’s Macroglobulinemia).

RESULTS:
Previous analyses found that DRDs received more negative recommendations than did non-rare drugs; both clinical and economic evidence were differentiating factors. The primary analysis provided an additional understanding of reasons for negative recommendations. There is low consistency across assessments and across the two CADTH review committees. The case studies illustrated the challenges for DRDs to overcome barriers of cost effectiveness and certainty of clinical evidence, even with the revised framework.

CONCLUSIONS:
This research challenges the premise that Health Technology Assessment for all drugs can result in fair and equitable recommendations for DRDs. Moreover, assessments based on “significant unmet need” do not appear to provide consistent or equitable guidelines for addressing the issues specific to rare diseases.

REFERENCES:
2. Rawson NSB. Are the cost-effectiveness rules used by public drug plans denying coverage to Canadians with rare disorders? Canadian Health
OP101 Do We Need To Extend Health Technology Assessment To Health Enhancement Assessment?

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ABSTRACT SUMMARY:
Several health technologies can be used for therapy and for health enhancement. However, Health Technology Assessment (HTA) has not been developed for assessing enhancements. This presentation explores three alternatives: a) to carve out a distinction between therapy and enhancement and limit HTA to therapy, b) use HTA for both therapy and enhancement, or c) develop a health enhancement assessment (HEA).

INTRODUCTION:
Several health technologies used for therapy can also be used for health enhancement. Drugs stimulating cognitive abilities are but one example. Health Technology Assessment (HTA) has not been developed for assessing enhancements. This raises the question of how HTA should address the blurred distinction between therapy and enhancement. Should we (i) carve out a distinction between therapy and enhancement and limit HTA to therapy, (ii) use HTA for both therapy and enhancement (with some modifications), or (iii) should we develop a separate health enhancement assessment (HEA)?

METHODS:
A literature search of the medical, philosophical, and bioethical literature was conducted for debates, arguments, and suggested solutions to the issue of therapy versus enhancement.

RESULTS:
The same improvement in health may be therapeutic in one patient, but an enhancement in another. Moreover, both therapy and enhancement share the same goal: increased health and wellbeing. A wide range of arguments try to establish a difference between therapy and enhancement. They refer to naturalness, rehabilitation, normality, species-typical functioning/potential, disease, sustainability, and responsibility. On closer scrutiny few of these arguments do the job in bolstering the therapy-enhancement distinction. We already use a wide range of means to extend human abilities. Moreover, the therapy-enhancement distinction raises a wide range of ethical issues that are relevant for the assessment of a number of emerging health technologies.

CONCLUSIONS:
Existing HTA methodology can address a wide range of non-therapeutic health enhancements. However, a series of broader issues related to the goal of health care and responsibility for altering human evolution may not be addressed within traditional HTA frameworks. Specific HEAs may therefore be helpful.
OP102 High Media Coverage Of Health Technology Assessment Reports: Lessons Learned

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ABSTRACT SUMMARY:
In 2016, two SBU reports were noticeable with respect to media coverage: anal sphincter injuries associated with childbirth and shaken baby syndrome. Communication strategies for these two high impact reports will be presented. The analysis of the communication work includes in-house work, interaction with experts as spokespeople, media reactions, and impact.

INTRODUCTION:
The communication department at the Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU, paid particular attention to dissemination of the reports on birth injury in women after vaginal birth and shaken baby syndrome. In both cases, SBU had a wide range of target groups including journalists, professional organisations within the health care sector, government officials, and the general public.

METHODS:
SBU decided to focus on social media as well as traditional media. Among the means of establishing new channels, SBU contacted members of a Facebook group of women with birth injuries. We also had a number of face-to-face meetings, especially regarding the shaken baby syndrome report. Our key to reaching the target audience was to involve our experts. The experts are academic professionals within the relevant fields and SBU prepared them for possible issues before publishing the reports. Regarding the report on shaken baby syndrome, SBU used a more reactive model of communication to avoid news leakage.

RESULTS:
The intense preparatory work in communications paid off, although there is much more potential for expansion in social media. The results of the reports, for example, knowledge gaps, came across clearly. The major Swedish tabloid paper had a three-day focus on birth injury in women where the SBU expert was the main spokesperson. The media attention led to a statement from the Minister for Health Care who confirmed that the government set aside money to improve health care and research in the area.

CONCLUSIONS:
Traditional media and social media are both important channels. However, the focus on traditional media had a larger impact in these two cases. In a longer perspective, social media has other advantages. Social media opens up possibilities to prolong the attention on the report and open dialogue with users, clients, and professionals, and thereby get a broader view.

OP103 CONITEC’s Rapid Reports As Technical Support In The Litigation

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ABSTRACT SUMMARY:
The National Committee for Health Technology Incorporation (CONITEC) provides technical assistance to the Brazilian Health Minister to help the decision-making process. This study describes CONITEC’s experience in communicating with stakeholders (judges, prosecutors and public lawyers). From 2012-2016, 2,773 reports about health technologies incorporation such as medicines, procedures or medical devices were produced, covering topics as treatments for diabetes, arterial hypertension, osteoporosis, oncology and epilepsy.

INTRODUCTION:
The Unified Health System (SUS) is based on the principle of health as a citizen’s right and the state’s duty, which must be guaranteed based on public policies. Although there are several legislations, lists of medicines and clinical guidelines, Brazilians who have been prescribed expensive technologies that are not part of the essential drug lists ask judges to issue court orders obliging public health managers to purchase these drugs or to provide elective medical procedures immediately. Due to the health technical inexperience from judges, prosecutors and public lawyers, a partnership has arisen for the National Committee for Health Technology Incorporation (CONITEC) to provide technical assistance to help their decision-making process. Thus the purpose of this study is to describe CONITEC’s experiences in communicating with stakeholders in this process.

METHODS:
A case study method was used and information about the rapid reports developed by CONITEC’s Executive Secretariat in response to the applicants in the period of 2012 to 2016, was retrieved from CONITEC database.

RESULTS:
Rapid reports (2,773) about health technologies incorporation such as medicines, procedures or medical devices were produced by CONITEC during this period. Most requests covering topics as treatments for diabetes, arterial hypertension, osteoporosis, oncology and epilepsy; diseases for which there are several treatment options in SUS. The data analysis indicated that CONITEC contributed to the evidence based decision-making. On one hand, the Prosecutor’s Office has been increasingly requesting information before starting lawsuits and Judiciary Power has increasingly used evidence-based technical information before deciding on the concession of injunctions; on the other hand, from 2012 to 2016 the number of requests decreased for information to State defense in lawsuits that has been already established.

CONCLUSIONS:
There is a growing interest in technical knowledge for fair decision making that respects the current organization of the evidence-based health system.

OP104 Health Technology Assessment’s Ethical Evaluation: Understanding The Diversity Of Approaches

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ABSTRACT SUMMARY:
To understand the diversity of approaches of ethical evaluation in Health Technology Assessment (HTA) we analyzed nine approaches commonly referred to in HTA. Three criteria were used to analyze each approach: (i) The characteristics of the ethical evaluation (ii) The disciplinary foundation of the ethical evaluation and (iii) The operational process of the ethical evaluation in HTA analysis.

INTRODUCTION:
The main difficulties encountered in the integration of ethics in Health Technology Assessment (HTA) were identified in our systematic review. In the process of analyzing these difficulties we then addressed the question of the diversity of ethical approaches (1) and the difficulties in their operationalization (2,3).

METHODS:
Nine ethical approaches were identified: principlism, casuistry, coherence analysis, wide reflexive equilibrium, axiology, socratic approach, triangular method, constructive technology assessment and social shaping of technology. Three criteria were used to clarify the nature of each of these approaches:

1. The characteristics of the ethical evaluation
2. The disciplinary foundation of the ethical evaluation
3. The operational process of the ethical evaluation in HTA analysis.

RESULTS:
In HTA, both norm-based ethics and value-based ethics are mobilized. This duality is fundamental since it proposes two different ethical evaluations: the first is based on the conformity to a norm, whereas the second rests on the actualization of values. The disciplinary foundation generates diversity as philosophy, sociology and theology propose different justifications for ethical evaluation. At the operational level, ethical evaluation’s characteristics are applied to the case at stake by specific practical reasoning. In a norm-based practical reasoning, one must substantiate the facts that will be correlated to a moral norm for clearly identifying conformity or non-conformity. In value-based practical reasoning, one must identify the impacts of the object of assessment that will be subject to ethical evaluation. Two difficulties arise: how to apply values to facts and prioritize amongst conflicting ethical evaluations of the impacts?

CONCLUSIONS:
Applying these three criteria to ethical approaches in HTA helps understanding their complexity and the difficulty of operationalizing them in HTA tools. The choice of any ethical evaluations is never neutral: it must be justified by a moral point of view. Developing tools for ethics in HTA is operationalizing a specific practical reasoning in ethics.

REFERENCES:
OP105 Systematically Reconstructing Trial Context-Role For CLUSTER Searches?

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ABSTRACT SUMMARY:
The previously reported CLUSTER approach may be useful in identifying additional reports associated with a trial and thus supplying useful context. However, the current CLUSTER approach is labour intensive. Use of a streamlined CLUSTER approach harnessing Publish or Perish software offers a feasible and economical alternative of particular value when conducting a mixed-methods Health Technology Assessment (HTA).

INTRODUCTION:
Randomized controlled trials (RCTs) of complex interventions are conducted in a context-specific environment. Principal trial reports, with a focus on main results, are unable to document adequately the context for an intervention, for example, word limits. Important context may be included in “sibling studies” (that is, studies conducted alongside the main trial, for example, process evaluations, and qualitative studies (1)). This presentation explores (i) to what extent is it possible to use a systematic and parsimonious method to identify sibling studies and (ii) what is the potential value of yield from these studies?

METHODS:
The systematic CLUSTER approach (2) to follow up of index studies (Citations, Lead authors, Unpublished materials, Scholar, Theories, Early examples Related projects) has demonstrated the value of retrieved items in qualitative terms. However, the CLUSTER approach is painstaking and laborious and may be prohibitive within a time-tight Health Technology Assessment (HTA). A streamlined CLUSTER approach, using freely available Publish or Perish software integrated with Google Scholar and Microsoft Excel, offers an economical way of building up “clusters” of study reports. A case study of a UK National Institute for Health Research (NIHR)-funded HTA on the management of medically unexplained symptoms in primary care, utilising quantitative and qualitative research studies, is used to examine the practical application of the approach.

RESULTS:
Systematic comparison of yield from sifting with yield from the Publish or Perish software reveals (i) major trials for which corresponding qualitative studies were not previously identified, (ii) qualitative studies identified independently from, and potentially unlinked to, associated trials, (iii) associated trial reports (for example, protocols, feasibility studies, etc.), economic evaluations and systematic reviews, and (iv) commentaries and correspondence; all with the potential to enhance understanding of trial context.

CONCLUSIONS:
The potential of the Publish or Perish-enabled CLUSTER approach to identify trials or qualitative studies, through “joining up” and mapping of clusters, potentially missed from separate quantitative/qualitative sift processes, means that it should be considered for any HTA that seeks to integrate quantitative and qualitative studies.

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2. Booth A, Harris J, Croot E et. al. Towards a methodology for cluster searching to provide

**OP106 The Impact Of Searching Fewer Databases In HTA Rapid Reviews**

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**ABSTRACT SUMMARY:**
In rapid reviews, time and resources are limited and modifications to the search methodology may be necessary. In this retrospective study, the impact of searching fewer databases for three completed rapid reviews for the UK National Institute for Health Research was investigated.

**INTRODUCTION:**
Multiple databases are often searched in Health Technology Assessment systematic reviews. However, in rapid reviews, time and resources are limited and modifications to the search methodology may be necessary. In this retrospective study, the impact of searching fewer databases for three completed rapid reviews (i) Severe Mental Illness (SMI), (ii) Cannabis Cessation (CC), (iii) Premature Ejaculation (PE) for the UK National Institute for Health Research was investigated.

**METHODS:**
The database coverage and indexing of the study references from the reviews were initially identified. The impact of fewer databases searched was then tested by (i) the number of studies that might be missed, (ii) the number of records for sifting and (iii) the overall rapid review conclusions.

**RESULTS:**
A total of 178 included study references were found in the reviews (SMI n=14 for 13 studies, CC n=34 for 33 studies, PE n=130 for 102 studies). Searching Medline only for SMI, Medline+Embase for CC, Medline+Embase+Cochrane Library for PE, would result in 1902 (74 percent), 466 (43 percent) and 240 (11 percent) fewer records needed to sift, respectively. There would also be a total of ten ‘would be missed’ references (SMI n=1, CC n=5 and PE n=4). However, nine out of the ten references were found to have no or minimal impact on the overall findings of the reviews. The ten references were secondary reports of an included study, papers that lacked sufficient data for meta-analysis such as a conference abstract or an ongoing trial.

**CONCLUSIONS:**
From the three reviews examined, limiting the search to fewer databases had no or minimal impact on the review conclusions despite the variable number of studies that would be missed and records needed to sift. More exploration during the scoping search prior to commencing the review will aid the decision on whether to limit the search to fewer databases.

**OP107 Sources Used To Find Studies For Systematic Reviews Of Economic Evaluations**

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ABSTRACT SUMMARY:
Following closure of the National Health Service Economic Evaluation Database (NHS EED) and the Health Economic Evaluations Database (HEED), we assessed which databases are now the best sources of economic evaluations (EEs) and identify the most efficient combination of databases to search when conducting a systematic review (SR) of EEs. Preliminary results suggest searching two or three databases for published EEs may be efficient, provided resources are searched using appropriate strategies.

INTRODUCTION:
Evidence about which information resources should be searched to identify economic evaluations (EEs) of healthcare interventions when conducting a systematic review (SR) predates closure of the National Health Service Economic Evaluation Database (NHS EED) and Health Economic Evaluations Database (HEED). We assessed which databases are now the best sources of EEs and identify the most efficient combination of databases, taking into account the order in which databases could be searched.

METHODS:
We gathered a reference set of EEs from published reviews of EEs undertaken to inform Health Technology Assessments (HTA). We calculated yield and relative recall (RR) (number of reference set records identified / total number of records in reference set) for each database, and combination of databases. We assessed the order in which databases should be searched, to identify the most efficient combination of databases to identify the reference set. We report the characteristics of records not included in any database studied and implications for identifying this type of evidence.

RESULTS:
To date, a reference set of fifty-five EEs from seven HTAs has been processed. Embase and Scopus each yielded 53/55 records (RR .96). MEDLINE yielded 52/55 (RR .95). Embase or Scopus included all of the journal publications in the reference set; no additional unique records were provided by MEDLINE, CEA Registry, EconLit, or Science and Social Science Citation Indexes. The two records that were not identified were unpublished evidence, one of which was included in the National Institute for Health Research (NIHR) HTA database. Processing will continue until we reach the threshold of a reference set of 350 records.

CONCLUSIONS:
Preliminary results suggest that searching two or three databases may be most efficient, provided that resources are searched using appropriate strategies. Searchers should concentrate on developing search strategies that work well in those databases to ensure adequate sensitivity, and use freed time to identify grey literature.

OP108 Health Intervention Assessment Report Adaptation: Tunisian Experience

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ABSTRACT SUMMARY:
INASanté has chosen to rely on adaptation process to develop its first Health Technology Assessment report. The PICO question related to the colorectal
cancer screening issue in Tunisia was determined. A strategy of literature search, data appraisal and evaluation of report adaptability were conducted. Results of a structured study of the Tunisian context were combined with the relevant data extracted.

INTRODUCTION:
Health Technology Assessment (HTA) reports adaptation process is an important tool for emerging HTA agencies. INASanté (National Instance for Accreditation in Healthcare) has chosen to rely on this approach, to develop its first health intervention assessment report: comparative study of computed tomographic colonography versus standard colonoscopy for colorectal cancer screening.

METHODS:
Following consultations with healthcare professionals, the PICO question related to the colorectal cancer screening issue in Tunisia was determined. A literature search strategy covering 10 years (2006-2016) was carried out. Several databases including HTA on the net were explored. Then two independent reviewers conducted literature screening and realised a PRISMA flow diagram. Full text selected reports were submitted to three critical appraisal tools: PRISMA checklist, INAHTA checklist and Critical Appraisal Tools (FLC 2.0). The EUnetHTA adaptation toolkit was used to determine reports adaptability by assessing relevance, reliability and transferability. A structured study of the Tunisian context based on a qualitative data analysis was elaborated. The data synthesis and reporting were finalised with the contribution of a working group. Then an external peer review was conducted before the report dissemination.

RESULTS:
Eighty reports were screened to finally retain four eligible. After a critical appraisal performed by two independent reviewers, two reports from the Canadian Agency for Drug and Technologies in Healthcare and AETSA were selected to be assessed using the EUnetHTA adaptation toolkit. Regarding transferability criteria, the second report was retained. The context study has consisted in a qualitative analysis of seventeen individual interviews with healthcare professionals involved in colorectal cancer screening issues and an up to date Tunisian literature review. The final adapted report was a combination between relevant extracted data from AETSA report and synthesis of the Tunisian context analysis.

CONCLUSIONS:
This HTA report represents a tool for policy makers to establish the appropriate colorectal cancer screening program for the Tunisian context. HTA reports adaptation process is the best way to give evidence on emerging technologies without wasting time and resources.

OP109 Making Best Use Of Other’s Health Technology Assessments By Both Adopting And Adapting

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ABSTRACT SUMMARY:
The initial step when conducting a Health Technology Assessment (HTA) is to look for what others have already done, because “reusing” relevant, timely, and high quality HTA information avoids work duplication and wasting resources. We have previously described how NIPHNO has taken advantage of EUnetHTA joint assessments for
national HTA commissions. Here, we explore details of this “reuse”, barriers and success factors.

INTRODUCTION:
The very first step in performing an HTA is to search for already existing HTAs on the same subject. In cases where others have performed an updated systematic literature search for studies relevant to our own research question, done a proper quality assessment, graded and summarized the evidence appropriately using validated tools, we can – and should – reuse the assessment. We are so-called “adopting” and/or “adapting” the HTA in question into our “local setting,” this to ultimately ensure a solid evidential ground for decision making and, importantly, not to waste resources on repeating the whole assessment ourselves.

EUnetHTA aims at facilitating the sharing of information and efficient use of resources available for HTA in Europe, such as the reuse of European HTAs, including those produced by the EUnetHTA itself. Many organizations from EU Member States, including Norway, have been involved in the production of joint assessments. However less is known about the reuse of these common joint HTAs, that is, how they actually were adopted and/or adapted, and if the “reuse” was actually worthwhile.

METHODS:
So far, the Norwegian Institute of Public Health (NIPHNO) has fruitfully taken advantage of three EUnetHTA-produced HTAs for carrying out own assessments. Two of these were commissioned directly by Norwegian Health Authorities, and one was carried out based on specific interest by Norwegian clinicians within the field of cardiology.

RESULTS:
In most cases, HTA information from the European HTAs could be transferred directly, including numericals and calculations. However, there were differences in reporting and formats, and in interpreting results. Hence, interpretations and sometimes conclusions had to be reformulated for some effectiveness outcomes, and especially for outcomes related to safety.

CONCLUSIONS:
Overall, our experience with using these three HTAs have been positive and was definitely worthwhile, and has allowed to define possible factors hampering and facilitating reuse of other’s HTA assessments in general.

OP110 Survey Of Health Technology Assessment Evaluation Strategies For Patient And Public Involvement

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ABSTRACT SUMMARY:
Although there is increased awareness of the need for involving patients and members of the public in Health Technology Assessment (HTA), evaluations of related initiatives are relatively scarce. We discuss a recent survey of international HTA organizations to better understand whether and how HTA programs are evaluating their engagement strategies and with what results, as well as perceived facilitators and barriers to evaluation.

INTRODUCTION:
Although there is increased awareness of patient and public involvement (PPI) among Health Technology Assessment (HTA) organizations,
evaluations of PPI initiatives are relatively scarce. Our objective as members of HTAi’s Patient and Citizen Involvement Group (PCIG) was to advance understanding of the range of evaluation strategies adopted by HTA organizations and their potential usefulness.

METHODS:
In March 2016, a survey was sent to HTA organizations through the International Network of Agencies for Health Technology Assessment (INAHTA) and contacts of members of HTAi’s PCIG. Respondents were asked about their organizational structure; how patients and members of the public are involved; whether and how PPI initiatives have been evaluated, and, if so, which facilitators and challenges to evaluation were found and how results were used and disseminated.

RESULTS:
Fifteen programs from twelve countries responded that involved patient (14/15) and members of the public (10/15) in HTA activities. Seven programs evaluated their PPI activities, including participant satisfaction (5/7), process evaluations (5/7) and impact evaluations (4/7). Evaluation results were used to improve PPI activities, identify education and training needs, and direct strategic priorities. Facilitators and challenges revolved around the need for stakeholder buy-in, sufficient resources, senior leadership, and including patients in evaluations. Participants also provided suggestions based on their experiences for others embarking on this work, for example including patients and members of the public in the process.

CONCLUSIONS:
We identified a small but diverse set of HTA organizations internationally that are evaluating their PPI activities. Our results add to the limited literature by documenting a range of evaluation strategies that reflect the range of rationales and approaches to PPI in HTA. It will be important for HTA organizations to draw on formal evaluation theories and methods when planning future evaluations, and to also share their approaches and experiences with evaluation.

OP111 Patient Input: A Definition For Optimizing Use

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ABSTRACT SUMMARY:
This presentation describes ‘patient input’ as the written and verbal information provided by patients and patient groups throughout a Health Technology Assessment (HTA). The aim is to enable HTA bodies and researchers to consider this information as distinct from research about patients’ needs, preferences, and experiences, and thus focus on its characteristics and optimal use.

INTRODUCTION:
Health Technology Assessment (HTA) bodies seek guidance on how to integrate information about patients’ needs, preferences, and experiences. One issue is that often when this information is considered, no distinction is made between evidence from research about patient aspects and the input provided by patients and patient groups participating in HTA. The term ‘patient input’ is proposed for the latter, arguing that making this distinction may allow HTA bodies to better understand the contribution this input can make, optimize its use, and share best practice.

METHODS:
During the development of the HTAi patient group submission templates to support one form of patient input, questions were raised by stakeholders about the form and value of patient input. These issues have been explored by studying HTA bodies'
processes and stakeholders’ reflections when developing a book on patient involvement in HTA.

RESULTS:
Input provided from patients and patient groups has different qualities to evidence from rigorous, critically-assessed research into patient aspects. Patient input is characterized by participation and akin to other expert input in an HTA. It provides a lens with which to assess or appraise the evidence (1) and has a role in achieving the shared learning and problem solving that occur in effective participation (2).

CONCLUSIONS:
Categorizing patient input as distinct from other information about patients’ needs, preferences, and experiences, may enable better consideration of its unique qualities and optimal use to ensure it adds value and minimizes the burden placed on patients (1). It should not be evaluated as evidence. Instead, its focus should be achieving credible and legitimate input (3) at any time in an HTA process to aid value judgments and provide important contextual knowledge, especially where uncertainties arise. The concept of patient input is new and is presented for debate and discussion.

REFERENCES:

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OP112 Extending Consumer Engagement Opportunities In Pharmaceutical Benefits Advisory Committee Processes

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ABSTRACT SUMMARY:
Evolving consumer engagement and educative opportunities for the Pharmaceutical Benefits Advisory Committee and the patient groups relevant to the drugs listing arrangements in Australia.

INTRODUCTION:
The Australian Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for recommending new medicines for subsidy by the Australian Government. No new medicines can be listed unless the committee makes a positive recommendation to the Australian Government via the Federal Health Minister. The committee is an independent expert body and members include doctors, health professionals, health economists, and a consumer representative. The focus on the committee for decision making about new drugs comes with high expectations from the clinical and patient communities, and challenges for the committee in engaging with stakeholders over the course of the formal assessment process can be significant. In 2015 the PBAC introduced a pilot process to conduct patient hearings prior to a formal decision being made on specific drugs under consideration and following a formal Health Technology Assessment (HTA) evaluation.

These hearings were developed with criteria to guide selection of the items for discussion, and also how to identify the appropriate patient representation for the face to face hearing.
discussions. Over the course of six formal committee meetings there were eleven individual hearings held with members of the committee to discuss patient inputs, preferences, and direct experiences with the drug(s) being considered for specific indications.

METHODS:
Findings of the consumer hearings are discussed, including assessments by the separate patient groups and individual PBAC members involved. The review included interviews and qualitative assessment in the form of ratings of the experience and description of outcomes.

RESULTS:
The recommendations from the review for future engagement opportunities between patients and the expert committee will be considered, as well as the implications for further refining the guidance provided to patients for delivering the relevant inputs that the committee seeks in this process.

CONCLUSIONS:
Finally, some reflections are offered on the general interactions between the patient groups and the committee in the context of the HTA framework in Australia for the public subsidy of medicines and access to them in a timely manner. Further recommendations from the Australian experience will be suggested for patient engagement models more broadly.

OP114 Shared Decision Making And Adoption Of Noninvasive Prenatal Testing?

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ABSTRACT SUMMARY:
This study aims to examine the association between pregnant women’s level of shared decision-making involvement and adoption of non-invasive prenatal testing (NIPT). A cross-sectional study was conducted in 15 hospitals from China and 194 pregnant women completed the survey. Shared decision making was found to be the most important predictor of pregnant women’s satisfaction with the decision-making process and adoption of NIPT in China.

INTRODUCTION:
Non-invasive prenatal testing (NIPT) has high sensitivity and specificity in detecting trisomy 21, and China has recently completed a national-wide NIPT pilot project. But, given the much higher cost of NIPT and greater need for counselling, it is important to ensure that women make informed decisions regarding prenatal testing. Shared decision making (SDM) is an essential component of patient-centered care, involving communication and discussions between physicians and patients on various options to meet their health needs. This study aims to examine the association between pregnant women’s level of SDM involvement and adoption of NIPT, with a view to providing research outcomes to guide clinical practice.

METHODS:
A cross-sectional study was conducted in 2016 in selected hospitals in Fujian Province, Sichuan Province, and Shanghai in China. Pregnant women completed a survey which contained the 9-item Shared Decision-Making Questionnaire (SDM-Q-9), questions about satisfaction with decision-making processes, and questions on NIPT. Correlation
analysis, multivariable logistic regression, and multivariable linear regression were used to analyze the data.

RESULTS:
One hundred and ninety-four pregnant women from fifteen hospitals in Fujian Province, Sichuan Province, and Shanghai completed the questionnaire. Their average age was 30 years; 42 percent from urban area; and 49.5 percent with college education; 94.3 percent of the pregnant women were supportive of SDM and 64.7 percent thought they had better communication with physicians regarding decision making. Pregnant women’s level of SDM involvement was found to be positively associated with their satisfaction with the decision-making process (P< .001) and their adoption of NIPT (P< .05). Also, satisfaction with treatment decision making was positively associated with adoption of NIPT (P< .001).

CONCLUSIONS:
Shared decision making was found to be the most important predictor of pregnant women’s satisfaction with the decision-making process and adoption of NIPT in China. However, the current level of SDM involvement by pregnant women is still not entirely in line with their preferences. Therefore, better communication between physicians and pregnant women is needed in order to improve SDM, which, in turn, could enhance the appropriate adoption of NIPT.

OP115 Effect Of Multiple Drug resistance On Costs For Patients With Intra-Abdominal Infections in China

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ABSTRACT SUMMARY:
This study includes inpatients with intra-abdominal infections from a teaching hospital, and takes both the resistance rate and the total medical costs (TMCs) into consideration, focusing on the impact of multiple drug resistance (MDR) on TMCs, and further estimates the additional costs to a national level. Moreover, this is one of the few real-world data analyses in Chinese patients.

INTRODUCTION:
Multiple drug resistance (MDR) intra-abdominal infections (IAIs) are associated with noteworthy direct and societal costs. Compared to previous studies, the present one takes both resistance rate and total medical costs (TMCs) into consideration, focusing on the impact of MDR on TMCs in IAIs, as well as further estimating the additional costs at a national level.

METHODS:
All inpatients discharged between 1 January 2014, and 31 December 2015 from a teaching hospital were included. Due to limits in budget and the large number of inpatients, the random between (bottom, top) function was applied to randomly select 40 percent of patients per year. Subsequently, we manually screened out 254 patients with IAIs, according to the International Classification of Disease (tenth revision) and electronic medical records. Eventually, 101 IAIs patients were included, in which 37 were infected by non-MDR bacteria and 64 by MDR bacteria. The Kruskal-wallis non-parametric test and multiple linear regression were employed to analyze the effect of single and multiple variables on TMCs.
RESULTS:
Compared to patients with non-MDR infections, those with MDR were associated with significantly higher TMCs, higher antimicrobial costs, increased insurance, combination antimicrobial therapy, higher usage of antimicrobial agents, greater number of pathogens, longer length of stay, and longer intensive care unit stays. In addition, the average TMCs among patients with MDR were CNY131,801.17 (1USD was equal to CNY 6.227 in 2015), which were CNY 90,200.99 higher than those with non-MDR infections. If our results are generalizable to the whole country, the total attributable TMCs are estimated to be CNY37.06 billion, and the societal costs of CNY111.18 billion in 2015.

CONCLUSIONS:
This real-world data analysis demonstrated the significant excessive burden MDR infections are posing to the current Chinese healthcare system in terms of both TMCs and healthcare resource utilization. Enhanced antimicrobial stewardship in China is necessary to curb the distribution of MDR bacteria.

OP116 Cost-effectiveness Of Sacubitril/Valsartan In Heart Failure

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ABSTRACT SUMMARY:
Economic evaluations help guide decision making about allocation of limited healthcare resources. This analysis provides insights into the cost effectiveness of sacubitril/valsartan, a novel heart failure (HF) treatment. It incorporates the uncertainty in treatment effect observed in the Asian subgroup of the PARADIGM-HF trial. The uncertain incremental cost-effectiveness ratio (ICER) highlights the cost-benefit trade-off that healthcare professionals and patients face when considering HF therapy.

INTRODUCTION:
Heart failure (HF) is a major public health problem worldwide and in Asia. Sacubitril/valsartan reduces cardiovascular death and hospitalisations for HF. However, decision makers need to determine whether its benefits are worth the additional costs, given the low-cost generic status of current standard of care.

METHODS:
Using a Markov model, we projected lifetime clinical and economic outcomes of sacubitril/valsartan versus enalapril for 66-year-old patients with HF in Singapore. Key health states included New York Heart Association (NYHA) classes; patients in each state incurred a monthly risk of hospitalisation for HF and cardiovascular death. Probabilities of events were based on the PARADIGM-HF trial. The uncertain treatment effect of sacubitril/valsartan in Asian patients was modelled using a hazard ratio (HR) of 1 as upper limit in sensitivity analyses. Utilities were obtained from published literature. Local national epidemiological and cost data were applied. Analyses were conducted from the Singapore healthcare payer’s perspective. Both one-way and Probabilistic Sensitivity Analyses (PSA) based on 10,000 Monte Carlo simulations were performed.

RESULTS:
Compared to enalapril, sacubitril/valsartan was associated with an incremental cost-effectiveness ratio (ICER) of SGD74k (USD52k) per quality-adjusted life year (QALY) gained. The cost-effectiveness of sacubitril/valsartan was highly
dependent on its effectiveness in reducing the risk of cardiovascular death. However, this was uncertain, particularly in the Asian subgroup, where results were not statistically significant. In sensitivity analyses using results from Asian patients, the ICERs ranged from SGD41k (USD30k) to SGD1.3 million (USD 0.94 million) per QALY gained. PSA showed the probability of sacubitril/valsartan being cost-effective was below 1 percent, 12 percent and 71 percent at thresholds of SGD20k (USD14k), SGD50k (USD36k) and SGD100k (USD 72k) per QALY gained, respectively.

CONCLUSIONS:
Given the uncertain ICER, sacubitril/valsartan may not provide good value for money compared to enalapril in reducing cardiovascular morbidity and mortality in patients with HF at the current daily cost. Our study highlights the cost-benefit trade-off that healthcare professionals and patients face when considering HF therapy.

OP117 Cost-Effectiveness Analysis Of Policies Based On The DAA-IFN Regimens

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ABSTRACT SUMMARY:
Cost effectiveness analysis of two different health policies based on the second generation DAA-IFN free regimens through a multi-cohort Markov model of real-life HCV chronically infected patients comparing two treatment strategies: (i) treat all patients of the cohort from earlier stages of liver disease (F0-F4); (ii) a relatively constrained treatment strategy (treatment at fibrosis stages F3 and F4).

INTRODUCTION:
New direct-acting antivirals (DAA) treatments for HCV infection are highly efficacious, but costly. Thus, many insurers cover therapy only in advanced fibrosis stages, but the cost effectiveness of early treatment has not been fully explored yet. The aim of this study is to perform a cost effectiveness analysis of two different health policies based on the second generation DAA-IFN free regimens.

METHODS:
A lifetime multi-cohort Markov model of real-life HCV chronically infected patients was used to compare two treatment strategies: (i) treat all patients of the cohort from earlier stages of liver disease (F0-F4); (ii) treatment at fibrosis stages F3 and F4. The analysis was carried out considering the Italian national health service perspective. Cost drivers were collected through a previous Italian survey on HCV patients. Transition probabilities, utility, and SVR rates were derived from the recent literature. The outcomes were expressed in terms of quality adjusted life years (QALYs). The discount rate applied to both costs and QALYs was 3 percent per year. Results of the model were reported in terms of incremental cost effectiveness ratio (ICER). One-way and multivariate probabilistic sensitivity analyses (PSA) were performed to test the robustness of the results as well as their consistency at an assumed cost-effectiveness threshold of EUR30,000/QALY.

RESULTS:
In the base case analysis, treating all fibrosis stages vs treating prioritized patients results to be cost effective with an ICER lower than the NICE acceptability threshold. The base case results can be considered robust as confirmed by the
PSA (ICERs remain below EUR30,000/QALY in 94 percent of the scenarios assumed and in 97 percent below EUR40,000/QALY).

CONCLUSIONS:
Treating HCV infection at any fibrosis stage appeared to improve health outcomes and be cost-effective. The results of the current analysis provide strong evidence based on the cost effectiveness of early treatment of HCV patients on the basis of real-world data.

OP118 CEA Of Molecular Profile selection for advanced Head and neck Cancer

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ABSTRACT SUMMARY:
Cetuximab plus platinum-based chemotherapy is considered the most effective first-line treatment for relapsed/metastatic head and neck cancer. However, it has been proven to be not cost-effective. Our analysis showed that a putative predictive molecular test to identify and treat only patients potentially responsive to cetuximab plus chemotherapy may be a cost-effective option for a molecular test cost lower than EUR5,750.

INTRODUCTION:
Relapsed/metastatic head and neck squamous cell cancer patients are offered a combination of platinum-based chemotherapy (PF, cisplatin-fluorouracil) plus cetuximab regimen (PF+C) according to results of the EXTREME trial (1). However, two economic evaluations showed that addition of cetuximab was not cost-effective.

This study aimed to evaluate the cost-effectiveness of a putative predictive molecular test (MT) to identify and treat only patients potentially responsive to cetuximab when added to PF.

METHODS:
A Markov model was developed to compare both health and economic outcomes of PF+C regimen administered to all patients (PF+C ALL) versus the regimen administered only to MT-positive patients (PF+C POS).

The model considered the following health states: partial/complete response with/out mild/severe adverse events (AEs), progression and death. Rates of progression and survival, response rates to systemic treatment and adverse events were retrieved from the EXTREME trial (1). According to Mesia et al. (2), we assumed that addition of cetuximab to PF would not negatively affect life quality compared to PF alone, and the baseline utility coefficients for disease control and progression were assumed as .67 and .52, respectively.

Only direct costs estimated from the Italian Health Service perspective were included (tariffs and Diagnosis Related Group - DRG - reimbursements).

The model was evaluated according to a cut-off of sensitivity at 85 percent and specificity at 70 percent. A 3 years horizon was chosen. Life expectancy, quality-adjusted life years (QALYs) and costs were discounted at 3.5 percent annually.

RESULTS:
Applying the World Health Organization (WHO) cost-effectiveness threshold of 3 times the gross domestic product for Italy (EUR66,402), PF+C POS resulted a cost-effective choice in comparison to PF+C ALL for a MT cost lower than EUR5,750.
CONCLUSIONS:
Adding cetuximab to PF only to patients positive to a predictive test may be cost-effective. Efforts should be spent to build such a test upon existing evidences in order to save resources for the health systems and spare unnecessary toxicities to patients.

REFERENCES:

OP119 Advanced Therapy Medicinal Products: Are Current Health Technology Assessment Methods Suitable?

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ABSTRACT SUMMARY:
High costs mean that Health Technology Assessment (HTA) and reimbursement decisions for advanced therapy medicinal products (ATMPs) are challenging for payers and manufacturers, even when the therapies are expected to offer good value for money. We present a review of one example, from the UK’s National Institute for Health and Care Excellence (NICE), who commissioned an external organisation to undertake a mock appraisal of a hypothetical ATMP using standard methods.

INTRODUCTION:
There is considerable excitement around the development of regenerative medicines (or advanced therapy medicinal products, ATMPs), with the expectation that they may bring substantial clinical gains and offer cures for previous debilitating and fatal diseases. However, high costs mean that Health Technology Assessment (HTA) and reimbursement decisions are challenging for payers and manufacturers, even when the therapies are expected to offer good value for money.

In Europe, seven ATMPs have market authorisation, yet only one has achieved national level reimbursement. Statistics such as these put HTA bodies under pressure to review their methods and consider how these can apply to regenerative medicines.

METHODS:
We present a review of one example, from the United Kingdom’s National Institute for Health and Care Excellence (NICE), who commissioned an external organisation to undertake a mock appraisal of a hypothetical ATMP using standard methods. The therapeutic area chosen for the mock appraisal was chimeric antigen receptor (CAR) T-cell therapy for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

RESULTS:
The role of uncertainty was a key consideration within the report, yet we found that the presentation of uncertainty within the mock appraisal was misleading for decision makers.

We found that the exercise represents a thorough mock HTA of CAR T-cell therapy. However, it focused on testing whether ATMPs could fit into the existing HTA pathway for conventional medicines, rather than seeking to identify the most suitable approach for assessing regenerative medicines. We suggest the latter would have been a more relevant question for the mock appraisal.
CONCLUSIONS:
Any significant departures from the usual HTA process must be based on solid economic rationale if we are to ensure efficient allocation of resources. Thus, in order for regenerative medicines to be given ‘special treatment,’ it must be demonstrated that societal preferences, or the full extent of health (or non-health) benefits, are not being realised for this group of treatments through existing HTA methods.

INTRODUCTION:
Budget impact analysis (BIA) provides short and medium-term estimated effect of new health interventions on budgets and resources. Since January 2016, BIA is required as part of economic dossiers submitted to the French National Authority for Health (HAS) by manufacturers for innovative drugs with an expected 2-year sales revenue above EUR50 million. To this end and in order to promote good practices for conducting BIA, HAS developed a guide for BIA.

Our objectives are:
• to present the guide development method and the resulting recommendations;
• to compare the HAS BIA guide with existing BIA guides.

METHODS:
The HAS guide development process rests on findings derived from a systematic literature review on BIA methodology, an HAS retrospective investigation of BIA, public consultation, international expert advice, and approval from the HAS Board and Committee of Health Economic and Public Evaluation (CEESP). Relevant publications were identified through Pubmed and EMBASE and the grey literature (search dates: January 2000 to June 2016).

RESULTS:
The search strategy captured 144 publications of which 31 were retained (14 methodological papers, 12 national guides and 5 learned society recommendations). On the basis of this result, an extraction template was designed to synthesize the methodological aspects of BIA. Based on its research findings, HAS developed its first BIA guide which includes recommendations on the following main topics: BIA definition, perspective, populations, time horizon, compared scenarios, BIA models, costing, discounting, choice of clinical data, reporting of BIA and uncertainty exploration.

Compared to existing BIA guides from other Health Technology Assessment (HTA) agencies, the HAS guide specifically described issues relating to off-label use of drugs, disease related-costs and scenario analysis. It is expected that the HAS BIA guide will improve the quality and standardization of BIA in France.

OP120 Recommendations From The Newly Developed French National Authority for Health (HAS) Guide On Budget Impact

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ABSTRACT SUMMARY:
The French National Authority for Health (HAS) developed its first Budget impact analysis (BIA) guide which includes eleven recommendations. Compared to existing BIA guides from other Health Technology Assessment (HTA) agencies, the HAS guide specifically described issues relating to off-label use of drugs, disease related-costs and scenario analysis. It is expected that the HAS BIA guide will improve the quality and standardization of BIA in France.
Technology Assessment (HTA) agencies, the HAS guide specifically described issues relating to off-label use of drugs, disease-related costs and scenario analysis.

CONCLUSIONS:
It is expected that the HAS BIA guide will improve the quality, transparency and standardization of BIA in France. It should also enhance the usefulness of BIA as an essential part of a comprehensive economic assessment of health care interventions.

INTRODUCTION:
Development of innovative drugs for melanoma is occurring rapidly. These drugs are often associated with marginal prolongation of overall survival, as well as increased toxicity profiles. Therefore, Health Technology Assessment (HTA) agencies increasingly require information on health-related quality of life (HRQoL) for the assessment of such drugs. This study explored the potential of using social media to assess patient perspectives on HRQoL in melanoma, and whether current cancer- and melanoma-specific HRQoL questionnaires represent these patient perspectives.

METHODS:
A web-based survey with open-ended questions to assess melanoma patients’ perspectives regarding HRQoL was distributed on social media channels of Melanoma Patient Network Europe (Facebook, Twitter, LinkedIn). Two researchers independently assessed completed surveys and conducted content analysis to identify key themes. Themes identified were subsequently compared to questions used in three current HRQoL questionnaires (EORTC QLQ-C30, EORTC QLQ-MEL38, FACT-M).

RESULTS:
In total, seventy-two patients and seventeen carers completed the survey. Patients indicated that family, having a normal life, and enjoying life were the three most important aspects of HRQoL. Carers indicated that being capable, having manageable adverse events, and being pain-free were the three most important aspects of HRQoL for patients. Respondents seem to find some questions from HRQoL questionnaires relevant (for example, ‘Have you felt able to carry on with things as normal?’) and others less relevant (for example, ‘Have you had swelling near your melanoma site?’). Additionally, wording may differ between patients and HRQoL questionnaires, whereby patients generally use a more positive tone. For example, FACT-M states ‘I have a lack of energy’, while patients rather focus on ‘having enough energy’.

OP121 Social Media To Collect Patient Perspectives On Health-related Quality of Life In Melanoma

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ABSTRACT SUMMARY:
HTA agencies increasingly require information on health-related quality of life (HRQoL). This study showed that social media may be a valuable tool to collect patient perspectives regarding HRQoL. Differences between patient and carer perspectives regarding HRQoL were made apparent. Also, current cancer- and melanoma-specific HRQoL questionnaires do not seem to correlate fully with patient perspectives.
CONCLUSIONS:
Social media may provide a valuable tool in assessing patient perspectives regarding HRQoL. However, differences emerge between patient and carer perspectives. Additionally, cancer- and melanoma-specific HRQoL questionnaires do not seem to correlate fully with patient perspectives.

OP122 The Financial Incentive To Market Secondary Patent Of Ritonavir

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ABSTRACT SUMMARY:
The intellectual property right encourage the pharmaceutical firm to be innovative. This might lead to negotiate higher prices and at the same time to extent of the originator patent. The consequence is a financial impact for the society by preventing competition from generic equivalent and the delay in the accessibility of innovation for the patient.

INTRODUCTION:
The World Intellectual Property Organization reported more than 9,750 patents of ritonavir from the discovery in December 1993. The patents aim at protecting intellectual property from the strong market competition and therefore encourage innovation as well as reward the pharmaceutical industry from their investment in the R&D of drugs. However, heatstable formulations or combinations with other chemicals might be patented and marketed at higher price and also when the original patent is about to expire, a so called evergreening strategy (1,2). We aimed to determine the financial incentive of marketing heatstable formulation using the proprietary melt-extrusion (Meltrex®) technology allowing in addition to reduce the pill count from six to four per day. The Meltrex® technology was applied to ritonavir stand alone formulation in October 2010 almost 4 years after the lopinavir/ritonavir (December 2006).

METHODS:
Frequency of administration and dosage for all patients under ritonavir and lopinavir/ritonavir were collected from the Geneva Swiss HIV Cohort Study from January 2003 to June 2016. Extra costs were calculated for three different scenarios assuming the replacement with the corresponding Swiss market price de-escalation of (i) lamivudine (ii) lamivudine/zidovudine and (iii) efavirenz over time. Prices were adjusted by the inflation rate.

RESULTS:
Over the study period the total cost was USD2,805,135 for the ritonavir and USD13,351,886 for the lopinavir/ritonavir. The increase in cost for the Meltrex® technology per patient was 17 percent for ritonavir 4 percent for lopinavir/ritonavir, leading to an extra cost of USD166,358 and USD368,255 respectively. Theoretical savings if generic ritonavir would enter the market after original ritonavir patent termination would be USD994,080 for lamivudine price de-escalation, USD750,917 for lamivudine/zidovudine and USD600,741 for efavirenz.

CONCLUSIONS:
The financial incentive encourage the pharmaceutical firm to be innovative leading to negotiate higher prices and at the same time to extent of the originator patent. The consequence is a financial impact for the society by preventing competition from generic equivalent and the delay in the accessibility of innovation for the patient.
OP123 Health Technology Assessment In Digital Health: A Rapid Approach To Assess Health Apps

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ABSTRACT SUMMARY:
The National Institute for Health and Care Excellence (NICE) is piloting the development of health app briefings. These are advice outputs which summarize the effectiveness and economic impact of the app. Novel features includes a rating value and a case study based on real-world data. Results for four proof of concept topics will be presented.

INTRODUCTION:
The Health Technology Assessment (HTA) of mobile health applications involves significant challenges including rapid product development cycles, sparse evidence and uncertainty over the economic impact. However, apps also provide unique opportunities, such as their potential reach and use of real-world data, which will facilitate their contribution to healthcare delivery. The National Institute for Health and Care Excellence (NICE), alongside other agencies, has been piloting the development of a health app assessment programme. This presentation reports the results of a study about the development of the Health App Briefing (HAB) which is designed as the output from a rapid assessment of the effectiveness and cost-saving potential of apps to inform decision makers in the United Kingdom National Health Service.

METHODS:
The HAB is built on the success of the NICE Medtech Innovation Briefings programme because many of the HTA challenges are similar to those found with medical devices. HAB development is grounded in four principles: rapid assessment; transparent process; independence from industry or the health service and input from commentators. The content includes an evidence summary for effectiveness including comments from specialist experts and users; a summary of information relating to the cost saving potential and a summary of other user benefits (including issues of access and usability). Novel features are the presentation of a rating of the potential value of the app to the health system and working with commissioners of the app to obtain real-world information for a case study about the economic impact.

RESULTS:
The development of four HABs along with a review of the learning from the piloting process will be presented. The review will include stakeholder feedback from a workshop.

CONCLUSIONS:
We believe the evaluation of this work presented here will be of interest to other HTA agencies around the world that are deciding how to approach the issues surrounding the assessment of health apps.
**OP124 Can Registry Failures Be Compensated By Medico-Administrative Database?**

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**ABSTRACT SUMMARY:**
Post-approval studies constitute an important tool in medical devices assessment usually supported by registries. However, registries are often poorly designed or incomplete. Medico-administrative databases collecting robust criteria can be used to support reimbursement renewal of high-risk implantable medical devices.

**INTRODUCTION:**
Post-approval studies (PAS) constitute an important tool in medical devices (MD) assessment usually supported by registries. However, registries are often poorly designed or incomplete. The French health insurance databases are organized since 2003 into a digital data warehouse, the Système national d’information inter-régime de l’assurance maladie (SNIIR-AM), and is the main source of information on patients, hospital activity and associated expenditure. The aim of the study was to determine if these medico-administrative data can be sufficiently relevant to guide a renewal of MD reimbursement in the context of registry failure.

**METHODS:**
The initial PAS aimed to assess the impact of the guidelines on practice (characteristics of patients, type of stenosis, indications, use of cerebral protection system, surgical procedure) and to determine the 30-day cumulative morbidity and mortality rate of endovascular procedure associated with stenting. Medico-administrative databases provide information on age, sex, symptomatic or asymptomatic stenosis in-hospital mortality and long-term mortality (with a linkage to epidemiological data) and morbidity estimated by ischemic stroke.

**RESULTS:**
The database allowed selection of a cohort of 2,071 patients in whom carotid stenting was performed in 161 centers (40 percent of stents were implanted in 14 centers) with a follow-up of 1 year. Carotid stents were mainly implanted in asymptomatic patients (81.6 percent). Morbidity in symptomatic patients at 30 days (9.2 percent: 5.7 percent stroke and 3.4 percent mortality) was similar with results observed in a French comparative study EVA-3S (9.6 percent: 2.8 percent stroke and 8.8 percent mortality). These data allow the concerned HAS (French Health Authority) committee to renew the reimbursement proposal of these stents.

**CONCLUSIONS:**
Medico-administrative database collecting robust criteria can be used to support reimbursement renewal of high risk implantable medical devices. The implementation of other criteria including the disease etiology and the complications imputability may allow to consider the use of these data for non-invasive MD.

**OP125 A New Collaborative Approach To Assess Innovative Health Technologies**

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ABSTRACT SUMMARY:
POETIS (Processus optimisé d’évaluation des technologies innovantes en santé) is a lifecycle approach to assess innovative health technologies. It aims to identify the technologies with the highest potential for positive impact on patients and the health system, in order to accelerate their implementation and promote their optimal use. It is based on an enhanced collaboration between stakeholders and on an iterative assessment of technologies.

INTRODUCTION:
Decision makers worldwide face the challenge of offering the best health care within a context of scarce resources. Technological developments have multiplied in the past decades, with the lifecycle of technologies becoming shorter. As a result, the traditional Health Technology Assessment (HTA) model is often caught in a too early, too late syndrome. In the province of Québec (Canada), there is no standardized process for assessing non-pharmaceutical technologies for reimbursement purposes, and technologies are therefore introduced via multiple sources. There are concerns that the introduction of some of the most promising technologies is delayed, and on the contrary, that others are introduced without providing a real added value to patients and the health system.

METHODS:
INESSS (Institut national d’excellence en santé et services sociaux), collectively with stakeholders of the Québec innovation field, has developed a dynamic process for assessing the added value of innovative technologies. POETIS (Processus optimisé d’évaluation des technologies innovantes en santé) aims to identify the technologies with the highest potential for positive impact on patients and the health system, in order to accelerate their implementation and promote their optimal use.

RESULTS:
POETIS comprises four phases aligned with the lifecycle of technologies: research and development, pre-implementation, limited implementation, and diffusion. It allows a continuum of assessment, from the promise of a technology to its real-world benefit. It differs from other approaches because of the sustained involvement of key stakeholders, including patients, and because it assesses technologies iteratively, therefore fostering their adaptation to better suit patients needs. It is hoped for the first technologies to be assessed in 2017.

CONCLUSIONS:
HTA has to adapt to the challenges of innovation, and this could be done with a lifecycle approach and an enhanced collaboration with end-users. Developed in Canada, the goals behind POETIS are common to many countries and the process could be adapted by other HTA agencies.

OP126 EUnetHTA Template To Aid Health Technology Assessment-Based Decisions

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ABSTRACT SUMMARY:
Health professionals often advocate/request innovative health technologies, perceiving Health Technology Assessment (HTA) as a counterargument to their requests. A system for technology requests submitted by professionals, based on adaptation of the EUnetHTA Submission
Template, proved successful in engaging professionals and decision makers in joint appraisal and shared decision making. The transparency and objectivity of the procedures allowed misgivings to be overcome and to institutionalize the process.

INTRODUCTION:
Health professionals often advocate and request innovative health technologies, perceiving Health Technology Assessment (HTA) as a delay or counterargument to their requests. To facilitate engagement of professionals and decision makers in the HTA process and endorsement of process outputs, a system for technology requests submission, based on the European Network for HTA (EUnetHTA) Submission Template, was established and subsequently piloted in a cancer research institute.

METHODS:
The “EUnetHTA medical devices evidence submission template” for companies (1) was adapted for use by professionals proposing a health technology for acquisition. Adaptation consisted mainly in: re-arrangement of chapters order with emphasis on the health problem, unmet needs, claimed additional benefits of the technology and potential for research; inclusion of information on costs/financial resources; and inclusion of a summary with a pre-defined set of brief statements to inform appraisal. The headings for the nine one-paragraph statements were: relevance of the health problem; degree of innovativeness of the technology; potential clinical impact; potential research relevance; comparative safety and effectiveness; economic impact; organizational impact; availability/quality of scientific literature; and degree of diffusion. Decision makers discussed the appraisal’s statements with the proponents before reaching a conclusion.

RESULTS:
From January 2016 technology requests were examined only if presented through the submission template. Results from submissions of three innovative technologies for prostate cancer treatment, endovascular procedures and cataract surgery will be discussed. Acceptability of the submission template was high and professionals supported by experts available in their institution (clinical engineers, epidemiologists and others) were successful in completing the dossier. Decision makers appraisal proved facilitated and transparent. Concerted decisions were taken within a few weeks from submission.

CONCLUSIONS:
The EUnetHTA tool proved flexible and valuable to initiate an HTA-based decision-making process. Appraisal was cooperative and proponents were involved in the decisions, through a process requiring a mean total time of 6 months. Participants misgivings were overcome by transparency and objectivity of the process.

REFERENCES:

OP127 Analysis Of The Competencies To Be Acquired In Health Technology Assessment

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ABSTRACT SUMMARY:
Although Health Technology Assessment (HTA) is a well-defined discipline that embraces a multidisciplinary and multidimensional approach to decision making in health care, competencies to be acquired by professionals are not well established and this defines a panorama in which HTA activities are so diverse and unequal (1). This report analyzed the competencies described in manuals and academic courses.

INTRODUCTION:
Health Technology Assessment (HTA) is a multidisciplinary activity that systematically examines different dimensions related to the direct and indirect consequences of health technologies when implemented in healthcare systems. HTA is developed by multidisciplinary teams in order to cover all the mentioned dimensions. However, the quality of the processes produced by HTA teams will depend upon the competencies that those teams will acquire and incorporate including knowledge, skills and attitudes (1). The aim of this research was to determine how well these dimensions and competencies are covered in HTA academic Masters degree courses and manuals.

METHODS:
We analyzed what had been done in terms of competencies definition in HTA: how it has been reflected; theoretically and according to the authors, and how competencies can be structured; know-how and values. We explored HTA manuals and HTA academic Masters degree courses. We searched in Google with specific terms: building capacities, HTA, programs, Masters, diplomas. We used the HTAi vortal and the information related to courses (for example Masters degrees) and HTA agencies and network webpages for programs. The inclusion criteria were formal programs that describe HTA capacity building and not partial teaching of certain aspects of HTA and we excluded non-recognized institutions, or where there was no description of the programs or lack of detail regarding objectives and competencies to be achieved.

RESULTS:
We found 105 courses or programs and analyzed 8 reports and 3 manuals. The main challenges that we faced were: that information was difficult to retrieve, not similarly structured, difficulties to find key information in webpages, no program description at all in some cases and the need to contact institutions staff or register as a student to receive the information and finally, it was difficult to obtain contact details of key people. We structured the information on competencies in knowledge, skills and attitudes.

CONCLUSIONS:
The analyzed Masters degree courses and manuals did not cover all of the dimensions of HTA analysis in an equal and standardized way. The ethical, legal, social and organizational aspects were lacking in some of the programs, while, on the contrary, clinical and economic aspects were substantially included. On the basis of the information retrieved it would be good to define core competencies for HTA.

REFERENCES:

OP128 Knowledge And Attitudes Of Healthcare Management Students Among Health Technology Assessment

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ABSTRACT SUMMARY:
This study aims to identify the knowledge and awareness level among the healthcare managers of the future with respect to health technology assessment (HTA). A survey including 14 questions was applied to 945 university students at the department of healthcare management.

INTRODUCTION:
The present study aims to identify the knowledge and awareness level among the healthcare managers of the future with respect to health technology assessment (HTA) and to assist in the determination of the content for theoretical and practical classes pertaining to health technology assessment.

METHODS:
The present study is conducted in the form of a questionnaire and includes fourteen questions that address the sociodemographic characteristics of the respondents and their opinions and attitudes on health technology assessment. The questionnaire was applied with the students of the Healthcare Management Departments of Selcuk University, Necmettin Erbakan University, Isparta Suleyman Demirel University, and Gumushane University in Turkey.

RESULTS:
The questionnaire was implemented with the participation of 945 students. Forty-seven percent of the students stated they had never heard the definition of “health technology assessment” before and 94.1 percent had not taken part in a training meeting on the same subject before. However, 87 percent of the students expressed that they would like to learn more about HTA.

CONCLUSIONS:
Theoretical and practical classes on health technology assessment should be added to the curricula of healthcare management students, who will assume a significant role in the identification of healthcare policies for the future.

OP129 Predictors Of Effectiveness In Patients With Rheumatoid Arthritis

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ABSTRACT SUMMARY:
Rheumatoid arthritis (RA) patients (n=266) treated with biological agents (adalimumab, etanercept, infliximab, abatacept, certolizumab, golimumab, tocilizumab and rituximab) completed six months of follow-up. The percentage of patients achieving remission or low disease activity was 40.6 percent. Functionality and use of previous biological agents are predictors in patients with RA treated with biological agents.

INTRODUCTION:
Biological disease-modifying anti-rheumatic drugs (bDMARDs) have become firmly established in the management of patients with rheumatoid arthritis (RA), but some patients do not improve despite therapy. This study evaluated the predictors of effectiveness of the bDMARDs on a cohort of patients with rheumatoid arthritis (RA) in the Brazilian Public Health System.

METHODS:
RA individuals treated with bDMARDs, were included in the open prospective cohort study. The Clinical Disease Activity Index (CDAI) was used...
to assess the effectiveness comparing results at baseline and after 6 months of follow-up. The association between socio-demographic and clinical characteristics with the disease activity measured by the CDAI was also investigated. The bDMARDs was considered effective when the patient achieved remission or low disease activity and considered not effective when there was still moderate or high disease activity. Pearson’s chi-square was applied for the univariate analysis to evaluate the association of effectiveness measured by the CDAI with the socio-demographic (gender, education, marital status and race) and clinical variables (type of drug, EuroQol (EQ)-5D and Health Assessment Questionnaire (HAQ)). Logistic regression was applied in the multivariate analysis of the variables that presented a p< .20 value during the univariate analysis.

RESULTS:
All 266 RA patients completed six months of follow-up. The most widely used bDMARDs was adalimumab (57.1 percent), with etanercept used by 22.2 percent, golimumab by 7.5 percent, abatacept by 4.5 percent, tocilizumab by 3.4 percent, infliximab by 2.6 percent, certolizumab by 1.5 percent, and rituximab by 1.1 percent. The bDMARDs reduced disease activity as measured by CDAI at six months of follow-up (p<.001). The percentage of patients achieving remission or low disease activity was 40.6 percent. bDMARDs were more effective in patients with better functionality (Odds Ratio, OR = 2.140 / 95 percent Confidence Interval, CI 1.219 - 3.756) at beginning of treatment and in patients who not had a previous bDMARDs (OR=2.150 / 95 percent CI 1.144 - 4.042).

CONCLUSIONS:
In this real-world study, functionality and use of previous bDMARDs are predictors in patients with RA treated with bDMARDs.
ambulance crews often leave patients at the scene without ongoing care. We aimed to determine clinical and cost effectiveness of a new clinical protocol which allowed paramedics to assess older people who had fallen and, if appropriate, refer them to community-based falls services.

**METHODS:**
We undertook a cluster randomised trial in three UK ambulance services between March 2011 and June 2012. We included patients aged 65 following an emergency call for a fall, attended by paramedics based at trial ambulance stations. Intervention paramedics could refer patients to a community based falls service instead of transporting the patient to an Emergency Department. Control paramedics provided care as usual. The primary outcome was subsequent emergency contacts or death. Trial registration Current Controlled Trials ISRCTN 60481756.

**RESULTS:**
One hundred and five paramedics based at 14 intervention stations attended 3,073 eligible patients; 110 paramedics based at 11 control stations attended 2,841 eligible patients. We analysed primary outcomes for 2,391 intervention and 2,264 control patients.

One-third of patients made further emergency contacts or died within 1 month, and two-thirds within 6 months, with no difference between the groups. Subsequent 999 call rates within 6 months were lower in the intervention arm (.0125 versus .0172; adjusted difference -.0045, 95 percent Confidence Interval, CI - .0073 to -.0017).

Intervention paramedics referred 8 percent (204/2,420) of patients to falls services and left fewer patients at scene without any ongoing care. Intervention patients reported higher satisfaction with interpersonal aspects of care. There were no other reported differences between groups.

Mean intervention cost was $23 per patient with no difference in overall resource use between groups at 1 or 6 months.

**CONCLUSIONS:**
A clinical protocol for paramedics reduced emergency ambulance calls in patients attended for a fall, safely and at modest cost.

**OP131 Cost-Effectiveness Of Dexamethasone And Adalimumab For Uveitis**

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**ABSTRACT SUMMARY:**
We analysed the cost effectiveness of dexamethasone implant and adalimumab compared with current practice in non-infectious uveitis. Systematic reviews were performed to identify evidence and a Markov model was built to estimate costs and benefits. The factor with the largest impact upon the incremental cost-effectiveness ratios (ICERs) was the proportion of blindness avoided by interventions. Results are highly uncertain due to the limited evidence.

**INTRODUCTION:**
Uveitis is inflammation inside the eye whose underlying cause may be infectious or non-infectious. The objective of our study was to assess the cost effectiveness of the dexamethasone implant and adalimumab compared with current practice (immunosuppressants and systemic corticosteroids) in patients with non-infectious intermediate, posterior or pan-uveitis.
**METHODS:**

A Markov model was built to estimate costs and benefits of the interventions. Systematic reviews were performed to identify the relevant evidence. Quality of life data collected in three key randomized-controlled trials (1-3) was used to estimate the interventions effectiveness compared with the trials comparator arms, which consisted of placebo plus limited current practice (LCP). An indirect treatment comparison between adalimumab and dexamethasone was considered inappropriate due to lack of necessary evidence. For adalimumab, patients with active and inactive uveitis were considered separately. Due to the short duration of the trials, the rate of blindness, an important complication of uveitis, was highly uncertain. Substantial exploratory analyses were therefore undertaken. The analysis was performed from the perspective of the National Health Service (NHS) and Personal Social Services (PSS). Costs were calculated based on standard UK sources.

**RESULTS:**

The estimated incremental cost-effectiveness (ICER) of dexamethasone compared with LCP was GBP19,509 per quality-adjusted life year (QALY) gained. The estimated ICER of adalimumab compared with LCP was GBP94,523 and GBP317,547 per QALY in patients with active and inactive uveitis respectively. The factors with the largest impact upon the ICERs were the rate of blindness and the proportion of cases of blindness avoided by interventions.

**CONCLUSIONS:**

Dexamethasone and adalimumab resulted in health gains, but at significant extra costs, especially adalimumab which is unlikely to be considered a cost-effective use of NHS resources. The results of the analysis are highly uncertain due to the limited availability of evidence on: the comparative effectiveness of dexamethasone, adalimumab and current practice; the effectiveness of treatments in avoiding blindness; and, the effectiveness of interventions in different subgroups.

**REFERENCES:**


**OP132 How A Shared Management Of Home Infusion Can Control Expenditure**

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**ABSTRACT SUMMARY:**

HAS has assessed the actual benefit of the medical devices for home-based infusion. Based on this medical assessment, the Ministry of Health has set up twenty-four packages for reimbursement with non-cumulative rules. The expected benefits are an adjusted evaluation of the necessary equipment and a control of health expenditure due to the fixed costs of each infusion package.
INTRODUCTION:
In France, medical devices (MDs) for home-based infusion used to be covered by the health insurance system if included on the list of products and services qualifying for reimbursement under a generic description corresponding to a class of products with the same indications. This coverage modality offered no resistance to unnecessary or wasteful spending. Besides, between 2010 and 2015 the expenditure related to these MDs have increased from EUR192million to EUR289million (+50 percent).

METHODS:
The French National Authority for Health (HAS) has assessed the actual benefit of these MDs which have the same indications as the drugs infused at home. This work led to standardize the infusion types (gravity, elastomeric pump or active system requiring an energy source) and the quantities of MDs needed to carry out the different cares (installation, connection, withdrawal) according to the infusion route. At this step, considering that the priority was to redefine the MDs required at home for each care type, no economical assessment had been conducted.

RESULTS:
Based on this medical assessment, the Ministry of Health has distinguished three types of infusion and three types of services (home installation, monitoring and consumables) since 2016. In total, twenty-four packages have been set up for reimbursement with non-cumulative rules. Doctors are in charge to prescribe the appropriate packages; providers and nurses determine together the optimal devices needed for each patient according to his environment.

CONCLUSIONS:
These HAS recommendations on practice standardization have been the keystone for cost negotiations. The new coverage modalities aim to motivate liberal nurses to choose the best fitted products and providers to deliver the right quantities to patients. The expected benefits are an adjusted evaluation of the necessary equipment and a control of health expenditure due to the fixed costs of each infusion package.

OP133 Health Technology Assessment In Brazil: A 5-year Review Of Brazilian Health System (CONITEC) Activities

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ABSTRACT SUMMARY:
The National Committee for Health Technology Incorporation in Brazil (CONITEC) was created in 2012 and is responsible for advising the Ministry of Health regarding the incorporation or disinvestment of health technologies. This study aimed to describe the results of its five years of operation, where the average annual incorporation has been tripled, involving a strong interaction with society.

INTRODUCTION:
Since the creation of the National Committee for Health Technology Incorporation in the Brazilian Health System (CONITEC), a new phase started in the public Brazilian Health System (SUS): a continuous updating of the system based on Health Technology Assessment (HTA). CONITEC was created by federal law in 2012 and is responsible for advising the Ministry of Health regarding the incorporation or disinvestment of health technologies. The whole process involves a strong interaction with society, including the composition
METHODS:
This is a retrospective descriptive study, based on information from the database (period 2012-2016) and CONITEC’s website.

RESULTS:
Since 2012, CONITEC assessed 541 technologies, including drugs (360), health products (71) and procedures (110). 303 assessment requests came from SUS agencies and institutions and the other 238 requests from pharmaceutical companies, medical societies, patient associations and the judiciary bodies. In this period, there were 190 public consultations, during which more than 24,000 feedback from society were received. The average time for evaluation was 146 days. The committee recommended the incorporation of 186 technologies into SUS, the disinvestment of 43 and was unfavorable to the incorporation of 88, generating a budgetary impact of approximately BRL2.5 billion (USD764 million).

CONCLUSIONS:
From 2012-2016, CONITEC tripled the average annual incorporation of new technologies compared to the period 2006-2011. In this process, it was necessary to assess efficacy, safety and cost-effectiveness of technologies, generating positive results for the expansion of access, health gains for patients and sustainability for the system. It should be considered that the use of evidence for decision making strengthens transparency in public management and the development of active processes of information, communication and social participation.

OP134 Predictors Of Public Health Outcomes: A Case Study From Turkey

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ABSTRACT SUMMARY:
This study aimed to assess predictor factors for public health outcomes in Turkey. Logistic regression and random forest classification were used to compare prediction performance. Analysis revealed the most important variables were total number of beds for mortality and percentage of higher education graduates for life expectancy. Results suggest further analysis of health outcomes is needed to improve social welfare.

INTRODUCTION:
In Turkey, there is a scarcity of knowledge about the predictors of health outcomes at a national level, and it is well known that there is a gap between rural and urban parts of developing countries in terms of the level of health outcomes. This study aims to find out predictor factors of the public health outcomes at a province level in Turkey.

METHODS:
Life expectancy at birth and mortality are used as public health outcome indicators. Logistic regression and Random Forest classification generated by using 50, 100, and 150 trees were used to compare prediction performance of health outcomes. The results of different prediction methods were recorded changing the “k” parameter from 3 to 20 in k-fold cross validation. The Area Under the ROC Curve (AUC) was used as a measure of prediction accuracy. Prediction performance differences were tested using Kruskall-Wallis analysis and visualized on a heatmap. Finally,
predictor variables of public health outcomes were shown on a decision tree.

RESULTS:
Study results revealed that Logistic regression outperformed Random Forest classification. The difference between all prediction methods to predict public health outcome indicators was statistically significant (p<.000). The heatmap show that AUC values to predict mortality have superior performance when compared with life expectancy at birth. Decision tree graphs present that the most important predictor variables were total number of beds for mortality and percentage of higher education graduates for life expectancy at birth.

CONCLUSIONS:
The results of this study represent a preliminary attempt to determine public health outcome indicators. It is hoped that the results of this study serve as a basis to understand the determinants of health care outcomes at province level with focus on a developing country. This study illustrates that there is a need to spend extra effort for future studies to analyse public health outcomes to improve social welfare functions in health systems.

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OP135 Confirmatory Versus Explorative Endpoints In Drug Approval Versus Health Technology Assessment

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ABSTRACT SUMMARY:
The early benefit assessment of drugs in Germany and their preceded market authorization pursue different objectives, resulting in divergent decision-making strategies. From a procedural point of view both seem to not be confirmatory since they include explorative endpoints. Yet, drug approval is, in terms of quality of endpoints, more confirmatory than early benefit assessment containing more primary endpoints.

INTRODUCTION:
The early benefit assessment of drugs in Germany and their preceded market authorization pursue different objectives, resulting in divergent decision-making strategies. This is reflected inter alia by the diverse inclusion of confirmatory endpoints within the assessments of oncological drugs. The pharmaceutical manufacturers are facing the challenge of meeting the requirements for both evaluation processes by the available evidence and avoiding hereby negative early benefit assessments. This is mainly due to the concept of mutually relevant clinical trials.

METHODS:
Identification and gathering of the endpoints is based on a specifically developed guide. The extracted data from the documents of completed assessments up to July 2015 are used to estimate both separately and together the impact of explorative in relation to confirmatory endpoints on the drug approval and early benefit assessment, by contrasting the European Medicines Agency’s risk-benefit-ratio and the benefit-harm-balancing of the national Health Technology Assessment (HTA) jurisdiction.

RESULTS:
Twenty-one of forty-one studies’ oncological assessments could be included in the endpoint analysis. From a procedural point of view both the drug approval and the early benefit assessment seem to be not confirmatory since they include explorative endpoints as well. Yet, drug approval is in terms of quality of endpoints more confirmatory than early benefit assessment since it contains a higher proportion of primary endpoints. The latter
implies only in 67 percent of the assessments a primary endpoint to be relevant for the benefit-harm-balancing. Moreover, explorative mortality endpoints reached the highest agreement and explorative endpoints capturing health-related quality of life no agreement, referring to the mutual relevance of endpoints for the risk-benefit-ratio and the benefit-harm-balancing.

CONCLUSIONS:
The missing information transparency of the assessment reports compared to the information offered within the early benefit assessment makes an assignment of endpoints with respect to the mutually relevant clinical trial sometimes troublesome. To warrant, in the long run, a broader confirmatory basis for decisions in health care supported by HTA, a closer inter-institutional cooperation of approval authorities and German HTA jurisdictions seems favorable.

INTRODUCTION:
In the last decade an increasing number of high-priced, new cancer treatments received marketing authorization in Europe. What is actually known about the clinical benefit of those therapies at the time of approval needs to be elucidated in order to inform decisions about the use and reimbursement of these novel treatment options. Thus, the aim of the current analysis was to systematically investigate oncological therapies approved between January 2009 and April 2016. We extracted, as well as quantified the level of knowledge of the clinical benefit at the time of marketing authorization.

METHODS:
To assess the benefit of new interventions as well as expanded indications, we extracted the median gain of the two study endpoints: progression-free survival (PFS) and overall survival (OS). Information is based on approval documents provided by the European Medicines Agency (EMA) and assessments from the Austrian Horizon Scanning programme (HSO). We included all cancer therapies approved in Europe between 1 January 2009 and 15 April 2016.

RESULTS:
Cancer drugs for 134 new indications approved since 2009 were identified. In the case of thirty-seven indications (27 percent), no data was available for PFS or for OS. A positive difference in median overall survival was reached by seventy-six licensed indications (55.5 percent); twenty-two (16 percent) of them showed a difference of more than three months. Regarding the study endpoint progression-free survival, an improvement was shown in ninety indications (65.2 percent).

CONCLUSIONS:
Scarce knowledge regarding the clinical benefit of anti-cancer therapies is available at the time of approval. In addition, the survival benefit of the approved indications is less than three months in the majority of approved therapies.
**OP137 Lawsuits To Receive Free Drugs: Expenditures For Brazilian Public Health System (SUS)**

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**ABSTRACT SUMMARY:**
With the Lawsuits to receive free medication, the acquisitions are carried out without planning or establishing minimum criteria such as: the presence of registration at ANVISA, incorporation in SUS and presence in RENAME, may compromise SUS sustainability. It is urgent that the Judiciary approaches the Executive stakeholders to initiate a responsible commitment to the health rights of the Brazilian population.

**INTRODUCTION:**
Due to the increasing demand for Lawsuits to receive free medication in Brazil, it is estimated that the increase in costs may compromise the sustainability of SUS. The aim of this work was to analyze Federal expenditures for the Brazilian Public Health System (SUS) with drugs obtained through lawsuits between the years 2011-2014.

**METHODS:**
A cross-sectional study, with descriptive and analytical characteristics. Data collected from the DW / COMPRASNET platform.

**RESULTS:**
In total 12,578 lawsuits were identified at the federal level and 15 drugs with the highest acquisition value were extracted. Of these, seven drugs corresponded to USD452,644,065.68 dollars of the federal budget, which represented 87 percent of the total expenditure of the actions studied, most of them were oncologic and rare diseases drugs. Of the 15 drugs / year studied, 14.28 percent (n = 4) were registered at the National Brazilian Surveillance Agency (ANVISA), were incorporated by the National Commission for the Incorporation of Technologies in SUS (CONITEC) and were part of the List of essential drugs (RENAME); 46.42 percent (n = 13) were registered with ANVISA, but not incorporated by CONITEC and not members of RENAME; 3.57 percent (n = 1) registered in ANVISA, incorporated by CONITEC and not RENAME members and 35.71 percent (n = 10) without ANVISA registration, not incorporated by CONITEC and not RENAME members.

**CONCLUSIONS:**
With the lawsuits to receive free medication, the acquisitions are carried out without planning or establishing minimum criteria such as the presence of registration in the regulatory institution, incorporation in SUS and presence in RENAME, may compromise SUS sustainability. It is urgent that the judiciary is approached by the technical authorities of the Executive Branch to initiate a culture of responsible commitment to the health rights of the Brazilian population.

**OP138 Access To Orphan Drugs In The United Kingdom And Other European Countries**

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**ABSTRACT SUMMARY:**
We analyzed the availability and access to orphan medicinal products since 2000 in the United Kingdom (UK), France, Germany, Italy and Spain. We compared the availability, which is the possibility to prescribe a given orphan medicinal product (OMP), to the access, which refers to the full or partial reimbursement by the public health service.

**INTRODUCTION:**
Under the Orphan Regulation, the European Medicines Agency (EMA) intended to incentivize the research and development of new treatments for rare and life-threatening conditions. Marketing authorisation of orphan medicinal products (OMPs) by the EMA is only the first step, as medicines are made available to patients when reimbursement or Health Technology Assessment (HTA) decisions are implemented by national health systems. We analyzed the availability and access to OMPs in the United Kingdom (UK), France, Germany, Italy and Spain. We compared the availability, which is the possibility to prescribe a given OMP, to the access, which refers to the full or partial reimbursement by the public health service.

**METHODS:**
We collected data on launches, HTA decisions, any centralized commissioning and/or reimbursement decision for all the OMPs authorised since 2000 in the UK countries (England, Scotland and Wales), France, Germany, Italy and Spain.

**RESULTS:**
Since the Orphan Regulation inception, the EMA granted marketing authorization to 143 OMPs. These OMPs are most widely accessible in Germany and France. Reimbursement in Germany is immediate after authorization. France and Italy present a delay of 19 months from authorization to reimbursement, which is shorter than in other countries. In England, less than 50 percent of centrally authorised OMPs are routinely funded by the National Health Service (NHS), including one-third of these recommended by the National Institute for Health and Care Excellence (NICE), and those reimbursed via commissioning policies and the Cancer Drugs Fund.

**CONCLUSIONS:**
The assessment of degree of access to OMPs across Europe is limited by differences in the national HTA and reimbursement systems and the heterogeneous information made publicly available on their decisions. Nonetheless, our study suggests that the primary purpose to grant equal availability to OMPs to the patients in the European Union via the implementation of the orphan regulation was partially achieved with important variations of access observed across the countries included in our study.

**OP139 Measuring Patient Experiences With Medications: PESaM-Questionnaire**

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**ABSTRACT SUMMARY:**
The importance of patient experiences when assessing the value of novel drug therapies is increasingly recognised. To date, patient
experiences are mostly considered through active patient participation, such as through consultation rounds with patients, patient memberships in committees, or personal anecdotes. We developed a measure to systematically evaluate patient experiences and satisfaction with medications.

**INTRODUCTION:**
The importance of patient experiences when assessing the value of novel drug therapies is increasingly recognised. To date, patient experiences are mostly considered through active patient participation, such as through consultation rounds with patients, patient memberships in committees, or personal anecdotes. A measure to systematically evaluate patient experiences with medications is lacking and could provide more scientific foundation for the incorporation of the patient perspective in decision making. We developed and pre-tested the Patient Experiences and Satisfaction with Medications (PESaM-) questionnaire.

**METHODS:**
The questionnaire was developed by a panel of experts using contents derived from existing measures, focus groups (n=13), and individual patient interviews (n=6), and was subsequently pre-tested in two patient groups; 1) idiopathic pulmonary fibrosis (IPF), and 2) atypical hemolytic uremic syndrome (aHUS). Individual patient interviews (n=18) were conducted to assess face validity, content validity, and time needed to fill-out the questionnaire.

**RESULTS:**
The PESaM-questionnaire consists of two disease-specific modules for treatment of IPF and aHUS respectively, a generic module, applicable to any medication, and a module to assess patient expectations of a new therapy. The modules focus on patients’ perceived effectiveness of the medication, side-effects, ease of use, and impact on health and daily life. The generic module additionally includes items on satisfaction with the medication. Individual interviews confirmed that questions and response options were clear and content validity was good. The mean time to complete the modules ranged from 6 minutes for the disease-specific (aHUS) module to 9 minutes for the generic module. The next step is to establish the questionnaire’s validity, reliability, and responsiveness, and translate into English for international use.

**CONCLUSIONS:**
We developed the PESaM-questionnaire to quantitatively assess patient experiences and satisfaction with medications to potentially inform treatment choices, clinical guideline development, and reimbursement decision making. A psychometric validation study is currently underway.

**OP140 Pictures Speak Louder Than Words: Visuals To Explain NICE Guidance**

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**ABSTRACT SUMMARY:**
The National Institute for Health and Care Excellence (NICE) makes extensive efforts to involve stakeholders in its decision making. This research explores ways in which existing documents could be complemented by visual forms of presentation, to increase transparency for stakeholders.
INTRODUCTION:
The National Institute for Health and Care Excellence (NICE) makes extensive efforts to involve stakeholders in its decision making. For example, patient and clinical experts participate in expert committee meetings for assessment of drugs. This research explores ways in which existing documents could be complemented by visual forms of presentation (visualizations), in order to increase transparency for stakeholders. The research was performed in collaboration with the Massachusetts Institute of Technology (MIT) - Center for Biomedical Innovation (CBI).

METHODS:
We use the User Centred Design process, which comprises the following stages in an iterative way: (Re)designing visual images that explained the rationale behind NICE guidance; producing prototype documents and visualizations; testing these with stakeholders including patient groups; and collecting feedback to refine the design. Stakeholder feedback is collected individually using surveys, as well as summary information using a focus group format.

RESULTS:
A number of visualizations have been developed for target audiences, in particular patients and lay audience. Here we present refined visualizations based on feedback from stakeholders, and the effect on their understanding of the decision-making processes.

CONCLUSIONS:
The visualizations for patient groups were developed with the aim to improve understanding of NICE decision-making processes. These alternative communication methods indicate enriching stakeholders understanding of key element of decision making that underpins Health Technology Assessment of drugs.

OP141 Patient Relevant Outcome Measures As Predictors Of Health Care Use In Multiple Sclerosis

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ABSTRACT SUMMARY:
Patient-relevant-outcome-measures (PROMS) are primarily used to measure individual disability and quality of life in people with MS. However, their relationship with health care resources utilisation (as well as productivity loss) is less clear. The IMPRESS data showed that PROMs may be useful tools to predict the economic impact of MS on healthcare providers and wider society.

INTRODUCTION:
Multiple-sclerosis (MS) is a highly disabling chronic disorder affecting young adults with long term economic consequences on society that escalate as MS disability increases (1,2). In the long-term, progression of MS results in increased level of disability and most patients will eventually experience some degree of functional impairment of the nervous system that impacts on mobility as well as sensory and coordination issues, bladder and sexual functioning, and mood and cognition (2). This is usually accompanied by a deterioration of their quality of life. Patient relevant outcome measures (PROMS) are largely used to measure individual disability, and quality of life in MS (2). International evidence from the International MultiPIE Sclerosis Study (IMPrESS) (2) was used to quantify the relationship between healthcare resources utilisation and disability, quality of life in individuals with MS.
METHODS:
Multivariable logistic regression was performed in order to identify patient-related variables reporting disability (Barthel) and utility (EQ-5D) that predict use of healthcare services (visits to GP, specialists, nurses, hospitalisation and treatment) and work limitation within the participants of the IMPRESS.

RESULTS:
Reponses were collected from 1,152 individuals across 21 countries of which 74.3 percent (856) were useful for analysis. Preliminary findings indicated that for the pooled data sets both EQ-5D and Barthel scores were predictors of healthcare resource use, across different categories (p<.05), except for nurse visits (Barthel only; p<.09). Overall the association between PROM data and use of healthcare resources appeared to be stronger with EQ-5D compared to Barthel. EQ-5D appeared to also predict the impact of MS on loss of productivity (in terms of work limitation; p<.05).

CONCLUSIONS:
PROMs can be used to predict the economic consequences of MS on healthcare providers and society, but more research is needed to confirm the robustness of the evidence and its validity across individual healthcare system settings.

REFERENCES:

POSTER PRESENTATIONS

**Poster Presentations**

**PP001 Ultrasound To Guide Treatment Decisions In Rheumatoid Arthritis**

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**ABSTRACT SUMMARY:**
A systematic review and a cost-effectiveness model investigated the addition of ultrasound (US) to clinical examination, to assess synovitis in rheumatoid arthritis, and inform treatment decisions. Use of US to monitor synovitis could potentially be a cost-effective approach, however, there is considerable uncertainty in this conclusion due to lack of robust data.

**INTRODUCTION:**
Ultrasound (US) detects synovitis more accurately than clinical examination (CE) in people with rheumatoid arthritis (RA). This review aimed to investigate the use of US, compared to CE alone, in treatment strategies for RA, and to estimate its potential to be cost-effective in making treatment decisions.

**METHODS:**
A systematic review was conducted of studies: investigating RA treatment response or strategies that compared US with CE-assessed synovitis; and of tapering RA treatment (1). A model was constructed to investigate the potential cost-effectiveness of US in (i) selecting patients suitable for treatment tapering; and (ii) avoiding treatment escalation (2).

**RESULTS:**
Seven prospective cohort studies suggested US-detected synovitis was significantly associated with a treatment response or tapering failure, whereas in most cases clinical examination alone was not. Two randomised controlled trials (RCTs) identified suggested that US added to the Disease Activity Index (DAS)-based treatment strategies but did not significantly improve primary outcomes, but was associated with improved rate of DAS remission. The evidence showed that some patients (proportions varied widely) who had achieved low disease activity could have treatment tapered, with no, or little, short-term harm to the patient.

The model estimated that an average reduction of 2.5 percent in the costs of biological disease-modifying anti-rheumatic drug (bDMARDs) was sufficient to cover the costs of performing US every three months. This value increased to 4 percent and 13 percent for the costs of conventional disease-modifying anti-rheumatic drug (cDMARDs) depending on the assumed regimen.

**CONCLUSIONS:**
Use of US to monitor synovitis could potentially be a cost-effective approach, given that low proportions of patients for whom clinicians consider amending treatment, would need to taper treatment, or remain on therapy without escalation. US could provide clinicians with more confidence in reducing the drug burden. However, there is considerable uncertainty in this conclusion due to lack of robust data relating to key parameters.

**REFERENCES:**


PP002 Sudden Cardiac Arrest: Wearable Cardioverter-Defibrillator Therapy

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ABSTRACT SUMMARY:
A Health Technology Assessment (HTA) was performed on a novel therapy – wearable cardioverter defibrillator (WCD, LifeVest®) – which could be used in the prevention of sudden cardiac arrest. No assessment of effectiveness could be performed due to the lack of prospective controlled trials. More (adequate) data on adverse events is required. Additionally more data on risk stratification of high risk patients is needed.

INTRODUCTION:
Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. Mostly, ventricular tachycardia (VT) and ventricular fibrillation (VF) are the underlying aetiology of SCA, which is claimed to be successfully treated by a novel therapy, a wearable cardioverter defibrillator (WCD, LifeVest®).

The assessment, performed within the European Network for HTA (EUnetHTA), aimed to provide valid data on clinical effectiveness and safety of the WCD. Furthermore, the project intended to elicit patients views on aspects regarding their cardiac disease and the WCD therapy as well as to identify neglected outcomes.

METHODS:
A synthesis of evidence on the basis of a systematic literature search in Medline via Ovid, Embase, the Cochrane Library, and the Centre for Reviews and Dissemination (CRD) databases was performed. The search was complemented by citation tracking and handsearch.

A face-to-face semi-structured focus group interview was performed with five cardiac disease patients in the scoping phase.

RESULTS:
Since no prospective controlled trials were found, no assessment of effectiveness could be performed. With regard to safety, five prospective studies were included, but the quality of the body of evidence was very low. Adverse events (AEs) reported were skin rash/itching (6 percent), false alarms (14 percent), palpitations/lightheadedness/fainting (9 percent) and discontinuation due to comfort/lifestyle issues (16-22 percent). Serious adverse events (SAEs) were inappropriate shocks (0-2 percent) and unsuccessful shocks (0-.7 percent). Frequency of SAEs leading to death was 0-.3 percent.

Patients of the focus group reported that experiencing a sense of security was crucial to them. The WCD therapy was not considered an option for weeks or months, due to expected restrictions in living a ‘normal’ and secure life.

CONCLUSIONS:
No statement can be made about the device effectiveness – further research is needed. More data and more adequate reporting of AEs and SAEs are needed in order to establish the device safety. In particular, more data is needed for risk
stratification of high risk patients in order to further narrow down the wide range of indications for the WCD use.

PP003 Theoretical Model For Influencing Mechanism Of Clinical Pathway Use

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ABSTRACT SUMMARY:
This study develops theoretical model for scientifically demonstrating the influencing mechanism of clinical pathway utilization. It integrated the whole practice process of a clinical pathway into four stages as follows, pathway production, pathway exchange, pathway utilization, pathway improvement. Additionally, it categorized the potential influencing factors of clinical pathway utilization into four levels, namely “evidence/pathway”, “user”, “organization” and “macro-environment”.

INTRODUCTION:
Insufficient clinical pathway utilization significantly plays negative roles in standardizing the procedures of diagnosis and treatment, ensuring the quality of health services and reducing the unreasonable medical expenses. However, for few systematic considerations of the whole practice process of clinical pathway under the guidance of certain scientific theory, the influencing mechanism of clinical pathway utilization still remains unknown (1–3). Therefore, this study aims to build a theoretical model for scientifically demonstrating the influencing mechanism of clinical pathway utilization.

METHODS:
Literature reviews were applied to collected research outcomes of knowledge translation, knowledge utilization, research utilization, especially about the conceptual framework or the theoretical model in the fields mentioned above. The information on the underlying influencing factors of clinical pathway utilization, as well as the whole practice process of clinical pathway, was collected to formulate the theoretical model.

RESULTS:
A theoretical model was developed to scientifically demonstrate the influencing mechanism of clinical pathway utilization. On the one hand, it integrated the whole practice process of clinical pathway into four stages as follows, pathway production, pathway exchange, pathway utilization, pathway improvement. For example, the “pathway utilization” stage consists of three steps, such as “pathway adoption”, “monitoring utilization”, “outcome evaluation”. On the other hand, this theoretical model categorized the potential influencing factors of clinical pathway utilization into four levels, namely “evidence/pathway”, “user”, “organization” and “macro-environment”.

CONCLUSIONS:
This developed theoretical model reveals that the clinical pathway utilization is one stage of the clinical pathway practice. It was closely related to the other stages of clinical pathway practice, such as “pathway production”, “pathway exchange”. Also, the clinical pathway utilization was influenced by multiple factors from different levels. This theoretical model can be used to provide some guidance to take effective measures to expand the utilization of clinical pathways.

REFERENCES:

PP004 Health Technology Assessment As A Driver For Innovative Public Funding Arrangements

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) has been the driver for an innovative administration arrangement for a new transcatheter aortic valve implantation (TAVI) service in Australia. The HTA process identified that the proposed TAVI service was only suitable for a small subset of the population, resulting in the development of unique arrangements designed to protect the patient population.

INTRODUCTION:
Australia has a well-developed Health Technology Assessment (HTA) system that is used to inform decisions about public and private healthcare funding for health interventions and technologies. A recent application for public funding of a transcatheter aortic valve implantation (TAVI) service has resulted in the development of innovative administration arrangements designed to limit the service to the most suitable population as identified in the HTA process.

METHODS:
The TAVI service application for public funding underwent a rigorous HTA process including public consultation, evidence based assessment, and consideration by the Medical Services Advisory Committee (MSAC). The MSAC’s role is to advise the Australian Minister for Health and Ageing on the strength of the evidence relating to the safety, effectiveness, and cost-effectiveness of medical technologies and procedures. MSAC recommended the TAVI service for public funding only in patients who are symptomatic with severe aortic stenosis and who are deemed to be at high risk for surgical aortic valve replacement or non-operable. The population limitation was considered necessary to ensure the best clinical outcomes, and protect the cost effectiveness of the service as evidenced through the HTA process.

RESULTS:
The Department of Health is in the process of implementing a number of innovative arrangements to limit the TAVI service to the recommended population. These arrangements include patient selection through a multidisciplinary heart team; accreditation of TAVI providers; TAVI facility limitations; and compulsory collection of patient outcome data. These funding arrangements are largely unprecedented in the current federal health funding system.

CONCLUSIONS:
HTA can be a driver for new and innovative funding arrangements as has been the case in the development of TAVI service for a limited population in Australia.

PP005 Micro-Costing Of Colorectal Cancer In China

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ABSTRACT SUMMARY:
To provide critical data support for future optimization of colorectal cancer (CRC) screening strategies in China, a micro-costing study was performed, to measure direct medical and non-medical costs for colorectal cancer screening, diagnosis, and treatment in China from a societal perspective. Direct costs for patients in different stages and with precancerous lesions were also calculated.

INTRODUCTION:
Cost is essential for further health economic analyses. Our objective was to generate direct cost estimates associated with colorectal cancer (CRC) screening, diagnosis, and treatment in China from a societal perspective.

METHODS:
From 2015 to 2016, a micro-costing study based on clinical pathway was conducted in Chongqing Cancer Hospital, to calculate medical costs of CRC screening, diagnosis, and treatment by applying quantities to prices of drugs, consumables, equipment, and labour. A total of 31 medical staff members were interviewed. From 2012 to 2014, a cross-sectional survey (n=1443) was performed to measure non-medical costs. The sum of medical and non-medical costs were direct costs. Cost data was converted to 2016 values and presented as USD.

RESULTS:
With 50,000 screened annually, average direct costs of high-risk factor questionnaire, fecal immunochemical test, and colonoscopy test were USD1.8, USD2.5, and USD34.4, respectively, with medical costs accounting 99.3 percent, 83.6 percent, and 98.8 percent, respectively. Average direct treatment costs of cancer patients were USD15,196.1, and direct costs of patients staging I to IV were USD8,027.0, USD9,606.4, USD16,035.6, and USD18,793.8, respectively. 98.2 percent of the overall direct costs were medical costs, of which drugs accounted for the most (50.6 percent), followed by consumables (31.6 percent), and labour (10.9 percent). In addition, average direct costs of precancer patients were USD2,208.9. Results of sensitivity analyses on a range of variables, including distribution of clinical stages and therapeutic regimens, compliance for chemotherapy, will be reported.

CONCLUSIONS:
Direct costs for CRC diagnosis and treatment increased gradually with the deterioration of health, which hints considerable savings might be achieved through early detection of cancer in China. Estimated costs seems higher than national estimated expenditure (USD9,693.3) for CRC diagnosis and treatment, and related reasons need to be further discussed combining with evidence from sensitivity analyses.

PP006 Ebola In The Netherlands: Costs Of Preparedness And Response

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ABSTRACT SUMMARY:
Costs of preparedness for and response to Ebola Virus Disease (EVD) made by the Dutch health system were estimated, using interviews with key professionals and information from the organisations involved. Thirteen possible cases and one confirmed case were admitted to a hospital. Total cost of EVD preparedness and response were averaged at EUR14.1 million, ranging from EUR7.6 to EUR24.9 million.

INTRODUCTION:
Between December 2013 and April 2016, an unprecedented epidemic of Ebola Virus Disease (EVD) took place. This epidemic urged countries all over the world to be prepared for the possibility of having an EVD patient (1). Besides morbidity and mortality of the disease, containment efforts also have economic consequences for society. In this study, costs of preparedness for and response to EVD made by the Dutch health system were estimated.

METHODS:
We used an activity-based costing method in which cost of personnel time targeted at preparedness, and response activities was based on a time recording system and interviews with key professionals of the organizations involved. In addition, patient days of hospitalizations, laboratory tests, personal protective equipment (PPE), as well as costs for additional cleaning and disinfection were acquired via the organizations. All costs are expressed at the 2015-euro price level.

RESULTS:
The estimated total costs of EVD preparedness and response in the Netherlands were averaged at EUR14.1 million, ranging from EUR7.6 to EUR24.9 million. There were thirteen possible cases clinically evaluated and one confirmed case, admitted through an international evacuation request, corresponding to approximately EUR1 million per case (2). Preparedness activities of personnel, especially of all ambulance care services and hospitals that could possibly receive a case, and expenditures on PPE, were the main cost drivers.

CONCLUSIONS:
The estimated total cost of EVD preparedness and response in the Netherlands was substantial. Costs made by healthcare organizations were higher than among public health organizations (3). Designating one ambulance care service and fewer hospitals for the assessment of possible patients with viral hemorrhagic fever or other highly infectious disease of high consequence might improve efficiency and reduce future costs. The experiences and collaboration of healthcare organisations that managed patients with possible EVD can serve as a valuable resource for future outbreaks of other highly infectious diseases.

REFERENCES:
PP007 Technology Adoption In Hospitals: Balancing Incentives - A Survey

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) in hospitals involves evaluating cost-effective benefits alongside needs, professional skills and patient-mix, within budgetary constraints. A survey among managers analyzed their ranking of clinical efficiency, risk-benefit, contribution to decision making and impact. Integrating the insights of managers (towards clinical advantages, competitive markets and national strategies) with personal and professional parameters, assists in bridging the gaps between local hospital activities and governance.

INTRODUCTION:
Health Technology Assessment (HTA) in the hospital framework involves evaluating safety and cost-effective benefits alongside additional perspectives. We must take into account: professional skills, patient mix, infrastructure costs, the competitive arena and promoting innovation as part of the hospital strategy. Within budgetary constraints, hospitals need to focus on clinical excellence, prioritizing selected technologies in key fields (1).

METHODS:
A survey was conducted among thirty-five mid-level managers; department directors and head nurses from eight medical centers. The data was collected from a structured questionnaire scoping five fields: clinical efficiency, risk, benefit, contribution of relevant “players” for decision making and impact of adoption.

RESULTS:
Personal characteristics of the responders correlated with certain trends: managers with longer seniority ranked life-saving higher than younger managers, as did men in comparison to women. Participants from the peripheral regions ranked improvement in quality of life higher than respondents from the center of the country. The importance of functional improvement of the patient was graded higher by nurses, compared to the physicians.

In operative aspects, improving staff communication was considered significantly higher among experienced managers, women, staff members in the central region hospitals and among nurses in comparison to physicians. Women ranked improvement of medical standards and guidelines higher, irrespective of their professional sector. At initial stages of the technology lifespan, scientific evidence on effectiveness was found to have a stronger influence on adoption decisions than national guidelines.

Budgetary repercussions of adopting a new technology were ranked significantly higher in the central region. Experienced managers attributed greater impact to economic issues than younger managers.

Social dimensions, such as providing care for a large population, reaching the target population, improvement of service and patient preferences were graded significantly higher by women.

CONCLUSIONS:
The survey highlights the insights of managers for decision making on adopting technologies in hospitals. Integrating the insights of managers (towards clinical advantages, competitive markets and national strategies) with personal and professional parameters assists in bridging the gaps between local hospital activities and governance.
PP008 Health Technology Assessment Analysis Of New Biological Drugs In Chronic Inflammatory Diseases

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ABSTRACT SUMMARY:
The study focuses on an analysis of therapeutic appropriateness carried out in three hospital departments to evaluate the use of biologics drugs and adherence to Guidelines in ensuring good clinical practice and at the same time evaluating pharmacoeconomic aspects so that there is no waste of public resources they may be intended for the treatment of other diseases.

INTRODUCTION:
Innovative therapies with high cost are increasing in every therapeutic area, making it increasingly difficult the role of the pharmacist in trying to rationalize the economic resources to satisfy the needs of the entire population. The analysis of therapeutic appropriateness has a key role in the management of chronic inflammatory diseases where the biological drugs are used by patients for a long period of time. With increasing competition among companies and the advent of the first biosimilar drugs, the costs are declining and the duty of the Pharmacist is the supervision of treatments so that there is a good cost / effectiveness in an attempt to free resources and safeguard the survival of the Health Service National.

METHODS:
In the year 2015 up to September 2016, all patients were monitored in the departments of Rheumatology, Gastroenterology and Dermatology based on the type of disease, drugs, route of administration and dosages. We evaluated the previous non-biological treatments of first line, therapeutic switch between any drugs with different mechanisms of action, the analysis on the state of the disease, any therapeutic dosages not reported in Summary of Product Characteristics and the reasons that lead the doctors to deviate from guidelines.

RESULTS:
The treatments of 684 patients were analyzed: 409 in Rheumatology, 212 in Gastroenterology and 63 in Dermatology. The most frequently used drugs are those that have major use in clinical practice: Adalimumab, Etanercept and Infliximab (three anti-TNF alpha drugs). The first two, having a subcutaneous administration compared to intravenous administration, allow greater patient compliance and are therefore preferred to Infliximab. In Rheumatology the use of newer drugs with different mechanisms of action by inhibition of TNF alpha is not negligible and this is an indication of poor accuracy in the application of the guidelines.

CONCLUSIONS:
Biologicals are well tolerated and improve the quality of life of people with highly disabling diseases. The therapeutic appropriateness and adherence to guidelines are the only way to try to contain costs. The hope is that, in this new year 2017, new biosimilar drugs are approved that would make, at least for the naïve subjects, more sustainable management of these diseases.

REFERENCES:

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PP009 Quality Assessment In A Clinical Setting: A Look Upstream From Health Technology Assessment

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ABSTRACT SUMMARY:
Quality improvement activities are one application of Health Technology Assessment. In this study we assessed patients’ satisfaction with anesthesia services in a Canadian tertiary care center. Using a Plan-Do-Study-Act scheme to frame the results, practitioners can help inform the needs assessment of further use of existing or new methods and technologies.

INTRODUCTION:
Health Technology Assessment (HTA) has various areas of application, one of which is quality improvement activities in clinical settings. Using patients’ satisfaction as indicator of quality of care can inform the ‘needs assessment’ of a clinical department.

The principal aim of this study is to quantify patients’ satisfaction with the anesthesia services received perioperatively at our hospital, including physical discomfort and anesthesia care. To this end, we asked the following question: “In adult patients who undergo day surgery at our hospital, what is the level of satisfaction with the anesthesia services received perioperatively?” A second aim is to discuss how quality assessment and HTA can intertwine.

METHODS:
This is a quality assessment study, using a patient self-administered survey method.

We included all patients who had a day-surgery at our hospital and we excluded those who cannot understand English or French, who present cognitive barriers, and those who were admitted the same day.

Patients were recruited postoperatively in phase II of recovery, using a nonprobability convenience sampling method. We used a validated questionnaire which addresses the two dimensions of anesthesia care related our research question: (i) physical discomfort and (ii) satisfaction with anesthesia care. We added to this questionnaire, a supplemental question to measure satisfaction with pre-operative anesthetic care. Parallel to this, we also gathered the data routinely collected by the recovery nurses during a 24 hour postoperative patient follow-up.

RESULTS:
We collected data from November 2015 to February 2016. A total of 156 questionnaires was completed. Two respondents (1.3 percent) said they were ‘unsatisfied’ or ‘very unsatisfied’ with the anesthesia care they received in general and thirty-six (23 percent) said they were ‘satisfied’. The most frequently reported physical discomfort symptoms were: thirst (78 percent), pain (72 percent), drowsiness (68 percent), cold (58 percent), and sore throat (54 percent).

CONCLUSIONS:
Our study suggests that, while reporting patients’ level of satisfaction regarding various aspects of the anesthesia care they received, such quality assessment study can identify gaps in the use of existing methods and technologies and help in acquisition prioritizing.
PP010 Promoting Access To Improved Quality Health Care

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ABSTRACT SUMMARY:
Integrated people-centred care systems strategy potentially generates significant benefits to the health care of all people, including improved access to care, improved health and clinical outcomes, better health literacy and self-care, increased satisfaction with care, improved job satisfaction, improved efficiency of services, and reduced overall costs.

INTRODUCTION:
This report is about promoting the World Health Organization (WHO) concept of “Integrated people-centred care systems strategy” as potentially generating significant benefits to the health care of all people, including improved access to care, improved health and clinical outcomes, better health literacy and self-care, increased satisfaction with care, improved job satisfaction, improved efficiency of services, and reduced overall costs (1). Focusing on the strategy, Uganda Alliance of Patient Organizations (UAPO) promotes engagement and involvement of patients and the community in building capacity for patient-centered healthcare, improved quality of health care, and other issues affecting healthcare systems, as well as promoting patient safety. It provides an opportunity to get cross-fertilization of ideas with regard to amplifying the patient voice, and feeds into the global, regional, and national level policy commitments, regional strategies, and initiatives in the area of Universal Health Coverage (UHC), primary health care, health system strengthening, and social determinants of health (2).

METHODS:
Patients come together with other healthcare stakeholders to share experiences. UAPO facilitates dialogues and exploring barriers to UHC within three areas: equity, quality, and financing, as key to promoting the WHO concept. Rainstorming on health technology assessment (HTA) as a system that enables comprehensive patient-centred and integrated assessment of complex technologies that enables

RESULTS:
Access to healthcare, must be safe, of high quality, and universal, tailored to patients’ needs. This is central to the WHO definition of universal health (UHC). Unsafe care places a large and needless financial burden both on patients and on healthcare systems that treat them.

CONCLUSIONS:
Involving patients and the community is significantly beneficial and complements program activities aimed at healthcare quality. Dialoguing paves the way for improved collaboration for safe, quality, and people-centered health care. It also contributes to the WHO’s PFPS program, which is a core initiative within the WHO Service Delivery and Safety, that aims to ensure patients and people are engaged in all efforts to create safer health care.

REFERENCES:
1. WHO Global strategy on integrated people-centred health service 2016-2026.
2. IAPO, 6th Global Congress on Patient-centred Approach to UHC.
PP011 Covering New Medical Devices With Low Cost-Effectiveness Evidence

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ABSTRACT SUMMARY:
Covering new technologies without incurring a severe financial burden presents a dilemma for the Korea National Health Insurance (K-NHI). We compare the K-NHI medical device coverage system to those in Japan and Taiwan so as to be better informed about how to cover and set prices for new medical devices.

INTRODUCTION:
The Korea National Health Insurance (K-NHI) has covered medical devices with low cost-effectiveness evidence by what is known as the Selective Benefit (SB) since December of 2013 as a type of conditional coverage. Most medical devices in the SB category are new technology and have higher levels of clinical effectiveness and/or functions than those in the benefit category, but they are characterized as being expensive. We compare the K-NHI medical device coverage system to those in Japan and Taiwan so as to be more informed about how to cover and set prices for new medical devices.

METHODS:
We searched for materials related to medical device coverage or the reimbursement systems of three countries (Korea, Japan, and Taiwan). National health insurance laws, policy reports, and the websites of the Ministries of Health of the respective countries, for instance, were also reviewed.

RESULTS:
The NHI systems of Korea, Japan, and Taiwan have several similarities with regard to their medical device benefit lists. They reimburse listed medical devices separately although they cover them basically by including procedures or a diagnosis-related group (DRG) fee. The K-NHI reimburses for medical devices with low cost-effectiveness using the actual market medical price, similar to other medical devices in the benefit category. However, there are no detailed rules regarding how to set prices for these devices. Every listed medical device is covered at the notified price in Japan, but the prices of new medical devices with improved functions can add 1 -100 percent of the price to the notified price. The prices of devices related to new medical procedures are determined by cost-accounting methods. The NHI service in Taiwan compensates for medical devices which are alternates but clinically improved types through a balance billing method.

CONCLUSIONS:
The NHI systems in Japan and Taiwan set prices with regard to reimbursements for new medical devices separately, specifically for devices which are advanced clinically or functionally but expensive. The K-NHI must consider establishing a pricing or reimbursement system for new medical devices through the discussion with stakeholders for reasonable reimbursements and decreasing the financial burden on the K-NHI.

PP012 Efficacy and Safety Of The ELIPSE Gastric Balloon For Weight Loss

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**ABSTRACT SUMMARY:**
The ELIPSE™ is a new gastric balloon designed for weight loss that is swallowed and does not require endoscopy or anesthesia. The device is designed to remain in the stomach and be expelled after a predetermined time. The objective of this work is to assess the efficacy and safety of the ELIPSE™ procedureless gastric balloon for weight loss.

**INTRODUCTION:**
Conventional gastric balloons for weight loss require endoscopy for placement and removal. The ELIPSE™ is a new gastric balloon designed for weight loss that is swallowed and does not require endoscopy or anesthesia. The device is designed to remain in the stomach and be expelled after a predetermined time of 4 months. The objective of this work is to assess the efficacy and safety of the ELIPSE™ procedureless gastric balloon for weight loss.

**METHODS:**
The ELIPSE™ procedureless gastric balloon was identified by the early Awareness and Alert System, “SINTESIS-new technologies,” of The Instituto De Salud Carlos III (AETS-ISCIII). An early assessment of the technology was conducted. The searched databases were: MEDLINE (PubMed), Centre for Reviews and Dissemination, and the Cochrane Library. Clinical studies using the device published in any language until 10 January 2017 were reviewed.

**RESULTS:**
A prospective, non-randomized, open label study supported by industry was retrieved. Thirty-four patients were enrolled. Six patients treated with an experimental device were excluded. Twenty-eight patients successfully swallowed the device. No endoscopy or anesthesia was required. All devices were excreted safely. Of the twenty-five patients finally studied, the mean percent total body weight loss was 10 percent (95 percent Confidence Interval, CI 7.3–12.7) and the mean waist circumference was reduced by 8.4cm (95 percent CI 5.7–11.8) at 4 months. Improvements were also seen in metabolic parameters (HbA1c, Low density lipoprotein, triglycerides and blood pressure). All aspects of quality of life measured by the Impact of Weight on Quality of Life (IWQoL) questionnaire demonstrated significant improvements. About safety, there were no serious adverse events or serious adverse device effects, however 64 percent of patients had vomiting, 54 percent experienced nausea, 25 percent had abdominal pain and 2 patients were excluded because of symptoms.

**CONCLUSIONS:**
The ELIPSE™ gastric balloon for weight loss it seems to be an effective therapy with an acceptable safety profile. However it would be necessary to continue further studies to confirm these results, including comparative studies with current treatments.

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**PP013 Pain Management And Substance Abuse In Sickle Cell Disease Patients**

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**ABSTRACT SUMMARY:**
The percentage of patients treated for Sickle
Cell Disease (SCD) at Hospital de Clinicas de Porto Alegre, Brazil, who abuse substances, including opioids was estimated, concluding that use of opioid analgesics for SCD painful crises management is safe and does not induce substance abuse. Regular follow-up of these patients is recommended. The information from this study might be useful in other countries.

INTRODUCTION:
Drug abuse is a social and public health problem because of its negative consequences of emotional and physical development in individuals. There are few studies evaluating substance abuse by individuals with sickle cell disease (SCD). These patients have severe and recurrent pain crises (1), frequently needing opioids to control it (2). The compromised quality of life can predispose this population to the occurrence of non-psychotic disorders such as depression, making them vulnerable to substance abuse (3).

METHODS:
We evaluated the consumption of alcohol and drugs in a cohort followed at the Sickle Cell Disease Reference Center (CRAF), at Hospital de Clinicas de Porto Alegre, estimating the percentage of patients in treatment of SCD who abuse alcohol and drugs, mainly opioids. A cross-sectional study was of a convenience sample of 139 patients with SCD treated at CRAF. The pattern of substance use was evaluated using the Brazilian version of Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). The exposure to opioids was measured by their use and prescription in the 24 months before the interview. The Self-Reporting Questionnaire (SRQ-20) was used to estimate the occurrence of non-psychotic disorders in this population. Descriptive analyzes were performed using absolute and relative frequencies. The association between the variables was verified using the chi-square test or Fisher’s exact test.

RESULTS:
The prevalence of abusive use was 1.5 percent for alcohol and 3.0 percent for tobacco, with no abusive use of any other substance including opioids was identified. Of note was the pattern for substance use that was not influenced by exposure to substances or the presence of non-psychotic disorders.

CONCLUSIONS:
Our data shows that use of opioid analgesics for the management of SCD painful crises is safe and does not induce substance abuse. Regular follow-up of these patients is recommended. The results of this study might be useful in other countries.

REFERENCES:
ABSTRACT SUMMARY:
To evaluate a policy proposed by younger members of Japan’s National Diet, Health Gold License, under which the copayment rate for those insured who manage their health by receiving medical checkups is reduced; we studied confounding factors between those insured who receive medical checkups and those who do not; and using employee-based claims data we estimated the effect of checkups on medical costs.

INTRODUCTION:
Mr. Shinjiro Koizumi and some younger members of Japan’s National Diet suggested a new policy, “Health Gold License” which would introduce financial incentives to encourage population health management, with people receiving medical checkups receiving a reduction in coinsurance from the current 30 percent to 20 percent. In this research, to evaluate the policy, we adjusted confounding factors of those insured who receive medical checkups (Medical-Checkup Group) and those who do not (Non-Medical-Checkup Group) using claims data, and estimated the effect of medical checkups on medical costs.

METHODS:
We analyzed Japanese employee-based claims data provided by the Japan Medical Data Center Co., Ltd. for the 3 million insured from January 2005 to December 2015. Two regression models were developed. Under model A, explanatory variables were year, age, dummy variables for various hierarchical condition categories and for medical checkups. Under model B, explanatory variables were estimated medical costs per patient per month (PMPM) in 2012 and a dummy variable for medical checkups. We also simulated the financial impact if Japan introduced Health Gold License for all insured.

RESULTS:
The coefficients of medical checkups in model A and in model B were -JPY4,816 PMPM and -JPY8,735 PMPM, respectively. The gap of medical costs between the Medical-Checkup Group and Non-Medical-Checkup Group was JPY4,588 PMPM, without any adjustment. If all of those insured received medical checkups, the breakeven coinsurance would be 27.2 percent.

CONCLUSIONS:
The Medical-Checkup Group is less expensive than Non-Medical-Checkup Group by at least 30%, therefore, the break-even coinsurance for them would be 0 percent. However, because most of those insured have already gone to medical check-ups every year, if the coinsurance were reduced from 30 percent to 20 percent for all insured, the finance would be largely negative. The break-even as 27.2 percent, we believe, would not incentivize the Non-Medical-Checkup Group to receive medical checkups. Therefore, the coinsurance reduction proposed under Health Gold License is not fully justified financially.

PP015 Methodological Quality Of Health Technology Assessment Reports

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ABSTRACT SUMMARY:
Health technology assessment (HTA) reports have a major impact on health care; they represent a potentially important source of information (e.g. as evidence syntheses) and thus should have a high methodological quality. Using AMSTAR we assessed the methodological quality of forty-one HTA reports and found that their quality was average.
INTRODUCTION:
Health Technology Assessment (HTA reports) may have a major impact on the health care provided in a country. Hence, one would assume that these reports have a high methodological quality and thus represent a potentially important source of information, for instance, for identifying primary studies for inclusion in the evidence syntheses for example, systematic reviews, Cochrane reviews, HTA reports). The aim of the present analysis is to evaluate the methodological quality of HTA reports used as a literature source for HTA reports produced by the German Institute for Quality and Efficiency in Health Care (IQWiG).

METHODS:
Eligible IQWiG reports were assessments of drug or non-drug interventions considering HTA reports as the literature source for primary studies and published up to October 2016. An HTA report included in the IQWiG report was considered in the analysis if it was a complete report published in English or German and indexed in the Health Technology Assessment Database (Wiley) or MEDLINE. Only the most current HTA report in an IQWiG report was considered; if more than one current HTA report was available, the one for inclusion in the analysis was randomly selected. The methodological quality of the HTA reports identified was evaluated with the AMSTAR (“Assessment of Multiple Systematic Reviews”) tool (1), which comprises 11 items on methodological quality (meaning a maximum achievable score of 11).

RESULTS:
A total of fifty eligible IQWiG reports using forty-one eligible HTA reports as literature sources were identified. The mean AMSTAR score of these HTA reports was 5.3 (95 percent Confidence Interval, CI: 4.3, 6.2). None of the HTA reports achieved a score of 11, nineteen (46 percent) had a score between six and ten, and twenty-two had a score below 6.

CONCLUSIONS:
HTA reports included in IQWiG reports only have an average methodological quality.

REFERENCES:

PP016 Hepatitis C Cost Study C, Brazil, 2014

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ABSTRACT SUMMARY:
To identify, measure, and evaluate the direct medical, non-medical, and indirect costs related to hepatitis C and associated conditions in Brazil. Methodology: The cost of hepatitis C (HCV) and associated conditions were estimated using the base year 2014. We adopted the perspective of the Unified Health System (SUS) and the society.

INTRODUCTION:
This study identifies and measures direct medical, non-medical, and indirect costs related to hepatitis C and associated conditions in Brazil.

METHODS:
The costs of hepatitis C (HCV) and associated conditions (1) were estimated using the base year 2014. The perspective of the Unified Health System (SUS) and that of society was adopted. The data were obtained from universal access information systems provided by the Ministry of Health. Direct medical, non-medical, and indirect costs were
evaluated using the macro-costing methodology for each of the clinical conditions (2) identified through the International Classification of Diseases (ICD 10).

RESULTS:
The estimated total medical direct cost of the different stages of HCV infection accounted for more than USD150 million in 2014. Chronic hepatitis C, liver transplantation, and liver fibrosis and cirrhosis were responsible for the largest portions of this amount, respectively 86.9 percent, 12.1 percent, and 0.6 percent of total direct medical costs. The non-medical direct cost, for all clinical conditions (CID), accounted for more than USD526,000. Transport costs of patients and caregivers in chronic hepatitis C accounted for 69.4 percent of this value. The estimated total cost for the indirect cost of hepatitis C and associated conditions was over USD2.26 million in 2014. The clinical condition responsible for 50 percent of this value was liver fibrosis and cirrhosis.

CONCLUSIONS:
This study showed the economic impact of hepatitis C and associated conditions in Brazil, from the perspective of the Unified Health System and that of society. Health expenditures and losses provide evidence for the need for actions aimed at prevention of HCV infection (3), as well as policies to reduce the price of antivirals; which may be important strategies to reduce the consumption of resources in this reality, both those used by the health service to defray the various actions and services, as well as the expenses or lost by society.

REFERENCES:

PP017 Social Cost Benefit Analysis Of Cognitive Behavioral Therapy For Alcohol And Cannabis Addiction

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ABSTRACT SUMMARY:
Cognitive Behavioral Therapy (CBT) in specialized addiction care centers has the potential to improve health and quality of life of people suffering from addiction. A social cost-benefit analysis of enhancing uptake of CBT showed that not only treated clients but also society will substantially benefit from an increase in people treated with CBT.

INTRODUCTION:
Due to their chronic nature and high prevalence, alcohol and cannabis addiction leads to a significant (disease) burden and high costs, both for those involved and for society. The latter includes effects on health care, quality of life, employment, criminality, education, social security, violence in the public and private domain, and traffic accidents. In the Netherlands, a considerable number of people with an alcohol or cannabis addiction currently do not receive addiction care. Cognitive Behavioral Therapy (CBT) is effective as a treatment for both alcohol and cannabis addiction and is widely used in specialized addiction care centers.
This social cost-benefit analysis (SCBA) models costs and benefits of increasing the uptake of CBT for persons with an alcohol addiction and for adolescents with a cannabis addiction, taking into account a wide range of social costs and effects (1).

**METHODS:**
The method follows general Dutch guidance for performing SCBA. A literature search was conducted to evaluate efficacy of CBT for alcohol and cannabis dependence. In addition, the social costs of alcohol and cannabis addiction for society were mapped, and the costs of enhancing the uptake of CBT were explored. Costs and benefits of increased uptake of CBT for different social domains were modeled for a ten year period, and compared with current (unchanged) uptake during this period. Compliance problems (about 50 percent of clients do not finish CBT) and fall-back to addiction behavior (decrease of effects of CBT over time) were taken into account in model estimations.

**RESULTS:**
Per client treated with CBT, the estimated benefits to society are EUR10,000-14,000 and EUR9,700-13,000, for alcohol and cannabis addiction, respectively. These benefits result from reduced morbidity and mortality, improved quality of life, higher productivity, fewer traffic accidents, and fewer criminal activities.

**CONCLUSIONS:**
This SCBA shows that not only treated clients but also society will benefit from an increase in people treated with CBT in specialized addiction care centers.

**REFERENCES:**

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**PP018 Clinical Risk Prediction Scores For Venous Thromboembolism In Hospitalized Patients**

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**ABSTRACT SUMMARY:**
Systematic review and meta-analysis of Venous Thromboembolism (VTE) risk prediction scores for hospitalized patients found that several scales had high sensitivity, but specificity is low and evidence is of only moderate strength.

**INTRODUCTION:**
Risk prediction scores have been devised to identify patients at increased risk for Venous Thromboembolism (VTE) in different patient populations and settings. Guideline recommendations for VTE risk assessment vary greatly. We performed a systematic review to synthesize evidence on clinical risk prediction scores for VTE in hospitalized medical and surgical patients.

**METHODS:**
We systematically searched Medline, EMBASE, Cochrane, National Institute of Health and Care Excellence (NICE), National Guidelines Clearinghouse (NGC), and Guidelines International Network (GIN) databases up to March 2016. We included studies validating risk prediction scores for adult hospitalized patients. We excluded studies for any of the following reasons: non-English publication, conducted in non-OECD (Organisation for Economic Co-operation and Development) countries, validation cohorts focused
solely on critical care patients, or scores developed for specific surgical or medical sub-specialty populations. We plotted receiver operating characteristic (ROC) curves of included studies and performed summary ROC meta-analyses for scores in which >1 external validation studies were combinable. Risk of bias was assessed qualitatively. We assessed the strength of the evidence base using Grading of Recommendations Assessment, Development and Evaluation (GRADE).

RESULTS:
We screened 110 primary studies and included 18 of those for analysis. There were seven studies of the Caprini score, three studies of the Padua score, two studies of the IMPROVE score; and one study each of the Arcelus, Geneva, Khorana, RAP, and Kucher scores. Strength of evidence was downgraded for study risk of bias because most studies disproportionately included patients at high risk of VTE. Our summary estimates of the performance of the three combinable scores at clinically-relevant thresholds are: Caprini score at a threshold of three in surgical patients – 96 percent sensitivity, 44 percent specificity; IMPROVE at a threshold of one in medical patients – 96 percent sensitivity, 20 percent specificity; and Padua at a threshold of 4–87 percent sensitivity and 58 percent specificity.

CONCLUSIONS:
There is moderate strength evidence for use of the Caprini score to predict VTE in surgical patients and for the Padua and IMPROVE scores in medical patients. Lower thresholds may be warranted to achieve sufficient sensitivity to identify low risk populations who may not require routine VTE prophylaxis. Studies making direct comparisons of risk prediction scores in similar patient populations are lacking and are necessary to ascertain which score is most effective.

PP019 Clostridium Difficile Infection Diagnosis: Hospital-Based Health Technology Assessment

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ABSTRACT SUMMARY:
Clostridium difficile infection is the leading cause of nosocomial diarrhea and may progress to death. The diagnosis needs laboratory tests more accurate to identify true carriers for a safer treatment. An analysis estimated the incremental expenditure between two tests and were found an incremental cost of USD152,730.00 to benefit a single patient by discontinuing empirical treatment.

INTRODUCTION:
Clostridium difficile infection is the leading cause of nosocomial diarrhea in developed countries and may progress to pseudomembranous colitis, sepsis and death. The risk factors are antibiotics use, advanced age and prolonged hospitalization. The diagnosis of Clostridium difficile infection is based on clinical history in combination with laboratory tests, which detect the Clostridium difficile presence or toxins. Clostridium difficile remains in spore form contaminating the environment and requiring measures to prevent hospital transmission. Tests with more accurate results to identify true carriers of Clostridium difficile allow the clinician to determine a safer treatment. This study evaluated accuracy and cost-effectiveness of the real-time polymerase chain reaction compared with the enzyme-linked immunosorbent assay from the perspective of a Brazilian public cardiology hospital.
METHODS:
A study diagram was constructed by type of test, linking the data of prevalence in hospital, accuracy and direct costs of tests. The costs were based on a hypothetical population comparing two strategies to identify the incremental expenditure between technologies. The analysis included comparisons for each test versus no test, and with each other. The prices were converted to the American currency taking into account the date of purchase of each product and respective price.

RESULTS:
For real-time polymerase chain reaction test versus no test, 214 patients would have tested to justify one empirical treatment suspension, at a cost of USD90,926.46. For enzyme-linked immunosorbent assay test, to prevent one unnecessary treatment, 375 patients would have to be tested at a cost of USD6,603.75. In the comparative analysis, only a single false-positive patient would have the treatment suspended after performing 375 real-time polymerase chain reaction tests at USD424.89 each one (USD159,333.75 in total). An incremental cost of USD152,730.00 may be necessary to benefit a single patient by discontinuing empirical treatment.

CONCLUSIONS:
The Real-time polymerase chain reaction test has restrictions as a test of choice for the diagnosis of Clostridium difficile infection, in services with low disease prevalence. It undergoes a significant change in its positive predictive value and does not offer a great impact in the clinical diagnosis.

PP020 Decision-Making Beyond Evidence Alone – Topic Prioritisation For Health Technology Assessment

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ABSTRACT SUMMARY:
This abstract presents an example where a prioritization decision was made beyond evidence on the high clinical, economic and budget impact of a technology. An evaluation on the potential impact of a Health Technology Assessment (HTA) considering the ethical/political grounds indicated a low impact of such a HTA. Thus prioritization decisions need to consider elements beyond evidence for HTA to make a difference.

INTRODUCTION:
The number of health technologies needing evaluation far outweighs available resources, and most Health Technology Assessment (HTA) agencies use criteria-based frameworks for topic prioritisation (1,2). Despite variability, most frameworks include clinical, economic and budget impact. Some limitations of current frameworks lack mentioning of any explicit political/ethical deliberation and an evaluation on the potential impact of the HTAs (1).

METHODS:
During a topic prioritisation for HTA, Left Ventricular Assist Device (LVAD) as destination therapy for adults with end-stage heart failure was submitted. The prioritization criteria used were largely in line with those described above. We also included criteria on ethical/equity consideration and the potential impact.
of an HTA on decision making. A literature search was conducted to gather clinical and economic evidence on LVAD for the target population, supplemented by local data on potential need for and budget impact of providing a LVAD service.

RESULTS:
LVAD was scored high on clinical, economic and budget impact with a moderately high need, which would generally subject it to an HTA in order to inform a policy decision. However, LVAD was also considered as a technology with a high impact on ethical and political grounds, given that it is a technology offering survival and quality-of-life benefits for a small group of patients for whom effective treatment is otherwise lacking. Through deliberation, the prioritization panel concluded that the impact of an HTA would be low, as a policy decision on whether a LVAD program should be funded would go beyond evidence. Therefore, an HTA was not recommended for LVAD.

CONCLUSIONS:
To inform decision making, an evaluation on the potential impact of the HTA itself taking into account of the ethical/political consideration of funding a technology is of equal importance as the evidence alone. Subsequently, limited HTA resources can be reserved for technologies where an HTA can truly make a difference.

REFERENCES:

PP021 Peer Review Innovations For Grant Applications: Efficient And Effective?

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ABSTRACT SUMMARY:
Peer review is a routine approach for selecting health research proposals for funding but has been criticized for being inefficient and ineffective. We developed a systematic map to characterize the primary research on peer review methods, and conducted a systematic review to evaluate which types of peer review innovation could improve efficiency and or effectiveness of research proposal selection.

INTRODUCTION:
Peer review of grant applications is employed routinely by health research funding bodies to determine which research proposals should be funded. Peer review faces a number of criticisms, however, especially that it is time consuming, financially expensive, and may not select the best proposals. Various modifications to peer review have been examined in research studies but these have not been systematically reviewed to guide Health Technology Assessment (HTA) funding agencies.

METHODS:
We developed a systematic map based on a logic model to summarise the characteristics of empirical studies that have investigated peer review of health research grant applications. Consultation with stakeholders from a major health research funder (the UK National Institute for Health Research,
NIHR) helped to identify topic areas within the map of particular interest. Innovations that could improve the efficiency and/or effectiveness of peer review were agreed as being a priority for more detailed analysis. Studies of these innovations were identified using pre-specified eligibility criteria and were subjected to a full systematic review.

RESULTS:
The systematic map includes eighty-one studies, most published since 2005, indicating an increasing area of investigation. Studies were mostly observational and retrospective in design, and a large proportion have been conducted in the United States, with many conducted by the National Institutes of Health. An example of an innovation is video training to improve reviewer reliability. Although research councils in the United Kingdom have conducted several relevant studies, these have mainly examined existing practices rather than testing peer review innovations. Full results of the systematic review will be provided in the presentation, and we will assess which innovations could improve the efficiency and/or effectiveness of peer review for selecting health research proposals.

CONCLUSIONS:
Despite considerable interest in, and criticism of, peer review for helping to select health research proposals, there have been few detailed systematic examinations of the primary research evidence in this area. Our evidence synthesis provides the most up-to-date overview of evidence in this important developing area, with recommendations for health research funders in their decision making.

PP022 New Models Are Needed To Optimise The Management Of New Medicines

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ABSTRACT SUMMARY:
Countries are struggling to fund new premium priced medicines with ever increasing prices. In addition, there are substantial savings as medicines lose their patents. This requires co-ordinated approaches. Models are being developed centering on three pillars: pre-launch including horizon scanning; peri-launch including Pricing and reimbursement (P & R)/ risk sharing; and post-launch including assessing effectiveness. This will continue to enable access to safe, effective and affordable medicines.

INTRODUCTION:
Countries are struggling to fund new premium priced medicines with ever increasing prices. In addition, there are substantial savings as medicines lose their patents. This requires co-ordinated approaches. Models are being developed centering on three pillars: pre-launch including horizon scanning; peri-launch including Pricing and reimbursement (P & R)/ risk sharing; and post-launch including assessing effectiveness (1,2). This will continue to enable access to safe, effective and affordable medicines.
METHODS:
Desk research of regulatory and other relevant policy documents as well as a thorough and extensive literature search in peer-reviewed databases were conducted.

RESULTS:
Models to optimise the use of new medicines are being developed. These center on three pillars: pre-launch activities including horizon scanning with a specific focus on unmet needs, drugs expected place in therapy, drugs preliminary budget impact and forecasting (including medicines likely to lose their patents); peri-launch activities including P & R assessment and assessments of risk sharing arrangements; and post-launch activities include assessing the effectiveness and safety of new medicines in routine clinical care (1,2). Pre-launch activities to agree the number of potential patients for new cancer medicines resulted in hospitals staying within budget (3); and health authorities that had instigated activities pre-launch saw limited excess bleeding with dabigatran (3). Risk-sharing arrangements have increased access to new medicines; however, concerns with their confidential nature and administrative burden (2,3). Qualitative and/or quantitative approaches are also being developed to better value (new) medicines. There is also growing use of patient level data post launch, for example, studies highlighted concerns with dabigatran prescribing in Spain and anti-obesity medicines in Sweden. Long-term follow-up studies have shown greater effectiveness of ciclosporin vs. tacrolimus for transplants despite the rhetoric.

CONCLUSIONS:
Stakeholders in the healthcare field are working together and developing methods to increase funding for new valued medicines whilst restricting their use where there are concerns to optimise resource use. This will (need to) continue to enable access to safe, (cost-) effective and affordable medicines.

REFERENCES:

PP023 Applying Oncology Patient Registries As A Health Technology Assessment Tool

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ABSTRACT SUMMARY:
Conventional, publicly available sources provide insufficient information on new drugs, especially on patient relevant outcomes in approved subpopulations. This type of information is largely available in registries. The registries approach could be used in Kazakhstan to develop a comprehensive model for health technology assessment and thus represents a key open access measure.

INTRODUCTION:
The limited health care resources have to be invested efficiently; Health Technology Assessment
(HTA) is applied ever more often in many health care systems for “rational decision-making”. The oncology patient registries (OPR) track the eligibility of patients and the complete flow of treatments, guaranteeing appropriateness in use of pharmaceutical products, according to approved indications.

**METHODS:**
Normative legal acts and other regulatory documents in the field of oncology medical and pharmaceutical activity, include content and maintenance oncology registries. The system, process and information analysis, direct observation, comparative analysis, logical modelling, sociological methods (surveys and expert opinions) are applied.

**RESULTS:**
A temporary coverage/funding of oncology drugs often requires additional collection of data on safety, effectiveness, cost-effectiveness, and the appropriate use of the drug. Many of the oncology drugs show little or marginal effectiveness at time of approval and reimbursement agencies demand further data before deciding whether to cover the new drug. Pragmatic clinical trials, patient access schemes and standard data requirements on patient relevant outcomes in OPR are some of the approaches to generate further evidence and to fill the gap between knowledge on efficacy at time of approval and demanded knowledge on effectiveness for coverage decisions. For each monitored drug, patients eligible for treatment are registered in the specific therapeutic indication dynamic monitoring database to collect epidemiologic and clinical data, including data on the safety profile, and ex-post information missing at first evaluation stage.

**CONCLUSIONS:**
OPR provide a detailed view of the morbidity, mortality and resource utilization associated with an oncologies diseases entity. This data is of prime importance in coming to decisions on coverage of a drug or treatment. The collation of information is also quick and efficient owing to better methods of data management. OPR of Kazakhstan are equipped with sophisticated data processing software and technologies.

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**PP024 Changes In Reporting Characteristics Of Systematic Reviews For The United Kingdom**

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**ABSTRACT SUMMARY:**
There have been marked improvements in the reporting and conduct of the United Kingdom (UK) Health Technology Assessment (HTA) programme systematic reviews in this comparison of reviews undertaken in 2004 and 2014.

**INTRODUCTION:**
A recent publication reported that increasing numbers of systematic reviews are being published and, although standards have improved, many are still poorly conducted and reported, especially non-Cochrane systematic reviews (1). The aim of this study was to assess the quality of the conduct and reporting of systematic reviews undertaken for the UK Health Technology Assessment (HTA) programme and published in the International Journal of Technology Assessment in Health Care (2) and compare those undertaken in 2004 and 2014.

**METHODS:**
A comparative sample of all systematic reviews published in 2004 and 2014 in the UK HTA
A monograph series was identified by a structured search of MEDLINE in August 2016. After piloting of the form, two reviewers each extracted relevant data. These data were tabulated and summarised.

RESULTS:
The search identified twenty-three systematic reviews from 2004 and thirty from 2014. By 2014, compared with 2004, a smaller proportion of treatment (53 percent vs 70 percent) and pharmaceutical (20 percent vs 57 percent) reviews were being published. In 2014, there were much higher percentages of review registrations (70 percent vs 0 percent) and available protocols (90 percent vs 17 percent); increased explicit inclusion of unpublished literature (65 percent vs 39 percent); less frequent use of local checklists (32 percent vs 61 percent) for critical appraisal; more complete reporting of study flow for inclusion (97 percent vs 57 percent) and exclusion (91 percent and 65 percent) of studies; and there were more reviews reporting limitations affecting the review itself (73 percent vs 49 percent). The process had clearly become more reflective and rigorous. However, some previous weaknesses persisted, including the general absence of any assessment of publication bias and the failure to report overall numbers of patients in the review.

CONCLUSIONS:
Marked improvements can be seen in the conduct and reporting of systematic reviews published by the UK HTA programme as a result of the publication and general acceptance of the PRISMA statement (3) and the increased application of a smaller number of relevant standards.

REFERENCES:

PP025 Thrombopoietin Receptor Agonist For Treatment Of Adults With Chronic ITP

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ABSTRACT SUMMARY:
To assess the difference of the reimbursement between Taiwan and other countries for the treatment of adult chronic spontaneous thrombocytopenic purpura (ITP), and to examine the cost-effectiveness of Thrombopoietin (TPO) receptor agonist in the long-term treatment of adult chronic ITP, in comparison with current medical practice in the context of Taiwan.

INTRODUCTION:
This study aims to report the clinical effectiveness and cost-effectiveness of Thrombopoietin (TPO) receptor agonist for the treatment of adults with spontaneous Immune Thrombocytopenic Purpura (ITP) in Taiwan.

METHODS:
In the clinical effectiveness evaluation section, particularly for the TPO receptor agonist, we searched PubMed, EMBASE, and the Cochrane
Central Register of Controlled Trials to identify all randomized trials in chronic ITP. In the economic evaluation section, we performed a long-term cost-effectiveness analysis using a Markov model to evaluate the value of TPO receptor agonist to achieve durable platelet response for chronic ITP patients.

RESULTS:
Our findings revealed that the National Health Insurance (NHI) in Taiwan covers TPO receptor agonists romiplostim and eltrombopag, which have also been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) of Australia and the National Institute for Health and Care Excellence (NICE) in the UK. In addition, a systematic review and meta-analysis combining six trials were included to assess the current evidence on the role of TPO receptor agonist in chronic ITP. The primary outcome of randomized controlled trials (RCTs) showed an improving trend in significant bleeding events; however, there was not any significant difference between the TPO receptor agonists group and the control group (placebo). The gain in life years and quality-adjusted life-years (QALYs) from introducing long-term use of TPO receptor agonists over current clinical practice were 1.52 years and 1.44 QALYs, respectively. Most of the sensitivity analysis results show that the ICER values were greater than 3GDP per capita in Taiwan.

CONCLUSIONS:
Compared to placebo, and despite a significantly increased platelet response, there was no evidence to demonstrate that TPO receptor agonists did improve significant bleeding events in chronic ITP. The effect on overall survival awaits further analysis. Although long-term studies are lacking, current data demonstrated that adverse effects of TPO receptor agonists were similar to that of placebo.

PP026 Effects On Decision Making Of Health Technology Assessment Reports: SAGEM Examples

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ABSTRACT SUMMARY:
This study reveals the effects of Health Technology Assessment (HTA) reports published by the Turkish MoH-SAGEM on decision making processes in health care. In the study has been carried out based on four HTA reports of SAGEM, literature review and changes of regulations or practices. Expert reviews have also been included as some authors are SAGEM staff responsible for HTA practices.

INTRODUCTION:
Health Technology Assessment (HTA) provides evidence based information support to policy makers in relation to clinical efficiency, safety, social and ethical aspects of medicines, medical devices and health systems by making comparisons with broad aspects (1).

Health care related expenditures are on the rise in Turkey as it is the case for the rest of the world. It is highly crucial to control these expenditures to deliver efficient and effective health care as well as to ensure the sustainability of these services. Using health technology assessment methods has been gradually become more important in the process of health policy development and to assess the cost effectiveness of health related interventions. On the other hand, HTA reports can also provide valuable inputs and support at all level of decision making processes in health care services.
This study reveals the possible effects of health technology assessment reports published by the Turkish Ministry of Health-General Directorate for Health Researches (MoH-SAGEM) on decision making processes in health care services by using abovementioned assumptions.

METHODS:
In this study, firstly, literature review about decision making process in health care system has been made. And the impacts on the regulations/practices of following four HTA reports published by SAGEM have examined. Then, expert reviews and observations have also been included as some authors are MoH-SAGEM' staff who are responsible for HTA practices.

RESULTS:
When the impacts of four HTA reports have examined:

• The suggestions contained in the full HTA report, only the recommendation on the amount and type of reimbursement was put into practice.

• The suggestions contained in the other three short HTA reports have been put into practice to a large extent.

CONCLUSIONS:
The use of HTA in the Turkish health care system in relation to the decision-making process is a relatively new concept. Encouragement of HTA studies by decision makers and further consideration of the recommendations in the HTA reports will have a positive impact on the sustainability of the health care system.

REFERENCES:


PP028 Hyperhidrosis Quality Of Life Measures: Review And Patient Perspective

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ABSTRACT SUMMARY:
Primary hyperhidrosis can significantly affect quality of life, and can lead to social embarrassment, loneliness, anxiety and depression. This literature review included 184 studies and identified numerous tools used to measure quality of life in studies of hyperhidrosis. The most commonly used were Dermatology Life Quality Index (DLQI), the Hyperhidrosis Disease Severity Scale (HDSS), and the Hyperhidrosis Quality of Life Questionnaire (HQLQ) but the recently developed Hyperhidrosis Quality of Life index (HidroQoL©) looks promising.
INTRODUCTION:
Primary hyperhidrosis has no discernible cause and is characterised by uncontrollable excessive and unpredictable sweating, which occurs at rest, regardless of temperature. The symptoms of hyperhidrosis can significantly affect quality of life, and can lead to social embarrassment, loneliness, anxiety and depression.

The aim of this literature review was to identify the tools used to measure quality of life in studies of hyperhidrosis. Patient advisors provided insight and their perspective.

METHODS:
Studies were identified through searches undertaken in January 2016. The search strategies combined topic terms for hyperhidrosis with a recognised search filter for “quality of life”. All studies that reported measuring quality of life or described a quality of life measure/tool in the context of primary hyperhidrosis were included. The information on the tools and their use in hyperhidrosis was summarised in a narrative synthesis. Patient advisors contributed to the interpretation of the findings.

RESULTS:
The review included 184 studies and many studies used multiple tools. Twenty-two individual tools were identified. The review identified disease specific, dermatology specific, and general health/utility tools. The most commonly identified tools were the Dermatology Life Quality Index (DLQI), the Hyperhidrosis Disease Severity Scale (HDSS), and the Hyperhidrosis Quality of Life Questionnaire (HQLQ). The Hyperhidrosis Quality of Life index (HidroQoL©) is recently designed and validated, and therefore was used only in its validation study.

When asked about these four quality of life tools patient advisors agreed that the HidroQoL© tool covered disease-specific quality of life dimensions relevant to them most comprehensively and was easy to complete. The DLQI was considered to be too general and too focussed on the skin. The HDSS was considered to be too basic and not sufficiently discriminating.

CONCLUSIONS:
Future studies of the effectiveness of interventions for hyperhidrosis on health-related quality of life may benefit from including the HidroQoL© tool.

PP029 Hospitalizations And Costs In Bipolar Disorder Patients Initiating Long-Acting Injectable Antipsychotics

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ABSTRACT SUMMARY:
Existing studies have not compared the effectiveness of different long-acting injectable antipsychotics (LAIs) in preventing hospitalizations among patients with bipolar disorder (BD). Our study findings show that aripiprazole LAI users had lower all-cause inpatient hospitalization utilization, compared to haloperidol, paliperidone, and risperidone LAI users. Among BD patients with any hospitalizations, the inpatient costs were lowest in the aripiprazole cohort.

INTRODUCTION:
Existing studies have not investigated the effectiveness of one long-acting injectable antipsychotic (LAI) versus another in preventing hospitalizations among patients with bipolar disorder (BD). This study was conducted to compare all-cause inpatient healthcare utilization
and associated costs among BD patients who
initiated LAIs.

METHODS:
This retrospective cohort analysis used the Truven Health Analytics MarketScan® Commercial and Medicaid claims database. Bipolar patients >18 years with at least one claim for one of the following LAIs were identified between 1 January 2013 and 30 June 2014 (identification period): aripiprazole, haloperidol, paliperidone, and risperidone. The first day of initiating an LAI was considered the index date. Logistic regression and generalized linear regression models were conducted to estimate risk of inpatient hospitalization and associated costs during the 1-year follow up.

RESULTS:
A total of 1,540 BD patients initiated an LAI: 14.5 percent aripiprazole, 16.3 percent risperidone, 21.0 percent haloperidol, and 48.1 percent paliperidone. With the aripiprazole cohort as the reference group, the odds of having any inpatient hospitalizations were significantly higher in haloperidol [Odds Ratio, OR (95 percent Confidence Interval, CI): 1.49 (1.01 - 2.19] and risperidone [1.78 (1.19 - 2.66)] cohorts. The paliperidone cohort also had a higher risk of having a hospitalization than aripiprazole, but the difference was not statistically significant (p>.05). Among LAI initiators having any inpatient hospitalizations, the adjusted mean all-cause inpatient costs were lowest in the aripiprazole cohort (USD26,002), followed by risperidone (USD27,937), haloperidol (USD30,411), and paliperidone (USD33,240). However, the cost difference was not statistically significant.

CONCLUSIONS:
Our study findings highlight the value of aripiprazole in reducing all-cause inpatient hospitalizations and associated costs among patients with BD during the 1-year follow-up. It is worthwhile to note that bipolar diagnoses were identified from healthcare claims coded for reimbursement purposes, thus misclassification was possible. Future studies are warranted to understand the impact of LAI use in a longer period of time.

PP030 Socioeconomics Of Cardiac Rehabilitation: A Meta-analysis

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ABSTRACT SUMMARY:
We reviewed fifty-nine literatures and identified three that matched to selection criteria. We showed significant improvements of mortality, life-year in cardiac rehabilitation (CR) arm compared with usual care arm. However, we confirmed that CR significantly not improved cost/LY (Standardized Mean Difference, SMD: 0.00; 95 percent Confidence Interval, CI: -0.17, 0.18). Therefore, we suggest short-term CR was not possibly cost-effective with current available data.

INTRODUCTION:
The Guidelines for Rehabilitation in Patients with Cardiovascular Disease recommends convalescent cardiac rehabilitation (CR) as the standard treatment for patients with ST elevation myocardial infarction (STEMI) (class I, evidence level B) (1). However, health economic evaluation of cardiac rehabilitation (CR) is limited.

METHODS:
This systematic review, meta-analysis study elucidated the cost-effectiveness of CR in the short term. The target population in this study included
convalescent and comprehensive CR patients with coronary artery disease (CAD), most with myocardial infarction (MI). We used mortality, life years (LY, expected life years), medical costs, and cost-effectiveness as the evaluation parameters in this analysis. We set medical costs in the analysis associated with testing, diagnosis, and treatment during the observation period related to CR. For cost-effectiveness analysis, we analyzed medical cost per LY. We examined the differences in effects for two comparisons (CR vs. Usual Care, UC) using the Risk Ratio (RR) and Standardized Mean Difference (SMD). We assumed the standard deviation (SD) of cost effectiveness in this study by applying the error propagation.

RESULTS:
We reviewed fifty-nine studies and identified three that matched our selection criteria. The studies had the following characteristics: two randomized clinical trials and one systematic review/meta-analysis; a control that does not include exercise in patients with CAD; an observation period longer than 1 year; adapting medical costs, LY, cost/LY, and mortality as the evaluation index. In total, 129,272 patients were included. Meta-analysis results revealed that the CR arm significantly improved LY (SMD: -.78, 95 percent Confidence Interval (CI): -1.37, -.19) compared with UC. Similar to LY, the CR arm significantly improved the mortality (SMD: .57, 95 percent CI: .22, 1.47) compared with UC arm. Since medical costs showed a high tendency (SMD: .02, 95 percent CI: -.08, .13), cost/LY demonstrated no improvement (SMD: .00; 95 percent CI: -.17, .18). Substantial statistical heterogeneity was observed between the studies with respect to LY and cost/LY.

CONCLUSIONS:
While sufficient evidence to conclude health economic efficiency is not available at present, these results suggest that CR is not potentially cost-effective in the short term.

REFERENCES:

PP031 iStent® For Open Angle Glaucoma: Standard Or Emerging Care?

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ABSTRACT SUMMARY:
The trabecular micro-bypass stent (iStent®) is gaining popularity for glaucoma treatment. The available evidence suggests that implantation of iStent® could reduce intraocular pressure and ocular hypotensive medication use in patients with mild-to-moderate open angle glaucoma. However, because of uncertainties on long-term benefits and safety, iStent® should be introduced as an emerging practice in healthcare settings.

INTRODUCTION:
Increased intraocular pressure (IOP) in open angle glaucoma (OAG) may lead to optic nerve damage due to progressive obstruction of aqueous humor drainage. Among surgery options, trabecular micro-bypass stent (iStent®) was recently introduced. This Health Technology Assessment (HTA) aimed to assess the effectiveness and safety of iStent®, combined or not with cataract surgery, in patients with mild-to-moderate OAG.
METHODS:
A systematic review (SR) was performed from 2000 to August 2016. Studies reporting data at three months or more on IOP and hypotensive medication use following iStent® implant were eligible. Governmental databases on safety issues were reviewed. The project involved an interdisciplinary group of experts.

RESULTS:
Two HTA reports, one SR, four randomized controlled trials (RCTs) and nine observational studies (OSs) were included. Compared to cataract surgery alone, implantation of iStent® combined with cataract surgery was associated with a decrease in IOP at 12 months in RCTs (-1.37 mmHg; 95 percent Confidence Interval, CI: - 2.76 to .03 mmHg, p = .055). Results from RCTs and OSs on the effect of iStent® combined or not with cataract surgery suggest also a 12-month positive effect on IOP (mean reduction: 1.5 to 9.5 mmHg) and on mean number of medications (reduction: .3 to 2.0) compared to baseline. Scattered results were found on the proportion of patients who no longer use glaucoma medications. Small sample size, short duration of follow-up, and potential conflicts of interest were among studies limitations. The most common adverse events reported were posterior capsular opacification, decrease in visual acuity, and stent obstruction or malposition.

CONCLUSIONS:
Appraisal of the effectiveness and safety suggests that iStent® implantation combined to cataract surgery in mild-to-moderate OAG is an emerging practice. Uncertainties related to clinical benefits, safety and care organization need to be clarified before an introduction as a standard of medical practice.

PP032 Holistic Patient Access Processes Of Medical Devices In South Korea

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ABSTRACT SUMMARY:
An alternative to heavily depending on premarket evidentiary requirements, transformation supporting post-market evidence generation and assessments are more ideal to solve uncertainty in early stage decision making and to supplement the early adoption of new and innovative medical devices.

INTRODUCTION:
Historically, patient access processes of new and innovative medical devices including in-vitro diagnostics are made in the sequence of regulatory approval, new Health Technology Assessment (nHTA) approval, reimbursement coverage and coding finally reaching the pricing approval stage in South Korea. Although the individual patient access process has its own distinct objective and perspective, there are still opportunities for the authorities or agencies in charge to streamline their processes by working together to promote earlier patient access of new and innovative medical devices to patients without impacting their own decision making.

METHODS:
This research examined and analyzed the current policies about: patient access processes with a holistic viewpoint, industry-wide survey about patient access practices, case studies of two
innovative medical devices for patient access in South Korea and also proposed new or alternative programs which can contribute to patient access harmonization efforts with a holistic approach.

RESULTS:
Historically, health authorities play defensive strategies by delaying the adoption of new and innovative medical devices and implementing certain periods (that is, 2 to 5 years) for a patient's out-of-pocket payment scheme. It is well illustrated with the statistic that only twenty-nine percent of new and innovative medical technologies which have successfully gone through the nHTA process were determined for reimbursement coverage in the past 7 years.

The survey by the medical device industry to determine the patient access lead-time of innovative medical devices with a holistic perspective indicated significantly delayed patient access even considerably exceeding the legally required decision-making lead time. The in-depth case studies with two innovative devices indicated the disadvantageous patient access processes to the innovator in terms of both final approval timing and the price level.

CONCLUSIONS:
The concurrent review process for reimbursement coverage decision making for medical procedures, medical devices and reimbursement coverage payment guidelines committed within the Health Insurance Review and Assessment Service shall be created. New programs to deal with uncertainty in reimbursement coverage decision making shall be considered such as coverage with evidence development, performance-based risk-sharing arrangement, multi-criteria decision analysis and economic evaluation.

PP033 Patient And Public Involvement In Health Technology Assessment: The Brazilian Experience

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ABSTRACT SUMMARY:
The patient and public involvement in Brazilian Health Technology Assessment (HTA) was institutionalized in 2011, with the law that created the National Committee for Health Technology Incorporation (CONITEC) (1). Even with the legal framework, considering the incipient culture of social participation in the country, several strategies have been improved and expanded to increase and qualify the user’s involvement.

INTRODUCTION:
The National Committee for Health Technology Incorporation (CONITEC) (1) was created in 2011, when the participation of civil society in the Health Technology Assessment (HTA) process was formalized in Brazil. According to legislation, patient and public involvement (PPI) in HTA occurs through: public consultations (PC); representation of SUS (Brazilian Public Health System) users in the plenary of CONITEC and by public hearings in relevant cases. Due the incipient culture of social participation in Brazil, strategies involving better communication, direct participation and popular education were developed to broaden and qualify this participation.
METHODS:

- Case study about PPI strategies developed in five years of CONITEC.
- Analysis of documents and official records from the Brazilian Ministry of Health.

RESULTS:

Since its creation, the innovations of CONITEC regarding PPI were: creation of specific PC form to reproduce or represent the perspectives of patients and caregivers; summarized versions of technical reports written in a simplified language to improve user’s involvement; surveys prior to elaborating clinical guidelines, a bi-weekly educational program transmitted by streaming, and the recent launch of an HTA Users Guide and a mobile app.

After the implementation of these strategies (which started in 2014), there was an increase of annual contributions, from 2,584 in 2014 to 13,619 in 2015. Most participants were patients, family members or caregivers. Surveys concerning clinical guidelines received about 3,000 contributions. There were thirty-seven published society reports until December 2016. The publication of the HTA Users Guide and other related actions increased the number of accesses to the CONITEC website and its subsection for social participation. The educational program had more than 800 online accesses in five months.

CONCLUSIONS:

These actions allowed expanding and qualifying PPI beyond what is legally defined, and it is possible to predict an increasingly favorable scenario regarding the patient and public participation in HTA in Brazil.

REFERENCES:


PP035 Systematic Review Of Diagnosis Of C. difficile Infection Using GDH

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ABSTRACT SUMMARY:

Based on the current literature review and meta analysis, Clostridium difficile glutamate dehydrogenase test (ELISA or ELFA) is a safe and effective technique to diagnose Clostridium difficile infection in patients suspected of the disease and suffering from diarrhea.

INTRODUCTION:

The Clostridium difficile Glutamate Dehydrogenase (GDH) Test is a technique to qualitatively measure the glutamate dehydrogenase antigens against Clostridium difficile infection in patients suspected of the condition, using ELISA (enzyme-linked immunosorbent assay) or ELFA (enzyme-linked fluorescent assay).

The purpose of this study is to evaluate the effectiveness of GDH ELISA/ELFA in the detection of Clostridium difficile infection.

METHODS:

For a literature review, eight domestic databases and foreign databases including Ovid-Medline, EMBASE, and Cochrane Library were used. Key words such as ‘glutamate dehydrogenase’, ‘Clostridium difficile’, and ‘Peptoclostridium difficile’ were used. Twelve documents were selected according to pre-set criteria and the quality of studies evaluated by the SIGN (Scottish Intercollegiate Guidelines Network) tool. Meta-analysis of GDH ELISA studies was performed using MedaDisc program.
Using a strategic search, a total of 452 articles were collected. Articles were excluded in case of animal experiment, preclinical experiment, not original research, not published in Korean or in English, or abstract only. After having applied the inclusion criteria to 319 articles (excluding 133 duplicated articles), 12 articles were included in the final assessment.

RESULTS:
Test accuracy of GDH ELISA was evaluated on the basis of 11 studies using cytotoxin assay and/or real time-polymerase chain reaction (PCR)/PCR for *C. difficile* toxin gene as the reference standard. GDH ELISA had sensitivity 83.6-100 percent and specificity 63-98 percent. The meta-analysis of GDH ELISA showed pooled sensitivity .93, pooled specificity .92, and summary receiver operating characteristic (SROC) area under the curve (AUC) .97. The test accuracy of GDH ELFA was sensitivity 93-95 percent and specificity 90-91.8 percent in one study, using cytotoxin assay as reference standard.

CONCLUSIONS:
Based on the current literature review, GDH ELISA and ELFA are safe and effective tests for diarrhea patient, suspected of Clostridium difficile infection.

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**PP036 Systematic Review Of Simultaneous Imaging Technology**

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**ABSTRACT SUMMARY:**
Based on the current literature review and statistic analysis, simultaneous imaging technology is a safe and effective technique to measure musculoskeletal abnormality by using low radiation imaging on the weight bearing frontal and lateral sides through biplane (EOS).

**INTRODUCTION:**
Simultaneous Imaging Technology is a technique to measure musculoskeletal abnormality by using low radiation imaging on the weight bearing frontal and lateral sides through biplane (EOS) in patients with musculoskeletal disease.

The purpose of this study is to evaluate the effectiveness of Simultaneous Imaging Technology in patients with musculoskeletal disease.

**METHODS:**
The assessment was carried out by literature search using eight national databases including KoreaMed and several international databases including Ovid-MEDLINE, Ovid-EMBASE, and Cochrane Library. Using a strategic search, a total of 982 articles were collected. Articles were excluded in case of animal experiment, preclinical experiment, not original research (abstract or review article). After having applied the inclusion criteria to 727 articles (excluding 255 duplicated articles), 13 articles were included in the final assessment.

The subcommittee and two additional reviewers independently performed each step of the Summary of Assessment including literature search, application of the inclusion criteria, evaluation of the article quality, and data extraction. The quality of the articles were evaluated using SIGN (Scottish Intercollegiate Guidelines Network), and the level of evidence and the grade of recommendation were carefully determined and documented based on the quality.

**RESULTS:**
The effectiveness of Simultaneous Imaging Technology was to be assessed by the correlation with the comparison test, consistency with the comparison test, image resolution, effects on the clinical result, and whether the bending view is
provided or not; however, there were no articles reporting effects on the clinical result or provision of the bending view.

The correlation between the comparison test and Simultaneous Imaging Technology was .107 (p=NS).

The consistency between the comparison test and Simultaneous Imaging Technology was statistically high (p<.01) with kappa (k) as .50 (correction value of .66), and the consistency was 94.98 percent.

**CONCLUSIONS:**
Simultaneous Imaging Technology is a safe and effective technique to measure musculoskeletal abnormality by using low radiation imaging on the weight bearing frontal and lateral sides through biplane.

**PP037 Quality Criteria And Good Practices In The Health Technology Assessment Spanish Network**

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**ABSTRACT SUMMARY:**
In Spain the Health Technology Assessment (HTA) agencies coordinate their work through a national network (REDETS). The necessity of considering a Quality Management System was detected and, based on a systematic review, a proposal for a self-assessment tool has been developed in order to have a baseline for a quality standardization process in every agency.

**INTRODUCTION:**
The Spanish Network of Agencies for Health Technology Assessment (REDETS) is a group of eight agencies, units and services, depending on National and Regional Governments that coordinate their work within a common methodological framework, guided by the principles of mutual recognition and cooperation. In this work, guided by the necessity of implementing a Quality Management System, we present the process to achieve this objective.

**METHODS:**
As an initial step, a review was carried out based on a structured search strategy in the main electronic databases Medline and EMBASE, and a manual search in websites of national and international agencies (March 2016) in order to collate previous knowledge and experiences. Through the information included in this review, a proposal to create a quality, self-evaluating tool is necessary.

**RESULTS:**
In total, 800 references were found and finally 6 studies were included in the review (1-3). All had a similar structure. Some lists of good practices, classified in dimensions related to different quality aspects in Health Technology Assessment (HTA) organizations, were found. Also, some information about questions for evaluating quality standards was indicated. Taking all this information, a proposal of 66 standard titles was put forward. These standards were then grouped into twelve quality criteria structured in four dimensions: I Responsibility, II Clients and Stakeholders, III Production Process and IV Resources.

**CONCLUSIONS:**
Based on the systematic review, we developed a proposal for a self-evaluating tool and this is the baseline for a common Quality Management System for the Spanish Network of HTA Agencies. The quality management process will require the development of a handbook by each member of REDETS that will be based on agreed quality standards.
REFERENCES:

PP038 EQ-5D-3L Electronic Version Development For The Brazilian Population

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ABSTRACT SUMMARY:
The EuroQol - 5 dimensions (EQ-5D) electronic version is a reliable and accurate method of utility estimation for the Brazilian population.

INTRODUCTION:
Quality of Life (QoL) is considered to be an important outcome which is widely used in Health Technology Assessment (HTA). In economic evaluations QoL is represented by quality-adjusted life years (QALYs) - adding utility scores to the years of life lived in a determined health status (1). The EuroQol - 5 dimensions (EQ-5D) is a QoL questionnaire that generates utility scores and provides a simple and generic measure of health (2). Electronic QoL instruments have been reported equivalent to paper-based methods, however no studies have assessed agreement between EQ-5D application methods in Brazil (3). Thus, our study aimed to evaluate the measurement equivalence between the original (paper) and adapted (tablet) versions of the EQ-5D-3L Brazilian questionnaire.

METHODS:
A cross-sectional study was conducted on 509 adult individuals selected at random in economically different regions of two major Brazilian cities. EQ-5D-3L and Visual Analogue Scale, paper and tablet versions, were applied. Subjects were randomized to two groups; one group assigned for test-retest assessment using only electronic media (tablet-tablet), and a crossover group - half of which answered the tablet version before the paper questionnaire (tablet-paper), and the other half which answered the tablet version after the paper questionnaire (paper-tablet). There was a washout period of a minimum of 24 hours and maximum of 7 days between applications. The Intraclass Correlation Coefficient (ICC) and kappa coefficient were used to determine the agreement between methods. The level of significance was set at .05 for all analyses.

RESULTS:
Females predominated in all groups, and the mean age ranged from 41 to 44 years. In the crossover group the obtained ICC values were: .76 (CI .58-.89) for EQ-5D scores and .77 (CI .68-.84) for Visual Analogue Scale (VAS) scores in the tablet-paper subjects; .83 (CI .75-.89) for EQ-5D scores and .75 (CI .67-.85) for VAS scores in the paper-tablet subjects. In the test-retest group, the ICC values were .85 (CI .73-.91) for EQ-5D scores, .79 (CI .66-.87) for VAS scores. Kappa values were higher than .69 in test-retest group. Internal consistency was similar between methods.
CONCLUSIONS:
Paper and tablet versions of the EQ-5D were equivalent. Test-retest and crossover agreement was high and the acceptability of the methods was similar.

REFERENCES:

PP039 Health Utility Values in Renal Cell Carcinoma: A Systematic Review

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ABSTRACT SUMMARY:
A systematic literature search (2006–2016) was conducted to elucidate available evidence on health state utility values in patients with previously treated advanced or metastatic renal cell carcinoma (RCC). Health-state utilities were assessed for specific treatments, at different time points and across different health states. Identified evidence confirms there is significant detriment to patients health-related utility in this indication.

INTRODUCTION:
Advanced or metastatic renal cell carcinoma (RCC) is associated with poor health outcomes; in particular in those whose disease progressed after first line treatment. A literature review was conducted to elucidate evidence on health-related utility associated with advanced and metastatic RCC.

METHODS:
A systematic literature search from 2006 onwards (date of search: July 2016) was conducted for studies evaluating health-related quality of life (QoL) and utility outcomes. Searches included Medline, Embase, National Health Service (NHS) Economic Evaluation Database and HTA Database and were supplemented by free internet search for key European Health Technology Assessment reports. Publications were limited to 2006 onwards as previous research (1) revealed no prior relevant evidence.

RESULTS:
The search yielded 4,178 records. The selection process revealed seventy-eight relevant publications. Generic EuroQol (EQ)-5D scale was most commonly used. Health-state utilities were assessed for specific treatments and at different time points. Mean reported value for patients after failure of one prior systemic therapy ranged from .79 - .62. For patients without progression (on and off-treatment) reported utility values were in range from .80 – .63. Utility in stable patients with adverse events ranged from .71 - .47. For patients with progressive diseases, utility was reported from .71 - .36. Utility for interventions due to skeletal-related events in patients with bone metastasis was reported to range between .46 and .15.
**CONCLUSIONS:**

Identified evidence confirms advanced or metastatic RCC leads to significant detriment to patients health-related utility. Further research efforts are warranted to assess health-state utility beyond clinical trial assessment.

**REFERENCES:**


**INTRODUCTION:**

Existing findings on effectiveness of long-acting injectable antipsychotics (LAIs) versus oral antipsychotics in preventing hospitalizations are inconclusive. This study was conducted to compare hospitalization costs between Medicaid patients diagnosed with schizophrenia who initiated a LAI and those who changed from one oral antipsychotic to another.

**METHODS:**

This retrospective cohort analysis used the Truven Health Analytics MarketScan® Medicaid claims database to study patients >18 years with schizophrenia. The two cohorts were: “LAI”, defined as initiating LAI (no prior LAI therapy) between 1 January 2013 and 30 June 2014; and “oral”, defined as changing from one oral antipsychotic to another during the same period. The first day of LAI or the new oral antipsychotic was the index date. A linear regression model was conducted to estimate hospitalization costs.

**RESULTS:**

The final sample included 2,861 (36.7 percent) LAI and 4,926 (63.3 percent) oral users. Compared to oral users, LAI patients were younger (mean [Standard Deviation, SD]: 39.9 (13.2) vs. 42.7 (13.1); p<.001) and had a lower mean Charlson Comorbidity Index score (mean (SD): 1.1 (1.9) vs. 1.7 (2.3); p<.001). Of the 877 LAI initiators and 1,688 oral users who were hospitalized during the 1-year post-index follow-up period, the unadjusted mean hospitalization costs for LAI and oral users were USD32,626 and USD36,048, respectively. After adjusting for patient demographic and clinical characteristics, baseline medication use, and baseline ED or hospitalizations, the adjusted average hospitalization costs were USD1,170 lower in LAI initiators than oral users. None of the unadjusted or adjusted differences were statistically significant.

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**PP040 Hospitalization Costs In Schizophrenia: Long-Acting Injectable Antipsychotics Versus Oral Antipsychotic Use**

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**ABSTRACT SUMMARY:**

Existing findings on effectiveness of long-acting injectable antipsychotics (LAIs) versus oral antipsychotics in preventing hospitalizations are inconclusive. In this real-world study, we found that among hospitalized patients, hospitalization costs are lower in LAI initiators than in oral antipsychotic users, although the difference is not statistically significant. Future studies are warranted to confirm the results in non-Medicaid patient populations.
CONCLUSIONS:
This real-world study suggests that among hospitalized patients, hospitalization costs are lower in LAI initiators than in oral antipsychotic users, although the difference is not statistically significant. Our study is limited as our results are reflective of a multi-state Medicaid population. Future studies are warranted to confirm the results in non-Medicaid patient populations.

PP041 Universal Coverage Through Innovative Telediagnosis Technology

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ABSTRACT SUMMARY:
Through technological innovations based on information and communication technologies (ICT), advantageous telediagnostic systems can be developed to facilitate the universal coverage of diagnostic services, promote efficient use of available resources and improve the health care of remote populations that do not have access to specialist doctors.

INTRODUCTION:
Through technological innovations based on information and communication technologies (ICT), advantageous telediagnostic systems can be developed to improve the health care of remote populations (1). In the context of universal coverage and the efficient use of available resources, there is a favorable opportunity to develop telemedicine towards an integrated ecosystem to improve health care in remote locations without access to specialists. This study, performed by the Telemedicine Unit (MoH) in collaboration with the Biomedical Engineering Dept (IICS-UNA) and the Basque Country University (UPV/EHU) evaluated a telediagnostic system implemented in 2014 in public health. The results of a cost utility analysis for this telediagnosis project in remote, regional and district hospitals in Paraguay are presented.

METHODS:
This is a prospective study, where the results of using telediagnosis implemented in remote hospitals over three years 2014-16 were evaluated. For these purposes, a utility analysis was carried out by comparing the cost of performing telediagnosis versus performing it “face to face” in a diagnosis center in the capital city.

RESULTS:
During the study 182,406 remote diagnoses were performed in the fifty-four remote hospitals using the telediagnosis tool. Of the total, 37.3 percent (68,085) corresponded to tomography (CT), 62.0 percent (113,059) to electrocardiography (ECG), 0.68 percent (1,243) to electroencephalography (EEG) and 0.01 percent (19) to ultrasound studies. The average cost of a tele-tomography, tele-ECG and tele-ultrasound was USD2.6, and USD8.6 for tele-EEG, respectively. The cost reduction through the telediagnosis was 26.4 times for tomography, 4.5 times for ECG, 8.0 times for EEG and 8.3 times for ultrasound. The cost utility analysis performed demonstrates an economic benefit of USD12.9 million to the citizens of the fifty-four communities included in this project.

CONCLUSIONS:
Despite the potential benefit of the telediagnosis (2) to facilitate the universal coverage, and optimize the use of scarce human and health financial resources shown in this study, other important aspects such as acceptance of the technology,
patient satisfaction and a widespread use-assessment should be analysed (3) before a large diffusion.

REFERENCES:

INTRODUCTION:
The Changi General Hospital (CGH) carries out viscosupplementation for patients with knee osteoarthritis through intra-articular hyaluronic acid injections, using Synvisc or Synvisc-One (containing hylan G-F 20). Some patients on Synvisc are susceptible to flare or pseudoseptic reaction on repeated therapy. It was proposed to procure Synolix V-A intra-articular injection as an alternative for these patients.

METHODS:
A rapid health technology assessment was carried out on the following PICO elements: Population - Patients with knee osteoarthritis, Intervention - Synolix V-A, Comparator - Synvisc, Outcomes - Risk of flare reaction/pseudoseptic arthritis.

RESULTS:
No publications reporting on flare/pseudoseptic reactions with Synolix V-A were found. There are limited case series of patients treated with Synolix V-A, with most evidence coming from a prospective post-marketing surveillance case series, which showed reduced pain and functional impairment at 6 months. Adverse reactions were rare. CGH's own small trial of Synolix V-A did not show any flare reactions.

In contrast, flare/pseudoseptic reactions with Synvisc are an established phenomenon. A systematic review of randomised controlled trials documented one flare reaction among 381 patients (0.26 percent) in Synvisc compared to none in patients receiving other hyaluronan products. Small case series of patients on Synvisc showed incidences of flare reaction of 21 percent (in repeat treatment) to 27 percent. CGH's own experience is that flare occurs in 4.7 percent of patients on Synvisc.
CONCLUSIONS:
It is reasonable for the hospital to stock an alternative for patients who show repeated flare reactions to Synvisc. The limited evidence base is not a barrier to using Synolis V-A as an alternative, given the local experience.

PP043 Medical Devices Under The New European Rule: Risks And Opportunities

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ABSTRACT SUMMARY:
During the past years, numerous serious health risks initiated by implanted medical devices unsettled both physicians and patients, and forced the European Commission to revise the Medical Device Directives (MDD), which come into effect during this year. To analyze the potential consequences of this new rule for the various stakeholders, a SWOT analysis has been performed.

INTRODUCTION:
Medical devices (MDs) are used to improve quality of life or to save lives of patients. To protect patients from threats caused by MDs and to safeguard the intended performance, devices must comply with the EU directives and be CE marked before entering the European market. Despite these high demands, during the past years numerous serious health risks initiated by implanted medical devices unsettled both physicians and patients, and forced the European Commission to revise the Medical Device Directives (MDD). Because of the new MDD, stakeholders (that is, manufacturers, regulatory bodies, physicians, patients) will be confronted with various changes. The aim of this work was to assess the strategic consequences of upcoming changes.

METHODS:
Based on high-risk medical devices, the direct and indirect consequences for stakeholders due to the new MDD has been assessed by a SWOT (strengths, weaknesses, opportunities, and threats) analysis.

RESULTS:
The SWOT analysis identified potentially direct consequences as well as effects, which will appear later. The direct impact due the implementation of the new MDD may result in increased workload and higher product development costs for manufactures, but also in an improved product safety for patients, higher quality of medical evidence to the attention of regulatory bodies and physicians. The secondary consequences of the implementation of the new MDD may result in for example, a decline of new and innovative products for diseases with a low prevalence or a reduction of small and mid-size manufacturers of MDs.

CONCLUSIONS:
Overall, the implementation of the new MDD results in benefits for each stakeholder. Nevertheless, an extended regulation may also cause unfavorable consequences. Even though the implementation of the new rule will take some time, it is important that society anticipate hidden consequences as early as possible. Therefore, the findings of the SWOT analysis may be further used to develop strategic recommendations for action.
**PP044 Adherence To Enzyme Replacement Therapy In Gaucher Disease**

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**ABSTRACT SUMMARY:**
Gaucher disease is a genetic disorder treated with enzyme replacement therapy at a high cost granted by the Brazilian Ministry of Health. Patients should follow the Brazilian clinical practice guideline for diagnosis and treatment and are asked to attend the infusions twice a month. Adherence has never been studied in that group of patients in Brazil.

**INTRODUCTION:**
Gaucher disease (GD) is a genetic autosomic disorder for which treatment has been funded by the Brazilian government since the 1990s. In our state, most patients are treated with enzyme replacement therapy (ERT) and followed by our Reference Center under the recommendation of the Ministry of Health Brazilian guidelines. There is a lack in the literature about adherence of patients to treatment. The objective was to describe adherence to the treatment in a cohort of all GD patients in the southern state of Brazil.

**METHODS:**
This was a cohort study of all GD patients treated with velaglucerase α, taliglucerase α and imiglucerase from January 2010 to January 2015.

Adherence was measured as recommended by the Brazilian guidelines as to perform more than 50 percent of the anticipated infusions per year.

**RESULTS:**
Our study included thirty-seven patients of both genders. Doses of ERT varied from 15 to 45IU/kg for type 1 patients and from 30 to 60 IU/kg for type 3 patients. A mean of 83 percent of anticipated infusions were performed and from all patients only one did not adhere to the treatment during the 5 years of our study. The majority of the patients performed at least 50 percent of all anticipated infusions.

**CONCLUSIONS:**
We noted a very high rate of adherence to treatment with a very few adverse effects. Our data might be showing that the very high rate of adherence in these chronic disease patients may be attributed to the value of treatment by patients and their family, and also due to the existence of a multidisciplinary team at the reference center. These data might be useful for public health policy making in other countries.

**PP045 From Health Technology Assessment Data To National Health Care Service Basket In Finland**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
Recommendations of the Council for choices are based on three principles: effectiveness, safety and ethical acceptability, and financial sustainability as
The presentation describes the acquisition and application of Health Technology Assessment information to the cases that the Council is dealing with. Foreign data on effectiveness and safety is more applicable to national decision making than the ethical and economic data.

**INTRODUCTION:**
The Council for Choices in Health Care in Finland was founded in 2014 to further develop definitions, principles, and criteria for the service basket of publicly funded healthcare services. It’s independent, but affiliated to the Ministry of Social Affairs and Health. The recommendations of the Council are based on three main principles derived from the Finnish legislation: effectiveness, safety and ethical acceptability, and financial sustainability as a whole. The application of the principles requires that the Council has access to evidence-based information collected, for example, by using Health Technology Assessment (HTA) process.

Foreign data on effectiveness and safety is more applicable to national decision making, while the ethical and economic evaluation has to be based on national values and circumstances.

The presentation describes the acquisition and application of HTA information to the cases that the Council is dealing with.

As an example of how to use HTA data in the prioritization process, the case of arthroscopy in the care of a degenerative knee is described.

The national HTA unit was asked to make a systematic literature overview on effectiveness and disadvantages of the intervention. On the basis of all the information received, the Council made a recommendation that using arthroscopy in the care of a degenerative knee does not belong to the Finnish publicly funded healthcare service range, except in the case of treatment of acute knee injury or knee lock.

**METHODS:**
This is a non-scientific description of the development work that is currently going on.

**RESULTS:**
See above: this is a non-scientific description of the how to use HTA-data in the process on prioritization in health care.

**CONCLUSIONS:**
For the implementation of the recommendations, a strong commitment of healthcare organizers and clinical decision makers is needed. The principles act as a mechanism for steering which services will be provided for the inhabitants by public funding. To achieve a knowledge-based, transparent, and reliable prioritization process, HTA knowledge is also needed.

**PP046 Screening In Women Vaccinated Against Human Papillomavirus: Governing Innovation**

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**ABSTRACT SUMMARY:**
Evidence-based cervical screening strategies for Human papillomavirus (HPV) vaccinated girls are needed: a consensus conference followed by an implementation plan has been conducted in Italy. The main changes in recommendations for girls vaccinated in their 12th year are: HPV as a
primary screening test to start screening at age 30. Research is needed to determine the best interval for re-screening those HPV negative.

**INTRODUCTION:**

In Italy, the cohorts of women who were offered Human papillomavirus (HPV) vaccination in 2007/08 will reach the age for cervical cancer (CC) screening from 2017. According to the National Prevention Plan 2014-18, HPV-based screening must be implemented for women ≥30 years old, following the Italian Health Technology Assessment (HTA) report recommendations (1). The simultaneous shift from cytology-based screening to HPV test-based screening gives the opportunity for unprecedented reorganisation of CC prevention.

**METHODS:**

The National Screening Monitoring Centre and the Italian Group for Cervical Screening, following a commitment by the Italian Ministry of Health (MoH), identified the consensus conference as the most suitable method for addressing this topic. The objective was defining the best screening methods in girls vaccinated against HPV and the knowledge needs for defining evidence-based screening strategies. During the consensus celebration (24 November 2015) a jury made recommendations about questions and proposals formulated by a panel of experts representative of Italian scientific societies involved in CC prevention and based on systematic reviews (2).

**RESULTS:**

The jury considered changing the screening protocols for girls vaccinated in their 12th year as appropriate. Tailored screening protocols based on vaccination status could be replaced by “one size fits all” protocols only when a herd immunity effect has been reached. Vaccinated women should start screening at age 30, instead of 25, with the HPV test. Furthermore, there is a strong rationale for applying longer intervals for re-screening HPV negative women than the currently recommended 5 years, but research is needed to determine the optimal screening time points. For non-vaccinated women and for women vaccinated in their 15th year or later, the current protocol should be kept.

**CONCLUSIONS:**

As further action, in 2016 the MoH funded a Health Technology Assessment program of new the screening protocol proposed by the consensus conference and a cohort study for determining a safe interval in vaccinated women.

**REFERENCES:**


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**PP047 Intravenous Iron Sucrose Therapy In Real-World Anemic Patients**

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ABSTRACT SUMMARY:
We report real-world data about the effectiveness and health resource utilization in anemic patients treated with intravenous (IV) iron sucrose in the hospital setting. Blood transfusions were associated with significantly longer length of stay, higher readmission rate and increased risk of in-hospital death.

INTRODUCTION:
Anemia is a major problem, frequently resulting from iron deficiency (1). Guidelines recommend the administration of intravenous (IV) iron, leaving blood transfusions for critical patients due to the potential impact in length of stay (LOS) and mortality (2,3). We aimed to characterize IV iron sucrose utilization and health resource utilization in anemic patients.

METHODS:
This is a retrospective ongoing cohort study. Patient records from a general Portuguese Hospital with an administration of iron sucrose in 2014-2015 were reviewed. Adult anemic patients with at least one hemoglobin (Hb) evaluation before and after the administration of IV iron were included. Endpoints assessed were: Hb level (baseline, 4 and 8 weeks after), anemia correction rate at weeks 4 and 8, blood transfusions, length of stay (LOS), rate of readmissions (<30 days) and inpatient mortality. Statistical analysis included non-parametric and chi-square tests to assess differences between groups and a logistic regression model, using a 5 percent significance level.

RESULTS:
Data was collected for 401 patients (63.1 percent female; mean age Standard Deviation, SD: 62.6 (21.7) years) and 431 IV iron sucrose administration episodes. Mean cumulative iron dose was 679.5 mg. Baseline Hb level was 84.5 g/l and increased to 94.3 g/l (week 4) and to 103.0 g/l (week 8). Blood transfusions were performed in 53.8 percent of the episodes. Overall 157 (36.4 percent) episodes had a >20 g/l increase in Hb level. Blood transfusions were associated with a higher proportion of Hb level increase >20 g/l (44.0 percent vs. 27.9 percent, p<.001). The overall mean LOS was 15.3 days, although episodes with transfusions had a significantly longer duration (17.5 days vs. 12.7 days; p<.001). Overall readmission rate was 25.8 percent, with a higher proportion in episodes with blood transfusions (29.3 percent vs. 21.6 percent). A total of 36 patients (9.0 percent) died at the hospital before discharge. Transfusions performed during or after IV iron administration increased 3.1 times the risk of in-hospital death (95 percent Confidence Interval, CI: 1.3-7.0; p=.008), after adjusting for age and sex.

CONCLUSIONS:
We observed a high rate of blood transfusions in this cohort treated with intravenous iron sucrose for anemia. Transfusions were associated with substantial burden of resource consumption and in-hospital mortality.

REFERENCES:
PP048 Quality Of Health Care Through The Integration: Experience Of Cochlear Implantation

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ABSTRACT SUMMARY:
A comprehensive assessment of ongoing government programs makes it possible to ensure their effectiveness. However, it requires the integration of all services. The result of the fragmentation of services was a lack of comprehensive evaluation.

INTRODUCTION:
The State Program for Health Development of the Republic of Kazakhstan (RK) “Densaulyk” for 2016-2019 initiated the modernization of primary health care with the introduction of family practice in order to ensure the availability, completeness and quality of health services on the basis of an integrated healthcare system focused on the needs of the population. The aim of this study was to determine the effectiveness of the cochlear implantation (CI) programs.

METHODS:
A literature search was conducted for all clinical trials, randomized controlled trials (RCTs), and reviews in the PubMed, Cochrane, and Center for Reviews and Dissemination databases. Two reviewers independently evaluated all publications for selection. The analysis included the cost-effectiveness and benefit from the CI program.

RESULTS:
We analyzed the effectiveness of the services for CI in the RK and other countries (1). In our analysis, we identified that there is no research on Quality-adjusted Life Years (QALYs) and Cost-Utility Analysis (CUA) in RK. We found that, in general, the cost of CI and pre-surgical procedures are comparable with other countries. The length of stay in Kazakhstan was much higher (an average of 8 days) compared with other countries (3 days). Also in RK, there were significantly lower prices per hospital day and cost of various consultations. Postoperative costs of other countries consisted of one-third to two-thirds of the total costs for preoperative and implantation stages (2, 3). There was a little information on the effectiveness of rehabilitation programs in RK.

CONCLUSIONS:
Economic research like QALYs and CUA are new directions in the healthcare system in the RK. Lack of integration between primary care, rehabilitation and other services leads to difficulties in assessing the effectiveness of CI programs (for example, in our case, there was the restriction of assessment in only postoperative costs).

REFERENCES:
PP049 Exploring The Utility Of A Validated Quality Appraisal Tool

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ABSTRACT SUMMARY:
This presentation aims to introduce the Institute of Health Economics quality appraisal tool for case series studies, summarize user experiences, outline potential challenges, and provide practical solutions for using or adapting the checklist to various Health Technology Assessment (HTA) topics.

INTRODUCTION:
The Health Technology Assessment (HTA) researchers at the Institute of Health Economics, in collaboration with researchers from two HTA agencies in Australia and Spain, developed, piloted, and validated a 20-criteria quality appraisal checklist specific for case series studies (before-after single arm studies with no control group) (1 - 3). Since its publication in 2012, the use of the checklist has spread globally through the HTA community and to researchers in other areas. This presentation will briefly introduce the tool, summarize user experiences, outline potential challenges, and provide practical solutions for using or adapting the checklist to various HTA topics.

METHODS:
Feedback from fifteen researchers was collected informally by email and/or formally by questionnaire. The questions included focused on the relevance, clarity, and usefulness of the checklist and its instructions, as well as potential revisions and/or addition of other criteria.

RESULTS:
While some of the checklist's criteria apply to all studies of a particular type, others are specific to the research question and/or the technology under investigation; discussion on the modification and/or adaptation of the checklist and its instructions is therefore required before commencing appraisal. Some criteria are difficult to score owing to study reporting limitations. Quality assessment can be challenging when multiple types of studies are included; however, currently there is no single universally validated tool available for diverse study designs. There are frequent demands for a cut-off point in order to separate high- from low-quality studies. However, no scale or numeric scoring was developed for the checklist, due to the well-recognized risks associated with such a scoring system.

CONCLUSIONS:
The increased use of the checklist and general positive feedback indicates the need for such a tool. User feedback helped improve our understanding of the checklist's applicability with various topics, as well as the potential refinements needed to increase its utility and robustness.

REFERENCES:


**PP050 Analysis Of Pharmacoeconomic Studies Published In The Scientific Electronic Library “eLIBRARY.RU” (RSCI)”**

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**ABSTRACT SUMMARY:**
To assess the level of development of pharmacoeconomics in the Russian Federation as a branch of science, analysis of pharmacoeconomic and clinical economic studies published in the scientific electronic library “eLIBRARY.RU” (RSCI) for the period from 2005 through 2015 was performed.

**INTRODUCTION:**
During the information search revealed that there is no published analysis reflecting the actual status of pharmacoeconomic and clinical-economic research, but there are databases that allow you to do so. The platform for searching research data was scientific electronic library “eLIBRARY.RU”. This portal is Russia’s largest internet library of scientific publications, with rich search capabilities and the timely receipt of necessary information.

**METHODS:**
A search was carried out during the period from 2005 to 2015 of research papers on Russian and foreign pharmacoeconomic and clinical-economic research was carried out as at 1 September 2016 on the words “pharmacoeconomic*”, “clinical and econom*” with the appropriate endings. The criteria for inclusion in this analysis were general accessibility and availability of full text scientific material on the portal.

**RESULTS:**
Over the last 10 years the number of publications in increased by four times. The leading destinations included cardiovascular, pulmonary, oncological and endocrinologial diseases. According to published reports pharmacoeconomic and clinical-economic studies carried out in fifty-two subjects of the Russian Federation on the basis of sixty-three Universities. In addition to researchers from the Russian Federation, has placed the representatives from eleven countries. Only one third of the published studies are generally cited. Among the methods of pharmacoeconomic analysis of the most popular in published studies is the analysis of “cost–effectiveness”, which is used in about 45 percent of the available studies.

**CONCLUSIONS:**
As a result, 1,425 articles were identified and analyzed. With the aim of providing concrete data that clearly illustrate the situation with the Russian scientific, pharmacoeconomic and clinical-economic writings to date all studies were classified according to the following parameters: geographical, temporary, local and nosological. In the framework of the analysis highlighted the authors whose works are most RISC (Russian Science Citation Index) with leading positions in the number of publications.

**PP051 Cost-Effectiveness Of Vedolizumab Compared With anti-TNF-α Therapies**

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ABSTRACT SUMMARY:
Ulcerative Colitis (UC) is a chronic, relapsing, Inflammatory Bowel Disease affecting the colon and the rectum. Before the introduction of vedolizumab, a gut-selective anti-integrin antibody that works by inhibiting leukocyte migration into gut mucosa, recently approved in Italy, anti-tumour necrosis factor alpha therapies were the only biologics available in Italy to treat patients with moderately to severely active UC.

INTRODUCTION:
Ulcerative Colitis (UC) is a chronic, relapsing, Inflammatory Bowel Disease (IBD) affecting the colon and the rectum.

The aim of this analysis is to assess the cost-effectiveness of vedolizumab versus anti-TNF-α therapies for the treatment of anti-TNF-α naïve patients with moderately-severely active UC from the Italian National Health Service perspective.

METHODS:
A Markov model was developed assuming a 10-year time-horizon. Patients enter the model in the induction phase (decision tree): those responding to the biologic therapy may either continue on their current biologic treatment up to 1 year (maintenance phase - Markov model) or discontinue the biologic therapy (due to adverse events). Patients discontinuing switch to the conventional therapy and are assumed to continue receiving it until the end of the model’s time horizon or until patients transition to the surgery health state or death. Only direct medical costs (1) were included. Health outcomes were expressed in terms of Quality-adjusted life years (QALYs) (2,3). Efficacy data were expressed in terms of response and remission rates. When appropriate, the Incremental Cost-effectiveness Ratio (ICER) was calculated. A one-way and multi-way sensitivity analyses were performed in order to assess the robustness of the results obtained.

RESULTS:
Vedolizumab showed the highest QALY gain across all the biologic therapies (5,913 QALY), achieving an increment of .080; .080; .138 and 0.108 QALYs versus infliximab originator, infliximab mix 65 percent originator and 35 percent biosimilar, adalimumab and golimumab respectively and allowed to reduce the resources consumed per patient by EUR4,328; EUR3,074; and EUR1,853 compared to infliximab originator, infliximab mix 65 percent originator and 35 percent biosimilar, and golimumab respectively. Compared with adalimumab, vedolizumab led to a minor incremental cost of EUR2,094. The comparison versus adalimumab led to an ICER of EUR15,177. Thus, vedolizumab appears to be dominant versus infliximab and golimumab and cost-effective versus adalimumab.

CONCLUSIONS:
Vedolizumab, employed as a first-line treatment for the management of patients with UC, could potentially be both cost-saving and cost-effective versus anti-TNF-α.

REFERENCES:
1. Tariffario Nazionale delle prestazioni di assistenza ospedaliera (2013); Tariffario nazionale delle prestazioni di assistenza specialistica Ambulatoriale (2011 e ss.).
PP052 Hospital-Based HTA Of Prasugrel In Patients With Stent: Outpatient Use

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ABSTRACT SUMMARY:
Cardiology hospital has standardized clopidogrel, ticagrelor and prasugrel. A study was requested to discuss a disinvestment proposal. Literature review, meta-analysis and cost estimates was performed. Stent thrombosis favorable to prasugrel and ticagrelor and major bleeding favorable to clopidogrel. Annual cost: clopidogrel = USD5,765.86; prasugrel = USD41,047.48; and ticagrelor = USD44,081.30. The evidences support a disinvestment process.

INTRODUCTION:
A reference hospital, specialized in cardiology, has standardized clopidogrel, ticagrelor and recently the incorporation of prasugrel was approved with an estimate of fifteen patients with stent implantation monthly. Stent thrombosis is a rare but serious complication and it is recommended that patients be treated with antiplatelet therapy. Considering the existing therapeutic options and the low adherence to treatment, a cost study was requested to discuss a disinvestment proposal.

METHODS:
Perspective of the hospital; Population: patients with myocardial infarction and stent implantation; Intervention: prasugrel; Comparators: clopidogrel and ticagrelor; Outcomes of interest: stent thrombosis and major bleeding; and types of study: meta-analyses and randomized clinical trials. Literature review was performed in the Medline database, via Pubmed and performed meta-analysis. Cost estimates: data collection made in the institution’s database.

RESULTS:
Thirteen articles were selected; there are no differences in the outcomes for prasugrel and ticagrelor; discontinuation of treatment is the most important risk factor for stent thrombosis and major bleeding is an important predictor of nonadherence to treatment. Quantitative analysis: three clinical trials. All showed a superiority of prasugrel and ticagrelor over clopidogrel for outcome of stent thrombosis (Odds Ratio, OR 0.60 Confidence Interval, CI 95 percent [.40; .90]), which was committed by the heterogeneity of studies (I2 = 64 percent); and favorable outcome for clopidogrel compared to ticagrelor and prasugrel for the outcome of major bleeding (OR 1.28 CI 95 percent [1.10; 1.50]). Annual cost with treatment of the fifteen patients: clopidogrel = USD5,765.86; prasugrel = USD41,047.48; and ticagrelor = USD44,081.30.

CONCLUSIONS:
The evidences found support the opening of a disinvestment process and suggest to the managers of the institution a reflection on: strategy to optimize adherence to treatment; and especially in the cost of opportunity with new technologies about 10 times more expensive.

PP053 A Case Study: Collective Individual Basis For The Judiciary Debate

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ABSTRACT SUMMARY:
In São Paulo State, Brazil, insulin glargine has the highest number of lawsuits. Random analysis of 153 (58 percent) insulin glargine lawsuits for adults were carried out on digital court records. Judicial decisions have an insufficient scientific evidence basis and objective diagnostic variables. Besides complementary drugs, the judges awareness of interdisciplinary measures for diabetic patients glycemic control, may improve judicialization.

INTRODUCTION:
The volume of lawsuits for drugs has increased in Brazil. The scientific evidence basis consideration by the Brazilian judiciary system is being debated. In the State of São Paulo, the drug with the highest number of lawsuits is insulin glargine. Between January and August 2016, the São Paulo State Department of Health lost 264 insulin glargine lawsuits requiring supply for adult patients (>18 years old). Insulin glargine has already been submitted and unfavorably assessed by the Health Ministry SUS Technology Incorporation National Commission (CONITEC), so is not available in the Brazilian public system.

METHODS:
Random analysis of 153 (58 percent) lawsuits were carried out on digital court records. Data collected from legal proceedings were: the type of diabetes (1, 2 or unspecified); age of the patient; origin of the order; specialty of the prescriber and the reason described for the request. Each record was structured with variables data within a matrix in Microsoft Excel® software. Analysis of frequencies, absolute and relative distribution of quantitative variables, as well as conceptual clusters in the qualitative textual analysis are presented.

RESULTS:
The mean age of the 153 patients was 49±17 years. The majority of patients requested insulin glargine to achieve glycemic control (n=116; 76 percent); because - “diabetes is uncontrolled and the analogous insulin is essential to get it” (n=106; 69 percent); or - “patient claims to have obtained glycemic control with insulin glargine but there are none of the mandatory laboratory tests results in lawsuits” (n=7; 5 percent); or - “ask replacement of insulin detemir with glargine for glycemic control” (n=3; 2 percent). Only 87 (57 percent) lawsuits reported the patients diabetes type: type 1 (n=42; 28% percent or 2 (n=45; 29 percent). Most of this judicialization came from private outpatient clinics (n=116; 76 percent) and 99 (65 percent) were prescribed by endocrinologists.

CONCLUSIONS:
Judicial decisions are still insufficiently underpinned by scientific evidence (only the patients drug needs claim has been recorded to justify supply) and are incomplete regarding objective diagnostic variables. Also, the judges awareness of interdisciplinary measures to achieve diabetic patients glycemic control, besides complementary drugs, may improve the Brazilian judicialization burden.

PP054 The All Wales Patient Reported Outcome Measures (PROMs), Patient Reported Experience Measures (PREMs) and Effectiveness Program

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ABSTRACT SUMMARY:
The All Wales PROMs, PREMs and Effectiveness Program has developed an electronic platform
to collect outcome and experience measures from secondary care patients across Wales. Data collected will allow us to measure the effectiveness of care and to identify factors which influence patient outcomes. This will facilitate service improvements and inform decision making.

INTRODUCTION:
Prudent health care aims to do the minimum needed to achieve the greatest patient benefit. This aim relies on the availability of evidence on the safety and efficacy of interventions to support decision making. The principles of prudent healthcare support co-production, whereby service users contribute to service provision. Collection of patient reported data is becoming more widespread, however use of this data to inform decision making is limited.

METHODS:
A national patient reported outcome measures (PROMs) program has been formed supported by the Welsh Government, Welsh Health Boards and the NHS Wales Informatics Service. An electronic platform has been developed to facilitate collection of PROMs and patient reported experience measures (PREMs) from patients treated in secondary care. We collected baseline PROMs where possible and invited patients to submit PROMs and PREMs post-treatment. Data collected included EuroQuol five dimensions questionnaire (EQ5D), co-morbidities, body mass index (BMI), smoking history and alcohol intake. Disease specific tools were used where available and responses linked to clinical data. Individual level data will be available during clinic consultations, and collated data analysed on national and health board levels to assess clinical effectiveness. The platform is currently being piloted in several sites across Wales.

RESULTS:
Initial baseline pilot data from hip replacement patients found that over 55 percent of responders were classed as overweight or obese, with over 80 percent carrying out less than the national guidelines for exercise.

The baseline scores for hip patients were; EQ-5D Index (Mean .29, median .29, range (-.59 -1)), EuroQol-visual analogue scales (EQ-VAS) (Mean 57.8, median 60, range (0:100)), and Oxford Hip Score (Mean 14.9, median 14, range (0:48)).

When compared to baseline scores collected by NHS England in 2015/16 (1), the average EQ5D Index and Oxford Hip Score collected in Wales was lower than that in England (p< .05).

CONCLUSIONS:
The program will provide a large dataset from patients across all of Wales with data on numerous chronic and acute conditions. The data collected will facilitate service improvements and will inform decision making as part of the prudent healthcare agenda.

REFERENCES:

PP055 Coverage Under Evidence Development: Proposals From The Italian HPF

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**ABSTRACT SUMMARY:**
The paper summarizes the role of coverage under evidence development (CED) in informing pricing and reimbursement decisions in the Italian National Healthcare Service according to the discussion that occurred within the Italian Health Policy Forum.

**INTRODUCTION:**
Coverage under evidence development (CED) represents a specific approach to the introduction of promising and innovative technologies aimed at boosting patients’ access to procedures, drugs, or medical devices, and orienting the production of new evidence. This topic was discussed among members of the Italian Health Policy Forum (HPF). This initiative, promoted by the Italian Society of Health Technology Assessment (SIHTA), involves representatives of industry, regulators, institutions, citizens, and patients.

**METHODS:**
Members discussed topics both in plenary sessions and subgroups. The main topics debated regarded the role of CED in medical devices and the prioritization of different sources of evidence for drugs at both the national and regional level.

**RESULTS:**
For medical devices, regional registries may contribute to evaluate the potential benefits of high-value technologies. However, it is important to identify quality parameters to comply with. Privacy issues are also a prominent aspect to consider in the development of new evidence generated from existing databases. To ensure the generalizability across settings, it is recommended to implement devices’ registries at a national level as well, and to focus on those costly medical devices. Concerning drugs, the priority rank assigned to evidence varies according to the stakeholders involved in the decision-making process. Despite the heterogeneity of perspectives, accessibility, comparative efficacy, effectiveness, and safety emerge as crucial criteria, as far as relevant aspects in evidence generation.

**CONCLUSIONS:**
The analysis of the impact of monitoring registries on the evidence generation process is fundamental in the whole HTA process. Moreover, further efforts should be done to identify weights for evidence prioritization.

**PP056 Multicomponent Interventions For Treating Obesity In Children**

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**ABSTRACT SUMMARY:**
Multicomponent lifestyle interventions are the treatment of choice in childhood obesity, but how effective are these interventions? Our meta-analysis of thirty-nine studies showed treatment effects at 6, 12, and 24 months post-baseline in children and adolescents compared to standard, minimal, or no treatment.

**INTRODUCTION:**
Treatment of childhood obesity is important to prevent development of obesity related diseases later in life. Multicomponent lifestyle interventions are preferred treatment choices. In this systematic review we evaluate the effect of multicomponent lifestyle interventions.

**METHODS:**
We performed systematic searches in nine databases up to February 2015. Randomized controlled trials were included in meta-analysis if they provided post-baseline data on change of
body mass index (BMI) and BMI standard deviation score (Z score) compared to standard, minimal or no treatment in children and adolescents at 6, 12 or 24 months. We used the risk of bias tool for study quality assessment and Grading of Recommendations, Assessment, Development, and Evaluation for assessment of the overall documentation.

RESULTS:
Thirty-nine studies met the criteria for meta-analysis. We found significant difference in BMI after 6 months (Mean Difference (MD) -0.99 [95 percent confidence interval (CI) -1.36 to -0.61]), 12 months (MD -0.67 [95 percent CI -1.01 to -0.32]) and 24 months (MD -0.96 [95 percent CI -1.63 to -0.29]) in favour of multicomponent lifestyle interventions compared to standard, minimal or no treatment. We also found significant difference in BMI Z scores after 6 months (MD -0.12 [95 percent CI -0.17 to -0.06]), 12 months (MD -0.16 [95 percent CI -0.21 to -0.11]) and 24 months (MD -0.16 [95 percent CI -0.21 to -0.10]) in favour of multicomponent lifestyle interventions. We consider the overall evidence to be of medium quality. Subgroup analysis suggested enlarged effect in specialist health care with a group component included in the intervention, and possibly when given to an obese population.

CONCLUSIONS:
Multicomponent lifestyle interventions have a moderate effect on change in BMI and BMI Z score after 6, 12 and 24 months compared with standard, minimal and no treatment. Further efforts to optimize the outcomes of multicomponent interventions are appreciated.

PP057 Health Technology Assessment Of Trifluridine/Tipiracil For Metastatic Colorectal Cancer

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ABSTRACT SUMMARY:
Trifluridine/tipiracil (TAS 102) is a new treatment option for refractory metastatic colorectal cancer (mCRC). It has been shown to be as effective as its main competitor, regorafenib, but better tolerated. TAS 102 is recommended for a third-line or subsequent-line treatment of mCRC and it allows for maintaining a good quality of life at a late stage of disease.

INTRODUCTION:
This Health Technology Assessment (HTA) report has been performed to analyze the impact of the introduction of trifluridine/tipiracil (TAS 102) for the treatment of metastatic colorectal cancer (mCRC).

METHODS:
A literature review was carried out to describe epidemiology and burden of mCRC; identify available treatments and their effectiveness; illustrate the latest European and Italian clinical guidelines for the management of patients with mCRC; describe efficacy and safety of TAS 102 as a new therapeutic option for refractory mCRC. Moreover, an economic evaluation is still ongoing.
RESULTS:

Worldwide, CRC is the third most frequently diagnosed cancer in men and the second in women and the fourth and the third most common cause of cancer death, respectively. In Italy, its prevalence amounts to 2,914 cases per 100,000 inhabitants >75 years and the patients with mCRC represent the 48 percent of the overall CRC patients (1). Treatment options for mCRC have increased over the last decades, by implementing a “continuum of care” approach to treatment which improved patients clinical outcomes and overall survival (OS) (1,2). In April 2016, the European Medicine Agency (EMA) approved TAS 102 for treatment of patients with mCRC refractory to antitumor therapy or with clinically significant adverse events (2,3). The addition of TAS 102 to best supportive care has been shown to increase median OS in patients with mCRC, showing similar efficacy of its main competitor regorafenib, but a better safety profile. Therefore, TAS 102 is recommended by European clinical guidelines for a third-line or subsequent-line treatment of mCRC (3).

CONCLUSIONS:

TAS 102 appears to be an effective and well tolerated treatment for patients with refractory mCRC, offering a survival benefit similar to that achieved with regorafenib but with limited toxicity. Hence, it could help in maintaining a reasonably good quality of life, which should be one of the main driver of the treatment at this stage of disease.

REFERENCES:


PP058 Incentive Of Pricing New Drug Using Pharmacoeconomics Within The Health Technology Assessment Dossier In Taiwan

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ABSTRACT SUMMARY:

National Health Insurance Act II has been announced since 2013 in Taiwan. Per preceding paragraphs in article 17 and 42, application for new drug price with PE models conducted within HTA dossier can be added up to 10%. This study is to summarize the statistics for the new drug price application after its announcement.

INTRODUCTION:

The National Health Insurance Act (NIHA) II has been launched in Taiwan since 2013. Preceding paragraph in article 17 and 42 have indicated the insurer may conduct a health technology evaluation about this new innovative medication before drafting the medical service items and fee schedule; a maximum of 10 percent can
be added to pricing the new drug if a local pharmacoeconomics (PE) study is conducted. The aims of this study is to review the subsequent approval results of those Health Technology Assessment (HTA) reports with PE evaluations being submitted to the government agency using NHIA appraised reports published on websites.

METHODS:
Information of new indication applications for reimbursement was extracted from HTA appraisal reports. The approval date was derived from Pharmaceutical Benefit and Reimbursement Standard (PBRS) meeting minutes. Information was derived to summarize the descriptive statistics of annual number of reviewed applications. Two proportional and Fisher’s exact tests were used to compare the reimbursement rates and those new medication prices being marked up. The annual trend of applications with local PE conducted was also tested.

RESULTS:
There were seventy-nine reimbursement applications derived between 2011 and 2016, in which sixty-seven applications were reimbursed (85 percent). The average time from NHIA received application to PBRS making decision was 161 days, with a case evaluation procedure in experts committee meeting before decision. Among these applications, eighteen (23 percent) cases submitted with local PE studies conducted, the applications with local PE evaluations conducted were slightly increased since 2013 (p=.045). Comparison of the reimbursement rates between applications with local PE reports and those without was statistically significant, the reimbursement rates were 100 percent and 80.3 percent respectively with p value .041. A Markov model is commonly used in the PE evaluations, with sensitivity analysis were performed in most of the PE modeling. Eleven of the approved reimbursement application received a marked-up unit price.

CONCLUSIONS:
HTA with local PE studies were increasingly conducted after the announcement of the NHI Act with 2. 6% of the applications for drug reimbursement benefit receiving the marked-up unit price up to 6 percent. Policy for markup of the price has incentive for drug pricing in Taiwan.

PP059 National Survey Of Current United Kingdom Ambulance Service Transient Ischemic Attack Referral Pathways

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ABSTRACT SUMMARY:
Patients presenting to emergency ambulance services with low-risk Transient Ischaemic Attack (TIA) are usually conveyed to the emergency department (ED) and subsequently referred to a specialist TIA clinic. There is opportunity for paramedics to make direct referral to these clinics, avoiding the ED. We surveyed United Kingdom Ambulance Trusts to identify existing alternative pathways for patients presenting with low-risk TIA.

INTRODUCTION:
Patients presenting to emergency ambulance services with Transient Ischemic Attack (TIA) are usually conveyed to the Emergency Department (ED) with subsequent referral to specialist
assessment at a TIA clinic within one week if at low risk of stroke. There is opportunity for paramedics to refer patients with TIA at low risk of recurrent stroke directly to specialist TIA clinic, avoiding the transportation and care at the ED however evidence is lacking about current practice, safety and effectiveness of this intervention.

We aimed to describe current service developments across the United Kingdom (UK) for the pre-hospital emergency care of patients with TIA, to inform the development of an intervention for testing.

METHODS:
We surveyed all UK Ambulance Trusts (n = 13) by email, asking them to identify initiatives related to the management of TIA, and followed up services reporting an alternative TIA pathway by telephone to gather further details.

RESULTS:
Twelve ambulance services responded to our survey. Eight reported that they had not developed or implemented TIA referral pathways. Three reported currently using a TIA referral pathway; one had discontinued their pathway due to service reconfiguration. All (4/4) pathways used the FAST test and ABCD2 tool to screen patients, in line with national guidelines, and classified patients as low risk if the ABCD2 score was ≤3. All indicated that eligible low-risk TIA patients should be referred by paramedics to specialist care, 2/4 by telephone, and 2/4 by fax.

Although protocol compliance was audited in an initial pilot in one service, no formal evaluation of effectiveness was reported.

CONCLUSIONS:
Several UK ambulance services have introduced similar referral pathways for low risk TIA patients, avoiding transportation of patients to the ED. Existing initiatives can inform the development of an intervention for evaluation in a randomized trial.

PP060 Burden Of Nervous System Diseases On The Social Security System

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ABSTRACT SUMMARY:
This study was conducted to estimate the benefits provided and pension costs related to central nervous system diseases, and specifically for multiple sclerosis by age between 2009 and 2015 in the Italian regions. The database of approved claims was analysed and the mean cost per benefit of the National Institute of Social Security determined.

INTRODUCTION:
The aim of the study was to estimate the benefits provided and pension costs of patients with central nervous system (CNS) diseases and specifically for multiple sclerosis (MS), between 2009 and 2015 by age in the Italian regions.

METHODS:
The database of approved claims was analyzed and the mean cost per benefit of the National Institute of Social Security (INPS) determined for four types of social security benefits: incapacity pensions (for workers without work ability), disability pensions and disability benefits (for workers with reduced work ability) and attendance allowance (for people without work ability with physical and/or mental disability). From this data we estimated the total benefit provided and the total costs for CNS and MS, considering the regional distribution and age of the applicants. A probabilistic model with a
Monte Carlo simulation was developed in order to estimate the total benefits provided and costs.

RESULTS:
The model estimated for CNS diseases a total of incapacity pensions paid (thirteen grants for each beneficiary for every single year) from 2009 to 2015 of about 1.7 million (13,000 beneficiaries on average annually with a mean annual increase of 1 percent) corresponding to EUR1.1 billion (EUR165 million each year with a mean annual increase of 2 percent); a total of disability pensions paid of about 9.8 million (180,000 annual beneficiaries with a mean annual decrease of -10 percent) for a cost of EUR5.3 billion (EUR763 million each year with a mean annual decrease of -9 percent) and a total of disability benefits provided of about 2.7 million (30,000 annual beneficiaries with a mean annual increase of 5 percent) corresponding to EUR1.8 billion (EUR255 million every year with a mean annual increase of 7 percent). For the attendance allowance the model estimated a total of 8,900 beneficiaries in 2015 for a total cost of EUR57 million. The results of the regional analysis showed that the central and part of the southern regions (in particular the Sardinia region) reported the highest rates of benefits provided related to the resident population.

CONCLUSIONS:
The most important indirect costs in Italy from 2009 to 2015 were represented by disability pensions (64 percent of the total cost), followed by disability benefits (21 percent of total indirect cost).

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ABSTRACT SUMMARY:
The “Judicialization of health” expenses related to the purchase of the physiotherapeutic devices pleaded was approximately USD812,500. The estimated direct costs were considered high when compared to Rio de Janeiro’s budgetary capacity. The majority of the requests were due to chronic respiratory diseases and the most judicialized devices were used for treatment of these conditions for patients over 60 years.

INTRODUCTION:
The “Judicialization of health” is a judicial option, provided by the Brazilian constitution, which aims to guarantee the access of the population to healthcare products or services to which they were denied or that were otherwise unavailable on the Unified Health System (SUS) (1). This highlights deficiencies in public policies (2). Considering the progressive impact of the judicialization on the budget and the lack of real-world evidence on the subject, the objective was to describe the judicialization profile of physiotherapeutic devices in the city of Rio de Janeiro and to estimate the spending on them within the system.

METHODS:
The profile was traced based on the analysis of the processes (n=243) submitted to the Technical Advice Unit of the Rio de Janeiro Justice Court between May 2013 and September 2015, which litigated the provision of physiotherapeutic devices. Direct cost information was obtained from both public and private sources. The analysis was carried out using the SUS perspective.

RESULTS:
About 63 percent of the patients were over 60 years old. The majority of the requests were due
to chronic respiratory diseases, the most common being obstructive sleep apnea-syndrome (31 percent), chronic obstructive pulmonary disease (14 percent) and pulmonary fibrosis (11 percent). The most judicialized devices were continuous positive airway pressure (21 percent), oxygen concentrator (17 percent) and portable oxygen cylinder (13 percent). None of these devices are currently covered by SUS. The expenses related to the purchase of the devices pleaded was approximately USD812,500 over 29 months.

CONCLUSIONS:
The total spend on these devices were considered very high when compared to Rio de Janeiro’s health budgetary capacity. This scenario could be worse if this type of demand were not planned, and needed to be accomplished quickly with urgent purchases. The results obtained shows that judicialization phenomenon has a meaningful impact on the economic viability of the Brazilian healthcare system.

REFERENCES:

PP062 Multiple Populations In A Single Economic Evaluation Of Cystic Fibrosis Transmembrane Conductance Regulator Testing

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ABSTRACT SUMMARY:
Genetic tests are complex to evaluate because results may impact individuals other than those initially tested. We attempted to assess the overall cost-effectiveness of cystic fibrosis transmembrane conductance regulator (CFTR) testing where suspected index cases would be tested and then cascade testing would be made available to additional populations (family members, partners, fetuses) following identification of positive results in the former populations.

INTRODUCTION:
Genetic tests are complex to evaluate because for familial diseases, the information gained may be relevant to individuals other than those initially tested. The costs and outcomes of testing should, where possible, take into account downstream costs and benefits, and further testing, across any extended population that is affected. We attempted to capture costs in all relevant populations in an assessment of the cost-effectiveness of testing for mutations on the cystic fibrosis transmembrane conductance regulator (CFTR) gene. While CFTR testing may have diagnostic value, and inform some treatment decisions in Cystic Fibrosis (CF), in this assessment the outcomes of interest are identification of mutation status to enable reproductive planning, and ultimately, avoidance of CF-affected births.
METHODS:
The populations for testing include; suspected CF index cases, biological family members of an index case or CF carriers (having one CFTR mutation), reproductive partners of index cases or carriers, and high-risk fetuses.

Initially an individual economic model is constructed for each population being tested, identifying immediate costs and outcomes associated with that test. Then the relationships between these populations is mapped. This identifies the number of people in extended populations (for example, partners, family members, and for family identified as carriers, their partners) that are anticipated to be associated with an index case, and for whom CFTR testing for reproductive planning is relevant. Ultimately, the number of potential high-risk pregnancies associated with identification of pairs of carriers, and the costs and outcomes of pre-natal testing is estimated.

RESULTS:
Total costs and outcomes, including the number of CF births averted, determined for individual populations and the whole cohort of linked populations will be presented, enabling a single aggregated estimate of the collective incremental cost-effectiveness ratio (in terms of costs per CF birth averted) of CFTR testing.

CONCLUSIONS:
For genetic testing across multiple populations, a series of individual economic analyses in specific populations is not as informative as a single economic analysis integrating all populations.

PP063 Clinical Pathway Of Stroke Therapy: An Approach In Health Technology Assessment

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ABSTRACT SUMMARY:
Increasing workloads have been observed for the hospital staff (nurses, doctors) during the past 10 years with an average increase of 30 percent more hospitalized stroke patients. During this project a comparative process study, including a process cost analysis were performed for acute hospitalized stroke patients. During this pilot study one gains critical evidence that clinical pathway orientated "stroke therapy".

INTRODUCTION:
Increasing workloads have been observed for the hospital staff (nurses, doctors) during the past 10 years, with an average increase of 30 percent more hospitalized stroke patients. Owing to the larger number of patients and the coincidental reduced length of stay of the stroke patients an increased workload is seen. Normally one would expect at this point an adopted risen staff but in Germany one simultaneously registered none additional staff. According to this situation one has to look for tools to assure the high level of patient safety, the patient outcome standards and the cost effectiveness.

METHODS:
During this project a comparative process study including a process cost analysis were performed for acute hospitalized stroke patients. For this analysis 534 patients (96 patients with a hemorrhagic apoplexia, 200 patients with an ischemic apoplexy without a lysis therapy and 238 patients with an ischemic apoplexy with a lysis therapy) were enrolled into this program. The medical outcomes were measured according the classic neurological tools.
RESULTS:
On the basis of the following neurological clinical tools the medical outcome was mapped: NIHSS (National Institute of Health Stroke Scale), mRS (modified Rankin Scale), FIM (Functional Independence Measure), FAM (Functional Assessment Measure), and FRB Early Rehabilitation-Barthel Index. On the basis of the evaluated nursing, diagnostic and therapeutic measures, clinical pathways for the above mentioned three patient groups were developed in combination with a cost benefit analysis. These study results will be presented during the presentation.

CONCLUSIONS:
During this pilot study one gains critical evidence that clinical pathway orientated “stroke therapy” can improve the medical outcome in this sample. Additionally, it appears that clinical pathway treated stroke-patients have positive benefits during the Health Technology Assessment analysis.

INTRODUCTION:
The use of applications (app) on mobile phones to health care is a trend. Its applications range from the use as energy calculators, monitoring clinical parameters, as well association with medical devices, personal health records or used to request appointments (1). Thus, it is intended to evaluate the regulatory instruments available in Brazil as to their sufficiency to analyze this new technology.

METHODS:
Assessment of regulatory instruments for mobile app registration by the Brazilian Health Regulatory Agency (Anvisa) (2). The main variables in the form of Class I and II are: Submission type, Postal Code, Electronic Site, Product code, Classification Rule, Class, Indication of Use / Purpose, Principle of Operation, Platform, Target Audience, Type of Environment, Compatibility, Safety Characteristics, Technical Standards used, Product Origin.

RESULTS:
Since 2010, the registration of software in Anvisa has been observed. The evaluation of Class I and II software is performed through the registration analysis to be completed by the requesting company. Class III (high risk) software is registered as a medical device embedded software (2).

Anvisa’s analysis of the software still depends directly on the application for registration of the companies. In this way most of the analyzed software are for use by health professionals and health services.

CONCLUSIONS:
There are Brazilian regulations for health products with software registration forecast, however its use as a health service still lacks studies mainly with the trends of new information and communication technologies (3).

The regulation of mobile applications becomes difficult because applications are freely downloaded in virtual stores, their domains are usually in foreign territory and their use is given directly by the user.
REFERENCES:


PP065 Impact Of A Population-Based Cervical Cancer Program Implementation

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ABSTRACT SUMMARY:
We estimated how the implementation of a Population-based Cervical Cancer Screening Program can impact on cervical cancer incidence and mortality, on Spanish National Health Service and on financial system.

INTRODUCTION:
Cervical cancer is a tumor with low incidence and mortality in Spain. This situation can be partly attributed to the fact that over several decades, a high percentage of Spanish women have undergone opportunistic screening. In addition, the recent introduction of a vaccine against Human Papillomavirus (HPV), and HPV detection techniques, will result in relevant changes. Recently, a group of experts in the European Union has updated the Guidelines for Quality Assurance (IARC) in Cervical Cancer Screening, which includes recommendations for improving Cervical Cancer Screening Programs in European Union.

METHODS:
A systematic bibliographic search was carried out to find studies that provide a higher level of evidence and, when possible, a meta-analysis was conducted. In other cases, a qualitatively analysis was performed.

The costs analysis was achieved from National Health System perspective. The direct costs were calculated according to a Population-based Cervical Cancer Screening Program in accordance with IARC recommendations.

RESULTS:
Organizational implications: An adequate organizational basis is a sine qua non requirement to ensure that implementation of a population-based screening program gives positive results in terms of safety and effectiveness.

The transition from opportunistic to population-based model should be performed gradually and with prior pilot schemes in one or more regions.

The implementation of a screening system based on the detection of HPV as primary test will have an important effect on the activity of laboratories. Therefore it is desirable to conduct prior pilot studies to allow adequate levels of quality at all levels to be verified.
It is important to assure correct interpretation of the information by women and healthcare professionals in order to avoid unnecessary testing that could lead to overuse of the resources available by up to 90 percent.

Economic implications: The total costs for one year of Population-based Cervical Cancer Screening Program is EUR1,461,455 assuming 117,343 invited women and 100,000 screened women. The program comprises a liquid-based cytology screening tests every 3 years for women aged 25 to 34 years and HPV DNA test for women aged 35 to 65 years at five-year intervals for those women with negative test.

If screening test is positive, women will be transferred to colposcopy. Detection of HPV or cytology will be conducted depending on age or diagnosis. If Human papillomavirus deoxyribonucleic (HPV DNA) test is positive and cytology negative, HPV DNA test will be repeated 12 months later.

The cost for one year of Opportunistic Cervical Cancer Screening Program is EUR1,235,000 considering 100,000 cervical cancer screening tests performed in women aged 25 to 65 years. The Opportunistic Program comprises conventional cytology (Pap smear tests) every three years for those women with negative results. If the cytology test positive, additional cytology one year later or a diagnostic colposcopy will be performed.

CONCLUSIONS:
The implementation in Spain of a Population-Based Cervical Cancer Screening Program may produce significant decrease in incidence and mortality of cervical cancer with respect to opportunistic screening, provided an organized method and an adequate quality control is provided.

PP066 Disseminate Results Through Social Video And Social Networks

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ABSTRACT SUMMARY:
How to reach broader impact and new target groups in a cost-effective way through social video and social networks.

INTRODUCTION:
We are experiencing a fundamental change in the way our target groups interact with information online, moving from passive consumption to more active creation of content, for example social video and social networks. This means a great potential in reaching more people in a cost-effective way which in the end will result in greater impact.

METHODS:
The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), have developed an easy way to produce and disseminate our results through social video and social networks.

SBU has a special social media editorial committee for communication via social media, which includes participants from different departments. The editorial committee discusses on a weekly basis the issues to be raised on the agency’s Twitter and LinkedIn accounts.

SBU works actively with social video as a message channel. During the past year several videos have been published with various themes (1 - 3). All of the members of the social media committee have attended a short training course in order to be able to produce and publish social videos. For shorter
production, we make ourselves with iPhones and editing with iMovie or Adobe Premiere Pro. For more extensive videos we produce together with a production agency.

RESULTS:
The number of followers on Twitter have increased from 500 in December 2015, to 1,400 in December 2016. Our followers are for example professors, doctors, nurses, physiotherapists, journalists, politicians, and opinion makers from patient organizations.

In our latest recruitment processes we have been experiencing significant number of qualified candidates, who found the link to our website through social media networks like Facebook and LinkedIn.

CONCLUSIONS:
Social media should be at the heart of digital transformation as it crosses boundaries: you will have a broader impact and it has a great potential in reaching your target groups in a cost-effective way.

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PP067 Tuscany Technological Equipment Centralized Management Procedure

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ABSTRACT SUMMARY:
The latest Tuscany Health System reorganisation created new conditions for the application of centralized management of technological adoption which is Health Technology Assessment (HTA)-based. The main objective of the presented procedure is to find a way to better manage the available technology equipment and guarantee an optimal activation, replacement and withdraw policy, and to give a continuous vision on required investments and technological improvements.

INTRODUCTION:
Several and relevant efforts are done worldwide for having an appropriate and sustainable technological equipment in healthcare environment.

The Tuscany Health System reorganisation (1,2) creates new conditions for the application of centralised management of technological adoption and Health Technology Assessment (HTA) finds a fertile ground on which to develop new approaches and introduce innovative technologies for a better support to the clinical activity (3).

The main objective of the described activities is to find a way to better manage the available technology equipment and guarantee an optimal activation, replacement and withdraw policy.
**METHODS:**
Tuscany Region addresses this issue by: (i) considering a comparison with other Italian and International health systems; recently good data are available related to the diagnostic imaging equipment and, considering its costs and relevance, this sector gives relevant information very useful for the definition of local strategy; (ii) defining a dedicated procedure for planning the replacements and withdraws of health equipment where prioritization criteria, based on equipment age, critical usage, average operation time, technological obsolescence and overall correspondence with needs and standards, are considered by simulating the calculation of a Priority Index to be ideally associated with all the available devices; (iii) overseeing the procedure application through the activation of a permanent board appointed to monitor the procedure and validate the results; and (iv) involving the local authorities representatives from the first phases of the procedure sharing approaches, methods, results and feedback.

**RESULTS:**
The results of the presented procedure allow the management of the technological equipment giving a continuous vision on required investments and technological improvements.

It may be replicated and adopted with minor adaptation by other regional, national or local health authorities.

**CONCLUSIONS:**
Appropriate and well-monitored management of the health technologies are very important to ensure better answers to the system new challenges. A detailed definition of standard technological equipment for any health structure may further improve the procedure.

**REFERENCES:**
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3. Delibera GRT 11 aprile 2016 n. 302 “L.R. 4072005, art. 10, comma 4 quinquiries. Approvazione linee di indirizzo per le attività di valutazione e per le modalità di funzionamento della Commissione per la valutazione delle tecnologie e degli investimenti sanitari”.

**PP068 Stakeholder Views On Peer Review Of National Institute for Health Research Grant Applications**

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**ABSTRACT SUMMARY:**
The NHS National Institute for Health Research (NIHR) is committed to improving the health and wealth of the nation through research, and is continually investigating ways of improving process efficiency in funding research. Deciding which studies to fund is crucial; this study focused on eliciting stakeholder views regarding possible improvements to the peer review process in making funding decisions.
INTRODUCTION:
It takes on average 17 years to translate a promising laboratory development into better patient treatments or services. About 10 years of this innovation process lies within the National Institute for Health Research (NIHR) research pathway. Innovations developed through research have both national and global impact, so selecting the most promising studies to fund is crucial. Peer review of applications is part of the NIHR research funding process, but requires considerable resources. The NIHR is committed to improving efficiency and proportionality of this process. This study is part of a wider piece of work being undertaken by NIHR (1) to reduce the complexity of the funding pathway and thus make a real difference to patients’ lives.

METHODS:
This study elicited the views of various stakeholders concerning current and possible future methods for peer review of applications for research funding. Stakeholder groups included: members of boards with responsibility for making funding decisions; applicants (both successful and unsuccessful); peer reviewers and NIHR staff. Qualitative interviews were conducted with stakeholders selected from each group, and results were analysed and integrated using a thematic template analytical method. The results were used to inform a larger online opinion survey which will be reported separately.

RESULTS:
The views and insights of thirty stakeholders across the four groups about the peer review process of applications for funding will be presented. Findings generalisable to other funding programs outside the NIHR will be emphasised. The key themes which emerged included: strengths and weaknesses of applications, feedback, targeting and acknowledgement of peer reviewers.

CONCLUSIONS:
The results of our study of peer review processes carried out by one national research funder has relevance for other funding organisations, both within our country and internationally.

REFERENCES:

PP069 Health Technology Assessment Of Radium-223 Dichloride In Resistant Metastatic Prostate Cancer

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ABSTRACT SUMMARY:
Radium-223 is a new treatment option for metastatic castration-resistant prostate cancer (mCRPC). It has been shown to be effective and to prolong overall survival with an excellent safety profile. It also showed a favorable economic impact and it has been recognized as an innovative product.
INTRODUCTION:
Metastatic castration-resistant prostate cancer (mCRPC) is an incurable disease and represents a significant clinical, economic, and social burden. The therapeutic scenario of mCRPC has completely changed over the last years with the approval of several treatments (1). Radium-223 is a new target-alpha therapy showing a significant survival benefit in mCRPC patients (2,3). The study aimed to evaluate the introduction of radium-223 in Italy using Health Technology Assessment methodology.

METHODS:
To assess epidemiological, clinical, economic, organizational, social, and ethical aspects, a literature review was carried out. A cost-effectiveness and a budget impact analysis were performed from the National Health Service (NHS) perspective to compare radium-223 with other treatments and determine the budgetary impact of the utilization of radium-223 for the treatment of mCRPC.

RESULTS:
In Italy, prostate cancer represents the most diagnosed cancer in men and the third in the whole population. When the disease becomes metastatic, approximately 80 percent of patients develop bone metastases, commonly associated to skeletal-related events (SREs) with a significant impact on survival, quality of life, and costs (1). Radium-223 is a novel alpha particle emitting therapeutic agent which targets new bone growth surrounding bone metastases. Different from other radiopharmaceuticals, radium-223 prolongs overall survival with a favorable safety profile (2,3). In order to optimize patient outcome, the management of radium-223 should be viewed in a multidisciplinary context. The administration is quite simple and requires only basal shielding. Currently it can be administered in hospital inpatient settings and in some regions the outpatient usage is allowed. Finally, radium-223 showed a favorable budget impact profile and cost-effectiveness when compared with best supportive care and new therapeutic agents (abiraterone, enzalutamide, cabazitaxel) (1).

CONCLUSIONS:
The introduction of radium-223 allows provision of a new therapy, offering a valid alternative to patient with mCRPC without any increase of costs for the NHS.

REFERENCES:

PP070 Home Mechanical Ventilation: A Health Technology Assessment

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ABSTRACT SUMMARY:
This presentation concerns home mechanical ventilation (HMV). The use of HMV is increasing in Danish regions, and there is limited knowledge...
on clinical, economic, organizational and ethical consequences. In this presentation, a cover of the current evidence in a Danish setting is shown. This evidence will contribute to decisions in relation to the use of HMV in Denmark.

**INTRODUCTION:**

This health technology assessment (HTA) concerns home mechanical ventilation, restricted to a group of patients in need of monitoring all day or most of the day. The use of home mechanical ventilation is increasing in Danish regions, and there is limited knowledge on clinical, economic, organizational and ethical consequences related to the use of the technology. Also, there is some uncertainty about the visitation criteria behind the choice of treatment.

This presentation is one of two presentations in which home mechanical ventilation is the subject. In this presentation, we wish to present the risks and effects of using home mechanical ventilation as well as economic and ethical consequences. Patient and organizational perspectives will be addressed in the other presentation. Home mechanical ventilation will be compared to relevant, alternative treatment initiatives or ways to organize the procedure.

**METHODS:**

Preparation of this HTA-report is based on EUnetHTA’s HTA Core Model. The HTA is based on national and international literature on the subject together with document studies. In conducting the literature review GRADE methodology is used.

**RESULTS:**

Results from this HTA is available in the spring (May), 2017.

**CONCLUSIONS:**

Conclusions regarding effects, risks and health economic consequences and criteria for referring patients to home mechanical ventilation will be presented. Moreover, there are significant ethical dilemmas and challenges in relation to home mechanical ventilation, which is essential as part of the decision-making process concerning home mechanical ventilation. A cover of the current evidence will thus contribute to decisions in relation to the use of home mechanical ventilation in Denmark.

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PP071 Health Technology Assessment In Bulgaria: A Review Of The First Fifteen Reports Assessed

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**ABSTRACT SUMMARY:**

In Bulgaria, the regulatory body sets for the first-time legal requirements for Health Technology Assessment (HTA) in Law on Medicinal Products in Human Medicine (LMPHM) on 27 June 2015. The next essential step for HTA capacity building was the promulgation of Ordinance 9 / 1 December 2015 on the conditions and procedures for conducting health technology assessment by the Ministry of Health.

**INTRODUCTION:**

In Bulgaria, the regulatory body sets for the first-time legal requirements for Health Technology Assessment (HTA) in Law on Medicinal Products in Human Medicine (LMPHM) on 27 June 2015. The next essential step for HTA capacity building was the promulgation of Ordinance 9 / December 1, 2015 on the conditions and procedures for conducting health technology assessment by the Ministry of Health (1). In the beginning of 2016, the
Main Price and Reimbursement Committee was set and launched a process for establishing the small working groups with the task of reviewing the first applicants reports of pharmaceuticals for inclusion in the Positive Drug List (PDL).

**METHODS:**

The objective of this study is to summarise the recommendations of the newly established HTA Committee in Bulgaria and to examine the characteristics of the technologies and the key considerations that led to those decisions. We systematically read all published by the Committee recommendations for 2016 and analyzed them under: type of recommendations (positive or negative for inclusion in PDL), population, specialization, type of service, type of justification and the impact on final conclusions.

**RESULTS:**

For the first year of its work the HTA Committee was able to assess fifteen technologies (pharmaceuticals) and only one received a negative recommendation (6 percent) from the working group. All the rest (n=14; 94 percent) were recommended for funding. The final recommendation from the Main Price and Reimbursement Committee is available for four (27 percent) technologies – all positive for inclusion in PDL. All recommendations were connected with adults and in oncology (n=4; 27 percent); heart diseases (n=4; 27 percent); Chronic Obstructive Pulmonary Disease, COPD (n=2; 13 percent); diabetes (n=2; 13 percent); psoriasis (n=2; 13 percent); Hepatitis C (n=1; 7 percent). The only negative recommendation was justified due to lack of robust evidence, safety issues and credibility of HTA analysis (2).

**CONCLUSIONS:**

The information about the number of applications received from the Committee is not available and correct conclusions about the capability is not possible, but indirect circumstances, as the lack of well-trained HTA experts, certainly impede establishment of the small working groups and slow the assessment process (3). At this point it is clear that additional efforts are needed to overcome the barriers and smooth adoption and implementation of HTA methods in Bulgaria.

**REFERENCES:**


**PP072 Applying Sensitivity Analysis For Robust Choice Of Health Technologies**

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ABSTRACT SUMMARY:
The aim of this work was to evaluate the stability and robustness of the solution obtained at the end of Health Technology Assessment (HTA) process by conducting a sensitivity analysis. A mathematical model was implemented to conduct a sensitivity analysis to evaluate the effects on Analytic Hierarchy Process (AHP) results induced by a change on initial values of each criterion of the decision-making model.

INTRODUCTION:
The aim of this work is to evaluate the stability and robustness of the solution obtained at the end of the Health Technology Assessment (HTA) process by conducting a sensitivity analysis. Sensitivity analysis allows identification of the elements representing the source of uncertainty and to determine the impact of this variability on the stability of the assessment results, in order to provide more adequate and objective support to decision-making process.

METHODS:
A new method for health technologies evaluation, Decision-oriented HTA (1), which integrates the Analytic Hierarchy Process (AHP) (2) in the model Core Model® of the European Network for HTA (EUnetHTA) was taken into account. In this context, a mathematical model was implemented to conduct a sensitivity analysis on weights and on performance values of the technology alternatives evaluated (2,3). The objective is to evaluate the effects on AHP results induced by a change on initial values of each criterion of the decision-making model. Sensitivity analysis was carried out by calculating the minimum changes of the weights and performances needed to reverse the current ranking of alternatives technologies (3).

RESULTS:
This approach was applied to some technology assessment studies such as videolaparoscopy, femtosecond laser, da Vinci robot, to test their efficacy and reliability. It is very important to perform a sensitivity analysis and assure the stability of the solution when the performance values associated to the technology alternatives are close because, in this case, a small change of performance values reversed the ranking of alternatives technologies.

CONCLUSIONS:
Applying sensitivity analysis to such decision-making processes is essential to ensure the consistency of final decisions. This evidence has shown that this method allows for a more rapid interpretation of results, thus facilitating the choice of decision-makers about the decision to invest or not in new technology.

REFERENCES:

PP073 Cost-Effectiveness Of E-US In The Unified Health System

PRESENTING AUTHOR:
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AUTHORS:
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ABSTRACT SUMMARY:
This study aims to evaluate the cost-effectiveness of the E - SUS Strategy in the Single Health System. Being e-SUS Basic Attention (e-SUS AB) is a strategy of the Department of Basic Attention to restructure the information of Basic Attention at national level. This action is in line with the more general proposal for the restructuring of Health

INTRODUCTION:
E-SUS, technically known as “The e-SUS Basic Attention Strategy”, seeks to implement technologies to make the work process of health and management teams easier, reducing the time spent on system use and feeding bureaucracy. Of health information that interface with Primary Care, the strategy seeks to ensure that the development of solutions advance in the adoption of international standards in the area of information technology in health, and with that expand the interoperability between health management systems and other areas in the municipality.

This work has the objective of realizing the cost-effectiveness of the E - SUS Strategy in the Single Health System.

METHODS:
It will be used two methods. Conduct a Systematic Review on the economic evaluation of health information systems in Brazil. In this review will be used several scientific databases such as Scielo, Embase, Virtual Health Library, PubMed, Lilacs, Medline, Periodical Capes.

The second methodology to be used will be “cost-effectiveness analysis (ACE)” in which it is predicted to carry out the survey of the costs of implementing new information technologies in health.

RESULTS:
This study is under development and not yet completed.

CONCLUSIONS:
It is hoped that this study demonstrates that it is worth investing in the e-SUS strategy as an option the reorganization, modernization and support for managers, health professionals and the ministry of health with regard to patient data and information. As well as giving support to encourage a new phase of computerization of health systems in Brazil.

PP074 Hormone-Dependent Metastatic Breast Cancer: Pharmacoeconomic Aspects

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ABSTRACT SUMMARY:
Pharmacoeconomic aspects of different strategies of drug therapy in postmenopausal patients with hormone-dependent metastatic breast cancer.

INTRODUCTION:
To assess optimal tactics of endocrine therapy on the background of tamoxifen administration on the basis of the predictive models of the probability of clinical outcomes and the pharmacoeconomic efficiency of various strategies of the second-line endocrine therapy.

METHODS:
The study was based on FINDER2 and BOLERO2 clinical studies. We conducted pharmacoeconomic modelling of the budget impact. Two tactics of patient management in the advanced stage of the disease after first-line endocrine therapy were considered in two groups of 100 patients: anastrozole (first group), and fulvestrant (second group). Transition from fulvestrant to anastrozole
in the second-line therapy was allowed in case of progression of the disease. The administration of anastrozole in the second-line therapy allowed two subsequent strategies in the 50/50 ratio: a) chemotherapy, and b) everolimus + exemestane therapy. Only direct costs of pharmacotherapy were considered. The cost-efficiency value was calculated with consideration of overall respond and clinical benefit rates. The time horizon of the developed model was 1 year.

RESULTS:
The costs of drug therapy with fulvestrant in the second-line therapy with subsequent transition to anastrozole is RUB62,161,280.00 in the group of 100 persons. In case of anastrozole administration in the second-line therapy with subsequent administration of everolimus and exemestane in the advanced stage of the disease, the costs reaches RUB155,721,000.00. With consideration to the possible everolimus + exemestane combination and chemotherapy (in 1:1 ratio), the costs reduce to RUB92,662,280.00. However, the costs are still higher than in the fulvestrant group.

CONCLUSIONS:
The use of fulvestrant as a selective estrogen receptor down-regulator seems to be the most rational strategy of second-line therapy in patients with metastatic breast cancer with estrogen positive/progesterone positive tumors.

ABSTRACT SUMMARY:
Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage. The individual process steps at the Klinikum rechts der Isar in Munich (MRI) were recorded to develop a process model. This Health Technology Assessment (HTA) shows that main costs for a drug product change arise due to additional staff costs on the ward.

INTRODUCTION:
Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage (1). The aim of this analysis is to develop a process model for drug product changes and to determine a hospital specific threshold when product change is reasonable, provided that the efficacy and safety of the new product is economically reasonable (2).

METHODS:
The individual process steps at the Klinikum rechts der Isar in Munich (MRI) were recorded to develop a process model. The required expenditure of time for the different process modules was documented and a process cost calculation undertaken.

RESULTS:
Product changes can be divided into three groups: generic changes, identical active ingredient but different brand name, and complex drug changes with different active ingredients or changed drug formulation. The later change is associated with a higher demand for information, which is reflected in higher process costs. Relevant costs arise during the process of product purchase and on the ward. The cost per product change inclusive operating expenses at the MRI range (3) from EUR2,300 to EUR6,420 and depend on the frequency of prescription and the complexity of the product.

PP075 Does Drug Replacement Have An Impact on Hospital Treatment? A Health Technology Assessment Debate

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CONCLUSIONS:
This Health Technology Assessment (HTA) shows that main costs for a drug product change arise due to additional staff costs on the ward. Reasonable thresholds can aid in decision making when considering cost effectiveness and potential risks of the medication or patient safety.

REFERENCES:

INTRODUCTION:
Drugs are a special commodity for treating diseases and protecting health. There are problems in China’s drug research, production, distribution and use (1) thus the national drug policies, including government long-term frameworks and specific policies, play an important role (2). This study summarized and analyzed drug policies in China since the New Medical Reform, to determine patterns of policy change, and aiming to provide theoretical support for drug policy making for the world.

METHODS:
We downloaded all drug policies issued between April 2009 to December 2016 on State Council, National Development and Reform Commission, National Health and Family Planning Commission, China Food and Drug Administration websites. These documents were combined with academic articles to extract data, which was processed in Microsoft Excel 2013. We also used the Advocacy Coalition Framework to analyze dynamic factors for drug policy change in China.

RESULTS:
There are 113 drug policies during last 8 years on 4 websites; seventy-six of them are released by a single ministry. Thirteen, ten, ten, fifteen, seven, fourteen, twenty-six and eighteen policies are issued each year, respectively. Fifteen are classified in long-term frameworks, while the other ninety-eight are specific policies. And fourteen of ninety-eight policies are focusing on basic drug systems, while six are on centralized purchases, nine on public hospitals reform, seven on drug safety, sixteen on prices, fourteen on distribution, twelve on administration, five on traditional medicine, and fifteen on specific drugs.

CONCLUSIONS:
After the basic drug system was built in 2009, the government started to focus on its distribution over the next 7 years. Policies on centralized purchases are mainly issued in 2010 and 2015, and
creative modes have been coming up since 2015. The Government cares not only about production safety, but also safety in sales. Prices were decided by government at first but then follow the market forces. Work focus shifted from the above contents to drug distribution, price, management and traditional medicine after 2012. The peak of policy releases occurred when the great reform took place, such as 2009 when reform began, and in 2012 the Twelfth Five-year plan began. There was a decrease in 2013 due to national leadership change (3). Overall, dynamic factors for policy change mainly are social conditions, public issues and opinions, and feedback on former policy effects.

REFERENCES:

PP077 Intravitreal Corticosteroids In Macular Edema: Quality Of The Evidence

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ABSTRACT SUMMARY:
Treatment options for macular edema include intravitreal corticosteroids. Considering the hypothesis that the use of these drugs is based on widely variable evidence in terms of methodological quality and robustness, the purpose of this analysis is to compare the quality of the evidence on efficacy and safety of three different formulations of intravitreal corticosteroids.

INTRODUCTION:
Treatment options for macular edema include intravitreal corticosteroids (1). Traditionally, an injectable suspension of triamcinolone acetonide (TA) had been employed off-label (2); in recent years, authorities have approved sustained-release drug delivery systems (DDSs) for corticosteroids (3). Considering the hypothesis that the use of these drugs is based on widely variable evidence in terms of methodological quality and robustness, the purpose of this analysis is to compare the quality of the evidence on efficacy and safety of three different formulations of intravitreal corticosteroids: the dexamethasone (DEX) implant, the fluocinolone acetonide (FA) implant, and the preservative-free injectable suspensions of TA, in the management of two retinal pathologies: diabetic macular edema (DME) and macular edema secondary to retinal vein occlusion (RVO).

METHODS:
A search of clinical trials on MEDLINE from 1 January 2000 to 16 December 2015 was performed. Studies were included in the analysis if they met the following criteria: (i) related to at least one of the preparations of interest in patients with DME or macular edema secondary to RVO; (ii) included a control group treated with placebo, observation, sham procedures or conventional treatments; and (iii) included visual acuity, retinal thickness and/or safety parameters as outcomes. Results were summarized in a narrative manner.
RESULTS:
Twenty-five publications from nineteen RCTs were included. We observed increased attention of researchers towards TA compared to DEX and FA; however, studies for TA are less robust. Scientific publications related to DEX and FA implants are of higher quality, especially in terms of randomization and masking procedures.

CONCLUSIONS:
Even though each of the three considered corticosteroid-containing medicines are approved for marketing and included in clinical guidelines for treatment of macular edema, a high degree of heterogeneity in terms of quality of evidence has been noticed among them. This observation underlines the need to review the requirements for drug approval and their inclusion in clinical recommendations, as well as the importance of post-marketing monitoring to generate new evidence.

REFERENCES:

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ABSTRACT SUMMARY:
HTA practice became a relevant aspect related to the sustainable management of technology in health. The main objective of the described activities is the definition and the application of a procedure that receive the innovative technologies advisory from all the stakeholders and produces widely available results. So it supports the transition from the technology management to the clinical pathway management.

INTRODUCTION:
Health Technology Assessment Assessment (HTA) practice became a relevant aspect related to the sustainable management of technology in health. The local authorities activated HTA structures with the objective to evaluate their innovation requests but a more centralized organization may improve such model allowing a better process efficiency.

The main objective of the described activities is the definition and the application of a procedure that receive the innovative technologies advisory from all the stakeholders and produces widely available results. It offers a new approach and the transition from the technology management to the clinical pathway management. It allows assessing not only the value of a single technology in large system, but also the examination of sequences of use for a range of alternative technologies that could be applied in specific patients clinical pathways.

METHODS:
Tuscany Region, applying the national laws related to the HTA centralization, activates a permanent regional board dedicated to the technology investments evaluation. The board operates through an operative board of experts, which proposes a centralized procedure for the regional
HTA process. The workflow considers internal, external and self-defined inputs, a prioritization algorithm, dedicated operative specific boards, final validation and public area for the produced results. A software procedure was activated to support the process.

RESULTS:
The results of the presented procedure allow a more efficient management of the HTA process over Tuscany. It involves the local authorities, regional agencies, and regional experts allowing a shared and interdisciplinary approach.

It may be replicated and adopted with minor adaptation by other regional, national or local health authorities.

CONCLUSIONS:
Appropriate, well-monitored and shared management of the health technology assessment are very important for a better answer to the health system new challenges. It permits to afford the most important requests and ensures better results for the regional system.

INTRODUCTION:
In 2014, the Ministry of Health, Labor and Welfare (MHLW) in Japan began to assume a cost-effectiveness perspective. Some expensive pharmaceutical and medical devices have been regulated, which resulted in a drastic change of the healthcare system.

The Japanese National Insurance Claims Database (NDB) is an administrative database based on claims data from Medical Insurance Claims since 2008. The government enacted the Act on Assurance of Medical Care for Elderly People during health care reform in 2008. In 2006, the MHLW commenced discussions on a framework for the optimization of the healthcare expenses, which aimed to evaluate the structure of the increase in healthcare expenditure.

The NDB was developed as a tool for investigation and analysis by the MHLW in the context of the Healthcare reform. In addition, the NDB was used for the development of academic research in order to contribute to the implementation and evaluation of healthcare policy management.

A major strength of the NDB is its exhaustiveness or completeness of insurance claims. The NDB collects data from all insured people nationwide and covers all medical institutions in Japan.

METHODS:
We applied to the Expert Meeting on Provision of Medical Insurance Claims to examine the research plan, items extracted, and data management. Inpatient and Outpatient information was extracted on medical procedures and payment. Diagnoses for both inpatients and outpatients are coded according to the International Classification of Diseases Tenth Edition (ICD-10). The coding of
treatments and surgeries follow Japan’s local procedure and surgical coding, which was specifically developed for insurance claims.

RESULTS:
We generated any personally traceable patient ID from the “hash ID” generated by patient name, sex, date of birth, and insurer number with the aim of protecting personal identifying information in the NDB. The disease of stroke was defined to analyze the database for cost-effectiveness analysis, and to connect disease information to. The prescription claims information described pharmaceutical names, prescription date, total dose, and number of days.

CONCLUSIONS:
Our study showed the new standard way of analysis for cost-effectiveness analysis using the Japanese National Insurance Claims Database.

PP080 Dementia As A Comorbidity Of Diabetes In Evaluating Interventions

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ABSTRACT SUMMARY:
This abstract presents the work that involved updating an existing diabetes prevention cost-effectiveness model to estimate the impact of including dementia in an evaluation of diabetes prevention policies in the United Kingdom.

INTRODUCTION:
The aim of the project was to update an existing diabetes prevention cost-effectiveness model to estimate the impact of including dementia in an evaluation of diabetes prevention policies in the United Kingdom.

METHODS:
The School for Public Health Research (SPHR) diabetes prevention model is an individual patient simulation model developed to evaluate the cost-effectiveness of a broad range of public health policies for diabetes prevention. The Diabetes Prevention Programme describes a programme of screening for individuals at high risk of type 2 diabetes and a lifestyle education programme. The lifestyle intervention is effective in reducing BMI, HbA1c, systolic blood pressure, and total cholesterol in individuals at high risk of type 2 diabetes. The programme has been shown to be effective and cost-effective in high risk groups.

The SPHR diabetes cost-effectiveness model was adapted to include dementia as an outcome and an evaluation of the Diabetes Prevention Programme was updated. A risk model that included diabetes, diabetes related comorbidities, BMI, systolic blood pressure, and cholesterol was used to estimate individualized incidence of dementia. Dementia diagnosis and disease progression was modelled based on existing dementia models and in consultation with experts.

RESULTS:
The model found that the Diabetes Prevention Programme was cost-saving. Including dementia as an outcome of the model generated additional cost savings and QALY gains from reducing the incidence of dementia as a consequence of the intervention. However, there is evidence of competing risks between the main outcomes of the model.

CONCLUSIONS:
The inclusion of dementia provides additional information in the evaluation of diabetes policies, and is particularly useful in evaluating policies targeting older age groups at greater risk of dementia.
PP081 Relation Between Pain And Treatment/Activity Based On Mobile App Data

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ABSTRACT SUMMARY:
Mobile apps to record symptoms and medication by patients themselves, have been developed. We analyzed data from one of these apps: “Itami Renrakucho” (Pain Diary, Welby Inc.) from 25 December 2015 to 9 December 2016 including 708 individuals. A tendency of relationship between degree of pain and medication frequency/timing, as well as activities in life was found in this analysis.

INTRODUCTION:
Recently, a number of mobile apps to record symptoms and medication by patients themselves have been developed. These apps are expected to improve the patients’ symptoms through self-management, and to enable a smooth decision making through effective communication between doctors and patients. “Itami Renrakucho” (Pain Diary, Welby Inc.) is one of these apps that records body pain, medication, physical conditions, and activity in life. We examined the relationship between pain and medication/activity based on its data.

METHODS:
Data between 25 December 2015 and 9 December 2016 were used. Medication and degree of pain (0-10, low < high) were recorded at morning, daytime, evening, and bedtime. Of nineteen activities, up to three were recorded about whether they could or could not do them. We compared the degree of pain among different frequency/timing of medication, or activities that they could or could not do.

RESULTS:
Data included 708 individuals. Among 561 individuals who answered about pain, the mean (Standard Deviation, SD) degree was 5.0 (2.3). The mean degree in individuals taking 0, 1, 2, 3, and 4 times medication a day were 4.6, 5.0, 5.4, 5.5, and 6.2, respectively. Regarding medication timing and degree of pain in two consecutive time points (t0, t1), regression towards the mean occurred for individuals without medication in both time points. The degree changed more for individuals taking medicine only at t0, but not for those taking at both time points. Weaker pain was reported when they could do hanging laundry and rising early than when they could not, but they could do shopping, strolling and light exercise even having stronger pain.

CONCLUSIONS:
We showed a tendency of relationship between pain and medication/activity based on the data from the app. More data and connecting to claims will help us to show characteristics of patients and diseases, select a treatment, and evaluate a medicine.

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PP082 Capacity Needs Towards Increased Increased Health Care And Networking

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ABSTRACT SUMMARY:
Integrating Health Technology Assessment in the East African region will promote the public’s right to proper health care, and contribute to the establishment of health and medical standards related to the assessment of health technology through systematic analysis and evaluation of technology introduced in the region’s health care and medical sectors.

**INTRODUCTION:**

Quite a number of uncoordinated health technologies (HTs) exist in the East Africa (EA) region. The number of people suffering from one or more chronic diseases is also rapidly increasing. Existing systems of care don’t adequately address the increasing conditions. To adequately address this issue, complex health technologies such as disease management programs or specialized palliative care services are needed. Integrated Health Technology Assessment (HTA) systems will enable comprehensive patient-centered (as opposed to simultaneous but independent) assessment of complex health technologies that will enable the assessment of, effectiveness, economic, social-cultural, ethical, and legal issues, such as; patient preferences and patient-specific moderators of treatment; contextual settings and implementation plans. The initiation of regional networking of HTAs in the EA region was successfully done at a meeting held in Uganda in October 2015, and supported by HTAi with an objective of building capacity of patients and hospital-based healthcare professionals to understand and utilize the HTA tool for effective health research and public policy. This initiative aimed at providing an overview of existing and new health technologies that may be utilized to improve health outcomes, enhance knowledge about and support the scientific and practical development, application, teaching, and promotion of HTA in EA region.

**METHODS:**

A two-day meeting was held to introduce HTA to targeted healthcare professionals, policy and decision-making bodies, academicians, researchers and patient group representatives, and other health stakeholders. High profile presentations, group discussions, and plenaries dialoguing on matters affecting patients and public policy, explored innovative synergies that address best practices in health policy and technological decision making, and opportunities for integrating HTA in regional health systems.

**RESULTS:**

Over fifty participants participated. A loose forum, EAHTAC, was formed, and a work plan for networking and piloting hospital-based HTA was crafted. A regional HTA meeting is being organized to strengthen the network, targeting healthcare professionals, health economists, administrators, and other stakeholders and patients.

**CONCLUSIONS:**

Integrating existing and new HTs and practices may improve health outcomes.

PP083 The Use Of Barbed Sutures In Partial Nephrectomy? A Systematic Review

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**ABSTRACT SUMMARY:**

A barbed suture is an effective and safe surgical technique in partial nephrectomy. However, more evidence with larger sample sizes and longer follow
Knotless barbed sutures can eliminate knot tying during partial nephrectomy (PN). Since various effects have been reported on patients and for surgeons, it is important to determine the effectiveness and safety of barbed sutures in PN.

**METHODS:**
PubMed, EMBASE, Cochrane Register of Clinical Studies, and ClinicalTrials.gov were searched for randomized controlled trials (RCTs) and cohort studies comparing barbed sutures with conventional sutures in PN (until 20 February 2015). Quality assessment was conducted based on Cochrane recommendations. Review Manager was applied to analyze the data, and we sequentially omitted each study to conduct sensitivity analyses.

**RESULTS:**
A total of eight cohort studies (low to moderate risk of bias) were included (431 patients), while no RCTs proved eligible. Compared to conventional sutures, pooling data showed that warm ischemia time (five studies, Mean difference (MD) = -7.13, 95 percent Confidence Interval, CI -8.65 to -5.61, P < .00001) and operative time (four studies, MD = -11.29, 95 percent CI -17.87 to -4.71, P = .0008) were significantly shorter in the barbed group, as well as fewer postoperative complications (eight studies, Odds ratio (OR) = 0.44, 95 percent CI .24 to .80, P = .007). Subgroup analysis, based on types of barbed suture, suggested that a unidirectional barbed suture led to fewer postoperative complications.

**CONCLUSIONS:**
The barbed suture is an effective and safe surgical technique in PN. More evidence with larger sample sizes and longer follow up are needed to validate this finding.

**PP084 Diabetic Macular Edema: A Comparison Between Treatment Options**

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**ABSTRACT SUMMARY:**
This project presents an HTA and MCDA experience concerning the DME alternatives multi-dimensional comparison, in three Italian Regions. No statistically significant differences were reported in the appraisal phase: Dexamethasone was attributed a higher score, considering the final normalised weight derived from the MCDA approach (p-value = .001).

**INTRODUCTION:**
Health Technology Assessment (HTA) aims at providing decision makers with relevant data, matching different perspectives, with an evidence-based approach. The most common framework used is the European Network for Health
Technology Assessment (EUnetHTA) Core Model (1): HTA may be further supported by a Multi-Criteria Decision Analysis (MCDA) (2,3), leading to a final quantitative synthesis, facilitating the appraisal phase.

This project presents a multi-dimensional comparison of the technologies available for the treatment of diabetic macular edema (Ranibizumab, Aflibercept, Dexamethasone implant and off-label Bevacizumab), comparing three Italian Regions: Lombardy, Liguria and Veneto.

METHODS:
The nine EUnetHTA dimensions were first prioritized by seventeen multidisciplinary evaluators. Thereafter a further nine professionals attributed a 3-level rating score (from “1” not performant, to “3” most performant) to each dimension and sub-dimension, after carefully assessing the three HTA reports. In conclusion, the investigation of statistically significant differences between the attributed scores of the evaluators was conducted, using a multi-variate analysis.

RESULTS:
No statistically significant differences were reported in the prioritization of each dimension, except for the equity (more important in Liguria and in Lombardy) and the economic financial dimensions (more relevant in Veneto and in Lombardy).

Notwithstanding the evaluators’ different professional titles, job roles, center size, and various Regional contexts, they attributed similar scores to the HTA dimensions during the appraisal phase (even though conducted in different years, in 2015 and 2016). This finding demonstrates the robustness of both the evaluations and the final MCDA results: i) no statistically inter-regional significant differences emerged regarding Ranibizumab and Aflibercept (p-value >.05); ii) no statistically significant inter-regional differences emerged regarding Dexamethasone, except for the assessments in the clinical dimensions (p-value=.026), since in Lombardy Region the evaluation was carried out earlier in the technology’s life-cycle.

CONCLUSIONS:
Dexamethasone was consistently attributed a higher total score, considering the final normalised weight derived from the MCDA approach (p-value =.001).

REFERENCES:

PP085 A Scoping Review Of Emergency Assessment And Referral Of Suspected Transient Ischemic Attack

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**ABSTRACT SUMMARY:**

Patients with Transient Ischaemic Attack (TIA) should be assessed and treated in a specialist clinic. We aimed to identify published studies describing pathways for emergency assessment and referral of patients with suspected TIA at first medical contact through a scoping review. Many suspected TIA patients present to ambulance services however, there are no effective pre-hospital assessment pathways for paramedic referral.

**INTRODUCTION:**

Patients who experience Transient Ischaemic Attack (TIA) should be assessed and treated in a specialist clinic to reduce risk of further TIA or stroke. But referrals are often delayed. We aimed to identify published studies describing pathways for emergency assessment and referral of patients with suspected TIA at first medical contact: primary care; ambulance services; and emergency department.

**METHODS:**

We conducted a scoping literature review. We searched four databases (PubMed, CINAHL, Web of Science, Scopus). We screened studies for eligibility. We extracted and analysed data to describe setting, assessment and referral processes reported in primary research on referral of suspected TIA patients directly to specialist outpatient services.

**RESULTS:**

We identified eight studies in nine papers from five countries: 1/9 randomised trial; 6/9 before-and-after designs; 2/9 descriptive account. Five pathways were used by family doctors and three by Emergency Department (ED) physicians. None were used by paramedics. Clinicians identified TIA patients using a checklist incorporating the ABCD2 tool to describe risk of further stroke, online decision support tool or clinical judgement. They referred to a specialist clinic, either directly or via a telephone helpline. Anti-platelet medication was often given, usually aspirin unless contraindicated. Some patients underwent neurological and blood tests before referral and discharge. Five studies reported reduced incident of stroke at 90 days, from 6-10 percent predicted rate to 1.2-2.1 percent actual rate. Between 44 percent and 83 percent of suspected TIA cases in these studies were directly referred to stroke clinics through the pathways.

**CONCLUSIONS:**

Research literature has focused on assessment and referral by family doctors and ED physicians to reduce hospitalisation of TIA patients. No pathways for paramedic use were reported. Since many suspected TIA patients present to ambulance services, effective pre-hospital assessment and referral pathways are needed. We will use review results to develop a paramedic referral pathway to test in a feasibility trial.

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**PP086 Horizon Scanning In Multiple Sclerosis Decisions In Brazil**

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**ABSTRACT SUMMARY:**

In Brazil, the pharmaceutical sector has requested an individual incorporation in the Brazilian public health system for each new drug for multiple sclerosis that receives sanitary authorization for marketing. Horizon Scanning within Brazilian Ministry of Health has played a key role in...
the recommendations made by the National Committee for Health Technology Incorporation (CONITEC).

INTRODUCTION:
In Brazil, the pharmaceutical sector has requested an individual incorporation in the Brazilian public health system (SUS) for each new drug for multiple sclerosis that receives sanitary authorization for marketing. Horizon Scanning within Brazilian Ministry of Health has played a key role in the recommendations made by the National Committee for Health Technology Incorporation (CONITEC). Horizon Scanning seeks to predict which technologies have potential to impact health care in SUS, before their formal request. This study aims to present the impact of horizon scanning in two assessments made by CONITEC on drugs to treat Multiple Sclerosis.

METHODS:
Grey literature was searched to find new and emerging drugs for multiple sclerosis treatment. Regulatory agencies were also searched: European Medicines Agency (EMA), Food and Drug Administration (FDA) and Brazilian Regulation and Health Surveillance Agency (Anvisa). A pre-defined standardized form was used. Information extracted about each drug was identified as: drugs name, mechanism of action, indication, administration route, finished phases of clinical trial and registration in other countries.

RESULTS:
In 2014, horizon scanning identified seven drugs while CONITEC was assessing Fingolimod for multiple sclerosis. In this case, the drug’s administration route was a differential, as only three new drugs identified were also orally administrated. Thus, Fingolimod received a positive recommendation for incorporation. In 2016, horizon scanning identified fourteen drugs while Teriflunomide was under assessment. At this moment, the orally administrated Fingolimod was already available and it was identified other eight new drugs with the same route. Therefore, the initial recommendation was against its incorporation.

CONCLUSIONS:
Horizon scanning has proved to be of major importance for assisting recommendation-making process of the committee. In the two cases presented, horizon scanning information could predict which technologies were being developed and could be registered in Brazil. These new technologies had influenced the recommendations made by CONITEC’s members. As a result, a horizon scanning section in all CONITEC’s reports became mandatory.

PP087 A Tool Of Transferability Of Cost Utility Analysis Of High Cost Drugs

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ABSTRACT SUMMARY:
The objective of the study is to identify a tool that allows transferring the results of Economic Evaluation from one country/agency to another. After a bibliographic search, we found Antoñanzas’ tool that provides a transferability index based in critical, non-critical, subjective and objective factors, both from the “exporting” system and the importing one that was appropriate for our environment.

INTRODUCTION:
Since the creation of the National Integrated
Health System, economic evaluations (EE), mainly cost-utility studies, became an indispensable requirement for the inclusion of a Drug to the Therapeutic Drug Formulary.

Cost-utility analysis allows calculation of cost of additional quality-adjusted life year generated by a specific treatment. This type of study is time consuming and requires the technical skill of a multidisciplinary team, dedicated and experienced in the subject. The objective of the study is to identify a tool that allows transferring the results of EE, carried out in agencies from other countries to our own environment.

METHODS:
A bibliographic search of instruments of transferability of EE was carried out in several databases of Health Technology Assessment. Complementary consultations were held with EE experts on their use of such instruments.

RESULTS:
Two transferability instruments were found, the first one developed by J.Nixon and M.Drummond and the second one by F. Antónanzas. After analyzing characteristics of both, the last one was selected as the most suitable for our system. This tool provides a transferability index based in critical, non-critical, subjective and objective factors, both from the “exporting” system or agency (where the EE was developed) and from the “importer” system (where the EE results will be adopted). The applicability of this instrument was assessed by comparing some reports of cost-utility developed in the Uruguayan context and the results of cost-utility analysis for the same drug performed in other contexts. The value of the transferability index was analyzed in relation to the similarity of results obtained in both contexts.

CONCLUSIONS:
This transferability tool has demonstrated to be useful in some specific situations in our context. It is a good alternative to complete EE when qualified human resources are scarce and evidence to decision making is required.

PP088 CEA Of Caspofungin Versus Voriconazole For Empirical Antifungal Therapy

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ABSTRACT SUMMARY:
Caspofungin and voriconazole have been proposed in China but their CEA is unknown. This study aims to compare the cost-effectiveness of them in China. A decision analytic model was developed from the perspective of society. It demonstrated that, compared with voriconazole, caspofungin was preferred by $161, $12,266, and $246 per patient treated, successfully treated patient, and patient survival, respectively.

INTRODUCTION:
Invasive fungal infections (IFI) in patients with febrile neutropenia are associated with significant high mortality and expenditure. Based on two major clinical trials, voriconazole and caspofungin were recommended as alternatives to the mainstay of IFI treatment. These two pharmaceutical therapies have been proposed in China but their cost-effectiveness is unknown. This study aims to compare the cost-effectiveness of caspofungin versus voriconazole as empirical treatment for IFI in patients undergoing febrile neutropenia in China.

METHODS:
A decision analytic model was developed from
the perspective of society. Treatment transition probabilities in the antifungal therapy were obtained from two clinical trials. The switched therapy after initial fungal therapy, duration as well as relevant tests and medication were derived from a panel discussion with sixteen Chinese clinical experts. Cost of medication, hospitalization, rescue, and the relevant antifungal tests were considered and obtained from latest standard prices of medical services in China. Tree Age Pro 2011 software was used and the sensitivity analysis were performed to demonstrate the robustness of the model.

RESULTS:
The base case scenario demonstrated that caspofungin induced a higher probability of success (33.95 percent versus 25.63 percent), and a higher probability of survival (92.36 percent versus 91.87 percent). The use of caspofungin also led to a lower expected mean cost per patient than voriconazole ($12,168 versus $12,330). Comparing with voriconazole, caspofungin was preferred by $161, $12,266, and $246 per patient treated, successfully treated patient, and patient survival, respectively. The result was moderately sensitive to the initial and switched therapy duration and acquisition cost of the antifungal agents.

CONCLUSIONS:
This is the first cost-effectiveness study of voriconazole versus caspofungin for empirical therapy, and caspofungin seems to be a dominant strategy in the empirical antifungal therapy of febrile neutropenia. The study may be helpful to use as evidence to inform the medical insurance formulary decision making in Chinese healthcare setting.

PP089 Health Technology Assessment Of An Automated Compounding Of Parenteral Nutrition

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ABSTRACT SUMMARY:
The aim of this study was to evaluate an automated parenteral nutrition (PN) admixture bags manufacturing system (automatic system) compared with a manual PN bags production method (manual system). Results showed that the automatic system can improve the quality of nursing care offering several advantages in terms of safety, quality and organizational impact.

INTRODUCTION:
Pediatric parenteral nutrition is mainly used in neonatal intensive care units (NICU) and requires close collaboration with the hospital pharmacy, especially for manufacturing time, application, preparation and delivery (1). In this context, a Health Technology Assessment (HTA) to evaluate an automatic system compared with a manual system was carried out.

METHODS:
The Decision-oriented HTA (DoHTA) method (2), coordinated by Bambino Gesù Children’s Hospital (BGCH) HTA Unit, was applied to carefully assess the technology. It was developed starting from the European Network for HTA (EUnetHTA) Core Model® and integrated with the Analytic Hierarchy Process (AHP). Its purpose is to identify
all the relevant assessment aspects of automatic system integrating the evidence from the scientific literature with experts’ judgments and the specific context analysis for BGCH: an evaluation scheme inherent safety, clinical effectiveness, technical and organizational aspects (represented by a decision tree at three levels: dimensions of evaluation, I and II level indicators) was subsequently created. A weight was finally associated to each identified element and the alternatives’ ranking was defined.

RESULTS:
The study results show a “performance value” associated with the automatic system greater than about thirty-two percentage points compared to the manual system.

CONCLUSIONS:
At the current state of the scientific evidence and the results of analysis carried out by the working group, it is believed that the choice should be made to introduce the automatic system is available in BGCH.

More specifically, from the point of view of safety, automatic system is safer for both patient and operators; about clinical effectiveness, the system improves the nutritional intake, allows a reduction of post-infusional adverse events and the use of antibiotic therapy; concerning economic aspects, the analysis of available data shows a substantial equivalence between the alternatives considered; the technical-functional aspects show an improvement according to almost all indicators; organizational aspects show a slight improvement in the working and in process management and finally the legal aspects indicate a slight advantage for the automatic system.

REFERENCES:

PP090 Reducing Low-Value Practices In Catalonia: Essential Project

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ABSTRACT SUMMARY:
In recent years, there has been a growing interest in reducing unnecessary care of healthcare services, which the harm outweigh the benefits, resulting in physical, psychological and financial impacts to patients. Essential Project launched in Catalonia elaborates recommendations to avoid low-value practices commonly used in our healthcare services identified by healthcare professionals through the implementations of the project.

INTRODUCTION:
In 2013 the Essential Project launched in Catalonia promotes the identification of low-value practices (LVP) by healthcare professionals and elaborates recommendations to avoid them. This project aims to reduce unnecessary care of health care services which harm outweighs the benefits, resulting in physical, psychological to the patients and wasteful health care services. The main objectives are to describe the implementation process at the primary care level and to evaluate the impact of recommendations on general practitioners (GPs) practice.
METHODS:
The implementation process consists in:

(i) Nomination of clinical leaders to promote the project among their primary care teams (PCT) and to lead the implementation activities by identification of barriers and enablers for change in clinical practice towards avoiding LVP.

(ii) Selection of recommendations to be implemented and definition of corresponding activities to be carried out by each PCT according to the specific characteristics of their organizations.

(iii) Development of related indicators and comparison between baseline status.

RESULTS:
One hundred and sixteen PCT (covering 30 percent of the Catalan population) participate in the pilot experience of implementation. 21 recommendations were selected such as: bisphosphonates in post-menopausal women with low risk of fracture, PSA screening and statins for primary prevention of cardiovascular disease, among others. At 12-month follow-up, use of bisphosphonates were reduced by 21 percent (p=.0005), PSA was reduced by 14 percent (p=.0009). The use of other treatments such as antidepressants, benzodiazepines for some specific clinical conditions decreases with no statistically significant changes.

CONCLUSIONS:
This is the first experience in Catalonia and Spain of implementation of the recommendations to avoid LVP with early involvement of target professionals. Follow-up results provide information about the early impact of recommendations at primary care level. Our challenge is to implement the recommendations at hospital level.

PP091 A Follow Up Study On Transcatheter Aortic Valve Implantation (TAVI)

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ABSTRACT SUMMARY:
Transcatheter aortic valve implantation (TAVI) is often presented as an option for aortic valve replacement in patients for whom conventional valve replacement is not suitable, or who are at very high risk for open surgery. Our experience on TAVI yielded worrisome results. In similarity to our findings, other authors described a higher risk for major vascular complications and mortality in patients undergoing TAVI.

INTRODUCTION:
Severe aortic stenosis with symptoms or left ventricular dysfunction has commonly a poor prognosis. Aortic valve replacement is usually performed for these patients aiming at improving their functional class and survival rate. Transcatheter aortic valve implantation (TAVI) is often presented as an option in patients with high surgical risk for conventional surgical valve replacement.(1) Nonetheless, in this group of patients, the literature has yielded conflicting evidence suggesting that benefits of TAVI for patients of high or intermediate surgical risk is not consistent.(2,3)
**METHODODOLOGY:**
This retrospective study aimed to evaluate the mortality rate from a cohort of patients after the correction of aortic valve dysfunction with TAVI. It consisted of a convenience sample of patients at high risk for open surgery for the correction of aortic valve dysfunction treated with TAVI from 2013 to 2016. All included patients were being provided healthcare assistance by a private nonprofit health maintenance organization (HMO) operating in Belo Horizonte, Brazil. Since TAVI is not currently covered by the Brazilian supplementary healthcare system, reimbursements were enforced by lawsuits. Data was extracted from an administrative database, using the software Oracle Business Intelligence®. Continuous variables were expressed as mean and standard deviation. The Kaplan-Meier method was used to adjust the 1-year survival curve using the software STATA 13.1 (Stata Corp, College Station, TX, USA). This historical cohort resulted in no interventions, neither during the course of the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance to the ethical principles of the Declaration of Helsinki.

**RESULTS:**
Overall, seventeen patients with a mean age of 80.5 years (68-91) underwent TAVI; 59 percent were women. Peri-operative mortality rate was 23.5 percent (n = 4) and accumulated overall one-year mortality was 35.3 percent (n=6). Mean length of hospital stay was 26.9 ± 16.6 days. Prolonged hospital stay (≥ 7 days) occurred in 14/17 cases (82.3 percent), with a maximum of 51 days.

**CONCLUSIONS:**
In similarity to our findings, other authors described a high early and late mortality rate in patients undergoing TAVI. The strategy to use TAVI as an alternative in patients at high risk for open surgery is still under debate and should be carefully discussed taking into consideration the local team expertise as well as local healthcare available recourses.

**REFERENCES:**

**PP092 Real World Data: Biologic Treatment For Naive Patients In Lazio Region**

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**ABSTRACT SUMMARY:**
The introduction of new biologic treatments has radically changed the management of Immune-mediated inflammatory diseases (IMID). The objective of this study was to identify the cohort of biologics treatment-naïve patients in the Lazio region using Real World Data. There were 2,929 patients were identified, and 12.5 percent switched Anatomical Therapeutic Chemical classification within 1 year. Overall adherence was 87.7 percent, low-adherence occurred in 21.5 percent of patients, and dose-increase in 18.1 percent.
INTRODUCTION:
The introduction of new biologic treatments has radically changed the management of Immune-mediated inflammatory diseases (IMID). Due to the high costs of the treatments a strong control and monitoring of claims databases could help decision makers to understand the consequences of their decisions.

The objective of the study was to identify the cohort of biologics treatment-naïve patients in the years 2011-2013 in the Lazio region (6 millions of inhabitants), in order to investigate the parameters influencing the biologic treatment expense at the regional level.

METHODS:
Patients were enrolled based on administrative databases of the Lazio region. Treatment-naïve patients were defined as subjects who did not have a prescription in the two years before the index prescription. Switcher patients were defined as those who had an Anatomical Therapeutic Chemical classification (ATC) prescription different than the one at enrolment, within one year of the index date. Treatment adherence was estimated as the number of doses actually prescribed as compared to the number indicated in the Summary of Product Characteristics (SPC).

RESULTS:
From a total number of 10,120 patients treated with biologic drugs between 2011-2013 in the Lazio region, 2,929 were estimated as treatment-naïve patients (42 percent male). The most frequently used drugs were etanercept (31 percent), adalimumab (30 percent) and infliximab (17 percent). Considering the disease treatment distribution, 28.6 percent of patients were treated for rheumatoid arthritis, 25.5 percent for psoriatic arthritis, 16.4 percent for psoriasis and the remaining patients for other diseases. Some patients switched biologic therapy (367), of which 22.6 percent were within the first 120 days. Total mean adherence was estimated in 87.7 percent: 21.5 percent of patients showed a low adherence (SPC< 60 percent) while 18.1 percent were estimated as dose increase patients (SPC>110 percent), 11.4 percent for rheumatic diseases, 32.3 percent for dermatological diseases and 26.9 percent for inflammatory bowel disease.

CONCLUSIONS:
The study provides a map of the current treatment setting with biologics in the Lazio region considering the disease, adherence and prescribed treatments. A considerable number of treatment-naïve patients were identified (2,929), 12.5 percent of whom switched ATC within 1 year. Total mean adherence was estimated in 87.7 percent, low adherence occurred in 21.5 percent of patients, while dose-increase was in 18.1 percent.

PP093 Bringing Evidence On Prevention Programs Cost-Effectiveness

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ABSTRACT SUMMARY:
Building capacity in economic evaluation for the General Health Insurance Company of the Czech Republic by creating prevention programs assessment guidelines. The Program evaluation of public expenses method was adapted with a strong causality to decision making. New guidelines are narrowly linked to value-for-money considerations. Challenges as for HR issues have been raised. A thorough training has to be performed.

INTRODUCTION:
The General Health Insurance Company of the
Czech Republic, which insures 60 percent of the Czech population, administrates a prevention fund. This fund is meant to cover special prevention projects with expected outcomes on the health status of the insured. These pilot projects are of strategic importance for the Company; they are supposed to generate money savings in the future and to attract new policyholders. This impact has nevertheless neither been systematically monitored nor evaluated. We are proposing evaluation process guidelines to fill in this gap.

METHODS:
International studies and Health Technology Assessment (HTA) methodological papers were reviewed in order to set up a framework for economic evaluation. Population studied are the policyholders of the Company. The method chosen is Program evaluation of public expenses. It is not only a tool of economic evaluation, but also equally a tool for strategic planning of resource allocation. The programs value can be demonstrated in relation to their strategic objectives.

RESULTS:
Program financing is a case when economic evaluation demonstrates a strong causality to decision making. Program financing allocates resources there, where their effectiveness was proved. The approach used is cost-utility analysis, comparing the evidence to a previously set goal. Program evaluation is thus narrowly linked to the value-for-money considerations. An interdisciplinary committee decides upon project proposals based on the indicator to goal fulfilment ratio, which can be seen as an ex-ante evaluation. Ex-post evaluation lies in economic effectiveness assessment, performed via a reference group global burden of disease modelling in comparison to the studied population. This assessment is discussed within the expert committee (consisting of professors in various clinical fields of medicine).

CONCLUSIONS:
We strongly propose using multiple interventions (projects) within one program. Only thus can a greater effectiveness, perceived as the goal fulfilment, be achieved. We are facing challenges as for the HR issues. A thorough training of the staff has to be performed. We have also come across a methodological issue, that is, the generalisability of our findings to the whole insurance portfolio. Further research in this direction is needed.

PP094 Autologous Stem Cell Transplantation For Multiple Sclerosis

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ABSTRACT SUMMARY:
To perform a systematic review of effectiveness and safety, a health economic evaluation, and discuss ethical considerations of autologous hematopoietic stem cell transplantation in patients with relapsing-remitting multiple sclerosis (RRMS) compared to other relevant treatments.

INTRODUCTION:
Multiple Sclerosis (MS) is an inflammatory neurological disease. The standard treatment is disease modifying drugs which may alleviate symptoms and slow the progress of disability, but not lead to remission. Autologous Hematopoietic Stem Cell Transplantation (AHSCT) is a new technology for treatment of MS in Norway. Disease remission in some patients treated with AHSCT has been postulated, in particular in patients in the early course of disease with high disease activity classified as having Relapsing-remitting multiple
sclerosis (RRMS), but severe complications have also been reported.

**METHODS:**
We conducted a systematic literature search. No restrictions were set in terms of study design, although case series should include at least ten patients with a majority having RRMS. We performed a cost analysis from a healthcare perspective with a time frame of one year.

**RESULTS:**
One Randomized Controlled Trial (RCT) (n=21, RRMS=7), one registry study (n=345), and seven case series (n=442, RRMS=277) without control groups were included. Estimated transplant-related mortality was 2 percent or lower. Serious adverse events, such as infections, were common during follow-up. Stabilization or improvement in neurological status was reported in 63 percent to 89 percent of the patients after three years, and the number of Gd+ and T2 lesion volume assessed by Magnetic Resonance Imaging was reduced. The quality of evidence assessed using the “Grading of Recommendation Assessment, Development, and Evaluation” tool was low for transplant-related mortality and very low for the other outcomes. HSCT costs were approximately between 480,000 and 605,000 Norwegian kroner per patient in the intervention year. A heterogeneous disease progression, significant risks associated with the method, lack of effective treatment options, and uncertainty about the benefit versus risk, implies that any decision to offer HSCT in the treatment of MS is ethically challenging.

**CONCLUSIONS:**
The main limitation in this HTA is the absence of controlled studies, which introduces a high risk of bias. Studies without control groups, including mainly patients with RRMS, reported that disease activity could be delayed or stopped for a period of up to three years in several patients, whereas adverse events were common. Ethical considerations are associated with significant uncertainty of benefit versus harm. The low level of evidence implies the need for controlled trials.

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**PP095 Assessment Of Magmaris Resorbable Metal Stent In Patients With Angina**

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**ABSTRACT SUMMARY:**
Magmaris™ is a new drug-eluting resorbable metal stent used for coronary reperfusion in patients with angina. An early assessment of Magmaris™, identified through the Early-Awareness and Alert-System, “SINTESIS-new technologies”, of The Instituto De Salud Carlos III (AEDES-ISCIII); retrieve a prospective, non-randomized, non-controlled, multicenter, clinical trial. Magmaris™ seems to be an effective and safe treatment in patients with angina. More research specially randomized controlled trials are necessary.

**INTRODUCTION:**
Ischaemic heart disease is the leading cause of death worldwide. Magmaris™ is a new drug-eluting resorbable stent used for coronary reperfusion during a balloon angioplasty. Magmaris™ is composed of absorbable magnesium scaffold and its surface is coated with bioresorbable poly-L-lactide, which incorporates Sirolimus. Magmaris™ has theoretical advantages as the stent body disappears after vascular constrictive remodeling. It would provide the stability and elasticity of non-resorbable metal stents, but without long-term problems such as endothelial dysfunction, delay in endothelialization, risk of thrombosis and complications due to long-term antiplatelet medication. The objective of this work is to assess
efficacy and safety of Magmaris™ in patients with angina or silent ischaemia.

METHODS:
Early assessment of Magmaris™ identified through the Early-Awareness and Alert-System, “SINTESIS-new technologies”, of The Instituto De Salud Carlos III (AETS-ISCIII). The searched databases were: MEDLINE (PubMed), EMBASE, WOS, Clinical Trials and Cochrane Library. Clinical studies using Magmaris™ published in any language until December 2016 were reviewed.

RESULTS:
One prospective, non-randomized, non-controlled, multicenter, clinical trial with two publications was retrieved. The first publication (123 patients) showed mainly imaging outcomes of angiography, intravascular ultrasound and tomography at 6 months of follow up. The second publication (118 patients) with data from 12 months of follow up also reported: Target lesion failure in four patients (3.4 percent; 95 percent Confidence Interval, CI:0.9–8.4); one target-vessel myocardial infarction (0.8 percent; one myocardial infarction (0.8 percent); two clinically driven target lesion revascularisation (1.7 percent) and two clinically driven target-vessel revascularisation (1.7 percent). No definite scaffold thrombosis was observed. No procedural complications were reported. This trial is expected to continue up to 36 months of follow up.

CONCLUSIONS:
Clinical data show that Magmaris™ seems to be an effective and safe treatment in patients with angina or silent ischaemia undergoing balloon angioplasty. More research specially randomized controlled trials are necessary to confirm these results.

PP096 EU-HTAs For Medical Devices: How To Overcome Reimbursement Divergence

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ABSTRACT SUMMARY:
National Health Technology Assessment (HTA) procedures for medical devices differ in several elements. EUnetHTA proposes itself as plausible platform for the HTA methodology across Europe. We compared methodology and approach of the German and the European HTA for medical devices by analyzing guidelines, requirements and output of EUnetHTA, and compared those aspects with the German G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) standard and IQWiG (Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) methods.

INTRODUCTION:
National Health Technology Assessments (HTAs) for medical devices are crucial to regulate the quality and costs of healthcare systems. However, there is diversity in several aspects among European countries. Consequently, controversial results might arise, generating contrary reimbursement decisions. The European Network for Health Technology Assessment (EUnetHTA) is an interface platform for the harmonization of HTA information across Europe. The European Commission expects national uptake of a European HTA. Thus, European HTAs might overcome the diversity of national HTA requirements.
METHODS:
We aimed to compare German and European HTAs for medical devices regarding processes, methods, timelines, and involvement of medical device companies. Therefore, we analyzed guidelines, requirements, and output of EUnetHTA and compared those aspects with the German G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) standard and IQWiG (Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) methods.

RESULTS:
We found differences between the European and German HTAs for medical devices regarding timelines, involvement of medical device companies, body of evidence, use of surrogate endpoints, and methodology. European HTAs for medical devices reflect the clinical reality by integrating the existing evidence (including real world data) and by using comprehensive statistical methods for medical devices. In contrast, German HTAs for medical device-based technologies are long lasting and are often restricted to a small body of evidence.

CONCLUSIONS:
As a conclusion, similar to pharmaceuticals, the European HTA framework might also become a worldwide platform for HTAs of medical device-based technologies with the potential to harmonize reimbursement decisions and patients health care across countries on the basis of clinical reality.

PP097 Challenges Of Rapid Reviews In Health Technology Assessment: Case Study From An Italian Region

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ABSTRACT SUMMARY:
The appraisal of a rapid assessment on the use of frequency domain (FD)-optical coherence tomography in percutaneous coronary interventions, based on a rapid review of the literature, was carried out using a methodological checklist proposed by Kaltenthaler and colleagues. The process highlighted some critical elements in our method and stimulated considerations on how to improve it.

INTRODUCTION:
Rapid reviews are an attractive tool for Health Technology Assessment (HTA) as they may be a support in decision making when time and resources are limited. Rapid reviews are carried out in few weeks (from 3 weeks to 6 months) and require adjustments from standard systematic review methods. Methodology on how to carry out rapid reviews is still debated and guidance regarding the most suitable method to apply is lacking. Kaltenthaler (1) has recently proposed a checklist of items to be considered when undertaking a rapid review. We appraised our rapid assessment on the use of frequency domain (FD)-optical coherence tomography in percutaneous coronary interventions, based on a rapid review of the literature, using the items proposed (1).
METHODS:
The checklist reports four key points to consider when planning a rapid review: (i) scoping search - needed to quantify the available evidence and to inform rapid review protocol, (ii) results reporting – considering heterogeneity of intervention, comparators, and outcomes, (iii) clear communication with policy makers - ensuring that review responds to the policy question and (iv) reporting on methods - methodology used, strengths and limitations.

RESULTS:
When we applied the checklist proposed by Kaltenthaler (1) to our rapid review on the use of FD-optical coherences tomography it resulted that: the scoping search revealed no useful systematic reviews to answer policy-makers questions and a high number of relevant studies. For results presentation, we used a narrative synthesis reporting outcome data grouped in domains previously defined by an evidence profile. Domains consisted of technical performance, safety, efficacy, and change in management. No metanalysis was performed due to paucity of randomized controlled trials (RCTs) for the efficacy domain and high heterogeneity in outcomes measures for technical performance. Analysis of some of the outcomes was extremely time-consuming (technical performance) and did not provide particularly useful information for the commissioning body. A clearer and more intensive dialog with policy makers to adjust extent of research question and/or outcomes to be investigated would have probably improved usability for final users. Description of methods was partial.

CONCLUSIONS:
The checklist by Kaltenthaler (1) helped us to reflect on the method we used to carry out rapid reviews and to pinpoint possible solutions to improve it.

REFERENCES:

PP099 Development Of Interface To Reactivate Old Generation Gamma Cameras

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ABSTRACT SUMMARY:
Gamma cameras are becoming obsolete, especially in developing countries, because they are analog or semidigital, and there are not many operatives. We want to evaluate the state of an analog gamma camera; develop a signal acquisition system; an image processing software and reactivate an out-of-service analog Gamma camera.

INTRODUCTION:
The gamma camera is an image capture device. The camera detects the gamma radiation injected into the patient and generates a two-dimensional image of the organ’s activity. It provides morphological and functional information.

It is desired to reactivate an out-of-service analog gamma camera by developing a low-cost system that performs the acquisition of detector signals and image processing.

To carry out a general survey of the current situation of an analogical equipment, in order to be able to diagnose the real problem it has and to propose the solution through low-cost microcomputers, with acquisition cards interconnected through local area networks; and the design of a new connection interface in order to make it operational again.
METHODS:
The methodology is based on the experimental study, through developments and tests. The equipment to be reconditioned is of the year 1971. The understanding of the operation of the equipment and its parts was due largely to the technical manual of the equipment and datasheets.

The developed system consists of an elaborate electronic card, which captures the area and intensity signals, coming from the head of the gamma camera.

Said plate allows the digitization of analog signals, which are then sent to a microcontroller, and from there, to a conventional computer, to carry out signal processing by the development of an image reconstruction algorithm.

This developed software will make it possible to record each study obtained with the gamma camera and quantify values and curves semi-automatically. All studies will be performed with pinhole collimators.

RESULTS:
This project arose from the current need in public and private diagnostic and treatment services in the oncology area. At the country level, there is little equipment to make the corresponding studies. At the moment it’s in the evaluation stage, being realized a general diagnosis of the equipment.

This has also been achieved by acquiring the analogue signals from the detectors, through basic simulation tests of image acquisition and reconstruction.

CONCLUSIONS:
It’s possible to reactivate gammacamaras, through the development of low cost system that allows to update old equipment, through acquisition cards and algorithms of reconstruction of images.

PP100 Economic Evaluation Of A New Non-antibiotic First-line Treatment Of Recurrent Urinary Tract Infections

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ABSTRACT SUMMARY:
Urinary tract infections (UTIs) are common in female patients in general practice. The aim of this work was to perform a cost-effectiveness analysis of a novel effective non-antibiotic treatment option for prophylaxis of female patients with a history of recurrent UTIs, based on intravesical administration of hyaluronic acid (HA) plus chondroitin sulfate (CS), as compared to recommended 1st-line antibiotic therapy.

INTRODUCTION:
Urinary tract infections (UTIs) are common in female patients in general practice. These bacterial infections affect half of all women at least once in their life. Antibiotics are usually prescribed for UTIs, and continuous low antimicrobial prophylaxis is administered to patients at high risk of recurrent UTI (rUTIs) (1). However, a major concern arises due to the increased rates of severe treatment-related side effects and emergence of antimicrobial resistance, which makes rUTIs management more challenging while seeking the use of more expensive alternatives. On this basis, clinical evaluations of rUTI interventions should be accompanied by economic evaluations in order to guide healthcare policy and decision making.
The aim of this work was to perform a cost-effectiveness analysis of a novel effective non-antibiotic treatment option for prophylaxis of female patients with a history of rUTIs, based on intravesical administration of hyaluronic acid (HA) plus chondroitin sulfate (CS), as compared to recommended 1st-line antibiotic therapy (2).

METHODS:
A cost-utility analysis was performed in order to estimate the effectiveness of each treatment, according to the number of UTIs annual episodes, and the incremental cost-effectiveness (ICER) for patients with UTI, starting from data collected during a multicentric observational case-cross-over clinical trial involving seven European centers (2). The economic model includes the costs of HA treatment and the costs associated with each UTI, such as costs of UTI diagnostics and antibiotic treatment, additional care by the elderly-care physician, additional nursing care, and hospitalizations, as well as the expected QALY, measured through the Short Form Health Survey (SF-36) questionnaires administered to patients, for both groups (3).

RESULTS:
At this stage, preliminary findings suggest that HA plus CS is a cost-effective alternative to antibiotics for the treatment of recurrent UTIs, that could reduce UTIs events in female patients with a history of recurrent UTI at an acceptable cost.

CONCLUSIONS:
The results of this study support the use of HA plus CS against antimicrobials as 1st-line therapy in the management of rUTIs.

REFERENCES:


INTRODUCTION:
In 2015, the province of Québec, Canada went through a major restructuring in its healthcare system which resulted in regional institutional merging. Our hospital-based Health Technology Assessment (HTA) unit is now part of a large network comprising fourteen institutions covering an area of 12,734 km². This new organizational context poses major challenges in terms of addressing various local needs and for involving stakeholders into our assessments. In this paper we present how we addressed these difficulties.

METHODS:
This case study presents the procedural method we developed for involving local and regional stakeholders into an HTA concerning the need to extend a regional prenatal ultrasound screening program. We describe how we collected local data and networked local to regional stakeholders for producing the assessment and recommendation.

RESULTS:
After completion of the literature review on first trimester ultrasound screening, local data from each institution were collected using a combination of focus group meetings with local managers, gynecologists and ultrasound technologists. Overall, fifteen people were consulted on diverse regional sites, including two services users. In order to assess the perception of the results regarding efficacy, user's preferences, cost and organizational impact of expanding the screening program, people were asked to complete an online survey. The results of this survey were then used to write a first draft of a recommendation. A second survey was generated in order to obtain agreement of the fifteen people regarding the recommendation. Overall, this method decreased the time required to complete the assessment and reduced project operating costs. However, divergence of opinions may be difficult to resolve by this method and many rounds of consultation may be needed.

CONCLUSIONS:
Our procedural method using a combination of focus groups and online surveys for collecting local and regional data and opinions from stakeholders and support recommendation, has succeeded to provide well contextualized information for supporting a decision.

PP102 Perceived Quality By Patients Hospitalized At Home Undergoing Domiciliary Radiography

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ABSTRACT SUMMARY:
Since 2007 in the Health City and Science of Turin, an experimental service of home radiology has been active that fits into the broader context of home diagnostics. Radiology at home (R@dhome) benefits are not limited to the clinical or financial aspects but also ethical, social and relational advantages may be possible.

INTRODUCTION:
Europe currently has the highest proportion of older people in the world and is expected to maintain this leading position for the next 50 years. A teleradiology service for frail patients living at home or in nursing-homes (R@dhome), funded by
the Italian Ministry of Health, has been operating from June 2013 to May 2015 (1). The goal was to offer, within the path of home care patients, radiologic care for fragile elderly patients (2). In this report of the study a secondary outcome was evaluated; the perceived quality for patients and caregivers undergoing home radiology.

**METHODS:**
The study was a randomized controlled trial (RCT) with 136 patients: 71 cases and 65 controls. The perceived quality assessment was only performed among home inpatient group cases, at home or in nursing homes and not in the control group patients (who had treatment in a hospital). The assessment instrument was a semi-structured interview based on the benchmark system SERQUAL®. The identified dimensions of quality were: tangible aspects, reliability, responsiveness and empathy in a subpopulation of non-dementia patients. Eligible subjects were interviewed between May 2014 and May 2015.

**RESULTS:**
The percentage of satisfied patients, evaluated on the dimensions of perceived quality, was 97.7 percent. The main reasons given were: short waiting time, best comfort and safety, efficiency, operator’s kindness and less need to travel for the treatment.

**CONCLUSIONS:**
Home benefits are not limited to clinical or financial aspects but ethical, social and relational advantages have also been shown in this study (3). Given the fragility of the patients, positive results were mostly achieved by reducing the risk of trauma in transport between their home and the hospital.

**REFERENCES:**

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**PP103 Characteristics Of Systems Applied To Language Rehabilitation**

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**ABSTRACT SUMMARY:**
Linguistic or communication disorder, attention and memory are the first functions that must be rehabilitated to intervene the other cognitive functions. The objective of this study is to determine if free augmentative communication systems have the characteristics to provide a low-cost solution for Traumatic Brain Injury patients in rural areas of Paraguay.

**INTRODUCTION:**
In Paraguay the main cause of Traumatic Brain Injury are the accidents in ground transportation. According to data from the Basic Health Indicators 2013 of the Ministry of Public Health and Social Welfare, the regions with the highest rate of accidents in ground transportation are located in the rural zone of the country.

Linguistic or communication disorder, attention
and memory are the first functions that must be rehabilitated. It is essential to improve the patient’s language skills to intervene in the other cognitive functions.

The objective of this study is to determine if free augmentative communication systems have the characteristics necessary for the cognitive rehabilitation of the language to provide a low-cost solution for Traumatic Brain Injury patients in rural areas of the country.

METHODS:
A list of seven characteristics that contributed to verbal comprehension and expression, reading and writing, logical-verbal reasoning and numeration and calculation were compiled and compared to the Gazespeaker, which is a free augmentative communication system.

RESULTS:
The Gazespeaker meets the seven characteristics required for language rehabilitation.

CONCLUSIONS:
For patients with Traumatic Brain Injury are required low cost tools and ease-to-use like the Gazespeaker. It is a good augmentative communication system which satisfies all the characteristics required for a good language rehabilitation. In addition, this free software allows the use of an eye tracking device that can be applied to patients with Traumatic Brain Injury and severe motor deficit.

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ABSTRACT SUMMARY:
Evaluation of the Health Council Monitoring System, based on registrations of 4,495 Municipal Health Councils, which represented 80.8 percent of the country’s councils, using the Pearson chi-square association test between the system data and the population size of each municipality.

INTRODUCTION:
This national scope study aims to describe and evaluate the data of the Health Council Monitoring System (SIACS), in relation to the Brazilian Municipal Health Councils (CMS), this system is online and was launched in 2012. All Councils should be registered in the system in order to comply with Brazilian laws.

METHODS:
This is a cross-sectional, analytical study with evaluation based on quantitative and qualitative variables using the software STATA 10 and NVIVO 11. A Pearson Chi-square association test was performed considering the population of the municipality and data from the system.

RESULTS:
The sample of the study was 4,495 Municipal Health Councils, which represented 80.8 percent of the country’s councils. In relation to the three dimensions used, it can be seen that the best performance was in the representativity axis, in all adopted population sizes. The structure of the council was associated with the size of the municipality, the lower the municipality the worse the structure. The lack of autonomy in the decision making of the Councils was found in all the population sizes. Regarding the representations of the segments of social participation, the users showed a syndicalist, agrarian and religious profile of the country.

PP104 Brazilian Health Council Monitoring System (SIACS): An Assessment

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CONCLUSIONS:
Finally, we recognize that the SIACS presents some technical problems of data extraction, however it is considered a system of low maintenance and easy access, in addition, the existence of a bank to follow up of Health Councils is an advance of Social Participation in the Health Unique System.

PP105 National Health Technology Assessment R&D Development For Evidence-Based Healthcare

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ABSTRACT SUMMARY:
For the purpose of evidence-based policy making, evidence generation and synthesis efforts through Health Technology Assessment (HTA) research needs to be supported by government. Korean government decided to support National HTA R&D program with NECA, as a coordinating center, and developed National HTA program based on other countries’ programs, especially NIHR in the UK and PCORI in the US.

INTRODUCTION:
Korea has a national health insurance (NHI) program which covers 97 percent of the population and introduced a positive list system for NHI pharmaceutical benefits based on cost effectiveness and a new health technology assessment system for health interventions in 2006. The National Evidence-based Healthcare Collaborating Agency (NECA), the national HTA research agency, was established in 2009. These efforts made Korea the leading country in the Asia-Pacific region but more efforts are needed to strengthen evidence-based health care.

During recent decades, US, UK, Canada, and Australia established national research programs for HTA or comparative effectiveness research (CER). The National Institute of Health Research (NIHR) in the UK and the Patient Centered Outcomes Research Institute (PCORI) in the US are the leading programs.

The Korean government decided to develop a national HTA research fund for local evidence generation, evidence synthesis, and infrastructure development for the purpose of improving the evidence-based healthcare system.

METHODS:
We reviewed other countries experiences through web searching and interviewed main experts, focusing on the NHIR and PCORI for the purpose of Korean HTA research program development. It includes three categories: research program, infrastructure and data system, and coordinating center for planning and support.

RESULTS:
National Health Clinical Research, the Korean HTA research program, has developed with 25 million USD for three years. Three types of research programs were developed: prospective study for evidence generation, outcomes research with secondary data, and public health research.

Coordinating center established in NECA gives support to establish HTA research infrastructure, including patient registry setting, big data and data linkage, HTA training program and researcher networking.

Coordinating center established advisory committee for planning the research program and evaluation representing government, national research centers, national health insurance agencies, and medical and HTA societies.
CONCLUSIONS:
National Health Clinical Research, the Korean HTA R&D program has been developed referencing NIHR and PCORI, focusing on local evidence generation with patient registries and big data available in Korea.

PP106 Regional Guidance On Aids For Ostomy

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ABSTRACT SUMMARY:
The Veneto Region established a Technical Panel for Continence (TPC) with the purpose of producing guidance for aids based on a Health Technology Assessment (HTA) approach. Currently the TPC is investigating aids for ostomy patients in order to provide the first Regional guidance on appropriateness and disease management for ostomy.

INTRODUCTION:
The Veneto Region established a Technical Panel for Continence (TPC) with the purpose of producing guidance for aids based on a Health Technology Assessment (HTA) approach. TPC is a multidisciplinary experts group that involves local clinicians, pharmacists, health economist and patients associations. Among its tasks, TPC can issue recommendations in the field of appropriate use, purchasing and distribution for aids. Currently the TPC is investigating aids for ostomy patients in order to provide the first regional guidance on appropriateness and disease management for ostomy.

METHODS:
The Regional Health Technology Assessment Unit (CRUF) conducted a literature review of the evidence on aids for ostomy. Grey literature, and National and Regional laws and regulations were also included in the analysis. TPC discussed the collected evidence by consensus. Final recommendations have been sent to the Regional Technical Committee on Medical Devices (CTRDM) for eventual remarks, before final approval.

RESULTS:
The literature review did not retrieve any relevant international studies on the topic, except for the Canadian clinical guidelines on ostomy. The upcoming regional guidance will suggest recommendations on: (i) appropriate patient disease management based on a multidisciplinary team evaluation; (ii) characteristics and selection criteria for ostomy aids and related accessories; (iii) prescribing medical specialists, authorisation and distribution features; and (iv) specific indicators for appropriateness monitoring.

CONCLUSIONS:
The regional guidance on aids and accessories for ostomy aim at ensuring the appropriateness throughout the Regional Health Service. The strict monitoring of agreed indicators is essential for appropriateness compliance and consequently the sustainability of regional medical devices expenditure.

PP107 Amiodarone For Arrhythmia In Chagas Patients: A Systematic Review

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ABSTRACT SUMMARY:
The availability of antiarrhythmic drugs capable of improvement of the arrhythmia is of utmost importance. This systematic review showed that in symptomatic patients with arrhythmia associated chronic Chagasic disease, treatment with amiodarone effectively improved ventricular extrasystoles and ventricular tachycardia.

INTRODUCTION:
Chagas disease, caused by the protozoan parasite Trypanosoma cruzi, is a neglected chronic condition with a high burden of morbidity and mortality. It affects about 6 million people in twenty-one countries of Latin America, and has recently become a global health concern (1), especially due to immigration from endemic areas into the developed world. Cardiac arrhythmias are common in patients with Chagas cardiomyopathy and amiodarone has been widely used as an antiarrhythmic drug. Amiodarone has been recommended as the treatment of choice for all patients with sustained ventricular tachycardia (2). The objective of this systematic review is to evaluate the effect of amiodarone in arrhythmia patients with the cardiac form of chronic Chagas disease.

METHODS:
Searches was conducted in MEDLINE (PubMed), EMBASE and LILACS from the inception to December 2016. Studies regarding the use of amiodarone to treat arrhythmia in patients affected by Chagas disease were included, and the outcomes were arrhythmia, adverse effects and sudden death. Selection of articles and data extraction were made by two independent reviewers.

RESULTS:
The database search found 378 articles but only 9 studies with 373 subjects fulfilled the eligibility criteria. The nine studies selected were composed of case series (two), crossover clinical trials (two), and clinical trials (five). Results showed that amiodarone reduced ventricular extrasystoles in all studies and ventricular tachycardia in eight studies. During treatment with amiodarone, patients in eight studies had side effects. Corneal microdeposits and gastric discomfort were the most common adverse effects present in studies. Three studies reported sudden death during follow-up.

CONCLUSIONS:
Amiodarone seems to be an effective antiarrhythmic drug for Chagasic patients, reducing uncomfortable symptoms such as tachycardia. This information can be useful in the primary care context, supporting general practitioners to manage Chagas cardiopathy, mainly when specialized cardiologic consultants are not available.

REFERENCES:

PP108 Health Technology Assessment Educational Programs In The Russian Federation

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ABSTRACT SUMMARY:
It was found that educational program “Modern requirements for conducting health technology assessment” for decision makers in the area of healthcare is held in Department of organization of medicinal provision and pharmacoeconomics of the I.M. Sechenov First Moscow State Medical University.

INTRODUCTION:
Health Technology Assessment (HTA) processes are extensively used during making decisions on the inclusion of medicinal products in Essential medicines lists. There is a high interest in HTA among specialists in the healthcare sphere and decision makers in Russia. According to a survey of chief physicians 62 percent of them would like to attend HTA educational programs. One of the steps necessary to disseminate HTA in Russia is the exploration of experience and best practices.

METHODS:
Information retrieval using websites of medical institutions in Russia were observed.

RESULTS:
As a result, it was found that educational program “Modern requirements for conducting health technology assessment” for decision makers in the area of health care is held in Department of organization of medicinal provision and pharmacoeconomics of the I.M. Sechenov First Moscow State Medical University. During this course basic methods of pharmacoeconomic analysis and their practical application, modern schemes of treatment and peculiarities of the conduct of pharmacoeconomic studies in different diseases, issues of HTA at different levels of the health system are covered. More than 1,900 specialists from 12 subjects of Russia (Samara, Nizhny Novgorod, Rostov, Orenburg, Bryansk, Astrakhan regions, Khanty-Mansi Autonomous Okrug, Altai, Krasnoyarsk, Stavropol and Perm territories, the Republic of Tatarstan) attended seminars including heads of regional health authorities, chief specialists of the ministries, chief physicians of hospitals, and heads of pharmacies.

CONCLUSIONS:
During the educational process the results of pharmacoeconomic analysis and their interpretation at the regional level, legislative changes in the sphere of health technologies circulation, the data requirements for inclusion of a medicinal product in the state lists, the rules of state procurement, and the interchangeability of medicines are highlighted. During educational process the results of pharmacoeconomic analysis and their interpretation at the regional level, legislative changes in the sphere of health technologies circulation, the data requirements for inclusion of a medicinal product in the state Lists, the rules of state procurement, and the interchangeability of medicines are highlighted.

PP109 Horizon Scanning For Information Providing In Brazil

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ABSTRACT SUMMARY:
Horizon Scanning methods have been used for providing the best available scientific information about new and emerging technologies for Brazilian’s Ministry of Health decision-makers. The
assessment of the technologies and the prediction of its potential for impact has helped the health policy making process in Brazil.

INTRODUCTION:
The last five years represented an advanced season for the establishment and reinforcement of the Brazilian Ministry of Health’s Horizon Scanning System. The recognition of Horizon Scanning (HS) as a tool for evidence-based decision making has been reflected in the requests for information directed to the Horizon Scanning’s team. These requests for information about new and emerging technologies come from cabinets offices and thematic departments of the Ministry of Health. The methodology of Horizon Scanning assessments described in EuroScan’s toolkit has been applied to guarantee that the information reach stakeholders at the right time. The National Committee for Health Technology Incorporation (CONITEC) was accepted as a member of EuroScan (1) in 2016, and this represented another important step of Brazil’s HS System.

METHODS:
In order to provide the specific information requested, the assessments of the technologies are done. So, databases on ongoing clinical trials, commercial pharmaceutical database, registration and licensing sites, proceedings and abstracts of scientific conferences and scientific databases are checked to collect the information. The extent and depth of the assessments depends on the stakeholders needs and time available to complete them. However, information as how the technology works, the clinical burden of disease, if there are available technologies in the Brazilian Public Health System to treat the disease, safety and effectiveness data, the regulatory status in the world as well costs, social, ethical and legal concerns are commonly given.

RESULTS:
The information provided using the HS methodology is used by stakeholders for several purposes as to defend the Ministry of Health in the Courts in the typical Latin American phenomena called “judicialization of health”; in assistance of the decision making of incorporation of technologies by the Brazilian Public Health and to support the definition of which medicines would be more strategic for establishment of Public-private partnerships for development of medicines, the named “Productive Development Partnerships (PDPs)”. 

CONCLUSIONS:
The assessment of the technologies and the prediction of its potential for impact has helped the health policy making process in Brazil.

REFERENCES:

PP110 Economic Impact Of Therapeutic Regime Reduction In The Hepatitis C Virus Infection

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ABSTRACT SUMMARY:
The reduction of the therapeutic regime in the treatment of patients with chronic HCV infection from 24 to 12 weeks and from 24 to 8 weeks leads to a lower use of economic resources to equal effectiveness.
INTRODUCTION:
Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide. The goal of HCV therapy is to eradicate the infection, which results in eliminating detectable circulating HCV after cessation of treatment, to prevent complications.

METHODS:
A prospective analysis was undertaken in the primary referral center in Turin. Throughout the use of questionnaires submitted to healthcare professionals, clinical and economic data from three different care pathways of HCV treatment were collected and processed. Costs were measured up to 8, 12, and 24-weeks treatment and based on time-driven activity-based costing (ABC) of the two main HCV treatments, Sovaldi and Harvoni. For the ABC analysis, three types of care pathways were considered, based on patient’s clinical history resources used: patients treated for 8, 12, and 24 weeks. Gastroenterologists, pharmacists, administrative personnel, and storemen were involved in the project. The aim of the analysis was to evaluate the organisational impact of the three different strategies for the treatment of HCV infection with Harvoni or Sovaldi and to estimate the differential cost.

RESULTS:
The data indicates that shortening treatment from 24 to 12 weeks and from 24 to 8 weeks leads to a saving of EUR192 and EUR766 for both treatment strategies. When drug costs are also taken into account, the reduction of treatment with shortening treatment from 12 to 8 weeks leads to a saving of EUR15,252.77, a reduction of EUR60,691.07 from 24 to 8 weeks for Harvoni treatment. The reduction of treatment with shortening from 24 to 12 weeks for Sovaldi leads to a saving of EUR37,668.30. The paths of 8 and 12 weeks are those associated with fewer resources in terms of professional’s time, costs relating to laboratory tests, and cost of drugs.

CONCLUSIONS:
The reduction of the amount of time spent by healthcare professionals in the 12 weeks and in the 8 weeks strategies allows a reallocation of the resources employed.

PP111 The Use Of Long-Acting Injectable Antipsychotics In Schizophrenia

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ABSTRACT SUMMARY:
The aim of this analysis was to evaluate the clinical and economic consequences of Long-acting injectable (LAI) treatment in patients with psychotic disorders, with a special focus on schizophrenia, in the Italian real-world practice. Two hundred and twenty-one patients were eligible for our analysis. In the six months after LAI administration period we estimate reductions in drugs and hospitalizations and an increase in adherence.
INTRODUCTION:
Schizophrenia is a severe mental disease that affects approximately 1 percent of the population with a relevant chronic impact on social and occupational functioning, and daily activities. The aim of this analysis was to evaluate the clinical and economic consequences of long-acting injectable (LAI) treatment in patients with psychotic disorders, with a special focus on schizophrenia, in Italian real-world practice.

METHODS:
A retrospective, observational mirror-study was developed to analyse outcomes measure referred to patients with psychotic disorders. Five hospital centers were involved in this study that collected patient level data from clinical databases. Retrospective data for each patient were referred to 6 months before LAI drug administration and 6 months after. A paired-Samples t-test was performed in order to identify statistical differences between pre- and post-LAI administration.

RESULTS:
A total number of 308 patients were enrolled in the study (65.6 percent male). Of these 221 were eligible for our analysis (119 with schizophrenia). In the six months after LAI administration period we estimate a 47.3 percent reduction of the antipsychotic drugs (43.8 percent for schizophrenic patients), 94.7 percent reduction of hospitalizations (94.0 percent for schizophrenic patients) and adherent patients increase to 198/221 patients (78/221 in pre-LAI administration period). All differences between pre- and post- LAI administration period were statistically significant with a p< .005. In Italy over 152 thousand schizophrenic treated patients were estimated. Assuming that 20-40 percent of patients are eligible to the Mo.Ma (Model of Management) approach, our model estimates a direct cost reduction during the first year of implementation of around EUR12 million. Additionally, EUR18 million of direct costs in the mid-term and EUR58 million of indirect costs could be saved in the mid-term estimating a total cost reduction, due to the Mo.Ma approach, of about EUR90 million.

CONCLUSIONS:
This new therapeutic approach could change the cost structure of schizophrenia by decreasing costs with efficient economic resource allocation guaranteed from efficient diagnostic and therapeutic pathways.

PP112 Cost Effectiveness Strategies For Homeless Persons With Tuberculosis

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ABSTRACT SUMMARY:
We performed a systematic review of economic evaluations of interventions conducted in homeless people with tuberculosis. We identified interventions related to prevention (BCG vaccine), diagnosis (IGRA and mobile screening) and treatment (incentives for continuation of treatment and housing program).

INTRODUCTION:
Tuberculosis is contagious communicable infectious disease and is still a major public health problem. In Brazil, the homeless persons are considered a priority population for disease control, but management costs are not yet measured. We performed a systematic review of economic evaluations of interventions conducted in homeless people with tuberculosis.
METHODS:
We conducted a search in Medline, Web of Science, Scopus, Science Direct, Centre for Reviews and Dissemination, and the Cochrane Library in June 2015 followed by an update on 10 January 2016. The eligibility criteria were original studies reporting economic evaluation results in homeless persons with tuberculosis, without language or year restriction. Two reviewers independently performed the studies selection, data collection and used the critical appraisal checklist developed by Drummond for quality assessment.

RESULTS:
We identified ninety-three articles, seven of them were eligible for inclusion, six conducted in the United States of America and one in United Kingdom. Four studies were full economic evaluations and three were partial. One study compared Interferon-y release assays (IGRA) with tuberculin test with an incremental ratio of $70,000 / QALY; one mobile radiography for active search compared to routine, with an incremental ratio of £6,000/ QALY. Other two diagnostic studies evaluated IGRA without comparator and sputum culture. One study evaluated prevention with the second dose of the BCG vaccine in adulthood. Two studies addressed support for adherence to treatment - one with financial incentives through directly observed treatment, and another with incentives for continuation of treatment and housing program.

CONCLUSIONS:
Economic evaluation with a focus in homeless with tuberculosis are scarce. In the interventions found, all were cost effective from the perspective of the government of the country to which they referred. This result demonstrated the need for economic analysis in Brazil, based on the recommendations of the national tuberculosis control program.

PP113 High-sensitivity C-Reactive Protein (hsCRP) Measurements And Burden In Patients With History of Myocardial Infarction

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ABSTRACT SUMMARY:
Published evidence providing insight on measurement of elevated hsCRP levels and associated burden of illness in patients with history of myocardial infarction was identified using a targeted literature review. Elevated hsCRP seems to be predictive of future CV events and mortality. Limited evidence on prevalence of elevated hsCRP and associated burden of illness warranted further research.

INTRODUCTION:
The inflammatory marker C-reactive protein (CRP) can be measured by a high-sensitivity assay (hsCRP) specific to vascular inflammation. We aimed to identify published literature on prevalence of elevated hsCRP and associated clinical, economic, and humanistic burden in patients with a history of myocardial infarction (MI).

METHODS:
A comprehensive literature search was performed for publications in English between January 2000 and February 2016 in MEDLINE, EMBASE, and MEDLINE In-Process. Search terms were variations on ‘Post myocardial infarction’, ‘CRP’, ‘epidemiology’ and ‘burden’. Clinical and real-world studies reporting baseline CRP levels in patients with a history of MI were included in the analysis.
RESULTS:
Ten studies (prevalence: two; burden: two; both: six) were included. Cut-off points in hsCRP assays varied from >2 mg/L to ≥5.9 mg/L. Prevalence of hsCRP levels >2, >2.3, ≥2.37 and >2.9 mg/L were reported in 36 percent, 49 percent, 50 percent and 33 percent of patients, respectively (one publication each). Two publications reported >3 mg/L levels in 27.6 percent and 53.7 percent of patients. Levels of ≥3.3, ≥3.8, ≥4.2 and ≥5.9 mg/L were found in 38.8 percent, 25 percent, 25 percent and 24.7 percent respectively (one publication each). Of six studies reported CV events, four studies found elevated hsCRP levels to be predictive of future risk. Elevated hsCRP levels independently predicted all-cause mortality in four studies and CV mortality in three studies. Three publications included data on comorbidities: Diabetes was associated with elevated hsCRP in two studies; hypertension in one out of two. No consistent associations between elevated hsCRP levels and hyperlipidaemia (one study), stroke or angina pectoris (one study) were found. No study reported economic, resource use or quality-of-life burden.

CONCLUSIONS:
Due to limited evidence on prevalence of elevated hsCRP and associated burden of illness in patients with a history of MI, further research is warranted. Variations in findings, cut-off points and methods between studies make generalisations difficult.

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ABSTRACT SUMMARY:
This study aimed to develop a comprehensive decision framework and identify preferences of patients and physicians in the management of unresectable, well- or moderately differentiated non-functioning GEP-NET using holistic Multi-criteria Decision Analysis (MCDA). Results showed that many aspects are considered by patients and physicians in their decisionmaking processes. Holistic MCDA revealed and structured the complexity and variability of what matters most to patients.

INTRODUCTION:
Patient-centered care implies identifying what matters most to patients and physicians through shared decisionmaking on disease management. EVIDEM provides a generic holistic Multi-criteria Decision Analysis (MCDA) platform to explore decision criteria and trade-offs. The study aimed to develop a comprehensive decision framework and identify preferences of patients and physicians in the management of unresectable, well- or moderately differentiated non-functioning GEP-NET.

METHODS:
A decision support framework was designed based on EVIDEM structure, literature review and insights from a Chatham-house panel of US physicians and patients, representative of different management approaches for GEP-NET. During a
second extended panel session (five patients, six physicians), participants provided criteria weights using Hierarchical Point Allocation and Direct Rating Scale (DRS, sensitivity analyses). Insights were collected in writing and through discussions.

RESULTS:
The decision support framework included 6 domains pertaining to Outcomes of the intervention (Effectiveness, Patient-Reported Outcomes, autonomy, dignity & convenience, Safety); Type of benefit; Need (Disease severity; Unmet needs; Population size); Costs & constraints (Intervention; Medical and Non-medical [to patients or the healthcare system]); Knowledge (Quality of evidence, Expert consensus) and Feasibility (System capacity). Of the thirty criteria and subcriteria, twenty-six were considered by more than 90 percent of participants. Criteria weights were widely distributed reflecting variability in individual perspectives on what matters most. At the group level, highest weights were attributed to Effectiveness (.18 ± Standard Deviation, SD .12 on a total of 1) and Disease severity (.12 ± .08), followed by Safety (.10 ± .09), Type of therapeutic benefit (.10 ± .08) and Quality of evidence (.09 ± .06). Most important Effectiveness subcriteria were Overall survival (33 percent of effectiveness criteria), followed by Progression-free survival (30 percent). DRS showed similar overall results.

CONCLUSIONS:
Many aspects are considered by patients and physicians in their decisionmaking processes. Holistic MCDA reveals and structures the complexity and variability of what matters most to patients.

PP115 Patient And Public Involvement In Health Technology Assessment: Update Of A Systematic Review

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ABSTRACT SUMMARY:
The aim of this study was to update a systematic review (published in 2011) on patient and public involvement in health technology assessment (HTA). The preliminary results show that the number of studies on patient and public involvement in HTA has increased in recent years. Findings from this update are mainly consistent with those of the original systematic review.

INTRODUCTION:
There is a general consensus on the need to involve patients and the public in Health Technology Assessment (HTA) but questions remain about the best strategies for involving them into HTA structures and activities. The aim of this study was to update a systematic review (published in 2011) on patient and public engagement in HTA.

METHODS:
We searched papers published between January 2009 (end of the initial search) and November 2016 in eight databases and HTA journals using specific search strategies. We identified other publications through citation tracking, Internet search engines, HTA agencies websites, and discussion with experts in the field. Studies in English or French were included if they met the following criteria: (i) qualitative, quantitative or mixed-methods study; (ii) describing patients or public involvement; and (iii) in the HTA field. We extracted information using
a pre-established grid including: characteristics of studies, type of activities for involving patients or public, effects on decisions, and factors facilitating or limiting involvement.

RESULTS:
We identified a total of 4,762 new publications from the main search strategy. Among them, twenty-eight articles (reporting on twenty-three studies) met the inclusion criteria, whereas seventeen articles were included in the previous systematic review. Research designs are qualitative (18/23), quantitative (3/23) or mixed (2/23). Two main strategies for involving patients and public are generally described. The first is when public representatives participate directly in decision-making processes (participation) and the second is when patient or public input is sought to inform decisions (consultation or indirect participation).

CONCLUSIONS:
The number of studies on patient and public involvement in HTA has increased in recent years. Findings from this update are mainly consistent with those of the previous systematic review. However, studies are still needed to assess the effectiveness of different strategies for involving patients and the public in HTA.

PP116 Data Linkage Across Ambulance Services And Emergency Departments

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ABSTRACT SUMMARY:
We report on a mixed-methods observational study of the process and potential benefits of linking ambulance and Emergency Department data in one region of the United Kingdom. We found the process of data linkage was feasible, but requires dedicated time from research and trust staff, over a prolonged period, to achieve set up.

INTRODUCTION:
Most callers to emergency ambulance services are transported to hospital emergency departments (EDs), but ambulance services receive no information on patient outcomes. Pre-Hospital and Emergency Department (PHED) Data is a two-year mixed-methods observational study of the process and potential benefits of linking ambulance and ED data to allow analysis of patient outcomes. We report on our first aim, to examine the potential opportunities and challenges of this data linkage initiative.

METHODS:
We approached six hospital trusts in an English metropolitan area. We used a structured learning log to collect data on the process, time input and reflections. We analyzed these data with descriptive statistics, and qualitatively for themes.

RESULTS:
All six trusts agreed to participate. We used an algorithm based on date, time and patient demographics to link data. We achieved a dataset of 775,018 records covering 2012 – 2016, and a linkage rate of 81 percent.

Initial set up tasks within the ambulance service took 30 hours 20 minutes. We then identified five stages of tasks with each hospital trust: negotiating senior approval; exploring data availability; information governance agreement; data transfer; and linking. Mean time spent by the research team on these processes was 30 hours 30 minutes per trust (range: 17 hours 20 minutes to 43 hours 10 minutes), plus additional time from staff of hospital trusts. The most intensive phases were: negotiating
senior approval (mean: 8 hours 5 minutes), and data linking (mean: 12 hours 40 minute). The stage which took the longest was information governance (mean: 19 weeks).

Key themes included the positive attitudes of trusts to participating, the range of decision makers involved, and the need for sustained input from the research team.

CONCLUSIONS:

We found the process of data linkage was feasible, but requires dedicated time from research and trust staff, over a prolonged period, to achieve set up. Linked data are now being analyzed.

PP117 Isosorbide And Nifedipine In Chagas Patients: A Systematic Review

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ABSTRACT SUMMARY:
This systematic review evaluated the effect of isosorbide and nifedipine on gastrointestinal symptoms of Chagas disease patients. The evidence indicates that isosorbide is effective on the improvement of digestive symptoms, but it causes important collateral effects. There is not enough evidence to evaluate the effectiveness of nifedipine, and therefore more studies are necessary.

INTRODUCTION:

Chagas disease, caused by the parasite Trypanosoma cruzi, affects more than seven million people worldwide and it is considered by the World Health Organization (WHO) a neglected tropical disease (1). About one third of Chagas patients develop gastrointestinal disorders, such as dysphagia and achalasia. Management of the disease focuses on symptom improvement and drugs that relax the lower esophageal sphincter pressure (LES), such as isosorbide and nifedipine. However, the use of these therapies is doubtful because of their side effects and palliative approach (2). The objective of this systematic review is to assess the effectiveness of isosorbide and nifedipine on gastrointestinal manifestation of Chagas disease.

METHODS:

We searched MEDLINE, EMBASE and LILACS databases to retrieve potentially relevant articles from inception to December 2016. Inclusion criteria: clinical trials, cohorts or cross-sectional design; adults (>18 years old); assessment of effects of isosorbide or nifedipine on gastrointestinal symptoms in Chagas patients. Two reviewers independently screened titles and abstracts, selected eligible studies and extracted data from each study. PROSPERO registration number: CRD42017055143.

RESULTS:

Eight studies were included (two case series, two clinical trials and four crossovers). Three studies evaluated the effect of isosorbide in LESP and three in esophageal emptying. All of them found that isosorbide rapidly reduces LESP and increases esophageal emptying rates, improving dysphagia. However, several patients reported collateral effects, such as gastroesophageal reflux, headaches and dizziness. One study evaluated the effect of nifedipine on LESP and one on esophageal emptying. Nifedipine decreased LESP, but there was no effect on esophageal emptying.
CONCLUSIONS:
The available evidence shows isosorbide is effective in the management of gastrointestinal symptoms. Frequently health care of Chagas disease patients is delivered by primary care physicians. So, information on effectiveness of interventions can be aggregated to clinical guidelines, having an important value to inform general practitioners on the decision-making process regarding treatment of this group of patients, avoiding referencing to a specialized care.

REFERENCES:

PP118 PlasmaJet™ As A Novel Surgical Approach To Ovarian Cancer Debulking

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ABSTRACT SUMMARY:
The PlasmaJet™ is a surgical device that originates a thin jet of neutral argon plasma that is rapidly dissipated as light, kinetic energy, and thermal energy. PlasmaJet™ allows desiccation and vaporization of soft of tissues and can be very useful in advanced Epithelial ovarian cancer debulking. The objective is to study the effectiveness and safety of PlasmaJet™ to ovarian cancer surgery.

INTRODUCTION:
Epithelial ovarian cancer (EOC) is the first cause of death from gynecological malignancies. Standard treatment of EOC is combination of surgery (to obtain complete cytoreduction) and chemotherapy. The PlasmaJet™ system can help the surgeon to obtain an optimal debulking. The device is a surgical device that originates a thin jet of neutral argon plasma that is rapidly dissipated as light, kinetic energy, and thermal energy. PlasmaJet™ allows desiccation and vaporization of soft of tissues and can be very useful in advanced EOC debulking where surgery is difficult because of extensive disease on the bowel, diaphragm, and peritoneum. The objective of this work was to study the effectiveness and safety of PlasmaJet™ to ovarian cancer surgery.

METHODS:
Early assessment of PlasmaJet™ identified through the Early-Awareness and Alert-System, “SINTESIS-new technologies”, of The Instituto De Salud Carlos III (AETS-ISCIII). The searched databases were: MEDLINE (PubMed), Centre for Reviews and Dissemination, Cochrane Library and Clinical trials. Clinical studies using the PlasmaJet™ published in English, French or Spanish until 10 January 2017 were reviewed.

RESULTS:
Five publications were retrieved. One case series and four abstracts (two case reports) which included a total of eighty-three patients. Also a clinical trial in progress (NCT02376231) was found. Regarding the effectiveness of PlasmaJet™, complete cytoreduction was obtained in 87 percent of the cases. One study reports the next median dates: operative time 270 minutes; blood loss, 700 ml; and length of stay, 9 days. About safety, in sixty-nine patients (83 percent) there were no direct complications related to procedure and in the other fourteen patients, six needed blood transfusion,
one ureteral injury, and eight pleural drained. Twelve patients had postoperative complications.

CONCLUSIONS:
The PlasmaJet™ seems to be an effective and safety device for ovarian cancer debulking. It would be necessary for further studies, including comparative studies with current advice, and a longer follow-up period to confirm these results.

RESULTS:
Currently in Kazakhstan, the Health Technology Assessment (HTA) process is funded from the budget. Applicants of the new technologies are mainly large medical centers, institutes, academic clinics, and others. HTA in general is focused on short reports, due to the time and experts number limits. Short HTA reports do not provide a complete picture of the impact of the technologies that are being introduced. In the current environment, health policymakers need complete integrated information about technologies and its efficiency at all stages of care.

CONCLUSIONS:
With the introduction in 2018 of the mandatory social health insurance working-age population, employers and the Ministry are assumed to make monthly payments. Due to the third-party payers’ appearance in the health system of Kazakhstan, interest in and demand for HTA are increasing for the rational use of limited resources.

PP119 Health Technology Assessment In The Mandatory Social Health Insurance Conditions

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ABSTRACT SUMMARY:
The aim of this study was to analyse of regulations for the implementation and reimbursement of new health technologies in the Republic of Kazakhstan and other countries was performed.

INTRODUCTION:
The health care system in Kazakhstan is undergoing a new phase of development with the implementation of mandatory social health insurance, under which the whole system of financing health care changes. The implementation of these programs and goals is focused on the development of a competitive market, through the introduction of new and innovative technologies.

METHODS:
The analysis of regulations for the implementation and reimbursement of new health technologies in the Republic of Kazakhstan and other countries was performed.

PP120 Health Technology Assessment Framework To Capture The Full Value Of Value Added Medicines

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ABSTRACT SUMMARY:
Value added medicines (VAM) are medicines based on known molecules that address healthcare needs
and deliver relevant improvements for patients, healthcare professionals and/or payers. Recently, the European Commission through the STAMP program, considered the issue of VAM development and regulatory process. The study objective was to identify how Health Technology Assessment frameworks should evolve to better reflect VAM value.

INTRODUCTION:
Value added medicines (VAM) are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers through drug repositioning, drug reformulation or drug combination (1-3). Recently, the European Commission, through the Safe and Timely Access to Medicines for Patients (STAMP) program, considered the issue of VAM development and regulatory process. Current Health Technology Assessment (HTA) tools may not fully capture the benefits of VAM, which could lead to obstacles for patient access to VAM in several European countries (1). The study objective was to identify how HTA frameworks should evolve to reflect VAM value.

METHODS:
HTA expert interviews were performed as a preparatory step to an advisory board meeting. The following topics were addressed: (i) Eligibility for HTA and early HTA dialogues; (ii) Attributes that should be considered in HTA; (iii) HTA methodology; and (iv) Involvement of stakeholders in HTA.

RESULTS:
VAMs bring additional benefit to patients and society. Therefore, the possibility for VAM assessment on a voluntary basis and within the appropriate assessment patterns/tools should be, in principle, included into HTA frameworks, as well as into early HTA dialogues. HTA should be patient-centric, and attributes such as patient preference, adherence, and patient reported outcomes should be considered where relevant. Unmet patient needs and disease burden should be used in a transparent and reproducible deliberative process. All these attributes should be used as explicitly and meaningfully weighted appraisal modifiers. HTA methodology should be comprehensive and should integrate societal perspectives. Patient representatives should take part in the decision-making process.

CONCLUSIONS:
Current HTA frameworks should evolve to enhance VAM value recognition and encourage industry investment in medicines with high potential value for society.

REFERENCES:

PP121 Cost Analysis Of The Pharmaceutical Care In Type 2 Diabetes Mellitus

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ABSTRACT SUMMARY:
Pharmaceutical care can lead to lower costs results per patient compared with the conventional care provided just by a physician (status quo).

INTRODUCTION:
The control of fasting plasma glucose and hemoglobin A1c (HbA1c) in type 2 diabetic mellitus (T2DM) patients can be improved by pharmaceutical care (PC).

METHODS:
This work aimed to assess the cost of PC in T2DM patients in Ribeirão Preto city, Brazil, compared with conventional care, provided just by the primary care physician (status quo). This article collected and analyzed data from a experimental prospective study. Seventy-one patients were divided into two groups: control and PC, of which, patients were followed up monthly by a single clinical pharmacist during 18 months, from March 2006 until August 2007. Thereafter, medical records were collected until 2011, including medication consumption, number of physician visits, pharmaceutical care visits, diabetes complications, and date of death. The cost analysis was taken from the government’s health policy perspective and was performed considering direct medical and non-medical costs, and indirect costs, calculated based on the government reimbursement rates and adjusted for inflation until December 2016.

RESULTS:
The direct medical costs (medication, physician visits, pharmaceutical care visits, and diabetes complications treatment) represent, in 2007: 60.8 percent (control) and 71.3 percent (PC), in 2008: 29.6 percent (control) and 62.2 percent (PC), in 2009: 31.8 percent (control) and 60.7 percent (PC), in 2010: 13.0 percent (control) and 59.5 percent (PC), and in 2011: 10.7 percent (control) and 57.4 percent (PC). The nonmedical direct costs (transportation) represent in 2007: 1.9 percent (control) and 2.4 percent (PC), in 2008: 1.8 percent (control) and 3.5 percent (PC), in 2009: 2.6 percent (control) and 3.9 percent (PC), in 2010: 1.0 percent (control) and 4.2 percent (PC) and in 2011: 1.0 percent (control) and 4.5 percent (PC). Considering indirect costs such as absenteeism and early retirement, in 2007: this represents 37.3 percent for the control group and 26.4 percent for PC group. In 2008: 68.6 percent (control) and 34.3 percent (PC), in 2009: 65.5 percent (control) and 35.4 percent (PC), in 2010: 85.9 percent (control) and 36.4 percent (PC), and in 2011: 88.2 percent (control) and 38.1 percent (PC).

CONCLUSIONS:
According to the costs results, the PC group had lower total costs per patient compared to the conventional group.

PP122 Strengthening Ethics Compliance In A Large Research Program: Uganda

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ABSTRACT SUMMARY:
There is still a need to strengthen research ethics in resource limited settings. Regulatory Affairs Information System (RAIS) is a web-based system developed with the aim of bridging ethical gaps in research. Between January 2015 and November
2016, 90.7 percent of studies were successfully uploaded on the program. RAIS has enabled continuity of study activities with timely annual renewal approvals.

INTRODUCTION:
The infectious Diseases Institute (IDI) is a research institute at the College of Health Sciences, Makerere University. Over the years, the number of research studies has greatly increased with an average of fifty active studies per year. Because of the voluminous study activities, investigators were faced with inadvertences of ethical approval deadlines (1). In 2015, a centralized electronic Regulatory Affairs Information System (RAIS) was developed and piloted to track the regulatory process of the entire research projects. RAIS is a web-based system, developed using a Net framework and runs on any operating system using a web browser such as “Google Chrome” and “Mozilla Firefox”.

METHODS:
A signed approval letter from an accredited Research Ethics Committee, National Drug Authority and Uganda National Council of Science and Technology, the reviewed protocol, consent forms and data collection tools are uploaded electronically into the RAIS with study staff contact information, CVs and Good Clinical Practice (GCP) certificates. RAIS sends automatic “no reply” emails to the investigators and research administration notifying for the need of annual renewal 56, 28 and 14 days before the expiry date of the approvals. The investigator or designated person prepares the application package which is then forwarded to the Research Regulatory Officer for review and submission to the regulatory authority.

RESULTS:
From January 2015 to November 2016, forty-three ongoing studies were uploaded to the RAIS of which eleven were clinical trials, twenty-one observational studies, seven diagnostic and four implementation studies. Studies that obtained their annual approvals before the expiry date was 90.7 percent, compared to 29 percent that had reported early submission for annual renewal between January 2013 and December 2014. RAIS has enabled continuity of study activities with timely annual renewed approvals, supported the tracking of staff GCP certificates and populated timely notifications to investigators, resulting in submission of annual application packages on time.

CONCLUSIONS:
RAIS has strengthened ethical regulatory compliance and provided an effective platform for tracking regulatory processes, thus enabled continuity of study activities with timely annual renewal approvals and greatly supported the tracking of staff GCP certificates.

REFERENCES:

PP123 Medical Devices Exclusivity: The Impact Of Hospital-based Health Technology Assessment On Procurement

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ABSTRACT SUMMARY:
In 2015, the Lombardy Region approved a
standard procedure for the assessment of exclusive medical devices. San Matteo Hospital acquired this procedure, adopting the hospital-based health technology assessment (HB-HTA) approach. Over the last two years, the Clinical Engineering Department evaluated more than 50 medical devices, of which only 12 percent were irreplaceable. The HB-HTA approach related to medical devices exclusivity improves the purchasing process.

INTRODUCTION:
The Italian National Healthcare System is based on Regional Healthcare Systems (RHS), one for each Italian Region. In 2015, the Lombardy Region approved the annual rules for its RHS, introducing a standard procedure for the assessment of exclusive medical devices.

In San Matteo Hospital, this procedure involves a panel of experts: clinical engineers, physicians, and economists. The Clinical Engineering Department collects information and collaborates with healthcare professionals in order to write short reports about each technology for hospital decision makers.

METHODS:
The hospital-based health technology assessment (HB-HTA) method is applied to the purchasing process of exclusive and so-called “irreplaceable” medical devices, to support the decision of hospital managers. The evaluation method, according to the HB-HTA approach, is focused on the most important aspects of the clinical use of the technology such as security, reliability, and organization impact. The standard procedure starts with the description of clinical needs by physicians through the compilation of a form related to a specific innovative medical device, then a scientific literature research and a market survey are carried out. From the data collected in the Italian Medical Devices Database of the Ministry of Health, possible technical and clinical alternatives are evaluated and compared.

RESULTS:
Over the last two years in San Matteo Hospital, clinicians requested more than 50 irreplaceable or exclusive medical devices. The Clinical Engineering Department produced the same amount of reports assessing that 70 percent were exclusive, 12 percent were irreplaceable, and 18 percent were neither. Therefore, for only 12 percent of cases it was not possible to publish new public tenders.

CONCLUSIONS:
Data collected show how the HB-HTA approach related to medical devices exclusivity improves the purchasing process, allowing concrete savings for the hospital. Moreover, the introduction of this procedure has caused a decrease in clinicians’ requests, a sign of better awareness of medical devices exclusivity.

PP124 The HTAi Vortal: A Comparative Analysis

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ABSTRACT SUMMARY:
The HTAi Vortal has collected resources in Health Technology ASessment (HTA) since 2005. The technical platform has been changed in 2011, and new editors joined in 2015. A study has been conducted to evaluate how the Vortal compares with similar on-line tools.

INTRODUCTION:
The HTAi Vortal is a product of the HTAi Information Retrieval Group (IRG) which has collected resources in the field of Health
Technology Assessment (HTA) since 2005.

In 2011, a new technical platform was set up and the legacy Vortal content was split in three sections: HTA producers and networks, Selected references and Career development (including trainings). The same year, a fourth section was created to host a new product of the IRG: SuRe.info.

In 2014, the Vortal added a new service to other Interest sub groups of HTAi: the hosting of “Custom bibliographies”. But while the Vortal was probably quite unique in 2005, other Websites have been developed since then to offer quite similar functionalities.

The present communication aims at evaluating how the Vortal compares with similar tools existing on the Web.

METHODS:
Vortal competitors have been identified using a quick empirical search of the Web.

Functionalities have been identified by testing the website or their archive; maintainers have been sometimes contacted to ask for complementary information. A grid listing all functionalities has been established and filled in with the collected information.

RESULTS:
Several competitors have been identified. The Vortal presents functionalities similar to online tools, but detailing level is different. Also, the Vortal provides a better integration resulting in more efficiency. And, the Vortal is the only Web platform to offer a service of publication of custom bibliographies to the different HTAi Interest Sub Groups.

CONCLUSIONS:
After 12 years of existence, the HTAi Vortal is still a recognised online resource about HTA. While some existing functionalities are to be found in other online tools, some remain unique to the Vortal. Further research is needed to evaluate the preferences of people with interest in HTA.

PP125 Evidence-Based Policy Making: Bottom-Up Heuristic Engagement Process

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ABSTRACT SUMMARY:
Healthcare professionals democratic participation through heuristic and public processes enhanced factual education, evidence-based heart, lung, liver, pancreas and hematopoietic cells Transplantation Immunosupression National Clinical and Therapeutic Protocols and real-world adjustments. This supported Brazilian Health Ministry decision making, fostered SUS processes and technology innovation with health benefits, provided modest budget impact and also warranted the transplantation program policy compliance.

INTRODUCTION:
Solid organ and hematopoietic cell transplantation are some of the more expensive procedures universally paid by the public Brazilian Unified Healthcare System (SUS). Transplanted patients depend on maintenance immunosuppression to prevent death or graft loss. A bottom-up heuristic process proposed new immunosuppression drugs for incorporation into the SUS.
METHODS:
Systematic evidence synthesis and Brazilian transplantation registries base-cases, Kaplan-Myer survival and economic assessments were presented in specialized national congresses with open public Delphi sessions to build professional Clinical and Therapeutic Protocols (PCDT) by consensus. Five consensus transplantation PCDTs with a SUS perspective budget impact and sensitivity analysis were submitted to the Health Ministry SUS Technology Incorporation National Commission (CONITEC) plenary for a decision. PCDTs were publicized in CONITEC Internet and Diário Oficial da União, an, official periodic publication, as well as undergoing widespread dissemination through mailings for Public Consultation. Public contributions were added to PCDTs to support Health Ministry policy making.

RESULTS:
The São Paulo State Health Secretariat coordinated the synthesis and economic assessments made by 115 experienced transplantation specialists and health technology evaluators over ten years. Heart, lung, liver, pancreas and hematopoietic cells transplantation PCDTs (with tacrolimus, sirolimus and everolimus alternative immunosuppression) can significantly prevent 27.8 percent, 28.1 percent, 7.2 percent, 11.1 percent and 4.3 percent graft loss or graft versus host disease and death, respectively, for refractory transplantees rescue during the first year post-transplantation, saving healthcare resources. Ten-year follow-up data demonstrated partial benefits were sustained. Analysis demonstrated +USD689,655.17, +USD501,567.40, -USD377,802.51, +USD221,289.42 and +USD50.734,08 budget impact, respectively, resulting in an overall USD1,085,443.55 for 2,146 transplantees. The 5 PCDTs were favorably voted by CONITEC plenary members, 155 public contributions were added by patients and stakeholders, and the Brazilian Health Ministry decided to adopt the SUS reimbursement listing.

CONCLUSIONS:
Democratic participation gave PCDTs real-world basis adjustments, SUS innovation and improved compliance.

PP126 MEA In Italy: Correlation Between Time To Payment By Result And Time To Off Treatment Curve

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ABSTRACT SUMMARY:
The aim of this analysis was to overview the Roche experience in terms of payment by results schemes and investigate the relation between timing for the evaluation of treatment failures and the mean treatment duration present in the clinical trials using the Time to Off Treatment curves, which considers discontinuation of treatment for progression, death and toxicity.

INTRODUCTION:
Payment by result agreements have been quite widely used in Italy to provide access for high costs oncologic drugs and minimize uncertainties of real life benefits (1). The aim of this analysis was to overview the Roche experience in terms of Payment by Result (Pbr) in oncology and investigate the relation between timing for the evaluation of treatment failures and observed Time to Off Treatment (TTOT) from Phase III clinical trials (2).
METHODS:
A retrospective analysis of the Roche payment by results schemes in place in Italy was conducted. For each drug included in the analysis it was collected: (i) the negotiated timing to assess the treatment failure for payment by result, (ii) the median time to off treatment curve observed in clinical trials for the experimental drug, (iii) the median time to off treatment observed in clinical trials for the control arm. The mean ratios between timing to assess the treatment failure for payment by result and the time to off treatment observed for the experimental drug or the median time to off treatment observed in the control arm were calculated to identify potential correlations. High level of correlation was expected if ratio was close to 1 (±.2).

RESULTS:
Roche products or different indications of the same product were identified as candidates for the analysis from 2008 to 2016. The timing for the evaluation of treatment failures for Pbr varies between 2 and 9 months, depending on the type of tumour and line of therapy. The mean Time to Payment By Result (TTPbr) / Control arm Time To Off Treatment (cTTOT) ratio was 1.16 (±.37) while the mean Time to Payment By Result (TTPbr) / Experimental arm Time To Off Treatment (eTTOT) ratio was .71 (±.13). Data analysis according to different time periods shows that the mean TTPbr/cTTOT and TTPbr/eTTOT for drugs negotiated from 2008 to 2015 were respectively 1.07 and 1.39 whereas for drugs negotiated in 2016 were respectively and .63 and 1.

CONCLUSIONS:
Good level of correlation between TTPbr and cTTOT was found. This finding is in line with the methodology used by Italian Medicines Agency so far, leveraging the cTTOT as the most appropriate proxy to assess any incremental effect of a new drug compared to the previous Standard of Care. The analysis over time of TTPbr shows that in the first years of payment by result negotiation TTPbr is more correlated to the cTTOT whereas in the last years is moving closer to the experimental one.

REFERENCES:

PP127 Organising Home Mechanical Ventilation: Lessons From Denmark

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ABSTRACT SUMMARY:
As part of a Danish Health Technology Assessment, this study outlines the current Danish visitation practice and organization of home mechanical ventilation (HMV). Furthermore, the study explores organizational challenges and opportunities in the current organization, and discusses organizational consequences of changes in visitation practice and organization of HMV to ensure optimal use of resources and high-quality patient courses.

INTRODUCTION:
Home mechanical ventilation (HMV) represents one of the most advanced and complicated types of medical treatment provisioned outside the hospital and there is wide variation in the use and organization of HMV throughout Europe. HMV is increasingly used in Denmark, however scientific research on the use and organization of HMV is limited. Thus, this study outlines the current Danish visitation practice and organization of HMV. Furthermore, the study explores organizational challenges and opportunities in the current
organization, and discusses organizational consequences of changes in visitation practice and organization of HMV in order to ensure optimal use of resources and high-quality patient courses. The study is conducted as part of a Danish Health Technology Assessment of patients receiving HMV under professional surveillance either during sleep or 24 hours a day.

METHODS:
The results are based on a combination of a systematic literature review and a qualitative interview study comprising telephone interviews (n=18) and focus group interviews (five interviews with three to five informants) with various representatives in the organization of home mechanical ventilation including doctors from hospitals, and municipal and regional employees.

RESULTS:
Results from the study are in preparation and will be available in spring 2017. Preliminary results show a high level of complexity and a considerable variability in the visitation practice and organization of HMV across Danish regions. Current organizational challenges relate to vague visitation criteria, limited national guidelines on assessment, visitation and organization of HMV including organisation of professional care teams, multi-sectorial collaboration, and highly complex patient courses. Completion of more precise visitation criteria and national guidelines on organization will help standardize and improve assessment, management, and organization of HMV.

CONCLUSIONS:
The study contributes to both practice and political decision making by identifying organizational challenges and opportunities associated with HMV and by presenting perspectives on more optimal use and organization of the technology.

PP128 Regional Guidance On Spinal Cord Stimulation For Chronic Pain

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ABSTRACT SUMMARY:
The Veneto Region usually establishes rigorous access criteria to high-cost medical devices defining Regional guidance approved by the Technical Committee on Medical Devices and a Health Technology Assessment procedure. The Regional guidance on Spinal Cord Stimulation aims at ensuring the appropriate use of neurostimulators in patients affected by resistant chronic pain.

INTRODUCTION:
Chronic Pain (CP) is the uncontrolled pain that affects patients for a long time. CP can be caused by many conditions, sometimes still poorly understood, and its levels can vary from moderate to intense. The management of resistant CP requires a stepwise approach and spinal cord stimulation (SCS) could be considered an extreme strategy. With the aim of ensuring the economic sustainability, the Veneto Region usually establishes rigorous access criteria to high-cost medical devices through its Regional Technical Committee on Medical Devices (CTRDM) and a Health Technology Assessment (HTA) procedure.

METHODS:
The Regional Health Technology Assessment Unit (CRUF) conducted through Pubmed a literature
review of randomized controlled trials, systematic reviews, meta-analysis on SCS published from March 2006 to February 2016. International and national clinical guidelines were included in the analysis as well. The regional multidisciplinary Working Group on CP, which involved local clinicians, pharmacists, clinical engineer and health economist, discussed the collected evidence by consensus. Final recommendations on the appropriate use were submitted to the CTRDM for final approval.

RESULTS:
The regional guidance describes the type of pain that can be treated with spinal neurostimulators and the criteria which determine the success of the test procedure. A comparative analysis of spinal neurostimulators available on the market and related patients eligibility criteria have been also included. Moreover, the guidelines stated a list of compulsory requirements in order to become a regional center authorised in performing spinal neurostimulation procedure. Finally, the document describes some indicators for appropriateness monitoring. The CTRDM approved the final version in October 2016.

CONCLUSIONS:
The regional guidance on SCS aims at ensuring the appropriate use of neurostimulators in patients affected by resistant CP. The strict monitoring of agreed indicators is essential for appropriateness and consequently the sustainability of medical devices expenditure throughout the Regional Health Service.

PP129 Methodological Issues With Assessing Newborn Screening Tests

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ABSTRACT SUMMARY:
This presentation outlines a number of important methodological issues associated with the assessment of primary studies that examined harms and efficacy/effectiveness of newborn screening test for a rare genetic disorder - severe combined immunodeficiency, and discusses its implication for the policy question of whether this test should be added to an existing provincial newborn screening panel.

INTRODUCTION:
To outline the methodological issues associated with the assessment of newborn screening for severe combined immunodeficiency, which was conducted to address the policy question of whether this test should be added to an existing newborn screening panel.

METHODS:
We conducted a systematic review of published primary studies and critically appraised the methodological quality of selected studies (1).

RESULTS:
Fifteen studies were included; six focused on screening test performance, seven on treatment effectiveness, and two on the effectiveness of a newborn screening program. The methodological issues identified included: (i) Overall poor methodological quality ratings of included studies using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2). This tool was originally developed for assessing diagnostic accuracy studies where subjects usually receive both index test and reference standard so a 2x2
table can be constructed; however, it is almost impossible to apply this cross-sectional approach to studies of a screening test for a rare disease like severe combined immunodeficiency. (ii) Case control design using healthy controls could inflate estimates of test accuracy compared to studies using a cohort of consecutive patients, possibly due to spectrum effects and limited-challenge bias. This type of study is useful in the early phase of test development, but estimates of test accuracy based on this type of study should be interpreted with caution. (iii) Some screening programs reported no false negatives, indicating a sensitivity of 100 percent. However, lack of a systematic search for “missed cases” created uncertainty in arriving at a true value for the sensitivity. (iv) Variations in inclusion of pre-term infants, races/ethnicities, and screening protocols made it difficult to compare screening test performance across different studies.

CONCLUSIONS:
Although severe combined immunodeficiency screening was the first addition to the US Recommended Uniform Screening Panel following an evidence-based review process, caution needs to be exercised when interpreting research findings due to important methodological issues.

REFERENCES:
1. Institute of Health Economics. *Newborn blood spot screening for galactosemia, tyrosinemia type I, homocystinuria, sickle cell anemia, sickle cell/beta-thalassemia, sickle cell/hemoglobin C disease, and severe combined immunodeficiency*. Edmonton (AB): Institute of Health Economics; 2016.
RESULTS:
Regardless of the potential issues related to nudging (manipulation or coercion), nudging is considered cost-effective and inevitable because of the malleability of human psychology, for example, alcoholic drinks served in smaller glasses nudge people to drink less alcohol.

No policy intervention, nudging or HTA, is value neutral and hence it requires an ethical evaluation. It takes traits of character, virtues, to discern which principle to apply in what circumstances and phronesis, practical wisdom, is the key virtue of a decision maker. Phronesis is not a moral judgement deducted from principles, but it is context specific, bottom-up, action orientated, and framed through dialogues. It focuses on the agent, the decision maker, who, via the use public scrutiny, should be held accountable for phronetic decisions made.

CONCLUSIONS:
Nudging is a cost-effective tool that can improve the populations health in a non-prescriptive way. Transparent reporting open to public scrutiny is necessary for the sake of evaluating whether the decisions made were phronetic for it takes traits of character, virtues, to decide between competing moral principles.

ABSTRACT SUMMARY:
A process for rational use of vitamin D testing was developed in a training and research hospital.

INTRODUCTION:
Ankara Numane Training and Research Hospital is one of the biggest training hospitals in Turkey, and has a hospital-based health technology assessment (HB-HTA) unit (ANHTA). One of the missions of this unit is to develop evidence-based recommendations for rational use of drugs and laboratory tests in the hospital. Vitamin D deficiency, testing and treatment, is a very hot discussion nowadays. There is increasing guidance in rationalizing vitamin D testing around the world, and our hospital has started a process to analyse the existing situation and provide guidance to our professionals. This abstract summarizes the process for rational use of vitamin D testing in our hospital.

METHODS:
Data from the hospital information management system was obtained to find out the current status of vitamin D testing. Total number and characteristic properties of vitamin D testing were determined. Literature review including international and national guidelines was done for rational use of vitamin D testing. Finally, guidance, including unique recommendations for our setting, was developed and given to hospital management.

RESULTS:
Total number of vitamin D tests were 42,302 for 2015 and 74,142 for 2016. Technique for vitamin D testing was chemiluminescent immunoassay method. Most of the tests were ordered by the internal medicine department. Some of the recommendations that were achieved after literature review were as follows: i) vitamin D testing should only be completed for patients with apparent symptoms of vitamin D deficiency, high risk of deficiency, or underlying health conditions; ii) the safest method for vitamin D testing is high performance liquid chromatography; and iii) vitamin D re-testing must be done at least 8 weeks after first testing.

PP131 A Process For Rational Use Of Vitamin D Testing In A Training And Research Hospital

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CONCLUSIONS:
We expect our guidance to help rationalize vitamin D testing in our hospital. The process will continue with meetings with professionals, further analysis of data to understand current testings’ relation to evidence, and follow-up of the impact of our interventions.

PP132 Using Health Technology Assessment For Managing Healthcare Information Systems

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ABSTRACT SUMMARY:
In spite of the large utilization of Health Technology Assessment (HTA) for the evaluation of single initiatives, the “HTA approach” is scarcely adopted for the management of healthcare information systems (HIS). A methodology for adopting the multidimensional HTA approach to the management of HIS has been studied by the “Laboratory of Healthcare Information Systems” at ALTEMS (Università Cattolica del Sacro Cuore, Roma).

INTRODUCTION:
In spite of the wide consensus and large utilization of the Health Technology Assessment (HTA) for the evaluation of single initiatives, the “HTA approach” is scarcely adopted for the assessment, implementation, planning and evolution of healthcare information systems (HIS).

However, the strategic, central role that the HIS has (or should have) in the entire organization cannot be underestimated, due to its spreading in the overall structure and the consequent influence on the characteristics, security, cost and up to the feasibility of the clinical and the processes. At the end, on the quality of the organization and of the services provided to the patients, including prevention and management of clinical risks.

METHODS:
A methodology for adopting the multidimensional HTA approach to the management of HIS has been studied by the “Laboratory of Healthcare Information Systems” at ALTEMS. It is based on three guidelines:

a) The analysis of the HIS through a holistic vision, relating ICT to the various aspects and requirements of the organization using three main standards widely adopted in the area of HealthCare Information Systems:
   • ISO/IEC 10746, as a reference model for decomposing and analysing the HIS under organisational, functional, information and technological viewpoints
   • ISO-12967, for the integration of all data and their availability throughout local and territorial processes
   • ISO-27001, for defining and evaluating all aspects related to security, not only from the technological viewpoint, but also from the clinical and organizational perspectives.

b) The analysis and assessment of the HIS described through these models according to the perspectives typical of the HTA approach.

c) The definition of indicators capable of providing objective and measurable terms of reference for comparing and evaluating different solutions, products and evolution strategies.

RESULTS:
By using this integrated HTA+ICT approach, a survey has been carried out, analysing the level of “overall security” of the information systems of more than 100 Italian organisations. It has been based on a questionnaire with 40 items, related to organizational, functional, information and technological aspects.
CONCLUSIONS:
Results of the survey will be available at the conference.

PP134 Does Shared Decision Making Influence Upon Adoption Of New Health Technology?

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ABSTRACT SUMMARY:
Recently, shared decision making (SDM) is an essential component of patient participation. This study aims to examine the association between SDM and adoption of new health technology in China. A total of 270 pairs of patients and their treating physicians were used for data analysis. SDM was the most important predictor of patients’ satisfaction and adoption of new health technology.

INTRODUCTION:
There is growing interest in the role of patients in treatment decision making. Recently, shared decision making (SDM) is an essential component of patient participation. It is critically important under the increasing tension or medical violence in health care settings in China, for addressing a deteriorating physician-patient relationship through better communication on new drugs and technologies. This study aims to examine the association between physician-patient SDM and adoption of new health technology in China.

METHODS:
A cross-sectional study was conducted from July 2016 to October 2016 in Fujian and Shanghai in Eastern China. Patients and their treating physicians completed the self-reported questionnaires on the patients-physician SDM, satisfaction with treatment decision making, and adoption of new health technology. Correlation analysis, multivariable logistic regression, and multivariable linear regression were performed.

RESULTS:
A total of 270 pairs of patients and their treating physicians were used for data analysis. More than half of the patients have adopted new health technology in the admission hospitals. And on the treatment decision making in the health technology adoption process, most (68.20 percent) of the patient’s preferred the SDM role and 67 percent of respondents perceived better communication with their physicians. Patient’s involvement with SDM was positively associated with patient’s satisfaction with treatment decision making (P< .001) and adoption of new health technology (P< .05). Better concordance between preference and actual SDM was positively associated with patients’ adoption behavior (P< .05), but no statistically significant association was found between concordance and satisfaction.

CONCLUSIONS:
SDM was the most important predictor of patients’ satisfaction with treatment decision making and adoption of new health technology. Therefore, better communication between physicians and patients is suggested to improve SDM, such that patient’s satisfaction with treatment decision making and adoption of health innovations can be enhanced in China.
PP135 Stakeholder Involvement In A Health Technology Assessment of Hyperhidrosis

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ABSTRACT SUMMARY:
Patient and clinician advisors contributed to this systematic review and economic model of secondary care treatments for primary hyperhidrosis. These advisors agreed with the effectiveness evidence supporting botulinum toxin injections for axillary hyperhidrosis and the sequence of treatments identified as being cost effective. They advocated a trial of botulinum toxin injections versus iontophoresis for palmar hyperhidrosis.

INTRODUCTION:
Hyperhidrosis is characterised by uncontrollable excessive sweating, which occurs at rest, regardless of temperature. Symptoms can significantly affect quality of life. There is substantial variation in the secondary care treatment of hyperhidrosis and uncertainty regarding optimal patient management. The objective of the Health Technology Assessment (HTA) was to review the evidence and establish the expected value of undertaking additional research into effective interventions for the management of primary hyperhidrosis in secondary care. Capturing the perspectives of patients and clinicians treating hyperhidrosis was an important part of the research.

METHODS:
The assessment included a systematic review and economic model, including value of information analysis. Patients, dermatologists, a vascular surgeon and a specialist nurse (who set up the UK Hyperhidrosis Support Group) provided advice at various stages, including at an end-of-project workshop, to help interpret results and prioritise research recommendations.

RESULTS:
Patient and clinician advisors were unsurprised by the finding that there is evidence of a large effect of botulinum toxin injections on axillary hyperhidrosis symptoms in the short to medium term; there was consensus amongst patients and clinicians that botulinum toxin injections were very effective. The advisors agreed that a trial of botulinum toxin injections (plus anesthetic) versus iontophoresis for palmar hyperhidrosis would be useful. Patients and clinicians were happy with the sequence of treatments identified as being cost effective for axillary hyperhidrosis: iontophoresis, botulinum toxin injections, anticholinergic medication, curettage, endoscopic thoracic sympathectomy. All patients agreed that the Hyperhidrosis Quality of Life index (HidroQoL®) tool was superior to other commonly used tools for assessing quality of life in hyperhidrosis.

CONCLUSIONS:
Patients and clinicians considered the key findings of the systematic review and economic analyses to be appropriate. Advisors advocated a trial of botulinum toxin injections (plus anaesthetic) versus iontophoresis for palmar hyperhidrosis. Patients preferred the HydroQoL® tool over other commonly used quality of life tools in hyperhidrosis research.
**PP136 The Effect Of The Rational Medical Devices Management On Sustainability**

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**ABSTRACT SUMMARY:**
Medical devices are an important part of health care delivery and its good management is crucial in terms of safety, efficiency and economy. In our work, applications related to rational medical device management in Turkey have been examined and the results of medical device applications have contributed positively to the sustainability in health economics.

**INTRODUCTION:**
According to WHO “4 As”—Availability, Accessibility, Appropriateness, and Affordability are crucial for medical devices. These four components help to widen the scope of the medical device agenda so that it does not just focus on “upstream” innovation efforts but also on choosing which medical devices to procure in a rational way, responding to the needs, and in ensuring that they are used as effectively as possible to best improve health.

Rational medical device management (RMDM) requires that medical devices be made accessible and sustainable in the easiest, safest and most economical way for all parties (practitioners, patients and decision makers) for medical and technical requirements or to raise quality of life, and to be used in a safe and effective manner by practitioners, in accordance with the purpose of production, regardless of all economic pressures, and safely disposed.

**METHODS:**
In this study, medical devices regulations carried out by MoH, registers of the Medicine and Medical Devices National Data Bank of the Republic of Turkey (TITUBB), sectoral licensing regulations, medical device market surveillance-audits and vigilance system activities have been examined, literature review and observational study on the impact of rational medical device management practices in Turkey on health services and health economics has been evaluated.

**RESULTS:**
The number of the MD producers/importers and their dealers gained from TITUBB. Turkish manuel is obliged in the scope of the MDD, “General Procurement of Goods and Services Related to MD” published by SHGM, “Communiqué on Procedures and Principles on the MD Vigilance System” and “Communiqué on Notified Bodies to Provide Activities in the Field of Medical Devices”, “Medical Device Sales Promotion Advertising Regulation” are important regulations for RMDM.

**CONCLUSIONS:**
Through rational management of MD is likely to contribute positively to improving the quality of health care delivery and sustainability also reducing external deficit for the importer countries. Thus, all aspects of rational medical device management must be actively implemented across the country and institutionalization of HTA should be completed to contribute to the RMDM.
PP137 Regional Process For Planning Medical Equipment Procurement In Italy

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ABSTRACT SUMMARY:
With the aim of planning medical equipment procurement, in North of Italy, Regional regulations were enacted in 2013 and 2014 by defining a process for the authorization of biomedical technologies requests of Hospitals and Local Health Authorities. Requests concerned in prevalence replacements of obsolete equipment, due to the absence of planning strategies deriving from being a Region in ’Recovery Plan’.

INTRODUCTION:
An appropriate governance of the installed equipment base, by defining replacements strategies and programming introductions of innovative Biomedical Technologies (BT), has direct effects on the efficiency and effectiveness of health systems. An effective health technology management is of paramount importance for providing safe, high quality and innovative care with the constraint of health-care budgets, safeguarding equity, access and choice principles. Data from the regional BT information flow show that, compared to the gold standard (1), the North Region of Italy has about 15 percent less of large medical equipment younger than 5 years and about 15 percent more of equipment older than 10 years.

METHODS:
In order to draw a unified path of BT procurement processes, in 2013 and 2014 regional regulations (2,3) were enacted. Each Public Hospital and Local Health Authorities (ASRs) defined a plan (PLTB) containing, regardless of the form of procurement and type of funding, all BT requests for a value greater than EUR40,000 distinguished in replacement/new acquisition/upgrade, innovative acquisition and donations. Requests of BT have to obtain the authorization by the Regional Healthcare Authority Commission (GTB), in compliance with defined criteria, including financial and sustainability aspects, after the evaluation of the Regional Clinical Engineering Commission (GIC) supported by IRES, Health Technology Assessment and Management research group.

RESULTS:
Over the years 2014 and 2015, the ASRs submitted 491 BT requests, of which 87 percent were replacement/new acquisition/upgrade, 9 percent innovative acquisition and 4 percent donations. Altogether 26 percent of these instances were urgent and 2 percent were unique BT on the market. Sixteen percent of requests for replacement/new acquisition/upgrade of BT related to large medical equipment with mean age of 13.3 years, 2 percent regarded innovative BT with average age of 8.4 years and 48 percent widespread technologies with mean age of 15.6 years.

CONCLUSIONS:
The limitations in investments deriving from being a Region in “Recovery Plan”, have originated an absence of BT programming, as shown in PLTB by the prevalence of requests for the replacement management of obsolete equipment with inadequate performance, high machine downtimes and elevated maintenance costs.

REFERENCES:
2. D.G.R. n. 36-6480 del 07/10/2013 “Istituzione di un Piano Regionale delle Tecnologie Biomediche (PRTB) e costituzione di una Commissione
PP138 Italian Medicines Agency Registries Distribution By Managed Entry Agreements and by Anatomical Therapeutic Area

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ABSTRACT SUMMARY:
The price of pharmaceuticals reimbursed by the National Health Service is set through negotiation between AIFA and manufacturers, applying specific agreements (MEAs) to regulate the reimbursement list based on cost-efficacy in order to ensure the full respect of Pharmaceutical Price Regulation criteria. The objective of this analysis was to identify a correlation between therapeutic disease area and different type of MEAs.

INTRODUCTION:
In a budget constrained environment characterized by an increasing number of high-cost medicines, manufacturers need to demonstrate that their drugs can provide value-for-money. In this complex environment Managed Entry Agreements (MEAs) have been developed with the aim of sharing the risk between the National Health Service (NHS) and manufacturers (1). The objective of this analysis was to identify a correlation between Anatomical Therapeutic Chemical Classification (ATC) and different type of agreements assigned taking into consideration the distribution of Italian Medicines Agency registries by ATC and by kind of agreement negotiated (financial or performance based) (2).

METHODS:
This analysis takes into account all drugs under monitoring AIFA registries in place in Italy from 2006. For each registry included in the analysis it was collected the status of the registry (active, closed or incoming), the disease area that the registry covers and the monitored drugs with or without an associated Managed Entry Agreements. Considering the high weight of oncology drugs, a sub-analysis was done to investigate registries distribution for each specific form of cancer.

RESULTS:
The majority of drugs monitored are under a registry with no associated risk sharing agreement according to AIFA (60 percent). For what concerned monitored drugs with an associated agreement, performance-based agreement is the most diffused type of MEA. In terms of therapeutic area involved in the monitoring registries activity, oncology was the most common area. Financial based agreements characterize principally medicines used for Leukemia and Hepatitis C, whereas drugs administrated for Melanoma, Breast and Ovarian Cancer and Ophthalmology diseases follow performance based agreements.

CONCLUSIONS:
MEAs represent a way to guarantee a sustainable access for innovative medicines. It is proven that oncology products are most likely to have a MEA since they represent some of the most expensive drugs launched in recent years. From this study appear a correlation between the therapeutic disease area of the monitored drugs and MEA assigned by AIFA which is influenced also by other factors like budget impact, risk-benefit ratio and the presence of appropriate endpoints to evaluate the treatment response.
REFERENCES:
1. Italian Medicines Agency Website - Monitoring Registries Section (http://www.agenziafarmaco.gov.it/it/content/lista-aggiornata-dei-nuovi-registri).

PP140 Effectiveness Of Telemonitoring Interventions For Asthma

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ABSTRACT SUMMARY:
To compare the clinical effectiveness of telemonitoring interventions with usual care.

INTRODUCTION:
Asthma is a chronic disease that causes reversible narrowing of the airways due to bronchoconstriction, inflammation, and mucus production. Technology can be used to improve health outcomes and prevent the need for emergency treatment for people with asthma and other long-term health conditions.

METHODS:
We searched all English-language articles in MEDLINE, EMBASE, the Cochrane Library, CINAHL, and 5 domestic databases up to March 2016. We included randomized controlled trials (RCT). Two review authors independently applied the extracted data and assessed study quality. We analysed dichotomous data as relative risk (RR), and continuous data as mean difference (MD) or standardized mean differences (SMD) while using random-effects models. Primary outcome was asthma control (measured on a validated scale, e.g., the asthma control questionnaire, asthma control test), asthma exacerbation rates, quality of life. Secondary outcome was hospitalization, emergency room visit, adherence, etc.

RESULTS:
We included seventeen RCTs (twenty-one papers) in this review. Meta-analysis showed that these interventions might be better or worse than usual care in asthma control (SMD .15, 95 percent Confidence Interval, CI -.07 to .38, I²=74 percent). Exacerbation rate was lower in the intervention group compared to the control group (RR .75, 95 percent CI .51 to 1.10, I²=46 percent), but there was no statistically significant effect. Also, meta-analysis showed that these interventions did not result in clinically important improvements in quality of life (SMD .10, 95% CI -.10 to .31, I²=57 percent).

CONCLUSIONS:
Telemonitoring interventions are unlikely to result in clinically relevant improvements in health outcomes, but some studies in our analysis suggest that telemonitoring interventions increase patient medication adherence. Further studies with longer intervention durations are needed to assess effects on clinical outcomes.

PP141 Legal Governance: How Does Law Circumscribe The Social Role Of Health Technology Assessment?

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One of the challenges of integrating ethics in Health Technology Assessment (HTA) relates to the social function of HTA. The main purpose of this research is to provide a better understanding of the way by which law circumscribes the social role of HTA. We will demonstrate the need for rethinking legal governance of HTA and discuss how to better integrate ethics in HTA.

# Introduction:
One of the barriers of integrating ethics in Health Technology Assessment (HTA) relates to the social role of HTA (1). The aim of this study is to provide a better understanding of the way by which law circumscribes the social role of HTA. Our hypothesis: HTA’s social role is embedded within a mixed governance based on hard law and soft law.

# Methods:
Three HTA agencies were conveniently selected for our study: Haute Autorité de santé (HAS) (France), National Institute for Health and Care Excellence (NICE) (United Kingdom) and Institut national d’excellence en santé et en services sociaux (INESSS) (Québec, Canada). Our analysis of the legal, administrative and procedural documents relating to the existence and assessment processes of these three agencies is guided by the following criteria:

1. The normative strength of the documents (categories of hard law or soft law) (2)

# Results:
Hard law contributes to establish a general mandate and some legal legitimacy for these agencies. Soft law, grounded in the HTA producers’ practices, plays a major role in the legal governance of HTA. Our results demonstrate that these agencies existing practices seem to circumscribe their social role further than their constitutive laws. In this context, social actors become responsible to define, structure and operationalize the implementation of HTA.

In addition, the legal framework (hard law) through which HTA unfolds does not clearly support its structural and social role. Despite existing legal frameworks, the normative legitimacy of HTA is not entirely established, as it depends on soft law. Taken altogether, this maintains a persisting conceptual vagueness in HTA governance.

# Conclusions:
The social role of HTA should be defined either through modifying existing legislations (hard law) or through harmonization of the agencies internal policies and regulations (soft law). Such legal initiatives would help clarify the aims of HTA evaluations: assessments (scientific) or appraisal (value-laden), and therefore give a clearer indication on how best to integrate ethics in HTA.

# References:

PP142 A Mental Health Hospital-based Health Technology Assessment In Quebec, Canada: Structure And Products

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ABSTRACT SUMMARY:
The structure of a Hospital-based Health Technology Assessment (HTA) unit, and the type of products offered to support the decision-making process concerning the implementation of new technologies and practices in mental health in Quebec, Canada are presented.

INTRODUCTION:
Our Hospital-based Health Technology Assessment unit (HB-HTA) was founded in 2011 following the nomination of Louis-H. Lafontaine hospital as the Montreal University Mental Health Institute (IUSMM). From the beginning, the HB-HTA has been supporting and advising the Chief Executive Officer of IUSMM in the decision-making process concerning the implementation of new technologies and practices in mental health. Since 2015, the HB-HTA is part of the East of Montreal Regional Integrated Health and Social Services Centre (CIUSSS de l’Est-de-l’Île de Montréal), continuing to support decisions in mental health. Currently, the HB-HTA unit is nested in the Quality, Performance and Ethics department.

METHODS:
Formed by a coordinator, a scientific advisor and a manager, the HB-HTA team plans, organizes and sets up the evaluation activities. The unit benefits from the support of a Steering Committee which consists of representatives of clinical, administrative and research directions, as well as of health users and families. This committee determine the strategic orientation of the HB-HTA unit, prioritise the projects, approves the evaluation products and gives indications on the knowledge transfer process.

RESULTS:
To answer the decision questions, our HB-HTA unit employs two types of products: evaluation reports and informative notes. Based on an exhaustive literature search and consultations with stakeholders, the evaluation reports offer recommendations to support the decision-making process. The informative notes are rapid responses based on a partial literature search. The nature of this type of analysis does not allow the formulation of recommendations, however, a conclusion of the consulted literature is offered.

CONCLUSIONS:
Based on the work of our HB-HTA unit, some important decisions were made by the IUSMM. As an example, the systematic screening of psychiatric patients for drug and alcohol was not favored by our institution; rather than this, priority was given to staff training, in order to better identify and treat psychiatric patients with substance abuse comorbidity.

PP143 Investigating The Transferability Of Test Accuracy For Decision Making

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ABSTRACT SUMMARY:
It is not always possible to evaluate a test's accuracy in primary care directly. Furthermore, secondary care evaluations of a test may not be transferable to primary care. Alternative approaches are required. Here we present two alternative approaches using electronic health records from a United Kingdom GP database to estimate test accuracy in primary care.

INTRODUCTION:
Decision makers such as the National Institute for Health and Care Excellence (NICE) are often required to make decisions about the availability of tests for patient care based on limited evidence. Transferring evidence between settings is one option to address the issue but is not always appropriate. Faecal calprotectin testing has been approved by NICE for the differential diagnosis of inflammatory bowel disease and irritable bowel syndrome in United Kingdom (UK) primary care, in adults with unexplained abdominal complaints. Faecal calprotectin is a marker for intestinal inflammation which can aid the selected referral of patients with high levels of faecal calprotectin. The approval was based on a positive cost-effectiveness assessment (1). Due to limited available evidence from primary care studies the assessment assumed that the measures of test accuracy were transferrable from secondary care studies. However, transferability of test accuracy estimates between settings cannot be assumed when patient populations differ between settings, and there appears to be a need to inform decision makers about possible consequences of such an approach. We therefore aim to investigate to what extent the cost-effectiveness of faecal calprotectin testing in primary care might have been overestimated by using secondary care test accuracy measures. In order to achieve this, knowledge of the true test accuracy of faecal calprotectin testing in primary care is required. In this submission two possible routes are presented to allow the estimation of test accuracy when a primary test accuracy study is unfeasible.

METHODS:
(i) We designed a test accuracy study using routine electronic health records collected in a database from over 600 UK general practices. (ii) We will compare the outcomes with the results from a tailored meta-analysis (2,3) of secondary care studies compatible with the test positive rate and prevalence found in primary care defined by information from the same primary care database.

RESULTS:
Results to come.

CONCLUSIONS:
Conclusion to come.

REFERENCES:
PP144 Challenge For The Health Technology Assessment And The Coverage Decision

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ABSTRACT SUMMARY:
The study provides an overview of the health technology assessment and decision making in Korea. We suggest the future framework for decisions of resource allocation to improve performance of HTA in Korea.

INTRODUCTION:
Korea implemented the health technology assessment (HTA) as the NHI required the system from 2007.

The study provides an overview of the health technology assessment and decision making in Korea. We suggest the future framework for decisions of resource allocation to improve performance of HTA in Korea.

METHODS:
We systematically collected and reviewed relevant information to describe the HTA process and reimbursement systems.

RESULTS:
New medical procedures should be assessed their safety and effectiveness by the HTA Committee to be listed to the Benefit Schedule in Korea. After that, the Expert Assessment Committee in Health Insurance Review and Assessment service (HIRA) reviews cost-effectiveness (economic value, substitutability) and benefit appropriateness (coverage principle, budget impact).

From 2012 to 2016, a total of 691 applications were submitted and 304 applications (44.0 percent) were eligible to be assessed. Among 106 cases in 2016, 20 cases were accepted as reimbursement, 62 cases were rejected and the others were in progress. In Korea, the result of decision making is dichotomous; ‘Covered’ or ‘Not covered’. There is no flexibility by the level of evidences of the medical procedures and devices in decision making.

We should consider followings to increase efficiency and transparency in the decision making. Firstly, we need to develop the flexible process of the new medical procedures and devices reflected on the technology’s characteristics. There is an increasing demand of intermediate decision such as conditional coverage, risk-sharing agreement, etc. Secondly, we consider improving the transparency in HTA reimbursement decision: engagement with patients, industry and citizen. And lastly, we need to set the monitoring and re-evaluation system for assessing new or potentially obsolete technologies.

CONCLUSIONS:
The process of HTA and decision making in Korea should improve efficiency and transparency. Engagement of stakeholders, development of the detail and explicit process in decision making, and setting re-evaluation system should be considered. Further study should work out a strategy in detail.

PP145 Selective Internal Radiation (SIR)-Spheres Y-90 Resin Microspheres In Patients With Metastatic Colorectal Cancer

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ABSTRACT SUMMARY:
This study provides an overview of the clinical, economic, organizational, legal, social, and ethical impacts of selective internal radiation therapy (SIRT) using SIR-Spheres Y-90 resin microspheres in the treatment of patients with unresectable, liver-dominant metastatic colorectal cancer who are refractory to or intolerant of chemotherapy.

INTRODUCTION:
Selective internal radiation therapy (SIRT) is a form of intra-arterial brachytherapy used to treat primary liver cancer and liver metastases. This study aims to provide an overview of the clinical, economic, organizational, legal, social, and ethical impacts of SIRT using SIR-Spheres Y-90 resin microspheres in the treatment of patients with unresectable, liver-dominant metastatic colorectal cancer who are refractory to or intolerant of chemotherapy.

METHODS:
A systematic literature review was performed by querying PubMed, Scopus, EBSCO, CRD, GIN. Two reviewers blindly screened the records retrieved against pre-defined inclusion/exclusion criteria. The selected studies were summarized following a simplified version of the EuNetHTA Core Model® 2.1. Also, a multidisciplinary advisory board with experts was established to provide opinion on some issues considered relevant within the Italian jurisdiction.

RESULTS:
The ninety-two studies which met the inclusion criteria all evaluated SIRT in first line or further line treatment and showed a good safety and tolerability profile as well as significant improvement in efficacy expressed as time to liver progression, progression free survival, and overall survival. To safeguard safety and quality of care, SIRT should be provided in specialized centers, and all the patients’ flow should be managed by a multidisciplinary team. A hub and spoke network of services could be a viable option to guarantee access to this technology in a more equitable way across jurisdictions. The lack of a specific DRG tariff accounting for the cost of the device could be seen as the major obstacle to a fair diffusion of this technology. The economic evaluations currently available show the cost-effectiveness of this technology in the population to be under study.

CONCLUSIONS:
SIRT using SIR-Spheres Y-90 resin microspheres appears to be a clinically effective and cost effective option for the treatment of mCRC patients who are chemotherapy refractory or chemotherapy intolerant.

PP147 Physician And Patient Reported Anxiety And Depression In Hemophilia

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ABSTRACT SUMMARY:
The monitoring of depression and anxiety in patients with severe hemophilia is often neglected by specialist treating physicians, despite being a major contributing factor to health-related quality of life. This study used European level data to assess the differences between physician- and patient-
reported anxiety and depression. We find patients reporting a higher prevalence of these conditions in comparison to their specialist physicians.

INTRODUCTION:
Anxiety and depression are major drivers of health-related quality of life, adherence to therapy, and motivation to self-manage chronic conditions. A number of studies have shown rates of anxiety and depression to be higher among individuals with hemophilia compared to that of the general population (1). As the primary point of care for persons with hemophilia, hematologists are well-placed to assess the mental health state of their patients (2). The aim of this study is to explore physician- and patient-reported rates of anxiety and depression among a cohort with severe hemophilia.

METHODS:
Data were drawn from the Cost of Haemophilia across Europe – a Socioeconomic Survey (CHESS), a cost-of-illness study in severe hemophilia A and B across five European countries (France, Germany, Italy, Spain, and the UK) (3). Physicians provided clinical and sociodemographic information for 1,285 adult patients, 551 of whom completed corresponding questionnaires, including EuroQol EQ-5D-3L. We compared the self-reported EQ-5D with physician reports of anxiety and depression.

RESULTS:
Across the five countries, physicians recorded a diagnosis of anxiety disorder in 189 patients (15 percent; range 4 percent–28 percent) and depression in 178 patients (14 percent; range 10 percent–28 percent). Seventy-three patients (6 percent) recorded comorbid anxiety and depression. Forty-six percent of patients with anxiety and 58 percent of patients with depression were receiving some form of treatment for their condition.

Within the EQ-5D measure, 42 percent of individuals recorded problems with anxiety or depression, with 6 percent of patients reporting “extreme” anxiety or depression. Twenty-two percent of individuals with a self-reported problem were not recorded with a corresponding diagnosis by their haematologist; 39 percent of patients reporting “extreme” anxiety or depression were absent of any physician-reported diagnosis.

CONCLUSIONS:
Anxiety and depression are notable conditions within the haemophilia community, particularly so among those with severe condition. The mental health of individuals with haemophilia is an important aspect in ensuring therapy adherence and overall wellbeing and should be considered as part of a multidisciplinary approach to management of the condition.

REFERENCES:

PP148 Development And Evaluation Of A Tool Supporting Prescription Behavior

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ABSTRACT SUMMARY:
The study illustrates a simple tool developed to assist clinicians in their decision-making about therapeutic options for the management of diabetes mellitus patients and presented results about the evaluation of the tool for its usefulness and ease to use in a sample of professionals.

INTRODUCTION:
The increasing complexity of decision-making in clinical practice and the financial pressure requires clinicians to develop some background about the economic consequences of their decisions and to become more and more managers of pre-defined budgets. The present work aims at describing a simple technology solution that could support prescription decisions and illustrates the results of a preliminary assessment of the tool in a sample of professionals. The solution has been developed to allow informed decision-making in the prescription of oral anti-diabetic drugs (OADs) in type II diabetes mellitus (T2DM) patients by supporting prescriptive appropriateness.

METHODS:
The tool developed is compatible with many kinds of hardware architectures and the most diffused web browsers. The system allows real-time reproduction of economic evaluation of the different therapeutic options for the management of T2DM patients. Assessment of “ease to use” and “usefulness” of the tool was performed in a convenience sample of clinicians and pharmacists through a specific questionnaire.

RESULTS:
The tool was developed to compare dipeptidyl-peptidase inhibitors (DPP4i) with sulfonylureas, as second line therapy, for T2DM patients. The tool has a user-friendly Graphical User Interface allowing users to quickly and easily select the therapeutic options to compare, choosing geographical context, perspective of analysis, and changing some model parameters. Feedback obtained from thirty-three different professionals were generally positive for the “ease to understand information offered”, “ease of introduction of the tool to support usual working activity”, “usefulness within the usual working activity”.

CONCLUSIONS:
The study showed that the introduction of the tool as a support for clinicians in optimizing their practice could satisfy unmet needs of professionals by supporting informed prescriptive appropriateness in the choice of OADs as it allows to consider diabetes drug related costs in a comprehensive way. The routinely use of the tool developed could become a solution helping clinicians in the management of several diseases.

PP149 Assessment Of New Medical Devices With Administrative Databases

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ABSTRACT SUMMARY:
The rapid pace of innovation characterizing medical devices poses a problem of traceability of their use in administrative data. The aim of this work was to investigate the capacity of the classification system currently used in Italy, which is at high risk of obsolescence, to identify innovative MDs.
INTRODUCTION:
Administrative data (for example, hospital discharge databases, HDDs) can be used as a real-world source of clinical and economic evidence for assessing new medical devices (MDs), provided that their use can be identified in the data. In absence of updated classification systems for procedures and diagnoses, which allow to identify the use of new technologies in the data, traceability can still be achieved thanks to authorities coding guidelines (that is, indication on how to combine the existing codes for procedures and/or diagnoses when new technologies are used).

In 2009 Italy adopted version 2007 of the International Classification System of Diseases (ICD-9-CM) and version 24 of Diagnosis Related Groups (DRGs), which are still in use. The aim of this work was to investigate the capacity of the classification system currently used in Italy, which is at high-risk of obsolescence, to identify innovative MDs.

METHODS:
To achieve our goal, we performed a systematic search of all the national and regional coding guidelines published from 2009 (that is, the year of introduction of the new classification systems) to 2015. We extracted from each document the list of technologies for which the Ministry of Health and/or the Regional Authorities provided with coding indications.

RESULTS:
Our results show that only a few recent technological innovations can be identified in the Italian HDDs. This reduces the possibility for decision makers to measure new technologies outcomes and costs in the real world clinical practice.

CONCLUSIONS:
The traceability of new MDs’ can support Heath Technology Assessment (HTA). Indeed, HTA programs should use real world evidence to re-assess MDs 2-3 years after their introduction in clinical practice. The use of routinely collected data, such as HDD, would allow to measure new technologies’ “real” effectiveness in “real” world, on “real” patients in “real” hospitals to complement the evidence from Randomized Controlled Trials.

PP150 Rapid Analgesia For Prehospital Hip Disruption: A Feasibility Study

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ABSTRACT SUMMARY:
The study reports on the use of Fascia Iliaca Compartment Block (FICB) by paramedics at the scene of a hip injury. This procedure is routinely undertaken by clinicians in emergency departments, but use by paramedics at the scene of emergency calls has not been evaluated. The study progression criteria will determine whether we undertake a multi-centre randomized control trial.

INTRODUCTION:
Adequate pain relief at the scene of injury and during transport to hospital is a major challenge
in all acute traumas, especially for those with hip fractures, whose injuries are difficult to immobilize and long-term outcomes may be adversely affected by administration of opiate analgesics. Fascia iliaca Compartment Block (FICB) is a procedure routinely undertaken by clinicians in emergency departments for hip fracture patients, but use by paramedics at the scene of emergency calls, is not yet evaluated (1).

METHODS:
We undertook a randomized controlled feasibility trial using novel audited scratchcard randomization to allocate eligible patients to FICB or usual care. Paramedics are recruited and trained to assess patients for hip fracture and carry out FICB. We will follow up patients to assess accuracy of paramedic diagnosis, acceptability to patients and paramedics, compliance of paramedics and also measures of pain, side effects, time in hospital and quality of life in order to plan a full trial if appropriate. The primary outcome measure is health related quality of life, measured using Short Form (SF)-12 at 1 and 6 months. Interviews and focus groups will be used to understand acceptability of FICB to patients and paramedics. This study was funded by Health and Care Research Wales (1003).

RESULTS:
We have developed:
- paramedic pathway to assess patients for hip fracture and FICB
- paramedic training package, delivered by Consultant Anaesthetist
- randomization scratchcards.
To date we have recruited nineteen paramedics; ten are fully trained and recruiting patients, the remainder are being trained. Fifty-four patients have been randomized and thirty-five have consented to follow-up. Thirteen 1-month and five 6-month follow-up questionnaires have been received.

CONCLUSIONS:
This study will enable us to recommend whether to undertake a definitive multi-centre randomized controlled trial of FICB by paramedics for hip fracture to determine if the procedure is effective for patients and worthwhile for the National Health Service.

REFERENCES:

PP151 Strategy For Decision Making Of Health Technology Assessment

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ABSTRACT SUMMARY:
Decision of each committee in Health Insurance Review and Assessment Service (HIRA) should be made efficiently in a given time. To make that possible, there is a need for a supporting system which enables evidence-based decision in time. This paper aims to introduce and suggest the decision making supporting system in HIRA.

INTRODUCTION:
The Health Insurance Review and Assessment Service (HIRA) in Korea is responsible for the benefit claims review, quality assessment, and the setting and management of benefit standards of the National Health Insurance System. HIRA operates a
variety of committees. Activity of each committee is decision making for health technology assessment and the review of the reimbursement and the management of benefits.

Decision of each committee in HIRA should be made efficiently in a given time. To make that possible, there is a need for a supporting system which enables evidence-based decision in time. This paper aims to introduce and suggest the future direction for the decision-making supporting system in HIRA.

METHODS:
The system is composed of two parts. One is to provide standardized format for meeting material based on a manual. The other is a cultivation program for HIRA’s human resources. First, the meeting documents for each committee are produced by HIRA’s staffs using Evidence Based Review Manual (EBRM) which is a HIRA’s exclusive application guideline based on literature reviews. Second, to improve the expertise of the employees and to train them, a suitable educational program is implemented for use of the EBRM. EBRM Masters are also selected to encourage application of EBRM to support the establishment of the system within their respective departments.

RESULTS:
To build up an evidence-based decision-making system, the formal education programs about EBRM is established for employees who belong to a department that operates the committee. In 2015, Committee meetings took place 318 times in HIRA. According to the guideline, the standard format documents are produced for the efficient decision-making process. In addition, the Masters obtain on internal qualification of HIRA, and serve to improve utilization of evidence and cooperation between staffs.

CONCLUSIONS:
Currently, HIRA has tried to maintain validity of EBRM and to develop the education program. For the future, HIRA has tried to develop the efficient review methods (EBRM) and to enhance the accessibility for systemized programs (web based education system). Also, to be the explicit and transparent decision making system, HIRA continues to make efforts for the advancement.

PP152 Health Technology Assessment Of The Combination Of Elbasvir/Grazoprevir

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ABSTRACT SUMMARY:
In Italy, Hepatitis C virus (HCV) is responsible for a significant epidemiological and economic burden. The new combination of elbasvir/grazoprevir has a high efficacy against the most prevalent genotypes, inducing a sustained virologic response (SVR) up to 95 percent, even in complex patients. The new treatment has a good safety profile and cost-effectiveness ratio, with positive economic, organizational, and ethical implications.

INTRODUCTION:
In developed countries, Hepatitis C virus (HCV) is a leading cause of chronic liver disease and
hepatocellular carcinoma, which represents the first indication for liver transplantation. The extraordinary development of direct-acting antiviral agents (DAAs) significantly ameliorated the sustained virologic response (SVR) rates in HCV patients, but it is causing a huge stress on several national health systems in terms of economic sustainability. This work summarizes a health technology assessment of elbasvir and grazoprevir, a new combination therapy available for oral daily treatment of HCV infections.

METHODS:
HCV epidemiology and burden were assessed using the best available international and national evidence. Efficacy and safety of the new drug were synthesized using clinical data. A cost-effectiveness analysis was performed by a markov model comparing the new technology to the standard of care. Organizational and ethical implications were considered. The perspective of the Italian National Health Systems has been chosen.

RESULTS:
According to the European Centre for Disease Prevention and Control (ECDC), more than 3 million of Italians suffered from HCV, with an overall prevalence of 5.2 percent. However, epidemiological studies were usually out-dated and without nationwide samples. More conservative estimations suggested that the prevalence of HCV antibody and RNA is around 2 percent and 1.5 percent, respectively. Genotypes 1 and 4 accounted for around 66 percent of these infections. The new combination of elbasvir and grazoprevir has a high efficacy against these genotypes, inducing a SVR rate up to 95 percent, even in complex patients. The new treatment has a good safety profile and cost-effectiveness ratio and it allows an organizational simplification of the HCV therapy, both for patients and for reference centres, implying an overall positive ethical evaluation.

CONCLUSIONS:
HCV is responsible for a significant epidemiological and economic burden at the national level. The typical multidisciplinary approach of this HTA provides a comprehensive evaluation of this new drug that is essential for ensuring real evidence-based decision making in the manifold field of HCV therapy. Furthermore, the introduction of elbasvir/grazoprevir within the Italian context would support HCV elimination strategy through a public health approach.

PP153 Loxapine Inhalation Powder For Agitation Control In Mental Illnesses

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ABSTRACT SUMMARY:
Inhalatory Loxapine is a new and innovative treatment option for acute agitation in schizophrenia and bipolar disorder. Through a non-invasive route of administration, it demonstrated a fast effect and a good safety profile, suggesting its use to limit the escalation of aggression and violence, and to preserve the therapeutic alliance between the patient and the physician.

INTRODUCTION:
Acute agitation could be associated with various disorders, among which are included mental illnesses, and it could evolve seamlessly into aggressive behavior. It is important to identify it as early as possible to prevent this evolution and to protect the patient and the subjects surrounding
him/her. The objective of this work was to evaluate the impact of loxapine inhalation powder use in the management of the agitation episodes in schizophrenic and bipolar patients.

METHODS:
A literature review was carried out to describe the epidemiology and the current management of psychomotor agitation episodes, identifying clinical guidelines, available treatments and effectiveness, and describing the efficacy and safety of loxapine inhalation powder as a new therapeutic option.

RESULTS:
Scientific literature concerning schizophrenia estimates an annual incidence of 11-24 per 100,000 (range 7-52 per 100,000) and 0.5 percent-3 percent prevalence; the prevalence of bipolar disorder oscillates between 0.1 percent-5 percent. The epidemiological data on the state of agitation in such patients tend to be scarce, ranging prevalence between 23.4 percent-38.4 percent in schizophrenia and 19.5 percent-29 percent in bipolar I disorder. These conditions are responsible for 11.4 percent-17.1 percent of all physical assaults.

Traditionally, psychomotor agitation requires first and second-generation antipsychotics or benzodiazepines using traditional routes of administration (oral, intramuscular, intravenous) and waiting at best 10 minutes for the onset of the efficacy. The loxapine inhalation formulation allows provision of a non-invasive rapid systemic injection through the nebulization of particles in aerosol form. Loxapine use is authorized in the hospital setting. Significant differences in Positive and Negative Syndrome Scale-Excited Component and Agitation Behavioral Rating Scale, along with a good safety profile, have been demonstrated.

CONCLUSIONS:
The early approach to agitation allows the prevention of the transition from a state of mild-moderate to severe agitation (escalation), limiting the multifactorial risk associated with this condition. The speed of action of loxapine inhalation formulation allows an early discharge and reduces the intensity of monitoring.

PP154 Developing Health Technology Assessment Designs For E-Health: A Systematic Review Of Reviews

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ABSTRACT SUMMARY:
The Norwegian centre for e-health research (NSE) is commissioned to assess e-health within a Health Technology Assessment (HTA) framework in collaboration with national and international bodies. We present preliminary results of a systematic review addressing methodologies used for e-health assessments within HTA traditions, with challenges summarized and proposals for further development to the benefit of different healthcare stakeholders. The purpose is to build capacities.

INTRODUCTION:
In 2009 the European Commission initiated a study to assess methodologies for assessing telemedicine, with the purpose of proposing timely and relevant approaches in a rapidly changing field. One of the results was the development of a model to assess telemedicine, Methodologies for Assessing Telemedicine (MAST). Other results were two systematic reviews: “Effectiveness of Telemedicine: a Systematic Review of Reviews” (2010) and “Methodologies for Assessing Telemedicine: a Systematic Review of Reviews” (2012). Health Technology Assessment (HTA)
approaches were not specifically addressed in those reviews, even if data were available. In 2016, the project “HTA for ICT” within the Norwegian centre for e-health research (NSE) initiated a follow-up study to take stock of developments in the field since the previous reviews, with an additional focus on e-HTA. This study reports preliminary results on HTAs identified in the review update, research approaches in the included primary studies, methodological challenges summarized as well as proposals for development in order to produce timely and relevant assessments, to build capacities within HTA.

METHODS:
A review of systematic reviews was conducted according to a protocol listing explicit methods, selection criteria, data collection and quality assessment procedures. Reviews were included where authors explicitly addressed and made recommendations for assessment methodologies. A qualitative analysis was performed on the included reviews, sensitized by broad methodological positions. In the previous reviews these included positivist and naturalistic approaches. This analysis focused on methodologies as reported in the primary studies included in the reviews and methodological recommendations made by the review authors.

RESULTS:
The search returned 6,426 hits and the selection work is ongoing. Results will be summarized in April and analysis will follow. We present preliminary results on the number of papers that were HTA reviews, their challenges described and recommendations.

CONCLUSIONS:
The outcomes of this study will include methodological recommendations that will contribute to guide the development of approaches for assessments of complex and dynamic e-health interventions in changing contexts, to the benefit of population health, resource allocation/cost, and health and medical care policy.

PP155 The Impact Of Lawsuits In The Brazilian Public Health System

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ABSTRACT SUMMARY:
Increasing litigation relating to the right to health, and the targets of litigation within the Brazilian Public Health System (SUS) has generated discussion among the judiciary and health care professionals. This study aimed to gather information on the use of evidence by law operators, who appear to use the evidence in a limited way. The National Committee for Health Technology Incorporation (CONITEC) has established actions in conjunction with law operators with the intention that the decisions are based on scientific evidence.

INTRODUCTION:
The increase of litigation in Brazil on the right to health, and the Brazilian Public Health System (SUS) targets of litigation, are phenomena that generate discussions both in the judiciary, and among researchers and managers of health. The lawsuits are based on the integrality that includes the right to any health technology. Our aim was to gather information on the use of scientific evidence by judges and other law professionals to support their decisions in lawsuits involving health care in Brazil.
**METHODS:**
A narrative review by literature search using key terms of legalization in specific databases was conducted.

**RESULTS:**
Twenty-five studies showed litigation matters relating to health care which were focused on legal claims about drugs. In general, law operators used the scientific evidences in a limited way when making decisions, by considering the medical report and medication label indications and disregarding therapeutic alternatives contemplated in the SUS list. The access to health technologies, by litigation, reveals that the gap between scientific knowledge and legal practice are similar to those found between science and decision-making in the formulation and implementation of health policies. The Health Technology Assessment studies have high potential for use by the judiciary as a reference source to support technical and scientific decisions in lawsuits on health care.

**CONCLUSIONS:**
For the judiciary to ensure not only access to health technologies, but also the efficacy and safety of technologies to system users, their decisions must be substantiated by scientific evidence. The National Committee for Health Technology Incorporation (CONITEC) in SUS has established actions in conjunction with law operators and society, such as a communication using e-mail, aiding the decision for the injunction and elaboration of technical reports and a policy brief, with the intention that the decisions are taken with the greatest possible knowledge about technologies provided by SUS, and based on scientific evidence.

**PP156 New Information And Communication Technologies And Hospital’s Design**

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**ABSTRACT SUMMARY:**
This work intends to evaluate the trends of impact of the new information and communication technologies (ICT) on hospitals’ structure. The new ICT will have an impact on the planning and building of the future healthcare facilities (HCF). The designs of today’s buildings should consider this trend so that the future reality is adequate and the regulatory requirements about HCF should be able to consider it.

**INTRODUCTION:**
The hospital’s design today must be prepared for changes resulting from the incorporation of new information and communication technologies (ICT) (1). These will affect non-finalistic (warehouse, archive), diagnostic support (laboratory and image) and finalistic activities (emergency, surgical center, clinics) (2). The Health Technology Assessment (HTA) is fundamental in the dimension of the impact of each technology on the structure of healthcare facilities (HCF). In this way, this work intends to evaluate the trends of impact of the new ICT on hospitals’ structure.

**METHODS:**
The main technologies under discussion in Management of HCF in Brazilian Health Regulatory Agency were raised. From this survey, an impact matrix was built with hospital environmental design and the trends of adequacy of its space.
RESULTS:
ICT that tend to decrease the physical space are: electronic health record for the archive, use of digital imaging for radiology, Radio-Frequency Identification (RFID) for the warehouse, point of care and automated laboratory equipment for clinical laboratories.

ICT that tend to increase physical space are: Telemedicine for the surgical center, Internet of Things - IoT for Intensive Care Units, beds for emergency and hospitalization.

The technologies that present an undefined tendency in relation to physical space are: automatic dispensers of drugs for nursing posts.

The use of database servers and the need for network points are still undefined due to the use of Wi-Fi technology and cloud storage. However, it’s possible to increase use of electricity and the internet.

CONCLUSIONS:
It is concluded that the new ICT will have an impact on the planning and building of the future HCF (3). The designs of today’s buildings should consider this trend so that the future reality is adequate and the regulatory requirements about HCF should be able to consider it.

REFERENCES:


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PP157 The Value-Based Model: Which Lessons From Multiple Myeloma

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ABSTRACT SUMMARY:
The value-based model has been pushing healthcare delivery organizations to a new goal: improve the value delivered to patients. The paper analyzes the case of multiple myeloma with the goal to understand which are the drivers and conditions to implement the value-based model. The analysis provides ways to integrate the clinical decision-making process with the organizational design.

INTRODUCTION:
The value-based model, which is increasingly influencing healthcare reforms all over the world, has been pushing healthcare delivery organizations to a new goal: improve the value delivered to patients. Value in healthcare is interpreted as “patient outcome achieved per dollar expended.” In this context, it is important for hospitals to understand which are the drivers and organizational conditions to actually create value.

METHODS:
The present paper analyzes the case of the multiple myeloma (MM) with the goal to understand which are the drivers and critical conditions to implement the value-based model. After a systematic literature review, we conducted a comparison of the organizational models in the management of MM in three different hospitals. In each hospital, we carried out ten semi-structured interviews to all the different actors (physicians, nurses, and pharmacists) involved in the entire healthcare chain.

RESULTS:
The analysis of the specific case of MM disease provides useful insights to understand how to implement the value-based framework in the design and management of healthcare delivery processes. First of all, the design of the process must start from the clinical decision-making process that should be based on the following key points:

1. adoption of a clinical pathway;
2. multidisciplinary approach;
3. continuity of care; and
4. network.

Secondly, the clinical decision-making process should be supported by coherent choices in the execution of the care process that should be based on the following principles:

1. timelines of diagnostics;
2. integration;
3. optimization of drugs administration activities;
4. active involvement of nurses; and
5. appropriateness of setting (inpatient vs. outpatient vs. day hospital).

CONCLUSIONS:
The analysis provides interesting and innovative ways to integrate the clinical decision-making process with coherent logistical and organizational choices capable to take into account costs and clinical efficacy, as well as two other important dimensions: (i) patient's satisfaction, and (ii) organizational efficiency.

PP158 Monitoring The French National Authority for Health (HAS) Initiative On Patient Contribution To Rapid Health Technology Assessment

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ABSTRACT SUMMARY:
The French National Authority for Health (HAS) introduced a new measure to include the patient perspective in rapid Health Technology Assessment on drugs and devices, which consists of written submissions from patient organizations. In order to prospectively follow the first 6 months, we defined a series of questions and indicators to inform the three categories of the Donabedian model: structure, process, outcomes.

INTRODUCTION:
In November 2016, the French National Authority for Health (HAS) introduced a new procedure to include the patient perspective in rapid Health Technology Assessment (HTA) on drugs and devices, which consists of written submissions from patient organizations (POs). In order to gain insight on implementation, adoption, and continuous improvement needs, the HAS launched a six-month examination of the entire process (December–May).

METHODS:
Our monitoring protocol consists of a series of questions and indicators that inform the three
categories of the Donabedian model:

- structure, which relates to the technical and human resources used;
- process, relating to the quantitative and qualitative aspects of the patient submission process; and
- outcomes, relating to the democratic dimension and scientific nature of patient engagement in HTA.

RESULTS:

Fifteen questions were defined as follows: structure (three), process (seven), and outcomes (five). Examples of questions are: To what extent do POs participate in this new activity? Are specific aspects of patient submissions explicitly considered in the HTA appraisal committee deliberations? Have POs gained a greater understanding of the decision-making process? Indicators were also developed for each question. An example of an indicator is number of patient submissions over number of HTAs open to patient contribution. Different sources of information were defined to inform the indicators: patient written submissions, short questionnaires completed by POs following each assessment, committee deliberations, and feedback discussions with members of the concerned HAS appraisal committees and departments.

CONCLUSIONS:

The 6-month analysis will serve as a basis to discuss, with POs and other stakeholders, the early phases of the patient contribution to rapid HTA initiative and how we may further build on our efforts (training sessions, tools). Results may also shed light on a need for additional follow-up, questions, and indicators to stop, maintain, or modify.

PP159 Children With Rare Chromosome Disorders: Families’ Experiences

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ABSTRACT SUMMARY:

Strategies for rare diseases may exclude families of children with rare chromosome disorders (RCDs). Families’ experiences of RCD diagnosis and counselling have been analysed over a ten year period (2003 – 2013) in the United Kingdom. Responses from 1,158 families have been compared in terms of seven stages of the clinical genetics service pathway; findings can be integrated into national strategy.

INTRODUCTION:

The United Kingdom (UK) 2014 Strategy for Rare Diseases (SRD) lists over fifty commitments to be achieved by 2020 (1); a strong emphasis is placed on empowering those affected by these diseases in order to improve diagnosis, intervention, and coordination of care in clinical genetics services. An important group to consider are families of children with a rare chromosome disorder (RCD). In general, patient-reported outcomes for genetics services are still in their infancy (2). To address this gap, two large-scale surveys measured the changing experiences of UK families with a child with a RCD over the ten years leading up to the launch of the national SRD.
METHODS:
Two national surveys were undertaken ten years apart (2003 and 2013) by Unique, an established Rare Chromosome Disorder Support Group (3). Matching questionnaires investigated experiences for seven stages of the clinical genetics service pathway: pre-testing process; testing and communication of test result; referral to genetics expert; conduct of genetics consultation; RCD information provided; follow-up genetics counselling; and sign-posting to peer support. A final question asked respondents to rate the quality of the overall service. Comparison of responses at the two time-points is used to reveal trends and changes over time, and identify areas for improvement.

RESULTS:
Responses from 583 UK families (2003) were compared to responses from 575 families in 2013. Mean age of respondents is similar (42.3 years and 43.0 years in 2013); while mothers’ responses reduced from 92.3 percent to 85.9 percent. Families with only one child with a RCD rose slightly from 86.1 percent to 92.3 percent. However, analysis shows that families’ experiences of the seven stages of the patient journey have not improved significantly over time; and overall service quality is not rated particularly high. Key areas for improvement are identified.

CONCLUSIONS:
The experiences of families with a child with a rare chromosome disorder are important to consider in any strategy to improve service provision for rare diseases, especially long-term provision (1). The findings of this study should hopefully enable the experiences of families of children with RCDs to be integrated more effectively into national strategies and policies for rare diseases.

REFERENCES:

PP160 The Pilot Implementation And Future Challenges Of Japan-Specific Health Technology Assessment

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ABSTRACT SUMMARY:
The new Health Technology Assessment (HTA) policy for value-based pricing implemented last April as a two-year pilot was reviewed on new rules and the first-year achievement. Consequently, the nivolumab case was problematic, and four questions in decision processes were identified with potential solutions. Those were left for challenges in the future, especially to clarify the vision and strategy to attain the goal.

INTRODUCTION:
Japan has developed ad hoc Health Technology Assessment (HTA) systems for more than fifty years, especially focused on cost-based pricing which, to some extent by political judgement, can reflect the clinical value of medical technologies. In April 2016, however, the Japanese Ministry of Health, Labor and Welfare introduced a new HTA policy for value-based re-pricing and set as a two-year pilot, addressing the public concerns for high-cost medical technologies.
**METHODS:**
The new HTA policy was reviewed on new rules and the first-year achievement in order to clarify questionable points regarding the consistency of public policy and scientific methods. In addition, a potential solution to overcome each question was sought and proposed in theory.

**RESULTS:**
Seven drugs and six medical devices which already exist in the market were selected as target technology for the new value-based re-pricing in 2018. The re-pricing case, regardless the new HTA rule, for nivolumab to extend the indication to advanced non–small-cell lung cancer was clearly inconsistent since nivolumab was listed as one of the seven drugs as targets. Also, careful examination of the new rules for re-pricing identified four points questionable, which included (i) comparability by the other outcome measures except quality-adjusted life-year (QALY), (ii) cost-effectiveness judgement without a threshold, (iii) cost-effectiveness judgement considering social and ethical factors, (iv) mapping a dichotomous conclusion of cost-effectiveness into numerical pricing. Potential solutions were suggested with the efficiency frontier method, multiple-threshold decisions, multi-criteria decision analysis (MCDA), and a tangent incremental cost-effectiveness ratio (ICER) approach, respectively for each question.

**CONCLUSIONS:**
The nivolumab case was problematic, and four questions in decision processes were identified with potential solutions. Those were left for challenges in the future, especially to clarify the vision and strategy to attain the goal.

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**PP161 Prevalence And Characteristics Of Drug-Induced Parkinsonism (DIP)**

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**ABSTRACT SUMMARY:**
Drug Induced Parkinsonism (DIP) is a clinically important disease because it can be fully cured and prevented by just stop taking parkinsonism-inducing drugs. We investigated the prevalence of drug-induced parkinsonism and secular trends in 2009–2014 in South Korea using Korean National Health Insurance Claims Data (KNHICD). Also, we explored the type of offending drugs. This study would be helpful for preventing DIP.

**INTRODUCTION:**
Drug Induced Parkinsonism (DIP) is very important not only in clinical aspects but also in healthcare policies because DIP is reversible by stopping the offending drug. However, there is not enough evidence on the prevalence and characteristics of DIP in South Korea. This study aimed to figure out the prevalence and the secular trends of DIP in 2009–2014. We also investigated prescribing patterns of offending drugs.

**METHODS:**
To measure the prevalence of DIP, we selected patients who were over 40 years of age from 2009 to 2014 using KNHICD. Trend of prevalence was analyzed by Cochran-Armitage test for five years. Also, age-standardized and gender-standardized prevalence were calculated by using data of the population distribution in South Korea in 2014.
RESULTS:
From 2009 to 2014, the number of DIP patients decreased by 0.95 times. The prevalence rate of female patients was higher than that of male patients in DIP every year. As for gender, the growth rate of prevalence rate of DIP of men was 1.10 times higher than that of women (0.99 times). The average annual growth rate of DIP sharply increased in their 40s while the rate decreased in their 60s and 70s. The offending drugs DIP patients had taken were mostly Levosulpiride (26.3 percent) and Itopride (17.7 percent).

CONCLUSIONS:
This is the first study of prevalence of DIP using Nationwide representative data. The prevalence of DIP had not been increasing. However, 43.7 percent of DIP patients were still taking Parkinsonism-inducing drugs. To reduce the prescription of Parkinsonism-inducing drugs, education and a systematic approach is needed.

PP162 Hydroxyurea Adherence Among Patients With Sickle Cell Disease

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ABSTRACT SUMMARY:
To assess adherence to hydroxyurea in patients with Sickle Cell Disease (SCD), the association between pharmacist’s evaluation of adherence based on medicine counting and the hematologic profile was examined. Few studies in the world analyze the adherence in this population and therefore it is very important to study different methods to evaluate and improve treatment adherence in SCD.

INTRODUCTION:
The Sickle Cell Disease (SCD) Reference Center (RC) at Hospital de Clinicas de Porto Alegre is one of two RC in the state of Rio Grande do Sul – Brazil, but it is the only one where hydroxyurea (HU) is dispensed at the same place and time of the medical consultation. HU is used in SCD patients to increase quality of life by promoting fetal hemoglobin (HbF) growth. During the pharmaceutical interview, adherence to HU is analyzed based on the amount of medicine dispensed on the previous consultation and the amount the patient still has when he/she returns to the ambulatory. The purpose of this investigation was to assess the treatment adherence through laboratory tests and the pharmacist’s adherence evaluation.

METHODS:
A sample of seventy-seven adults and eighteen children (<12 years old) using HU was selected for this research. The data collected from the patients’ electronic medical record were: age; HU start date; hemoglobin electrophoresis and blood count pre and post HU use; and adherence evaluation. The data was analyzed with the software SPSS – version 22.

RESULTS:
All the parameters – HbF, S hemoglobin, hemoglobin and mean corpuscular volume – behaved as clinically expected with HU use in both groups. The mean of HbF in the adult non-adherent-group was 12.9 percent and the adherent-group was 20 percent. In children, the non-adherent-group mean was 18 percent, while the adherent-group mean was 23.9 percent.
CONCLUSIONS:
The research shows that thirty-eight adults (49.35 percent) and twelve children (66.66 percent) were classified as adherent and these both groups presented the highest levels of HbF. It is essential that methods which assess adherence to HU in patients with SCD are determined in order to eliminate barriers to medicine’s use and improve treatment adherence.

PP163 Long Term Outcomes Of Endoscopic Submucosal Dissection (ESD) For Early Gastric Cancer In Korea

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ABSTRACT SUMMARY:
The purpose of this study was to evaluate the clinical efficacy and safety of Endoscopic Submucosal Dissection (ESD) For Early Gastric Cancer based on 5-year survival and recurrence rate.

INTRODUCTION:
Traditionally, gastrectomy has been a standard treatment for early gastric cancer (EGC), but it has disadvantages such as high mortality and morbidity, severe weight loss or difficulty in food intake after surgery. Gastric endoscopic submucosal dissection (ESD) has been established as one of the reduced treatment options for selected cases of EGC. The purpose of this study was to evaluate the clinical efficacy and safety of ESD for EGC based on 5-year survival and recurrence rate.

METHODS:
For this study, a prospective cohort was established at 12 medical institutions in South Korea. Patients who underwent ESD for EGC were enrolled between 2010 and 2011 and followed up to 5 years from the date of the final registration. An independent central pathology review committee performed pathological evaluations of ESD to reduce interobserver variations. The primary outcome was the 5-year disease-free survival rate (DSFS) and the secondary outcome was the 5-year overall survival rate (OS) and recurrence rate. A retrospective control group was set up to compare with gastrectomy based on the 5-year OS.

RESULTS:
Out of 712 patients registered, 697 patients were analyzed in this study. The 5-year DSFS rate was 90.6 percent and the 5-year OS rate was 96.6 percent. Compared with the 5-year OS rate of the gastrectomy as a retrospective control group, the non-inferiority of the ESD procedure was confirmed. The 5-year recurrence rate was 7.46 percent. Severe adverse events (SAEs) were observed in forty-eight cases and most of the SAEs were not related to ESD procedure.

CONCLUSIONS:
Our results suggest that ESD is not inferior to gastrectomy in long-term survival, and can be an evidence for expanding the insurance benefits that are currently limited to the absolute indications.

PP164 Sugar-sweetened Beverages Consumption And Price Sensitivity Among Brazilians

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ABSTRACT SUMMARY:
The prevalence of overweight and obesity has reached alarming rates worldwide in the past 30 years. The aim of this essay is to estimate the price elasticity for soda and fruit drink in Brazil and the price effects on weight outcomes and obesity prevalence. The results also confirm that groups with higher consumption are more sensitive to higher prices.

INTRODUCTION:
The prevalence of overweight and obesity has reached alarming rates worldwide in the past 30 years. In Brazil, specially, existing data shows that 1 in 6 Brazilian adults are obese and this number is projected to reach 33 percent by 2025. Concomitantly to rising obesity, Brazilian citizens have changed their patterns food consumption patterns, substantially raising the consumption of sugar-sweetened beverages (SSB). In this context, the challenge of this essay is to estimate the price elasticity for soda and fruit drink in Brazil and the price effects on weight outcomes and obesity prevalence.

METHODS:
The elasticity was measured through a two-part model (TPM) estimated for all sample and different subgroups. The empirical model explains the quantities of SSB demanded as function of its prices and other variables.

RESULTS:
Overall, the results display a smaller prevalence and lower consumption with higher prices. The TPM model predicts a reduction of 348.3g in weekly soda consumption and 4.5g of fruit drink to each one Real increased price. For all sample estimates, price elasticity is -0.61 for soda and -1.32 for fruit drinks, suggesting that a 20 percent increase in price was associated with a decline of soda and fruit drink in weekly consumption by 12.2 percent and 26.4 percent, respectively. This evidence shows a higher sensitivity to price changes for juice drinks than for soda, in spite of the higher consumption of soda.

CONCLUSIONS:
Our main findings suggest that tax policy might be an effective tool to reduce the soda and juice drink consumption and body weight. We also identified that subgroups who consume higher amounts of SSB are relatively more price sensitive and in these cases pricing policies have an expressive potential in reducing SSB consumption and body weight.

PP165 A Strategy To Face Judicialization Of The Right Of Health

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ABSTRACT SUMMARY:
The purpose of this study is to assess the experience of Uruguay in developing a new strategy to face the judicialization of the access to high cost drugs. The methodology used was the comparison of the number of requests for high cost drugs during 2014-2015 and in 2016. A decrease in the number of writs of protection occurred in 2016.

INTRODUCTION:
Different strategies to face the judicialization of the right of health are being implemented in Latin America using Health Technology Assessment (HTA) as a tool. The purpose of this study is to assess the experience of
Uruguay to develop a new strategy to face the process of judicialization of the access to high cost drugs with the support of HTA. A Commission was set up to analyze case by case, the request of access to high cost drugs sent by citizens to the Ministry of Health. The objective of this strategy is to decrease the number of cases of writ of protection, which have been increasing since 2010. The Commission is integrated by a representative of HTA Agency, members of the Ministry of Health and a consultant clinician.

METHODS:
Methodology used for the assessment of the implementation of this strategy was based in the comparison of the number of requests to high cost drugs by writ of protection during the period 2014-2015 with data of 2016 when the Commission started working. The process included, the review of internal documents and databases from the Ministry of Health.

RESULTS:
During 2014 and 2015 the number of writ of protections were 98 and 132 respectively. In 2016, since this strategy was fully implemented, 252 citizens requested high cost drugs but only 27 ended in writ of protection (primary data).

CONCLUSIONS:
Even though the strategy implemented, reduced writ of protection, it was not effective in reducing the growing number of requests of high cost drugs that has continued increasing during 2016. It is essential addressing the problem in a broad debate and promoting understanding between different stakeholders.

PP166 From An Institutional Strategic Plan To A Knowledge Transfer Tool For Health Technology Assessment: Case Of Drug-eluting Stents

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ABSTRACT SUMMARY:
We used the new strategic plan developed by our organization to better communicate the results of our Health Technology Assessment (HTA) unit. We illustrate this by the case study of a systematic literature review on drug-eluting stent (DES) versus bare metal stents (BMS) for coronary disease.

INTRODUCTION:
Knowledge transfer (KT) of Health Technology Assessment (HTA) results presents numerous challenges, one being the lack of time of busy decision makers. Our hospital-based HTA unit is now part of a large network comprising 100 installations. To bridge the gap between complex HTAs and even more limited time by executive officers and managers, we needed to develop a new approach to deliver effectively key HTA messages. We initiated a new strategy with a report on drug-eluting stent (DES). DES may have the potential to eradicate restenosis and the necessity to perform multiple revascularization procedures subsequent to percutaneous coronary intervention (PCI). However, the technology is expensive and some concerns about safety remain. The second
generation of DES stents show promising results in terms of efficacy and safety.

**METHODS:**
We conducted a systematic review of meta-analyses comparing bare-metal stents (BMS) with second generation DES. Data extracted were used to perform a cost-benefit analysis for our organization. Main findings were illustrated in relation to the strategic plan of our institution.

**RESULTS:**
As compared to BMS, the second generation of DES is very effective and potentially leads to huge savings. Safety is improved as regard to myocardial infarction, but not to mortality. For our institution, the use of second-generation DES has the potential to reduce waiting lists for a PCI. In an effort to improve clarity of the results and increase knowledge transfer among managers, we developed a new communication strategy involving the six axes considered as strategic by our Chief Executive Officer, namely: university mission, judicious use of resources, accessibility and quality of care and services, to build for and with the staff, and to act for and with the patient and his family. This led to a smart visual scheme directly showing the results in terms of what is important for our hospital. This initiative was very appreciated by managers.

**CONCLUSIONS:**
Using our institutional strategic plan to communicate our results allowed a greater visibility of HTA activities and was greatly appreciated by managers. This will help in disseminating our results locally and in promoting the utility of HTA.

**PP167 Health Technology Assessment Nucleus In A Reference Hospital In Brazil**

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**ABSTRACT SUMMARY:**
In Brazil, Health Technology Assessment Nucleus (NATS) nested in reference hospitals were created in 2012. To evaluate the results of NATS implementation in our institution, we reviewed its decisions and technical production. Of the seventy-three health technologies incorporation requests thirty were accepted and of all incorporated technologies, 43 percent were innovations, this proportion was even lower between the medicines incorporated.

**INTRODUCTION:**
In Brazil, the Science and Technology Department of Ministry of Health (DECIT/MS) is leading efforts in Health Technology Assessment (HTA) aiming to apply the best available evidence for incorporation of health technologies in the public health system. In 2011 the Ministry of Health funded the implementation of twenty-four Health Technology Assessment Nucleus (NATS) nested in reference hospitals nationwide distributed. Hospital de Clinicas de Porto Alegre (HCPA) is a university-affiliated public hospital and was one of the chosen hospitals. Different committees carried on the HTA activities until 2012 when NATS was created. The results of NATS implementation are evaluated.

**METHODS:**
We reviewed all requests for inclusion of health technologies sent to NATS and to Drugs and...
Therapeutics Committee (COMEDI) since October, 2012. The database evaluated included the online requests of health technologies filled during the time and the register of both committee meetings. The results of the requests for health technologies inclusion were categorized as accepted or rejected and also classified as innovation or not (United Kingdom-NHS Innovation Center criteria for devices and ‘Morgan et al (1)’ criteria for medicines).

RESULTS:
During the period of time (Oct/2012-Dec/2016) there were in total seventy-three requests for inclusion of new health technologies (equipment, vaccines, health products and medicines) in the HCPA. Thirty-three of these requests concern the inclusion of equipment, vaccines or ‘health products’ and forty were related to medicines. Of the seventy-three requests thirty (thirteen equipment/vaccines/health products and seventeen medicines) were accepted, 41 percent of all requests. Also, 41 percent of all incorporation requests regarded innovative products. Of all incorporated technologies, 43 percent were considered innovations (<40 percent of the medicines included were innovative).

CONCLUSIONS:
Of all requests for health technology inclusion, less than half were accepted after evaluation. Considering the aspect innovation only 43 percent of incorporated health technologies represented innovative products, this proportion was even lower between the medicines. Possible causes are the high cost of these products and what does the term innovation could represent, notable when discussing innovate drugs—the variability of the ‘level’ of innovation is an important variable to consider.

REFERENCES:

PP168 Combination Therapy Versus Intensification Of Statin Monotherapy

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ABSTRACT SUMMARY:
The burden of coronary heart disease (CHD) is a real challenge for Tunisia causing 27.14 percent of total mortality. INASanté has launched a Health Technology Assessment (HTA) study to compare the intensification of statin monotherapy versus a combination therapy for CHD prevention. The aim of this updated and contextualized HTA report is to reduce prescription variability and not justified therapies.

INTRODUCTION:
Coronary heart disease (CHD) is the most common cause of mortality globally. The burden of CHD is a challenge for Tunisia causing 27.14 percent of total mortality (1).

Statins are the leading molecules used to prevent CHD in Tunisia. The amount paid by the national insurance fund for statins in 2015 represents 9 percent of total drug expenditures (2).

INASanté has launched a Health Technology Assessment (HTA) study to compare the intensification of statin monotherapy versus a
combination therapy for the CHD prevention in patients with moderate to high cardiovascular risk. The aim of this contextualized HTA report is to diminish prescription variability and not justified therapies.

METHODS:
Research was carried out in the following databases: CRD, NICE search evidence, Cochrane, Belgian Health Care Knowledge Centre (KCE), Canadian Agency for Drugs and Technologies in Health (CADTH), Adelaide Health Technology Assessment (AHTA), Institut National d’excellence En Santé et en Services Sociaux (INESS), Euroscan International Network, National Institute for Health Research (NIHR), Agency for Healthcare Research and Quality (AHRQ) and Haute Autorité de Santé (HAS) from 2006 to 2017. Title, abstract and full text screening were performed by two independent reviewers relying on prespecified eligibility criteria. Critical appraisal of literature was conducted using INAHTA and PRISMA checklists, FLC 2.0 and The European Network for HTA (EUnetHTA) adaptation toolkit. One review from AHRQ was retained.

An adaptation process has been launched. Data on lipid lowering agents intake from key institutions have been gathered and a qualitative study has been started through interviews with thirty-three cardiologists and general practitioners from public, private sector and scientific societies. Interviews have been analysed using NVivo. After results discussion with the working group, the report will be synthesized and validated.

RESULTS:
According to the AHRQ report, all evidence for clinical outcomes were graded insufficient when comparing the therapies. Results on lowering low density lipoprotein (LDL-C) depend on the combination agent Ezetimibe has shown remarkable results (3).

The Tunisian context shows that there is no standardized method to assess the cardiovascular risk according to the preliminary results. The only combination therapy reported is with fibrates, mainly in case of associated hypertriglyceridemia. Ezetimibe has not yet obtained the marketing authorization.

CONCLUSIONS:
There are significant differences between contexts and among practitioners prescriptions. This can be related to the lack of common guidelines and inequitable access to drugs and healthcare resources in general.

REFERENCES:

PP169 Risks And Barriers For Adopting Internet Of People In Health Care

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ABSTRACT SUMMARY:
Connectivity and digitalization have the potential
to disrupt healthcare by changing interactions between patients, providers, and other related care delivery processes. The new grid of interactions forms the “Internet of People” where personal healthcare data and knowledge are shared among stakeholders. This study aimed to identify improvement potential and barriers to adoption of new digital interactions and processes in health care.

INTRODUCTION:
Growing connectivity and digitalization can disrupt healthcare by changing interactions between patients, healthcare providers and processes, forming the new grid of interactions called “Internet of People” where healthcare data and knowledge are shared to support personalized, participative, predictive and preventive care. However, some barriers can limit the potential of internet of people to improve health care. Our study investigates the adoption barriers of the internet of people in health care using a system perspective.

METHODS:
Based on the literature, we developed a questionnaire addressing six risk categories related to digitalization changes in healthcare (i.e. human, social, political, regulatory, ethical-legal, technological, financial risks) (1-3). The questionnaire was distributed online to stakeholders within healthcare digitalization recruited via authors’ networks, social media and snowballing effect.

RESULTS:
Of 177 participants living in 24 countries, patient or patient relative (34 percent) and a healthcare professional (18 percent) were the 2 largest groups. The risks related to ethical, legal, political and regulatory were rated by most participants (49 percent) as the biggest risk. The top five risks perceived by survey participants as the biggest risks within the risks related to ethical, legal, political and regulatory including “Ownership and access of which data” (60 percent), “Inequality in accessing technology” (53 percent), “Different rules and regulations in different geographical areas can inhibit globalization of digital data flows” (39 percent), “Different IT laws and regulations in different countries” (25 percent), and “Unclear governance structures to promote public trust in the use of digital data” (24 percent).

CONCLUSIONS:
To release the full potential of future healthcare delivery schemes, data governance models, trust creation and collaboration among stakeholders are needed to ensure trustworthy use of personalized information of all relevant stakeholders.

REFERENCES:

PP170 Health Impact Assessment Of Teleradiology Programs In Disadvantaged Areas

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ABSTRACT SUMMARY:
The aim of this work was to implement an assessment, based on Health Impact Analysis (HIA) criteria, within the Home Radiology Program of Piedmont Region - the health intervention of R@dhome - in the Cortemilia-Langhe Region. The intervention consisted of minor services being provided in rural areas to provide simple radiological services to vulnerable patients, in outpatient settings in their homes.

INTRODUCTION:
Within the Home Radiology service of the Piedmont Region - R@dhome (1) - it was decided to employ a mobile radiological service to allow minor radiological procedures to be conducted in rural areas. Cortemilia (average age of population 51.6 years, population over 65 yrs 33.6 percent) is situated in Piedmont (Langhe region) and it is about 40 kilometres, with bad roads, from the nearest hospital. For this reason it’s important to optimize the potential offered by telemedicine. The purpose of R@dhome is to provide simple radiological services (ambulatory) to vulnerable patients in outpatient settings. The aim of this work was to implement an assessment, based on Health Impact Analysis (HIA) (2,3) criteria, of the health intervention provided by the R@dhome service.

METHODS:
From January 2016 to December 2016 the following were assessed:
- number of patients examined in the local radiological ambulatory service
- inhabitants opinions (using questionnaires)
- General Practitioner, Pharmacist, Family nurse opinions (using semi-structured interviews)
- stakeholder opinions (Mayor, local politicians, using semi-structured interviews)
- number of cars and ambulances used for the transport of patients to the nearest hospital
- number of patients who avoided transportation to the nearest hospital
- pollutants PM10 (particle size 10) related to cars and ambulance traffic.

RESULTS:
Forty percent of people interviewed were more than 60 years old, 76 percent needed x-rays (in 2015), 96.8 percent considered it useful to have a closer x-ray service, only 42 percent had a driver’s licence but preferred not to drive; GP’s said that 50 percent of local patients had trouble reaching the hospital and that 30 percent of local patients need informal or formal care. From January to December 2016 we examined (mainly chest and bone x-rays) in 598 patients using as an alternative to private cars and ambulances the radiological mobile station, and the pollutant emissions were shown to be reduced by 85 percent.

CONCLUSIONS:
This study has provided a comprehensive HIA report which shows that the R@dhome intervention improves patient’s QOL, reduces social costs, reduces the number of patients in the Hospital Radiology Department, reduces rate of hospitalization and pollution.

REFERENCES:
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PP171 Immuno-Oncology: A Patient Perspective

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ABSTRACT SUMMARY:
New immunotherapies have had great successes, but also incredibly debilitating side effects for patients. This discrepancy needs to be a focus of pharmaceutical companies because it will affect the way health technology assessment (HTA) agencies review drugs. This research looks at case studies of patient and caregiver experiences surrounding immuno-oncology clinical trials.

INTRODUCTION:
New immunotherapies have had great successes, but also incredibly debilitating side effects for patients. This discrepancy needs to be a focus of pharmaceutical companies because it will affect the way Health Technology Assessment (HTA) agencies review drugs. Two or three case studies of patient and caregiver experiences surrounding immuno-oncology clinical trials, both past and ongoing, will be used in order to gain a better understanding of how these trials have impacted individuals.

METHODS:
Conduct in-person or telephone interviews with patients and their caregivers to find out more about patient experiences and see how key takeaways can help pharmaceutical companies better prepare submissions for HTA agencies as they launch future immuno-oncology drugs.

RESULTS:
Preliminary results indicated that a patient completed a course of treatment and is very happy with the results. She had metastatic melanoma on her scalp. When she was being prepared for surgery, two new tumors on her scalp were discovered. As a result, she was included in a melanoma clinical trial.

Another patient is still undergoing treatment and is responding, but is experiencing severe side effects that are impacting his life and that of his primary caregiver. He was hospitalized once for sepsis.

CONCLUSIONS:
Patient experiences can wildly vary. It is an area that needs more careful study, using both formal metrics and individual stories. Giving more attention to quality of life creates an opportunity for stronger submissions to HTA agencies and better assessments by those agencies.

PP172 Recruiting Academic Physicians Without Financial Conflict Of Interest

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INTRODUCTION:
To minimize the potential impact of conflicts of interest on health recommendations, several health institutions may be reluctant to recruit academic
physicians due to their potential close relationship with industry. The present study aimed at evaluating the influence of academic physicians (AP) on the "rate of deport" due to financial support in the national commission of the HAS assessing medical devices.

METHODS:
After the renewal of this commission in November 2015, introducing patients representatives and more academic physicians, two periods of 12 months immediately before and after that date have been compared regarding the rate of deport during the sessions. Deport were decided by the legal section of our institution one week before each meeting according to a complete analysis of potential financial conflict of interest related to the medical device assessed. Only members without significant financial conflicts were allowed to participate to the discussion and the vote. The assessment of potential conflict of interest of all members followed the same criteria during the two periods.

RESULTS:
The number of physicians increased in the second period (nineteen versus twenty-three) with a significant higher rate of academic physicians (63 percent versus. 82 percent, p=.001). The mean attendance of physicians was significantly lower during the second period (80 percent versus. 65 percent, p=.03). During the two periods, the number of meetings (n=22) was similar and the number of dossiers assessing new products was comparable (96 versus 104, p=.872). The decision to reimburse the medical devices was similar in the two periods (78 percent versus. 73 percent, p=.681). The number of cases when physicians’ members were deported for conflict of interest was similar during the two periods (30 versus 28, p=.482) with not any increase among academic physicians.

CONCLUSIONS:
This study showed that it is possible to recruit several academic physicians without major financial conflicts of interest providing that their status could alter their assiduity.
VP001 Effect Of Early Life Socioeconomic Status On Trajectories Of Chinese Elders Health

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ABSTRACT SUMMARY:
This study used data from all seven waves (1998-2014) of the Chinese Longitudinal Healthy Longevity Survey and covered 6,483 respondents aged 80 to 105 years in baseline. Group-based trajectory modeling was used to show the different aging procedure of elders, and to explore effects of childhood and adulthood socioeconomic status on oldest-elders physical health in China.

INTRODUCTION:
China, with the largest aging population which is fast increasing, faces great challenges. Increasingly, researchers are looking at the relationship between whole life conditions from birth to death and health status in old age using a life-course approach. Few researchers have paid attention to developing countries like China where early life conditions were worse than those in western countries in the early twentieth century. China has had a complex social and political history in the twentieth century. This study investigates trajectories of aging and the effects of childhood and adulthood Socioeconomic Status (SES) encompassing education, job and family condition, on oldest-elders physical health in China.

METHODS:
The data used in this study was from all seven waves (1998-2014) of the Chinese Longitudinal Healthy Longevity Survey and covered 6,483 respondents aged 80 to 105 years in baseline. Measuring the limitation in activities of daily living represents physical health. Group-based trajectory modeling is used to identify groups of individuals with statistically similar developmental characteristics or trajectories. Multinomial logistic regression is used to compare the differences among trajectory groups.

RESULTS:
Three-group models best fit the data for males and females. Along with increasing age, there was an increase in the limitation in activities of daily living. Some groups changed gradually, while others rose rapidly. Some childhood and adulthood socioeconomic status characteristics influenced trajectory-group membership. For both genders, group one and two had similar childhood socioeconomic status, while higher adulthood socioeconomic status like jobs were associated with less favorable health status. For group three of males suffering the hardest childhood in regard to education, had stable health status instead.

CONCLUSIONS:
Diversity exists among aging procedure. Childhood and adulthood socioeconomic status influence health conditions of the oldest-elders in complex ways. Education is a remarkably positive factor significantly contributing to better health status.

VP002 Are Journal Editors A Barrier To Publication Of Real World Evidence?

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) bodies often rely heavily upon evidence from peer-review publications to inform their recommendations. Given past skepticism of real world evidence (RWE) study designs, journal editors perceptions of and possible biases toward RWE are important to understand as they may impact dissemination and, therefore, uptake of research findings. This study examined views of current journal editors towards RWE.

INTRODUCTION:
Health technology assessment (HTA) bodies often rely heavily upon evidence from peer-review publications to inform their recommendations. Since journal editors attitudes likely influence the types of study designs that are accepted through the peer-review process and on to publication, journal editors serve as gatekeepers to translation of evidence, including real world evidence (RWE), into practice. Given past skepticism of RWE study designs, journal editors perceptions of and possible biases toward RWE are important to understand as they may impact dissemination and, therefore, uptake of research findings. The objective of this study was to examine current views of journal editors regarding the: (i) value of RWE studies and (ii) challenges editors face in managing, reviewing, and publishing RWE manuscripts.

METHODS:
Journal editors representing general medicine (GM), specialty medicine (SM), health policy/services research (HSR) were invited to participate in a telephone interview, a survey, and an in-person, roundtable discussion.

RESULTS:
In total, seventy-nine journals were approached, resulting in: 15 interviews (GM=2; SM=5; HSR=8), 17 survey responses (GM=2; SM=6; HSR=9) and 8 roundtable participants. RWE was viewed favorably by interviewed editors (n=15). Characteristics of high-quality RWE manuscripts included: research question novelty/relevance, rigorous methodology, alignment of data with question, and the extent data-source advantages are optimized. Similar manuscript review processes and challenges were voiced for RWE and other study designs. HSR editors were more likely than SM or GM editors to participate, potentially indicating these researchers are more comfortable or interested in RWE. A possible study limitation was that editors favorable toward RWE may have been more likely to participate.

CONCLUSIONS:
Peer-review journal editors appear to have favorable views regarding RWE studies and can be accelerators to dissemination of RWE findings. However, they do report that studies and processes could be improved. One suggested improvement included a checklist for editors to speed rejections and improve communications with authors.

VP003 Review Of Patient-Powered Research Networks For Relative Effectiveness

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ABSTRACT SUMMARY:
Patient-powered research networks (PPRNs) have the potential to be a source of data for relative or comparative effectiveness research. To better understand the potential, a literature review was conducted to understand their applicability and limitations. Existing PPRNs were identified and characterised.

INTRODUCTION:
Patient-powered research networks (PPRNs) are online platforms run and developed by patients, carers, clinicians, researchers, and patient organisations. PPRNs collect and organise both patient-reported health data as well as clinical data from the patients’ electronic medical records (EMR). Whilst stakeholders have highlighted the potential of PPRNs to provide information to support HTA, there has been no systematic evaluation of their potential utility to inform relative or comparative effectiveness of new medicines. This work, commissioned as part of IMI GetReal (1), aimed to identify and categorise existing PPRNs on their potential for this purpose.

METHODS:
A pragmatic literature review, using Medline, EMBASE and Google Scholar, was used to identify literature relating to the use of PPRNs in comparative effectiveness research (CER). Identified titles and abstracts were screened, and full texts were reviewed for eligibility. CER results were reported for quantitative studies and authors’ perspectives collected from opinion papers. Thematic analysis identified examples of successful use, future opportunities, and potential challenges of PPRNs for CER.

Further desktop research using twenty-three searches in Google identified available PPRNs. PPRNs were classified according to key characteristics and a scoring system developed to demonstrate their usefulness for CER.

RESULTS:
Eighteen publications were identified in the review. Only one study used PPRN data for CER; most were opinion pieces which revealed ongoing debate about the applicability of PPRNs for CER. Themes included potential challenges and potential future use of PPRNs. Thirty-three PPRNs were identified, covering a wide range of diseases. All collected some information considered essential for CER (such as demographics & outcomes) but other information was inconsistently collected (such as dosage and frequency of pharmacological treatment and co-morbidities).

CONCLUSIONS:
While the outlook on using PPRNs for CER is generally positive, they are still approached with caution. Very few existing PPRNs were considered adequate for this purpose and further development would be required, including collecting both patient-reported and EMR data, and more aspects of drug exposure and other covariates.

REFERENCES:
1. The IMI GetReal project: www.imi-getreal.eu.

VP004 Cost Analysis After Minimally Invasive Versus Open Lumbar Surgery

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ABSTRACT SUMMARY:
Minimally invasive spine (MIS) surgeries are increasingly recognized as equivalent to open surgery procedures. To date, no cost analysis
studies comparing the two approaches have been performed in South Korea. In this study, an acute hospital cost analysis comparing MIS with open surgery was conducted using National Health Insurance Claims Big Data with 2,371 patients.

INTRODUCTION:
Minimally invasive spine (MIS) surgeries are increasingly recognized as equivalent to open surgery procedures. To date, no cost analysis studies comparing the two approaches have been performed in South Korea. In this study, an acute hospital cost analysis comparing MIS with open surgery was conducted using National Health Insurance Claims Big Data.

METHODS:
This study analyzed inpatient hospital records & costs from the 2014 National Inpatient Sample Database (NISD), including patients who underwent a posterior lumbar fusion with interbody cage placement by Korea ICD-10 code, and had implant charge codes that allowed determination if MIS pedicle screws were utilized. Exclusion criteria included a re-surgery, deformity, >2 levels, and anterior fusion. Total costs were adjusted for covariates (age, sex, race, hospital type, and comorbidities) using an analysis of covariance model.

RESULTS:
A total of 2,371 patients were identified (891 MIS and 1,480 open surgery). Length of stay (LOS) for 1-level MIS surgery averaged 2.55 days versus 3.5 days for open surgery (P<.003). Total inflation adjusted acute hospitalization cost averaged $5,736 for 1-level MIS procedures versus $7,204 for open surgery, a significant difference (P=.046). Cost savings were attributable primarily to short hospitalization, operating fee, blood transfusion, and laboratory costs in the MIS group.

CONCLUSIONS:
This data from a large nationwide sample of hospitalizations demonstrates that MIS lumbar interbody fusion results in a statistically significant reduction in hospital LOS and a reduction in total hospital costs. The majority of cost savings from MIS surgery were due to more rapid mobilization and discharge, as well as a reduction in outliers with extended hospitalizations.

VP005 Comprehensive Evaluation Of An Evolving Transcatheter Technology?

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ABSTRACT SUMMARY:
Our cardiovascular evaluation unit collaborates with multidisciplinary clinical experts to update recommendations for optimal use of transcatheter aortic valve implantation (TAVI). As part of a comprehensive evaluation model, we collect “real world” data on an ongoing basis to examine the evolving portrait of use. Systematic literature review facilitates the interpretation of these results and the formulation of provincial quality standards.

INTRODUCTION:
Our cardiovascular evaluation unit is mandated to evaluate transcatheter aortic valve implantation (TAVI) in the province of Québec. In 2012, it was recommended that only patients at too high risk for surgery receive TAVI. In partnership with our six hospital TAVI programs, we have measured indicators of structure, process and outcomes since
2013. We are collaborating with multidisciplinary clinical experts to update recommendations for optimal use. Herein, we present the evolving portrait of TAVI in Québec and identify priority issues.

METHODS:
Clinical data were collected and analyzed for all TAVI performed from 1 April 2013 to 31 March 2016. Regular site feedback was provided. A systematic review of recent guidelines and randomized trials facilitated the interpretation of “real world” results and formulation of provincial quality standards.

RESULTS:
Provincial TAVI volume increased from 294 in 2013-14 to 340 in 2014-15, and to 360 in 2015-16. Patient age and sex distribution remained relatively constant over time (median age 83 years; 47 percent female). However, the median predicted risk of operative mortality (STS score) decreased in the latest period [6 percent (Interquartile Range, IQR: 4-9) versus 7 percent (IQR: 4-9) versus 4 percent (IQR: 3-7)], suggesting TAVI is increasingly being performed in lower-risk patients. Clinical documentation and processes of care generally improved. Thirty-day mortality decreased (6.1 percent versus 4.1 percent versus 2.8 percent). The literature review identified two central issues: TAVI futility in patients who are too sick and apparent non-inferiority of TAVI compared with surgical valve replacement in medium-risk patients.

CONCLUSIONS:
Our province-wide TAVI evaluation indicates improving processes and outcomes. Patient selection remains the key in our universal healthcare system, with the need to minimize futile and costly therapy and offer TAVI to those most likely to benefit. Continued monitoring of clinical practice and newly-established quality standards, in close collaboration with clinical teams, remains essential to promote optimal use of this evolving technology.

VP006 BRCA1/2-Related Ovarian Cancer Morbidity In Russia

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ABSTRACT SUMMARY:
The results of the analysis for prevalence of ovarian cancers (OC) with consideration to BRCA1/2 genotype in the population of Russian women. Genotyping for BRCA1/2 mutation is advised in all females with OC for clinical and economic reasons independent of their family history.

INTRODUCTION:
To evaluate the prevalence of ovarian cancers (OC) with consideration to BRCA1/2 genotype in the population of Russian women. To create a predictive model of the rate of inherited OC with respect to the stage of the disease. To assess the demand for screening programs for potential female patients (I-II degree relatives of patients with OC), who should be in the risk group for OC and undergo genetic testing.

METHODS:
In the first stage of the study we performed the data mining analyses on the OC prevalence and morbidity in Russia, including patients with mutations in BRCA1/2 genes, and analysis of clinical recommendations on the course and outcomes of OC in different clinical groups of patients. In the next stage, we developed a clinical statistical model of OC and distinguished the group of patients subject to screening and treatment programs.

RESULTS:
In 2016, there are probably 362-486 persons with newly diagnosed patients with early stages
of OC and mutation in BRCA1/2, and 1,197-1,437 persons with advanced OC. The prevalence of OC with BRCA1/2 mutation in this period is 10,176-12,095 persons. According to expert estimations, 1,683-1,762 relatives of patients are carriers of the mutation in BRCA1/2, and 673-705 will have OC during lifetime (0.4 risk of this subtype of OC). The survival rate in the “genotyped” group is 2.4 times higher than in the group without genotyping of relatives.

**CONCLUSIONS:**

Genotyping for BRCA1/2 mutation should be taken into account in all females with OC for clinical and economic reasons independent of their family history. The detection of relatives with BRCA mutations helps to avoid significant load on public budget in social security, and the load on health care budgets on various levels connected with the optimization of the existing treatment schedules.

**INTRODUCTION:**

A conventional approach to communicating value is to model the budget impact of a medicine and the associated formulations in which it is available to be prescribed. However, such an approach does not demonstrate the actual realization of the proposed impact. This abstract outlines an approach to presenting retrospective data back to healthcare professionals (HCP) that blends assumptions and real-world data. For illustrative purposes, we present the results of an application of the model for subcutaneously delivered trastuzumab in an anonymized trust in Yorkshire and Humber.

**METHODS:**

The authors developed a model that examined one calendar year (from April 2014) of redistributed sales data for both the intravenous and subcutaneous formulations of trastuzumab for every National Health Service (NHS) trust in England. A series of baseline assumptions (1) were used to model the resource impact of different formulations such as chair time, HCP time, pharmacy preparation time, consumables, wastage, and other considerations. Impacts were estimated at the individual attendance level and scaled to the caseload. These baseline assumptions could then be overwritten by the individual trust using local data.

**RESULTS:**

The site delivered approximately 985 doses of subcutaneous trastuzumab over a period of 12 months from April 2014, which represented about 76 percent of the total number of doses delivered. Chair time is estimated to have reduced by 22 minutes per attendance, resulting in a total saving of 361 hours. HCP administration time is estimated to have reduced by 23 minutes per attendance, resulting in a total saving of 378 hours based on changing 985 IV doses to SC therapy.

**CONCLUSIONS:**

Blending real data and assumptions to provide a retrospective assessment of actual benefits realized...
back to HCPs is a powerful tool for demonstrating real-world value at both an individual trust and system level.

REFERENCES:

INTRODUCTION:
Reimbursement decisions are usually based on evidence from randomized controlled trials (RCT) with high internal validity but lower external validity. Real-World Data (RWD) may provide complimentary evidence for relative effectiveness assessments (REA’s) and cost-effectiveness assessments (CEA’s) of treatments. This study explores to which extent RWD is incorporated in REA’s and CEA’s of drugs used to treat metastatic melanoma (MM) by five Health Technology Assessment agencies.

METHODS:
Dossiers for MM drugs published between 1 January 2011 and 31 December 2016 were retrieved for HTA agencies in five countries: the United Kingdom (NICE), Scotland (SMC), France (HAS), Germany (IQWiG) and the Netherlands (ZIN). A standardized data-extraction form was used to extract data on RWD mentioned in the assessment and its impact on appraisal (for example, positive, negative, neutral or unknown) for both REA and CEA.

RESULTS:
In total, forty-nine dossiers were retrieved: NICE=10, SMC=13, IQWiG=16, HAS=8 and ZIN=2. Nine dossiers (18.4 percent included RWD in REA’s for several parameters: to describe effectiveness (n=5) and/or the safety (n=2) of the drug, and/or the prevalence of MM (n=4). CEA’s were included in 25/49 dossiers (IQWiG and HAS did not perform CEA’s). Of the twenty-five CEA’s, twenty (80 percent) included RWD to extrapolate long-term effectiveness (n=19), and/or identify costs associated with treatments (n=7). When RWD was included in REA’s (n=9), its impact on the appraisal was negative (n=4), neutral (n=2), unknown (n=1) or was not discussed in the appraisal (n=2). When RWD was included in CEA’s (n=11), its impact on the appraisal varied between positive (n=2), negative (n=5) and unknown (n=4).
CONCLUSIONS:
Generally, RWD is more often included in CEA's than REA's (80 percent versus 18.4 percent, respectively). When included, RWD was mostly used to describe the effectiveness of the drug (REA) or to predict long-term effectiveness (CEA). The impact of RWD on the appraisal varied greatly within both REA's and CEA's.

METHODS:
A revision of the health assessment uses and information collected by arthroplasty registers was made. The information provided from international networks like NORE, ISAR and ICOR was also considered. Arthroplasty registers collect data of patients undergoing joint replacement surgery (mainly hip and knee) along with implant information. They provide longitudinal information useful to assess implant survival (expressed as revision rate and calculated from the primary surgery to implant revision). They also data from the surgical procedure and, more recently, a number of registries incorporate patient reported outcomes (PROMs) information.

RESULTS:
Arthroplasty registers provide information from multiple perspectives:

(i) Decision-makers and healthcare providers/authorities: the comparison of revision rates by using funnel plots is a useful methodology to benchmark implants and to identify outliers, or models with significantly different revision rate in comparison to their peers. Besides, data available in registers has proven to be useful to define sets of indicators related to safety, effectiveness, efficiency, patient-centered healthcare and perceived health outcomes.

(ii) Surgeons: Some ongoing initiatives, like ODEP, aiming at providing a benchmark rating for implant survivorship, are gaining interest by professionals promoting an evidence-based clinical practice.

(iii) Industry: the large amount of data recorded so far may allow obtaining robust information of prosthesis behavior.

(iv) Patients: there is an increasing number of registers that incorporate PROMs. Moreover, a growing interest to promote patient engagement in arthroplasty decision making has been observed.
CONCLUSIONS:
Long-standing arthroplasty registries have untapped potential. Beyond the assessment of implant survival, they have been consolidated as a useful tool for decision-makers.

METHODS:
In order to assess the role of FD-OCT, an evidence profile of the technology was set up (1). Primary studies were searched in Pubmed (July 2016) using keywords and Mesh descriptors (for both device and condition), risk of bias was assessed with quality checklists according to study design and level of evidence was judged according to GRADE methodology. We included only prospective studies with at least ten patients.

RESULTS:
We retrieved 1,539 records and included 34 primary studies. Only two RCTs assessed FD-OCT efficacy; safety was assessed in twenty-three, diagnostic accuracy in eight, change in management in four and technical performance in twenty-seven studies, respectively. Two 6-month RCTs (340 patients) of moderate quality assessed efficacy of FD-OCT plus angiography versus angiography alone in guiding PCI and investigated surrogate outcomes. At follow-up, percentage of uncovered struts (4.3 percent versus 9.0 percent; p<.01) and post-PCI FFR values (.94±.04 versus .92±.05; p=.005) were significantly better than in only angiography-guided group. Studies were not powered to investigate major cardiac events or mortality. Regarding safety incidence and type of procedural adverse events seem to be comparable to those occurring during angio- or IVUS plus angio-guided PCI; studies on diagnostic accuracy used heterogeneous measures not allowing a summary estimate.

CONCLUSIONS:
Presently available evidence reassures on safety of FD-OCT but it is not considered sufficient to claim on clinical efficacy, as presently published RCTs were not powered to demonstrate improvement of long-term patient-important outcomes. Assessment of diagnostic accuracy would benefit from using validated thresholds for coronaries’ parameters. Three out of ten ongoing RCTs are powered to investigate patient-important outcomes on longer follow-ups (1-5 years) and will probably solve some uncertainties on FD-
OCT’s role in guiding PCI. Our findings are in line with a previous assessment by NICE suggesting the controlled use of FD-OCT due to its limited evidence.

REFERENCES:

VP011 Implantation Of Magnetically Controlled Growing Rod: Systematic Review

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ABSTRACT SUMMARY:
Implantation of magnetically controlled growing rods (MCGR) is developed to reduce repeated lengthening procedures using external remote controller. As a result of a systematic review, MCGR is a safe and effective treatment requiring fewer surgical procedures to correct spinal curve and to increase spinal length without neurological damage or fusion for patients with early onset scoliosis.

INTRODUCTION:
Implantation of magnetically controlled growing rods (MCGR) is a treatment technique for patients with early onset scoliosis to assist spinal curve correction and spinal growth, and also to reduce the number of repeated lengthening procedures using external remote controller. The objective of this review is to pool the results of MCGR in terms of safety and effectiveness.

METHODS:
Two reviewers independently selected articles using eight Korean databases, MEDLINE, EMBASE, and Cochrane Library, and collected data regarding safety outcomes based on surgical procedure frequency and complications, and for effectiveness outcomes based on the spinal curve correction, spine or rod lengthening, pulmonary function, and quality of life.

RESULTS:
Using a strategic search, a total of 208 articles were retrieved and 8 articles which met the inclusion criteria were included in this review. There was one comparative study which compared MCGR with implantation of traditional growing rods (TGR), and seven single arm trials, which were conducted in China, Egypt, Turkey, the United Kingdom, and the United States of America. One comparative study reported fewer complication events (four events, twelve events, respectively) and surgical procedures (0.5 per year, 1.5 per year, respectively) in the MCGR group than the TGR group and similar spinal curve correction (21 degrees and 22 degrees, respectively) and spine lengthening (growth rate for T1-S1: 8.1mm per year and 9.7mm per year, respectively; p=.83) between the two groups. Seven single arm trials reported improved results on spinal curve correction, spinal or rod lengthening, pulmonary function, and quality of life. In addition, none of the articles reported neurological damage or premature fusion.

CONCLUSIONS:
On the basis of current data, MCGR is a safe and effective technique requiring fewer surgical procedures, lessening the burden of open surgery, correcting spinal curve, and increasing spinal length without neurological damage or fusion for patients with early onset scoliosis.
VP012 The Effectiveness and Safety Of 3D Printing Technology In Orthopedics

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ABSTRACT SUMMARY:
By literature retrieval, 25 studies were included in the research according to inclusion and exclusion criteria. The research showed that clinical application of three dimensional-printing technology used in orthopedics reduced operational duration by about 26 minutes, decreased intraoperative blood loss by about 77 ml, increased accuracy rate of screw implanting, and reduced complication rate.

INTRODUCTION:
With the characteristics of digitalization, precision, and individualization, three-dimensional (3D) printing technology has been developed and used in orthopedics. But its effectiveness and safety has been paid attention by the physicians in orthopedics and hospital managers. This paper was to assess the effectiveness and safety of 3D printing technology used in orthopedics, adopting the method of meta-analysis.

METHODS:
Based on inclusion and exclusion criteria, the literature related to the research on 3D printing technology used in orthopedics were searched and retrieved from three databases, including CBM, CNKI, and PubMed. The inclusion criteria include: comparision with clinical application effects of traditional technology, clear data comparision results, for example, and the exclusion criteria contain: incapable of effectively extracting data of clinical application results, not rigorous statistical treatment, repetitive published papers and literature reviews, etc. The effectiveness and safety of 3D printing technology used in orthopedics were assessed and compared with traditional standardized technology adopting fixed and random effects model.

RESULTS:
Twenty-five studies were included in the research. The results showed that the accuracy rate of screw implanting was higher (Weighted Odds Ratio (OR) = 2.1, 95 percent Confidence Interval (CI) was 1.22,3.61) and the operational duration was lower (weighted mean difference (MD) = -25.93 minutes, 95 percent CI was -34.65,-17.21 minutes) in 3D printing group than that in the traditional standardized group. In the meantime, the amount of intraoperative bleeding was less (weighted MD = -77.52 ml, 95 percent CI was -104.81,-50.23 ml) and the complication rate was lower (Weighted OR = 0.60, 95 percent CI was 0.33,1.09) in 3D printing group than that in traditional standardized group.

CONCLUSIONS:
The 3D printing technology used in orthopedics increased the accuracy in screw implanting, and reduced the operational duration, intraoperative bleeding, and complication rate. However, its long-term effectiveness and safety has not been studied yet because it was a newly developed technology.
VP013 Relation Between Magnetic Resonance Imaging Use And Hip Or Knee Replacements In The Organisation For Economic Co-operation And Development

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ABSTRACT SUMMARY:
We conducted a multivariate analysis of Organisation for Economic Co-operation and Development (OECD) data of Magnetic resonance imaging (MRI) use and the relationship to hip or knee replacements. Potential confounders were held constant. We found signs for inappropriate use of MRI in connection with total knee replacements but not in connection with hip replacements. We conclude that inappropriate use of MRI might contribute to unnecessary total knee replacements.

INTRODUCTION:
A high degree of geographic variation in the use of medical interventions is usually considered as a sign for inappropriate use. However, the plain geographic variation has the disadvantage that the variation might also be appropriate due to differences in the regions. Hence, we conducted a more comprehensive analysis on Magnetic Resonance Imaging (MRI) use and the relationship to hip or knee replacements. We evaluated whether there is evidence that guideline recommendations regarding hip replacements and total knee replacements are being followed. Additionally, we tried to assess whether the use of MRI is related to subsequent interventions.

METHODS:
We extracted recommendations of the American College of Radiology (ACR) on the use of MRI relevant to hip replacements and total knee replacements. Subsequently, we created three hypotheses on MRI for hip or total knee replacements on what to expect from the data when these recommendations are being followed.

For each hypothesis, we calculated a multiple linear regression to analyze Organisation for Economic Co-operation and Development (OECD) data. This was necessary to control for other important variables that might have had an influence on the number of interventions despite the MRI use (e.g. healthcare spending, or Computed Tomography (CT) use).

RESULTS:
The initial results on (primary) hip replacement and secondary hip replacement were heavily influenced by outliers. After the exclusion of the outliers (Turkey and Belgium), (primary) hip replacements were related to MRI use but not secondary hip replacements. The results on MRI and (primary) hip replacement suggest that the relationship between MRI and hip replacement in Turkey is lower than in the other OECD nations.

Regarding knee replacements, we detected a relationship between the MRI use and total knee replacement. An increase of 10 MRI examinations per 1,000 population would, according to our model, result in 9.8 additional total knee replacements per 100,000 population.

CONCLUSIONS:
The relationship of MRI and (primary) hip replacement hints to inappropriate use of MRI in Turkey since the data shows a substantial deviation in the relationship compared to the other OECD nations. Apart from this, we found no evidence for inappropriate use of MRI in connection with hip replacements.

However, our results suggest that MRI is inappropriately used in relation to total knee replacements. This might contribute to potentially unnecessary total knee replacements.
VP014 Screening Recommendations For Socioeconomic Disadvantages In Pregnancy

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ABSTRACT SUMMARY:
International studies report that poverty may lead to an increased risk of complications and pathologies during pregnancy. Due to the proven link between poverty and health risks, special attention must be paid to socioeconomically disadvantaged pregnant women. Therefore, research on non-stigmatizing instruments, which can identify vulnerable women, is of great importance.

INTRODUCTION:
In 2015, 18.3 percent of the Austrian population were at risk of poverty and social exclusion - about 211,000 (20 percent) women aged 20-39 years were affected. International studies report that poverty may lead to an increased risk of complications and pathologies during pregnancy. Further, children who grow up in poverty often have poorer long-term health outcomes.

METHODS:
In order to identify recent guidelines (2011-2016) a comprehensive handsearch was conducted in the guideline databases National Guideline Clearinghouse (NGC) and Guidelines International Network (GIN). Moreover, a handsearch for systematic reviews and primary studies was conducted in PubMed.

RESULTS:
Two guidelines, the British National Institute for Health and Clinical Excellence (NICE) Guideline “Pregnancy and Complex Social Factors”, as well as the Australian Health Ministers’ Advisory Council (AHMAC) Guideline “Antenatal Care”, address socioeconomic disadvantages of women during antenatal care. The recommendation of the AHMAC is that pregnancy care should be offered to all pregnant women. In addition, an individual approach will help to pay particular attention to socioeconomic factors and to incorporate them in routine examinations. NICE recommends in its guideline, affected women should be supported in order to ensure adequate prenatal care. NICE also defines criteria which are used to identify pregnant women who are in greater need of support. The only identified study developed and tested a tool for the identification of patients affected by poverty. The authors of this Canadian pilot study concluded that the defined questions helped to identify socioeconomically disadvantaged persons during anamnesis without stigmatizing.

CONCLUSIONS:
Due to the proven link between poverty and health risks, special attention must be paid to socioeconomically disadvantaged pregnant women. Research on non-stigmatizing instruments, which can identify vulnerable women, is of great importance. In addition to social policy measures, it is necessary to ensure that low-threshold services are available for socioeconomic disadvantaged women and their children.

VP015 A Comparison Of Reporting In United Kingdom Health Technology Assessment And Other Systematic Reviews

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ABSTRACT SUMMARY:
United Kingdom Health Technology Assessment (HTA) programme systematic reviews are comparable to Cochrane reviews and better reported than other systematic reviews: An assessment of publications in 2014.

INTRODUCTION:
A recent study claimed that increasing numbers of reviews are being published and many are poorly conducted and reported (1). The aim of the present study was to assess how well reporting standards in systematic reviews published in 2014 in the United Kingdom Health Technology Assessment (UK HTA) monograph series compared with the reporting in Cochrane and other “non-Cochrane” systematic reviews from the same year, as reported by Page et al (1).

METHODS:
All relevant UK HTA programme systematic reviews published in 2014 were identified. After piloting of the form, two reviewers each extracted relevant data on conduct and reporting from these reviews. These data were compared with data for Cochrane and “non-Cochrane” systematic reviews from 2014, as published by Page et al (1). All data were tabulated and summarized.

RESULTS:
There were 30 UK HTA programme systematic reviews and 300 other systematic reviews, including Cochrane reviews (n=45). Fewer UK HTA reviews covered therapeutic and pharmaceutical topics (53 percent and 20 percent respectively) than Cochrane (100 percent and 51 percent). The percentage of HTA reviews with required elements of conduct and reporting was frequently very similar to Cochrane and much higher than all other systematic reviews: for example, availability of protocols (90 percent, 98 percent and 16 percent respectively); the specification of study design criteria (100 percent, 100 percent, 79 percent); the reporting of outcomes (100 percent, 100 percent, 78 percent), quality assessment (100 percent, 100 percent, 70 percent) and other processes; the searching of trial registries for unpublished data (70 percent, 62 percent, 19 percent); reporting of reasons for excluding studies (91 percent, 91 percent and 70 percent) and reporting of authors’ conflicts of interest (100 percent, 100 percent, 87 percent). However, HTA reviews compare less favourably with Cochrane and other reviews in the assessment of publication bias and reporting overall numbers of patients in the review.

CONCLUSIONS:
UK HTA systematic reviews are often produced within a specific policy-making context and cover a greater variety of topics than Cochrane reviews. This has implications for timelines, tools and resources. However, they still tend to present standards of conduct and reporting equivalent to “gold standard” Cochrane reviews and are superior to systematic reviews more generally.

REFERENCES:

VP016 Interventional Management Of Hyperhidrosis: A Systematic Review

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ABSTRACT SUMMARY:
This review assessed the clinical effectiveness of secondary care treatments for hyperhidrosis. Fifty studies of various interventions were included. The evidence was limited overall and few firm conclusions can be drawn. However, moderate quality evidence supports the use of botulinum toxin for axillary hyperhidrosis. A trial comparing botulinum toxin with iontophoresis for palmar hyperhidrosis is warranted.

INTRODUCTION:
Hyperhidrosis is characterized by uncontrollable excessive sweating, which occurs at rest, regardless of temperature, and can significantly affect quality of life. There is substantial variation in the availability of treatments in secondary care and uncertainty regarding optimal patient management. A systematic review was undertaken to assess the clinical effectiveness of treatments prescribed by dermatologists (iontophoresis, anticholinergic medications, botulinum toxin injections) and minor surgical treatments (curettage and newer energy based technologies) for primary hyperhidrosis and identify areas for further research.

METHODS:
Fifteen databases and trial registers were searched to July 2016. Pairwise meta-analyses were conducted for comparisons between botulinum toxin injections and placebo for axillary hyperhidrosis. For other treatments data were synthesised narratively due to limited and heterogeneous data.

RESULTS:
Fifty studies were included in the review; thirty-two randomized controlled trials (RCTs), seventeen non-RCTs and one case series. There was substantial variation between the studies in terms of country of origin (indicating climate and population differences), interventions and methods of outcome assessment. Most studies were small, at high risk of bias and poorly reported. There was moderate quality evidence of a large statistically significant effect of botulinum toxin injections on axillary hyperhidrosis symptoms in the short to medium term (up to 16 weeks), compared with placebo. There was weak but consistent evidence for iontophoresis for palmar hyperhidrosis. Evidence for other interventions was low or very low quality. Combining the evidence and patient advisor input, we established that further research on the clinical and cost-effectiveness of botulinum toxin injections (with anaesthesia) versus iontophoresis for palmar hyperhidrosis would be useful.

CONCLUSIONS:
The evidence for the effectiveness and safety of treatments for primary hyperhidrosis is limited overall and few firm conclusions can be drawn. However, there is moderate quality evidence to support the use of botulinum toxin injections for axillary hyperhidrosis. A trial comparing botulinum toxin injections with iontophoresis for palmar hyperhidrosis is warranted.

VP017 Physicians’ Perception Of The Effects Of Clinical Pathways In China

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ABSTRACT SUMMARY:
Physicians’ perception of effects on clinical pathways (CPs) was surveyed by 11 items in 1,552 physicians from 54 public hospitals in China. The overall mean score of the positive effects of CPs on medical care, patient and staff satisfaction was 3.61 (full score=5). Physicians in public hospitals of China did not highly acknowledge the positive effects of CPs.

INTRODUCTION:
Clinical pathways (CPs) have been implemented widely and there have been 1,010 CPs for specific conditions released by National Health and Family Planning Commission of China since 2009. However, their effects on medical care remained under discussion, and few researches focused on physicians’ perception of these issues. We surveyed physicians in public hospitals of China on their perception of the effects of CPs.

METHODS:
Stratified sampling was used to determine fifty-four surveyed hospitals in three provinces, including thirty-six public secondary general hospitals and eighteen public tertiary general hospitals. Ten percent physicians in each surveyed hospital were randomly selected and surveyed using a questionnaire with eleven items. The items were related to the positive effects of CPs on medical cost, efficiency, length of stay, medical standardization, medical consistency, safety, antibiotic utilization, readmission, medical record quality, patient satisfaction, and staff satisfaction. The response was ranked using Likert score (1-5).

RESULTS:
A total of 1,552 physicians were involved in this study. The overall mean score of the positive effects of CPs on medical care, patient and staff satisfaction was 3.61. The positive effects of CPs on antibiotic utilization (3.78), medical record quality (3.74) and medical standardization (3.73) had the highest scores, while the positive effects of CPs on staff satisfaction (3.38) had the lowest score.

There was no significant difference in the overall physicians’ perception on the positive effects of CPs on medical care among the physicians from the hospitals in different provinces or at different levels, although there were some items were perceived differently.

CONCLUSIONS:
The physicians in public hospitals of China did not highly acknowledge the positive effects of CPs on medical care overall, especially perceived relatively lower staff satisfaction. Better CPs’ implementation strategies are needed to improve the actual and perceived effects of CPs.

VP018 Early Awareness And Alert System In Sweden: History And Current Status

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ABSTRACT SUMMARY:
We describe the evolution and the current state of the Swedish Early Awareness and Alert System (EAA) for new drugs, a national level EAA system successfully implemented in a country with decentralized health care managed by twenty-one regions. Our work is of interest to countries already having EAA systems in place as well as to those seeking to establish EAA activities.
INTRODUCTION:
Over the past decades, early awareness and alert (EAA) activities and systems have gained importance and become a key early Health Technology Assessment (HTA) tool. While a pioneer in HTA, Sweden had no national level EAA activities until recently. We describe the evolution and current status of the Swedish EAA System.

METHODS:
This was a historical analysis based on the knowledge and experience of the authors supplemented by a targeted review of published and grey literature, as well as documents produced by or relating to the Swedish EAA System. Key milestones and a description of the current state of the Swedish EAA System are presented.

RESULTS:
Initiatives to establish a system for the identification and assessment of emerging health technologies in Sweden date back to the 1980s. Since the 1990s, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) supported the development of EuroScan and was one of its founding members. In the mid-2000s, an independent regional initiative, driven by the Stockholm Drug and Therapeutics Committee, resulted in the establishment of a regional horizon scanning unit. By 2009, this work had expanded to a collaboration between the four biggest regions in Sweden. The following year it was further expanded to the national level. Today, the Swedish EAA System carries out identification, filtration and prioritization of new drugs, early assessment of the prioritized drugs, and dissemination of the information. Its outputs are used to select new drugs for inclusion in the Swedish national process for managed introduction and follow-up.

CONCLUSIONS:
The Swedish EAA System started as a regional initiative and rapidly grew to become a national level activity. An important feature of the system today is its complete integration into the national process for managed introduction and follow-up of new drugs. The system will continue to evolve as a response both to the changing landscape of health innovations and to new policy initiatives at the regional, national and international levels.

VP019 Estimation Of Melanoma Direct Costs According To A Clinical Pathway

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ABSTRACT SUMMARY:
This study aims to estimate the direct costs of melanoma by the phase of treatment and stage at diagnosis, expected from a clinical pathway adoption. We define a detailed decision model to describe the patient pathway from the diagnosis to the subsequent activities. Costs varied greatly according to the stage, especially regarding the medical therapy.

INTRODUCTION:
The incidence rate of cutaneous malignant melanoma has steadily increased over the past decades (1,2). Indeed, cutaneous melanoma has become a great concern for healthcare systems, also according to an economic point of view.
This study aims to estimate the direct costs of melanoma by phase of treatment and stage at diagnosis expected from the clinical pathway coming into force.

METHODS:
Starting from the diagnostic therapeutic pathway (PDTA) edited by the ROV (Rete Oncologica Veneta) for malignant cutaneous melanoma (3), we created a highly detailed decision model to describe the patient pathway from the diagnosis to all the subsequent staging, therapeutic, and follow-up activities. For each melanoma stage, the decision analytic model associates to the possible activities defined by the PDTA a measure of their likelihood and a cost. From this model, it is possible to estimate the expected cost of each diagnostic or treatment option under evaluation as the sum of the costs weighted by their probabilities. The clinical probabilities were estimated from literature and from a clinical database of 1,440 patients followed by the Regional Oncologic Institute (IOV) during the period 2011–2014. Most of the process probabilities were drawn from PDTA definitions or other clinical guidelines. However, in some cases, it was necessary to consult an expert panel to define the most credible estimates, through a Delphi survey.

RESULTS:
The mean per-patient cost of cutaneous melanoma ranges from about EUR148.6 for a stage 0 to more than EUR60,000 for a stage IV patient. Overall, it reaches about EUR4,000 in average. So, the costs related to each treatment phase varied greatly by stage, especially with regards to the medical therapy.

CONCLUSIONS:
The modeling of a clinical pathway allows identifying the main spending sources and, therefore, it gives policy makers a view for future planning to appropriately allocate resources in a rational way.

REFERENCES:

VP020 A Data Envelopment Analysis For Evaluating Peru’s Health System

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ABSTRACT SUMMARY:
Health systems’ efficiency is one of the most sensitive topics in health economics; we employed data envelopment analysis to measure efficiency on healthcare regional governments spending, calculating expenditure per capita on strategic health resources, human resources, medical equipment, and medicines, comparing with chronic malnutrition rate and life expectancy regional indicators.

INTRODUCTION:
The health sector in Peru is highly fragmented, consisting of a poorly integrated set of subsystems
serving different sections of the population. One of its members is the regional governments, who have managed their own economic resources since seven years ago. There is inequity in the improvement of national indicators such as life expectancy and the chronic malnutrition rate among regions. Our objective is to know if efficient spending on strategic resources in health by regional governments in health has influenced the improvement (or not) of these indicators.

**METHODS:**
The efficiency of regional Peruvian governments on health results was analyzed using the data envelopment analysis (DEA) on twenty-five Peruvian regions. Public expenditure information and regional health indicators were obtained from the online database and national surveys from the Ministry of Economy. We selected input variables as per capita expenditure on human resources, medical equipment, and medical drugs. Outputs used were life expectancy increase and the chronic malnutrition rate in children. Finally, to determine the efficiency of health expenditure in each region, we applied DEA. A DEA index with a value under one defined the health expenditure per capita of each region, with respect to the indicators, as inefficient.

**RESULTS:**
The average health expenditure per capita was $123.00 ($79.70 - $1255.58). Fourteen regions allocate more than 50 percent of public health expenditure to human resources. Three regions spend more than half of their budget on medical equipment. From the linear regression analysis, only the expenditure on medical equipment showed a relationship with the decrease in the chronic malnutrition rate in children (p = .03). Seventy-one percent of the regions had a DEA index with a value under 1.

**CONCLUSIONS:**
Peruvian regional government health spending is inequitable and deficient in Peruvian regions.

National economic and health policies must be implemented to improve public spending on health.

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**VP021 Telemedicine As A Tool For Public Health Planning**

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**ABSTRACT SUMMARY:**
This study aims to evaluate the utility of telemedicine as a tool for public health planning using remote tomography, electrocardiography (ECG), electroencephalography (EEG) and ultrasound diagnosis.

**INTRODUCTION:**
The telediagnostic systems can achieve relevant epidemiological information from local community needs to global countrywide opportunities. In this context the telemedicine applications should be directed to gain the prevalence of pathologies towards developing better equity in the provision of services (1), and greater concern for the effectiveness and usefulness of health technologies in remote locations without access to specialists (2). This study, has evaluated the results of a telemedicine system in remote public regional and district hospitals in Paraguay (3), in order to show the epidemiological trends in communities of a low-income country.
METHODS:
This prospective study used the results of telemedicine for diagnosis in remote regional and district hospitals to evaluate a tool to determine the prevalence of pathologies countrywide over three years (2014-16). For these purposes, type and frequency of pathology diagnosed was determined. Sampling was non-probabilistic of convenience.

RESULTS:
A total of 182,406 telediagnoses were performed in 54 hospitals. The electrocardiography (ECG) diagnosis performed in the 52 hospitals were normal (62.1 percent), unspecified arrhythmias (12.5 percent), sinus bradycardia (10.4 percent), left ventricular hypertrophy (4.1 percent), sinus tachycardia (4.4 percent), right bundle branch block (3.5 percent), ischemia (1.4 percent), atrial fibrillation (1.0 percent) and left bundle branch block (0.6 percent). Teletomography was performed in twelve hospitals, where 54.4 percent corresponded to skull as a consequence of accidents (motorcycles) and cerebrovascular diseases, 13.8 percent chest, 6.2 percent dorsal spine, 5.4 percent abdominal and the rest the other anatomical regions. Regarding electroencephalography (EEG), antecedents of seizure (54.3 percent), evolutionary control (14.0 percent), headache (11.5 percent), cognitive impairment (2.0 percent), attention deficit in children (learning) (2.0 percent), brain death (1.0 percent), abnormal movements (0.8 percent), and sleep disturbances (0.3 percent) were diagnosed. The nineteen ultrasound studies corresponded to prenatal controls.

CONCLUSIONS:
Despite the results of the telediagnosis implemented in the public health system to determine the prevalence of pathologies countrywide, a widespread use-assessment should be analysed before deciding a large diffusion as a tool for public health planning.

REFERENCES:
INTRODUCTION:
As of July 2016, funding from England’s Cancer Drugs Fund (CDF) is dispensed based on the results of National Institute for Health and Care Excellence (NICE) technology appraisal guidances instead of independent CDF appraisals (1). NICE can recommend providing temporary CDF funding for drugs that have potential to demonstrate cost-effectiveness after further data collection (2). This analysis examines drugs considered for temporary CDF funding since the start of this new process in July 2016.

METHODS:
We collected all final NICE oncology technology appraisal guidances completed before the end of 2016 and noted whether each drug was considered for or awarded CDF funding and which factors impacted the decision to give or withhold CDF funding (3).

RESULTS:
We identified twenty-one NICE oncology reviews completed between July 2016 and the end of 2016. Of these reviews, only one was recommended for temporary funding under the CDF because further data collection had the potential to significantly reduce incremental cost-effectiveness ratios (ICERs). Three further reviews were considered for temporary CDF funding but ultimately received negative decisions. In all three cases, NICE found no potential for further data collection to sufficiently improve ICERs. The evaluations also noted that the manufacturers either did not intend or did not have sufficient time to prepare a case for CDF funding.

CONCLUSIONS:
NICE focused strongly on evidence maturity in making CDF funding decisions. The only drug recommended for CDF funding had immature trial data with uncertainties that could be resolved by further data collection. The three drugs that did not receive CDF funding had relatively mature evidence that would not be improved through further data collection. Timing was also an issue: two reviews specifically noted that the manufacturers had insufficient time to prepare strong cases for CDF funding. The CDF historically had significant budget issues, so NICE may be trying to be more judicious in allocating CDF funding.

REFERENCES:
INTRODUCTION:
Selective benefit, a type of conditional coverage, was introduced to decrease the economic burden on patients in Korea. Medical devices with economic uncertainty have been covered as a selective health benefit by the Korea National Health Insurance (K-NHI) since December of 2013. We aim to analyze the impact of this selective benefit on medical expenditures and provider behavior with a focus on patients for which ultrasonic scalpel techniques and electrosurgery for gastric cancer were covered since December of 2014.

METHODS:
We used National Health Insurance Claims data pertaining to 2,698 patients who underwent gastric cancer surgery between August of 2014 and March of 2015. Medical costs and patient sharing per inpatient day were analyzed to verify that covering ultrasonic scalpel procedures and electrosurgery increased medical expenditures and changed provider behavior as evidenced by moving from open surgery to endoscopic or laparoscopic surgery. Additionally, we analyzed the claim rates of medical devices or goods related to gastric endoscopic and laparoscopic surgery.

RESULTS:
Medical costs and patient sharing per inpatient day were increased after coverage began for ultrasonic scalpel procedures and electrosurgery as a selective benefit KRW39,724(USD33) However, there were no medical expenditure increases after adjusting for claims of ultrasonic scalpel procedures or electrosurgery, and patient sharing showed a decrease of KRW1,057(USD1). The selective health benefit coverage did not increase the claim rates for medical devices or goods related to endoscopic or laparoscopic surgery either.

CONCLUSIONS:
Covering ultrasonic scalpel procedures and electrosurgery decreased the economic burden on patients and did not change provider behavior.

Expanding the selective benefit is necessary to decrease the economic burden on patients in severe need. Further study should evaluate long-term effects with accumulated data.

VP024 The Development Of A Quality Management Tool For Health Technology Assessment Agencies In Spain

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ABSTRACT SUMMARY:
In Spain, the Health Technology Assessment (HTA) agencies coordinate their work through a national network (Redets). Based on a previous list of quality standard titles from a literature review, we have developed a self-evaluation tool with consensus of the workgroups of all member of Redets. The tool is a useful instrument for evaluating and implementing quality handbooks in each member agency.
INTRODUCTION:
The Spanish National Network (REDETS) is a group of eight agencies, units and services, depending on National and Regional Governments that coordinate their work within a common methodological framework, guided by the principles of mutual recognition and cooperation. The necessity of considering a Quality Management System has been detected and, consequently, a common tool for all the members needs to be developed. We describe in this study the process to achieve that goal.

METHODS:
Based on both a review of previous literature and the proposal for a self-evaluating tool, a group of experts from each agency through consensus have developed a tool for self-evaluation in Health Technology Assessment (HTA) agencies. Through the structure described in the handbook of the Andalusian Agency for Healthcare Quality (ACSA), each standard should have a statement or proposal that needs to also include evidence or good practices, and the corresponding evaluation questions. In separate workgroups, the definition of these proposals, evidence and evaluation questions were developed. One face-to-face meeting and two meetings via teleconference were necessary to achieve a final document with all the quality standards.

RESULTS:
From a proposed structure of sixty-six standards, the titles, definitions, statements and evidence as well as good practices and evaluation questions were established in workgroups with consensus among all of the members (1 - 3). The final version of the self-assessment tool was composed of sixty-eight standards, grouped in twelve quality criteria structured in four dimensions: I Responsibility, II Clients and Stakeholders, III Production Process, and IV Resources.

CONCLUSIONS:
Quality management requires an evaluation tool and this version, based on a systematic review and consensus, is a useful and practical instrument for developing a handbook by each member of Redets. An online version of the tool is in process of development.

REFERENCES:

VP025 African Countries Are Working Together To Enhance Medicine Use

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ABSTRACT SUMMARY:
There is a growing burden of infectious and non-communicable diseases (NCDs) across Africa, for example, 70 percent of the world’s human immunodeficiency virus (HIV) patients live in sub-Saharan Africa and 30 to 45 percent of adults have hypertension. This requires groups to collaborate, and this is happening through groups such as the South African Health Technology Assessment Society (SAHTAS), Pharmacology for Africa (PharfA) and the Medicines Utilisation Research in Africa (MURIA) group. MURIA is researching antibiotic use, adherence to medicines and strengthening Drugs and Therapeutic Committees (DTCs). This should continue to optimise medicine use and scarce resources.

INTRODUCTION:
The socioeconomic burden of diseases is increasing in Africa. For instance, in 2011, 70 percent of the world’s human immunodeficiency virus (HIV) population resided in sub-Sahara Africa. There are also growing rates of Antimicrobial Resistance (AMR), which necessitates newer more expensive antibiotics adding to costs. There is also a growing burden of non-communicable diseases (NCDs), three out of four patients with hypertension currently live in low and middle income countries (LMICs), with prevalence rates up to 30 to 45 percent among adults in Africa. Alongside this, up to 70 percent of total healthcare expenditure is spent on medicines in LMICs; much of this out-of-pocket. Consequently, there is an urgent need to strengthen collaborative research to improve medicine use.

METHODS:
Summary of groups working together in Africa including the Medicines Utilisation Research in Africa (MURIA) group.

RESULTS:
African Strategies for Health identifies and advocates best practices, as well as works with others to develop sustainable solutions.

Pharmacology for Africa (PharfA) organises and promotes pharmacology on the African continent, including research in clinical pharmacology, alongside the International Union of Basic and Clinical Pharmacology (IUPHAR) sub-division. International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Africa co-ordinates activities from the different African country chapters. The South African Health Technology Assessment Society (SAHTAS) is a scientific and professional society for all those who produce, use, or encounter Health Technology Assessment (HTA) in Southern Africa, and the World Health Organization (WHO) International and Regional groups are improving antibiotic drug utilisation capabilities in Africa. The MURIA group was established in 2015 (1). Ongoing collaborative research includes (i) initiatives to optimise antibiotic use; (ii) methods to enhance adherence to anti-infective prescribing guidance, (iii) approaches to improve adherence to HIV and NCDs; (iv) researching current anti-hypertensive utilisation patterns and knowledge; (v) approaches to enhance Drugs and Therapeutic Committees (DTC) activities, and (vi) strengthening medicine utilisation capabilities (2,3). These activities have already strengthened research ties across Africa.

CONCLUSIONS:
A number of groups are already working across Africa to enhance appropriate medicine use, and should continue. Ongoing MURIA activities include antibiotic point-prevalence studies, ongoing research into infectious diseases, NCDs and DTCs including adherence as well as the third workshop and symposium in Namibia in 2017.

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VP026 Comparing Statistical Methods For Meta-analysis Of Rare Event Data

PRESENTING AUTHOR: Tarang Sharma, Denmark

AUTHORS: Peter Gøtzsche, Denmark
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ABSTRACT SUMMARY:
Meta-analyses of sparse data should employ different methods compared to regular data and Cochrane recommends the use of the Yusuf-Peto method. However, when the odds ratio deviates from 1, this method is no longer reliable, as it underestimates the treatment harm and overestimates its precision, as it ignores studies that have null events in both arms (referred to as double-zero studies).

INTRODUCTION:
We aimed to identify the validity and robustness of effect estimates for serious rare adverse events in clinical study reports of antidepressant trials, across different meta-analysis methods for rare binary events data (1,2).

METHODS:
Four serious rare adverse events (all-cause mortality, suicidality, aggressive behaviour and akathisia) were meta-analysed using different methods (3). The Yusuf-Peto odds ratio (OR), which ignores studies with no events in the treatment arms, was compared with the alternative approaches of generalised linear mixed models (GLMM), conditional logistic regression, a Bayesian approach using Markov Chain Monte Carlo (MCMC) and a beta-binomial regression model.

RESULTS:
Though the estimates for the four outcomes did not change substantially across the different analysis methods, the Yusuf-Peto method underestimated the treatment harm and overestimated its precision, especially when the estimated odds ratio (OR) deviated greatly from 1. For example the OR for suicidality for children and adolescents was 2.39 (95 percent Confidence Interval, CI 1.32 to 4.33, using the Yusuf-Peto method), but increased to 2.64 (95 percent CI 1.33 to 5.26) using conditional logistic regression, to 2.69 (95 percent CI 1.19 to 6.09) using beta-binomial, to 2.73 (95 percent CI 1.37 to 5.42) using the GLMM and finally to 2.87 (95 percent CI 1.42 to 5.98) using the MCMC approach.

CONCLUSIONS:
The method used for meta-analysis of rare events data influences the estimates obtained and the exclusion of double zero-event studies can give misleading results. To ensure reduction of bias and erroneous inferences, sensitivity analyses should be performed using different methods and we recommend that the Yusuf-Peto approach should no longer be used. Other methods, in particular the beta-binomial method that was shown to be superior, should be considered instead.

REFERENCES:
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**VP027 Does Health Technology Assessment Methodology Affect The Decision To Fund Medical Tests?**

**PRESENTING AUTHOR:**
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**AUTHORS:**
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Philip Ryan, Australia

**ABSTRACT SUMMARY:**
We tested whether the type of Health Technology Assessment (HTA) method used for evaluating medical tests can predict whether policy makers will publicly fund them. We found that formally linking pieces of evidence to estimate the clinical impact of a test appears to be associated with an increase in decision certainty, with less need for interim (provisional) funding decisions.

**INTRODUCTION:**
The Linked Evidence Approach (LEA) is used in Health Technology Assessment (HTA) to evaluate the clinical utility of new medical tests in the absence of direct trial evidence. Our objective was to determine whether the use of LEA affects decisions by policy makers to publicly fund medical tests (1).

**METHODS:**
HTAs evaluating medical tests, before and after LEA was mandated in Australia (in 2005), were screened for eligibility. Data were extracted on a number of variables concerning test purpose, methodological approach and quality of the evidence base. A proforma was used and duplicate data extraction was conducted for approximately one-third of the eligible test indications. The impact of LEA and other possible clinical predictors on funding decisions was modelled. Regression diagnostics were performed to estimate model fit, model specification and to inform model selection. The unit of analysis was per clinical indication for each new test, so analyses were adjusted for clustering.

**RESULTS:**
Eighty-three HTAs (for 173 clinical indications) were eligible from the 259 screened. When health policy was compared before and after 2005, there was an 11 percent reduction in overall positive funding decisions, including a 25 percent decrease in ‘interim’ (provisional) funding decisions. The odds of obtaining interim funding reduced by 98 percent after 2005 (Odds Ratio, OR=0.02, 95 percent Confidence Interval, CI .0005, .17) but there was no change in the direction of funding decisions (OR=1.36, 95 percent CI .62, 3.01). Across both time periods, when LEA was used there was a very strong likelihood that the medical test would not receive interim funding ($X^2=12.63$, df=1, $p=.001$). For positive funding decisions, the strongest predictors were whether or not the new test would replace an existing test and whether or not the available evidence was limited.

**CONCLUSIONS:**
The use of LEA does not predict the direction (positive or negative) of funding decisions. Application of the method does predict that a provisional funding decision is unlikely. This suggests that LEA may increase decision certainty and reduce the need for ‘coverage with evidence development’.

**REFERENCES:**
VP028 The Use Of Ethnographic Fieldwork In Health Technology Assessment

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ABSTRACT SUMMARY:
Ethnographic fieldwork can provide robust scientific evidence insights into patients’ experiences of their illness or use of a health technology, and so could contribute important new knowledge to inform Health Technology Assessment. It will be highly relevant in relation to the assessment of screening procedures, tele-health solutions, and collaboration between different sectors such as hospital, municipalities and general practice.

INTRODUCTION:
The aim of the study was to introduce ethnographic fieldwork (1), including participant-observation and ethnographic interviews. Ethnographic fieldwork is a robust research methodology to study patients’ experiences and perspectives and, therefore, particularly valuable for Health Technology Assessment (HTA). Conducting ethnographic fieldwork requires that the researcher joins the people under study where they live or work for a period of time to observe and experience their everyday life and grasp their point of view in relation to the assessment of a health technology.

METHODS:
The presentation focuses on ethnographic fieldwork with participant-observation and ethnographic interviews. In relation to HTA, fieldwork can be highly relevant in order to understand the social world of the patients, for instance how they perceive and act in relation to a health technology. Furthermore fieldnotes, considerations on the analytic process and the production of knowledge will be a focus in the presentation.

RESULTS:
We argue, that a small fieldwork study based on participant-observation can do much more than just act as supplements to different forms of interviews. We demonstrate that in the production of an HTA, patient knowledge should not depend on or prioritize one method like interviews or recorded talks. We show the importance of good fieldnotes in the process of analysis together with a discussion of the production of knowledge.

CONCLUSIONS:
To explore patients perspectives is thus not to identify one ‘true’ perspective through an individual interview. Patients perspectives and experiences are emerging, relational and shifting. Therefore, there is a need for enhancing methodological and epistemological reflections and discussions about future development of ethnographic fieldwork in relation to HTA and patient involvement. The potential use of ethnographic fieldwork including participant-observation and ethnographic interviews will be highly relevant in relation to the assessment of new screening procedures, tele-health solutions, and collaboration between different sectors such as hospital, municipalities and general practice. Furthermore, ethnographic fieldwork would be of importance for exploring how technology is working in local settings.
REFERENCES:

METHODS:
A literature review was performed by extracting full HTA reports through INAHTA (International Network of Agencies for Health Technology Assessment) members websites, HTA agencies and snowball search, and the aspects relating to the organizational assessment were analysed. A quantitative and qualitative analysis was performed on the retrieved reports and the results were compared with a framework of five domains and fifteen subdomains from EUnetHTA’s CoreModel 3.0. A Multiple Correspondence Analysis was carried out in order to evaluate the power of CoreModel and identify new common domains to guide the organizational assessments in HTA reports.

RESULTS:
The assessments of organizational issues in the reports were significantly heterogeneous and less common than inclusion of other classic assessments. When included, domains and subdomains of the CoreModel were not covered homogeneously by the organizational assessments (representation level varied from 19 percent to 62 percent). The statistical analysis performed on the current data and the subsequent clustering of items offered the possibility to develop a new methodology based on three new composite indicators.

CONCLUSIONS:
This ongoing study analyzed the relevance of organizational assessments in current literature and the challenges of promoting an international approach to the matter. In this sense, according to the current state of the research, we proposed a new methodology to cover the most relevant aspects of organizational appraisal according to new, more homogeneous domains and a less context-oriented approach to encourage health professionals to perform organizational analysis and better fulfill the needs of future HTA research.
VP030 Research and Analysis of European Health Technology Assessment Processes

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ABSTRACT SUMMARY:
Research and analysis of European Health Technology Assessment (HTA) processes to identify implementation issues and develop strategies to overcome them.

INTRODUCTION:
As part of the European Network for Health Technology Assessment (EUnetHTA) Joint Action 3, the National Institute for Health and Care Excellence (NICE) in collaboration with forty-nine Health Technology Assessment (HTA) agencies and payer organizations, is leading on research to gain a high-level understanding of HTA processes across Europe. This will help to facilitate improved collaboration and use of EUnetHTA HTA reports and tools across member states and decrease the duplication of work.

To analyse the similarities and differences in HTA processes and decision making on the reimbursement of pharmaceuticals and medical devices across Europe.

METHODS:
National agencies involved in the HTA and reimbursement processes shared data on HTA and decision-making processes. Data provided was extracted into an excel workbook including information relating to pharmaceuticals, medical devices, inpatient and outpatient care and assessments that inform reimbursement, pricing and other processes.

RESULTS:
Thirty-one countries provided fifty-eight sets of HTA process and procedural documents for both medical devices and pharmaceuticals. This information was translated into the workbook which consisted of eleven sections (general information, capacity, overview of the process, topic selection, assessment process, advice and decision making, legal and procedural issues, reassessment, stakeholders engagement, HTA information used and HTA information held).

The first stage of data analysis is a descriptive write up of existing processes from horizon scanning and topic selection up to decision making. The second stage is an analysis showing how collaboration and use of EUnetHTA outputs can be implemented into existing processes. An additional questionnaire will be developed to gain further understanding of EUnetHTA partners views on national engagement in the EUnetHTA procedures, implications of joint production, what EUnetHTA products are most valued and what mechanism might support better information sharing and more efficient use of HTA reports between jurisdictions.

CONCLUSIONS:
The analysis of the above data will provide detailed information on how EUnetHTA products or HTA products from other jurisdictions could be introduced into HTA and reimbursement processes across member states and at what point could EUnetHTA partners best engage in joint and cooperative work.
VP031 Health Technology Assessment Evidence On E-Health/M-Health Technologies: Fields For Improvement

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ABSTRACT SUMMARY:
E-Health/m-Health technologies are increasingly present in the field of Health Technology Assessment (HTA), but most of the reports miss to respond to relevant assessment elements especially ethical, social and organizational implications. There is a need for strengthening and standardizing methods used for the evaluation of E-Health/m-Health technologies in order to adequately respond to multidisciplinary nature of the HTA.

INTRODUCTION:
Evaluation is crucial for integration of e-Health/m-Health applications into healthcare systems and their further sustainability. However, evaluation of these technologies is often challenged by poor quality of research design, lack of common outcome indicators and no consensus on appropriate methodology. Health Technology Assessment (HTA) could offer a sound methodological basis for these evaluations (1). The aim of this study was to look for HTA reports on e-Health/m-Health technologies and to describe their characteristics and analyze transparency, consistency and thoroughness, with the goal to detect fields for improvements.

METHODS:
A literature search was performed on PubMed, ISI WOS and University of York – Centre for Reviews and Dissemination (CRD) electronic databases, in order to identify reports that had evaluated e-Health/m-Health technologies, published until 1 April 2016. We used the International Network of Agencies for Health Technology Assessment (INAHTA) checklist (2) to evaluate transparency and consistency of included reports. We also assessed thoroughness of reports by checking the presence of the domains suggested by European Network for HTA (EUnetHTA) HTA Core Model (3).

RESULTS:
Twenty-eight reports published between 1999 and 2015 were included. Most of reports (71.4 percent) were delivered by non-European countries and only 35.7 percent were classified as full reports. E-Health/m-Health technologies from several fields of medicine, mostly cardiology (21.4 percent) and psychiatry (17.9 percent) were evaluated. Policy question was clearly defined in 32.1 percent of reports, whereas ethical (21.4 percent) and legal implications (3.6 percent) were domains with the least presence. With respect to the EUnetHTA Core Model, around 70 percent of reports dealt with effectiveness and economic evaluation, more than 50 percent described health problem and around 40 percent organizational and social aspects. Remaining domains were evaluated in very few reports.

CONCLUSIONS:
E-Health/m-Health technologies are increasingly present in the field of HTA. Our work identified a number of elements not being included in the available reports. Several reports missed to respond to relevant assessment elements especially ethical, social and organizational implications. There is a need for strengthening and standardizing methods used for the evaluation of these technologies.
VP032 Improving The Efficiency Of Early Awareness For Non-Drugs In Spain

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ABSTRACT SUMMARY:
Early awareness and alert systems try to anticipate the impact of new and emerging technologies in healthcare systems, however not many resources are devoted to these activities. This experience in Spain describes ways to improve efficiency through networking and joint distribution of tasks, and according to context needs.

INTRODUCTION:
Early awareness and alert systems (EAAS) try to anticipate the impact of new technologies in the healthcare systems. Spain, which has a decentralized health system with public provision and universal health coverage, has been a pioneer in establishing EAAS activities. From 2006 a network of regional agencies coordinated EAAS activities. Taking into account the individual agencies’ scarce resources and in order to improve efficiency, this collaboration decided to distribute tasks when identifying and early assessment of new and emerging health technologies. The aim was to inform the common benefit package of the Spanish public health system.

METHODS:
Four out of eight Spanish Health Technology Assessment (HTA) agencies had EAAS in Spain (AETS-Carlos III Institute; AETSA-Andalusia; Avalia-t-Galicia; Osteba-Basque Country). Each agency has taken care of different sources for the identification of new and emerging non-drug health technologies: industry and innovator contacts, health expert networks, mass media and EAAS databases. Members of the network used the same filtration criteria to reach the final list. The system will run in parallel to a biannual identification process in major databases.

RESULTS:
In 2016, the network identified and filtered sixty-three technologies: ten by mass media; five by health experts; thirty-five other EAAS and thirteen by direct contact with industry and innovators. Main represented specialties were: endocrinology
(seven); gynecology and obstetrics (six); cardiology and cardiac surgery (five); emergency medicine (four); dermatology (three) and pneumology (three). Technologies were grouped by specialty in order to inform the different commissions that discuss inclusion in the Spanish Benefit Package. Specialty monographs will be published to inform stakeholders.

CONCLUSIONS:
The approach is feasible, and increases the capacity of individual agencies to address the needs of the national and regional systems by improving their efficiency. There is a need to previously define the methods and the criteria that will be used for the identification and filtration.

VP033 Decision Making Clinical Scenarios: A Support Method For Health Technology Assessment

PRESENTING AUTHOR:
Luiz Santoro Neto, Brazil

ABSTRACT SUMMARY:
This study presents a new method to support decisions in the Health Technology Assessment (HTA) process. The method suggests a conjugation of social, economic, funding, ethical, epidemiological, technical and clinical criteria, through the stakeholders points of view. The advent of clinical scenarios allows the use of multiple factors that impact the clinical outcomes, under the reliability of situations that mimic real world HTA dilemmas.

INTRODUCTION:
The method appraises the stakeholders value judgments in the Health Technology Assessment (HTA) process, through a new model of research that addresses clinical scenarios to simulate real world HTA dilemmas and support decision making. The scenarios are based on criteria, such as clinical and epidemiological elements, and also, economic, social and ethical factors. The stakeholders decisions can induce strategic impacts in different HTA fields. We agreed to call this model Decision Making Clinical Scenarios (DMCS).

METHODS:
The model of research is based on a cross exploratory research, through a DMCS questionnaire applied to stakeholder respondents. The first survey was composed of four scenarios. The scenarios introduce value judgments, preferences and structuring choices, under specific circumstances. The scenarios are based on trade-offs involving HTA, such as budget impact, sources of funding, patients eligibility, technology characteristics and disease epidemiology. The stakeholders points of view are analyzed, through groups that represent payers, suppliers, developers, researchers, prescribers, regulators, government, patients and society.

RESULTS:
The scenarios have been shown to be understandable for all stakeholders groups. When testing the model with hypothetical dilemmas through clinical scenarios, the results are strongly influenced by each presented trade-off. We can observe specific trends and motivations when analyzing the stakeholders groups separately. The results are always evaluated and validated through statistical analysis. A total of 193 stakeholders answered the survey. The majority were male (n= 104; 53.9 percent) and aged between 31 and 40 years (n= 71; 36.8 percent). In scenario 1, almost half of respondents (n= 95; 49.2 percent opted not to incorporate the new drug and in scenario 2, an even higher proportion chose not to incorporate the new drug (n= 112; 58.0 percent). In scenario 3, most have responded to not incorporate the new treatment for any age group (n= 81; 42.0 percent). In scenario 4, 65 percent of respondents opted for the preferential allocation for prevention, rather
than treatment (n = 125; 64.8 percent). Overall results showed a conservative trend, considering the presented criteria and trade-offs.

**CONCLUSIONS:**
We concluded that most stakeholders are not guided only by the clinical benefit of a decision. They valorize the importance of funding mechanisms and budget control, and consider economic, social, ethical, clinical and epidemiological aspects. This study model seems to be useful to evaluate the trends of decision makers conduct. We understand that the use of clinical scenarios brings the discussion into the environment and dynamics of the HTA process, where outcome impacts can be analyzed properly. This model can be explored in further research, using flexible criteria for each desired scenario, through real world situations. This model can be used to evaluate impacts in strategic subjects, as budget allocation, public healthcare policies, and patient-shared decision making.

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**VP034 Economic Impact Of Influenza-Like Illness In Vietnam**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
A prospective study was conducted in March 2016 in pharmacies and private clinics at four provinces at Ho Chi Minh City and Hospital of Tropical Diseases, in Southern Vietnam. Average costs associated with the Influenza-Like-Illness (ILI) were USD88.09 per case among all age groups, with direct non-medical costs more dominant than direct medical costs accounting for 39.5 percent in pharmacies, 71.1 percent in clinics and 64.2 percent in hospitals. Total average cost was estimated to be EUR105 in children, and EUR514 in adults in Germany (1); and in South China, direct medical cost of ILI would be USD22.69 (2).

**CONCLUSIONS:**
The cost of ILI was the reason for the economic burden of patients and their families. This study provides the data for the future research, programs and policies which can be applied for influenza or ILI in Vietnam.

**REFERENCES:**

VP035 Economic Consequences Of A Restricted Dutch Sexually Transmitted Infection-Testing Policy

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ABSTRACT SUMMARY:
The Dutch restricted 2015-testing policy for young heterosexuals could save over EUR1 million annually, leading to approximately three missed human immunodeficiency virus (HIV) and seven syphilis infections. The testing policy could be improved by offering second-generation immigrants an HIV and syphilis test. In case of a positive chlamydia or gonorrhoea diagnosis an additional HIV and syphilis test is to be considered.

INTRODUCTION:
Due to the rising costs caused by an increasing demand for Sexually Transmitted Infection (STI) care, the Dutch government changed the funding of STI-clinics (1). A more restrictive testing policy introduced in 2015 no longer required syphilis and human immunodeficiency virus (HIV) tests for younger, heterosexual clients. A less extensive testing policy could be detrimental to the aim of finding and treating STIs (2,3). Infections that remain undetected could possibly lead to an increase in both the total and individual burden of disease, due to transmission and the need for more intensive treatment resulting in higher healthcare costs in the long term. In this study, we evaluated the new Dutch testing policy with respect to intended savings and missed syphilis and/or HIV infections. Moreover, we explored the efficiency of alternative test policies.

METHODS:
Using national surveillance data from 2011 to 2013 with still comprehensive testing for all, we estimated the effects of restrictive testing on test costs, number of infections missed, costs per missed infection, costs per Quality Adjusted Life Year (QALY) lost, and calculated the net monetary benefit.

RESULTS:
The 2015-policy led to estimated savings of EUR1.1 million, while missing approximately three of ten HIV infections and seven of twenty syphilis infections among all younger heterosexual clients (in total 143,612 consultations) per year. Savings were EUR435,000 per QALY lost. Standard testing second-generation immigrants for syphilis and HIV saved EUR525,000/QALY lost. Offering an HIV test when diagnosed with chlamydia or gonorrhoea resulted in savings of EUR568,000/ QALY lost.

CONCLUSIONS:
The 2015-testing policy resulted in substantial savings as few missed HIV and syphilis infections caused QALY losses. Additional standard syphilis and HIV tests for second-generation immigrants and an additional HIV test in case of positive chlamydia or gonorrhoea diagnosis could reduce missed infections in a cost-effective way.

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VP036 Cost-Effectiveness Of Non-Invasive Prenatal Testing For Down Syndrome

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ABSTRACT SUMMARY:
The analysis of cell-free fetal DNA in maternal blood, also called non-invasive prenatal test (NIPT), represents an emerging technology and a possible alternative/complement to current prenatal screening based on biochemical and sonographic markers for Down Syndrome (DS) detection. A cost-effectiveness analysis was conducted to compare the application of NIPT with the prenatal diagnosis/screening procedures currently applied in the Basque Country.

INTRODUCTION:
The analysis of cell-free fetal DNA in maternal blood, also called Non-Invasive Prenatal Testing (NIPT), represents an emerging technology and a possible alternative/complement to current prenatal screening based on biochemical and sonographic markers for Down Syndrome (DS) detection.

The aim of the study was to compare the application of NIPT with the prenatal diagnosis/screening procedures currently applied in the Basque Country.

METHODS:
An analytical decision model was developed to assess the costs and consequences, comparing current prenatal screening, NIPT as a contingency test in high-risk cases and NIPT as a first-line screening test. An economic analysis was conducted to determine which strategy was more cost-effective. Sensitivity analyses were performed (1).

RESULTS:
For a population of 97,074 pregnant women in gestational week 14 and a cut-off point of 1:270, NIPT as a contingent test was not cost-effective, detecting two cases less of DS and causing a lower number of miscarriages related to invasive-testing (4 versus 23) at a slightly lower cost (EUR8,111,351 versus EUR8,901,872).

For risk cut-off points of 1:500 or 1:1000 for contingent NIPT, the number of DS cases detected increased, as did the cost. It could be cost-effective compared with current prenatal screening, (EUR61,763 or EUR256,123 per extra DS case detected, respectively).

Using the NIPT as a primary test detected more DS cases (296 versus 271) and caused less miscarriages (5 versus 23), at a substantially higher cost (EUR41,395,645 versus EUR8,901,872). Cost-effectiveness analysis indicated that it was more expensive and more effective.

Univariate sensitivity-analysis showed that when the price of the NIPT as primary test was EUR76, it was dominant compared with current prenatal screening. It was also cost-effective compared with the NIPT as a contingent test (EUR9,869 per extra DS case detected).

CONCLUSIONS:
The study shows that NIPT had higher detection
rates for DS in different scenarios, but the cost constitutes a limiting factor for implementation in the Basque Health System.

REFERENCES:

VP037 Cost-Effectiveness Of PET-CT For Primary Aldosteronism Diagnosis

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ABSTRACT SUMMARY:
A discrete event simulation has shown that PET-CT is dominant (less costly, more beneficial) in the United Kingdom setting over adrenal vein sampling (AVS) for the identification of patients whose hypertension is caused by primary aldosteronism, who could be cured by surgery. The increased diagnosis rate with PET-CT led to a greater number of successful surgeries and hence better long-term outcomes.

INTRODUCTION:
Primary aldosteronism (PA) is caused by a benign adrenal gland tumour and leads to the development of hypertension (high blood pressure). PA is the cause of 11 percent of all hypertension cases. It can be cured by surgical removal of the affected gland (if unilateral), but is not always diagnosed as the current technique (adrenal vein sampling [AVS]) has a high failure rate and is unpleasant for patients.

METHODS:
A discrete event simulation was developed to compare the cost-effectiveness of PET-CT with AVS for the identification of PA patients suitable for surgery. Anonymized individual patient data from Addenbrooke’s hospital (Cambridge, UK) were used to inform the patient characteristics of those screened. Sensitivity and specificity of the diagnostics were taken from the literature and the outcomes of surgery on hypertension were modelled. The model captured the impact of hypertension on the risk of cardiovascular events and death. The model used a United Kingdom National Health Service (UK NHS) perspective, a lifetime time horizon, and a 3.5 percent annual discount rate. NHS reference costs were used and utilities were taken from the literature.

RESULTS:
PET-CT resulted in 0.04 additional QALYs (11.340 versus 11.299 for PET-CT vs AVS, respectively) and GBP64.43 fewer costs (GBP8,571.93 versus GBP8,636.36 for PET-CT vs AVS, respectively), meaning that PET-CT dominated AVS. PET-CT remained dominant across the majority of one-way sensitivity analyses, with positive ICERs under GBP10,000/QALY only for the upper bound of PET-CT cost (GBP6,997/QALY), upper bound of cost of laparoscopic adrenalectomy (GBP246/QALY) and lower bound of AVS cost (GBP7,702/QALY).

CONCLUSIONS:
Despite being a more costly procedure, PET-CT was overall a cost saving alternative to AVS for the diagnosis of unilateral PA, due to the greater number of successful surgeries and hence better long-term outcomes. This could change the
The way that PA is diagnosed in clinical practice, providing a less traumatic method for patients. The main limitation of the model is that probabilistic sensitivity analysis could not be run due to computational time required.

**VP038 The Impact Of Treatment Timing On The Cost-Effectiveness Of Tests**

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**ABSTRACT SUMMARY:**
When modelling the cost-effectiveness of a test, it is commonly assumed treatment initiation is based solely on the additional information provided by the test. However, other factors may be relevant. We present a case study in which different conclusions regarding the cost-effectiveness of a test were reached when these other factors were modelled.

**INTRODUCTION:**
Economic evaluations of diagnostic tests often assume treatment initiation is determined by the test result. Reality may be more complex, particularly where delays in treatment can have clinical consequences. We present a case study of nucleic acid amplification testing (NAAT) added to acid fast bacilli testing (AFBT) to improve the diagnosis of tuberculosis (TB) and to identify multi-drug resistant-TB (MDR-TB).

**METHODS:**
The analysis was for the Australian setting where there is a low prevalence of TB and some MDR-TB. AFBT with NAAT can identify both TB and MDR-TB, but can take 8 weeks to confirm by culture and susceptibility testing. While untreated, a person with TB is unwell and contagious. Previous economic evaluations of NAAT in low prevalence settings assume all treatment initiation would be guided by AFBT (with or without NAAT) results (1-3), but we considered this unrealistic. We assumed that the decision to treat and the timing of treatment would depend on a patient’s pre-test probability of TB. Patients with a high probability of TB would be treated immediately, irrespective of AFBT results, so AFBT with NAAT would inform initiation of multi-drug resistant (MDR) treatment only. In patients with low probability of TB, treatment would be guided by the AFBT, and NAAT could improve the targeting of treatment, including identifying MDR-TB.

Both approaches (where pre-test probability of TB informs the timing of treatment, and where treatment is guided by test results only) were investigated and compared.

**RESULTS:**
When a high pre-test probability was the trigger for treatment initiation, the incremental cost effectiveness (ICER) per additional quality-adjusted life year (QALY) gained was $90,728. When it was assumed treatment was guided by test results alone, the ICER was $18,533/QALY.

**CONCLUSIONS:**
Economic evaluations of diagnostic tests should consider all factors that may affect the decision to initiate treatment when assessing the cost-effectiveness of a test.

**REFERENCES:**


VP039 Health Impacts And Costs: A Prevention Lab In Piemonte (Italy)

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ABSTRACT SUMMARY:
In 2016 a “prevention lab” was set up in Piedmont. A multidisciplinary group identifies prevention priorities based on: disease burden, risk-factors, effectiveness of interventions, and cost-benefit ratio. Based on more relevant preventable risk factors, fifty effective interventions were identified and combined in different scenarios to estimate their impact (in terms of Disability-Adjusted Life Years, DALYs avoided) and costs.

INTRODUCTION:
The WHO estimates show that in Italy the loss of almost 70 percent of years of life is due to cardiovascular diseases and cancers, similar to most European countries. Whereas the Italian population is aging with a significant increase of non-communicable chronic diseases, it seems a priority to try to reduce the incidence of such diseases, or at least to delay their onset. To address this scenario, a “prevention lab” was set up in Piedmont, and was included among the governance actions of the regional prevention plan. The prevention lab aims at identifying priority prevention interventions for the Piedmont region on the basis of: the burden of disease, the most relevant risk factors, the effectiveness of prevention interventions, and their cost-benefit ratio, to drive regional policies.

METHODS:
The prevention lab brings together multidisciplinary experts from different fields: politics, public health, economy, law, sociology. The activities are managed through regular meetings, and driven by an analysis of the diseases and their main risk factors that cause most of the disability burden (Disability-Adjusted Life Years: DALYs) at the national and regional level. Through a literature review, effective interventions were identified and then used to build some scenarios of intervention, with analysis of cost-benefit.

RESULTS:
The lab, started in December 2015, involved twenty-five professionals in multidisciplinary activities. Overall burden of disease in Italy, were 16,337,000 of DALYs in 2015 of which the 89.7 percent are attributable to non-communicable disease (IHME - GBD 2015). The first four causes of disability are: cardiovascular diseases (15.6 percent of total DALYs), cancer (18 percent), musculoskeletal diseases (13.8 percent), and mental illness (9 percent). Based on the risk factors that cause this burden of disease (hypertension, smoking, alcohol abuse, physical inactivity, and poor diet) about fifty effective interventions were identified and combined in different scenarios to estimate their impact (in terms of DALYs avoided) and costs.

CONCLUSIONS:
The use of resources in prevention should not only be interpreted as expenditure, but also as an investment and an avoided cost. Prevention allows for the gain of years of healthy life, potentially reducing or postponing the onset of disease.
**VP040 Comprehensive Evaluation Of Islet Transplantation For Type I Diabetes**

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**ABSTRACT SUMMARY:**
Islet transplantation is a promising, emerging therapy for the patients with type I diabetes. This article systematically reviewed and meta-analyzed the worldwide experiences of islet transplantation to evaluate its effectiveness, safety, economy, and social ethics. Islet transplantation offers patients a chance to achieve insulin independence and better cost-effectiveness, and is relatively safe. However, there are some obstacles to its wide utilization.

**INTRODUCTION:**
Despite several therapeutic options exist for the patients with type I diabetes, the patients are still at high-risk for severe acute and chronic complications (1). Pancreatic islet transplantation is a promising therapy to achieve good glycemic control with no or little additional insulin (2). This study was to evaluate the effectiveness, safety, economics and social ethics of islet transplantation (IT) for the patients with type I diabetes.

**METHODS:**
We searched PubMed, Cochrane Library, CNKI and CBM to retrieve eligible literatures. The values of H1bAc before and after transplantation, the rates of insulin independence and functional islet graft at the last follow-up, and the insulin dose per patient-day were analyzed. Descriptive statistics, t tests and random effects meta-analyses were used in the study.

**RESULTS:**
Totally 21 original papers with 488 cases from 9 different countries were reviewed and analyzed. The studies showed that the H1bAc was decreased from 7.7 percent (95 percent Confidence Interval, CI: 7.4, 8.1) before IT to 6.2 percent (95 percent CI: 5.9, 6.4) after IT. At the last follow-up, the rate of insulin independence was 48.96 percent (95 percent CI: 31.32, 66.73) and the rate of functional islet graft was 65.79 percent (95 percent CI: 47.06, 82.21). The daily insulin requirement dropped from 0.52U/kg/d to 0.21 U/kg/d. The main adverse events of islet transplantation were bleeding (7.01 percent) and the complications related to immunosuppression therapy (6.37 percent), but they were less than those of whole pancreas transplantation.

Another study with a 20-year follow-up also showed that the cost-effectiveness of islet transplantation (USD47,800 per QALY) was better than that of insulin therapy (USD71,000 per QALY). In spite of the better evidences of islet transplantation, the insufficient organ donation and issues of cell purification and immunological rejection limited islet transplantation’s widespread utilization (1).

**CONCLUSIONS:**
The islet transplantation therapy for the patients with type I diabetes has a potential to achieve insulin independence and better cost-effectiveness, and is relatively safe. But there are some obstacles for its widely utilization.

**REFERENCES:**
VP041 Introducing New Health Technologies: Making Good Local Decisions

PRESENTING AUTHOR:
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Judith Swan, Australia

ABSTRACT SUMMARY:
This Australian research provides a model for a regional health technology assessment (HTA) platform that complements national and state processes by building on local resources that support local decisions. The key recommendations are: (i) leverage and coordinate existing local HTA capabilities to support current committees and processes; (ii) build local capability through education, training, and on-line support; and (iii) support cultural shift towards transparent, robust decision making across the system.

INTRODUCTION:
This project aimed to develop a Health Technology Assessment (HTA) platform for an Australian regional health and research hub that:

- complements national and state HTA processes but considers local context
- informs, guides and promotes the introduction of health technologies and policies across primary, secondary and tertiary care, with the aim of optimising patient outcomes.

METHODS:
Following a review of the literature, interviews were conducted across the region to understand the current state of regional decision making and to assess local capability and capacity in conducting HTA.

RESULTS:
There are both formal and informal structures and processes used to support decision making regarding adoption of new technologies. Our research identified that these tend to act in isolation from each other, do not share knowledge beyond an immediate interest group, and rarely have the resources to undertake all required HTA functions. There is wide variation in the level of confidence in decision making with variable levels of evidence used and sometimes limited skills in interpreting the evidence.

A wide range of HTA skills was identified across the region but there was no coordination of these resources and no explicit alignment with regional strategic directions. There are therefore significant inefficiencies and gaps in HTA delivered at the regional level.

CONCLUSIONS:
This research has informed the development of a regional HTA Platform that:

(i) Leverages existing local HTA abilities by coordinating them to support current committees and processes.

(ii) Builds local capability through education, training and on-line support

(iii) Supports cultural shift towards transparent, robust decision-making across the system

(iv) Addresses low value healthcare through strategies to reduce its use.

This research provides a model for a regional HTA platform that complements national and state processes by building on local resources that support local decisions.
VP042 Cost-Consequences Of Medicine Management In A Cross-Sectorial Setting

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ABSTRACT SUMMARY:
We evaluated a comprehensive pharmaceutical intervention, comprising medication review, discharge dialogue, and follow-up for elderly polypharmacy patients. Total healthcare costs were estimated at the individual patient level, from a modified societal perspective. The preliminary results indicate that the intervention is cost-effective and that the positive effects can outweigh the costs of the intervention.

INTRODUCTION:
Medication errors are a common complication in the transition from hospital to primary care and are associated with morbidity and increased health care costs. In this study we evaluated the cost and consequences of a comprehensive pharmaceutical intervention, comprising medication review, discharge dialogue and follow-up for elderly polypharmacy patients.

METHODS:
The economic evaluation was nested within a randomized controlled trial and followed international guidelines for conducting and reporting economic evaluations. Patients were randomized to either basic intervention group (n=499) receiving medication review, full intervention group (n=497) receiving medication review, discharge interview and follow-up or a control group (n=503) that received standard care. Medication reviews consisted of a structured assessment of patients’ medicines with the aim of optimizing medical treatment. Discharge interview aimed at guiding the patient in his or her medicinal treatment. The follow-up component aimed at ensuring that the patient coped with the treatment in primary care and detected potential drug-related problems. Total healthcare costs were estimated over a 6-month period at the individual patient level from a health sector perspective.

RESULTS:
The mean cost per patient was lower in the intervention groups (basic EUR16,725; extended EUR15,631) compared to the control group (EUR17,288), although this difference did not reach statistical significance. The costs of additional time used on medication reviews, discharge dialogues and follow-ups (EUR88) were outweighed by a decrease in costs of admissions. Differences between the groups in costs of healthcare consumption medication were not statistically significant. The results of the clinical study favored the extended intervention group on clinical outcomes, with statistical significance on number of readmissions (Hazard Ratio 0.76, 95 percent confidence interval 0.65 – 0.91).

CONCLUSIONS:
While this comprehensive pharmaceutical intervention increases the costs per patient, the intervention was not costly, and positive effects were seen in the clinical outcomes reaching a decrease in total cost per patient on average. The results thus indicate that the intervention is cost-effective and that the positive effects can justify the costs of the intervention.
VP043 Hospital-based Health Technology Assessment Stakeholders’ Perspectives In Cipto Mangunkusumo Hospital

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ABSTRACT SUMMARY:
To explore perceptions, needs, expectations, and resistance of various stakeholders regarding hospital-based HTA (HB-HTA) activities in Dr. Cipto Mangunkusumo General Hospital, Jakarta, Indonesia, focus-group discussions (FGD) and an in-depth interview were conducted involving various stakeholders in the hospital. The results of this study provide feedback to the HB-HTA unit regarding important aspects needed in the development of HB-HTA at CMH.

INTRODUCTION:
Dr. Cipto Mangunkusumo General Hospital (CMH), a national referral hospital located in Jakarta, Indonesia, established a hospital-based HTA (HB-HTA) unit to conduct assessments to provide evidence-based recommendations for decision making in CMH. The HB-HTA continuous process, which consists of priority settings, assessment, appraisals, dissemination, and implementation, involves various stakeholders with presumably different backgrounds and insight regarding the HB-HTA process in CMH. This study was conducted to explore perceptions, needs, expectations, and resistance of various stakeholders regarding HB-HTA activities in CMH.

METHODS:
Forty stakeholders (clinicians, hospital committee, healthcare units, and supporting units) and six members of the CMH board of directors (BODs) participated in focus-group discussions (FGD) and an in-depth interview, respectively. A thematic analysis of the transcribed interviews was performed.

RESULTS:
Analysis of transcribed interviews from FGD revealed various perceptions across different groups of people with different levels of involvement in HB-HTA concerning HTA organization and structure, stakeholder involvement, as well as topic nominations and selections. All stakeholders have similar needs and expectations toward HTA governance in CMH, that is, a top-down governance involving BODs, medical departments, and the HB-HTA Unit. However, they emphasized the importance of a transparent decision-making process by also considering the perspective of well-informed HTA users. The lengthy time required for HTA process was one of the emerging issues for resistance. Analysis of in-depth interview is currently in progress and will be included in the final report.

CONCLUSIONS:
Although perceptions regarding HTA vary, the needs and expectations, in particular regarding HTA governance in CMH, are fairly similar between stakeholders. A transparent decision-making process based on HTA recommendations is important for the other HB-HTA stakeholders at CMH. A more comprehensive conclusion will be formulated by incorporating the results from in-depth interview with BOD as decision makers, in order to provide feedback to the HB-HTA unit regarding important aspects needed in the development of HB-HTA at CMH.
VP044 Rapid Health Technology Assessment: High-intensity Focused Ultrasound For Breast Fibroadenomas And Benign Thyroid Nodules

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ABSTRACT SUMMARY:
A rapid Health Technology Assessment (HTA) on the clinical effectiveness of High-intensity focused ultrasound (HIFU) for benign breast fibroadenomas and thyroid nodules was carried out. The peer-reviewed literature showed fibroadenoma/nodule reduction in the short term (up to 12 months) but no long term outcomes. Professional opinion from current guidelines does not mention HIFU as a therapeutic option.

INTRODUCTION:
High-intensity focused ultrasound (HIFU) is a non-invasive ablative technique to treat breast fibroadenomas and benign thyroid nodules. A rapid Health Technology Assessment (HTA) was commissioned to inform the Changi General Hospital’s decision on procuring a HIFU system.

METHODS:
A systematic literature search was conducted for systematic reviews, HTA reports and clinical practice guidelines on the clinical effectiveness of HIFU systems with the following PICO elements:

- Patients = patients with benign breast fibroadenomas or thyroid nodules
- Intervention = HIFU
- Comparator = conventional treatment
- Outcomes = clinical outcomes
- Retrieved studies were summarised in a narrative synthesis.

RESULTS:
A few small case series showed reduction in volume of fibroadenomas/nodules in the short term and side effects were minor. Additionally, in HIFU for benign thyroid nodules, conference abstracts described a small open-label, randomised controlled trial where patients receiving HIFU had nodule volume reduction of over 30 percent compared to no reduction in the observation group, at 6 months; and a small non-randomised controlled study where volume reduction was about 70 percent in patients receiving HIFU compared to active observation.

Recent clinical guidelines do not mention HIFU as a therapeutic option for fibroadenomas/nodules. Major United States health insurers do not cover HIFU and consider it experimental, investigational or unproven. In Germany, HIFU for breast fibroadenomas and benign thyroid nodules are covered by some insurers under special integrated care contracts.

CONCLUSIONS:
HIFU for fibroadenomas/nodules is a technology still developing its evidence base. The peer-reviewed literature comprises a few small case series and two controlled trials showing fibroadenoma/nodule reduction in the short term (up to 12 months) but no long-term outcomes. Professional opinion from current guidelines does not mention HIFU as an option.

It may be prudent to await stronger evidence on long-term patient-important outcomes before offering the treatment as a hospital service. HIFU may be suitable for further clinical research.
**VP045 Hospital Efficiency and Utilization Of High-Tech Medical Equipment**

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**ABSTRACT SUMMARY:**
This is the first study to examine the association between hospital cost inefficiency and the utilization of high-technology medical equipment. A panel data analysis was estimated as a function of inefficiency scores. It suggest that hospitals with higher inefficiency scores were more likely to use high-technology medical equipment in the inpatient department, and showed no association in the outpatient and emergency departments.

**INTRODUCTION:**
As part of a growing research on hospital efficiency in recent years, several studies examined the relationship between hospital efficiency and outcomes of hospital care. However, none of the published studies have assessed how hospital efficiency affects utilization of high-technology medical equipment, such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI), both of which have created complicated consequences for healthcare outcomes after their widespread use across the world. This study aims to fill the gap using empirical data from China.

**METHODS:**
We selected our sample of 131 hospitals by a 3-step process, including first randomly selecting six provinces, then two cities within each selected province, and finally 25 percent of the hospitals within each selected city. We conducted a questionnaire survey of the sampled hospitals. The study period covered five years, 2009 - 2013. We first estimated hospital cost inefficiency scores through stochastic frontier analysis using the Cobb-Douglas cost function. Then, we examined how the scores were associated with CT and MRI utilization rates by conducting a descriptive analysis and specifying a series of linear regression models with hospital-level fixed effect.

**RESULTS:**
Our results suggested that the inpatient CT and MRI utilization rates were 41.41 percent and 16.28 percent, which were higher than those of outpatient and emergency CT and MRI utilization rates, 4.52 percent and 1.01 percent, respectively. Regarding the cost-inefficiency, the average scores from 2009 to 2013 was 19.77 percent. Correlation and multivariable liner regression suggest that hospitals with higher inefficiency scores were more likely to use high-technology medical equipment in the inpatient department (P< .05), and showed no association between hospital cost inefficiency scores and high-technology medical equipment utilization rate in the outpatient and emergency departments (P> .05).

**CONCLUSIONS:**
Utilization of CT and MRI in inpatient care increased with hospital cost inefficiency. The finding has important policy implications for the ongoing hospital reform in China.
VP046 Cost Analysis Of Popliteal Aneurysm Management

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ABSTRACT SUMMARY:
The objective of this study was to compare the cost of endovascular popliteal artery aneurysm repair (EPAR) and open popliteal artery aneurysm repair (OPAR), using data from Lausanne University Hospital (Switzerland). Results showed higher cost for OPAR (+42 percent), as implant cost of EPAR is more than offset by longer length of stay and operating time of OPAR.

INTRODUCTION:
Popliteal artery aneurysm (PAA) is the most common peripheral arterial aneurysm and the second most common aneurysm after abdominal aortic aneurysm (AAA). It presents a risk of occlusion, which may lead to acute ischemia and leg amputation. To prevent these risks, asymptomatic PAA >2cm and symptomatic PAA must be treated. Although open PAA repair (OPAR) is still the gold standard, endovascular PAA repair (EPAR) is increasingly used to manage PAA. The objective of this study is to compare the cost of these two medical procedures from the hospital perspective.

METHODS:
Data were retrieved from the administrative database of Lausanne University Hospital (CHUV – Switzerland). Based on diagnostic codes and medical procedure codes, we selected all patients who underwent OPAR or EPAR between 2011 and 2015. Patient’s age, length of stay and cost were compared between both groups using Student t-test.

RESULTS:
We included seventy-three patient stays (OPAR forty and EPAR thirty-three). Gender balance was identical between groups (97 percent of male), but age was statistically significantly different (OPAR 67.5, EPAR 73, p=.04). EPAR induced shorter mean length of stay (5.1 days versus 11.7 days, p=.0000) and lower mean global cost (CHF 16,555 versus CHF23,514, p=.0085). Cost of procedure amounted to CHF 9,536 for OPAR versus CHF 3,848 for EPAR, medical supply and implants amounted to CHF 1,284 for OPAR versus CHF 7,041 for EPAR and other costs of hospital stay amounted to CHF 12,694 for OPAR versus CHF 5,666 for EPAR. (CHF 1.00 = USD1.00 = EURO 0.93)

CONCLUSIONS:
With higher patency rate, OPAR is still associated with better medical outcomes than EPAR. But EPAR is significantly less costly than OPAR. Implant cost of EPAR is more than offset by longer length of stay and operating time of OPAR.

VP047 Health Technology Assessment Of Intensive Care Ventilators For Pediatric Patients

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**ABSTRACT SUMMARY:**
The purpose of the study was to evaluate different type and manufacturers of intensive care ventilators in order to identify strengths and limits of the most recent intensive care ventilators’ models in the specific contexts of use to support the healthcare decision-making process about the choice to adopt the best available technology for the hospital.

**INTRODUCTION:**
The purpose of the study was to evaluate different type and manufacturers of intensive care ventilators in order to support the healthcare decision-making process about the choice to adopt the best available technology for ventilation of pediatric patient in intensive care units at Bambino Gesù Children’s Hospital.

**METHODS:**
The technology assessment process was developed by using a new methodology, the Decision-oriented Health Technology Assessment (HTA) (DoHTA), a new implementation of the European Network for Health Technology Assessment (EUnetHTA) CoreModel, integrating the Analytic Hierarchy Process (1). A literature review was carried out to gather evidence on safety and overall effectiveness of different kind of intensive care ventilators, with several ventilation modalities and strategies. The synthesis of scientific evidence, and results of the specific context analysis resulted in the definition of components of the decisional hierarchy structure, consisting in detailed characteristics of the technology’s performances covering the aspects on feasibility, safety, efficacy, costs, and organizational and technical characteristics of the technology. A subgroup of these indicators has been included in a checklist form for the evaluation of different type and manufacturers of intensive care ventilators, each of which was tested in three independent runs performed in three different departments. In addition, an economic evaluation was also carried out.

**RESULTS:**
Preliminary DoHTA results showed that the domains with the highest impacts within the evaluation are safety and clinical effectiveness (34.8 percent and 25.7 percent, respectively) followed by organizational aspects, technical characteristics of technology and costs and economic evaluation. The final objective is to define the alternatives’ ranking through a comparison between alternative technologies’ performances.

**CONCLUSIONS:**
The technology assessment project allowed to identify strengths and limits of the most recent intensive care ventilator’ models in the specific contexts of use by involving all health professionals interested, and eventually identify the best option for the hospital.

**REFERENCES:**

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**VP048 The Costs And Cost-Effectiveness Of Bacillus Calmette-Guérin (BCG) Vaccination In Estonia**

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ABSTRACT SUMMARY:
The aim of the study was to assess the costs and cost effectiveness of Bacillus Calmette-Guérin (BCG) vaccination in Estonia. The cost per case of tuberculosis (TB) averted was high compared with the cost of treating one case of TB. In conclusion, several organizational challenges need to be addressed if the universal program is replaced with selective BCG vaccination.

INTRODUCTION:
Many countries that have used Bacillus Calmette-Guérin (BCG) vaccine against tuberculosis (TB) have switched from universal vaccination of infants and children to selective vaccination, or discontinued with vaccination at all. The aim of the study is to assess the costs and cost-effectiveness of BCG vaccination in Estonia.

METHODS:
A Markov cohort model and budget impact analysis were used to compare the current, universal BCG vaccination to selective and non-vaccination strategies. The epidemiological and economic impact of BCG vaccination were estimated for the period 2018–2032 following the hypothetical change in the vaccination policy in 2018. The results were presented as the cost per case of TB averted, changes in the occurrence of TB and yearly (undiscounted) costs associated with vaccination and TB treatment.

RESULTS:
In a cohort of 13,500 infants over a time-period of 15 years Estonian universal BCG vaccination prevents around two TB cases compared to selective or non-vaccination strategies. The cost per one TB case averted for the universal strategy compared to non-vaccination strategy was EUR12,234 (EUR4,059–28,748 in sensitivity analysis) and compared to selective vaccination EUR3,847 (EUR504–10,568). The number of TB cases in 0–14-year old children in 2032 was estimated to be 1.3 for universal vaccination, 2.7 for selective and 2.9 for non-vaccination strategy. The total costs of vaccination and TB treatment in 2032 were estimated to be EUR23,764, EUR16,459 and EUR7,553 respectively.

CONCLUSIONS:
The cost per case of TB averted is dependent on vaccine efficacy, and is high compared with the cost of treating one case of TB. At the same time, the total costs of BCG vaccination and TB treatment are marginal compared to other vaccination programs used in Estonia. Despite the limited budget impact, several organizational challenges need to be addressed if the universal program is replaced with selective BCG vaccination.

VP049 Brazilian Consumer Willingness To Pay For Dengue Vaccine (CYD-TDV)

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ABSTRACT SUMMARY:
Dengue virus is a serious global health problem and in 2015 the first vaccine (CYD-TDV) for dengue prevention was approved in Brazil. We conducted a cross-sectional study in Brazil about their willingness to pay for this vaccine. The maximum median value of consumers willingness to pay for CYD-TDV is USD33.61 (BRL120.00). This study can contribute for economic evaluation discussions applied this important infection.
INTRODUCTION:
Dengue virus is a serious global health problem with an estimated 3.97 billion people at risk for infection worldwide. In December 2015, the first vaccine (CYD-TDV) for dengue prevention was approved in Brazil, developed by Sanofi Pasteur (1). However, given that the vaccine will potentially be paid via the public health system, information is needed regarding consumers willingness to pay for the dengue vaccine in the country, as well as discussions related to the possible inclusion of this vaccine into the public health system at prices suggested by the manufacturer. This was the objective of this research.

METHODS:
We conducted a cross-sectional study with residents of Greater Belo Horizonte, Minas Gerais, about their willingness to pay for the CYD-TDV vaccine. Respondents had to be over 18 years and not currently have the disease although they may have had dengue in the past (2,3).

RESULTS:
Five-hundred and seven individuals were interviewed, who were mostly female (62.4 percent), had completed high school (62.2 percent), were working (74.4 percent), had private health insurance (64.5 percent) and did not have dengue (67.4 percent). The maximum median value of consumers willingness to pay for the CYD-TDV vaccine, assuming vaccine efficacy against virologically-confirmed symptomatic dengue illness of approximately 60 percent, is USD33.61 (BRL120.00) for the complete 3-course schedule and USD11.20 (BRL40.00) per dose. At the price currently being assessed by the Brazil’s regulatory chamber of pharmaceutical products market (CMED) for Dengvaxia® for three doses, only 17 percent of the population expressed a willingness to pay for the vaccine at this price.

CONCLUSIONS:
Brazil is currently one of the largest markets for dengue vaccine in the world and the price established is a key issue. The manufacturer should assess the possibility of lowering its price in Brazil to reach a larger audience among the Brazilian population, especially as other public health activities to control the disease will continue.

REFERENCES:

VP050 Cost-Analysis Of Covered Stent-transjugular Intrahepatic Portosystemic Shunts (c-TIPS) Versus Paracentesis In Recurrent Ascites Patients

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ABSTRACT SUMMARY:
Cost-effectiveness evaluation of covered
INTRODUCTION:
Large volume paracentesis (LVP+A) is the standard treatment for patients with refractory ascites and portal hypertension. A recent clinical study of patients with cirrhosis and recurrent ascites showed that covered stent-transjugular intrahepatic portosystemic shunts (c-TIPS) represents a superior alternative to LVP+A by reducing the recurrence of ascites and subsequent LVP+A sessions and reducing mortality, with no increase in rates of hepatic encephalopathy (Bureau 2017). A cost-effectiveness analysis was developed studying the use of c-TIPS with expanded polytetrafluoroethylene (ePTFE) covered stent-grafts compared to LVP+A in patients with recurrent ascites.

METHODS:
A Markov model was adapted to the Spanish National Healthcare System perspective in order to measure clinical and economic consequences of c-TIPS with ePTFE stent-graft compared to LVP+A in patients with recurrent ascites. Clinical management patterns and resources used were defined by an interview process with Spanish key opinion leaders. The model was populated with clinical data from published literature (Bureau 2017). Healthcare costs were obtained from Spanish databases and expressed in EUR 2015. Univariate sensitivity analyses were performed to test the robustness of the model.

RESULTS:
The economic model showed that c-TIPS with ePTFE covered stent-graft represents a cost-effective option compared to LVP+A in patients with recurrent ascites. At 1 year, the total treatment costs per patient were EUR10,943.27 for c-TIPS and EUR9,831.99 for LVP+A, with EUR1,111.28 incremental cost per patient. Mortality was reduced in the c-TIPS arm by 81.05 percent compared to LVP+A treatment, resulting in 0.21 life-years gained (LYG) per patient. Incremental cost-effectiveness ratio (ICER) resulted EUR5,189.07 per LYG. Sensitivity analysis corroborated the robustness of the model indicating that the c-TIPS treatment could result in cost savings over a longer time horizon.

CONCLUSIONS:
At 1 year, c-TIPS with ePTFE covered stent-grafts compared to LVP+A represents a cost-effective therapeutic option in the management of patients with recurrent ascites with a greater survival rate, similar rates of hepatic encephalopathy, and reducing hospital stay together with the amount of paracentesis sessions.

VP051 Hospitalizations and Costs in Schizophrenia Patients Initiating Long-Acting Injectable Antipsychotics

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ABSTRACT SUMMARY:
Existing evidence on clinical and economic effectiveness of one long-acting injectable antipsychotic (LAI) versus another in successful
management of schizophrenia is scarce. Our study findings show that aripiprazole LAI users had lower inpatient hospitalization utilization, compared to fluphenazine, haloperidol, paliperidone palmitate, and risperidone LAI users.

Among BD patients with any hospitalizations, the inpatient costs were lowest in the aripiprazole cohort.

INTRODUCTION:
Existing evidence on clinical and economic effectiveness of one long-acting injectable antipsychotic (LAI) versus another in successful management of schizophrenia is scarce. The study was conducted to compare all-cause inpatient healthcare utilization and associated costs among Medicaid patients with schizophrenia who initiated LAIs.

METHODS:
This retrospective cohort analysis used the Truven Health Analytics MarketScan® Medicaid claims database. Schizophrenia patients >18 years with at least one claim for one of the following LAI were identified between 1 January 2013 and 30 June 2014 (identification period): aripiprazole, fluphenazine, haloperidol, paliperidone palmitate, and risperidone. The first day of initiating an LAI was considered the index date. Patients were followed for 1 year from index date. Logistic and general linear regression models were used to estimate risk of inpatient hospitalization and associated costs during follow up.

RESULTS:
Of the identified Medicaid patients with schizophrenia, 1,672 (36.7 percent) initiated an LAI: 44.0 percent received paliperidone, 26.4 percent haloperidol, 13.8 percent risperidone, 9.2 percent aripiprazole, and 6.6 percent fluphenazine. With the aripiprazole cohort as the reference group, the odds of having any inpatient hospitalizations were significantly higher in haloperidol [Odds Ratio, OR (95 percent Confidence Interval, CI): 1.51 (1.05 - 2.16)] and risperidone [OR (95 percent CI): 1.58 (1.07 - 2.33)] cohorts. Fluphenazine and paliperidone palmitate cohorts also had higher risk of having any inpatient hospitalizations compared with aripiprazole, but the differences were not statistically significant (p>.05). Among LAI initiators with any inpatient hospitalizations, the adjusted mean inpatient costs were lowest in the aripiprazole cohort (USD25,616), followed by haloperidol (USD30,811), paliperidone (USD30,833), risperidone (USD31,584), and fluphenazine (USD37,338), although differences were not statistically significant.

CONCLUSIONS:
Our study findings highlight the value of aripiprazole in reducing inpatient hospitalizations and associated costs among patients with schizophrenia. However, our study is limited as our results are reflective of a multi-state Medicaid population. Future studies are warranted to confirm the results in non-Medicaid patient populations.

VP052 Cost-Effectiveness Of Percutaneous Closure Of Patent Foramen Ovale

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ABSTRACT SUMMARY:
Compared with medical therapy alone, recent publications showed that percutaneous device closure of patent foramen ovale reduces the short- and long-term risks of recurrence of ischemic stroke in young to middle-aged patients who had a cryptogenic stroke. Findings herein suggested that the percutaneous device closure is a highly cost-effective stroke prevention strategy in the context of the United Kingdom healthcare system.

INTRODUCTION:
Recent publications reported that percutaneous closure of a patent foramen ovale (PFO) in carefully selected young to middle-aged patients who have had a cryptogenic ischemic stroke reduces the risk of short- and long-term recurrence of ischemic stroke compared to medical therapy alone. The aim of this study was to evaluate the cost effectiveness of this therapy in the United Kingdom (UK).

METHODS:
A lifetime Markov cohort model consisted of four health states (stable state, post mild and moderate acute recurrent stroke state, and death) was developed to simulate the projected clinical and economic outcomes based on a UK health system perspective. Event rates were extracted from a randomized clinical trial (RESPECT) with a median 5.9 years follow-up. Health utilities and direct medical costs were obtained from the published sources. One-way, probabilistic sensitivity and scenario analyses were performed to assess the robustness of the model. Monte Carlo simulations were used to estimate the 95 percent confidence intervals (CI) of the modeled outcomes. The model was discounted at 3.5 percent and reported in 2016 UK pounds.

RESULTS:
Compared with medical therapy alone and using the commonly accepted willingness-to-pay (WTP) threshold of GBP20,000, PFO closure reached cost-effectiveness in less than 4 years (at year 3.68). The cost-effectiveness ratios (ICERs) at years 4, 6 (the approximate duration of the trial follow-up) and 10 were: GBP18,390 (95 percent Confidence Interval, CI: GBP17,921-GBP20,410), GBP10,726 (95 percent CI: GBP9,816-GBP11,543) and GBP3,878 (95 percent CI: GBP3,066-GBP4,762), respectively, per each quality-adjusted life-year (QALY) gained. Cost-effectiveness (CE) acceptability curve indicated 84 percent probability that the ICERs would be lower than the WTP threshold at year 4. Sensitivity and scenario analyses, as well as undiscounted results showed that the model was robust.

CONCLUSIONS:
Considering the UK healthcare system perspective, percutaneous PFO closure in patients with a definitive diagnosis of a cryptogenic ischemic stroke is a highly cost-effective secondary stroke prevention strategy compared to medical therapy alone.

VP053 Cost-Utility Analysis: Adalimumab Verus Etanercept in Rheumatoid Arthritis – Brazil

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ABSTRACT SUMMARY:
Rheumatoid arthritis (RA) is an inflammatory, autoimmune disease of unknown etiology that usually results in joint lesions and physical incapacitation. In this study we carried out a cost-
utility analysis comparing Adalimumab (ADA) versus Etanercept (ETA), with or without synthetic Disease-Modifying Antirheumatic Drugs (± sDMARD).

INTRODUCTION:
Rheumatoid arthritis (RA) is an inflammatory, autoimmune disease of unknown etiology that usually results in joint lesions and physical incapacitation. RA treatment includes disease-modifying antirheumatic drugs (DMARD), synthetic (sDMARD) and/or biologics (bDMARD). In this study we carried out a cost-utility analysis comparing Adalimumab (ADA) versus Etanercept (ETA), with or without synthetic DMARDs (± sDMARD).

METHODS:
Effectiveness measures used were the Clinical Disease Activity Index (CDAI) and Quality-Adjusted Life Years (QALY) obtained from an open prospective cohort study with Brazilian RA patients. Costs were obtained from a historical cohort composed of every patient who was prescribed medicines to treat RA in the State of Minas Gerais, Brazil. A public sector perspective was adopted. The Markov model included six-month cycles, time horizon of 5 years and 5 percent discount rates. Sensitivity analyses were performed by varying costs and outcome values.

RESULTS:
There was no significant difference in effectiveness between the two bDMARDs. Treatment with ETA (± sDMARD) was more expensive after 5 years of follow-up: incremental cost of USD28,210.87. Overall, treatment with ADA (± sDMARD) was more cost-effective: incremental cost-effectiveness ratio for ETA (± sDMARD) was USD79,148.34/ QALY. Sensitivity analysis showed that outcomes are sensitive to changes in the cost of ETA (± sDMARD) treatment. Overall, both therapeutic alternatives are valuable from the public sector perspective especially when the Clinical Protocol and Therapeutic Guidelines are properly applied in patients no longer responding to treatment. Alternatives are needed as some patients will respond differently to different anti-TNF alpha medicines.

COnClUsiOns:
Currently two Anti-tumour Necrosis Factor Alpha (anti-TNF alpha) medicines – ADA and ETA are available within the Brazilian public health system in addition to infliximab. Treatment with ADA (±sDMARD) was more cost-effective with an incremental cost effectiveness ratio for ETA (±sDMARD) at USD79,148.34 per QALY. Sensitivity analysis showed that outcomes are sensitive to changes in the cost of ETA (± sDMARD) treatment. Overall, both therapeutic alternatives are valuable from the public sector perspective especially when the Clinical Protocol and Therapeutic Guidelines are properly applied in patients no longer responding to treatment. Alternatives are needed as some patients will respond differently to different anti-TNF alpha medicines.

VP054 Costs And Benefits Of Intensive Inpatient Rehabilitation After Stroke

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ABSTRACT SUMMARY:
The study estimated the costs and benefits of the intensive inpatient rehabilitation treatments on patients after stroke using the interim results of the Korean Stroke Cohort for Functioning and Rehabilitation (KOSCO) from the societal perspective.

INTRODUCTION:
This study estimated, from the societal perspective, the costs and benefits of the intensive inpatient rehabilitation treatments (IIRT) on patients after stroke using the interim results of a large ongoing registry in Korea, the Korean Stroke Cohort for Functioning and Rehabilitation (KOSCO) (1).

METHODS:
Among others, the benefits were measured by two
RESULTS:
The disability grade improvements showed savings of government subsidy by USD58.65 to USD478.39 depending on the patient income from the registry. The average caregiving cost decrease was USD6,042 annually. The average cost of IIRT on post-stroke patients was USD926.34 for the first year.

CONCLUSIONS:
This study estimated the cost-benefit of IIRT on post-stroke patients using the KOSCO study interim data. The intensive rehabilitation treatment improves patients functional status significantly enough to save two major cost items, the disability grades which also resulted in a decrease in government subsidy amounts and the caregiver costs which the patient family has to pay in Korea. The results warrant the use of IIRT for the post-stroke patients in Korea from the societal perspective.

REFERENCES:

VP055 Health Technology Assessment Of Orphan Drugs: The Case Of Hereditary Angioedema In Italy

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ABSTRACT SUMMARY:
Orphan drugs are usually characterized by high acquisition costs and less robust evidence from clinical trials, leading to incremental cost-effectiveness ratios far beyond usually accepted thresholds. Hereditary Angioedema (HAE) is a rare disease causing recurrent angioedema attacks in affected patients. Using unpublished real-world data and a bayesian framework we estimated the cost-effectiveness of Icantibant for the treatment of HAE attacks.

INTRODUCTION:
The evaluation of orphan drugs raises both positive and normative issues. Due to the rarity of the disease, higher drug costs and greater uncertainty on effectiveness often result in incremental cost-effectiveness ratios (ICER) far beyond the usually accepted thresholds for reimbursement. However, decision makers may need to consider other
criteria to assess the social value of orphan drugs such as equity, the rule of rescue, and the perceived need in the community. Hereditary Angioedema (HAE) is a rare congenital deficiency resulting in recurrent attacks of angioedema in affected patients. These episodes cause extreme pain and distress, and may even be fatal when air pathways are involved. In Italy, icatibant or C1-Esterase-Inhibitors (C1-INH) are the indicated treatments for acute attacks. Although more expensive, icatibant may reduce time to symptom-relief and the need for further treatments. Nonetheless, evidence on its social value is missing. The present study aims at evaluating the cost-effectiveness of icatibant and providing new insights on other potentially relevant criteria for decision making on HAE treatments.

METHODS:
A cost-effectiveness model of icatibant versus C1-INH (Berinert) was developed. Using a two-part bayesian model, costs were estimated from real-world data of an unpublished national registry. Efficacy data were synthesized from both the registry and an indirect comparison of existing trials, whereas utilities were derived from the literature.

RESULTS:
In our Italian registry, respectively 98 percent and 60 percent of patients self-administered icatibant or Berinert at home in absence of medical personnel. On average, per treatment costs were 60 percent higher and attack duration 25 percent shorter with icatibant compared to Berinert. The resulting ICER greatly exceeded the considered threshold of EUR30,000.

CONCLUSIONS:
On cost-effectiveness grounds icatibant did not demonstrate good value for money compared to Berinert. However, further considerations are needed on whether standard health-related quality of life measures are able to truly reflect societal preferences for HAE treatments. The use of real-world data for the economic evaluation of orphan drugs can support decision making when evidence from clinical studies is too sparse.

VP056 Health Technology Assessment Of A System For Patients Traceability And Safety

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ABSTRACT SUMMARY:
We assessed a software which improves efficiency of hospital procedures, but also safety and traceability of patients. The software allows the patient to be followed in the hospital, especially from wards to theatres and back, including all safety procedures before surgery. Efficacy is linked to the registration of all hospital procedures.

INTRODUCTION:
The software HCS has been introduced in IRCCS Galeazzi to improve efficiency and efficacy. The system was the first in Europe and is based on an information technology which allows the patient to be followed in the hospital, especially from wards to theatres, and back. The software is used by touch screen monitors by nurses in the wards and in the theaters, by anesthesiologists in operating rooms, and by surgeons. All processes are registered and validated by skilled personnel in charge of different procedures.

IRCCS Galeazzi is a leading hospital in orthopedic sciences characterized by high throughput and high efficiency. The introduction of HCS software had the aim to optimize times, to decrease times lost by personnel for communication, and to increase safety of patients, possibly increasing also their compliance.
METHODS:
The evaluation of the system was performed by health technology assessment procedures, following the model based on nine different dimensions, six quantitative and three qualitative, commonly used in Regione Lombardia. The model was established according to EUnetHTA rules and recommendations.

RESULTS:
Relevance: the use of the system is relevant for hospital personnel and management, and for patients.

Reliability: the system, after 16 months of application, is reliable for a high throughput surgical hospital.

Transferability: the system is transferable to all operating rooms and all hospitals.

Safety: the technology is safe, the safety of patients is improved.

Efficiency: the hospital improved efficiency by 15 percent.

Effectiveness: the system could also serve as registries with patient related outcome measurements and research department.

Economical impact and organization: the impact of the system was powerful, decreasing FTEs devoted to communication and improving the information about patients.

Equity and ethical impact: traceability could assure equity of access.

Social impact: patients are safer and their compliance is improved, involving also legal aspects while traceability of data could decrease litigations and unmet needs.

CONCLUSIONS:
The system is reliable, efficient, and effective. The improvement in communication and traceability is a real improvement for personnel and patients.

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VP057 Test-Retest Reliability Analysis Of The Patient Reported Outcomes Burdens And Experiences (PROBE) Study Questionnaire Test-Retest Reliability Analysis Of The PROBE Study Questionnaire

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ABSTRACT SUMMARY:
The Patient Reported Outcomes Burdens and Experiences (PROBE) questionnaire was developed for assessing health status in patients with bleeding disorders, specifically, hemophilia. PROBE is a research project developed with direct patient involvement in questionnaire design, conduct, and analysis using patient-centered outcomes. Phase 1 confirmed robustness of methodology and feasibility. Phase 2 assessed reliability.

INTRODUCTION:
The Patient Reported Outcomes Burdens and Experiences (PROBE) questionnaire was developed with direct patient involvement in questionnaire design, conduct and analysis using patient-centered outcomes to assess health status in patients with hemophilia (PWH). Phase 1 confirmed robustness of the methodology and feasibility.
Phase 2a investigated individual test-retest reliability. Phase 2b will explore population level reproducibility.

**METHODS:**

PWH and non-PWH individuals who attended a hemophilia-related workshop were asked to complete the PROBE questionnaire 3 times (paper-based survey on 2 consecutive days and then a web-based version). Test-retest reliability was analyzed using the percentage agreement and Kappa statistic. Kappa coefficient interpretation .81-1.00 almost perfect, .61-.80 substantial; .41-.60 moderate; .21-.40 fair; .00-.20, slight; and < .00 poor agreement.

**RESULTS:**

Sixty-three participants from twenty-one countries were enrolled with a median age of 50 (range 14-76) years. Of these, thirty (47.6 percent) were PWH or carriers, thirty-three (52.5 percent) were participants with no known bleeding disorders. On general health domain, Kappa coefficients ranged from .69 to .92, indicating substantial to almost perfect agreement, for all items. Reliability of the web-based questionnaire showed moderate to substantial agreement for all except one item. For the hemophilia-related domain, Kappa coefficients ranged from .5-.1.0. Of these, five of eleven items were in perfect agreement (Kappa=1.0). Reliability of web-based questionnaire items were in substantial to almost perfect agreement. For overall health related quality of life, the EuroQol five dimensions questionnaire (EQ-5D) had Kappa coefficients of .62 to .92. Intraclass correlation coefficient of visual analog scale (VAS) was .90 (95 percent confidence interval; .83-.94). Test-retest reliability was comparable between hemophilia patients and participants with no known bleed.

**CONCLUSIONS:**

Phase 2a demonstrated individual test-retest reliability and suggests PROBE is a reliable tool to assess Patient Reported Outcomes in PWH. The Web-based questionnaire has an acceptable agreement with the standard paper-based version in all domains. PROBE Phase 2b, to demonstrate reproducibility at the population level, is on-going. To date, 1,039 participants have been recruited from 10 countries.

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**VP058 PREFER: Patient Preferences To Support Decision Making**

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**ABSTRACT SUMMARY:**

PREFER is a 5-year Innovative Medicines Initiative project run by a consortium of thirty-two public and private partners and supported by Health Technology Assessment agencies, regulators, payers and patients. PREFER aims at determining how patient preferences may support decision making across the medicinal product life cycle.

**INTRODUCTION:**

Methodologies for patient preference elicitation are available and have been used frequently in market research and in health economics and outcomes research. However, it is unclear to what extent these methodologies are suited and accepted for regulatory licensing, Health Technology Assessment (HTA) or reimbursement decision making. While stakeholders have over the last years gained experience individually on involving and engaging patients in decision making, the PREFER project aims to bring all stakeholders together taking a structured approach to the use of patient-preference information and methodologies for patient-preference elicitation.
METHODS:
PREFER will identify desires, expectations, concerns, needs, and requirements of these stakeholders about the timing and use of patient preferences and methodologies for patient preference elicitation to support making well-informed decisions regarding medicinal products. The project will further identify and assess various methods in case studies in three different disease areas. The final deliverable of PREFER is a set of recommendations on how and when patient-preference studies should be performed and how the results could be used to support and inform decision making.

RESULTS:
The aims of this session are to:
• present the PREFER project,
• show how the project gathers information from various stakeholder groups views regarding the timing and use of patient preferences and patient preference elicitation methods to support well-informed decision making regarding medicinal products,
• stimulate a discussion with particular focus on how patient preferences studies can be incorporated into assessments and decision-making by HTA-bodies and reimbursement agencies.

CONCLUSIONS:
The presentation will include the following:

a. Introduction to PREFER: Aims, scope, structure and work plan

b. Challenges of eliciting and incorporating patient preferences into Research and Development decisions, regulatory decisions, health technology assessment and reimbursement decisions.

VP059 Patients Views On Providing Evidence: Feeding Into The Health Technology Assessment Ecosystem

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ABSTRACT SUMMARY:
Based on the international Health Technology Assessment International (HTAi) patient submission template for medicines, the National Institute for Health and Care Excellence (NICE) developed a new patient organisation evidence submission template which was reviewed in 2016. The key recommendation was to extend the review to more patient organizations to gain a greater response and understanding. This has been undertaken; these local findings are an opportunity to contribute to the global HTA ecosystem.

INTRODUCTION:
Patient evidence is submitted to the National Institute for Health and Care Excellence (NICE) by patient organizations and individual patient experts. Previously NICE developed a new patient organization evidence submissions template, based on the international HTAi patient submission template for medicines (1). The NICE template was reviewed by surveying committee members and also patient organizations who had used the submission template. The findings were presented at HTAi 2016.

The limitation of that review was the low response rate from patient organizations. The key recommendation was to extend the survey to include a larger number of patient organizations. These local findings are an opportunity to...
contribute to the global Health Technology Assessment (HTA) ecosystem.

METHODS:
A project group was convened consisting of NICE staff, a committee lay member and a patient organization representative. Together we reassessed the suitability of the previous feedback survey. This was then sent out to patient groups who had completed the submission template from July 2014 to November 2016. Additionally, public involvement staff telephoned selected patient organizations to increase the feedback response rate and gain greater understanding. The anonymised results were shared with patients involved in NICE who helped interpret the results from a patient organization’s perspective.

RESULTS:
Key findings are that patient organizations find:
- the template clear
- it was easiest to provide information about living with the condition
- it was hardest to give information on equality issues and research evidence.

They would also like a submission guide, and to receive feedback on their submissions.

CONCLUSIONS:
Although it was difficult to obtain feedback from the patient organizations on the submission template, the depth of information provided by them was fundamental to updating the template and producing a supporting guide.

This feedback on the local English needs can be used when evaluating the international submission template to form a greater part of the HTA ecosystem.

REFERENCES:
METHODS:
The European Cancer Patient Coalition (ECPC) developed a model for engagement of patients in HTA based on the experience from:

- ECPC’s ‘Value of Innovation in Oncology’ White Paper, which includes input from ECPC’s membership
- ECPC’s leading role in the Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle (PREFER) study, funded by the Innovative Medicines Initiative, to develop guidelines on how patient-preference studies should be performed throughout the development of new medical treatments.

RESULTS:
The ECPC ‘Value of Innovation in Oncology’ White Paper was launched in 2017. The paper provides ECPC’s policy position on key obstacles to equitable access to meaningful innovation. The paper recommends the establishment of an EU-wide HTA body to reduce delays and variations in access and to avoid duplication of effort by individual Member States. The paper also recommends that patients should be formally and routinely included in HTA policy and operations at EU and at national levels. These recommendations were also submitted to the European Commission’s public consultation on strengthening EU cooperation on HTA.

Through its work in PREFER, ECPC is helping to improve how patient preferences are measured and valued to capture the impact of health technology on patients daily life. Patient preferences are concerned with measuring how patients value components such as treatment end points, route of administration, treatment duration, treatment frequency, frequency of side-effects, price, and quality of life.

CONCLUSIONS:
Patient organization involvement in HTA is vital. Patient organizations offer unique insights, experiences, identify unmet needs, and can help to produce practical recommendations.

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VP061 Patients Views Of Health Technology Assessment At The National Institute Of Health And Care Excellence (NICE): Enhancing Involvement Opportunities

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ABSTRACT SUMMARY:
The National Institute for Health and Care Excellence (NICE) Health Technology Assessments (HTAs) involve patients throughout. We built on previous evaluation projects with more formal research into the views of patient organizations and individual patient experts on their involvement, including exploring barriers to involvement. Key findings and recommendations will be shared, including improving correspondence and new videos explaining decision-making in lay language. This research hopefully can inform the wider HTA ecosystem.

INTRODUCTION:
The National Institute for Health and Care Excellence (NICE) medicines health technology assessments (HTAs) involve patients throughout: scoping the topic, evidence submission, attending committee as ‘patient experts’, consultation and appeal. A 2013 Health Select Committee report stated “It is important for the credibility of NICE and for the decisions that it makes that the patient voice
is effectively and openly represented in all its work”. We thus wished to build on previous evaluation projects with more formal research into the views of patient organizations and individual patient experts on their involvement. We additionally sought to explore barriers to involvement.

**METHODS:**
The research was a collaboration between staff from three teams at NICE: public involvement, market research, and HTA committee support. A mix of interviews, focus groups and surveys was used to gather feedback – from patients and organizations who have engaged with NICE, but also those who had not, plus NICE committee chairs and staff. Facilitators and barriers to involvement were investigated, along with attitudes towards process and support. We used qualitative thematic analysis alongside quantitative methods.

**RESULTS:**
Key findings were that patients and patient organizations mostly:

- hold favourable opinions of NICE
- have a good understanding of process and expectations
- remain unsure of the impact of their inputs.

Improvements identified include clarifying communications, language and roles. Plus increasing transparency of decision making and patient impact.

**CONCLUSIONS:**
The research findings and action plan, although specific to NICE, hopefully can inform others in the wider HTA ecosystem. Resources developed will be shared with Health Technology Assessment International (HTAi) networks, including updated correspondence templates and new videos explaining decision making in lay language. The research further adds to discussions around appropriate use of patient organizations scarce resources, and how best to feedback to participants and demonstrate impact of patient involvement.

**REFERENCES:**

**VP062 Deciding On The Right Innovations: The Future Of The Patient Centric Approach**

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**ABSTRACT SUMMARY:**
By interviewing key people around the patient, we were able to get a complete mapping of the patient journey through our healthcare system. We identified at an early stage what were true patient needs for a population of comorbid elderly that could not speak for themselves.

**INTRODUCTION:**
How can decision makers in health care decide on new technologies? A patient centered approach may help them distinguish what innovations are based on true patient needs. By involving patients and their interests at an early stage, one can make decisions about a technology at a much earlier stage. How can decision makers in health care
decide on new technologies? A patient centered approach may help them distinguish what innovations are based on true patient needs. By involving patients and their interests at an early stage, one can make decisions about a technology at a much earlier stage.

The “Vel Hjem” project is a service innovation project aimed at discovering glitches and faults through the patient journey from home through hospital and back home for comorbid elderly patients. Normally, we would try to involve the patients in the project and use them to iterate our approach while doing the project. In this specific case, however, the target group was severely ill and could hardly complete an interview, much less be involved in our project group.

METHODS:
To obtain a picture of the patient journey through the health system, we identified four patients, interviewed them and everyone around them; next of kin, home nurse, general practitioner, nurses and doctors at the hospital. By penetrating actors around the patient, we were able to obtain the whole picture of needs for the patient.

RESULTS:
The patient voice disappeared in transitions between caregivers. Sometimes, next of kin or home nurses were able to speak on the patients behalf. In two cases, no one was present to do so, and consequently the care received by the patients where worsened.

CONCLUSIONS:
We identified at an early stage what were true patient needs for a population that could not speak for themselves and that we needed to strengthening communication between actors to strengthen their voice.

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**VP063 National Institute For Health And Care Excellence (NICE) Technology Appraisal Patient Expert Expert Feedback: 15 Month Analysis**

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**ABSTRACT SUMMARY:**
A National Institute for Health and Care Excellence (NICE) 2014 report on Health Technology Assessment (HTA) Patient Experts experiences identified a need to routinely survey patient experts. This has been ongoing since October 2015. Responses demonstrate that progress has been made since 2012, although some tensions remain between NICE’s remit and processes, and patients expectations of these. We continue to routinely measure experiences to identify and address evolving issues.

**INTRODUCTION:**
The National Institute for Health and Care Excellence (NICE) has a formal policy stating patients, carers and citizens are involved throughout each Health Technology Assessment (HTA). One key way patient/carer organisations are involved is by nominating patient experts to participate in appraisal committee meetings.

A NICE 2014 report (1) on Patient Experts experiences identified a need to routinely survey Patient Experts. This has been ongoing since October 2015. This study highlights key findings, including new recommendations and whether previous concerns have been addressed.
METHODS:
We refined the 2012 survey to be routinely sent to all patient experts that attended a NICE technology appraisal committee meeting. Between October 2015 and December 2016 this online survey was sent to eighty-eight patient experts. After analysis, the findings were compared to the previous report to identify whether concerns have been addressed and whether new recommendations should be considered.

RESULTS:
There was a response rate of 47 percent (n=41). Quantitative results and qualitative quotes demonstrate that patient experience varies widely. Key findings from the new data revealed that patient experts feel supported by the Public Involvement Programme, however would welcome more opportunities to speak. Notable improvements since 2012 include favourable opinions of support documents and the Chair more regularly introducing themselves to the patient expert before the meeting. Some experts still find the paperwork cumbersome and find the meetings very technical.

CONCLUSIONS:
Progress has been made since 2012, but further improvements could facilitate even more effective patient involvement. We continue to routinely measure experiences to identify and address evolving issues. Some tensions remain between NICE’s remit and processes, and patients expectations of these. The findings, although specific to NICE, hopefully can feed into other patient involvement developments in the wider HTA ecosystem.

REFERENCES:

VP064 Post-graduation Selection Using Multi-Criteria Decision Analysis

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ABSTRACT SUMMARY:
This study aims to describe the use of Multicriteria Decision Analysis in the selection of candidates for master degree program in health technology assessment (HTA). The highest weight (24 percent) was attributed to the “Potential to work in HTA area”.

INTRODUCTION:
Selecting candidates for graduate programs is considered to be a complex task, often subject to failures, especially regarding to the appraisal of non-cognitive (1,2) skills (for example, Motivation). Identifying suitable candidates is important for the overall success of the graduate programs, since dropouts and low productivity negatively affect the program classification by the Brazilian Governmental Agency.

This study aims to describe the use of Multicriteria Decision Analysis (3) in the selection of candidates for a master degree program in Health Technology Assessment (HTA).

METHODS:
The Multicriteria Decision Analysis (MCDA) technique was used to measure value in the selection of students applying for a masters degree program, in 2017, using Multi-Attribute Value Theory methods (MAVT) method. The examiners group consisting of full-time professors who selected the criteria, blinded ranked and assigned
weight relative to each criterion, using swing weights technique, normalized to 100 percent. During the face to face interview with the students, each evaluator professor filled an individual spreadsheet based on pre-defined questions and curriculum analysis. The results were summarized with a mean. For criterion performance, a value from 0 until 3 was assigned if the candidate didn’t meet the criterion, partially meet and fully meet. The performance scores were multiplied by the weight of each criterion, the results were summarized by simple additive model, and the candidates were ranked.

RESULTS:
An interview was conducted with the examining group evaluating MCDA asking for difficulties, time consumed and if the result was considered fair. Seven criteria were listed: “Comprehension of HTA”, “Motivation”, “Ability to disseminate information”, “Availability to attend the course”, “Scientific production”, “Potential to work in HTA area” and “Scientific writing skills”.

The highest weight (24 percent) was attributed to the “Potential to work in HTA area” and “Scientific writing skills” (20 percent). The evaluating group was unanimous in considering the process easy, fast and fair.

CONCLUSIONS:
The MCDA technique was applied successfully in student selection. Further prospective studies are needed.

REFERENCES:


VP065 A Clearinghouse For African Health Technologies

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ABSTRACT SUMMARY:
An Health Technology Assessment (HTA) competency center represents a natural extension to the vision set out in the Pharmaceutical Manufacturing Plan for Africa (PMPA). The harmonization of medicines regulation in Africa will put pressure on healthcare providers and their healthcare systems to make informed choices on what technologies they can afford to make available.

INTRODUCTION:
An Health Technology Assessment (HTA) competency center represents a natural extension to the vision set out in the Pharmaceutical Manufacturing Plan for Africa (PMPA) by serving as a preparedness mechanism that helps to enable access to affordable and high quality medicines and medical technologies across Africa. The continent’s impending harmonization of the regulatory approval process for medicines will ultimately put pressure on healthcare service providers and health system administrators to make informed and timely decisions on which specific technologies (medicines, diagnostic tests, medical devices) they allow access to by the patients in their healthcare systems.
METHODS:
Extant (country-specific) health technology and regulatory mechanisms as well as nascent pan-national bodies are reviewed in terms of their capabilities, mandates and effectiveness; and (cases of) specific technologies are examined in light of these mechanisms and decisions rendered/anticipated.

RESULTS:
A “clearinghouse” for health technologies would permit decision makers to make the most efficient use of the evidence base on health technologies and treatment practices in Africa, while also potentially serving as a passive broker of innovative technologies. The availability of a neutral African regional perspective on the costs, benefits and priorities of innovative therapies would be highly useful, for example, in the current consideration of Mosquirix, the GSK malaria vaccine recently granted marketing authorization by the European Medicines Agency (EMA) and expected to be recommended by the World Health Organization (WHO).

CONCLUSIONS:
An HTA function dovetails with increasing African engagement in healthcare management and governance; and offers the potential to collaborate closely with global counterparts for advocacy and best-practice sharing. As governments in many of the countries on the continent gradually take on the responsibility of providing health care for their populations, there will be a crucial need for objective evidence-based guidance to aid their decision-making on which technologies and services to take up.

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VP066 Perception Of Decision Makers And Researchers Towards Health Technology Assessment In Ghana

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ABSTRACT SUMMARY:
Ghanaian policy makers are moving towards the use of Health Technology Assessment (HTA) for decision making in the health system. This study aimed at assessing the knowledge and perception of decision makers and researchers towards the use of HTA. This is to provide useful information for the planning and development of an HTA agency to ensure uptake and expected impact in the health system.

INTRODUCTION:
In recent years, the Ghana health system has been faced with the challenge of financial sustainability. New ways of making decisions in a cost-effective manner that ensure efficient use of available resources is being explored. Consequently, Ghana has been pursuing the formal introduction of Health Technology Assessment (HTA) for decision making in the health system.

However, the limited use and impact of HTA on health systems has been associated with reasons including, and not restricted to, the knowledge and perception of decision makers towards it (1-3). Therefore as Ghana gears towards using HTA formally, it is important to assess the knowledge and attitude of potential users and producers of HTA. This will provide useful information for the setting up of an HTA agency.
METHODS:
A qualitative research approach using in-depth interviews was utilised. Twenty-three decision makers both at the national and district levels, and four researchers were interviewed. Thematic analysis was conducted using NVivo software.

RESULTS:
Only seven respondents had knowledge about HTA. Respondents perceived HTA differently, and the word ‘technology’, was often misconstrued as a device for communication such as mobile phone. Two main barriers to the use of HTA emerged; lack of resources (human, data, and finance) and politico-cultural issues. To address these barriers respondents recommended that stakeholders be involved in decisions concerning the guidelines for its conduct, composition of the appraisal team, and the focus of HTA. Generating of human, data and financial resources were also indicated.

CONCLUSIONS:
There is paucity of knowledge about HTA in Ghana. For Ghana to successfully introduce HTA for health decision making and realise its expected benefits, there will be a need to address the perceived barriers in a comprehensive manner. Also, to mitigate data and human resource barrier, Ghana will have to examine the available local data and human resource to build on.

REFERENCES:

VP067 The Value Of The European Network For Health Technology Assessment (EUnetHTA) Outputs For National Health Technology Assessment: The French Experience

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ABSTRACT SUMMARY:
The French national authority for health has actively participated in different EUnetHTA projects since the network’s creation. This report presents a summary of the agency’s contribution to EUnetHTA projects, and their value and impact for national HTA production.

INTRODUCTION:
The French National Authority for Health (HAS) has participated in the work of the European Network for Health Technology Assessment (EUnetHTA) since its creation in 2006. HAS has been an active partner in most EUnetHTA activities, and the lead partner of specific work packages.

METHODS:
This report presents a summary of the main contribution of HAS to the two latest EUnet-HTA projects (Joint Action (JA) 1 and Joint Action 2 (JA2)), their impact on national production, and Health Technology Assessment (HTA) doers feedback as to the opportunities and challenges of participating to the network and using its outputs.
RESULTS:
In JA1 and JA2 projects, HAS has: coordinated activities related to Early Dialogues and Additional Evidence Generation; coordinated the development of nine JA1 methodological guidelines for rapid relative effectiveness assessment (REA) of pharmaceuticals; participated in the production of two JA2 methodological guidelines; participated in the production of one JA1 and seven JA2 rapid REA reports, and two JA2 full HTAs.

The national uptake of EUnetHTA outputs included entire adoption of one REA report and adaptation of another. EUnetHTA templates and methodological guidelines have been taken into account when updating or developing national ones. Thanks to the network, HAS HTA doers could exchange on ongoing assessments with European colleagues, have enhanced their methodological know-how and enlarged their professional network.

As for the challenges encountered, it turned out that the re-use of EUnetHTA reports for a technology of interest to HAS was not always possible, mainly due to discordances in deadlines or assessment questions between EUnetHTA and national productions.

CONCLUSIONS:
HAS has actively participated in different EUnetHTA projects since the network’s creation. This collaboration has enabled HAS HTA doers, among others, to optimize national assessments and enhance their methodological know-how.

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ABSTRACT SUMMARY:
The objective of this study was to identify the scientific collaboration relationships between the authors who produced and disseminated the HTA studies registered in the period of 2009 to 2014. The social network analysis was the methodology employed. The study showed that REBRATS demonstrated capacity of interaction between the researchers and conducting health technology assessment studies.

INTRODUCTION:
The Brazilian Network of Health Technology Assessment (REBRATS) is formed by educational and research institutions dedicated on the generation and synthesis of scientific evidence to assess effects and efficiency of technology for Unified Health System (SUS). The objective of this study was to identify the scientific collaboration relationships between the authors who produced and disseminated the Health Technology Assessment (HTA) studies - Systematic Reviews, Rapid Reviews, Economic Evaluation - included in the REBRATS Information System, registered in the period of 2009 to September 2014.

METHODS:
The social network analysis (SNA) was the methodology employed to identify the collaboration between the authors of the studies. A co-authoring matrix was used based on the mirror of the SISREBRATS database. We analyzed the degree of authors (number of collaborations) equal to or greater than twenty-nine. This cut-off point was considered to facilitate the visual analysis of the most collaborative authors. The usual SNA indicators were divided into centrality measures and were used to verify how much one node (author) is more important than the other nodes in the network.
RESULTS:
The network shows 1,094 authors (nodes) and 4,998 edges (relationships) and 396 studies produced in Portuguese. One researcher collaborated on average with nine other researchers. This performance strengthens the capacity of conducting HTA studies.

CONCLUSIONS:
There is an expressive capacity of interaction between the researchers of REBRATS. This interaction allows more efficient sharing of knowledge and information, and can contribute to management, regulation and health care provided under the SUS.

VP069 Mapping Brazilian Nuclear Medicine Installed Capacity And Perspectives

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ABSTRACT SUMMARY:
To investigate the Brazilian Unified Health System (SUS) outpatient access to nuclear medicine procedures through SUS data comparison with those from the National Commission of Nuclear Energy (CNEN: Comissão Nacional de Energia Nuclear).

METHODS:
Data provided by the SUS outpatient database (SIA-DATASUS) regarding procedures performed from 2013 to 2016 was compared with data from institutions (Nuclear Medicine Services and Cyclotron Facilities) and radioprotection supervisors with numbers certified by CNEN.

RESULTS:
CNEN has authorized 420 nuclear medicine institutions (.20 per million inhabitants) and certified 294 radioprotection supervisors (.14 per million inhabitants), and 1.4 services per supervisor. There are 457 graduated professionals qualified for radioactive sources preparation, use and handling for diagnostic and therapeutic radiopharmaceuticals (.9 professionals/installation). During the last four years, just 08 new nuclear medicine facilities were authorized by CNEN according to its public official website. The number of nuclear medicine procedures performed slightly increased in the South, but remained constant in other regions. Annual SUS reimbursements increased by 21.2 percent on average for the 03 PET/CT (Positron emission tomography–computed tomography) adopted procedures: regional analysis showed the Central-West as the highest growth area (70.8 percent), compared to the South (53.4 percent), North-East region (30.8 percent), and the South-East (5 percent). Currently, thirteen Cyclotron Facilities operate in Brazil: South-East (six), South (three), North-East (three) and Central-West (one). Some nuclear medicine procedures largely outnumber the average increase: for example, reticuloendothelial system scintigraphy (513.9 percent), gastric transit scintigraphy (112.8 percent), and thyroid screening with suppression/stimulation test (100.6 percent). However, myocardial scintigraphy (stress and rest) and bone scintigraphy with or without blood flow still
correspond to 82 percent of total nuclear medicine in vivo procedures.

CONCLUSIONS:
Regional disparity is quantitatively depicted in Brazil and reflects access to SUS nuclear medicine procedures. This denotes a potential for improvements related to nuclear medicine areas, for example developments concerning new PET/CT coverage, new radiopharmaceuticals research, and national and international training.

VP070 Structuring The Process Of Innovation Uptake In Tunisia

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ABSTRACT SUMMARY:
In many low and middle-income countries decisions on health technologies implementation are taken at different places and they are not informed, generating inefficiency in the overall process and inequity in the access to services. By means of the EuroScan toolkit, this research explores the possibility of improving such a process in a Middle-Income Country.

INTRODUCTION:
Tunisia recently implemented a Health Technology Assessment (HTA) agency (INASanté) to inform decisions around health technologies and to improve clinical practice by means of the elaboration of Clinical Practice Guidelines (CPG). However, many decisions on new and emerging technologies, their implementation and coverage in the health care system are still taken at the hospital level without any structured process that informs the decisions. The aim of this project was to improve the methods and flow-chart of decision-making processes on innovation uptake in the Tunisia Healthcare System.

METHODS:
By means of the toolkit of EuroScan for the implementation of an early awareness and alert system (EAAS), and its checklist, it was discussed specifically within INASanté the characteristics of the Tunisia Healthcare System and its specificities regarding decisions on drugs and medical devices. The analysis included the process of innovation uptake at the hospital level and its specific flow-chart. In depth interviews and a devoted workshop were performed with personal in INASanté: two physicians (one involved in CPG elaboration and the second in accreditation), three pharmacists (HTA), one nutritionist (HTA), two librarians and other stakeholders, including the Directorate of Hospitals.

RESULTS:
The uptake of innovations in Tunisia does not follow a structured process. In fact, there is no central purchase of medical devices in Tunisia and most medical devices are purchased by hospitals within a tender process in accordance with the Tunisian public procurement law. The main pitfalls are: lack of awareness around innovations that could impact the system, non-structured process of information sharing among the different decision-makers that promotes inequity in access to technologies and services, and lack of explicit criteria that determine decisions around health technologies.

CONCLUSIONS:
Tunisia requires a structured and informed process on decisions around innovation uptake in the
healthcare system. The principles that should govern this system are: anticipation of the impact of new health technologies, establishing priorities and criteria for decision making in all places of decision. The decisions should be recorded and publicly shared to avoid inequities in the access to technologies.

VP071 Health Technology Assessment In Japan: Current Issues And Challenges

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ABSTRACT SUMMARY:
Japan plans to introduce Health Technology Assessment (HTA) in 2018. A pilot-based HTA is currently implemented for certain innovative products to examine conditions prior to full-scale introduction. A survey was conducted with the Japanese pharmaceutical industry, and differences between Japanese and non-Japanese pharmaceutical companies were observed. Critical issues were raised due to HTA personnel shortages, which may affect its implementation.

INTRODUCTION:
Japan plans to introduce Health Technology Assessment (HTA) in 2018 after a two-year trial period. Japan currently requires HTA for certain innovative products which may have a large budget impact. Through this trial implementation, the government can examine the criteria of applicable products, the necessary infrastructure to conduct and evaluate HTA, the quality of data content, and localization to meet the current Japanese reimbursement and pricing scheme. However, the pharmaceutical industry in Japan is still puzzled by this introduction. The aim of this study is to visualize the issues and implementation challenges of HTA in Japan through a survey of the pharmaceutical industry.

METHODS:
A semi-structured nineteen-item questionnaire was designed and the survey was conducted through face-to-face or phone interviews. Answers were summarized after the interview and confirmed with the respondents via e-mail. The survey focused on pharmaceutical companies which develop new innovative products.

RESULTS:
The differences between Japanese and non-Japanese pharmaceutical companies were observed in terms of HTA staff expertise and experience, the source of HTA data, and relationships with external vendors. Many respondents stated that a sufficient number of HTA professionals in Japan is critical to implement HTA, and raised a concern that the same public experts who are involved in HTA preparation may also review HTA submissions. Although companies are generally pessimistic about HTA for pharmaceutical pricing, they also have some positive views that HTA may be used as an indicator to enable stakeholders to understand product value. Many are unsure about the link between HTA and pharmaceutical prices.

CONCLUSIONS:
If HTA is implemented for an extended number of products, a shortage of experts may cause delays of HTA review and appraisal processes. Consequently, product launch and patient access will be delayed. Practical timing of HTA review and appraisal after product launch could affect the results of re-pricing.
VP072 Development Trend Analysis On New Health Technology: Based On Euroscan

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ABSTRACT SUMMARY:
Based on the international information network on new and emerging health technologies (EUROSCAN), this article analyzed the early assessment reports of new and emerging health technologies during 2000-2016 published in the EUROSCAN database, in order to reflect the 21st century development trend of the emerging health technologies.

INTRODUCTION:
Emerging health technologies (EHT) are important to meet the challenges faced by healthcare systems but a major pressure on health systems as well (1). The International Information Network on New and Emerging Health Technologies (EUROSCAN) is a collaborative network to manage the introduction of EHT and share information on the results of early identification and assessment of EHT (2). This article analyzed the early assessment reports of EHT during 2000-2016 published in the EUROSCAN database (3), in order to reflect the 21st century development trend of the EHT.

METHODS:
The EHT report data was downloaded by researchers from the official website of the EUROSCAN and arranged using Excel 2007. A descriptive analysis on the number and growth rate of EHT, distribution of technology type and specialties, developmental trend of the integrated technologies were conducted with SAS 9.3.

RESULTS:
Health technology early assessment reports (3,151) have been published in the past 17 years, of which drugs had the highest proportion (57.06 percent). Most of new and emerging health technologies were adopted in oncology and radiotherapy (33.74 percent). The average growth rate every 4 years of EHT from 2001 to 2016 was 24.2 percent, the fastest-growing period was between 2005 and 2008 (Ring growth 57.38 percent). Rehabilitation & disability was the fastest-growing EHT specialty (111.47 percent) and the integrated technologies was the fastest-growing EHT type (45.34 percent).

CONCLUSIONS:
With the objective needs of effective technologies to deal with cancer and chronic disease, as well as the revolution of science, EHT were in the process of vigorous development, especially oncology & radiotherapy technologies. The integrated technologies and the ones applied in multidisciplinary areas have become a new spotlight. Early identification and timely assessment of new and emerging health technologies has aroused wide public concern. It is suggested to establish an Early Awareness and Alert System in China.

REFERENCES:
VP073 Primary Health Care Structure Evaluation For Prenatal Care In Brazil

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ABSTRACT SUMMARY:
Primary Health Care is the main gate for Public Health Service in Brazil. Prenatal care is one of the most important tasks in Primary Health. Qualified prenatal care needs proper health care unities structure issues. This study aimed to describe structure units evaluation in the context of prenatal care in a Brazilian city using data from a specific tool.

INTRODUCTION:
Primary Health Care is the main gate for Public Health Services in Brazil. Low risk prenatal care is one of the most important tasks in Primary Health Care. Qualified prenatal care needs proper health care unities structure issues. This study aimed to describe variables related to structure, comprehending physical, human and material resources, and organizational issues, in the context of prenatal care offered by Family Health Care, in Niteroi city, in Rio de Janeiro State.

METHODS:
A crosssectional study was conducted using data from a National program for Improving primary health care access and quality, an external evaluation tool applied by Ministry of Health from 2012 to 2013. There were sixty-nine interviews with health professional teams from twenty-seven health units in Niteroi city, Brazil. This tool covered the following five dimensions to evaluate unit structure for proper prenatal care: human resources, physical unit, equipments and supplies, guidelines and service network.

RESULTS:
The results showed that 34.8 percent professionals worked for less than one year in the local health unit and less than 40.0 percent had training related to Family Health Care. An average of 1,863 inhabitants was assisted by each one of the 69 health teams. Institutional supervision was referred by 94 percent of the professionals. Few units had proper accessibility equipment. Specific equipment and supplies for prenatal care, anti-tetanus and anti-hepatitis B vaccines, scheduling appointments for ultrasonography were present at almost all the units. Regarding to sexually transmitted infections treatment, many components were absent in the units. Organizational issues analysis revealed that 31.9 percent had defined guidelines for early identification of pregnant women or for intercurrences during pregnancy. Among health teams, 13.0 percent referred not having a maternity schedule for deliveries.

CONCLUSIONS:
This evaluation tool was useful to access units structure for proper prenatal care. There is a need for improvement in accessibility, management, mainly in organizational issues, and reference for maternity. Other structure issues were adequate in Niteroi Family Health Care units, offering good conditions for prenatal care.

VP074 Russian System Of Medicines Provision: Status And Future Aspects

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ABSTRACT SUMMARY:
Russian system of medicines provision is one of the biggest in the world and, probably, one of the most complicated. In this paper, we make an effort to clarify main principles and aspects.

INTRODUCTION:
Russian system of medicines provision is one of the biggest in the world. It covers 85 regions, around 17.1 million square kilometers and 146.5 million people; therefore, the organizing of a stable and effective system is a challenge for decision makers. In this paper, we make an effort to clarify main principles and aspects.

METHODS:
To systemize all the information concerning Russian medicines provision system, we review legislation, literature and made interview of experts.

RESULTS:
By 2015 more than 3,230 International Nonproprietary Names and 26,239 Trade names were registered in the Russian Federation. The pharmaceutical market consists of the commercial drug sector, drug reimbursement and hospital sector: 8 percent, 22 percent and 70 percent in monetary values and 1 percent, 19 percent and 80 percent in volume terms, respectively. Medicines provision through compulsory health insurance is divided into in-patient health services (first health and sanitary treatment, special health treatment and palliative treatment) and emergency services. Three drug lists form the reimbursement system: “list of vital and essential medicines”, “7 disease areas” and “Medicines provision population”. The “List of vital and essential medicines” is a basis for all other drug lists and fixes the maximum sale price for drugs. The “7 disease areas” detach high-priced drugs that are used in treatment of particular diseases and optimize the financing of treatment of people with high-cost diseases. The “Medicines provision for population” states the list of drugs that are reimbursed by the federal budget. Federal and regional budgets divides medicines into fully and partly reimbursed medicines.

CONCLUSIONS:
At the present time, the Russian system of medicines provision is rather complicated. Nevertheless, the system still develops: in 2016 Russian Ministry of Health began the development of the concept of medicines insurance system.

VP075 CEA Of Pneumococcal Vaccination In Immunocompromised Adults In Taiwan

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ABSTRACT SUMMARY:
This study aimed to evaluate the cost-effectiveness of PPV23-PCV13 sequence versus PPV23 alone vaccinations for immunocompromised adults. Micro-simulation model for 70 years of time horizon was applied to examine cost-effectiveness using societal perspective and all parameters were derived from published literature, government statistics and databases. In summary, PPV23-PCV13 sequence vaccination of immunocompromised adults could be cost-saving in Taiwan.

INTRODUCTION:
In 2012, the advisory committee on Immunization Practices (ACIP) in USA recommended
13-valent pneumococcal conjugate vaccine (PCV13) for immunocompromised adults. Furthermore, the ACIP also recommended that immunocompromised adults who already received 23-Valent Pneumococcal Polysaccharide Vaccine (PPV23) should receive a dose of PCV13 (PPV23-PCV13 sequence). However, the cost-effectiveness of PPV23-PCV13 sequence vaccination to immunocompromised adults is not clear. The aim is to predict the cost-effectiveness of PPV23-PCV13 sequence vaccination versus PPV23 alone vaccination for immunocompromised adults in Taiwan.

**METHODS:**
Micro-simulation model approach using societal perspective was applied to examine the cost-effectiveness of PPV23-PCV13 sequence vaccination versus PPV23 alone vaccination for immunocompromised adults. A modelling horizon is 70 years, considered lifetime for adults, and all parameters in our micro-simulation model were derived from published literature, government statistics, and Taiwan’s National Health Insurance Database. Results of the micro-simulation model were expressed by the incremental cost-effectiveness ratio (ICER) to illustrate the incremental cost (in New Taiwan Dollars, NTD) for one additional life-year (LY) gained. Sensitivity analysis was applied to test the robustness of the results of the micro-simulation model.

**RESULTS:**
Discounted life-years per person for PPV23 alone vaccination was slightly higher than that for PPV23-PCV13 sequence vaccination (21.2594 versus 21.2576) while the total medical cost per person for PPV23 alone vaccination was significantly higher than that for PPV23-PCV13 sequence vaccination (114,657 NTDs versus 113,401 NTDs). Compared with PPV23 alone vaccination, the ICER for PPV23-PCV13 sequence vaccination in immunocompromised adults was about 700,000 NTDs per LY gained.

**CONCLUSIONS:**
Compared with PPV23 alone vaccination, vaccination of a single dose of PPV23 followed by PCV13 can prevent more deaths, outpatient visits and hospitalizations due to pneumococcal infection resulting in lower total costs including direct medical and indirect costs. In overall, PPV23-PCV13 sequence vaccination of immunocompromised adults would be cost-saving in Taiwan.

VP076 European Collaboration In Health Technology Assessment: Experiences And Possible Benefits

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**ABSTRACT SUMMARY:**
Experiences and benefits of European collaboration in medical device assessment are described. Challenges include the choice of topics and timing of reports. The wide implementation of jointly established methods and quality standards is crucial. Benefits for stakeholders comprise an increase in quality of reports, a harmonised and transparent assessment process and a resource-efficient assessment of a bigger amount of technologies.

**INTRODUCTION:**
Consistently high-quality health care is expected throughout Europe while concurrently, financial resources of member states are decreasing. National Health Technology Assessment (HTA) institutes are informing evidence-based reimbursement decisions in the national context,
leading to redundancies in HTA production and tying up limited resources. Since 2006, the European Union project, the European Network for HTA (EUnetHTA) is aiming at enhancing the efficient use of HTA resources and facilitating transnational collaboration. Our aim is to present previous experience in joint assessment of medical devices. Furthermore, possible benefits of European collaboration for stakeholders will be discussed.

METHODS:

Processes and challenges of the completed EUnetHTA Joint Action (JA) 2 are summarised and discussed. Benefits, aims and opportunities of the ongoing EUnetHTA JA 3 are described.

RESULTS:

Six rapid assessments of medical devices, focusing on the assessment of effectiveness and safety, were published during EUnetHTA JA 2. Challenges in European medical device assessment encompass the choice of topics, the time point of assessments and the lack of European standards for systematic patient involvement. Characteristics of medical devices, like learning curves, call for monitoring them throughout their lifecycle.

The benefit of European collaboration for stakeholders is manifold: uncertainty with regard to actual added value of a technology is minimized through Early Dialogues; harmonized and transparent assessment processes increase the quality of reports; work division among HTA organizations allows a resource-efficient assessment of a bigger amount of technologies; patient involvement ensures consideration of patient relevant endpoints.

The importance of cross-border collaboration in HTA is shown in the continuation of the EUnetHTA project, which aims to sustainably strengthen international collaboration even after expiration of EU-funding.

CONCLUSIONS:

European collaboration in medical device assessment can ensure cross-border health care and efficient cooperation of national health systems. The focus should be set on a wide implementation of jointly established methods and quality standards. The European collaboration can lead to a concrete benefit for various stakeholders.

VP077 Listen, Learn, And Adapt: Engagement Of EUnetHTA’s Stakeholders

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ABSTRACT SUMMARY:

There are numerous stakeholder groups with which the European Network for Health Technology Assessment (EUnetHTA) interacts, including patients, clinicians, manufacturers, regulators, and payers – all of whom have a unique perspective to provide regarding EUnetHTA’s activities. Input from stakeholders has shaped the evolution of EUnetHTA products and processes. In this presentation, specific examples will be discussed.

INTRODUCTION:

For over 10 years, European countries have been collaborating to develop reliable, timely, transparent, and transferable information to support health technology-related policy and decision making. The European network for Health Technology Assessment (EUnetHTA) was established to further strengthen the scientific cooperation on Health Technology Assessment (HTA) across Europe. This collaborative approach brings added value at the European, national,
and regional levels by encouraging efficient use of resources for HTA. To date, EUnetHTA has developed tools aimed at facilitating collaboration between HTA agencies Europe and has successfully produced twenty joint assessments. In the current phase of work, the focus is on increasing the production and subsequent uptake of high-quality HTA joint work.

**METHODS:**
There are numerous stakeholder groups with which EUnetHTA interacts, including patients, clinicians, manufacturers, regulators, and payers – all of whom have a unique perspective to provide regarding EUnetHTA’s activities. In the previous phase, feedback was requested from all participants (for example, manufacturers, authors, reviewers, etc.) in the process following each joint assessment. In addition, more recently feedback has been received via bilateral meetings between particular stakeholder groups and the EUnetHTA directorate. Input from stakeholders has shaped the evolution of EUnetHTA products and processes. In this presentation, specific examples will be discussed.

**RESULTS:**
Specific examples of stakeholder-led change include: a shift in focus on rapid rather full relative effectiveness assessments; a focus on timely completion of assessments with a goal of aligning timelines with market authorisation; and an emphasis on implementation of EUnetHTA’s products (specifically joint or collaborative assessments) at the national/regional level.

**CONCLUSIONS:**
Listening and responding to stakeholders in the HTA space is key to a successful European HTA collaboration. Indeed, involvement of and feedback from stakeholders has helped to shape EUnetHTA processes and products, and contributes to continuous improvement towards a high-quality and relevant product.

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**VP078 Cross-Country Variation In Health Technology Assessment Preferences: An International Survey**

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**ABSTRACT SUMMARY:**
Health Technology Assessment (HTA) coverage decisions vary across countries for the same product despite similar assessment methodologies. Agency-specific risk and evidentiary requirement preferences might underlie such variation. An international survey of HTA stakeholders preferences demonstrated cross-country prioritization differences in a number of clinical and economic criteria, and a greater variation in how countries valued unmet need and innovation in HTAs.

**INTRODUCTION:**
Several studies have explored how Health Technology Assessment (HTA) processes, HTA submission requirements, perception and handling of uncertainties vary across different jurisdictions (1-3). However, no study has elicited HTA stakeholders’ preferences/priorities on criteria that shape coverage decisions across countries. We aimed to identify the extent to which preferences on criteria, uncertainties and other factors that shape HTA recommendations differ across countries.

**METHODS:**
HTA stakeholders in Brazil, England, France, Italy, Netherlands, Spain and Sweden were invited via email to complete a web-survey. A number of clinical, economic and other criteria (that is, rarity/orphan status and stakeholder input, among others)
considered in HTAs, along with additional factors related to clinical evidence uncertainties, unmet need and innovative nature of treatment were ranked in terms of their importance on a 7-point Likert-scale. Responses were anonymised and analysed using descriptive statistics.

RESULTS:
Responses were received from Brazil (n=9), England (n=7), France (n=10), Italy (n=6), Netherlands (n=3), Spain (n=3) and Sweden (n=3). “Achievement of/Concerns around clinical benefit” was the only clinical criterion/uncertainty scoring equally important across countries (100 percent of respondents in each country). The requirement for/uncertainty around “Appropriate comparators” scored high in importance overall but was not consistent across countries, nor was the “Acceptability of surrogate rather than clinical endpoints”. Variation was seen in all economic criteria, apart from “Budget impact analysis” (equally important for more than 80 percent of respondents in each country). Greater differences were observed in the level of priority that innovation, disease severity and stakeholder input have towards HTA coverage decisions across countries.

CONCLUSIONS:
Although agreement was seen in preferences mostly for some of the clinical criteria and/or evidentiary requirements ranked, there were notable differences on countries’ priorities for economic evidence criteria/uncertainties and the extent to which unmet need, disease burden and innovation are considered important towards HTA decision-making, possibly explaining differences in HTA recommendations.

REFERENCES:

VP079 Primary Health Care Assessment With Primary Care Assessment Tool (PCATool) In Brazil

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ABSTRACT SUMMARY:
Primary Care Assessment Tool (PCATool) has been used worldwide to evaluate the extent of Primary Health Care (PHC) regard to access to first contact, continuity, coordination of care, comprehensiveness, community orientation, and family orientation. This study aimed to analyze the evaluation of PHC attributes of Brazilian FHC units by using PCATool.

INTRODUCTION:
Primary Care Assessment Tool (PCATool) has been used worldwide to evaluate the extent of Primary Health Care (PHC) regard to access to first contact, continuity, coordination of care, comprehensiveness, community orientation, and family orientation. There are no other validated instruments that aim to measure the presence and the extension of PHC
attributes in different national health services in Brazil, from the perspective of health users, health professionals and health managers. PCATool may be used to evaluate and monitor PHC quality in the scope of Family Health Care in Brazil. This study aimed to analyze the evaluation of PHC attributes of Brazilian FHC units by using PCATool.

METHODS:
A review was conducted in 2016, through the databases BIREME, LILACS and PUBMED. The descriptors used were “Family health care”, “Primary health Care”, “Public Health”, and “PCATool”. There were included only articles that approached FHC in Brazil, published at any year or language.

RESULTS:
There were identified forty-one studies, published between 2006 and 2014. The studies were conducted mainly in Brazil South Region (39 percent), and 71 percent evaluated only health user’s perspective. Regarding the PHC attributes, 66 percent evaluated all of them, and the worst attribute measured by PCATool was access to first contact, even in health units with FHC. There are still some obstacles hindering user access to PHC services.

CONCLUSIONS:
We suggest that more studies should be developed in Brazil using PCATool, measuring all PHC attributes and assessing the perspective of health users, healthcare professionals and health managers at the same time. This will contribute to compare Brazil evolution to other countries regard to PHC quality and effectiveness.

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ABSTRACT SUMMARY:
FACT-B is a widespread breast cancer specific quality of life instrument, and theoretically, has higher sensitivity than generic ones. However, the FACT-B scores can’t be directly converted into health utilities which are important for cost-utility analysis. Based on a large multicenter cross-sectional survey of 2,525 cancer patients in China, this study aims to develop mapping models to estimate EQ-5D when only FACT-B is assessed.

INTRODUCTION:
The Functional Assessment of Cancer Therapy-Breast (FACT-B) is a widespread breast cancer specific quality of life instrument, and theoretically, has higher sensitivity than generic ones. However, the FACT-B scores can’t be directly converted into health utilities which are important for cost-utility analysis. The aim of the study was to develop models for mapping FACT-B scores to the EuroQol-5D (EQ-5D) utility scores.

METHODS:
A total of 2,525 breast cancer patients in 12 provinces across China were interviewed with the two instruments in 2013-2014. The FACT-B scores were standardized to 0-100, and EQ-5D
utility scores were generated by Chinese value set. Responses were randomly divided into development (n=1,263) and validation (n=1,262) datasets with equal distributions. Three models were applied, including ordinary least squares (OLS), generalized linear models (GLM), and censored least absolute deviations (CLAD). Subscales of FACT-B and some key variables were entered the regression models successively. The main predictive indicators included root mean squared error (RMSE), mean absolute error (MAE), and correlation coefficient with the observed scores (R).

RESULTS:
The mean of FACT-B scores and EQ-5D utility scores were 42.4±9.0 (range: 2.7-74.3) and .780±.2 (range: -.149-1.000), respectively. All the FACT-B subscales were highly correlated with EQ-5D (p<.05), except subscale of social well-being. When considering FACT-B subscales only, the GLM model performed the best among the three models (RMSE=.191, MAE=.147, R=.480), with the physical and functional well-being subscales significantly predictive. After adding variables of education, clinical stage, and interview time point, the best performance was observed in the OLS model (RMSE=.190, MAE=.146, R=.482).

CONCLUSIONS:
Mapping approach might be a solution to obtain utility scores from FACT-B data. The GLM model is recommended when only FACT-B subscales data is available, while the OLS model could be an option when more variables are existed.

VP081 Health Technology Assessment And Rare Disease Decision Making: Focus On Orphan Drugs

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ABSTRACT SUMMARY:
Health technology assessment (HTA) is applied to determine the value of innovative technologies. HTA usually relies on robust assessment of the clinical cost-effectiveness of the technology, while clinical and economic evidence required for this purpose are often not available for orphan medicinal products.

INTRODUCTION:
Health Technology Assessment (HTA) is applied to determine the value of innovative technologies. It usually relies on robust assessment of the clinical cost-effectiveness of the technology, while clinical and economic evidence required for this purpose are often not available for orphan drugs (OD) (1,2). The objective of the study is to undertake a systematic comparison between HTA agencies worldwide in order to identify similarities and differences in the methods and processes in HTA of OD.

METHODS:
A cross-sectional web-based survey was conducted between September 2013 and May 2015. The data were obtained from a semi-structured questionnaire. We received responses from 161 HTA organizations based in 39 countries.
RESULTS:

HTA of OD is performed by agencies in South America (38.5 percent), followed by agencies in Australia (37.5 percent) and Europe (36.1 percent). The agencies in high income countries produce more assessments of OD (36.8 percent), which in 31.2 percent they determine as innovative technologies compared with 11.8 percent of the units based in low income countries and active in OD assessment (11.1 percent). We prove association (p< .05) between (i) the type of HTA and income per capita; the level at which the organization operates; its main activity; and the level of recommendation dissemination; (ii) the main target group and consumers of the final HTA product; the stage of evolution of the technology, on which it is likely to be assessed; and approaches to identify innovative technologies. The most active in the preparation of HTA reports are biomedical companies or other organizations in the private sector (50.0 percent) and organizations in the pharmaceutical and/or medical industry (66.7 percent). HTA bodies that assess OD develop (36.0 percent) and distribute recommendations (35.9 percent) nationally; their main activity is to produce guidelines for good clinical practice (46.9 percent). Agencies that perform OD assessment are active in evaluation of innovative (37.2 percent) and emerging (35.9 percent) technologies, which are able to be identified by developing early warning systems (32.0 percent).

CONCLUSIONS:

Making coverage decisions based on HTA recommendations control the technologies introduction into the healthcare system, that is why it’s very important that this tool is properly adjusted to the specific needs of OD assessment (3).

REFERENCES:

VP082 Economic Evaluation Of Dementia: Diagnosis And Disease Progression

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ABSTRACT SUMMARY:

Dementia is a very important concern in most countries due to the increase in ageing population. To support efficient resource allocation, we present a comprehensive economic model to allow accurate prediction of health and care demand for the dementia patient.

INTRODUCTION:

Dementia is a very important concern in most countries due to the increase in ageing population. To support efficient resource allocation, there is a need for a comprehensive economic model to allow accurate prediction of health and care demand for the dementia patient.

METHODS:

A comprehensive dementia model that can address diagnosis, disease progression, and service delivery issues is highlighted in this presentation. A systematic review of existing dementia models
was performed and data extraction was performed on the studies evaluating pharmacological interventions and diagnostic interventions. Expert opinion was sought in developing the dementia model – in particular, advice on the appropriate conditions to include in the model, key data sources, and literature. Conceptual modelling was performed to finalise the structure of the model before programming in modelling software. The model was subjected to internal and external validation to ensure the robustness in predicting dementia outcomes.

RESULTS:
The systematic review identified sixty-nine relevant articles evaluating pharmacological interventions and diagnostic interventions, and data extraction was performed on these studies. Based on this review, Alzheimer’s disease and vascular dementia were included within the ‘dementia’ model. The model is an individual patient-level simulation model and uses mini-mental state examination (MMSE) scores to model disease progression. Institutionalization and mortality was also modelled. Transition probabilities were modelled based on published literature. The model incorporates diagnosis, disease progression, and service delivery aspects of the patient pathway. The model takes a lifetime perspective, estimating the impact of interventions on costs, clinical outcomes, survival, and quality-adjusted life years.

CONCLUSIONS:
The dementia model indicates that early diagnosis may not be cost effective, given the current evidence. The key drivers include the accuracy of the diagnosis and the effectiveness of dementia interventions. The model is highly flexible and has broad potential application to evaluate different diagnostic strategies and pharmacological/non-pharmacological interventions in dementia.

VP083 How To Identify Technologies Eligible For Health Technology Assessment: A Bottom-Up Approach

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ABSTRACT SUMMARY:
We describe a bottom-up, shared approach to produce a tool to identify health technologies eligible for a regional Health Technology Assessment (HTA). Two panels of regional stakeholders (clinicians and decision-makers) were convened: a qualitative approach and methodology of focus group were used. The tool is made of thirty-two items to be valued on a Likert scale.

INTRODUCTION:
Governance of health technologies in Emilia-Romagna region, Italy, includes a local and a regional level. Medical devices (MDs) are requested by clinicians to hospital committees that may carry out an evaluation at local level or ask for a regional evaluation using Health Technology Assessment (HTA) methodology. Until the past year, committees weren’t provided with a clear pathway to identify technologies for regional HTA evaluation. The aim of this study was to describe a bottom-up, shared approach to produce a tool with elements to be considered when judging if a technology is eligible for regional HTA or not.
METHODS:
To identify elements, we adopted a qualitative approach and the methodology of focus group (1,2) which consisted in starting from health professionals experience to build a shared knowledge. Two panels of stakeholders were convened, the first one comprising regional decision-makers deciding whether to reimburse and introduce a MD in Regional Health System; the second panel comprised regional clinicians that use, test and ask for MDs. Panels were asked to capture possible elements of MDs that should be considered for identifying the most promising and interesting ones for a regional HTA.

RESULTS:
The two panels (seventeen regional clinicians and twenty-two decision makers, respectively) had two operative meetings and worked in parallel. At the end of the second meeting, a draft of the tool with elements identified by both groups was built. Panels were asked to test the draft on few medical devices and identify possible tool’s criticalities limiting transferability. Tool resulted user-friendly and complete, requiring no changes. The final version, approved by two panels convened together during the last meeting, reports thirty-two distinct items referred to five domains (that is, potential: innovativeness, clinical, economic, and organizational impact, environmental factors). Each item must be valued on a Likert scale. The tool will be applied on every MD requested by regional clinicians and before implementation it will be tested during a 6-month pilot phase beginning March 2017.

CONCLUSIONS:
The process was plain and feedback from stakeholders has been positive. The tool is expected to increase transparency and homogeneity in identifying technologies eligible for regional HTA.

REFERENCES:

VP084 A Synthetic Index To Assess The Quality Of Care Of Acute Hospitals

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ABSTRACT SUMMARY:
We present a new methodology to construct a synthetic indicator to obtain a global ranking that assess the quality of care and recognizes the best acute hospitals in Catalonia.

INTRODUCTION:
One of the initiatives promoted by the Department of Health of Catalonia to promote the policies of clinical safety and quality of care was the construction of a synthetic indicator to obtain a global ranking that assess the quality of care and recognizes the best acute hospitals in Catalonia.

METHODS:
For the selection of dimensions and individual indicators, focus groups with experts, focus groups with patient representatives and a wide consensus
process with health professionals were carried out. Weights of dimensions and indicators have been obtained from this consensus with experts. We identified forty-seven individual indicators grouped into four dimensions, forty-nine hospitals grouped into five categories were included. Goal programming methodology was used to construct synthetic dimensional indicators and then aggregate to obtain the global ranking based on the global synthetic indicator.

RESULTS:
The best situation regarding quality of care of general acute hospitals is achieved in hospitals with better indicators of both the clinical effectiveness and adequacy dimension and patient safety, specifically the synthetic indicator places the hospitals with lowest percentage of patients with postoperative complications or with lowest percentage of infections of organ-space surgical localization in elective colonic or rectal surgery in a better position. Both in the synthetic global indicator and in the synthetic dimensional indicators, position the county hospitals as the best in the ranking, followed by reference hospitals.

CONCLUSIONS:
We have presented a new methodology to assess the quality of care of hospitals which offers several advantages over existing ones. It is designed to be practical and to facilitate obtaining synthetic indicators that can be easily interpreted, based on information provided by the reference value corresponding to each indicator and adjusted by the clinical criterion supported by the consensus of more than 300 experts in the field of the evaluation of hospital care quality.

VP085 Multiple Surrogate Endpoints In Advanced Colorectal Cancer

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ABSTRACT SUMMARY:
Progression free survival (PFS) has been investigated as a surrogate endpoint for overall survival (OS) in advanced colorectal cancer. The aim of this research was to assess if PFS and treatment response used jointly as surrogate endpoints to OS improve their predictive value. Multivariate meta-analysis was used to model the association between treatment effect on surrogate (PFS and response) and final (OS) endpoints.

INTRODUCTION:
Surrogate endpoints play an important role in health technology assessment, especially if they can be measured early compared to the final endpoint, allowing for early reimbursement decisions. Progression free survival (PFS) has been investigated as a surrogate endpoint for overall survival (OS) in advanced/metastatic colorectal cancer by a number of researchers, however inconclusively. In recent years, meta-analytic methods allowing for use of multiple surrogate endpoints jointly have been proposed. The aim of this research was to assess if PFS and treatment response used jointly as surrogate endpoints to OS improve their predictive value.
METHODS:
Data was obtained from a systematic review of randomised control trials in advanced/metastatic colorectal cancer on effectiveness of pharmacological therapies (systemic chemotherapy (SC), anti-EGFR, and antiangiogenic). Multivariate meta-analysis was used to model the association between treatment effect on surrogate (PFS and response) and final (OS) endpoints when used jointly, on all data and in subgroups of subclass therapy.

RESULTS:
Bivariate meta-analysis showed significant association between treatment effects on PFS and OS, which was only minimally improved in the trivariate analysis modelling the effect on two surrogate outcomes jointly. For subclass therapies, there was a moderate improvement in the association for SC, with increased precision by 9 percent of the regression coefficient between effects on OS and PFS, but not for the other two subclasses. Predicted treatment effects on OS were obtained with higher precision only for SC and antiangiogenics (reduction in uncertainty on average 1.7 percent and 2.4 percent respectively) when using both surrogates jointly.

CONCLUSIONS:
Joint use of two surrogate endpoints did not lead to much improvement in the association between treatment effects on surrogate and final endpoint but in some subclasses led to improved precision of the predicted effects on OS, likely due to the more accurate estimation of PFS when both surrogates were modelled jointly.

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VP086 Early Warning To Ensure Timely Evidence-Based Decision-Making

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ABSTRACT SUMMARY:
To ensure that new technologies are prioritized for HTA in a timely process, an early awareness (EA) service was established in Norway in 2015. The impact of this EA service on national level HTA production will be presented.

INTRODUCTION:
A national system for managed introduction of new health technologies within the Specialist Health Service in Norway was launched in 2013. The system is based on a broad cooperation between the four Regional Health Authorities, the Procurement services for Health Enterprises Ltd, the Norwegian Institute of Public Health, the Norwegian Medicines Agency, the Norwegian Directorate of Health, and the Norwegian Radiation Protection Authority. Three types of Health Technology Assessments (HTAs) serve as grounds for decisions: hospital-based HTA, single technology assessments, and full HTA. A major objection to HTA is that it may delay the introduction of important technologies. To ensure a timely process, an early awareness (EA) service became part of the National system in 2015.

METHODS:
The main outcomes of the EA service are short, two-page summaries (alerts) which are made publicly available and serve as suggestions for prioritization of HTA on the national level. New
technologies are identified from public sources on international web-sites including the European Medicinal Agency (EMA), the Euroscan network, and collaborating HTA agencies. For non-pharmaceuticals, the service follows selected technologies over time.

RESULTS:
Between January 2015 and December 2017 we produced a total of 79 alerts on pharmaceuticals and 41 alerts on non-pharmaceuticals. A majority of these led to an HTA report used in a national decision process. For pharmaceuticals, an important challenge for the service is the lack of public information made available by producers at the time of alert production (for example, before approval by EMA). For non-pharmaceuticals, timeliness is to a larger extent limited by resources available for the processes of identification and selection (horizon scanning).

CONCLUSIONS:
Timeliness of HTA may benefit from more systematic international collaboration on horizon scanning and early awareness aiming at making early information on new health technologies publicly available.

VP087 Extrapolation From Progression Free Survival To Overall Survival In Oncology

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ABSTRACT SUMMARY:
Overall survival (OS) is regarded as the most important outcome in oncology trials, but this information is often not available for some years. If progression-free survival (PFS) is highly correlated with OS, information about the size of OS can be inferred using PFS. We examine the aspects of cancer treatment that make the evaluation of the quality of PFS problematic.

INTRODUCTION:
The outcomes from clinical and other healthcare trials of most interest to patients and health systems are usually increases in the quality and length of life (overall survival (OS)). This poses a problem, because complete knowledge on the true increase in OS is not available until the last person in the trial dies. However, if OS is sufficiently correlated with a surrogate endpoint that is observable within the trial period or soon after the treatment has finished, this can be used to estimate OS, without much error. The most widely-used surrogate endpoint in oncology is progression-free survival (PFS). We aim at (i) analysing the methods used to extrapolate from PFS to OS in the field of oncology; (ii) identifying whether a clear guidance exists in the literature about what is considered to be ‘best practice’ in extrapolation from PFS to OS; (iii) determining the key limitations, weaknesses and gaps in the current literature and method used to test PFS surrogacy.

METHODS:
We extend the literature review carried out previously (1), we interview experts from regulatory and reimbursement bodies, and we explore academic research into the methodology of surrogacy and the need for better reporting of surrogacy papers.

RESULTS:
A number of factors affect the relationship between PFS and OS. Therefore, there is no unique correct answer for the question of whether PFS is an appropriate surrogate for OS in oncology. Many
of these factors are related to the length and characteristics of post-progression survival (PPS).

CONCLUSIONS:
Any consideration of evidence relating to PFS should consider both tumour type and other factors, particularly those related to PPS. Protocols of future follow-up of clinical trial patients should specify procedures for gathering information about the effect of post-progression management of the disease. This should allow stronger conclusions to be extracted from statistical analyses. Improved reporting standards will aid in achieving this goal. In addition, it is very likely that increasing the use of IPD will result in greater precision in estimating the benefits of worthwhile drugs.

REFERENCES:

VP088 Transient Ischaemic Attack Referral (TIER) Intervention Development

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ABSTRACT SUMMARY:
Transient Ischaemic Attack (TIA) is a neurologic event with symptom resolution within 24 hours. Early specialist assessment reduces risk of stroke and death. A clinical panel used survey and review results to develop a complex intervention for patients with low risk TIA presenting to the emergency ambulance service, for testing in the TIER feasibility trial.

INTRODUCTION:
Transient Ischaemic Attack (TIA) is a neurologic event with symptom resolution within 24 hours. Early specialist assessment of TIA reduces risk of stroke and death. National United Kingdom (UK) guidelines recommend patients with TIA are seen in specialist clinics within 24 hours (high risk) or seven days (low risk).

We aimed to develop a complex intervention for patients with low risk TIA presenting to the emergency ambulance service. The intervention is being tested in the TIER feasibility trial, in line with Medical Research Council (MRC) guidance on staged development and evaluation of complex interventions.

METHODS:
We conducted three interrelated activities to produce the TIER intervention:

- Survey of UK Ambulance Services (n = 13) to gather information about TIA pathways already in use
- Scoping review of literature describing prehospital care of patients with TIA
- Synthesis of data and definition of intervention by specialist panel of: paramedics; Emergency Department (ED) and stroke consultants; service users; ambulance service managers.
RESULTS:
The panel used results to define the TIER intervention, to include:

1. Protocol for paramedics to assess patients presenting with TIA and identify and refer low risk patients for prompt (< 7 day) specialist review at TIA clinic
2. Patient Group Directive and information pack to allow paramedic administration of aspirin to patients left at home with referral to TIA clinic
3. Referral process via ambulance control room
4. Training package for paramedics
5. Agreement with TIA clinic service provider including rapid review of referred patients

CONCLUSIONS:
We followed MRC guidance to develop a clinical intervention for assessment and referral of low risk TIA patients attended by emergency ambulance paramedic. We are testing feasibility of implementing and evaluating this intervention in the TIER feasibility trial which may lead to fully powered multicentre randomized controlled trial (RCT) if predefined progression criteria are met.

ABSTRACT SUMMARY:
The use of mHealth is increasing. Literature review and focus groups with experts and end-users has helped us to develop an mHealth assessment framework to support informed decisions when developing, integrating, selecting, recommending or adopting mHealth solutions.

INTRODUCTION:
The use of health apps is rapidly increasing. They intend to promote health or to treat diseases; in some cases, substituting medical duties. No specific frameworks to assess mHealth solutions in a broad scope and in a comprehensive way have been identified. We aim to propose a framework for mHealth assessment.

METHODS:
The framework development was based on:
- Literature review to identify existing assessment models including the evaluation of health effects
- Exploratory analysis with experts and user group discussions
- Definition of the assessment model, following the domains of health technology assessment.

RESULTS:
Existing frameworks are mainly focused on certification criteria. Professionals and users agreed on the need to undertake mHealth assessments as to better inform user decisions. Assessments should be sensible to continuous changes of these technologies and be undertaken by independent organizations.

The proposed framework offers a step-by-step process by which any mHealth solution can be categorized and analyzed, according to: (i) Risk classification matrix: combining intervention type and patient type, (ii) Users: patients, professionals, informal caregivers individually or all of these together and (iii) Integration: stand-alone, fully integrated.
The model has four evaluation domains: technical maturity, risks, benefits and resources needed, including the commonly accepted evaluation perspectives: technical, contents, clinical/health, user perspective, organizational and socio-economic. Sub-domains are defined as: end-user, organization, healthcare system and community (society as a whole). Aspects to be assessed are selected according to the purpose of the evaluation (intended use / intended impact) and vary depending on the type of the mHealth solution: product or service.

CONCLUSIONS:
The mHealth assessment process is needed and should be: (i) continuous/iterative, providing timely conclusions and recommendations for improvement, (ii) inclusive/collaborative, involving all stakeholders, and (iii) constantly adapting to standards. The proposed framework is intended to support informed decisions when developing, integrating, selecting, recommending, or adopting mHealth solutions.

INTRODUCTION:
With the possibility to analyze gene expression a plethora of new genomic tests are surging into the medical market. The assessment of these new technologies in Health Technology Assessment (HTA) reports is challenging and we need international consensus on uniform criteria to support HTA, but also to establish clear and standardized requirements for clinical studies.

METHODS:
The German Institute for Quality and Efficiency in Health Care (IQWiG) has been commissioned to assess the benefits and harms of biomarkers to predict which women would benefit from chemotherapy treatment after surgery of primary breast cancer. The final report was published in October, 2016 (1).

RESULTS:
Only eight studies complied with the inclusion criteria of the systematic review. No prognostic study fulfilled the inclusion criteria. Only two randomized controlled trials (RCTs) delivered information utilizable for benefit assessment. Based mainly on 5-year results from the MINDACT trial, the report concluded that there currently is not enough information to support a positive decision on biomarkers in this specific indication. Ongoing randomised controlled trials like TailorX, PlanB, RxPONDER, ADAPT or OPTIMA are expected to provide some additional evidence in the near future. After publication of the IQWiG report an extensive debate on several methodological characteristics of this report was fuelled. In addition, some other HTA agencies, such as the National Institute for Health and Care Excellence (NICE) made slightly different conclusions.

CONCLUSIONS:
The presentation will give a résumé of the main arguments and focus on differences between the IQWiG report and other HTA reports. Questions, like the required study type, study characteristics (for example, attrition rate, follow up, outcomes),

VP090 Uniform Assessment Methods To Assess New Genomic Tests

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ABSTRACT SUMMARY:
The urgent need for more uniform assessment methods – example of the German Institute for Quality and Efficiency in Health Care (IQWiG)-report on biomarkers for primary breast cancer.
data quality, cut-offs or patient preferences in diagnostic information will be provided. The aim of the presentation and discussion is to get a step forward in defining key characteristics and elements of benefit assessment and primary studies for these new technologies. A consensus among HTA reviewers in these approaches seems to be essential in the near future.

REFERENCES:

INTRODUCTION:
A robust medical claims review system is crucial for addressing fraud and abuse and ensuring financial viability of health insurance organizations. This paper assesses claims adjustment rate of the paper- and electronic-based claims reviews of the National Health Insurance Scheme in Ghana.

METHODS:
The study was a cross-sectional comparative assessment of paper- and electronic-based claims reviews of the National Health Insurance Scheme. Medical claims of subscribers for the year, 2014 were requested from the claims directorate and analysed. Proportions of claims adjusted by the paper- and electronic-based claims reviews were determined for each type of healthcare facility. Bivariate analyses were also conducted to test for differences in claims adjustments between healthcare facility types, and between the two claims reviews.

RESULTS:
The electronic-based review made overall adjustment of 17.0 percent from GHS10.09 million (USD2.64m) claims cost whilst the paper-based review adjusted 4.9 percent from a total of GHS57.50 million (USD15.09m) claims cost received, and the difference was statistically significant (p<.001). However, there were no significant differences in claims cost adjustment rate between healthcare facility types by the electronic-based (p=.0656) and by the paper-based reviews (p=.6484).

CONCLUSIONS:
The electronic-based review adjusted significantly higher claims cost than the paper-based claims review. Scaling up the electronic-based review to cover claims from all accredited care providers could reduce spurious claims cost to the scheme and ensure long term financial sustainability.
VP092 Quantifying Health Need To Inform Funding Decisions

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ABSTRACT SUMMARY:
New Zealand is seeking to improve how health need is considered in funding decisions. This presentation summarises two literature reviews on how health need can be measured and how it is used in other jurisdictions. We then propose a set of methods to systematically measure health need and to include it in decisions on prioritization of health funding.

INTRODUCTION:
The concepts of health need, burden of illness, disease severity, and health benefits to informal caregivers are sometimes used to modify the results of cost-effectiveness studies in reimbursement decisions. The underlying concern appears to be that agencies that rely only on incremental cost-utility analysis may undervalue some treatments. Examples are treatments for rare or severe conditions, or for conditions that affect the health of people beyond the person with the condition. New Zealand quantifies health need and considers it in funding decisions. We are seeking to improve our measures of health need, and to then develop a consistent approach to measuring health need and health benefits to others, that can be used in future funding decisions.

METHODS:
A literature review sought information on how health funding authorities assess and use health need in their decision making. A second literature review identified studies that used a quantitative HR-QOL instrument to measure health effects to unpaid caregivers. The literature reviews have informed an approach for estimating and presenting information on the health need of individuals, and of their families and caregivers.

RESULTS:
Many countries include a qualitative description of health need in their decision-making framework, but few attempt to routinely quantify it. Similarly, while there is good evidence on the health need attributable to many health conditions, it is not systematically used in health economic assessments or reimbursement decisions.

CONCLUSIONS:
Health need can be systematically quantified. In many chronic health conditions, the health need of patients and of their families, whānau, and caregivers is comparable to the incremental health gains offered by many new health technologies. PHARMAC (www.pharmac.govt.nz) routinely quantifies the health need of people affected by new funding proposals. There is a good evidence base that New Zealand could draw on to consider both modifiable and background Health Need when prioritising options for investment in health services.

VP093 Budget Impact Analysis Of Non Invasive Prenatal Testing For Down Syndrome

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ABSTRACT SUMMARY:
Non-invasive prenatal testing (NIPT) is more accurate than conventional maternal serum screening (MSS), but is more costly. The aim of this study is to provide a budget impact analysis on MSS and NIPT for Down syndrome screening from a health insurance perspective and to provide suggestions for policy making.

INTRODUCTION:
In China, prenatal screening of non-invasive prenatal testing (NIPT) for Down syndrome has been used in some hospitals as pilot projects. NIPT is more accurate than conventional maternal serum screening (MSS), but is more costly. The aim of this study is to provide a budget impact analysis on MSS and NIPT for Down syndrome screening from a health insurance perspective and to provide suggestions for policy making.

METHODS:
Based on a systematic review and the results of a field survey a budget impact model involving a cohort of 167,822 pregnant women, which represented the general population of pregnant women of one city in southern China, was developed to compare three different screening strategies: (i) current clinical practice using MSS only (MSS strategy); (ii) implementing NIPT as an optional secondary screening test for those identified as high risk (contingent screening strategy); and (iii) NIPT as a primary screening test, replacing MSS (universal strategy). We used health economic methods to perform the budget impact analysis on prenatal testing costs.

RESULTS:
By adjusting the proportions of pregnant women receiving NIPT, the total cost of the MSS strategy was $2,906,748 (representing payment of $2,629,383 by health insurance and payment of $277,365 by patients); the total cost of the contingent screening strategy was $4,435,465 (representing payment of $3,255,418 by health insurance and payment of $1,180,046 by patients); and the total cost of the universal strategy was $43,999,033 (representing payment of $15,904,361 by health insurance and payment of $28,094,671 by patients). Comparing the MSS strategy with the contingent screening strategy, the difference in total cost was $1,528,717. Comparing the MSS strategy with the universal strategy, the difference in total cost was $41,092,285. Thus, although the universal strategy may not be acceptable to all pregnant women (as much of the prenatal testing cost will be paid by them under present health insurance arrangements), using the contingent screening strategy could substantially reduce the economic burden of pregnant women while simultaneously increasing Down syndrome detection rates.

CONCLUSIONS:
It is an economic and feasible way to promote NIPT as contingent screening strategy in China.

VP094 Framework Of High-Quality Value Assessment Criteria In Health Care

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ABSTRACT SUMMARY:
No single assessment can evaluate the wide spectrum of health technologies pending access to healthcare systems, nor can a single tool meet all of the goals held by stakeholders, health professionals, and decision and policy makers. It is important to envision a complex systematic framework, in which different instruments are used for different purposes.
INTRODUCTION:
No single assessment can evaluate the wide spectrum of health technologies pending access to healthcare systems. It is important to envision a complex systematic framework, in which different instruments are used for different purposes - all criteria should be used to ensure the transparency of the process, and should model good assessment and implementation practices (1,2).

METHODS:
A cross-sectional web-based survey was conducted from September 2013 to May 2015 which was designed to gain information about the present status of Health Technology Assessment (HTA) activities; to examine its institutional contexts and the kind of application of its principles, logic, assessment methods, tools and best practices.

RESULTS:
A total number of 161 questionnaires from 39 countries on 6 continents were received representing a 41.7 percent response rate. Based on analysis of the results, a complex systematic framework for value assessment was designed. Five major features define the framework that can fully measure the common and support the evaluation of more complex health technologies: (i) implementation of higher-order evaluation approaches that support complex multi-criteria assessment, rather than emphasizing only the use of basic evaluation procedures; (ii) precise evaluation of critical criteria, that measure technologies directly as they will be used in actual practical settings; (iii) assessment approaches, based on international best HTA practices that are accurate, in terms of the content and context of the evaluated technology, as well as the expected performance; (iv) high-fidelity priority-setting elements that are evaluation sensitive; and (v) assessments that are sound, unbiased, and transparent – in order to be truly valid for a wide range of technologies, assessments should evaluate them accurately and do so reliably across technology content and context. They should be unbiased and accessible and used in ways that support superior outcomes and higher quality for healthcare systems.

CONCLUSIONS:
The healthcare systems that decide to use this framework should evaluate the set of assessments they select and develop them against the standards required, and should use them in ways for which they have been appropriately validated and in contexts that ensure a transparent evaluation process (3).

REFERENCES:

VP095 The Monetary Value Of A Statistical Life Year: A Systematic Review

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ABSTRACT SUMMARY:
A systematic review of the literature on the economic value of a statistical life (VSL) yielded a total of 132 VSL estimates. The median VSLY was 6.4 times GDP/capita or EUR165,000 (year 2014). We found significant differences by regional source of data and by methodology. This finding indicates that the VSLY estimates based on empirical data exceed commonly used benchmarks.

INTRODUCTION:
Among economists, there is widespread agreement that the monetary valuation of health gains should reflect the preferences of those who will be affected by resource allocation decisions. In the context of Health Technology Assessments (HTAs), this view implies a need for reliable empirical estimates of the value of statistical life year (VSLY), which should provide a useful point of reference for cost benefit analyses.

METHODS:
We conducted a systematic review of the literature on the economic value of a statistical life (VSL). We searched in the EconBiz and EconLit databases for studies, which reported VSL estimates based on original research and were published between 1995 and 2015. We classified studies by methodology, that is, revealed preference (RP) or stated preference (SP; that is, CV, contingent valuation, or DCE, discrete choice experiment) approach, and by regional origin of data. We transformed VSL estimates into VSLY expressed in year 2014 Euros, using life expectancy tables for the populations studied, a real discount rate of 3 percent, national Consumer Price Indices for inflating, and purchasing power parities for currency conversion. In addition, we calculated ratios of VSLY to gross domestic product (GDP) per capita.

RESULTS:
Our search yielded 120 studies appropriate for inclusion. From these, we extracted a total of 132 VSL estimates (RP, n=60; SP, n=72). The median VSLY was 6.4 times GDP/capita. Transformed into Euro (2014), the median VSLY was EUR165,000 (mean, EUR217,000). We found significant differences by regional source of data (North American, median EUR272,000; European, EUR158,000) and by method (RP, EUR241,000; SP: CV, EUR117,000; DCE, EUR187,000). VSLY estimates were sensitive to discount rate.

CONCLUSIONS:
Our data indicate that VSLY estimates based on empirical data exceed benchmarks commonly used in the context of HTAs. However, inter-study variability, methodological limitations, and normative considerations, all suggest to exercise caution before translating this observation into actual policy.

VP096 Information Flow As Base For Planning Biomedical Technologies In Italy

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ABSTRACT SUMMARY:
In a North Region of Italy, an information flow of biomedical technologies (FITeB) allows to monitor and follow-up large medical equipment, innovative equipment and widespread technologies. The distribution of Biomedical Technologies (BT), their age profile, technological burden, innovative components and overall economic value, have been estimated with FITeB. FITeB indicators represent the knowledge base for BT assessment and procurement planning.
INTRODUCTION:
An effective installed medical equipment base management requires an information flow of Biomedical Technologies (BT) providing a common and standardized methodology for data collection and inventories management, representing the knowledge base for the BT assessment and procurement planning.

METHODS:
In a North Region of Italy a standardized methodology for BT regional codification has been defined to univocally identify BT, by classifying health fields and specialities, technological classes, models and manufacturers. Since 2012, an information flow of BT, named FITeB, allows to monitor and follow-up large medical equipment (LME), innovative equipment (IE) and widespread technologies (WT) set up in public settings, through biannual equipment census (1,2). Data about classification, identification, location, age, operating status, way of acquisition, economic value and maintenance have been analytically collected for LME and IE. LME data have been integrated with the information flow for public funding management allocated to regional healthcare buildings through other procedure. The number and economic value of WT have been collected. FITeB data have been used for the Regional planning procedure for medical equipment procurement (3).

RESULTS:
The distribution of BT, their age profile, technological burden and innovative components as well as the overall economic value, have been estimated with FITeB. In 2016, information about 341 LME was collected; LME mean age was 7.4 years with a value of EUR248,353,000. The 293 IE were set up with mean age of 5.9 years and an overall economic value of EUR20,167,000. The WT amounted to 45,263 equipment with a value of EUR843,353,000. Over the years 2014 and 2015, the Public Hospitals and Local Health Authorities (ASRs) submitted 491 BT requests, of which 87 percent were replacement/new acquisition/upgrade, 9 percent innovative acquisition and 4 percent donations.

CONCLUSIONS:
Critical issues can be identified from FITeB indicators representing the basis for BT procurements assessment and definition of strategies of replacement, introduction or relocation of medical equipments in the Region. An integrated information flow, as the case of FITeB, is an useful knowledge tool for appropriate governance, planning and management of BT.

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VP097 The Economic And Fiscal Impact Of Vaccination In Italy

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**ABSTRACT SUMMARY:**
The paper investigates the value of immunization programmes for invasive pneumococcal disease (IPD), influenza (FLU), and herpes zoster (HZ), under the perspective of the public sector, looking at the impact of these conditions on direct and indirect costs of disease-related disability as well as reduced revenues for the public sector in case of ill-health.

**INTRODUCTION:**
Immunization programs have spillover effects on non-health divisions of the public sector. Assessing them under the perspective of the public sector means to quantify the direct (pensions/allowances to be corresponded the sick person) and indirect (changes in consumption patterns affecting revenues from VAT) cost of disability. The study aims to assess the value of immunization programs in the working population for invasive pneumococcal disease, influenza, and herpes zoster.

**METHODS:**
A review on the cost of the diseases under study is being conducted. Its results will be used to populate a simulation model along with data concerning the impact of these conditions in terms of early retirement, cost of temporary or permanent disability, and reduced revenues for the public sector resulting from changes in consumption patterns due to ill-health. The model will adopt a lifetime horizon and the value of vaccination programs will be computed as the difference between the total benefit deriving from the prevention of diseases and the overall cost of the programs.

**RESULTS:**
The net benefit of vaccination programs is expected to be greater than zero, because the savings for the public sector resulting from better health are expected to offset the cost of vaccination programs. Moreover, such a value is expected to increase for higher levels of coverage.

**CONCLUSIONS:**
Vaccinations represent a good field of application of this approach to economic evaluation. Considering the spillover effects of vaccination programs is crucial to inform uptake or design decisions on these technologies.

**VP098 Cost Effectiveness Of Public Access Defibrillation In Japan**

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**ABSTRACT SUMMARY:**
This study conducted an economic evaluation of installed automated external defibrillators and suggested policy implications for improving the control of public-access defibrillation systems and their overall societal value.

**INTRODUCTION:**
The effectiveness of public-access defibrillation (PAD) has been demonstrated in that it reduces mortality rates in out-of-hospital cardiac arrest cases. However, the recent rise in the installation of automated external defibrillators (AEDs) in public spaces has not been fully studied in terms of their costs and benefits, especially in Japan. This study conducts an economic evaluation of installed AEDs and suggests policy implications for improving the control of PAD systems and their overall societal value.

**METHODS:**
Cost-effectiveness analysis (CEA) was used to examine the effects of installed AEDs at various locations in Osaka City. Outcome data (prognoses of cardiac arrest cases) were derived from the Utstein Osaka Project database, and cost data were collected from a tertiary emergency unit of a...
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university-affiliated hospital. The outcome of the CEA was expressed in terms of the incremental cost-effectiveness ratio (ICER), which represents the additional cost per quality-adjusted life-year (QALY). The ICER was calculated by dividing the incremental cost by incremental QALY for the AED and non-AED groups using a Markov model. An analysis of location-specific AEDs was conducted by scaling down the number of patients, AEDs, and life expectancies in each location. The robustness of the results was confirmed by probabilistic sensitivity analysis.

RESULTS:
The ICER of deploying AEDs was $44,590.84 in the base case. Schools, hospitals, offices, sport centers and stations were the cost-effective locations. On the contrary, the installation of AEDs in public facilities and nursing homes were not the cost-effective approach to improving the survival rate and quality of life of patients after an out-of-hospital cardiac arrest.

CONCLUSIONS:
According to the place-specific analysis, the AEDs installed in public facilities and nursing homes were not efficient to improve survival and quality of life after a cardiac arrest. In such places, a one-AED increase leads to a substantial negative change in net benefits, careful studies are required when purchasing new AEDs.

REFERENCES:

VP099 Economic Impact Of rpFVIII In The Management Of Acquired Hemophilia A

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ABSTRACT SUMMARY:
The study analyses the economic impact of the introduction of recombinant pFVIII compared to the other available therapies in order to manage the bleeding episodes in acquired hemophilia A patients. The budget impact analysis was conducted from the perspective of the Italian National Health System (INHS) in a three-year time horizon.

INTRODUCTION:
Acquired hemophilia A (AHA) is a rare coagulation disease characterized by frequent bleeding episodes treated with plasma-derived products and bypassing agents as rFVIIa and aPCC. Similar to the previous plasma-derived porcine FVIII and without its side effects, pFVIII (Obizur®) is a porcine recombinant factor VIII produced with the recombinant DNA technique. The study analyses the economic impact of pFVIII compared to the other available therapies in order to manage the bleeding episodes in AHA patients.

METHODS:
To assess the impact of the introduction of pFVIII in the market-mix of products for the management of AHA a budget impact analysis was conducted from the perspective of the Italian National Health System.
ABSTRACT SUMMARY:
Decision analytical models for Primary Progressive (PPMS) can use a similar structure used in the models for Relapsing Remitting Multiple Sclerosis (RRMS). However, more robust data on PPMS and some structural change are needed to provide a good tool to assess cost-effectiveness of disease-modifying therapies (DMTs) in PPMS.

INTRODUCTION:
In the past decades the cost-effectiveness of new effective disease-modifying therapies (DMTs) for Relapsing Remitting Multiple Sclerosis (RRMS) form was assessed through decision analytical models. Recently, new treatment option for the Primary Progressive (PPMS) form was developed. Aim of this work was assessing the similarities and differences of PPMS and RRMS and their impact in the development of decision analytical model for PPMS.

METHODS:
Literature review was performed to retrieve information on natural history of PPMS and RRMS and impact of DMTs agents on the progression of these conditions. Further, a review of the published cost-effectiveness models for RRMS was performed. Based on these data, an analysis on the difference and similarities between the two MS forms that could have an impact on the development of decision analytical model for PPMS was performed.

RESULTS:
Based on the analysis, similar structure model used for RRMS could be applied for PPMS. Health states of the model could be based on Expanded Disability Status Scale score as already done for RRMS. The relapse events considered for RRMS should not be included in PPMS model, and no possibility to develop another form, as the Secondary Progressive, should be included. While RRMS models should include at least a second line treatment option due to alternative DMTs available, only first treatment line should be considered for

System (INHS) and considering a three-year time horizon. Consumption of products, needs for additional treatment in case of failure of first line therapy, laboratory tests, hospitalization and drug wastage were considered for cost estimation. Model inputs were derived from literature, preliminary experience with the use of pFVIII for compassionate use, and from the updating of previous evidence by data collected among a panel of clinical experts. Univariate sensitivity analysis was performed to explore overall uncertainties in input parameters.

RESULTS:
The management of a bleeding episode considering conventional treatment is EUR8,229,621 per year, with an overall cost over three years equal to EUR24,688,864. The introduction of pFVIII leads to an overall costs saving ranging from EUR2,253,938 and EUR1,196,985 when the treatment duration is varied between 5 and 6.5 days, according to data from compassionate use or literature, respectively.

CONCLUSIONS:
The model outlined a significant reduction of all the components of direct costs for the INHS when Obizur® is introduced into the market with an ex-factory unit price equal to EUR2.32/IU.

VP100 Disease Modelling Approaches In Multiple Sclerosis

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PPMS. Assessing data available to populate the model, poor data on the natural history, utility and cost associated to PPMS were available and assumption or expert opinions will be needed to overcome the lack of robust data.

CONCLUSIONS:
A decision analytical models for PPMS can used a similar structure used in the models for RRMS. However, more robust data on PPMS and some structural change are needed to provide a good tool to assess cost-effectiveness of DMTS in PPMS.

INTRODUCTION:
While optimal medical therapy (OMT) represents the current standard of care for treatment-resistant hypertension, non-pharmaceutical therapeutic approaches, such as renal denervation and carotid baroreceptor stimulation therapy, have been proposed. The present Health Technology Assessment (HTA) project was aimed at assessing benefits and risk of those approaches versus OMT.

METHODS:
A systematic review of evidence on effectiveness and safety was performed together with a review of economic studies. A contextual analysis of market availability and use of the technology in Italy was also performed.

RESULTS:
In Italy, ninety-nine renal denervation procedures were performed in 2014. Ten studies from six trials were included in the review and meta-analysis. No evidence of dominance or increased harms of renal denervation compared to OMT were found. Four economic evaluations were included and reported dominance of renal denervation. These were based on short-term clinical data and three evaluations used the same Markov model assuming dominance of renal denervation. Estimated average prospective cost of the procedure was EUR6,129.90 (range EUR3,821.15 – EUR9,714.23). We updated the results of an earlier assessment published by an Italian Regional agency on carotid baroreceptor stimulation therapy (1). None of the three studies identified as ongoing in 2015 were completed or had published preliminary results and the technology was not assessed further within the present HTA project.

CONCLUSIONS:
Even if follow-up was limited to 6 months, randomised evidence showed no benefits of the procedure. Economic evaluations were unreliable, based on unrealistic assumptions of effectiveness and contrived therapy regimes. Further investment in renal denervation should await the results of
well-designed and adequately followed-up trials assessing the impact of renal denervation on major cardiovascular events compared to OMT. Future economic evaluations should be based on realistic assumptions of cost and effectiveness.

REFERENCES:

VP102 The Determinants Of Diffusion Of New Technologies Across Life Cycle

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ABSTRACT SUMMARY:
The aim of this study was to identify the determinants of adoption and diffusion of innovative medical technologies. The knowledge of such factors is relevant for policymakers because it helps them implementing evidence-based health policies aimed at influencing the use of new technologies, reducing inequities in uptake rates across areas and populations.

INTRODUCTION:
The proliferation and uneven diffusion of new medical technologies in recent years has been raising concerns on affordability and equity of care, and inspiring the publication of scientific articles on the determinants of their uptake and adoption (1). Indeed, the knowledge of the determinants spurring the adoption and diffusion of innovative medical technologies is relevant for policymakers because it helps them implementing evidence-based health policies aimed at influencing the use of new technologies, thus reducing inequities in uptake rates across areas and populations.

The aims of this study were (i) to identify the empirical literature investigating the determinants of adoption and diffusion of innovative non-pharmaceutical health technologies, and (ii) to discuss the existence of consensus on the direction and significance of the factors that influence their adoption in each phase of technologies life cycle (that is, early adoption, adoption, diffusion).

METHODS:
We performed a systematic literature review of quantitative empirical literature.

RESULTS:
We identified a total of thirty-three studies, published between 1977 and 2014. We concluded that early adoption of innovative technologies is positively affected by physician characteristics (for example, experience with new technology by the practitioner or by other physicians in the same hospital) and by the fee-for-service reimbursement scheme. The probability of adoption is mainly driven by provider characteristics (for example, size, importance of being perceived as technology leaders, previous adoption of similar or substitute technologies, strong medical staff involvement in decisions of acquisition), by physician experience with the technology and by the new technology expected impact on hospitals and physicians revenues. Socio-economic determinants (for example, health expenditure), hospitals and physicians reimbursement schemes, market structure (for example, number of providers, number of substitute procedures), provider features (for example, size, quality of care, reputation), and physician characteristics (for example, experience
with technology, innovator status of the team) significantly increased the extent of diffusion.

CONCLUSIONS:
Our results can be used as a guide by policymakers who wish to make evidence-based decisions.

REFERENCES:

VP103 Health Technology Assessment Of Genetic Tests For Cystic Fibrosis Carrier Screening In Italy

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ABSTRACT SUMMARY:
The purpose of genetic testing on healthy carriers is to inform the individuals about the relationship between identified mutations and the likelihood of disease in their offspring. Cystic Fibrosis (CF) is responsible for a significant epidemiological and economic burden. This HTA report provides sound scientific basis needed before considering the introduction of genetic tests for CF carrier screening into the healthcare system.

INTRODUCTION:
Cystic Fibrosis (CF) is a genetic disorder caused by mutations in CFTR gene. In Italy, reported prevalence is approximately .70 per 10,000 inhabitants (1). The practice and recommendations for Cystic Fibrosis carrier screening are very heterogeneous in Europe. A proposal of a carrier genetic test in the general population raises many questions. Health Technology Assessment (HTA) could offer a sound methodological basis for this evaluation. The aim of this work was to summarize the available evidence, using the HTA approach, on the genetic tests for Cystic Fibrosis carrier screening.

METHODS:
A systematic literature search was used to find the best available international and national evidence on genetics test for CF carrier screening. In this report, we specifically addressed the health problem of disease, description and technical characteristics of tests – its analytic and clinical validity, and clinical utility. Economic evaluation of different scenarios was synthesized from the literature. Ethical, organizational, and social aspects of CF and genetic screening were also considered.

RESULTS:
Several screening strategies have been evaluated in the literature and screening options can be characterized by different timing, model and place of screening (2). The reported cost of a screening test ranged from EUR25 to EUR212 (3). Estimated life time cost of care for CF patients ranged from EUR291,048 to EUR1,105,452. Ethical analysis emphasized that the use of these tests is an advantage in terms of the acquisition of knowledge and of responsible management of choices, but at the same time raises many ethical questions.
Social considerations reported among patients and their families an overall positive attitude toward population CF carrier screening.

CONCLUSIONS:
The advances in the molecular genetics technology have made CF carrier testing reliable and affordable. The multidisciplinary approach of this HTA provided an evidence-based evaluation of genetic tests and offers a firm scientific background for the decision-makers to consider the implementation of a screening for Cystic Fibrosis carriers into the Italian health care system.

REFERENCES:

ABSTRACT SUMMARY:
This study estimates the effects of the SSB tax considering the productive relations and the distributional issues associated with this policy. To achieve this goal, we used the Leontief price model derived from the input-output matrix for Brazil. The main conclusion is that a tax increase applied to SSB reduces the household consumption and generates negative impacts on the economy.

INTRODUCTION:
Obesity is increasingly prevalent abroad, and it has becoming a major public health problem. Studies show a positive association between increased weight and soft drink consumption and support the policy proposal based on additional taxes. This study aims to estimate and discusses the effects and implications of this measure with special focus on macroeconomic and sectoral variables, considering the productive relations and the distributional issues associated with this policy.

METHODS:
To achieve this goal, we used the Leontief price model derived from the input-output matrix for Brazil, 2009.

RESULTS:
The results show that the sugary drinks sector is weak intersectoral relations and will not appear as a key sector for the Brazilian economy. Considering these connections, simulating a tax increase of 10 percent on the production of sugary drinks causes a contraction of 2.84 percent in the gross value of production, while the economy as a whole reduced by 0.017 percent. Concerning to employment, the economy loses 10,020 jobs, among which 38.45 percent occur in the sector itself, and the remaining in sectors directly related to the SSB or sectors related to food and drinks in general. The highest deciles of income distribution are those that lose more with taxation. With the tax increase, it is estimated an increase in government revenue at BRL597 million. Finally, this policy would have an

VP104 The Economic Impact Of SSB Taxes In Brazil: An Input-Output Analysis

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effect on general prices in the economy, raising the price index at 0.017 percent.

CONCLUSIONS:
The main conclusion of this study is that a tax increase applied to the soft drinks industry generates negative impacts on the economy, but it reaches the expected effect: reduction of household consumption for this product. Considering an additional tax of 10 percent, it was identified a little reduction in aggregate output given that (i) the sector has few intersectoral relations, (ii) it is intended to meet final demand and (iii) it has small share in the total economy. However, the increase in tax would significantly reduce the consumption of sugary drinks in the short term. These results reflect the short-term effect of rising prices on the economy. Over time, it is expected that raising the price would change the consumption profile of families and that they would further reduce the sugary drinks consumption.

INTRODUCTION:
The sustained health-related quality-of-life of patients surviving community-acquired pneumonia has not been accurately quantified. The aim of the current study was to quantify differences in health-related quality-of-life of community-dwelling elderly with and without community-acquired pneumonia during a 12-month follow-up period.

METHODS:
In a matched cohort study design, nested in a prospective randomized double-blind placebo-controlled trial on the efficacy of the 13-valent pneumococcal vaccine in community-dwelling persons of ≥65 years, health-related quality-of-life was assessed in 562 subjects hospitalized with suspected community-acquired pneumonia (that is, diseased cohort) and 1145 unaffected persons (that is, non-diseased cohort) matched to pneumonia cases on age, sex, and health status (EQ-5D-3L-index). Health-related quality-of-life was determined 1-2 weeks after hospital discharge/inclusion and one, six, and twelve months thereafter, using Euroqol EQ-5D-3L and Short Form-36 Health survey questionnaires. One-year quality-adjusted life years (QALY) were estimated for both diseased and non-diseased cohorts. Separate analyses were performed for pneumonia cases with and without radiologically confirmed community-acquired pneumonia.

RESULTS:
The one-year excess QALY loss attributed to community-acquired pneumonia was .13. Mortality in the post-discharge follow-up year was 8.4 percent in community-acquired pneumonia patients and 1.2 percent in non-diseased persons (p<.001). During follow-up, health-related quality-of-life was persistently lower in community-acquired pneumonia patients, compared to non-diseased persons, but differences in health-related quality-of-life between radiologically confirmed

VP105 The Impact Of Community-Acquired Pneumonia On The Health-Related Quality Of Life In Elderly

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ABSTRACT SUMMARY:
Community-acquired pneumonia was associated with a six-fold increased mortality and 16 percent lower quality-of-life in the post-discharge year among patients surviving hospitalization for community-acquired pneumonia, compared to non-diseased subjects.
Community-acquired pneumonia was associated with a six-fold increased mortality and 16 percent lower quality-of-life in the post-discharge year among patients surviving hospitalization for community-acquired pneumonia, compared to non-diseased persons.

**CONCLUSIONS:**

Community-acquired pneumonia was associated with a six-fold increased mortality and 16 percent lower quality-of-life in the post-discharge year among patients surviving hospitalization for community-acquired pneumonia, compared to non-diseased persons.

**METHODS:**

The study was undertaken from the Turkish healthcare payer perspective. An excel sheet was formed to calculate the results. Resource data were obtained from literature review.

**RESULTS:**

Biosimilars were defined in 2008 in the context of the biosimilar guideline published by the Ministry of Health. Until today, cumulatively there are 294 biotech drugs and 47 biosimilar drugs licensed by the Ministry of Health based on 2016 data. The first five countries from which biotech drugs are imported are, respectively, Germany, USA, Denmark, Switzerland, and France. All biotech and biosimilar drugs are subject to the reference pricing system; locally manufactured biosimilars can have a 15 percent premium price regarding the cost card, and they are classified as original products and reimbursed with 11 percent discount the first year and 41 percent public discount the following years. The first biosimilar drug to be manufactured locally was licensed in the oncology therapeutic area in Turkey in 2016. Biotechnologies have an approximately 20 percent market share in the total pharmaceutical expenditure.

**CONCLUSIONS:**

There is not a differentiated pricing and reimbursement procedure or HTA procedure for biotech and biosimilar drugs than for original drugs in Turkey, but this application is being considered. Moreover, prioritization and localization incentives are on the agenda of the decision makers.

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**VP106 Biotechnology And Biosimilar Landscape In Turkey**

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**ABSTRACT SUMMARY:**

The purpose of this study is to analyze the regulations and policies of the biotech and biosimilar drug market and to identify its market share in the pharmaceutical industry. Methods: Resource data were obtained from literature review. Results: Biotechnologies have approximately 20 percent of the market share in the total pharmaceutical expenditure. Conclusion: Prioritization and localization incentives are on the agenda of the decision makers.

**INTRODUCTION:**

In recent years, with the development of the technology, the importance of biotechnological drugs has been increasing. In addition to biosimilar drugs as an alternative to biotechnologic drugs, the pricing and reimbursement policies of these drugs are being discussed by decision makers and also play a significant role in the Turkish pharmaceutical market. The purpose of this study is to analyze the regulations and policies of the biotech and biosimilar drug market and to identify its market share in the pharmaceutical industry.
VP107 Pharmaceutical Industry’s Experiences with the German Health Technology Assessment Scientific Advice

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ABSTRACT SUMMARY:
Before submitting the manufacturer’s dossier, optional scientific advice is offered by the Federal Joint Committee in Germany. Regarding this advice, manufacturers experienced inconsistencies, a perception of lack of expertise with conducting clinical trials, partially incomplete answers and a low readiness to engage in dialogue. On the other hand, the majority of respondents showed a positive attitude concerning unambiguosity, completeness, traceability, atmosphere and the protocol of advice provided.

INTRODUCTION:
The early benefit assessment of drugs was introduced in Germany with the ‘Act to Reorganize the Pharmaceuticals’ Market in the SHI’ (AMNOG) in 2011. Before submitting the manufacturer’s dossier, optional scientific advice is offered by the Federal Joint Committee (G-BA). The objective was to elicit manufacturers experience with the scientific advice offered by the Federal Joint Committee.

METHODS:
To prepare the survey, several manufacturers were interviewed on their experience with the scientific advice offered by the Federal Joint Committee. Subsequently, a questionnaire was developed to collect information for this purpose, comprising eight items on different topics aimed at understanding the perceived quality of the scientific advice provided.

RESULTS:
The qualitative part comprised seven manufacturers who had received between one and ten advisories before the end of 2012. With regard to the quantitative elicitation part, a total of sixty-one completed questionnaires from nineteen manufacturers were included until the beginning of 2015 (corresponding to almost 25 percent of the overall implemented scientific advice). Fourteen cases were about so called “early” scientific advice in terms of relating to evidence before commencing phase-III trials, forty-four cases concerned “late” scientific advice (pivotal trials were just conducted or already terminated), another two concerned repeated scientific advice and finally, four referred to miscellaneous contents (multiple answers possible). Both, the preceding qualitative and the following quantitative part of the elicitation, highlighted points about the process as well as the content shortcomings from an industry’s point of view: inconsistencies, lacking expertise with conducting clinical trials, partially incomplete answers and a low readiness to engage in dialogue were criticized. On the other hand, the majority of respondents showed a positive attitude concerning unambiguosity, completeness, traceability, atmosphere and the protocol of the advice. Over the course of time, propositions on study design, agreement with the determined appropriate comparative therapy and subgroup definitions improved significantly.

CONCLUSIONS:
A more active involvement of further stakeholders and the incorporation of procedural elements from other health care systems with longer experience could improve the scientific advice provided.


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VP108 Environmental Sustainability In Hospitals Health Technology Assessment: A Survey

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ABSTRACT SUMMARY:
We investigated the engaging of 178 hospital managers, physicians, architects and the public for the need to preserve the environment, and analyzed their viewpoints on how to merge efficiently with ecological trends to create a “green” hospital. We revealed their ranking towards the relative contribution to hospital economic effectiveness, managers accountability, quality-targeted work surroundings and patients wellbeing, conceiving a harmonious community.

INTRODUCTION:
In the age of limited resources, hospital managers confront the need to strictly balance resource allocation at their disposal between drugs, wages, purchases and operation costs. This entails an endless search for creative pathways to efficiently merge the trends to preserve the environment.

A “green” hospital is an entity that is planned, built and operated so as to minimize the ‘ecological footprint’: for example, saving energy by utilizing natural light; recycling water, paper or waste; and using insulation and soundproofing.

‘Evidence-based environmental design’, a new approach to advanced building techniques, is gaining momentum worldwide. It synergizes with additional trends: promoting quality, improving potential utility, raising the accountability of hospital workers and involving the public and patients in overcoming health system dilemmas (1).

The aim was to analyze the standpoints of professionals in health and architecture regarding environmental accountability, in comparison to public opinion, and enhance the dialogue between these three groups to create wise decision making toward improvements in the health system.

METHODS:
A structured questionnaire was prepared to examine environmental responsibility, focusing on hospital contours. The questionnaire was distributed among three groups to be completed anonymously: hospital employees (physicians and medical managers), professionals from the field of architecture and the general public. The distribution was via the internet and to the general public through a social network using the “snowball” mechanism.

RESULTS:
Distribution of the survey raised debates on the subject. We compared the views of 178 respondents (80 healthcare professionals, 47 from the field of architecture and 51 from the general public). Demographic and other criteria included age, gender, profession, priority setting, concepts of environmental responsibility and social values. Physicians prioritized economic factors as the main barrier (more than architects or the general public) and marked internal incentives as key factors. Environmental responsibility correlated with high quality of care and service among healthcare workers.

CONCLUSIONS:
Logistics and physical infrastructure interventions can enhance economic effectiveness. Moreso, they can initiate social and environmental responsibility and increase the level of confidentiality regarding the accountability of their managers towards quality-targeted work surroundings.
REFERENCES:

VP109 Identifying Priorities For A National Health Research Funder

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ABSTRACT SUMMARY:
Identifying research priorities for a national research funder can be challenging, particularly for complex health problems. This study investigated the use of Delphi type survey methods in identifying important national research priorities. These methods were found to be effective in obtaining opinions from a range of relevant experts identifying priority topic areas where there is a need for research evidence.

INTRODUCTION:
It is vitally important that research questions posed are important and that funded research meets a research need or a gap in evidence; these needs may be observed at a local, national or international level. Identifying such research priorities for a national research funder can be challenging, particularly for complex health problems such as health inequalities, where there is a need to consult a large number of experts with a range of expertise. Many methods are used in the identification of such research priorities, however, these can be resource intensive, costly, and logistically challenging particularly where large numbers of people are required and geographical distances are great.

METHODS:
This study investigated the use of Delphi type survey methods in identifying important research priorities related to health inequalities. Public health professionals with an interest in health inequalities were asked to identify research priorities, these research priorities were subsequently compared to those identified using different methods.

RESULTS:
Fifty-two public health professionals agreed to take part, the response rates were high, (69 percent, 50 percent and 40 percent) across three survey rounds; which indicated that participants were receptive to the methodology and motivated to respond. The themes identified as encompassing the most important research priorities were: mental health, environmental issues and health behaviours. Within these themes, topic areas which emerged most strongly included: community interventions for prevention of mental health problems, and the food and alcohol environment.

CONCLUSIONS:
Delphi type survey methods are effective as a means of obtaining opinions from a wide number of relevant experts identifying potential priority topic areas where there is a need for research evidence. Opinions may be sought at local and national levels in order to inform national research priorities.

VP110 Building Capacity In Health Technology Assessment Through Plain Language

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Transforming Health Technology Assessments (HTAs) into easily understandable text is a necessity for facilitating HTA collaboration beyond borders and integrating HTA into healthcare practice. Adopting a plain language (PL) approach to documents facilitates transparency and allows for greater uptake of information, whether geared to health care professionals and all those interested in HTA or the lay public.

INTRODUCTION:
Health Technology Assessments (HTAs) and policy papers are generally written in academic style using industry jargon — pharmaceutical, medical, or scientific terminology — with a generous use of abbreviations. Transforming technical or biomedical data into easily understandable text is a necessity and a challenge for all of us if our goal is to facilitate HTA collaboration beyond borders and integrate HTA into healthcare practice. Many countries have legislated for plain language (PL), and organizations globally are beginning to recognize how it helps in the uptake of information, whether geared to healthcare professionals and all those interested in HTA, or the lay public.

METHODS:
A preliminary, informal online search for legislative and supporting guidance on PL was conducted, and a query sent out to forty-eight International Network of Agencies for Health Technology Assessment (INAHTA) members.

RESULTS:
• The United States Plain Writing Act of 2010 has legislated that federal agencies use “clear Government communication that the public can understand and use” (1). Of the twenty-one respondents from INAHTA Listserv, seven use plain language in either their knowledge transfer tools (such as executive and research summaries, booklets and fact sheets, and patient or lay material).
• The Government of Canada promotes plain language in all of its communications (2).
• McMaster University’s 2014 Health Forum on strengthening public and patient engagement in HTA in Ontario supported “clarity and consistency in the use of public- and patient-engagement terminology” in HTAs.
• A growing number of international health-related and HTA organizations promote PL in their reports and HTAs to help with their health literacy.
• Many pharmaceutical companies encourage PL communication in their writing (3).
• Of the eighteen INAHTA responses received, eight reported that they use PL in their report summaries, knowledge transfer materials, and/or patient education tools.

CONCLUSIONS:
Adopting the practice of clear, straightforward writing and editing in all biomedical communication — including HTAs and journal articles — encourages interaction and engagement among patient, public, and healthcare stakeholders invested in HTAs, and their desire to have measured decision making based on comprehensive, informed, and easily understandable information. However, it remains to be seen if PL will be embraced by organizations worldwide. This preliminary, informal inquiry as to its use suggests that the adoption of PL by governments, HTA organizations, and the scientific community worldwide has not yet been fully embraced.

REFERENCES:
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ABSTRACT SUMMARY:
A referral center for multiple myeloma patient care in the public health setting is being described as the best strategy of management and care of this severe disease as to reduce time to transplantation.

INTRODUCTION:
Within the Brazilian Health System, Referral Centers (RCs) are care facilities that provide specialized services. The objective of this study was to evaluate the efficacy of care provided to patients with multiple myeloma (MM) at a specialized Referral Centers (Hospital de Clinicas de Porto Alegre Referral Center for Multiple Myeloma, CRMM-HCPA) and to compare quality of life between patients with MM treated at CRMM-HCPA and those treated at non-RC facilities.

METHODS:
A 6-month cohort study was conducted in patients with MM receiving thalidomide from the State Health Department and treated at CRMM-HCPA, and patients receiving treatment at other non-RC facilities. Thirty-two patients were included in the study, nineteen from CRMM-HCPA and thirteen from other institutions. To analyze the efficacy of care provided at CRMM-HCPA, the main outcome measure was the time from diagnosis to referral for autologous hematopoietic stem cell transplantation. This outcome measure was assessed using questionnaires specifically designed for this study. Quality of life was also assessed, using the Short-Form 36 Item Health Survey (SF-36) questionnaire.

RESULTS:
Time from MM diagnosis to referral for autologous hematopoietic stem cell transplantation in each group was measured only in patients aged 65 years (n = 25); of these, 15 were recruited from CRMM-HCPA and 10 from other institutions. In this analysis, there was a significant difference (p = .036) in time elapsed between diagnosis and referral for autologous hematopoietic stem cell transplantation, which was significantly shorter for patients treated at CRMM-HCPA (median, 9 months; Interquartile Range, IQR, 8.5–14.5) than for those treated elsewhere (median, 24 months; IQR, 16–24). On quality of life analysis, there was a significant difference in the Social Functioning, which relates to performance of social activities (p = .02).

CONCLUSIONS:
The Referral Centers model provided seems to be a more efficient treatment strategy as compared with other health care facilities, as it enabled a reduction in time to transplantation. Patients treated at CRMM-HCPA demonstrated greater ease in performing social activities, with less interference from physical or emotional problems.
**VP112 Can We Use Administrative Data To Estimate The Costs Of An Intensive Care Unit Stay?**

**PRESENTING AUTHOR:**
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**AUTHORS:**
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Francesca Valent, Italy
Loris Zanier, Italy
Ludovica Borsoi, Italy

**ABSTRACT SUMMARY:**
Administrative databases might prove a powerful tool for measuring outcomes and resource use. We investigated their role in relation to intensive care. We relied on administrative data to compare outcomes and resource use between patients who had or had not spent time in Intensive care units (ICU). We derived estimates of ICU stay costs across three main diagnoses and patient types.

**INTRODUCTION:**
Intensive care units (ICU) consume considerable resources due to high staff/patient ratios, complex case mix, and advanced technology. We sought to measure differences in resource use, reimbursement levels, and outcomes for inpatients with some ICU care versus those without. Differences between costs generated and reimbursements provided were explored.

**METHODS:**
Inpatients admitted for a main (ICD-9) diagnosis of stroke, acute myocardial infarction (AMI), or hip fracture (HF), and follow-up admissions for any diagnosis, were extracted from the hospital discharge database of the Friuli-Venezia-Giulia region of Italy from 2009 to 2013, and linked to the mortality register. Patient characteristics (age, gender, residence), health outcomes (mortality, complications), and resource use (length of stay [LOS], ICU LOS [0-24, 24–48, 48–72, and >72 hours], transfers, readmissions) were measured for patients with and without an ICU stay of any length within their admission, also noting patient type (elective/emergency surgery, trauma).

**RESULTS:**
In 138,134 records analysed, about 9 percent included an ICU stay. ICU versus non-ICU patient results showed: higher prevalence of males (+3-7 percent); slightly lower average age; greater likelihood (about 3x) for transfer to additional acute care; hospital and 7-day crude mortality measures roughly double; 365-day mortality rates at least 13 percent higher for >72 hour stays in ICU versus 0-24 hours; significantly higher ICU/non-ICU ratios for LOS: 16.2/11.8 days (stroke), 11.9/8.5 (AMI), 19.1/12.3 (HF). Average reimbursement for ICU versus non was EUR4158 higher (+77 percent) for stroke, EUR562 higher (+9.1 percent) for AMI, EUR3289 higher (+55.6 percent) for HF. Reimbursement levels and LOS approximately doubled for surgery (elective, emergency) patients with some ICU care. Hospitals differentiated greatly in patient type, LOS, mortality, and complications.

**CONCLUSIONS:**
Administrative data provides opportunities for measuring outcomes/resource use in relation to ICU care. The method, generalizable to other countries, is useful for programming, policy making, and evaluating reimbursement levels. We plan to further explore variability.

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**VP113 Reframing “Disinvestment”: Appropriateness And Real-Time Data Capture**

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ABSTRACT SUMMARY:
Administrative databases might prove a powerful tool for measuring outcomes and resource use. We investigated their role in relation to intensive care. We relied on administrative data to compare outcomes and resource use between patients who had or had not spent time in Intensive care units (ICU). We derived estimates of ICU stay costs across three main diagnoses and patient types.

INTRODUCTION:
Intensive care units (ICU) consume considerable resources due to high staff/patient ratios, complex case mix, and advanced technology. We sought to measure differences in resource use, reimbursement levels, and outcomes for inpatients with some ICU care versus those without. Differences between costs generated and reimbursements provided were explored.

METHODS:
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RESULTS:
In 138,134 records analysed, about 9 percent included an ICU stay. ICU versus non-ICU patient results showed: higher prevalence of males (+3-7 percent); slightly lower average age; greater likelihood (about 3x) for transfer to additional acute care; hospital and 7-day crude mortality measures roughly double; 365-day mortality rates at least 13 percent higher for >72 hour stays in ICU versus 0-24 hours; significantly higher ICU/non-ICU ratios for LOS: 16.2/11.8 days (stroke), 11.9/8.5 (AMI), 19.1/12.3 (HF). Average reimbursement for ICU versus non was EUR4158 higher (+77 percent) for stroke, EUR562 higher (+9.1 percent) for AMI, EUR3289 higher (+55.6 percent) for HF. Reimbursement levels and LOS approximately doubled for surgery (elective, emergency) patients with some ICU care. Hospitals differentiated greatly in patient type, LOS, mortality, and complications.

CONCLUSIONS:
Administrative data provides opportunities for measuring outcomes/resource use in relation to ICU care. The method, generalizable to other countries, is useful for programming, policy making, and evaluating reimbursement levels. We plan to further explore variability.

VP114 Nationwide Registries To Inform On Economic Burden Of A Rare Disease

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ABSTRACT SUMMARY:
Generating high-quality real-world evidence in the setting of a rare disease and individualized treatment approaches to overcome lack of clinical consensus, identify treatment patterns, quantify resource use and costs, and meet Health Technology Assessment requirements: the example of an analysis of Swedish registers in uncontrolled carcinoid syndrome treated by SSA to inform a global value package.

INTRODUCTION:
About 30 percent of carcinoid syndrome (CS) patients have uncontrolled symptoms while treated by somatostatin analogues (SSA). Due to the orphan nature of the disease and individualized treatment choices, a lack of consensus around treatment approaches and a scarcity of data around treatment patterns exist. At the same time, Health Technology Assessment (HTA) authorities are increasingly requiring high-quality real-world evidence to inform decision making also for rare diseases, and experts’ opinion is often not considered an optimal option. The objective was to get global perception of clinical practice and to quantify resource use and costs in uncontrolled CS through a nationwide register study.

METHODS:
This was an observational retrospective study based on data collected from nationwide Swedish registers between 07/01/2005 –12/31/2013. Swedish data were chosen for their exhaustiveness, comprehensiveness and precision of linkage between registers. Resource use and costs were assessed 8 months before and after patients became uncontrolled. Direct healthcare resources: surgeries, medical interventions (for example, chemoembolization, PRRT), examinations, imaging, outpatient visits, hospitalizations, and CS related drugs were collected and costed at 2015 euro rate.

RESULTS:
The study population included 64 patients. A general trend of increase in resource use between the two periods was observed for all main categories except IFN-alpha. The CS related costs increased in average by 6.2 kEUR/patient (40 percent increase) over 8 months when patients became uncontrolled. This was mainly driven by greater use of off-label dose of SSA and invasive interventions.

CONCLUSIONS:
When CS is uncontrolled its financial burden increases considerably as compared to controlled CS. CS is treated symptomatically but its debilitating effects on patients’ lives and the lack of alternatives lead to the use of costly and invasive procedures. The results should be interpreted in light of limitations such as retrospective study design in a limited number of patients, as a result of the rarity of the disease.

VP115 Practical Issues Of Using Real-World Data In Effectiveness Research

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ABSTRACT SUMMARY:
Research on methods to estimate drug effectiveness using real-world data (RWD) and/or RCT data necessitate data accessibility from both sources. Experiences from Innovative Medicines Initiative, IMI-GetReal demonstrated barriers in accessing data, the resulting datasets available and restrictions on data use. Such barriers can delay effectiveness research, restrict opportunities for development of methods incorporating RWD
and diminish the potential use of RWD in decision making.

INTRODUCTION:
The Innovative Medicines Initiative, IMI-GetReal project aimed to explore incorporation of robust methods for real-world data (RWD) collection and synthesis earlier in the medicines development process, both by pharmaceutical companies and healthcare decision makers. The focus was on the potential use of RWD, alone or in combination with randomized controlled trials (RCTs), to demonstrate effectiveness of new interventions. Four case studies were conducted in multiple disease areas to examine methods for predicting drug effectiveness and the perspectives of different stakeholders on these methods. This study aimed to identify practical obstacles in accessing and using RWD and RCT data for effectiveness research conducted as part of these case studies.

METHODS:
Qualitative content analysis was conducted to identify and characterize key issues relating to accessing and analysing study data from external sources, both RWD and RCTs.

RESULTS:
Accessing RWD from registries proved difficult due to multiple reasons, including: complex and non-transparent application procedures, resistance from registry owners to discuss applications and datasets not being research-ready within project timeframes. There were also issues with the RWD eventually accessed, including a lack of individual participant data (IPD) and incomplete data. Where access to IPD from RCTs was obtainable, there were restrictions imposed on how it could be used. For example, it could not be used to target analysis on an individual product, but rather explore methodologies for data synthesis in a product-anonymised setting. This condition encouraged additional data sharing by other stakeholders.

CONCLUSIONS:
Despite the collaborative, multi-stakeholder nature of IMI-GetReal and proper disclosures with data owners, access to data proved challenging. Such barriers to data accessibility can delay effectiveness research, restrict opportunities for the development of methods incorporating RWD and diminish the potential use of RWD in decision making. Where data is intended to be used for this purpose, sufficient attention should be paid to these potential barriers.

VP116 Comparison Between Time To Off treatment and Italian Medicines Agency Registries Treatment Duration

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ABSTRACT SUMMARY:
The aim of this analysis was to compare for specific Roche products the treatment duration obtained by AIFA Registries and the treatment duration seen in the clinical trials, considering discontinuation of treatment for progression, death or toxicity. Similar treatment durations were seen.

INTRODUCTION:
The Italian Medicines Agency Registry represents a tool that could be a precious source of information regarding the mean treatment duration of a drug in a real world context. Monitoring registries are applied at the national level after market authorisation and are designed not only to apply the Managed Entry Agreements (MEAs) but
also to collect Real World Data on drugs safety, effectiveness and real life utilization. The purpose of this analysis was to compare the treatment duration from clinical trials and the mean treatment duration calculated using data from monitoring registries (1).

METHODS:
For each drug included in the analysis it was collected the treatment duration from Time To Off Treatment curves for the experimental drug (eTTOT) from Phase III clinical trials and the mean treatment duration data calculated by using the number of cycles (converted in months of treatment) of all treated patients extracted from AIFA registries (TTAR). The mean ratios between the Time of Treatment of Italian Medicines Agency and Experimental arm time to off treatment were calculated to identify potential correlations. High level of correlation was expected if Time to Payment By Result /Time To Off Treatment ratio was close to 1 (+.2).

RESULTS:
Six Roche products or different indications of the same product were identified as candidates for the analysis from 2013 to 2016. The mean TTAR/ eTTOT ratio observed in patients treated from 2013 to 2016 was .97 (+.10), meaning that the mean treatment duration calculated from AIFA Registries is strongly comparable with the treatment duration observed in clinical trials. In one case the TTAR is even more major than eTTOT.

CONCLUSIONS:
A high level of correlation between TTAR and eTTOT was found. Additional analyses considering different cohorts of patients over time could be useful to have a more precise estimate of real world drug utilization. Even though RCTs remain the gold standard for demonstrating clinical efficacy in restricted trial setting, Real World Evidence from AIFA registries can contribute to the evidence base needed for healthcare decisions.

REFERENCES:
1. Italian Medicines Agency website - AIFA Registries SAS Platform.

VP117 Analysis Of Mortality Of Ectopic Pregnancy In Shanghai, 1979-2010

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
In order to improve quality of maternal health management and reduce maternal mortality rate (MMR) in Shanghai, we analyzed the maternal deaths and relevant factors of ectopic pregnancy from 1979 to 2010.

INTRODUCTION:
Ectopic pregnancy is a common disease causing acute abdominal pain, and is also a threat to women’s health and lives. The incidence of ectopic pregnancy has been increasing in recent years. We studied mortality of ectopic pregnancy and relevant experiences and problems in maternal mortality management in the past 32 years to provide evidence for implementing interventions to reduce the maternal mortality rate (MMR) in Shanghai.

METHODS:
A retrospective study of ectopic pregnancy deaths in Shanghai from 1979 to 2010 was conducted; 70 cases were collected, and 38 cases were audited by the Maternal Death Review Committee since 1987. All relevant documents, including medical charts, experts audit documents, and Shanghai Maternity and Children Health Report Forms, were assembled for reviewing.
RESULTS:
1. There were 70 deaths due to ectopic pregnancy during the past 32 years, including 57 Shanghai permanent residents and 13 migrant population. The mortality rate of ectopic pregnancy was 1.61 per 100,000, and it took up 6.45 percent of the total MMR in Shanghai. The number of deaths due to ectopic pregnancy fluctuated during the period.

2. There were 39 cases of ectopic pregnancy misdiagnosed in the first visit, accounting for 55.71 percent of the whole. Among these 39 cases, 51.28 percent were misdiagnosed as internal diseases, 28.21 percent were misdiagnosed as other gynecologic diseases, and 20.51 percent were misdiagnosed as surgical diseases. 48.72 percent of the misdiagnosed cases took place in internal medical departments.

3. Abdominal pain and hemorrhage were the most common symptoms, taking up 88.57 percent and 34.29 percent respectively; 18.57 percent of the patients did not go to the hospital in time (≥24 hours); and 22.86 percent of the patients were not treated immediately and properly.

4. 52.73 percent of the cases were audited as avoidable deaths.

CONCLUSIONS:
To avoid deaths caused by ectopic pregnancy, every medical worker should be on alert. Related professional training for medical and healthcare groups should be strengthened so that diagnosis can be more accurate and treatment can be provided in a timely manner. Meanwhile health education should be enhanced to improve women’s, especially migrant women’s, healthcare awareness and behavior.

VP118 Using MedicineInsight Data To Improve Clinical Care In Australia

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ABSTRACT SUMMARY:
MedicineInsight is a national general practice data program developed and managed by NPS MedicineWise and funded by the Australian government. It extracts longitudinal de-identified patient health records from clinical practice software already used by general practitioners to manage patient records. The program enables powerful and flexible insights to support practice quality improvement, pharmacovigilance, population health analysis, health policy, and research.

INTRODUCTION:
Translating evidence into practice is challenging for busy clinicians. Use of real-world data can guide ongoing practice improvement. MedicineInsight is a national general practice dataset developed by NPS MedicineWise and funded by the Australian government. MedicineInsight extracts longitudinal, de-identified patient data from more than 500 general practices to generate powerful and flexible insights.

METHODS:
Data are used to generate tailored practice reports for each of 592 participating practices, focusing on chronic disease management. Reports provide insights about use of medicines and other...
VP119 Improve Emergency Ambulance Care For People With Mental Health

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ABSTRACT SUMMARY:
In this study we describe current workload, practice and service availability in order to develop an intervention (INVENT) for patients with mental health problems, avoiding Emergency Departments (ED) when appropriate, for evaluation through a randomized trial. We reviewed ambulance call center and paramedic completed patient records to identify and describe mental health calls, and reviewed mental health service provision.

INTRODUCTION:
A significant proportion of Emergency Medical Services (EMS) workload relates to mental health problems (1). Little is known about volume, casemix or local service availability for this population (2,3). We aimed to describe current workload, practice and service availability in order to develop an intervention (INVENT) for patients with mental health problems, avoiding Emergency Departments (ED) when appropriate, for evaluation through a randomized trial.

METHODS:
1. We reviewed ambulance call centre and paramedic completed patient records to identify and describe mental health calls nationally in Wales over one month; and call centre records only from two other ambulance services in England.
2. We mapped available mental health services in three ambulance service areas.

RESULTS:
In one month 5.8 percent of all calls to the Welsh ambulance service (n = 1678/28,731) were coded by call takers as being related to mental health problems; corresponding figures in two participating services in England were (n= 827) and 4.2 percent (n=2908). During the same period 5.7 percent (n = 1629/28731) of patients attended by ambulance crews were coded with a mental health problem. However, free text suggests additional patients with underlying or associated mental health problems. Conveyance rates for all mental health categories were over 80 percent (with the exception of anxiety (60.9 percent (n = 39/64)).

The service mapping exercise highlighted commonality in service provision to inform the design of a generic protocol, INVENT - a prehospital mental health referral pathway of care for use by attending ambulance crew.

CONCLUSIONS:
Routinely reported coded data underestimate the volume of mental health related emergency calls. The INVENT protocol, informed by a new understanding of the epidemiology of emergency ambulance calls for people with mental health problems and service mapping aims to support paramedics to make more appropriate referrals to pre-existing community care provision, and reduce unnecessary transfers to ED.

REFERENCES:
medical technology guidance and diagnostics guidance. The research commissioning framework involves NICE’s external assessment centers collaborating with clinical researchers to secure funding and to design, conduct, and publish a study to address research recommendations within 3 years of guidance publications. We aimed to describe the early results of the framework.

METHODS:
Publically available information and results from an informal survey of NICE’s external assessment centers were reviewed.

RESULTS:
As of December 2016, NICE has published a total of thirty medical technology guidance topics and twenty-four diagnostics guidance topics, five and twenty of which have research recommendations, respectively. A total of fourteen research commissioning framework-facilitated projects have been initiated. Two research projects have successfully secured external funding for a clinical trial: (i) non-contact low frequency ultrasound therapy for wound healing; and (ii) Parafricta booties for pressure ulcer prevention. Further projects have produced published outputs without external funding. Four projects have been completed and undergone guidance review; one guidance topic was withdrawn and three have been transferred to the “static list”. Early experiences of NICE’s research commissioning framework suggest that securing financial support from manufacturers or funding bodies for interventional clinical trials to answer single technology research questions within a short time frame is challenging but possible. The value of early feasibility studies to assess the likelihood of obtaining funding and of addressing NICE’s research recommendations was recognised.

CONCLUSIONS:
NICE can facilitate independent research through its research commissioning framework initiative. Securing funding has proved challenging but recent successes have shown that approach is possible.

Outputs which fill the evidence gap to an extent where a definitive guidance update is possible have been rare.

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VP121 Network Meta-Analysis For Managing Biosimilars

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ABSTRACT SUMMARY:
To increase the amount of clinical evidence supporting biosimilars, we propose to carry out for each new biosimilar a network meta-analysis that includes the equivalence study comparing the biosimilar with the originator and all randomized studies comparing the originator with the previous standard of care (1). This approach has been applied to the biosimilars of infliximab and etanercept.

INTRODUCTION:
The criterion adopted by European Medicines Agency (EMA) for approving biosimilars is that these agents must be supported by a comparability exercise; at the same time, an equivalence study must be conducted through “traditional” methods of clinical research. Since biosimilars are supported by less clinical research than originators, some clinicians are reluctant to use these agents in clinical practice and prefer originators. On the other hand, using biosimilars implies an economic advantage for national health systems.
METHODS:
To increase the amount of clinical evidence supporting biosimilars, we have proposed an approach that is based on the conduction of a network meta-analysis that includes not only the equivalence study comparing the biosimilar with the originator but also the randomized studies comparing the originator with the previous standard of care (1). Since June 2016, we have systematically applied this method of “strengthened” clinical evidence to all the new biosimilars as they received market authorization. Our purpose was to promote the use of these biosimilars in our region.

RESULTS:
Infliximab biosimilar, available under two brand names (Inflectra and Remsima; infliximab originator = Remicade), and etanercept biosimilar (Benepali; etanercept originator = Enbrel) have so far been evaluated with this method. With reference to the end-point of American College of Rheumatology (ACR50) response in rheumatoid arthritis unresponsive to methotrexate monotherapy, our network meta-analysis confirmed for infliximab biosimilar the risk difference (RD) obtained from the equivalence trial. Likewise, with reference to the same end-point (ACR50 response in rheumatoid arthritis unresponsive to methotrexate monotherapy), our network meta-analysis confirmed for etanercept biosimilar the RD obtained from the equivalence trial. The 95 percent confidence interval of these RDs calculated from strengthened evidence was narrower.

CONCLUSIONS:
This method of strengthened evidence can contribute to reduce the reluctance with which some physicians manage biosimilars.

REFERENCES:

VP122 Cryoballoon Versus Radiofrequency Ablation For Atrial Fibrillation

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ABSTRACT SUMMARY:
Cryoballoon ablation (CBA) is an emerging therapy for patients with atrial fibrillation. This study conducted a meta-analysis (SRMA) on the effectiveness of CBA and radiofrequency ablation (RFA). From seventeen studies under SRMA, CBA and RFA were found to have the similar clinical effectiveness, while CBA appeared to be associated with a shorter procedural time and a lower acute pulmonary vein isolation rate.

INTRODUCTION:
Pulmonary vein isolation (PVI) is a new effective treatment for atrial fibrillation (AF) (1). The standard of care for ablation methods using radiofrequency (RF) is time-consuming and technically challenging (2), and restricted to a few specialized centers, which causes the limited availability of ablation therapy (3). Therefore, cryoballoon (CB) ablation has been developed to shorten and simplify the procedure. The objective of this systematic literature review and meta-analysis was to compare the effectiveness of cryoballoon ablation (CBA) with radiofrequency ablation (RFA) for the treatment of AF.
METHODS:
We searched the Cochrane Library and PubMed from 2009 to October 2016 to screen the eligible literature according to the inclusion and exclusion criteria. The effectiveness measures were the acute pulmonary vein (PV) isolation rate, procedure time, complications and the proportion of patients free from AF (follow-up > 3 months). Meta-analysis and descriptive statistics were used in this study.

RESULTS:
A total of seventeen articles with 5,806 cases (2,288 from CBA group, 3,518 from RFA group) from seven different countries were reviewed and analyzed. Pooled analyses indicated that CBA was more beneficial in terms of procedural time (Standard mean difference, SMD = -.501; 95 percent Confidence Interval, CI: -1.093 – 0.091; P<.05) for RFA; but the acute PV isolation rate (Odds ratio, OR=.06; 95 percent CI: .03 – .13; P < .05) in RFA was higher than for CBA; also, after median follow-up of 14 months (range 9–28 months), the proportion of patients free from AF (OR=.965; 95 percent CI:.859—1.085; P = .554) and the total complication rates (OR=.937; 95 percent CI:.753–1.167; P = .562) were not significantly different between CBA and RFA.

In the four randomized controlled trials (RCTs) of the seventeen studies, the proportion of patients free from AF (OR=.951; 95 percent CI:.752–1.202; P = .672) and the complications (OR=1.521; 95 percent CI:.570–4.058; P = .402) were not significantly different between CBA and RFA.

CONCLUSIONS:
Overall, compared with RFA for the treatment of patients with AF, CBA had similar clinical effectiveness on the proportion of people free from AF and the number of complications, and yet greater improvement in total procedure time referred for CBA and higher acute PVI rate referred for RFA.

REFERENCES:

VP123 Erlotinib Versus Docetacel In Advanced Non-Small Cell Lung Cancer: A Meta-Analysis

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ABSTRACT SUMMARY:
The efficacy and toxicities between targeted drugs and traditional chemotherapy drugs are still controversial. We performed a meta-analysis of randomized controlled trials to compare the safety and efficacy of erlotinib with docetaxel in previously treated advanced non-small-cell lung cancer.
INTRODUCTION:
Erlotinib is an oral tyrosine kinase inhibitor against the epidermal growth factor receptor (EGFR). It has been shown to be active in patients with advanced non-small cell lung cancer (NSCLC) whose tumors contain EGFR mutations. We performed a meta-analysis of randomized controlled trials to compare the efficacy and toxicities of erlotinib with docetaxel in previously treated advanced non-small-cell lung cancer.

METHODS:
The PubMed database, the Cochrane Library, and references of published trials were searched. Two reviewers independently assessed the quality of the trials and extracted data. The hazard ratios (HRs) for overall survival (OS) and progression-free survival (PFS), and odds ratios (ORs) for main toxicities were pooled using package stata12.0.

RESULTS:
Three multicenter, randomized controlled trials involving 928 patients with previously treated advanced NSCLC were ultimately analyzed. The pooled HRs showed no significant difference in OS and PFS between the two groups (HR=1.05, 95 percent CI =.92-1.20, p=.00; HR=.89, 95 percent CI=.77-1.03, p=.36, respectively). Erlotinib had more grade 3 or 4 side effects (OR=3.75, 95 percent CI=2.19-6.44, p<.001) than docetaxel.

CONCLUSIONS:
Erlotinib showed no advantage over docetaxel in terms of OS and PFS, and docetaxel had fewer grade 3 or 4 side effects than erlotinib. Considering only three randomized controlled trials involving 928 unselected patients included in our study, more clinical trials are needed to compare the safety and efficacy of the two drugs in the future.

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VP124 The End Of A French Medical Dogma For Hepatitis B And C Diagnosis

PRESENTING AUTHOR:
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AUTHORS:
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ABSTRACT SUMMARY:
Since the 90s in France, Hepatitis B (HBV) or Hepatitis C (HCV) diagnosis is acknowledged when detection of HBs antigen or anti-HCV antibody is positive on a 1st test line and further replicated on an independent blood sample. Our aim is to assess the clinical relevance of this repetition.

INTRODUCTION:
Since the 1990s in France, based on contemporary French consensus conferences, for Hepatitis B (HBV) or Hepatitis C (HCV), diagnosis is acknowledged when detection of HBs antigen or anti-HCV antibody is positive on a 1st test line and further replicated on an independent blood sample.

The replication was introduced to alleviate the low performance of immunoassay and avoid false positive results.

Currently, the Haute Autorité de santé (HAS) is managing an update of diagnostic tests reimbursed for HBV and HCV to fully cover diagnostic needs.

Our aim is to assess the clinical relevance of this repetition.

METHODS:
The assessment involves a critical analysis of national and international guidelines identified by a systematic literature search, and stakeholders’ views (professionals and public authorities).
RESULTS:
Since the 1990s, new tools were introduced (that is, polymerase chain reaction (PCR) for diagnosis and follow-up), and performances were improved for both enzyme immunoassay tests and PCR. Despite those change, replications are still performed nowadays in France.

Neither guidelines nor stakeholders’ contributions mentioned any replication tests’ clinical relevance. The Ministry of Health confirms that replications have not any legal basis contrary to HIV diagnosis procedures. Also, the French National agency for health products safety confirms there are neither technological pitfalls nor reagent vigilance signals involving HBV or HCV in vitro diagnostic tests. Furthermore, after 1st line positive results, a second blood sample is always collected to test other markers such as HBV DNA or HCV RNA which represent the best 2nd proof of infection.

CONCLUSIONS:
This work has enlightened a lack of clinical relevance for the replication of the same serological makers’ detection. It may obliterate soon this French medical dogma. This work has illustrated that short assessment based on critical guideline analysis linked with stakeholders’ views allows a rapid answer without assessment quality reduction. This HAS work will contribute to medical practice rationalization and cost reduction.

AUTHORS:
Claude Farah, Australia
Judy Morona, Australia
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ABSTRACT SUMMARY:
We conducted a meta-analysis of trials to examine the effectiveness of PD-1/PD-L1 immunotherapy in advanced lung cancer. Our results showed that as PD-L1 expression increases, the reduction in risk of death was better. However, different studies used different PD-L1 tests and thus the results should be interpreted with caution.

INTRODUCTION:
Advanced non-small cell lung cancer (NSCLC) has limited treatment options. Antiprogrammed cell death receptor 1 (PD-1)/ligand 1 (PD-L1) inhibitors have shown promising results in treating NSCLC. Published meta-analyses of these inhibitors suffer from many limitations including the use of ‘objective response’ as the outcome of interest rather than overall survival (OS) and the inclusion of single arm data (1-3). We present a meta-analysis of randomized controlled trials (RCTs) to assess the comparative OS benefit and comparative harm associated with these inhibitors, compared with standard of care, in Stage IIIB/IV NSCLC.

METHODS:
A systematic literature search for RCTs was undertaken. Studies were included if they reported OS hazard ratios (HRs) and drug-related Grade 3–4 adverse events (AEs). PD-L1 expression could be measured on the tumour cell/immune cell depending on the trial testing method. Data were pooled using the random effects model. Treatment effect variation by PD-L1 expression threshold and NSCLC histotype and heterogeneity across were examined.

VP125 A Systematic Review Of PD-1/PD-L1 Inhibitors In Advanced Advanced Non-small Cell Lung Cancer

PRESENTING AUTHOR:
David Tamblyn, Australia
RESULTS:
Five trials with a low risk of bias for OS were included. The pooled HR decreased with increasing PD-L1 expression threshold, corresponding to the following statistically significant reductions in risk of death: 33 percent, 38 percent, 42 percent, and 50 percent for the ≥1 percent, ≥5 percent, ≥10 percent, and ≥50 percent PD-L1 expression thresholds, respectively. OS results by histology and safety analyses are forthcoming.

CONCLUSIONS:
Preliminary analyses indicate a dose-response trend towards an increasing reduction in risk of death as the threshold of PD-L1 expression increases. Interpretation of these results should consider that the different trials used different testing methods to assess PD-L1 expression which may have led to the heterogeneity observed in some of the analyses. Further research is warranted to examine the validity of a PD-L1 threshold dose-response and to specify a reasonable PD-L1 threshold for access to a PD-1/PD-L1 inhibitor treatment.

REFERENCES:

VP126 The Effectiveness And Safety Of Barbed Sutures In Bariatric Surgery

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ABSTRACT SUMMARY:
The barbed suture is an effective and safe surgical technique in Bariatric Surgery. More evidence with randomized design, larger sample sizes and longer follow up are needed to compel validations of this state-of-the-art product in the future.

INTRODUCTION:
Knotless barbed sutures can eliminate knot tying during the bariatric surgery (BS) (1). Since effects reported by patients and surgeons are ambiguous, the aim of this study was to establish the safety and efficacy of barbed sutures for intestinal sutures to close the gastrojejunal anastomosis in obese patients undergoing BS.

METHODS:
PubMed, EMBASE, Cochrane Register of Clinical Studies, and ClinicalTrials.gov were searched for randomized controlled trials (RCTs) and cohort studies comparing barbed sutures with conventional sutures in BS (until 30 June 2016). Quality assessment was conducted using to Cochrane recommendations. Review Manager was applied to analyze the data, and we sequentially omitted each study to perform sensitivity analyses.
RESULTS:
A total of five cohort studies (low to moderate risk of bias) \( n=859 \), and no RCTs provided eligible patients. BS includes laparoscopic Roux-en-Y gastric bypass and Laparoscopic sleeve gastrectomy. Comparing to conventional sutures, pooling data showed that suture time (Mean Difference, MD = -5.73, 95 percent Confidence Interval, CI -6.25 to -5.21, \( P < .01 \)) and operative time (MD = - 7.67 , 95 percent CI -10.49 to -4.85, \( P < .01 \)) decreased significantly in the barbed group. Although the postoperative complications did not suggest significant changes (Odds Ratio, OR = 1.56, 95 percent CI .79 to 3.07, \( P = .2 \)), the pooling results of hospital stay suggested that a significantly longer duration happened in the barbed groups, despite the fact that there may be only 0.18 day longer (MD = 0.18, 95 percent CI .06 to .29, \( P = .003 \)).

CONCLUSIONS:
The barbed suture is an effective and safe surgical technique in BS. More evidence with randomized design, larger sample sizes and longer follow up need to compel validations of this state-of-the-art product in the future (2,3).

REFERENCES:

VP127 Comparison Of Efficacy, Safety, And Cost Of Radiofrequency Ablation With Surgical Resection For Hepatocellular Carcinoma

PRESENTING AUTHOR:
Kun Xiong, China

AUTHORS:
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ABSTRACT SUMMARY:
This study systematically reviewed and compared the efficacy, safety, and cost of radiofrequency ablation (RFA) with surgical resection (SR) in the treatment of HCC in China. The SR for the patients with small HCC has higher efficacy than that of RFA therapy, although the safety and economic efficiency is not as good as those of RFA therapy.

INTRODUCTION:
Radiofrequency ablation (RFA) and surgical resection (SR) are the only two therapies that can be used regularly to cure early hepatocellular carcinoma (HCC) in China. However, there is no consensus on which one is the best therapy for small HCC (<5cm). This study is to compare the efficacy, safety, and cost of RFA with those of SR in the treatment of small HCC in China.

METHODS:
All eligible literature related to the comparison of the efficacy, safety, and cost of RFA with those of SR in the treatment of HCC and involved controlled clinical trials in China were collected from three databases (including PubMed, CBM, and CNKI) and reviewed. The complete necrosis rate, overall survival rate, intrahepatic recurrence rate, disease-free survival rate, length of hospital stay, hospital medical cost, and the incidence rate of some major
complications were analyzed in the study, using M-H fixed or D-L random meta models. The Egger’s tests and Begg’s tests indicated no publication bias were involved in the studies.

RESULTS:
Forty-five studies, including 11 randomized controlled trials (RCTs) and 34 Non-RCTs, with 4,858 patients in the RFA group and 5,250 patients in the SR group, were used in the analyses. The complete necrosis rate of the SR group was higher than that of the RFA group (RR=1.05, 95 percent Confidence Interval, CI was 1.03,1.07). The overall survival rates for 1 year, 3 years, and 5 years in the SR group were slightly higher than those in the RFA group (Relative Risk, RR1OS =1.02, RR3OS =1.06 and RR5OS =1.12), while the disease-free survival rates for 1 year, 3 years, and 5 years in the SR group were significantly higher than those in the RFA group (RR1DFS =1.10, RR3DFS =1.33 and RR5DFS =1.45). Furthermore, the intrahepatic recurrence rates for 3 years and 5 years in the SR group were significantly lower than for those in the RFA group (RR3=.75 and RR5=.79). However, the incidence rate of postoperative pleural effusion, ascites, bile leakage, infection, length of hospital stay, and hospital medical cost in the SR group were significantly higher than those in the RFA group.

CONCLUSIONS:
The SR for the patients with small HCC has higher efficacy than that of RFA therapy, although the safety and economic efficiency of SR is not as good as those of RFA therapy in the short run. The long-term safety and economic efficiency of them should be further explored.

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VP128 Cost-Effectiveness Of E-Cigarettes For Smoking Cessation

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ABSTRACT SUMMARY:
This analysis examines the cost-effectiveness of e-cigarettes as a smoking cessation intervention, compared with alternative pharmacological interventions or unassisted quitting. It finds that although this intervention is the most cost-effective option, given the low incremental cost-effective ratios (ICERs) for more effective interventions e-cigarettes are unlikely to be the optimal strategy using conventional willingness to pay thresholds.

INTRODUCTION:
E-cigarettes can justifiably be considered a disruptive innovation. In the short space of time since their introduction they have successfully displaced long established interventions for smoking cessation, challenged existing roles and values of health care practitioners, and had a significant societal impact. This analysis is the first to examine the cost-effectiveness of e-cigarettes as a smoking cessation intervention, compared with alternative pharmacological interventions or unassisted quitting.

METHODS:
A cost utility analysis was carried out using a quasi-societal perspective that included the costs...
of smoking cessation interventions paid for by the health system or by smokers in Ireland, as well as the cost of treating smoking related illness. A open population model was used to estimate differences in costs and utilities in each comparator over a 20 year time horizon, using a discount rate of 5 percent. This model compared individual smoking cessation interventions to each other, as well as comparing alternatives to current practice among the overall population of Irish smokers trying to quit.

RESULTS:
E-cigarettes are on the cost-effectiveness frontier for quit interventions, with an incremental cost-effective ratio (ICER) compared to unassisted quitting of EUR5,222/QALY. This result is very sensitive to changes in the estimate of the relative effectiveness and costs of e-cigarettes. Both of these parameters are associated with a high degree of uncertainty, given the current lack of high quality studies examining e-cigarettes as a smoking cessation aid, coupled with the wide variety of continually evolving e-cigarette products available to smokers. The most effective intervention on the frontier (varenicline in combination with nicotine replacement therapy) has an ICER of EUR6,176/QALY.

CONCLUSIONS:
Based on the available evidence, e-cigarettes are the most cost-effective intervention for smoking cessation, but given the low ICERs for more effective alternatives, they are unlikely to be the optimal strategy using conventional willingness to pay thresholds in western European countries. At a population level, the rising trend in e-cigarette use is likely to increase overall smoking cessation rates compared with current practice.

VP129 Social Cost Benefit Analysis (SCBA) Of Three Alcohol Policy Measures

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ABSTRACT SUMMARY:
The high prevalence in alcohol abuse leads to costs to the society, that is, healthcare costs, reduced productivity, criminality, traffic accidents, and violence. This Social Cost Benefit Analysis (SCBA) presents the costs and benefits of three policy measures: tax increase, closure of sales venues, and advertising ban. All scenarios lead to net benefits, with tax increases showing highest net benefits.

INTRODUCTION:
Alcohol abuse and addiction lead to a high disease burden for the persons concerned. Moreover, it has economic consequences for society, including costs of health care, costs due to reduced productivity, criminal activities, traffic accidents, and violence, both in private and public domains. The aim of this study was to perform a social cost-benefit analysis (SCBA) of three policy measures (tax increase, reducing number of sales venues, and advertising ban) over a period of 50 years, along with the distribution of costs and benefits among stakeholders (1).
METHODS:
The analysis follows Dutch guidelines for performing SCBAs. Costs and benefits in eight different domains were comprehensively identified. Model simulations were used to estimate future social costs and benefits of three policy measures, compared to not intervening.

RESULTS:
Over a period of 50 years, the greatest social benefits were expected from a tax increase. The cumulative discounted net monetary benefit over a period of 50 years is EUR12 billion (95 percent Confidence Interval, CI EUR11-EUR13 billion) in the 50 percent tax increase scenario. The net benefits of the other two measures are smaller. The cumulative discounted value to society of a 10 percent decrease in outlet density over a 50-year period amounts to EUR4 billion (range: EUR3 - EUR5 billion). A total media ban with an estimated reduction of 4 percent in alcohol consumption leads to an expected cumulative discounted value to society over a 50-year period of EUR7 billion.

CONCLUSIONS:
All policy scenarios lead more or less to positive effects for society. The greatest benefits are associated with measures aimed at raising the excise tax on alcohol. Estimations as made in this study may serve to inform alcohol policy in the Netherlands.

REFERENCES:

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VP130 Burden Of Illness For Urothelial Bladder Cancer (UBC) In Italy

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ABSTRACT SUMMARY:
Urothelial Bladder Cancer is the ninth worldwide most common cancer. In Italy the disease prevalence is about 10 percent, with a significant impact on the Healthcare System. An economic analysis in National Health Service perspective was carried out to evaluate the burden of disease collecting direct and indirect costs. This analysis represents the first real life evidence of the current therapeutic algorithm.

INTRODUCTION:
Urothelial Bladder Cancer (UBC) is the ninth worldwide most common cancer. In Italy the prevalence of the disease is about 10 percent, representing the third most prevalent cancer with 180,775 cases in men and 42,757 cases in women. The increase in the incidence requires continuous surveillance and care, resulting in a significant burden on Italian Healthcare System, making any improvement to the strategy for diagnosing and treating this disease important to the medical and scientific community. The aim of this study was to evaluate the burden of UBC in the Italian context, collecting and measuring the total costs of the disease.
METHODS:
An economic analysis in the National Health Service perspective was carried out, evaluating in six centers direct costs in terms of outpatient, inpatient and emergency care, pharmaceuticals and follow up procedures and indirect costs in terms of productivity losses. Data were collected through aggregated form reports, focusing on patients with an existing diagnosis of UBC who were taken in charge in the last year. Statistical analysis was conducted in order to explore variations between centers.

RESULTS:
Mean total annual cost per patients was EUR11,310, increasing for disease severity from EUR6,954 for superficial disease to EUR24,896 for metastatic stage. The analysis confirmed a proportional relation between disease severity and disability grade. The total burden of the disease considering all patients, including prevalence and incidence data coming from AIOM guidelines 2015, was EUR2,833,655,822, of which 15 percent is represented by estimated productivity losses.

CONCLUSIONS:
Our analysis represents the first economic burden study of UBC in the Italian context as well as the first real life evidence of the current therapeutic algorithm. This study opens the possibility for further analysis on the indirect costs components that represent a great burden for the society, especially for the stages of the disease with high disability grade.

Authors:
Jonathan Campbell, United States

Abstract Summary:
Our objective was to compare one-way sensitivity analysis results when using two common approaches for one-way sensitivity analyses: evidence-based probability distributions from published sources and constant percentage variation. Findings suggest evidence-based uncertainty in inputs should be used in all sensitivity analyses to reflect realistic uncertainty in an outcome and aid decision making about future research strategies.

Introduction:
A common approach to one-way sensitivity analysis is to vary inputs by a constant percentage. An alternative is to derive ranges using evidence-based probability distributions from published sources. Our objective was to compare one-way sensitivity analysis results when using these two approaches for a reference case model, along with two additional case studies.

Methods:
For the reference case, we replicated a published Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) cost-effectiveness Markov model (zidovudine versus zidovudine plus lamivudine in the United Kingdom) using TreeAge®. Health states included three HIV/AIDS states and death. We generated one-way sensitivity analyses by varying inputs in two ways: (i) using ±15 percent for all inputs, and (ii) using the 2.5 and 97.5 percentile values of the evidence-based probability distributions for all inputs. Our outcome was the mean difference between lower and upper incremental cost-effectiveness ratios (ICERs) for each variation method for the ten most influential inputs. We assessed the number of inputs with a mean difference between lower and upper ICERs of >10 percent of the deterministic ICER.

VP131 Comparison Of Variation Methods For One-Way Sensitivity Analyses

Presenting Author:
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RESULTS:
The deterministic ICER was £7,654/QALY (quality adjusted life year) for combination therapy vs. monotherapy. The mean difference in ICER uncertainty for the evidence-based vs. ±15 percent variation method was £3,251/QALY (p=.0096). Six inputs had a mean difference in ICER uncertainty of >10 percent of £7,654/QALY (i.e. mean difference in ICER uncertainty > £765) for the evidence-based variation method, compared to only two inputs for the constant percentage variation method.

CONCLUSIONS:
For the reference case, the magnitude of uncertainty in the outcome was larger for the evidence-based variation method compared to the constant percentage variation method. Evidence-based uncertainty in inputs should be used in all sensitivity analyses to reflect realistic uncertainty in an outcome and aid decision-making about future research strategies. Additional case studies will be presented using validated models in diabetes and asthma.

ABSTRACT SUMMARY:
In one area of the UK, we evaluated a predictive risk stratification model designed to support primary care practitioners to identify and manage patients at high risk of admission. We found that the costs of implementing the model were low, but it was associated with an unexpected and undesirable increase in healthcare expenditure.

INTRODUCTION:
Emergency admissions to hospital are a major financial burden on health services. In one area of the United Kingdom (UK), we evaluated a predictive risk stratification tool (PRISM) designed to support primary care practitioners to identify and manage patients at high risk of admission. We assessed the costs of implementing PRISM and its impact on health services costs. At the same time as the study, but independent of it, an incentive payment (‘QOF’) was introduced to encourage primary care practitioners to identify high risk patients and manage their care.

METHODS:
We conducted a randomized stepped wedge trial in thirty-two practices, with cluster-defined control and intervention phases, and participant-level anonymised linked outcomes. We analysed routine linked data on patient outcomes for 18 months (February 2013 – September 2014). We assigned standard unit costs in pound sterling to the resources utilised by each patient. Cost differences between the two study phases were
used in conjunction with differences in the primary outcome (emergency admissions) to undertake a cost-effectiveness analysis.

RESULTS:
We included outcomes for 230,099 registered patients. We estimated a PRISM implementation cost of £0.12 per patient per year.

Costs of emergency department attendances, outpatient visits, emergency and elective admissions to hospital, and general practice activity were higher per patient per year in the intervention phase than control phase (adjusted δ= £76, 95 percent Confidence Interval, CI £46, £106), an effect that was consistent and generally increased with risk level.

CONCLUSIONS:
Despite low reported use of PRISM, it was associated with increased healthcare expenditure. This effect was unexpected and in the opposite direction to that intended. We cannot disentangle the effects of introducing the PRISM tool from those of imposing the QOF targets; however, since across the UK predictive risk stratification tools for emergency admissions have been introduced alongside incentives to focus on patients at risk, we believe that our findings are generalisable.

ABSTRACT SUMMARY:
The CLARINET study collected patient reported European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 data: 1,053 observations from 204 patients were mapped to Euroqol (EQ)-5D utilities using the McKenzie algorithm. Based on the random effect model, the difference in utilities based on progression status is statistically significant and the estimated utilities for stable and progressive disease are .776 and .726, respectively.

INTRODUCTION:
Gastroenteropancreatic neuroendocrine tumours (GEP-NETs) are rare cancers most often found in the gastrointestinal system or the pancreas. However, patient-reported health state utilities based on clinical trials have not been previously reported in this disease area.

METHODS:
The CLARINET study collected the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 data from patients in both stable and progressive disease states, although data for the latter were only available during the early stage of progression due to trial design. Using published algorithms, data were mapped to EQ-5D utility values. Random-effects generalised least squares models were used to investigate the impacts of progression status, tumour site and other patient characteristics on mapped utility values.

RESULTS:
In total, 1,053 observations from 204 patients were mapped to EuroQol (EQ-5D) utilities using the McKenzie mapping algorithm. The final random-effects model included age, gender, baseline utility and progression status as covariates; it was not feasible to investigate time-to-death utility due to a limited number of death in the CLARINET study. Tumour location (midgut vs pancreas) does not seem to affect utility. However, the difference in utilities based on progression status is statistically significant.

VP133 Patient-Reported Health State Utilities in Neuroendocrine Tumours

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AUTHORS:
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significant (p<.05) in the base case analysis, and the estimated utilities for stable and progressive disease are .776 and .726, respectively. Furthermore, scenario analyses showed that utility for progressive disease is numerically lower than for stable disease, but this may not be statistically significant in some scenarios.

CONCLUSIONS:

Patients with GEP-NETs experience worse utility values in the progressive disease state compared to the stable disease state, based on patient-reported health-related quality of life (HRQL) data from the CLARINET study. The decline of utility in the progressive disease state may be underestimated because progressive HRQL data were only collected shortly after the progression event in the trial. The estimated trial-based utilities can be used in future economic evaluations for GEP-NET treatments and to provide more insights to physicians on patient-reported quality of life outcomes in GEP-NETs.

INTRODUCTION:

In reference to the quotation: “... all models are wrong: the practical question is how wrong do they have to be not to be useful.” (1), in this presentation we use evidence to attempt to raise a practical question: how wrong might models have to be in order to no longer be useful?

METHODS:

To address this question, estimates derived from information collected ‘alongside’ a trial are compared to estimates derived from models in the literature. A systematic literature review is undertaken to retrieve information relating to PSA-based systematic screening for prostate cancer estimated as part of published cost-effectiveness models. In addition, a set of national registers covering, for example, prescription medication reimbursements, inpatient care, and outpatient care are linked together to produce healthcare-cost estimates for men diagnosed with prostate cancer during a 15-year follow-up of the 80,000+ men in a prostate cancer screening trial.

RESULTS:

The findings concerning the estimates associated with systematic PSA-based screening vary in the literature. Estimates from a pragmatic trial suggest that, over the first fifteen years, e.g., prostate cancer screening has a noticeable impact on the average cumulative costs of men diagnosed with prostate cancer, but those estimates seem to be markedly lower than from many of those observed in modelling studies.

CONCLUSIONS:

HTA practitioners work on a range of policy questions, but a dogmatic over-reliance on model-based forms of economic evaluation seems unlikely to be equally helpful in all decision problems. Decision modelling is often portrayed as a method to produce ‘better decisions,’ but this portrayal seems to fail to confront the possibility that some decision models can be constructed at a point in time when they are far from complete, or when
they are dependent on unverified assumptions. If models do not necessarily produce either qualitatively or quantitatively accurate evidence, then it seems likely that their relevance in the policy-making process should be assessed on a case-by-case basis.

REFERENCES:

VP135 Clustering Surgical Indicators And Predictors Of Catastrophic Expenses

PRESENTING AUTHOR:
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AUTHORS:
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ABSTRACT SUMMARY:
This study classified 177 countries by surgical care indicators and predictors of catastrophic expenditures through using k-means clustering and decision trees on World Health Organization and World Bank data. Countries were delineated into four groups by income level. Surgeon and imaging technology densities were determiners of catastrophic expenditures. Healthcare distribution must become more effective to overcome worldwide surgical care inequality.

INTRODUCTION:
Increasing access to surgical care is crucial in improving the general health status of a population. Despite studies indicating the cross-country differences of general health indicators, there is a scarcity of knowledge focusing on the cross-country differences of surgical indicators. This study aims to classify countries according to surgical care indicators and identify risk predictors of catastrophic surgical care expenditures.

METHODS:
For this study, data were used from the World Health Organization and the World Bank on 177 countries. The following variable groups were chosen: total density of medical imaging technologies, surgical workforce distribution, number of surgical procedures, and risk of catastrophic surgical care expenditures. The k-means clustering algorithm was used to classify countries according to the surgical indicators. The optimal number of clusters was determined with a within-cluster sum of squares and a scree plot. A Silhouette index was used to examine clustering performance, and a random forest decision tree approach was used to determine risk predictors of catastrophic surgical care expenditures.

RESULTS:
The surgical care indicator results delineated the countries into four groups according to each country’s income level. The cluster plot indicated that most high-income countries (for example, United States, United Kingdom, Norway) are in the first cluster. The second cluster consisted of four countries: Japan, San Marino, Marshall Islands, and Monaco. Low-income countries (for example, Ethiopia, Guatemala, Kenya) and middle-income countries (for example, Brazil, Turkey, Hungary) are represented in the third and fourth clusters, respectively. The third cluster had a high Silhouette index value (.75). The densities of both surgeons and medical imaging technology were risk determiners of catastrophic surgical care expenditures (Area Under Curve = .82).

CONCLUSIONS:
Our results demonstrate a need for more effective health plans if the differences between countries surgical care indicators are to be overcome. We recommend that health policymakers reconsider distribution strategies for the surgical workforce.
and medical imaging technology in the interest of accessibility and equality.

VP136 The Impact Of Hospital Costing Methods On Economic Evaluations

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AUTHORS:
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ABSTRACT SUMMARY:
This study investigates the implications of choosing a particular hospital costing method on economic evaluations. We employed a cost-utility model developed to compare secondary fracture prevention models of care for hip fracture patients in England. For each source of diagnosis-related group (DRG)-based costs (tariffs, Finished Consultant Episodes (FCE)-level, spell-level), the estimated hospital costs, decision uncertainty and adoption of models of care were evaluated.

INTRODUCTION:
There are several methods to cost hospital contacts when estimating the cost effectiveness of a new intervention. In England, the National Institute for Health and Care Excellence (NICE) recommends the use of diagnosis-related group (DRG)-based costs as a valuable way of costing hospital resource use. There are three main sources of unit costs of a DRG: (i) tariffs as used for reimbursement purposes, (ii) benchmarking finished consultant episode (FCE)-level reference costs and (iii) benchmarking spell-level reference costs.

The purpose of this work is to compare the implications of choosing a particular source of DRG-based unit costs when conducting an economic evaluation.

METHODS:
As a case study, we used a cost-utility model developed to compare secondary fracture prevention models of care for hip fracture patients (1). A Markov model was derived from large primary and hospital care administrative datasets in England. Utilities were informed by a meta-regression of thirty-two studies. Hospital resource use (inpatient, outpatient, critical care and emergency care) was valued using the three different 2014-15 DRG-based unit costs and regression-based costing models were derived from 33,000 hip fracture patients to inform the health states of the model (2). For each source of DRG-based costs, we calculated mean life years, Quality-Adjusted Life Years (QALYs) and costs for a representative male and female associated with three models of care: (i) orthogeriatrician (OG)-led, (ii) nurse-led fracture liaison services and (iii) usual care.

RESULTS:
Using the benchmarking FCE-level DRG-based costs, the OG-led model was estimated to be the most effective model of care (1.77 QALYs, 95 percent Confidence Interval, CI 1.56-1.98) at a threshold of GBP30,000/QALY. However, it also resulted in the highest costs per patient. We will report the cost-effectiveness results using the two remaining DRG-based costs.

CONCLUSIONS:
Choosing a particular hospital costing method may have an impact on economic evaluations. We will reflect on the implications for the estimated hospital costs, decision uncertainty and adoption of models of care.

REFERENCES:

VP137 Why We Should Not Meet Unmet Needs!

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
When using several different criteria for decision making in Health Technology Assessment (HTA), we risk conceptual overlap. In the presentation, the relationship between severity of disease and unmet need is analyzed from a conceptual and normative perspective. The results show that there is a conceptual overlap, making unmet need as criterion more or less redundant except in specific situations.

INTRODUCTION:
In formulating criteria for Health Technology Assessment (HTA) and priority setting, a number of such criteria have been suggested and are used, for example in multi-criteria decision making. Besides taking central aspects like severity of disease, effectiveness, cost-effectiveness and patient safety into account, we also find references to criteria like unmet needs, and lack of alternative treatment. Often these criteria are treated as on par with each other, only given different weights in decision making. However, it seems like there is a conceptual overlap between some of these criteria and if that remains unnoticed, there is a risk of taking the same criteria into account twice. One such example is the relationship between severity of disease and unmet need. The aim of this presentation is to present a tentative analysis of the relationship between severity of disease and unmet need.

METHODS:
The presentation is based on a conceptual and normative analysis.

RESULTS:
First it will be argued that we have reason to clarify what is meant by unmet needs, whether it is a need which is not met to any degree or if it is a need for which there is no treatment with curative intent or for which there is only palliative treatment, for example. Second, analysing unmet needs in relation to severity, a number of different scenarios will be examined, showing that unmet needs can be captured in terms of severity of disease (to some extent dependent upon how we operationalize severity of disease).

CONCLUSIONS:
The general conclusion of the study is that we have reason to carefully analyze criteria used for decision making in HTA from a conceptual and normative perspective in order to uncover logical relationships and avoid overlapping criteria. In relation to the specific question of unmet needs versus severity of disease, the conclusion is that in most cases unmet need will be redundant in relation to severity and we should be careful using both of them in decision making unless we can provide reasons for why it is an exceptional case.

VP138 Integration Of Ethics In Health Technology Assessment

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**ABSTRACT SUMMARY:**
The objective was to identify the conceptual and methodological issues surrounding integration of ethics in Health Technology Assessment (HTA). We conducted a systematic review. While few experimentations were identified, no clear operational method was found. Our results constitute the basis for developing a new theoretical and practical method.

**INTRODUCTION:**
The objective was to identify the conceptual and methodological issues surrounding integration of ethics in Health Technology Assessment (HTA). We conducted a systematic review examining: (i) social needs, (ii) methodological and procedural barriers, (iii) concepts or processes of ethics assessment used and (iv) results of experimentations for integrating ethics in HTA.

**METHODS:**
Search criteria included 'ethic', 'technology assessment' and 'HTA'. The literature search was done up to 21 November 2016 in Medline/Ovid, SCOPUS, CINAHL, PsycINFO and international HTA Database. Screening of citations, screening of full-text and data extraction were performed by two subgroups of two independent reviewers. The first group was constituted of HTA experts, and the second of ethics and philosophy experts. Data extracted from articles were regrouped in categories for each objective.

**RESULTS:**
A list of 2,420 citations was obtained while 1,646 remained after the removal of duplicates. Of these, 132 were fully reviewed, yielding 67 eligible articles for analysis. Eight categories were identified within the social needs. The mostly evoked were 'Informed policy decision making' (n=16) and 'Informed public/patient decision making' (n=12). Ten categories of methodological and procedural barriers were identified. The most mentioned were 'Lack of standardized and recognized proceedings for ethical analysis' (n=28) and 'Lack of shared consensus on the role of ethical theory and ethical expertise' (n=17). Within the concepts or processes of ethics assessment, thirteen categories were identified. The most mentioned were 'Fairness and Equity' (n=12), 'Beneficence and Non-maleficence' (n=10) and, 'Autonomy' (n=10). Within results of experimentations, five categories were identified. The most mentioned was 'Usefulness of ethics for identifying relevant problems' (n=3). While few experimentations were identified, no clear operational method was found in our research.

**CONCLUSIONS:**
This study confirms the necessity to design an operational method integrating ethics and addressing social needs of HTA. Our results constitute the basis for developing a new theoretical and practical method.

**VP139 Broadening The Scope: Assessment Of Methods Used In Social Services**

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**ABSTRACT SUMMARY:**
SBU, the Swedish Health Technology Assessment agency, has since 2015 had an expanded mission...
including methods used in social services. Experiences of working within this field will be presented.

INTRODUCTION:
For many years SBU’s (Swedish Agency for Health Technology Assessment and Assessment of Social Services) mandate was limited to assessment of methods used within the health and medical services. However, SBU’s method of conducting systematic scientific quantitative and qualitative reviews can theoretically be applied to other fields of research. In 2015, SBU’s mandate expanded to include assessment of methods used in the social services including LSS (Law regulating Support and Service to Persons with Certain Functional Disabilities).

METHODS:
To approach this new field we have worked at three levels: (i) providing information and started a dialogue about SBU and SBU’s methodology to the new target groups and key opinion leaders; (ii) application of SBU’s traditional methodology on several assessments on methods used in the social services; (iii) by using experiences from SBU’s existing strategy for regional educational activities within Health Technology Assessment (HTA) as a template, we have started to build a similar, but not identical, structure within the field of social services.

RESULTS:
We have presented SBU and our methodology at several conferences within the field of social services and have been invited to four universities to hold courses on the topic. A number of assessments have been published for example, “Programs for youth with antisocial problems in institutional care” and “Kinship care for the safety, permanency, and well-being of children removed from the home for maltreatment” and several are ongoing, for example, “Interventions for unaccompanied asylum-seeking young people” and “Parenting interventions for the prevention of physical or psychological child abuse or neglect.”

CONCLUSIONS:
When broadening the scope to fields outside health care, our experience so far is the need for an extra communication and information effort to the new target groups. However, the well-established methodology that SBU and many other HTA agencies around the world use seems applicable also when assessing methods used within social services.

VP140 Methods For Ethical Analysis In The Health Technology Assessment

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ABSTRACT SUMMARY:
This paper is based on a narrative review to identify and describe approaches to incorporate ethical aspects in Health Technology Assessment (HTA). The result showed great diversity of approaches to inclusion of the ethical dimension in studies evaluating health technologies, which can even be used together.

INTRODUCTION:
This paper is based on a narrative review to identify and describe approaches to incorporate ethical aspects in Health Technology Assessment (HTA). On the first decade HTA was being established as a new area of research, the social and ethical dimensions seemed to play an essential role. This perspective, centered on the social impact of technology contrasts with the current definition, which focuses on the technical conditions of technology, especially properties and effects. Some
authors have discussed the obstacles to include the ethical dimension into this area to a large extent. Those authors were motivated by the perception that there are few sections explicitly dedicated to these dimensions in the evaluation reports.

**METHODS:**

We searched these scientific databases: Pubmed, Cochrane Library, Centre for Review and Dissemination (CRD), PDQ - Evidence and Virtual Health Library (VHL), and selected studies that presented procedures and methodologies for the inclusion of ethical analysis in HTA.

**RESULTS:**

A total of 308 articles were retrieved, nine of them were included. The identified methods were classified into four groups according to the parameters and procedures: (i) normative-based evaluation, (ii) case comparison-based evaluation; (iii) predefined questionnaire application-based evaluation and iv) debate and deliberation-based evaluation.

The result showed a great diversity of approaches (1 - 3) for the inclusion of the ethical dimension in the evaluation studies of health technologies, which can even be used together. It is suggested that its use considers the characteristics and needs of each different application contexts.

**CONCLUSIONS:**

This work presented as methodological base of approaches for the integration of the ethical dimension in the HTA field. Nonetheless, the proposed approaches to the incorporation of philosophical field of ethics into the systematization and objectivity field of the HTA reveal a considerable approach diversity that is applied productively. Since it has been agreed that technology evaluation is contextual, different approaches would help to meet the needs for possible adjustment.

**REFERENCES:**


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**VP141 Ask The Internet: Analysis Of Online Discussions On Value Frameworks**

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**ABSTRACT SUMMARY:**

A pragmatic literature review, which aimed to explore online discussions and opinions on five value frameworks, was conducted using Google. A total of 67 records were included, providing 252 opinions. The Institute for Clinical and Economic Review (ICER) had the greatest proportion of negative comments (82%) and was the most discussed value framework.
INTRODUCTION:
Value frameworks are a new and emerging field in the United States (US). Since their introduction, the utility of value frameworks has been the subject of much online debate. We aimed to explore online discussions and opinions on five existing value frameworks.

METHODS:
A pragmatic literature review was conducted in Google using search terms for the Institute for Clinical and Economic Review (ICER), American Society of Clinical Oncology (ASCO), Memorial Sloan Kettering Cancer Center DrugAbacus (MSKCC), and National Comprehensive Cancer Network (NCCN) frameworks, and the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK). The first 60 results for each term were screened against inclusion criteria. Eligible records included journal articles, blogs, and open letters. Independent opinions were extracted for analysis and classified as positive/negative/neutral.

RESULTS:
A total of 67 records were included, providing 252 opinions for analysis. ICER was the most frequently discussed framework (50% of all opinions), yet 82% of comments on ICER were negative. Commonly cited criticisms included lack of transparency and reproducibility of economic models and need for more patient-centered evidence. The majority of negative comments were from patient representatives, clinicians, and pharmaceutical companies. NICE, ASCO, and MSKCC had 62%, 58%, and 50% negative opinions, respectively. The NCCN framework had the highest percentage of positive opinions (76%) related to being of significant value to physicians, transparent for patients, and affiliated with outstanding research.

CONCLUSIONS:
ICER was the most discussed framework, but had the most negative comments, possibly due to ICER’s call for feedback in July 2016. NCCN appeared to be the most positively received framework. Despite NICE being an established framework in the UK, the majority of opinions were negative. Our results demonstrate the controversy surrounding the use of value frameworks. Addressing transparency and methodology issues may improve stakeholder opinion. Limitations of this study include use of Google only and subjective opinion selection.

VP142 Assessing Human Enhancements: Exposing And Elucidating Ethical Issues

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ABSTRACT SUMMARY:
Assessing human enhancement technologies can differ from Health Technology Assessments (HTAs). A method for exposing and elucidating the ethical issues with human cognitive enhancement technologies in a HTA setting has been developed and will be presented.

INTRODUCTION:
Human enhancement technologies need assessments, but they differ from other health technologies. Therefore we may need other methods for their assessment, also with regard to addressing its ethical issues. The objective of this paper is to describe the elaboration of a method for exposing and elucidating ethical issues with human cognitive enhancement. The approach is elaborated in order to support and facilitate open and transparent deliberation and decision making with an emerging type of technology with great potential and formative implications for individuals and society.
METHODS:
The literature search identified relevant approaches. Conventional content analysis of the identified papers and methods revealed their suitability for assessing human cognitive enhancement. Four selection criteria were applied and followed by method development. Pilot testing on smart-glasses (1) resulted in amendments.

RESULTS:
A method for exposing and elucidating ethical issues in the assessment of human cognitive enhancement technologies was developed based on three existing approaches in Health Technology Assessment (HTA) (2). The method consists of six steps and a guiding list of forty-three questions. An overview of the approach will be presented.

CONCLUSIONS:
A method for exposing and elucidating ethical issues in the assessment of human cognitive enhancement has been developed. The method paves the way for context specific ethical assessment and analysis of a new and emerging type of technology.

REFERENCES:

VP143 An Adaptation Of Multi-criteria Decision Analysis In Health Technology Assessment Of Orphan Drugs

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ABSTRACT SUMMARY:
The aim of this study is an attempt to adopt the so called ‘multi-criteria decision analysis model’ or MCDA as an alternative method of orphan drugs’ Health Technology Assessment.

INTRODUCTION:
Rare diseases are often chronic and life-threatening, having a high impact on patients and caregivers. Intensive treatment and medicinal products (for example, orphan drugs) are often associated with very high costs, leading to restrictions in reimbursement and thus patient access. Moreover, orphan drugs often don’t fit in conventional Health Technology Assessment (HTA) models, due to the extremely small patient populations, a common lack of (statistically significant) evidence, and very high individual treatment costs. No tailored approach exists that addresses the special circumstances of rare diseases and orphan drugs. The aim of this study is an attempt to adopt the so called ‘multi-criteria decision analysis model’ or Multi-criteria Decision Analysis (MCDA) as an alternative method of orphan drugs’ HTA.
**METHODS:**
This questionnaire is based on an MCDA model adopted for rare disorders and it will be sent to rare disorder experts involved in reimbursement processes, pricing, and market access, including stakeholders from governmental agencies and the pharmaceutical industry, HCP’s, patients’ associations, and ‘regular’ citizens. The respondents were asked to assign weights to different criteria to various factors in the rare disorder HTA process. The Laser Analytica group did a pilot with this questionnaire in a few countries. Our objective is to extend the study to more countries, increase the validity of the outcomes, and compare the results between Eastern Europe, Eurasia, and Western Europe. This will generate a comparison of a wide range of data, and opinions of different stakeholders in different political and HTA environments. Our study will be conducted in Poland, Kazakhstan, Ukraine, Russia, Turkey, and Holland.

**RESULTS:**
A detailed overview of orphan drug policies has been recently performed in fourteen European/Eurasian countries (including countries where the MCDA study will be conducted) to better understand cultural and political aspects as well as the HTA environments, which will help to assess the upcoming MCDA questionnaire and put the results into perspective. The collection of completed questionnaires is planned for the end of February and the data analysis by the end of March.

**CONCLUSIONS:**
An approach that can factor in the true costs and benefits of orphan drugs, while giving payers more evidence to base

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**VP144 Health Technology Assessment In Hospitals: Determinants Of Performance**

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**ABSTRACT SUMMARY:**
This study aims at crystallising those determinants that may positively contribute to the Health Technology Assessment (HTA) units' effectiveness and efficiency, useful for both HTA scholars and hospital strategic management boards. Size and previous HTA skills are related to an increase in effectiveness, whereas size, multidisciplinary, trust among members, HTA previous skills and organizational support most explained the variance of efficiency.

**INTRODUCTION:**
While “how to perform” a rigorous Health Technology Assessment (HTA) at the institutional level is well established (1), very little has been experienced for empirically approaching an HTA in hospitals: no scientific evidence is available concerning the correct organizational model, to maximise and to improve the functioning, the performance and the effectiveness of the HTA units (2).

This study aims at crystallising those design options that may positively contribute to the HTA units’ effectiveness (quality) and/or to the efficiency (timely) (3).
METHODS:
After the collection of qualitative data from ninety-five healthcare professionals by means of ad hoc questionnaires and interviews, a hierarchical sequential linear regression model was conducted to verify the existence of HTA units determinants. Size, multidisciplinary, trust among members, HTA previous skills and organizational support were the variables investigated, determining team performance.

RESULTS:
A greater size and the presence of different specialties within the working unit positively influenced effectiveness, even if they spent more time to complete the assessment. Trust, previous HTA skills and organisational support played a key role in team performance. Size and previous HTA skills most explained the variance of team effectiveness (R² = .317; Adjusted R² = .249). The five investigated variables presented a higher explanatory nature regarding team efficiency (R² = .246; Adjusted R² = .165).

CONCLUSIONS:
The study suggested the creation of multi-dimensional and multi-disciplinary HTA units to increase their effectiveness. HTA units should be monitored by the hospital management board, because an excessive increase in multidisciplinary and size could determine inefficiency. Trust within members and the attendance of HTA training course improve performance. According to these results, the study gave solutions both to the scholars of HTA and to hospitals strategic management boards, paving the way to the determination of a more efficient and effective HTA units composition.

REFERENCES:

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VP145 Web-Based Cardiac Rehabilitation For Decliners: HTA Feasibility Trial

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ABSTRACT SUMMARY:
Although structured and supervised cardiac rehabilitation (CR) is recommended in international guidelines, nearly half of eligible patients decline. Web-based CR may offer a cost-effective alternative. A feasibility randomized controlled trial in England is collecting qualitative data, particularly in relation to patient preferences and acceptability, and quantitative data on costs/outcomes for people who decline or drop out of conventional CR.

INTRODUCTION:
International guidelines recommend structured supervised cardiac rehabilitation (CR). However <50 percent of eligible patients take up this form of CR (1). Alternatives may be needed to accommodate
patient choice and work/lifestyle. An observational study of web-based CR has demonstrated significant improvements (p<.05) in depression, exercise capacity, and quality-of-life (2). It is uncertain whether patients who currently decline conventional CR would accept web-based CR. Therefore, a feasibility trial is being undertaken prior to a full-scale randomized controlled trial (RCT).

METHODS:
A two-centre trial has collected qualitative and quantitative data to assess the feasibility of a trial recruiting people who decline or drop out of conventional CR. Participants were randomly allocated either to a web-based CR programme (3) or standard care for 6 months. Main outcome measures were: recruitment rates/retention; intervention completion rate/web usage; clinical symptoms; anxiety/depression; self-efficacy; health-related quality-of-life; resource use. Outcomes were measured pre and post (8 weeks and 6 months). Qualitative interviews with a sample of participants and staff explored the experience of delivering/participating in the study. Data used to develop a preliminary model for future Health Technology Assessment (HTA) analysis.

RESULTS:
Target sample of sixty patients achieved. Enabled assessment of recruitment/retention rates and estimation of outcomes with sufficient precision (SE <8 percent) for planning subsequent trial. Four patients withdrew. Six-month follow-up data completed April 2017. Qualitative interviews with fourteen patients and six professionals per center. Resource use questionnaires uploaded to national database (www.dirum.org) recorded hospital inpatient and outpatient episodes; community health and social care costs; patient borne costs; and changes to employment status.

CONCLUSIONS:
Findings from this feasibility study, particularly in relation to patient preferences and acceptability, will inform the design of a subsequent RCT. International and national visitors can come to share our findings on cost-effectiveness which we anticipate will stimulate interest in the study worldwide. The National Health Improvement Team indicate an annual saving of GBP30 million if 65 percent uptake achieved in England.

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VP146 A Comparative Assessment Of 3D/2D Laparoscopic Display Systems

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ABSTRACT SUMMARY:
The purpose of this study was to gather evidence on safety and overall effectiveness of performing laparoscopic surgery by using 3D versus 2D display systems in a variety of pediatric surgical procedures. The decision-oriented HTA (DoHTA) method was applied to assess the technology. Results showed that the 3D system might be a
good alternative to the 2D system satisfying criteria of clinical effectiveness and safety.

**INTRODUCTION:**

The purpose of the study was to gather evidence on safety and overall effectiveness of performing laparoscopic surgery by using 3D versus 2D display systems in a variety of pediatric surgical procedures in order to efficiently support the final investment decision on the video system to be acquired.

**METHODS:**

A new methodology, that is, Decision-oriented HTA (DoHTA) (1) was applied to assess the technology on clinical, technical, organizational, economic, social, ethical and safety domains. A decision-tree covering all the relevant assessment aspects of 3D systems has been derived and weighted following the Analytic Hierarchy Process. Afterwards, another pairwise comparison list was set up to compare both alternative technologies with respect to every lowest indicator.

**RESULTS:**

DoHTA results of the 3D system has mainly forecast its impact on clinical efficacy and productivity within the specific context of use. The 3D system is particularly suitable in reducing the mean error rate, thanks to the stereoscopic depth cues which are lost in 2D vision (2,3). From the technical perspective, the analyses have indicated the reduction in median instrument path length, an enhancement of median motion smoothness, and the decrease in grasper frequency with the 3D display. However, the comparative cost analysis has pointed out that the 3D procedure cost was higher that its comparator.

**CONCLUSIONS:**

The assessment of the 3D visual system seems to reasonably satisfy the criteria of feasibility, clinical effectiveness and safety. However, the adoption of the 3D display system in surgical practice could involve increased hospital costs, mainly because of the initial cost of the technology. Indeed, based on the appreciation of the results of DoHTA, especially taking into account the positive technical and clinical features, we conclude that the 3D system may be a good alternative to the 2D system.

**REFERENCES:**


**VP147 Implementing Electronic Health Record In A Children’s Hospital**

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**ABSTRACT SUMMARY:**

The purpose of the study is to gather evidence on safety and overall effectiveness of electronic health record (EHR) implementation in Bambino Gesù Children’s Hospital applying the decision-oriented HTA (DoHTA) method. Results showed
that EHR implementation might offer many benefits in terms of safety and clinical effectiveness such as improved continuity and quality of care and increased accessibility of the data.

INTRODUCTION:

Since the adoption of electronic health record (EHR) systems, which contain large volumes of aggregated longitudinal clinical data, promises a number of substantial benefits including better care, improved safety issues and decreased healthcare costs (1). It is also associated with significant costs and large technical and organizational impacts, therefore it is important to conduct comprehensive evaluations of healthcare delivery outcomes. The purpose of the study is to gather evidence on safety and overall effectiveness of EHR implementation in Bambino Gesù Children’s Hospital (OPBG).

METHODS:

Decision-oriented HTA (DoHTA) method (2) was applied to assess the technology on clinical, technical, organizational, economic, legal, ethical and safety domains. It’s a new implementation of the European Network for Health Technology Assessment (EUnetHTA) CoreModel integrated with the Analytic Hierarchy Process. It allows defining an evaluation structure represented by a hierarchical decision tree filled by indicators of technology’s performances, each of which was given a weight proportional to the impact that this criterion provides to achieve the purpose of the decision problem; finally, the alternatives’ ranking was defined.

RESULTS:

The multidisciplinary assessment took into consideration all of the aspects and recommendations about the benefits and disadvantages of EHR (3). The synthesis of scientific evidence integrated with results of the specific context analysis, resulted in the definition of components of the decisional hierarchy structure. In particular, EHR seems to offer many benefits in terms of safety and clinical effectiveness such as improved continuity and quality of care, and increased accessibility of the data. The implementation of EHR resulted in important organizational outcome such as EHR configuration, learning curve and training. For these reasons, the usability was the main technical characteristics of the technology taken into account. Finally, legal aspects on privacy and security of data, covered a key role in the assessment.

CONCLUSIONS:

A thorough evaluation of the EHR before its implementation has permitted hospital’s decision makers to choose knowingly.

REFERENCES:


VP148 Health Technology Assessment Of Femtosecond Laser: A New Frontier In Cataract Surgery

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ABSTRACT SUMMARY:
The aim of this study is to describe the application of the new method “Decision-oriented HTA (DoHTA)”, to assess the femtosecond laser-assisted cataract surgery (FLACS) compared to conventional cataract surgery (CCS). DoHTA results showed that FLACS improves the quality of cataract surgery, increased precision of anterior capsulotomy and the accuracy and consistency in surgical results as well as better visual outcomes.

INTRODUCTION:
Cataract surgery is one of the most frequent ophthalmological surgical procedures performed in children. However, clinical outcomes in younger patients are generally unpredictable. Currently, cataract surgery can be performed through the traditional phacoemulsification ultrasound probe or Femtosecond Laser (1). The aim of this study is to describe the application of Decision-oriented Health Technology Assessment (HTA) (DoHTA) to assess the femtosecond laser-assisted cataract surgery (FLACS) compared to conventional cataract surgery (CCS).

METHODS:
To evaluate safety, costs, organizational aspects, effectiveness and technical characteristics of FLACS compared to CCS, a DoHTA method was applied (2). DoHTA is a new implementation of the European Network For HTA (EUnetHTA) Core Model®, which integrates the Multi-Criteria Decision Analysis (MCDA) using the Analytic Hierarchy Process (AHP). All the relevant assessment aspects of FLACS are summarized in a hierarchical decision tree by means of Key Performance Indicators (KPI), subsequently weighted through pairwise comparisons. Lastly, FLACS and CCS were ranked against lowest indicators of decision tree.

RESULTS:
The multidisciplinary assessment took into consideration all the aspects and recommendations about the benefits and disadvantages of FLACS compared to CCS. DoHTA results showed that FLACS surgery is safe and effective for pediatric patients. Furthermore, FLACS seems to overcome CCS with several important developments such as increased precision of anterior capsulotomy, reduced ultrasound power requirement during phacoemulsification, decreased collateral tissue damage, increased accuracy and consistency in surgical results as well as better visual outcomes. Notwithstanding such clinical improvements, FLACS is more expensive than its comparator.

CONCLUSIONS:
The DoHTA results integrated the evidence from the scientific literature (which is still limited) with experts judgments. Indeed, although FLACS had the highest purchase price, DoHTA results showed that FL improves the quality of cataract surgery. Based on our results and taking into consideration the positive safety and clinical effectiveness features, we conclude that FLACS may be a good alternative to CCS.

REFERENCES:
VP149 Sustained Low Efficiency Dialysis (SLED): A Rapid Review.

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ABSTRACT SUMMARY:
This rapid review determined the effectiveness of the Sustained Low Efficiency Dialysis (SLED) when compared to Continuous Renal Replacement Therapy (CRRT) and Continuous Veno-Venous Hemofiltration (CVVH) in the treatment of acute renal failure. The review suggests that SLED can be used as an alternative to CRRT, as the outcomes were similar and the costs associated with SLED were significantly lower.

INTRODUCTION:
This rapid review aimed to determine the effectiveness of Sustained Low Efficiency Dialysis (SLED) when compared to Continuous Renal Replacement Therapy (CRRT) and Continuous Veno-Venous Hemofiltration (CVVH) in the treatment of acute renal failure (ARF) with a view to implementing SLED in a tertiary hospital in 2014.

METHODS:
A rapid review was performed on the effect of SLED for patients with ARF compared with CRRT or CVVH. The outcomes of interest were mortality, hemodynamic stability, reduced utilisation of intensive care unit (ICU) and cost-effectiveness. The search terms (“sustained low-efficiency dialysis[MESH]”) were used to search PubMed, the Cochrane Library, UK NHS Centre for Reviews and Dissemination databases and the US National Guidelines Clearinghouse for relevant articles until 2014.

RESULTS:
Four observational and two randomized controlled trial (RCT) studies were found. The results showed that 90-day mortality was similar between groups (SLED: 49.6 percent vs. CVVH: 55.6 percent, p = .43). Hemodynamic stability did not differ between SLED and CVVH and between SLED and CRRT. Patients in the SLED group had significantly fewer days of mechanical ventilation (17.7 ± 19.4 vs. 20.9 ± 19.8, p = .047) and fewer days in the ICU (19.6 ± 20.1 vs. 23.7 ± 21.9, p = .04). Patients treated with SLED needed fewer blood transfusions (1,375 ± 2,573 ml vs. 1,976 ± 3,316 ml, p = .02) and had a substantial reduction in nursing time (p < .001). The hospital weekly costs were CAD1,431 for SLED, CAD2,607 for CRRT with heparin, and CAD 3,089 for CRRT with citrate. Dialysis using SLED was associated with higher first post-dialysis mean arterial pressure (p = .003) than those treated with CVVH, which led to lower mortality.

CONCLUSIONS:
The evidence suggests that SLED can be used as an alternative to CRRT, as the outcomes were similar. SLED provides solute removal equivalent to CRRT at significantly lower cost.

VP150 Health Technology Assessment As A Tool For Hospital Innovation

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ABSTRACT SUMMARY:
At the university hospitals in Odense (Denmark),
Oslo (Norway), and Barcelona (Spain), innovation units are using Health Technology Assessment (HTA) in assessment of the value of new innovative medical technologies. This presentation describes how HTA can be used in innovations processes at hospital level.

**INTRODUCTION:**

In Europe, governments are increasing their focus on hospital innovation. Innovation can be defined in many ways, for example, Varkey, et al. (1) define innovation as the successful implementation of a novel idea in a way that creates compelling value for some or all of the stakeholders. To be able to produce innovation, an innovation process must take place in which the new technology is being developed, often in collaboration with private companies. Examples of such medical innovations are new e-health services and clinical health information systems.

At the university hospitals in Odense (Denmark), Oslo (Norway), and Barcelona (Spain), innovation units are using Health Technology Assessment (HTA) in assessment of the value of new innovative medical technologies. The aim of this presentation is to describe how HTA can be used in innovations processes at hospital level.

**METHODS:**

Information about the use of HTA in innovation process has been collected from the three university hospitals by interview with the heads of the innovation units. Focus has been on when HTA of new technologies are performed, how frequently assessment is repeated, which domains are included in the assessment, methods used for data collection, and how the results are described.

**RESULTS:**

Information from the interviews shows that HTA is increasingly being used in innovation process in the three hospitals to produce information about the value of new innovations. However, the use of HTA is still not systematic. In the beginning of an innovation process HTA is often used in pilot studies. Results from these early HTAs are often used to improve the content of the medical technology. Later in the process HTA is used as a structure for larger randomized controlled trials or observational studies. The advantage of HTA is that it can ensure comprehensive assessment. However, the use of HTA is challenged by the risk for low quality assessments and that assessment must be repeated over time when changes in the technology are made.

**CONCLUSIONS:**

HTA is useable as a tool for hospitals in the innovation process. A number of European university hospitals have experience in the use of this type of HTA and examples have been identified, but more work is needed to identify best practice of HTA in hospital innovation.

**REFERENCES:**


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**VP151 Endovenous Iron Deficiency Anemia Treatment in Inflammatory Bowel Disease: Hospital-Based Health Technology Assessment**

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**ABSTRACT SUMMARY:**
Iron Deficiency Anemia is one of the main extraintestinal manifestations affecting patients with inflammatory bowel disease. The introduction of a new intravenous iron treatment (ferric carboxymaltose) in the Italian setting was thoroughly evaluated using a hospital-based HTA approach. Analysis of organizational, economic and ethical aspects have led to a positive opinion on the introduction of this treatment option in the national outpatient setting.

**INTRODUCTION:**
Iron Deficiency Anemia (IDA), a common cause of anemia in the world, is a frequently neglected disease that represents the main extraintestinal manifestation affecting patients with inflammatory bowel disease (IBD) (1). The release of new intravenous (IV) iron compounds represents a great opportunity for both physicians and patients, but the higher costs might hold back their optimal diffusion. A Health Technology Assessment (HTA) approach was used to provide insights on the sustainability of the IV iron formulations in a hospital setting, with a special focus on ferric carboxymaltose.

**METHODS:**
Epidemiology of IBD, as well as IDA associated with these conditions, was assessed with a systematic appraisal of the published literature. Data on efficacy and safety of IV iron formulations currently used in Italy were retrieved from the available medical electronic databases. A hospital based cost-analysis of the outpatient delivery of IV iron treatments was performed. Organizational and ethical implications were discussed.

**RESULTS:**
The reported prevalence of anemia in patients with IBD varies markedly from 10 to 73 percent for Crohn’s Disease and from 9 to 67 percent for Ulcerative Colitis. Although there are no studies on direct comparison of different IV iron preparations, the literature indicates good efficacy and safety profiles of these formulations. However, ferric carboxymaltose seemed to provide a better and faster correction of hemoglobin and serum ferritin levels in iron-deficient patients (2,3). Our analyses indicated that ferric carboxymaltose, in spite of a greater price, would have positive benefits for the hospital, in terms of reduced costs related to individual patient management, and for the patients themselves, by reducing the number of infusions and accesses to health facilities.

**CONCLUSIONS:**
This hospital-based HTA reports an overall positive organizational, economic and ethical evaluation for the sustainable introduction of ferric carboxymaltose in the Italian outpatient setting.

**REFERENCES:**
VP153 Health Technology Assessment Reports in Gene and Cellular Therapy Products: A Scoping Review

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ABSTRACT SUMMARY:
A scoping review was performed with no publication time restriction about Health Technology Assessment (HTA) reports on gene and cellular therapy products, aiming to summarize assessment reports including recommendations and opinions released from HTA agencies for gene and cellular therapy products. The authors summarized HTA reports from thirteen HTA agencies in North America and Western Europe.

INTRODUCTION:
The approval of Strimvelis from GlaxoSmithKline (GSK) for the treatment of “bubble boy” raised questions about pricing and payment in the field of gene and cellular therapy products. In the United States, the Food and Drug Administration (FDA) approved thirteen cellular products; In European Union (EU), the European Medicine Agency (EMA) has delivered scientific recommendations to 195 medicines on the classification of advanced therapy medicinal products until November 2016. There are two gene therapy products in EU market. The aim of this study is to summarize assessment reports including recommendations and opinions released from Health Technology Assessment (HTA) agencies for gene and cellular therapy products in North America and Western Europe.

METHODS:
A scoping review was performed about HTA reports on gene and cellular therapy products in HTA agency homepage. The HTA agencies from thirteen countries were scanned by the authors with keywords: gene-therapy, cell-therapy, stem-cell, Strimvelis and Glybera. No publication time restriction was used.

RESULTS:
Through scanning homepage from each HTA agency, we found that there is substantial difference in structure and contents between HTA reports from different HTA agencies. The National Institute for Health and Care Excellence (NICE) has more structured reporting system. NICE released eleven scoping reports and three HTA reports on stem cell, one of them was considered not appropriate. The recommended cost of product was reported in five scoping reports and three HTA reports. The Institute for Quality and Efficiency in Health Care (IQWiG) has released six HTA reports on stem-cell. The IQWiG and The French National Authority for Health (HAS) have more updated information on assessment of first gene therapy Glybera. The Canadian Agency for Drugs and Technologies in Health (CADTH) from Canada released four HTA reports with clear structure and literature lists on each product.

CONCLUSIONS:
Gene and Cellular therapy as novel disease-modifying therapeutics and with increasing number of usage in the market, their use is expected to increase in the next decade. Through learning from each other, HTA agencies can develop more structured reports on this emerging technology to make assessment and appraise comparable and transparent.
VP154 School-Based Interventions For Smoking Prevention

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ABSTRACT SUMMARY:
Established in 2015, the Korea Disease Preventive Services Task Force conducted evidence-based public health topics. The objective of this review was to evaluate effectiveness of school-based interventions for changing smoking behavior. School-based interventions may affect smoking prevention. In particular, intensive programs including frequent education and long-term intervention reduces smoking prevalence.

INTRODUCTION:
Established in 2015, the Korea Disease Preventive Services Task Force conducted evidence-based public health topics. The objective of this review was to evaluate effectiveness of school-based interventions for changing smoking behavior.

METHODS:
A comprehensive literature search was conducted using English databases, as well as seven domestic databases, until June 2016. Primary outcome was behavior change in smoking behavior, such as smoking prevalence change or cessation rate. Success rate on smoking cessation, smoking intention, and attitude/knowledge for smoking were included as secondary outcomes. Data was synthesized quantitatively or qualitatively depending on type of extracted data. In the case of the quantitative approach, data was pooled separately by the outcome’s definition.

RESULTS:
Seventy-one studies (fifty-seven trials) were finally selected for this review. Characteristics of the included studies varied not only in the study interventions’ characteristics, but also outcome definitions. A meta-analysis was conducted on forty-one trials that reported smoking prevalence and twenty trials that reported smoking initiation. Smoking initiation was the effect of the intervention on the smoking status of those who reported no use of tobacco at baseline. Smoking prevalence (Odds Ratio, OR 0.86, 95 percent Confidence Interval, CI .81 to .91, I²=51 percent) and smoking initiation (OR 0.78, 95 percent CI .69 to .98, I²=72 percent) were both significantly lower in the intervention group compared to the control group. In the sub-group analysis, the comprehensive (education + social activity) programs and intensive (11 times or more) programs showed a statistically significant effect in preventing smoking (OR 0.83, 95 percent CI .76 to .91; OR .83, 95 percent CI .77 to .90). Also, subgroup analyses also detected significant effects in programs with a social influences curriculum (OR .76, 95 percent CI .66 to .88).

CONCLUSIONS:
School-based interventions may affect smoking prevention. In particular, an intensive program which included frequent education and long-term intervention reduces smoking prevalence. Well-designed comparative trials are needed to validate our finding.
VP155 Synchronisation Of Regulatory Approval And Health Technology Assessment Recommendation Timing

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ABSTRACT SUMMARY:
Data collected for new active substances were first appraised by the Health Technology Assessment (HTA) agencies in Scotland, France, Germany, Australia and Canada that reached an outcome in 2014 and 2015. They revealed that synchronised HTA and regulatory decision making is effective in Australia, whilst there remains a synchronisation disconnect between the regulatory and HTA decision timing in other countries.

INTRODUCTION:
Minimising the delay between regulatory approval and Health Technology Assessment (HTA) recommendation is critical to ensure patients access to medicines of therapeutic value. The aim of this study was to evaluate the level of synchronization between the regulatory decision and HTA recommendation.

METHODS:
Data were collected from the public domain for new active substances that were first appraised by the HTA agency in Scotland (SMC - Scottish Medicines Consortium), France (HAS - Haute Autorité de Santé), Germany (IQWIG - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Australia (PBAC - Pharmaceutical Benefits Advisory Committee) and Canada (CADTH - Canadian Agency for Drugs and Technologies), and that reached an outcome in 2014 and 2015. The year the product was approved by the European Medicines Agency (EMA), Australian Therapeutic Goods Administration (TGA) and Health Canada were also assessed.

RESULTS:
In 2014 and 2015, fifty-one products with HTA recommendations were identified for SMC and IQWIG, forty-two for HAS, forty for PBAC and thirty-eight for CADTH.

Of the HTA agencies studied, CADTH had the lowest percentage of HTA recommendations occurring the same year as jurisdictional regulatory approval. Of the products with CADTH recommendations in 2014, only 7 percent were approved by Health Canada in the same year. By comparison, all of the products with PBAC recommendations in 2015 were approved by TGA in the same year.

For 2014 and 2015, comparing the percentage of HTA recommendations with the jurisdictional regulatory agency approval the same year showed 7 percent (2014) vs 29 percent (2015) for CADTH: 35 percent vs 37 percent for SMC: 35 percent vs 44 percent for HAS; 56 percent vs 57 percent for IQWIG; and 91 percent vs 100 percent for PBAC.

CONCLUSIONS:
This study shows that the parallel submission mechanism to enable synchronizing HTA and regulatory decision making is effective in Australia, whilst there remains a synchronization disconnect in other countries; although this may be improving. The extent of decision timing disconnect, influence of company strategy and type of HTA outcome were also studied. This initial analysis suggests gaps between the timing of regulatory approval and HTA recommendation for HTA agencies outside of Australia.
VP156 Early Health Technology Assessment Dialogue: Trends And Evolution Toward Integrated Advice

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ABSTRACT SUMMARY:
A solid understanding of the differences and the trends in the evolving scientific advice processes is the first, fundamental step toward selection of the appropriate process to meet strategic objectives.

INTRODUCTION:
In recent years, there has been an increase in multi-stakeholder scientific advice processes involving HTA bodies (HTABs) and regulatory bodies. Seeking integrated scientific advice can impact the ability to meet both marketing authorisation and reimbursement requirements by optimising clinical development programmes to generate evidence that is relevant for patients, regulators, HTABs, and payers. The objective of this study was to review global scientific advice processes involving HTABs and evaluate how these processes evolved over time.

METHODS:
A review of HTABs offering scientific advice was performed. Each advice process was evaluated in terms of regulatory agency participation and the following key attributes: years since introduction, timeline, fees, briefing book requirements, output, health economic assessment, language, meeting length, number of company attendees, external expert involvement, and patient involvement. An analysis of the evolution of HTA scientific advice over time was conducted to understand the changing scientific advice dialogue for treatments.

RESULTS:
In total, there are more than twenty early scientific advice processes involving HTABs in Europe, North America, Canada, and Australia. These may be broadly categorised into four types: 1) single-country HTA; 2) multi-country HTA; 3) parallel single/multi HTA-regulatory; and 4) joint national HTA-regulatory. There are similarities and differences in attributes across scientific advice processes involving HTABs, with the most striking differences being the engagement fees, the meeting length and output, and broader stakeholder participation.

CONCLUSIONS:
Selecting an appropriate scientific advice process depends on the strategic objectives in the decision to obtain scientific advice and the specific regulatory and HTA complexities for the therapeutic area. Trends show an increase in integrated scientific advice processes and number of engagements over time as manufacturers value the ability to pressure test and shape clinical development plans to meet the requirements for both marketing authorisation and reimbursement to enable patient access.

VP157 What Is The Response To Immuno-Oncology By Health Technology Assessment Agencies?

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ABSTRACT SUMMARY:
This analysis evaluates the initial reception of immunotherapies by health technology assessment (HTA) agencies.

INTRODUCTION:
Immunotherapies are a relatively new innovative class of drug that have garnered excitement in the fight against cancer. In 2011, the immunotherapy drug, ipilimumab, was approved. Since then, four additional drugs have gained approval. This analysis evaluates the initial reception of immunotherapies by Health Technology Assessment (HTA) agencies.

METHODS:
The Context Matters Data Model was used to evaluate the regulatory and HTA agency decisions surrounding the five approved immunotherapies through November 2016: atezolizumab, elotuzumab, ipilimumab, nivolumab, and pembrolizumab. Thirty-three labels from Australia, Canada, Europe, and the United States, and ninety-two assessments from Agenzia Italiana del Farmaco (AIFA), Gemeinsamer Bundesausschuss (Federal Joint Committee; G-BA), Haute Autorité de Santé (French National Authority for Health; HAS), Institute for Clinical and Economic Review (ICER), Institute for Quality and Efficiency in Health Care (IQWiG), National Institute for Health and Care Excellence (NICE), Pharmaceutical Benefits Advisory Committee (PBAC), pan-Canadian Oncology Drug Review (pCODR), and Scottish Medicines Consortium (SMC) were found. Using a sample t-test and a chi-squared test, reimbursement agencies’ decisions were evaluated, and the clinical and economic factors that went into these decisions were examined.

RESULTS:
Of the evaluated reviews: sixty-four were for melanoma indications, fourteen were for non-small-cell lung cancer (NSCLC) indications, and seven were for kidney cancer indications. Many of the reviews did not reach any decision, but 75 percent of HTA decisions (n=72; p=.0000) reached were positive. Elotuzumab, approved for multiple myeloma, received a positive decision from G-BA and a negative one from SMC. There was an association between different disease conditions or drugs and the rate of positive decisions.

For reviews that had clinical reasons for their decisions, 72.9 percent (n=59; p=.0000) had positive clinical rationales that were associated with positive decisions (p=.000). Economic rationales for decisions were more mixed, with only 48.4 percent (n=31; p=.0000) receiving positive decisions. Positive economic evaluations were also associated with positive decisions (p=.000). Atezolizumab, approved only in the United States at the time of this writing, has yet to be reviewed by any of the HTA agencies.

CONCLUSIONS:
Immunotherapies are promising new options for the treatment of cancer. Thus far, reception by HTA agencies has generally been positive.

VP158 Reflective Multi-criteria Decision Analysis To Identify Decision Drivers For Patients With GEP-NET

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ABSTRACT SUMMARY:
Somatostatin analogs (SSAs) or watchful-waiting are recommended for management of unresectable, well- or moderately-differentiated non-functioning GEP-NET. This study developed a comprehensive shared decision-making Multi-criteria Decision Analysis (MCDA)-framework and explored drivers of decision for GEP-NET management on the basis of two decision scenarios. Holistic MCDA embedded with evidence revealed the diversity of participants perspectives and supported individual reflection and informed shared decision making.

INTRODUCTION:
GEP-NET are slow-growing tumors with heterogeneous presentation. Somatostatin analogs (SSAs) or watchful-waiting are recommended for management of unresectable, well- or moderately-differentiated non-functioning GEP-NET. This study aimed to develop a comprehensive shared decision-making Multi-criteria Decision Analysis (MCDA)-framework, and explore drivers of decision.

METHODS:
A decision support tool was designed using a holistic MCDA-framework (EVIDEM), literature review, and insights from a Chatham-house panel of US physicians and patients with GEP-NET. A second extended panel (five patients, six physicians) explored drivers of decision using two scenarios (SSA [reference case lanreotide] versus observation; lanreotide versus octreotide). Evidence was synthesized from a comprehensive literature review. Participants assigned weights through two techniques. For each criterion, participants were prompted to share experiential insights and knowledge, and assign a score (+5 [Much in favor of option 1] to -5 [Much in favor of option 2]). Value contributions (NormWeightXScore) were calculated for each criterion. Sensitivity analyses were performed.

RESULTS:
At group level, when exploring treatment over watchful-waiting, type of therapeutic benefit, disease severity, effectiveness (mainly due to progression-free survival and disease symptom), and quality of evidence favored treatment (mean value contribution: .08 ± Standard Deviation, SD .06, .07 ± .09, .07 ± .09 and .06 ± .06 respectively) whereas costs as aspects (interventions, medical and non-medical) favored watchful-waiting. When comparing two treatment options, the majority of criteria did not favor one option over another. System capacity (.02 ± .02) and non-medical costs and constraints (.02 ± .03) tip the scale in favor of lanreotide and cost of intervention in favor of octreotide (.08 ± .12). Sub-criteria impact on autonomy and impact on dignity favored lanreotide. Wide SDs reflect variability of drivers of decision across participants.

CONCLUSIONS:
Exploration of scenarios identified drivers of decision for GEP-NET management and revealed the diversity of participants perspectives. Holistic MCDA embedded with evidence supports individual reflection and informed shared decision making.
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ABSTRACT SUMMARY:
The lack of supportive supervision of primary health care system and involvement of patient and consumer stakeholders have rendered the health care system being underused. However, there’s is hope of fostering Patient and consumer involvement and amend primary health care (PHC) policies.

INTRODUCTION:
The Health system in Nigeria is structured into three tiers which include tertiary health care, secondary health care and primary health care (PHC). The latter forms the grassroots system of delivering basic health services to communities in both rural and urban centers. However PHC in Nigeria have been affected by poor service delivery. This has resulted in underuse of PHC due to the acceptance and utilization of health services delivered through this system. This research seek to bridge the gap of inequality, reaffirm that implementing PHC is a human right/duty and fosters patient and consumer involvement for economic, social and environmental sustainability of PHC.

METHODS:
A qualitative method of research was adopted using a participatory research model. The relative data was sourced secondarily from recent findings (July 2015) carried out in seventy-three primary health centers across Anambra State, Benue State, Kaduna State, Plateau State and Federal Capital Territory (FCT) of Nigeria. Issues that were examined included: client perspective and community involvement, status of available services, utilization and service delivery, and infrastructure and human resource capacities. The respondent of 294 client/service user population from interview were recorded and analyzed.

RESULTS:
The assessment showed client dissatisfaction to services being provided. In most centers, National Primary Health Care Development Agency (NPHCDA) requirements like availability of basic functional equipment, well trained health workers, patient record system, and access to water and sanitation were not met. Most of the facilities visited reported to be disconnected from the health system due to supportive supervision.

CONCLUSIONS:
Conclusively, the interest of the underserved Nigerian could be advocated for through local committees of consumer organizations. Their involvement will have an impact in PHC evaluation, policy making, and implementation of action plans aimed at improving PHC services.

VP161 Identification Of Needs Of Pigmented Villonodular Synovitis Patients Using Online Bulletin Board

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ABSTRACT SUMMARY:
An online bulletin board qualitative market research methodology was used to uncover the needs of patients with pigmented villonodular synovitis. The approach proved very effective at uncovering patient needs, including emotional and financial impact of the disease, to inform early drug development strategies. Pain is the primary concern.
INTRODUCTION:
Pigmented villonodular synovitis (PVNS) is a very rare, benign proliferative tumor affecting the inner lining of synovial joints and tendon sheets. Information on treatment needs of PVNS patients to inform drug development is currently scarce, hence we conducted qualitative research with patients using an online bulletin board (OBB) methodology to generate insights on objective and emotional aspects related to the medical journey and living with this disease.

METHODS:
OBB is an asynchronous, online qualitative market research tool that allows participants to comprehensively answer pre-defined questions in a comprehensive manner. Patients were recruited via physician referral and underwent screening questions to ensure eligibility for the study and willingness to participate. The discussion was moderated, structured, and allowed open answers and in response to other participants posts. Analysis was conducted using a combination of different qualitative analytical tools.

RESULTS:
The patient OBB ran for 4 days with eleven participants (n=3 Canada, n=4 United Kingdom, n=4 United States of America) aged 28-57 years, suffering from PVNS for 2-27 years. The key patient insights were: (i) pain is the primary factor, constituting a significant emotional and psychological burden; (ii) surgery (arthroscopy) does not get rid of PVNS, relapse rate was high in these patients; and (iii) PVNS has a big financial impact on patients, their families, and the healthcare system, due in particular to time off work/lost wages (patient & caretaker), for healthcare system it is repeat costs for surgeries/hospital stays plus other medical expenses. We also identified orthopedic specialists/surgeons are the physicians who predominantly manage PVNS at this point, as surgery is the only option.

CONCLUSIONS:
This study shows the suitability of the OBB for uncovering qualitative patient insights to inform decision making and strategy in early pharmaceutical drug development. OBB lends itself very well to uncovering patient insights which might not be revealed in focus group or telephone interviews, particularly in a rare disease like this. PVNS patients are in need of a medical drug treatment which can reduce pain, relapses and provide an alternative to surgery, the current standard of care.
INTRODUCTION:
In 2014, Scottish Medicines Consortium (SMC) reviewed its approach to how patient and carer views and experiences are captured and used as part of the health technology assessment (HTA) decision-making process.

METHODS:
A stakeholder review (1) was conducted to establish required areas of improvement and development for public involvement activities. Key issues covered by the review included:

- Supporting patient group submissions. Increasing awareness of opportunities to submit.
- Improving the experience of public involvement.

The review highlighted lack of stakeholder satisfaction in the SMC patient group submission process. This resulted in a number of changes:

2. New registration and submission process for patient and carer representatives.
3. New PIN advisory group (including patient, carer, and public representatives).
4. Improved education, information, and support provided to submitting patient group partners.
5. New pro-active approach adopted for encouraging patient group submissions to SMC.
6. Revised process for presenting patient and carer views at SMC committee meetings.

RESULTS:
This new approach has led to patient group submissions to SMC more than doubling, with 102 patient group submissions in 2016. Furthermore, there has been a sustained reduction in the number of appraisals without a patient group submission. For example, in 2016 there were sixty-three of the seventy-one medicines appraised that had at least one patient group submission - this compares to forty-six out of the seventy medicines in 2014.

Submitting patient group partners have expressed satisfaction with the level of support and information provided to them during the submission process, with 84 percent of submitting patient groups rating their experience as excellent and 14 percent rating their experience as good.

CONCLUSIONS:
SMC has significantly improved the quality and quantity of patient group submissions. Furthermore, it has improved stakeholder satisfaction in how SMC captures and presents the patient and carer voice in HTA process for new medicines.

REFERENCES:
1. Public Involvement Review: www.scottishmedicines.org.uk/Public_Involvement/Our_commitment_to_continuous_improvement.

VP163 Patient Involvement In The Development Of Multi-Criteria Decision Tool

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ABSTRACT SUMMARY:
This study describes the process and results of involving patient representatives, along with other stakeholders, in the development of a multi-criteria decision support tool that could be used to identify, evaluate and prioritize health technologies.
or interventions according to their clinical appropriateness. Patient representatives differ from other stakeholders in their ranking of criteria related to accessibility and organizational aspects.

**INTRODUCTION:**
Healthcare organizations should assess the relevance of both existing and new practices. Involving patients in decisions regarding which health technologies and interventions should be prioritized could favor a better fit between strategic choices and patients needs.

**METHODS:**
Following a systematic review of existing multi-criteria decision support tools and a consultation with hospital clinicians and managers, a set of potentially relevant criteria was identified. A three-round modified Delphi study was then conducted among four groups (hospital managers, heads of department, clinicians, and patient representatives) in order to reach consensus on criteria that should be considered in the tool.

**RESULTS:**
In total, seventy-four participants completed the third round of the Delphi study. Consensus was obtained on twelve criteria. There were some significant differences between groups in priority scores given to criteria. Patient representatives differed significantly from other groups on two criteria. Their ranking of the accessibility criteria was higher, and their ranking of the organizational aspect criteria was lower than for the other groups.

**CONCLUSIONS:**
Patient representatives can be involved in the development of a multi-criteria decision support tool to identify, evaluate and prioritize high value-added health technologies and interventions in order to enhancing clinical appropriateness. The fact that accessibility aspects were more important for patient representatives calls for specific attention to these criteria when prioritizing health technologies or interventions. Furthermore, we need to ensure that the decisions made regarding the relevance of these technologies and interventions also reflect patients’ preferences.

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**VP164 Applying Health Technology Assessment To Pharmacy: The Italian-Medicine-Use-Review Health Technology Assessment**

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**ABSTRACT SUMMARY:**
There is a lack of Health-Technology-Assessment (HTA) tools in pharmacy practice and the collection of real-world-evidence (RWE) in community pharmacy to populate longer-term-disease-progression-modelling. This project is looking at the development and application of a novel Patient-Reported-Outcome-Measure (PROM) that can enable active patient involvement into policy-decision-making and pharmacy service implementation for asthma.
patient health outcomes and ‘utilities’; the collection of RWE and evaluate long-term effect of care; to provide different stakeholders with unique evidence-based information that help formulate health policies in community pharmacy that are safe, effective, patient-focused and cost-effective, balancing access to innovation and cost containment.

METHODS:
Evidence from the Italian-Medicine-Use-Review (I-MUR) trial (2) showed that the I-MUR intervention provided by community pharmacists to asthma patients is effective, cost-saving and cost-effective (3). The trial allowed to model a framework (I-MUR-HTA) that would enable to routinely deliver the intervention, but also collect and analyse PROM data on its clinical-effectiveness, quality-of-life and cost-effectiveness. I-MUR-HTA was discussed within three expert-panel discussions including policy-makers, commissioners, academics, healthcare-professionals and patient-representatives in Italy, United Kingdom and Europe. Current plan includes testing the use of the tool in the real world environment.

RESULTS:
Evidence collected from the panel discussions confirmed that I-MUR-HTA evidence-based information is relevant to meet current National-Health-Care-System plans and this is what is needed to support the evaluation of innovative effective and cost-effective health policies and promote their implementation across nations. Current Italian law on pharmacy services provides the appropriate institutional framework to regulate the introduction of I-MUR-HTA across the territory. Its implementation is underway and a real-world pilot is planned to take place in Italy.

CONCLUSIONS:
I-MUR-HTA appears to be an innovative tool to promote active patient involvement into policy-decision-making and pharmacy-service.

REFERENCES:

VP165 Landscape Assessment: Patient Engagement In Health Technology Assessment

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**ABSTRACT SUMMARY:**
This study found that there is substantial heterogeneity in the terms used to describe patient engagement activities across organizations. While a variety of opportunities for patient engagement are described, lack of clear evidence to how patient engagement practices are consistently used may contribute to the perception that engagement by Health Technology Assessments (HTAs) and other value assessors is “tokenistic.”

**INTRODUCTION:**
Understanding the current landscape of patient engagement across value decision-making bodies internationally is a critical first step toward improving the patient centrality of Health Technology Assessment (HTA). This study assessed: (i) Terms and definitions used; (ii) Patient engagement opportunities; (iii) Evidence of patient engagement.

**METHODS:**
A sample of country-specific HTA’s (HTA; n=6), professional organizations (PO; n=4), and collaborations/independent organizations (CO; n=3) was selected for representativeness. Information was gathered through: (i) targeted web search and (ii) emailing organizations directly. Definitions, HTA methods documents, and the three most recent evaluations were identified, abstracted, and compared. Data were collected between September-October 2016.

**RESULTS:**
Numerous terms are used to describe patient engagement: patient input (HTA=1, PO=1), patient-group submitted information (HTA=1), cooperation with patients/users (HTA=1), public consultation (HTA=1), patient perspectives (HTA=1, PO=1), involvement of people affected (HTA=1), patient involvement (HTA=2), patient and public involvement (HTA=1), lay involvement (HTA=1), inclusion of patient representative (PO=3), patient reports (PO=1), patient preference (PO=2), public consultation (CO=1), stakeholder consultation (CO=1), open input (CO=1), stakeholder engagement (CO=1), and patient participation (CO=1). Opportunities for patient engagement were described as: patient questionnaire (HTA=2); comment period (HTA=1; CO=1); committee participation (HTA=3; PO=3); propose topics (HTA=1); draft guidance (HTA=1); general stakeholder forum (CO=1). While organizations outline opportunities for patient engagement, not all organizations have clear evidence the practices are used or have impact. Recent evaluations demonstrate clear evidence of engagement (HTA=2); Unclear or mixed evidence (HTA=1; PO=1; CO=2); No evidence (HTA=3; PO=3; CO=1).

**CONCLUSIONS:**
There is substantial heterogeneity in the terms used to describe patient engagement activities across organizations. While a variety of opportunities for patient engagement are described, lack of clear evidence to how patient engagement practices are consistently used may contribute to the perception that engagement by HTAs.

**VP166 Selecting Rapid Review Methods For Health Technology Assessment**

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**ABSTRACT SUMMARY:**
Rapid reviews are of increasing importance in Health Technology Assessment (HTA). When selecting rapid review methods it is important to consider the evidence base, type of included studies and the expectations of commissioners.
INTRODUCTION:
Rapid reviews are of increasing importance within Health Technology Assessment (HTA) due to the need for timely evidence to underpin the assessment of new technologies as well as financial constraints. There are many rapid review methods available (1) although there is little guidance as to the most suitable methods (2). A recent paper outlines issues to consider when selecting rapid review methods (3). The aim of this presentation is to present key aspects to consider when selecting rapid review methods.

METHODS:
We searched the evidence base for guidance on the selection of rapid review methods. We also examined three recently completed systematic reviews to identify rapid review methods used, the reasons for selection and the strengths and weaknesses of each method. Finally we identified key aspects to consider when selecting rapid review methods.

RESULTS:
The evidence on guidance identified for the selection of rapid review methods was very limited. The analysis of the three reviews found that each review had distinctly different challenges, such as large numbers of relevant trials and heterogeneity in terms of populations, interventions, comparators and outcomes. All reviews included at least ten randomised controlled trials and numerous outcome measures. Three different approaches to the rapid review of the evidence were used in the three reviews. Key themes to consider when selecting rapid review methods were identified. These include: the size and nature of the evidence base, the characteristics of included studies and the expectations of those commissioning the review.

CONCLUSIONS:
Rapid review methods need to be chosen to fit the needs of the review, each of which may have different challenges. Collaboration between those producing rapid reviews and commissioners is crucial when choosing methods to ensure that the needs of commissioners are met and limitations associated with the chosen methods are understood.

REFERENCES:

VP167 Comparison Of Methodology In Mixed Treatment Comparisons Of Treatments For Multiple Sclerosis

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ABSTRACT SUMMARY:
The expanding range of disease modifying therapies (DMT) for relapsing–remitting multiple sclerosis (RRMS) has led to the publication of several mixed treatment comparisons (MTC). There
is substantial heterogeneity between MTCs with regard to inclusion criteria, outcome definitions, effect measures and statistical methods. There is a requirement for a consistent approach to health technology assessment (HTA) of DMTs for RRMS.

INTRODUCTION:
The expanding range of disease modifying therapies (DMT) for relapsing-remitting multiple sclerosis (RRMS) has led to increased interest in the relative effects of different DMTs. Previous mixed treatment comparisons (MTCs) have used different methods to address similar questions highlighting the need for a consistent approach to the assessment of treatments in RRMS.

METHODS:
We compared the methodology of six published MTCs of DMTs for RRMS identified by a systematic search of the literature. We assessed sources of evidence, DMTs included, outcomes reported and methods of data synthesis.

RESULTS:
All six MTCs were based on systematic reviews that included randomized controlled trials (RCTs). MS relapse was reported as the rate ratio based on annualised relapse rates (four MTCs) and as odds ratios or relative risk (one MTC each) based on the proportion with relapse. The analysis of relapse included between sixteen and twenty-seven RCTs and seven to twenty DMTs in different MTCs. One MTC reported both disability progression confirmed after three months (CDP3M) and disability progression confirmed after six months (CDP6M) as hazard ratios. One MTC combined CDP3M and CDP6M as a single outcome. One MTC reported only CDP3M based on hazard ratios. Two MTCs reported only CDP6M as either odds ratios or risk ratios (one MTC each). In one MTC the definition of disability progression was not reported. The analysis of disability included between seven and twenty-six RCTs and between six and nineteen DMTs in different MTCs. All six MTCs fitted a random effects MTC model using either Bayesian (four MTCs) or frequentist (two MTCs) methods.

CONCLUSIONS:
There is substantial heterogeneity between published MTCs in RRMS with regard to inclusion criteria, outcome definitions, effect measures and statistical methods. There is a clear requirement for a consistent approach to health technology assessment of DMTs for RRMS.

VP168 Assessment Of Plasmapheresis For Alzheimer’s Disease Systematic Review

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ABSTRACT SUMMARY:
Alzheimer’s disease (AD) is the most common type of dementia. Plasmapheresis is a procedure consisting of removing the plasma, or specific elements which are considered to be involved in pathological processes. Plasmapheresis could reduce the A beta peptides load in the brain. The objective of this work is to study the safety and efficacy of plasmapheresis for AD.

INTRODUCTION:
Alzheimer’s disease (AD) is the most common type of dementia. Plasmapheresis is a procedure consisting of removing the plasma, or specific elements which are considered to be involved in pathological processes. Plasmapheresis could reduce the A beta peptides load in the brain. The objective is to study the safety and efficacy of plasmapheresis for AD.
METHODS:

Systematic review, with all studies published before April 2016 reviewed. Selected studies included patients with AD treated with plasmapheresis. GRADE was used to assess quality. Efficacy outcomes include: (i) Cognitive, functional and behavior status, through Mini Mental State Examination, and Alzheimer Disease Assessment Scale-Cognitive test; (ii) Plasma and cerebrospinal fluid A beta levels; (iii) Brain-imaging and functional neuroimaging studies. Safety outcomes included side effects related to the treatment.

RESULTS:

Two papers reporting results from three studies were selected: (i) pilot study (n=10), (ii) its extended study (12 months more of follow-up) (n=7), and (iii) clinical trial (n=39). The quality of evidence was very low. About efficacy, the studies didn’t report quantitative results and were inconclusive. The pilot study and its extended study reported (1): a tendency towards stabilization in cognitive status; the plasma levels of A beta peptides didn’t show a clear pattern; and the brain-imaging assessment suggested a progressive volume increase in the hippocampus. The clinical trial reported in the experimental group vs control (2): a better score for the cognitive status; an increase of plasma A beta peptides; and did not find significant differences between groups for cerebrospinal fluid A beta peptides. The brain-imaging assessment showed a progressive loss of hippocampus volume in both groups. Regarding safety, the studies didn’t report quantitative data. We didn’t find economic evaluation studies.

CONCLUSIONS:

The included studies had very high risk of bias and very low quality. We found no evidence on efficacy and safety of plasmapheresis treating AD. Plasmapheresis isn’t a priority line in research of AD treatment.

REFERENCES:


VP169 Grouping Treat-to-Target Studies In Systematic Reviews

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ABSTRACT SUMMARY:

This study compared how treat-to-target study designs are grouped in systematic reviews of diabetes and hypertension with a recent Health Technology Assessment (HTA) systematic review in rheumatoid arthritis.

INTRODUCTION:

A Health Technology Assessment (HTA) systematic review was undertaken in rheumatoid arthritis (RA) of treat-to-target (TTT) studies (n=16) in which studies were grouped according to: TTT vs. usual care, trials comparing different targets, or trials
Comparing different treatment protocols. To our knowledge, this was the first RA TTT review where studies were grouped in this way. We wanted to compare if our approach had been adopted in reviews of hypertension, hyperlipidemia or diabetes.

**METHODS:**
We searched MEDLINE for systematic reviews (SRs) of TTT studies in hypertension, hyperlipidaemia or diabetes.

**RESULTS:**
Eleven SRs were included; eight were in diabetes, and four were in hypertension, while none were in hyperlipidaemia. The diabetes SRs evaluated different insulin regimens (n=3), non-insulin medications (n=1), any antidiabetic treatment (n=2), metformin monotherapy vs. combination therapy (n=1), and tight vs. conventional glucose control (n=1). The metformin review grouped studies by outcome whereas all other diabetes SRs grouped studies by treatment. Two hypertension SRs evaluated the effects of any treatment on two blood pressure targets, whereas one evaluated two different treatment regimen effects on the same blood pressure target. No SR in hypertension or diabetes included a mix of TTT vs. usual care, and/or same treatment protocol different targets, and/or different treatment protocols same target study designs.

**CONCLUSIONS:**
In RA TTT does not refer to a single concept but a range of different approaches to the treatment of patients and the evidence reflects this. Whilst our approach to grouping RA TTT studies in a review was novel, this made it complex for us to synthesise evidence and draw general conclusions. We did not identify any TTT reviews in hypertension or diabetes including a mix of the TTT approaches we identified in RA. At present, a comparison of the strengths and limitations of our TTT review study grouping with reviews of hypertension, hyperlipidemia or diabetes cannot be made.

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**VP171 The Safety Of Barbed Sutures In Cosmetic Surgery**

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**ABSTRACT SUMMARY:**
Cohort studies in cosmetic surgery (CS) have suggested that barbed sutures resulted in fewer adverse events with longer follow-up. Thus barbed sutures are considered a safe surgical technique in CS. More evidence with larger sample sizes and longer follow up are needed to confirm the advantages of this technique in the future.

**INTRODUCTION:**
Knotless barbed sutures can eliminate knot tying when patients are undergoing cosmetic surgery (CS). Although benefits reported on clinical outcomes are obvious, many studies have failed to demonstrate the potential for barbed sutures to mitigate adverse events. Thus, this study aimed to determine the safety of knotless barbed suture in CS.

**METHODS:**
PubMed, EMBASE, Cochrane Register of Clinical Studies, and ClinicalTrials.gov were searched for randomized controlled trials (RCTs) and cohort studies comparing barbed sutures with conventional sutures in CS (until 30 June 2016). Quality assessment was conducted using Cochrane recommendations. Review Manager was applied to analyze the data, and we sequentially omitted each study to perform sensitivity analyses.
RESyLOts:
A total of five RCTs (low to moderate risk of bias) and six cohort studies (low to moderate risk of bias), proved eligible (3,481 patients). The CS included body contouring operations, breast reconstruction, lipoabdominoplasty, abdominoplasty and wound closure of cesarean delivery. Comparing to conventional sutures, pooling data showed that general adverse events of barbed sutures were not significantly different (Odds Ratio, OR = .6, 95 percent Confidence Interval, CI .24 to 1.52, P = .28), while the subgroup analysis showed that fewer adverse events occurred in cohort studies, though with high heterogeneity (I^2=87 percent). Specifically, no significant differences were shown between barbed and traditional sutures in wound dehiscence (OR = .55, 95 percent CI .29 to 1.03, P = .06), incisional infection (OR = .56, 95 percent CI .22 to 1.48, P = .25), seroma (OR = .87, 95 percent CI .42 to 1.79, P = .70) and hematoma (OR = 1.52, 95 percent CI .29 to 7.99, P = .62).

CoNClUsiOns:
No differences were found between knotless barbed sutures and traditional sutures generally, but the cohort studies suggested barbed sutures resulted in fewer adverse events with longer follow-up. Thus, barbed sutures are considered a safe surgical technique in CS. More evidence with larger sample sizes and longer follow up are needed to confirm the advantages of this technique in the future.

VP172 Clinical Effectiveness Of A Predictive Risk Model In Primary Care

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ABSTRACT SUMMARY:
A predictive risk stratification tool (PRISM) identifies each registered patient’s risk of an emergency admission in the following year, allowing practitioners to identify and manage those at higher risk. We evaluated the introduction of PRISM in primary care in one area of the United Kingdom, and found an unexpected association with increased service use.

INtroDUCtiOn:
New approaches are needed to safely reduce emergency admissions to hospital by targeting interventions effectively in primary care. A predictive risk stratification tool (PRISM) identifies each registered patient’s risk of an emergency admission in the following year, allowing practitioners to identify and manage those at higher risk. We evaluated the introduction of PRISM in primary care in one area of the United Kingdom, assessing its impact on emergency admissions and other service use.

MeTHODs:
We conducted a randomised stepped wedge trial with cluster-defined control and intervention phases, and participant-level anonymised linked
outcomes. PRISM was implemented in eleven primary care practice clusters (total thirty-two practices) over a year from March 2013. We analysed routine linked data outcomes for 18 months.

RESULTS:
We included outcomes for 230,099 registered patients, assigned to ranked risk groups.

Overall, the rate of emergency admissions was higher in the intervention phase than in the control phase: adjusted difference in number of emergency admissions per participant per year at risk, delta = .011 (95 percent Confidence Interval, CI .010, .013). Patients in the intervention phase spent more days in hospital per year: adjusted delta = .029 (95 percent CI .026, .031). Both effects were consistent across risk groups.

Primary care activity increased in the intervention phase overall delta = .011 (95 percent CI .007, .014), except for the two highest risk groups which showed a decrease in the number of days with recorded activity.

CONCLUSIONS:
Introduction of a predictive risk model in primary care was associated with increased emergency episodes across the general practice population and at each risk level, in contrast to the intended purpose of the model. Future evaluation work could assess the impact of targeting of different services to patients across different levels of risk, rather than the current policy focus on those at highest risk.

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VP173 Determinants Of Behavioral Health System Efficiency In Organization For Economic Cooperation And Development (OECD) Countries

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ABSTRACT SUMMARY:
This study examined the technical efficiency determinants of each Organization for Economic Cooperation and Development (OECD) country’s behavioral health system (BHS) through data envelopment analysis, model combinations, and decision trees. Fruit consumption, smoking, and suicide rates were predictor variables of efficiency; >45 percent of OECD countries have an efficient BHS. Policymakers must promote an internationally-oriented BHS to improve health and equality worldwide.

INTRODUCTION:
This study examined the technical efficiency determinants of each Organization for Economic Cooperation and Development (OECD) country’s behavioral health system (BHS).

METHODS:
The technical efficiency of each OECD country’s BHS was analyzed through data envelopment analysis with model combinations ranging from 1-11 models, with each model constructed with different BHS input and output variable combinations. A decision tree was generated from the efficiency scores of the model with the highest mean technical efficiency score as a predictor.
variable. Data was obtained from 2013 OECD and Eurostat statistics.

RESULTS:
Different model combinations indicated that the model with the highest mean technical efficiency score (.9214) for OECD countries included (i) input variables for smoking, alcohol consumption, daily fruit consumption, the number of psychiatrists, the percentage of live births of young mothers first children, and the time devoted to leisure and personal care and (ii) output variables for death rate by mental and behavioral disorders, diabetes hospital admissions in adults, and suicide rates. Among all model combinations, >45 percent of OECD countries have an efficient BHS. The decision tree graph shows that daily fruit consumption, smoking, and suicide rates are predictor variables of the technical efficiency of an OECD country’s BHS.

CONCLUSIONS:
The study results offer important insights regarding the development of BHS in OECD countries. Health policymakers must develop collaborative activities and implement comprehensive policies promoting internationally-oriented BHS in order to improve the health status of people worldwide and reduce health inequality.

VP174 Atlases Of Quality: Assessing Integrated Care In Chronic Diseases

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ABSTRACT SUMMARY:
Atlases of Quality aim to evaluate the quality of care in relation to specific diseases or procedures in the Catalan territory with a focus on outcomes of care in order to promote best practices.

INTRODUCTION:
The Comprehensive Public Healthcare System of Catalonia (SISCAT) Atlases of Quality aim to evaluate the quality of care in relation to specific diseases or procedures in the Catalan territory with a focus on outcomes of care in order to promote best practices. The first Atlas of Quality aimed to assess the quality of integrated care for chronic patients.

METHODS:
Methodology was articulated in four stages: (i) Establishment of a conceptual framework of reference specific for each intervention/technology being assessed, (ii) Definition and consensus of the assessment indicators, and (iii) Implementation of indicators using the Basic Health Areas (ABS) of Catalonia as a unit of analysis, comparing ABS with vs without the intervention (such as integrated care for chronicity). Indicators were obtained from the SISCAT databases and implemented through risk adjustment models. For performance assessment, we calculated the observed and expected indicator rates for each ABS, and for the benchmarking analysis, these ratios were represented in funnel plots (Confidence Interval, CI 95 percent and 99.8 percent for exclusion zones). (iv) Evaluation of the intervention and identification of specific success factors.

RESULTS:
For the assessment of integrated care interventions for chronicity, the defined framework in stage 1 was base on the Kaiser Pyramid (population distribution), and the Porter and the Donabedian’s approaches (structure, processes, outcomes) (1). In stage 2 more than 500 experts, using several qualitative techniques, considered 18 indicators as relevant and feasible for the assessment (2).
Ten of them were implemented in stage 3 for congestive heart failure and pulmonary obstructive chronic disease. Significant values were found both in ABS with and without chronicity care programmes (phase 3).

CONCLUSIONS:
The subsequent analysis (phase 4) will allow identification of practices of each ABS that best explain these results. Some limitations must be considered such as the availability of the consensued indicators in the SISCAT databases.

REFERENCES:

VP175 Validating Outcome Assessments For Health Technology Assessment In Ceroid Lipofuscinosism Neuronal 2 (CLN2), An Ultra-Rare Disease

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ABSTRACT SUMMARY:
Ceroid lipofuscinosism neuronal 2 (CLN2) disease, a form of Batten disease, is a rare, degenerative neurometabolic disorder. Disease burden is best captured using observer-reported outcomes. However, validation is challenging in ultra-orphan diseases, requiring flexible methods. The study assessed the content validation of clinical trial measures using focus groups and interviews with caregivers.

INTRODUCTION:
Ceroid lipofuscinosism neuronal 2 (CLN2) disease, a form of Batten disease, is a rare, degenerative neurometabolic disorder. Disease onset around 2–4 years is followed by rapid decline in motor and neurologic function and mortality in early teenage years (1). Disease burden is best captured using observer-reported outcomes. However, validation is challenging in ultra-orphan diseases, requiring flexible methods and reasonable acceptance of limitations related to participant access.

The study aim was to assess content validation of clinical trial measures (i) CLN2 Disease Based Quality of Life Assessment (Sponsor-developed), (ii) EQ-5D-5L, (iii) Pediatric Quality of Life Inventory (PedsQL); and (iv) PedsQL Family Impact Module.

METHODS:
The Batten Disease Family Association recruited UK caregivers of a child with CLN2 disease (aged 3-7 years, non-participants in any CLN2 trial), to:
1. Focus groups with symptom elicitation
2. Cognitive interviews to assess measures.

RESULTS:
The Focus group comprised eleven caregivers (eight female, three male) from six families. Three families were current caregivers and remainders
bereaved. Symptom and disease impact elicited showed the majority of measures domains were relevant.

The interview sample comprised sixteen current caregivers (twelve female, four male) from ten families (caring for eleven children). Overall measures were relevant, easy to understand and answer. However, several items were difficult to apply to children with advanced disease (for example, Euroqol, EQ-5D-5L “overall health”), when ability is lost (for example, PedsQL walking), with misinterpretation of “no difficulties” with eating where child feeds using gastrostomy (CLN2 QoL). Caregivers found it difficult to know how their uncommunicative child was feeling (PedsQL worrying, EQ-5D-5L depression). Some symptoms and impacts were missing (for example, constipation, working life).

CONCLUSIONS:
The mixed-methods approach enabled content validity assessment of multiple measures. While these measures were largely relevant, adjustments could strengthen these for use in this fatal pediatric condition population and increase their acceptance within health technology assessment (HTA).

REFERENCES:

VP176 Effectiveness Of Anti-Tumor Necrosis Factor In Patients With Psoriatic Arthritis

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ABSTRACT SUMMARY:
Data of effectiveness of these drugs are scarce in the Latin American population. This study included fifty-four patients with Psoriatic Arthritis (PsA) who completed six months of follow-up. The anti-tumor necrosis factor (TNF) reduced disease activity measured by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Clinical Disease Activity Index (CDAI) at six months of follow-up (p<.001). The percentage of patients achieving the effectiveness with anti-TNF was 61.1 percent measured by BASDAI and 53.7 percent by CDAI.

INTRODUCTION:
Anti-tumor necrosis factor drugs (anti-TNF) are the last line of treatment for psoriatic arthritis (PsA) in the guideline of Brazilian Public Health System (SUS). Data of effectiveness of these drugs are scarce in the Latin American population. This study evaluated the effectiveness of the anti-TNF on a cohort of patients with PA in the SUS.

METHODS:
PsA patients treated with anti-TNF, were included in an open prospective cohort study. The Bath
Ankylosing Spondylitis Disease Activity Index (BASDAI) and Clinical Disease Activity Index (CDAI) were used to assess the effectiveness at six months of follow-up. The anti-TNF was considered effective when the patient achieves scores of four or less measured for BASDAI or scores of ten or less for CDAI. Frequency distributions were compiled for the sociodemographic variables and mean and standard deviation (SD) was used for clinical variables. The paired Student t-test was established to evaluate the differences between baseline and 6 months evaluated for BASDAI and CDAI.

RESULTS:
Fifty-four patients with PsA completed six months of follow-up. The mean age of patients was 54.03 years (10.44) and the mean disease duration was 8.00 years (7.49). Furthermore, 50 percent of the patients were female, 61.1 percent white and 59.6 percent married. The most used anti-TNF was adalimumab (63.0 percent), followed by etanercept (20.4 percent) and infliximab (16.7 percent). The anti-TNF reduced disease activity measured by BASDAI and CDAI at six months of follow-up (p<.001). The percentage of patients achieving the effectiveness with anti-TNF was 61.1 percent measured by BASDAI and 53.7 percent by CDAI.

CONCLUSIONS:
Anti-TNF drugs demonstrated to be effective in more than half of patients at six months. This result highlighted the importance of the treatment with the anti-TNF drugs in the Brazilian population. Long-term data are needed to confirm these results.

VP177 Older People With Cancer: To Treat Or Not To Treat With Chemotherapy?

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ABSTRACT SUMMARY:
We conducted six systematic reviews to explore the effectiveness and tolerability of systemic anti-cancer therapy for older people with cancer. We found that, for the majority of fit older patients with cancer, chemotherapy can represent an effective and tolerable treatment option and age should not be viewed as a barrier to treatment for the older population.

INTRODUCTION:
Older people with cancer are less likely to receive radical treatment for cancer. We conducted a series of systematic reviews to explore the effectiveness and tolerability of systemic anti-cancer therapy for older people with cancer. The reviews were conducted on behalf of the National Cancer Equality Initiative to establish an understanding of the current body of research and to enable the development of more personalized treatment protocols for elderly patients that take into account fitness and personal choice.

METHODS:
We conducted six systematic reviews that considered the effectiveness and tolerability of treatment for older people with cancer (breast, colorectal, lung, renal cell, chronic myeloid leukaemia and non-Hodgkin’s lymphoma). Four electronic databases were searched from 2010 to 2013. Data were extracted on a range of outcomes from published studies (randomised controlled trials, subgroup analyses, pooled analyses, cohort studies and retrospective studies).

RESULTS:
We found a large quantity of published research from a wide range of study types. We included a total of 490 studies (64 randomised controlled trials, 30 subgroup analyses, 24 pooled analyses,
Most of the randomised controlled trials enrolled fitter and healthier patients than those seen in routine clinical practice. The evidence indicates that older patients with good performance status can, and do, respond well to chemotherapy, frequently achieving similar survival benefit to younger patients.

We found no consistent definitions of ‘old’ or ‘elderly’ and these varied from 50 years to 85 years across studies.

The study results demonstrate that comprehensive geriatric assessment has not been routinely conducted in clinical cancer studies and that readily available assessment tools were not used by study investigators.

**CONCLUSIONS:**

Age should not be a barrier to treatment for the older population. Research is needed to determine which treatment regimens offer the appropriate balance of clinical effect and likelihood of adverse events within older populations. Future randomized controlled trials could be designed to include either higher proportions of older people, or only older people.

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**ABSTRACT SUMMARY:**

To analyze the allocation and utilization of CT in China within the context of the certificate of need policy, the allocation number of CT in 5 provinces and 88 Sample hospitals with 128 CTs from 5 provinces were investigated. The results showed that the increasing speed and utilization was relatively reasonable.

**INTRODUCTION:**

CT is a piece of common medical equipment and is widely used in the hospital. The allocation and utilization of CT has a great impact on access to care, quality, and efficiency, but few studies are available in China, especially combined with the certificate of need policy (CON) implemented in 2005.

**METHODS:**

The allocation number of CT in 5 provinces (A and B from eastern regions of China, C and D from central regions of China, E from western regions of China) was obtained from the provincial health administrative department. Eighty-eight sample hospitals with 128 CTs from the 5 provinces were investigated. The number of CT per million population, average annual service quantity per CT, and positive rate were used to analyze the allocation and utilization of CT in China.

**RESULTS:**

The total number of CT in 5 provinces (A, B, C, D, and E) increased from 1122 to 2234, with an average annual growth rate of 10.3 percent from 2006 to 2013. The number of CT in 5 provinces increased from 178 to 429, 265 to 722, 334 to 406, 194 to 423, and 151 to 254, with the average annual growth rate of 13.4 percent, 15.4 percent, 2.8 percent, 11.8 percent, and 7.7 percent respectively. The number of CT per million population changed from 3.8 to 8.9, 2.8 to 6.6, 4.9 to 5.6, 5.2 to 11.2, and 4.5 to 9.7, still below that of 13.6 which was the median of OECD countries in 2012.
As to the average annual service quantity per CT of the samples in 5 provinces, it varied from 18,584 to 31,473, 8,790 to 16,229, 12,985 to 27,039, 20,943 to 29,884, and 11,978 to 17,282 in the period from 2009 to 2013. While the variation trend of the positive rate was from 62.7 percent to 73.6 percent, 72.8 percent to 83.9 percent, 75.0 percent to 71.5 percent, 76.2 percent to 83.0 percent, and 64.5 percent to 62.9 percent.

**CONCLUSIONS:**
Owing to the CON policy, the number of CT increases with a reasonable growth rate, and the growth rate was relatively slow in Western China. The number of CT per million population was also rising, but still below than that of the average in OECD countries. The utilization of CT was relatively good with the CON policy, but measures shall still be taken to enhance the suitability of CT in western China.

**VP179 Health Technology Assessment Of Tolvaptan In The Treatment Of Autosomal Dominant Polycystic Kidney Disease**

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**ABSTRACT SUMMARY:**
The study provides a multidimensional evaluation of tolvaptan in patients with polycystic kidney autosomal dominant disease in line with the methodologies and logics of the Health Technology Assessment, under the perspective of the Italian National Health Service.

**INTRODUCTION:**
Autosomal dominant polycystic kidney disease (ADPKD) represents the fourth leading cause of chronic renal failure. Kidney transplant and dialysis currently represent the only treatment options for patients with ADPKD who reach ESRD stadium. Tolvaptan is the first treatment approved by EMA able to delay disease progression and benefit the symptoms of the disease. The aim of this study is to provide a multidimensional evaluation of tolvaptan in patients with ADPKD in line with the methodologies and logics of the Health Technology Assessment (HTA), under the perspective of the Italian National Health Service.

**METHODS:**
A targeted literature search on PubMed and a review of gray literature were conducted. Information collected was organized and summarized following the themes reported in a short HTA Template adapted from the EunetHTA Core Model® 2.1.

**RESULTS:**
Safety and efficacy was generated in the pivotal trial study for tolvaptan, TEMPO 3:4. In the study TEMPO 3:4, tolvaptan showed a safety profile in line with the placebo and a treatment adherence close to 90 percent. Concerning the efficacy endpoints, tolvaptan performed significantly better than placebo in the pivotal studies. Since tolvaptan delays the progression of the disease, its introduction into clinical practice could generate savings for the National Health Service (NHS). However, although some evidence of cost-effectiveness are available at international level, the cost-effectiveness of the treatment in the Italian context deserves further investigation.

**CONCLUSIONS:**
Currently tolvaptan represents the only option approved by EMA for patients with ADPKD that
has been proven to delay disease progression. Tolvaptan has been approved for reimbursement by several European Reimbursement Agencies (that is, NICE, SMC (Scotland), HAS, GBA) and it is advisable that the drug also be available for Italian patients. New national level evidences of cost-effectiveness might be useful to be able to inform clinical and pricing and reimbursement decisions and, if necessary, determine priorities between subgroups of patients.

**VP180 Effect Of Two-Invoice System On Drug Distribution And Price In China**

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**ABSTRACT SUMMARY:**
The Two-invoice System is China’s first policy specifically working on drug distribution. We are doing qualitative and quantitative studies on how the policy affects drug distribution and price. The evidence shows that the Two-invoice System reduces intermediate circulation, increases industrial concentration, and thus affects production and prices. However, ex-factory prices tend to be higher, and we are still working on how retail prices change afterwards.

**INTRODUCTION:**
Drug prices are mainly determined by production costs, commercial circulation and use in medical institutions. In 2015, total sales of the Chinese drug distribution industry was CNY1,613.3 billion (USD248.6 billion at 31 December 2015 exchange rate), with CNY28.3 billion (USD4.4 billion) profit and an average cost rate of 5.4 percent due to high logistics costs (1). Under Multi-invoice Systems in China, drugs are delivered through national, provincial, local agents, with invoiced and prices going up each time (2). The Two-invoice System, which comes up in April 2016, is China’s first drug distribution policy aiming to compress circulation, and reduce unrealistically high prices. There will be only two invoices, one from production enterprises to distributors, the other from distributors to medical institutions. The objective of this study is to evaluate the effect of the Two-invoice System on drug distribution and price in China.

**METHODS:**
We conducted a literature review of relevant articles and policies in five provinces on China National Knowledge Infrastructure (CNKI), Wanfang, PubMed and government websites. We conducted in-depth individual interviews for qualitative research on policy mechanisms with two government officials and four drug production and distribution enterprise managers. The quantitative study on policy effect measured indicators, namely, number of distributors, concentration ratio index (CR), net sales ratio, and ex-factory price. We compared the pilot province before and after the policy, with national level and other provinces. We considered related drug policies to eliminate confounding. Focus group discussion on conclusions and suggestions will be conducted.

**RESULTS:**
There are no peer review articles, only news media on this topic. In Fujian Province, the number of distributors dropped from 246 to 62. In 2015, the Top 3 drug wholesalers reached a market share of 36 percent (CR3), and Top 10 for 86 percent (CR10). Compared to the whole country, CR3 is 26 percent and CR100 is 86 percent. Net sales in the drug wholesale market in Fujian accounted for 75.6 percent, with an increase of 4.3 percent. While at the national level, it is only 57.2 percent with an increase of 0.3 percent (3).

**CONCLUSIONS:**
The Two-invoice System in China reduces
intermediate circulation, and increases industrial concentration. Net sales directly to hospitals are encouraged, which affects distribution and production areas. Production enterprises tend to invoice with higher prices instead of offering reserve prices to agents.

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VP181 From National To European Assessment: The German Case

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ABSTRACT SUMMARY:
National Health Technology Assessment (HTA) procedures differ in several elements. EUnetHTA proposes itself as a plausible platform for the HTA methodology across Europe. We compared the methodology and approach of the German and the European HTA observing that the involvement of pharmaceutical companies and the HTA bodies can lead to more comprehensive and reliable outcomes, which is in the interest of both sides.

INTRODUCTION:
Health Technology Assessment (HTA) processes have become a fundamental part in the lifecycle of new medicines. However, their deep relation with national legislation creates ambiguous and controversial results between the European countries. Can they be standardized across Europe?

METHODS:
Sources of national differences have been identified in timelines, documents, methods, data interpretation, and conclusions. In order to harmonize and standardize HTA cooperation across Europe the European Network for HTA (EUnetHTA) was established. We analyzed guidelines, requirements, and output of EUnetHTA and noted the differences between those guidelines and the German G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) standard and IQWiG (Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) methods.

RESULTS:
The comparison between German and European HTAs highlights that although both procedures follow the rules of Evidence-Based Medicine, differences in Body of Evidence, Comparator, Surrogate Endpoints, Subgroups, and Evidence Synthesis may lead to diverging HTA outcomes. The European HTA framework facilitates the appropriate depiction of clinical reality through comprehensive inclusion of the existing evidence with context specific statistical methods. It might
become a worldwide platform for HTA evaluation and discussion.

CONCLUSIONS:
Only the involvement of both, pharmaceutical companies and HTA bodies within a unified European framework can lead to a mature and transparent procedure with a reliable outcome independent of legal requirements.

VP182 Network Amongst The Health Technology Assessment Ecosystem

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ABSTRACT SUMMARY:
This study examined the main drivers of collaboration between Health Technology Assessment (HTA) organizations by using social network analysis to measure collaborative performance. HTA could be improved by integrating the private sector. HTA is shaped by local dynamics without a gold standard for HTA implementation, therefore collaborative efforts are the only way to make health technologies available for everyone.

INTRODUCTION:
There has been a growing interest in international collaboration among Health Technology Assessment (HTA) organizations on macro, meso, and micro policy-making levels. Global member-driven professional HTA societies make contributions to scientific improvement and enhance interactions in the HTA ecosystem. However, little is known about collaboration between HTA organizations at the global level. This study intends to examine the main drivers of network relationships of HTA organizations.

METHODS:
Social network analysis was used to ascertain the relationships between HTA organizations and to visualize the main drivers of collaboration. The total number of memberships of the HTA organizations of the International Society For Pharmacoeconomics and Outcomes Research (ISPOR), Health Technology Assessment International (HTAi), International Network of Agencies for HTA (INAHTA), EuroScan, European Network for HTA (EUnetHTA), HTAsiaLink, Red de Evaluación de Tecnologías en Salud de las Américas (RedETSA) were considered to create the network. Ten different types of HTA organizations were considered in the analysis including the Ministry of Health (MoH), university, for-profit, and hospitals. The Fruchterman-Reingold algorithm was used to perform network analysis; average clustering coefficient and average path length were examined to measure collaborative performance.

RESULTS:
A network graph of the HTA ecosystem shows the highest collaborative frequency in terms of HTA organizations, occurred with members of the Ministry of Health, government agencies, universities, and non-profit organizations. The average path length was 2.21 and the average clustering coefficient was 36.576 which indicates an obvious clustering effect.

CONCLUSIONS:
These study results highlight that the network throughout the HTA ecosystem is driven by government organizations. Integrating the private sector into the system, creating common information and data sharing strategies, and improving the number of internationally experienced HTA professionals are essential strategies to foster collaboration in HTA organizations. As HTA is shaped by local
dynamics and there is no gold standard for HTA implementation, encouragement of collaborative efforts is the only way to prevent duplication of effort and to make health technologies available for everyone.

VP183 National Policy: Impact On Antipsychotic Prescribing In Care Homes

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ABSTRACT SUMMARY:
The United Kingdom launched a National Dementia Strategy (NDS) in 2009 to improve care of people with dementia. A key target is a reduction in antipsychotic prescribing. More than one-third of UK individuals with dementia live in care homes but little is currently known about medications prescribed. This study examined antipsychotic use in 616 care homes over 4-years post NDS launch.

INTRODUCTION:
There continues to be international debate about the care of older people with dementia, especially those living in care homes (1). In the United Kingdom (UK), a National Dementia Strategy (NDS) recommended a two thirds reduction in antipsychotic use over 3 years (2). This study examined associations between the launch of the NDS and antipsychotic prescribing in long-term residential care (LTC) in England (3).

METHODS:
Retrospective analysis of prescribing patterns in 616 LTC institutions (31,619 residents) following launch of the NDS, using large-scale data from electronic medicines management system. Primary and secondary outcome measures: Antipsychotic prescribing point-prevalence (PP) for all residents in LTC setting over a 4-year period following NDS launch. Secondary outcomes included: dosages, length of treatment, and use of recommended second-generation antipsychotics (SGA) versus first-generation antipsychotics (FGA). Associations between facility-level PP values and institutional characteristics and resident demographics were explored. Variations across geographical areas were examined. Variations across geographical areas were explored. Prescription net ingredient costs were calculated.

RESULTS:
No significant decrease in antipsychotic prescribing rates over the 4-year period (Kolmogorov-Smirnov test p=0.60), and no significant shift towards newer SGAs (KS test p=.32). Dosage above maximum in only 1.3 percent of cases, but duration of prescribing excessive in 69.7 percent of cases. Care homes in highest prescribing quintile are more likely (p<.001) to be: i) located in a deprived area (Rate Ratio [Q5/Q1] RR = 5.89; 95 percent Confidence Interval [CI] 4.35, 7.99); and ii) registered for dementia (RR =3.38, 95 percent CI 3.06, 3.73); those in the lowest quintile are more likely to be served by a single general practice (RR = .48; 95 percent CI .37 , .63). There was a six-fold variation in PP levels between geographical areas. Average annual expenditure on antipsychotics was only GBP65.6 per resident.

CONCLUSIONS:
The UK National Dementia Strategy was not associated with a reduction in antipsychotic prescribing in care homes. Further research is needed to explore why. Clear standards specifying recommended agents, dosages, and length of treatment in care homes, plus routine data monitoring and greater accountability for antipsychotic prescribing, may be required.
REFERENCES:


VP184 A Cost Analysis Of Flash Glucose Monitoring Systems In Veneto Region

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ABSTRACT SUMMARY:
A novel, sensor-based, factory-calibrated Flash Monitoring System (FMS) has recently proved to be an effective alternative to conventional self-monitoring of blood glucose (SMBG) in patients affected by type 1 and type 2 diabetes. The 14-days adhesive sensor, that continuously measures glucose levels in the interstitial fluid, can transfer glucose levels data to a handheld reader or a smartphone equipped with a specific medical app. The uptake of the new technology has been limited so far, because of its high costs. A cost analysis has been conducted to identify the optimal target population of introducing FMS in Veneto.

METHODS:
The model was designed with a 1-year time horizon for patients with diabetes using intensive insulin in Veneto region. The costs of the new technology was estimated using inputs from the two main randomised controlled trials (the IMPACT study and the REPLACE study) published in the international literature, Regional evidence-based guidelines and administrative database. Resource utilization included strips, lancets, needles, sensors, distribution and patients training. Regional unit costs were adopted.

RESULTS:
FSM has not shown so far relevant and statically significant benefits in terms of severe adverse events’ reduction. Estimated yearly costs for a FSM user included glucose monitoring, technology training and distribution costs, for a total of EUR1,277 per patient. The new technology has been shown to be affordable in diabetic patients with i) 4years.

CONCLUSIONS:
The Veneto Region should carefully consider prescribing extension to other diabetic patients categories, since the high cost of the new technology. A strict prescribing monitoring is strongly recommended with the aim of ensuring appropriateness and avoiding overspending.
VP185 Coronary Disease Preferences: A Systematic Review

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ABSTRACT SUMMARY:
This study provides the first systematic review of the methods used in research into patient preferences between angioplasty and surgery for coronary disease. Preferences may be particularly relevant for approximately 12 percent of patients who are eligible for either angioplasty or surgery. Patients appear willing to accept considerable risk with angioplasty. New trials should improve outcomes and physician communication.

INTRODUCTION:
In clinical scenarios on which exists more than one clinically appropriate intervention strategy, patients’ preferences should inform decision making. Preferences for different treatments may be particularly relevant for approximately 12 percent of patients with coronary artery disease (CAD) who are eligible for either angioplasty or surgery. While cardiologists debate on optimal revascularization method, little is understood about the patient viewpoint (1). This study aims to systematically identify published healthcare preference studies related to CAD.

METHODS:
Data sources Medline, EMBASE and Lilacs were searched on 10 December 2016. Two researchers independently reviewed titles. Disagreements were resolved by consensus. Study eligibility criteria involved preference studies related to CAD.

RESULTS:
Of the 1,001 citations, 11 met the inclusion criteria. Total sample size was 3,499 patients and 177 physicians. Studies were conducted in the USA (n=7) and Europe (n=4). The studies used conjoint analysis (n=1), standard gamble (n=1), rating (n=3), ranking (n=1), and willingness to pay (n=1). Importantly, many outcomes not used in clinical trials were valued as more important than repeat revascularization, a very usual outcome. Physicians chose angioplasty over surgery significantly less than the patients when risk of death was quoted as 4 percent and 6 percent. Overall, respondents preferred angioplasty to surgery, even when the hypothetic risk of repeat procedure was three times the risk observed in surgery (1). Patients weighted stroke more significantly than clinicians did (2); they also considered stroke worse than death (3).

CONCLUSIONS:
This study is the first systematic review of the methods used to explore patients preferences between angioplasty and surgery. We considered the data scarce and identified some methodological challenges. Trials should include outcomes that are more important than repeat angioplasty and improve physician communication: neither the information given to patients nor the methods of presentation have been standardized. Compared to physicians, patients appear willing to accept considerable risk with angioplasty to avoid surgery.

REFERENCES:
VP186 The Importance Of The Therapeutic Adherence In Chronic Diseases

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ABSTRACT SUMMARY:
By therapeutic adherence is intended the degree of correlation between a patient’s behavior aimed to manage a specific disease and the actual prescription indicated for the same specific disease by the physician. Governments should develop policy interventions and incentive systems aimed to improve the level of therapeutic adherence of the patients.

INTRODUCTION:
By therapeutic adherence is intended the degree of correlation between a patient’s behavior aimed to manage a specific disease and the actual prescription indicated for the same specific disease by the physician. The aim of this study is to determine the extent to which specific parameters included in the analysis affect the level of adherence to the therapy assigned to the patient.

METHODS:
Researchers developed a two-stage Markov model differentiating four patients’ possible behaviors: a. patient compliant and persistent; b. patient non-compliant and non-persistent; c. patient compliant and non-persistent; and d. patient non-compliant and persistent, defining by “compliance” the way of administration of the drug at intervals defined by the physician and by “persistence” the period of time for which the patient is continuously treated with a given drug. Patients move across the four behaviors differently according to parameters such as age, sex, cognitive deficit, stress or depression (endogenous parameters) or chronic condition, characteristics of the Health System etc. (exogenous parameters). The model associated to each behavior both a specific level of benefit, expressed in terms of quality-adjusted life years (QALY), and a specific level of resources’ consumption. Where appropriate, results are expressed in terms of incremental cost-effectiveness ratio (ICER).

RESULTS:
The level of a patient’s therapeutic adherence is influenced both by exogenous and endogenous parameters. Increasing the level of adherence might improve the results achievable in terms of quality of life and amount of resources consumed. Furthermore, increased adherence would imply the achievement of a positive fiscal impact.

CONCLUSIONS:
Governments should develop policy interventions and incentive systems aimed to improve the level of therapeutic adherence of the patients, to obtain both an increased level of welfare and an important reduction of wasted resources.

VP187 Budgetary Impact Analysis: Real-World Evidence Versus Theoretical Results

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ABSTRACT SUMMARY:
To compare the theoretical results of the budgetary impact analysis, calculated according to Brazilian guidelines, and the real-world evidence for the treatment of rheumatoid arthritis with adalimumab. There is a need to review the Brazilian budgetary impact analysis guidelines to incorporate methodological advances.

INTRODUCTION:
Objective: To know and to compare the theoretical results of the budgetary impact analysis (BIA), calculated according to Brazilian guidelines, and the real-world evidence (RWE) - expenditures in the Brazilian Unified Health System (SUS) for the treatment of rheumatoid arthritis (RA) with adalimumab (ADA).

METHODS:
This analysis was performed to 2006 and 2010, based on the clinical protocol and therapeutic guidelines for AR in force on the period. The theoretical model was calculated by the methodological guidelines - SUS for BIA. RWE was collected in SUS databases. 1 EUA/USD = 1,6662001 REAL BRASIL/BRL (December/31/2016).

RESULTS:
In the theoretical model, the number of patients with biological drugs was 32,188 and with ADA was 11,153. RWE the number of patients with biological drugs was 15,222 and with ADA was 7,320. In the theoretical model, the projected expenditures for biological treatments was USD2.10 billion, and USD0.71 billion with ADA. RWE the expenditures for biological treatments was USD0.63 billion, and with ADA was USD304 million.

CONCLUSIONS:
Although BIA is an important stage of health technology assessment, this is still a recent technique and requires development and improvement. The results obtained showed the need to revise the Brazilian BIA guidelines to incorporate methodological advances.

VP188 Cost-Effectiveness Of Outpatient Treatment Of Febrile Neutropenia

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ABSTRACT SUMMARY:
Febrile neutropenia (FN) occurs in 80 percent of children with cancer. Inpatient treatment of FN is costly and risky. We aimed to perform an economic evaluation of outpatient management of FN through a randomized controlled clinical trial. Interim analysis showed that outpatient strategy is less costly and more effective than inpatient. These results are promising for Mexican hospitals delivering pediatric cancer care.

INTRODUCTION:
Febrile neutropenia (FN) is the most frequent complication due to chemotherapy in cancer patients (1). FN occurs in 80 percent of children
with leukemia (2). Pediatric hospitals in Mexico deliver inpatient care every time a patient has an FN event since oncologists have no experience with outpatient management of FN, as currently occurs in other countries (3). Inpatient care of FN may have an unfavorable impact on the budget of Mexican hospitals, but patients may also be affected due to nosocomial infections. The purpose of our study was to perform an economic evaluation of outpatient care for children with cancer experiencing FN events.

METHODS:
This is a randomized controlled clinical trial currently in progress in three third level hospitals in Mexico. Inclusion criteria: child with cancer older than 1 years old, patient with FN event that during first 24-48 hours has been afebrile, hemodynamically stable, with negative culture. Patients were randomly assigned to inpatient or outpatient management of FN. Sample size estimated was 68 FN events per group, plus 20 percent for loss of follow up. Data collection includes clinical outcomes (favorable or unfavorable) and medical inputs consumed. Parametric and nonparametric statistical analysis were performed for comparisons between groups.

RESULTS:
From July 2015 to November 2016, 235 candidates were identified; 163 were excluded, 7 refused to participate, and 65 were included. The results come from the interim analysis. Of the clinical and demographic variables, only the proportion of men/women was different between groups. Fever restart occurred in three patients in the inpatient group; no patients with unfavorable outcome were observed in the outpatient group. Mean total cost was USD699.63 for the inpatient group, while for outpatient group it was USD266.79. Cost-effectiveness ratio was not estimated since the outpatient management has demonstrated been less costly and more effective.

CONCLUSIONS:
Ambulatory care for NF in children with cancer has been used in developed countries, but Mexican oncologists have had uncertainty about it. The results of this interim analysis are promising, and we hope the clinical and economic differences reported will remain unchanged to inform the clinical and economic decision markers of the healthcare system.

REFERENCES:

VP189 Hemolysis Induced By Modern Infusion Pumps During Blood Transfusion

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ABSTRACT SUMMARY:
We compared the hemolysis and potassium levels induced by the use of three modern infusion pumps. Results indicated that low hemolysis levels were induced.
INTRODUCTION:
Following a first field evaluation conducted in 2013, we found that hemolysis can be induced by infusion pumps during blood transfusion. Actually, limited data is available on the risk of hemolysis associated with the most used infusion pumps in Quebec hospitals: InfusomatSpace (peristaltic), Plum A+TM (piston) and ColleagueCXE (shuttle).

METHODS:
Staff from the blood bank and the Health Technology Assessment (HTA) unit in our hospital collaborated in 2016 to assess the hemolysis and potassium level (that is, a blood test sensitive to hemolysis) induced by the use of the three infusion pumps mentioned above. Measurements were taken for each pump at five flow rates, from 30 to 450 ml/hour, and were compared with measurements taken before using the pumps. Tests were conducted with 135 red blood cell (RBC) units. RBC units were aged from 10 to 28 days.

RESULTS:
The shuttle- and piston-type pumps resulted in low hemolysis levels. The peristaltic-type pump produced significantly more hemolysis. However, the absolute value of hemolysis remained within the range recommended by the regulatory agencies in North America and Europe. Potassium levels did not increase with the use of the pumps.

CONCLUSIONS:
The collaboration between the blood bank and the HTA unit led to the conclusion that modern infusion pumps widely used in Quebec hospitals produce non-threatening levels of hemolysis during blood transfusion. This finding is important to ensure safe practices.

VP190 A Review Of Best Practices In Five Mental Disorders In Youth

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ABSTRACT SUMMARY:
A review of reviews on effective interventions for five most common mental disorders in young populations was conducted by our hospital-based Health Technology Assessment (HTA) unit in order to support service planning of the youth program of the East of Montreal Health and Social Services Board, and potentially of other similar programs across the Quebec province.

INTRODUCTION:
In order to support service planning of the youth program of the East of Montreal Health and Social Services Board, and potentially of the other twenty-five programs across the Quebec province, our hospital-based Health Technology Assessment (HTA) unit was asked to bring evidence of the effective interventions for five most common mental disorders in children and young populations, namely anxious-depressive disorders, attention deficit and hyperactivity disorder, oppositional and conduct disorders, substance abuse disorders, and suicide attempts.
METHODS:
A review of reviews was conducted for the five disorders in young populations aged 6 to 25 years. This was based exclusively on systematic reviews and meta-analysis of a minimum two randomized-controlled trials. The review was completed with examples of Quebec’s good practices in youth mental health gathered from personal research experience of clinical researchers involved in the project. The project involved collaboration with three other hospital units and provincial HTA agencies.

RESULTS:
No review supporting screening and early detection for the five disorders was identified. Prevention, however, was better covered in the literature, and a clear distinction was made between universal, targeted and indicated interventions. In general, targeted and indicated prevention interventions were effective in the case of anxio-depressive (1) and substance use disorders, while universal prevention strategies seemed to reduce suicide attempts and suicide ideation (2). Effective treatments also exist for these mental disorders. In general, psychotherapies dominated for anxio-depressive and substance use disorders; parental skills dominated in oppositional disorders, whilst pharmacological treatment dominated in attention deficit and hyperactivity disorder (3). Evidence was limited for suicide attempts. The overview of Quebec’s good practices allowed identification of interventions or practices already in use in the province.

CONCLUSIONS:
The review summarized effective interventions for five most common mental disorders in young populations. It also permitted to identify several research gaps, and therefore research recommendations were formulated for the province’s health research agency.

REFERENCES:

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VP191 Peripheral Nerve Field Stimulation For Chronic Low Back Pain

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ABSTRACT SUMMARY:
A Hospital-based Health Technology Assessment (HTA) was performed to evaluate effectiveness and safety associated with the use of peripheral nerve field stimulation for chronic low back pain. Evidence suggested that this innovative treatment is potentially beneficial but long terms effects have to be assessed through a rigorous framework before its introduction as a standard medical practice.
INTRODUCTION:
Despite numerous medical, pharmacological and surgical approaches for chronic low back pain (LBP), many patients continue to complain of severe disabling pain. Peripheral nerve field stimulation (PNfS), alone or combined with spinal cord stimulation, is a neuromodulation procedure that have been recently developed and implemented in our hospital. We conducted a Health Technology Assessment (HTA) to determine if PNfS may be considered as a standard of practice in the management of intractable LBP and failed back surgery syndrome (FBSS).

METHODS:
An interdisciplinary group of experts was involved in the project. A systematic review (SR) was performed in several databases and grey literature to identify clinical practice guidelines, SR and observational studies published through September 2016. A survey was conducted among other chronic pain centers in Canada to document PNfS use in LBP and FBSS treatment.

RESULTS:
Data on effectiveness and safety of PNfS in chronic LBP treatment were scarce. Short-term results (3–12 months) from small sample and low quality studies suggest that PNfS, alone or combined with spinal cord stimulation, is associated with pain intensity and opioid use reductions. Effects on functional status and quality of life remain undetermined. Most frequent adverse events reported with PNfS devices are lead migrations, discomfort or pain and surgical site infections. No other Canadian pain centers were found to use PNfS in chronic LBP or FBSS.

CONCLUSIONS:
PNfS is potentially a beneficial treatment option for patients with chronic low back pain or FBSS. However, the value of this innovative treatment remains unknown. Among factors to be clarified are target population (any chronic low back pain or FBSS), use of PNfS alone or combined with spinal cord stimulation, long-term effects, and comparison with conventional medical management. PNfS use in chronic LBP has to be assessed through a rigorous framework before its introduction as a standard medical practice.

VP192 Importance Of Contextual Data In Producing Health Technology Assessment Recommendations

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ABSTRACT SUMMARY:
Despite the lack of evidence in the scientific literature, there may be sufficient interest and expected benefits toward a technology to recommend its adoption in a given context. We illustrate this possibility by a case study about biplane angiography for vascular neurointervention.

INTRODUCTION:
Available data in the scientific literature is not always sufficient to make a clear Health Technology Assessment (HTA) recommendation without any other source of data. Contextual data and local expertise are an important source of data that cannot be ignored in HTA process. Despite a lack of evidence in the scientific literature, a technology can be recommended in a given context. We illustrate this by a case study about biplane angiography for vascular neurointervention.

METHODS:
A systematic review was conducted. The level of evidence was assessed by the grid of Downs and Black. An analysis of the context in our setting
was also conducted. The main outcomes were: radiation doses, clinical complications, procedure times, purchase cost, impact on teaching programs, confidence of clinicians in the technology, quality of care, and volume of activity. A committee constituted of managers, clinical experts, physicians, physicists and HTA experts was created to produce a recommendation about biplane technology acquisition.

RESULTS:
A list of 257 citations was obtained yielding 9 eligible articles for analysis. Despite the lack of evidence found in the literature (median of Downs and Black: 3/32), the biplane system appears to reduce ionizing radiation and medical complications as well as shorten procedure time. Contextual data indicated that biplane system could improve operator’s confidence, which could translate into reduced risk, especially for complex procedures. We estimate that a minimum of 50 cases can be done in our context (University hospital center covering a population of 306,322 people) with a higher level of patient safety. In addition, the biplane system can support our institution in advanced procedures teaching program.

CONCLUSIONS:
Given on the advantages provided by the biplane technology in our setting, the committee has recommended its acquisition. However, this technology should be implemented with a responsibility in collecting outcome data to optimize clinical protocol in doses of ionizing delivered.

VP193 Criteria For Opting For Either Hospital (Local) Hta Or National Hta

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ABSTRACT SUMMARY:
Since 2013, both local mini-Health Technology Assessments (HTAs) and national HTA have been produced within the system for introducing new technologies in the Norwegian specialist health care. To decide upon the most suitable HTA product to support decision making, criteria have been used, but these are continuously being discussed. Here we show how our experience so far may contribute in further determining these criteria.

INTRODUCTION:
The Norwegian health authorities established a system for introduction of new health technologies in the specialist healthcare in 2013. Mini-HTA is the basis of this system, along with horizon scanning, single technology assessments (STA), and health technology assessments (HTA). Whereas mini-HTAs are performed at the local level in hospitals, early warnings (horizon scanning), STAs, and full HTAs are produced by the national HTA centers with the aim of informing and supporting decision making at the regional and national levels. Mini-HTA is a tool designed to support evidence-based decisions before uptake of new technologies at the hospital level, and is used primarily to assess medical devices, procedures, and diagnostic and organizational technologies. A mini-HTA uses the same methodological approaches as in an HTA, but is a simplified version, and is estimated...
to take a few weeks (one to four) to accomplish. Deciding on whether a mini-HTA is “sufficient” or an assessment at the national level is necessary has large implications on the following decision making processes and use of resources. Therefore, several overall guiding criteria have been set to help this decision, however the use of these is currently being discussed.

**METHODS:**
Among the nearly forty mini-HTAs that have been carried out within the system for introduction of new health technologies, so far three of them have been “redirected” to the national level. We have used these to try to isolate possible determinants that might influence the decision on whether a medical device or other non-pharmaceutical technology should be evaluated in a mini-HTA, that is, at the local level or in STA or HTA at the national level.

**RESULTS:**
Observations from our three selected examples indicate that main determinants are related to economical (budget impact), organizational, and ethical issues.

**CONCLUSIONS:**
We have got useful information from our preliminary observations, however more experience is needed to definitely decide upon the specific criteria that should be taken into account (and their order of priority) when opting for either a hospital-based or national HTA.

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**VP194 Health Technology Assessment Applied To Nurse Retention And Development: A Sickle Cell Example**

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**ABSTRACT SUMMARY:**
We are applying Health Technology Assessment (HTA) methods to evaluate interventions intended to reduce caregiver stress and increase job satisfaction. An example for nurses who care for patients with sickle cell disease is presented.

**INTRODUCTION:**
Health Technology Assessment (HTA) methods are usually applied to the evaluation of drugs, devices, and procedures. We have used HTA to promote evidence-based decision-making on topics relating to staffing and career development for healthcare professionals. Interventions to reduce the stress associated with caring for patients who need repeated hospitalization such as patients with sickle cell disease are thought to improve job satisfaction and nurse retention, but is there scientific evidence to support them?

**METHODS:**
We systematically searched Medline, CINAHL, PsycINFO, Cochrane, and Joanna Briggs Institute databases for published studies evaluating interventions targeting healthcare personnel. Searches combined terms for sickle cell disease with terms for job stress, turnover, and other career-related outcomes. We evaluated the quality of individual studies using standardized checklists and constructed evidence tables.
RESULTS:
We found one randomized trial (RCT) of an education program for nurses and physicians, a pre-post analysis of a communication skills and cultural awareness program, and a case study of a nurse support group. The RCT found that an education program significantly improved participants’ attitude towards patients but did not measure any outcomes relating to caregiver stress or job satisfaction. The pre-post study found that a communication skills program significantly improved nurses’ confidence in their ability to communicate with patients. The case study reported that nurses found the support group useful and felt their attitudes were improved, but there was no control group to compare their responses to. The education program was graded as moderate-strength evidence and the other programs had low-strength evidence. There was no meta-analysis or other data synthesis of the results because of the differing interventions and outcome measures.

CONCLUSIONS:
There have been few quantitative scientific evaluations of the effectiveness of interventions to reduce the stress nurses feel when caring for sickle cell disease patient. The studies that have been published have favorable conclusions towards these interventions, but the strength of evidence is not high.

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VP195 Using The ISSG Search Filter Resource In Health Technology Assessment

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ABSTRACT SUMMARY:
Information specialists and others searching for health technology assessments can use the ISSG Search Filter Resource (SFR) to identify filters to incorporate into search strategies. This can create more efficient searches that retrieve fewer and possibly more relevant database records. There are sections listing filters to identify: adverse effects, aetiology, economic evaluations, health state utility values, public views, and quality of life.

INTRODUCTION:
Information specialists and others searching for Health Technology Assessments (HTAs) can use the ISSG Search Filter resource (SFR) to identify filters to incorporate into search strategies. This can save time and effort when designing searches and create more efficient searches that retrieve fewer and possibly more relevant database records (link available here: https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home).

What are search filters?
Search filters are collections of search terms designed to retrieve selections of records from bibliographic databases. Some filters are designed to retrieve records of specific study designs such as randomized controlled trials (RCTs) or systematic reviews; others aim to retrieve records relating to other features or topics such as the age or gender of study participants.

Search filters may be designed to be sensitive, precise or balanced between sensitivity and precision.

METHODS:
When would you use a search filter in HTA?
Search filters can be added to search strategies to limit to specific study types, for example, RCTs, mixed methods studies, systematic reviews. They can also be used when searching for other aspects of HTA such as patient views or specific age groups.

The ISSG SFR includes sections listing search
filters to help identify adverse effects, aetiology, economic evaluations, health state utility values, public views, and quality of life.

RESULTS:
How are filters used?

A search filter is often used in combination with a topic search to restrict the search results to a specific type of record, for example, records reporting health state utility values or records of randomized controlled trials.

CONCLUSIONS:
Further guidance on the use of search filters can be found in the SuRe Info Search Filters chapter (http://vortal.htai.org/?q=node/573).

VP196 Impact Of Trial Registry Search Features On Searches In CT.gov/International Clinical Trials Registry Platform (ICTRP)

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ABSTRACT SUMMARY:
We analysed the trial registries ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP) to determine the importance of search features (e.g. searches using synonyms) for identifying studies of new drugs. The findings showed that search features of trial registries have a major impact on the sensitivity of searches. In addition, search features of CT.gov are more effective than those of ICTRIP.

INTRODUCTION:
In contrast to bibliographic databases, trial registries do not offer the option of formulating complex search queries, thus making targeted searches more difficult. However, ClinicalTrials.gov (CT.gov) and the International Clinical Trials Registry Platform (ICTRP) offer different search features that may help compensate this limitation. Our aim was to determine the importance of search features (for example, searches using synonyms or, additionally in CT.gov, automatic inclusion of further search fields) for trial registry searches.

METHODS:
We conducted a project called “Trial registry searches for studies of newly approved drugs” (1). One analysis investigated the question as to whether searches for different health conditions and interventions (new drugs) directly identified registry entries with the search terms entered or whether certain search features were responsible for this. We searched CT.gov and ICTRP for different conditions and interventions using the advanced search interface. For each search, we documented the synonyms listed in the two registries. We imported the registry entries into EndNote and evaluated whether the search terms used were available in the corresponding search fields (condition; intervention).

RESULTS:
For CT.gov, 96 registry entries on 18 interventions and 190 entries on 12 conditions were analysed. Of these, twenty-three (24 percent) entries for interventions and thirty-eight (20 percent) for conditions were identified by search features, not by search terms. For ICTRP, 32 entries on 10 interventions and 100 entries on 9 conditions were analysed. Of these, five (16 percent) entries for interventions and eight (8 percent) for conditions were identified by search features.

CONCLUSIONS:
Trial registry search features have an important impact on the sensitivity of searches. Many studies
are not identified by the search terms entered, but by searches using synonyms and, additionally in CT.gov, by automatic inclusion of further search fields. Moreover, search features in CT.gov are more effective than in ICTRP – even though the same search terms are used, they consistently yield higher sensitivities.

REFERENCES:

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VP197 Sustainable Production Of Rapid Health Technology Assessments And Clinical Guidelines

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ABSTRACT SUMMARY:
The Scottish Health Technologies Group (SHTG) participated in two collaborative rapid Health Technology Assessment (HTA) review and adaptation projects to test whether this could save time and resource, whilst providing a product as robust and relevant as if developed locally. The report produced was subsequently used to update a Scottish clinical guideline recommendation. Our learning and experience from this work are described.

INTRODUCTION:
With increasing resource pressures on health systems, rapid developments in innovative technologies and limited numbers of skilled assessors, there is a need to establish sustainable methods to provide advice on healthcare technologies for decision makers. The European Network for Health Technology Assessment (EUnetHTA) has been testing an approach of collaborative production of rapid Health Technology Assessments (HTAs) and adaptation of these locally. The Scottish Health Technologies Group (SHTG) participated in two collaborative and adaptation projects to test whether this could save time and resource, whilst providing a product as robust and relevant as if developed locally. Concurrently the Scottish Intercollegiate Guidelines Network (SIGN) has been exploring ways to develop clinical guidelines more efficiently, including the use of rapid HTAs to inform recommendations.

METHODS:
Having established the relevance of the topics to NHS Scotland, SHTG participated as peer reviewers for EUnetHTA reviews on mitral valve repair and mechanical thrombectomy. On completion, SHTG summarised their content to fit with the well-accepted rapid review report format used in Scotland. Content was supplemented with a review of economic evidence, currently not included in the European reports, local epidemiological information and recently published studies. The thrombectomy report and associated Advice Statement were used by a small expert group to update a SIGN clinical guideline recommendation.

RESULTS:
Providing advice through adaptation proved feasible and acceptable to stakeholders. Limited time was saved because of the supplementary work undertaken, and lessons have been learned about what should and should not be done in future. The guideline recommendation was updated and made available more quickly than similar previous updates.
CONCLUSIONS:
Further such collaborations and adaptations will be pursued as this appears to be a sustainable approach for the future. The process could be aided by EUnetHTA publishing forward work plans and also by the inclusion of economic information, with details of the decision-making context provided, to allow assessment of its relevance locally.

VP198 Efficient Retrieval Of Trial Protocols: An Empirical Study

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ABSTRACT SUMMARY:
An empirical study was conducted in the context of a systematic review, investigating the differential coverage of sources and the relative efficiency of retrieval methods for identifying trial protocols. Recommendations for prioritizing sources and methods will aid Information Specialists and inform future search methods guidance for systematic reviews.

INTRODUCTION:
Registration of trial protocols has become increasingly important in recent years. In the context of systematic reviews, published trial protocols facilitate the identification of studies. Data recorded in trials registers requires standardization to assist with ease of identification, and availability of the most current protocol version. Searching sources of trial protocols, for example trials registers, has issues relating to currency, coverage, functionality and indexing.

METHODS:
In a systematic review of primary care interventions for medically unexplained symptoms, seventy-four trials were identified as potential included studies. To search for the seventy-four trial protocols, multiple sources and methods were utilised to identify the the differential coverage of sources and the relative efficiency of retrieval methods. Retrieval methods included searching trials registers and bibliographic databases, internet searching, checking journal websites and contacting authors.

RESULTS:
Results included; (i) number of trial protocols that were referenced in the corresponding study publication(s), (ii) percentage of protocols indexed in each checked source, including MEDLINE and various trials registers, (iii) number of authors that responded to email contact, (iv) number of authors that provided a reference to, or copy of, the protocol. Information on when the trial protocol was published, funding sources, and trial registration, was also recorded.

CONCLUSIONS:
Conclusions are made regarding the coverage of different sources of trial protocols. This will enable Information Specialists to prioritise retrieval methods for identifying trial protocols to inform future search methods guidance. The main barriers to retrieving protocols are discussed together with recommendations for future empirical studies.
VP199 Limitations Of Studies On Oxygen Therapy In Acute Care Settings

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ABSTRACT SUMMARY:
The Health Technology Assessment review provides a summary of the published information on oxygen therapy issues studied in the past 10 years in acute care settings. The report includes a summary of audit studies that aimed to address appropriate/inappropriate use of oxygen, and explores the safety and quality issues identified in the literature associated with oxygen prescription, administration, and monitoring.

INTRODUCTION:
A high-level, rapid review (1) was conducted on oxygen therapy issues studied in the past 10 years in acute care settings. The main objective was to determine the appropriateness/inappropriateness of use, safety issues, and quality of care associated with oxygen prescription, administration, and monitoring. The results from this review were used to inform an upcoming provincial oxygen summit.

METHODS:
The Health Technology Assessment review (1) used a standardized rapid review approach: a comprehensive search of literature (published in English from 2005 to 2016), study selection using a priori developed criteria, and a qualitative synthesis of the results. Iterative interactions with the requester were necessary to clarify and refine the research questions, scope, and inclusion criteria.

RESULTS:
Twenty-four audit studies were reviewed, the majority published after 2011, in the United Kingdom, and also in single institutions. Twelve studies reported effects after implementing interventions for improvement of oxygen prescription. Many studies had caveats on design, data reporting, and outcomes, or they lacked an explanation of the methods of analysis. Studies conducted in rural settings, and on infants and children were unavailable. The reported issues with oxygen therapy included: a lack or an inconsistency of compliance with guidelines, local policies, and standards; inappropriate prescription and administration; variability in practice among healthcare providers; and suboptimal monitoring, including poor standards of medical chart documentation for patients receiving oxygen therapy, such as incomplete details on flow rate and oxygen concentration.

CONCLUSIONS:
Possibly due to the general tendency to publish research findings that have statistically significant results, relatively few publications were found in the literature search. The universal use of oxygen therapy and the enrolment of consecutive patients in some of the studies increase the applicability of the findings to other institutions. The rapid review provided a timely synthesis of the available, credible research for use by local stakeholders for further discussions and planning.

REFERENCES:
VP200 Untangling What Information Specialists Should Document and Report

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ABSTRACT SUMMARY:
The documentation of comprehensive search strategies is an essential part of the information retrieval process in Health Technology Assessment (HTA). A clearly and richly described strategy showcases the robustness and accuracy of the search. As part of the Summarized Research in Information Retrieval (SuRe Info) Project, we conducted a review of all current reporting standards relevant to HTAs and systematic reviews.

INTRODUCTION:
Thorough documentation and clear reporting are essential when conducting a comprehensive literature search for a health technology assessment (HTA) or systematic review. The ultimate goal of this process is transparency and reproducibility with the added benefit of increasing the reader’s confidence in the research. Thorough documentation of the search also allows for critical appraisal of the methodology used and facilitates future updating of a review (1,2).

It has been found that large numbers of systematic review searches are inadequately documented and there is little consensus on best practices for reporting standards (3).

As part of the SuRe Info Project, we conducted a review of all current reporting standards relevant to HTAs and systematic reviews in addition to looking at the published literature on this topic in order to synthesize the evidence in this area and create a standard set of agreed upon recommendations.

METHODS:
We conducted a comprehensive search of Medline, Embase, and LISA (Library & Info Studies Abstracts) databases. We also examined the Equator Network (http://www.equator-network.org/) website. Reference lists of included studies and reporting guidelines were also consulted. Eleven reporting guidelines and eight studies were included in the review by two independent reviewers. Anything published before 2006, that was not a research article (other than the guidelines), and/or that did not provide new recommendations (i.e. a review of another set of recommendations) was excluded.

RESULTS:
After collecting data on the suggested reporting elements described in the literature, we pooled our results to create an overarching list of the most commonly recommended elements to describe and the most commonly recommended methods to use when documenting a comprehensive search. Not only did these elements pertain to documenting the search strategy for the final report, but they also pertained to the protocol and the abstract of a review.

CONCLUSIONS:
It is hoped that this overview of the literature and compilation of the evidence will clarify some of the confusion that seems to exist when documenting and reporting searches and perhaps it will even help to reduce the existence of poorly described strategies in the research literature.

REFERENCES:
VP201 From A Systematic Review To Addressing Evidence Gaps

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ABSTRACT SUMMARY:
When systematically collected and analyzed, evidence gaps identified by systematic reviews can highlight areas where research is greatly needed. Areas that could need assistance in building a more solid research structure. It can also serve as a tool for research prioritization processes involving patients, consumers and clinicians.

INTRODUCTION:
In both health care and social services it is important to continuously summarize and analyze existing research in the form of systematic reviews. At the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) (www.SBU.se) we collect the evidence gaps identified by systematic reviews in a database. These evidence gaps are methods used in health care/social services for which there is not enough good quality research available. By analyzing this database we can highlight populations or methods where evidence gaps are more frequent. This knowledge can be used to find areas that might need assistance in developing research structure and also when arranging research prioritization processes involving patients, consumers and clinicians.

METHODS:
Systematic reviews and evidence maps (methodical collections of systematic reviews) are used by SBU to identify evidence gaps. SBU has adapted the James Lindh alliance approach to give patients, consumers, relatives and clinicians the opportunity to give their view of what research they find most important to execute. SBU also collaborates with governmental research funders to communicate the content of the SBU database.

RESULTS:
A prioritizing process regarding evidence gaps within Attention Deficit Hyperactivity Disorder (ADHD)-treatment has been finalized (1). This was accomplished by people with ADHD and caretakers, as well as clinicians and staff. Another prioritization process on the topic of treatments for injuries after vaginal birth is ongoing. In November 2016 the Swedish government presented the research policy bill where they, based on analyses of the SBU database, pointed out areas of specific importance in future research.

CONCLUSIONS:
It is of great importance that evidence gaps get addressed and that new research is promoted in order to fill these gaps. In areas where there are numerous gaps, prioritizations involving different stakeholders is needed. Considering areas with large amounts of evidence gaps the primary focus might be on building infrastructure surrounding research before research calls can be directed towards these areas.

REFERENCES:
VP202 EVIPNet Brazil And The Experience Of Knowledge Translation Projects

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ABSTRACT SUMMARY:
This work aims to present the 1st Public Call in knowledge translation projects which was invested BRL400,000 (~USD128,000) by the Brazilian Ministry of Health. It contracted nine projects in knowledge translation to develop evidence briefs for policies in many health topics, to conduct and report policy dialogues and to enable working groups in SUPPORT Tools.

INTRODUCTION:
The Evidence-informed Policy Network (EVIPNet) is an initiative of the World Health Organization (WHO) to promote the appropriate use of scientific evidence in the development and implementation of health policies, programs and services. In Brazil, the Ministry of Health manages this network and promoted the 1st Public Call. It selected proposals to grant financial support to knowledge translation projects for evidence-informed policies aiming at strengthening the Brazilian Public Health System (SUS), and the integration between health research and decision making for the improvement of public health management, health care and equity.

METHODS:
The total amount of funding was BRL400,000 (~USD128,000). From twenty-four projects submitted, only ten were selected and nine projects signed a contract. Each project received BRL40,000 (~USD12,800) and should present the following four deliverables: a) an evidence-informed brief; b) a policy conference to start a dialogue on health policies; c) a summary document of this policy dialogue and d) a local capacity-building workshop of SUPPORT Tools for evidence-informed policies. All deliverables should be developed based on SUPPORT Tools.

RESULTS:
Up to January 2017, eight of the nine contracted projects presented the expected products and the evidence brief for policies are already published, and approximately 100 people were trained in SUPPORT Tools. By the end of 2017, a book will be published with the nine articles reporting the policy dialogues on the topic developed in the syntheses. The themes developed in the synthesis were: Arterial hypertension; Type two diabetes mellitus; Sickle cell disease; Atmospheric pollutants; Tuberculosis; Early childhood development; Congenital heart disease; Leprosy and the problem of overcrowding in emergency services. The result of this work has been widely disseminated throughout the country.

CONCLUSIONS:
In December 2016, the Executive Secretariat of EVIPNet Brazil held the First National Meeting of the Network for Evidence-Informed Policies where eight working groups presented a panel followed by discussions about the themes developed in the evidence-informed brief. This process allowed an information exchange between researchers, managers and civil society. Moreover, the EVIPNet Brazil launched the 2nd Public Call with increased funding for BRL500,000 (~USD160,000).

VP203 Performance Evaluation Of Eye-Tracking Devices

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ABSTRACT SUMMARY:
It’s proposed to evaluate the operation of eye tracking devices used in alternative communication systems for people with motor impairments. The project seeks to provide a feedback tool that serves as an efficient solution for individuals. Accuracy and precision tests were performed, which yielded important data about the reliability of an eye tracker and recorded previously calculated interest values.

INTRODUCTION:
There are different devices, systems and technologies for people with disabilities. It’s necessary to provide information on the effectiveness of products in the market and competitiveness in terms of price-quality, and providing an endorsement in the acquisition of technologies that improve their quality of life. The use of eye tracking devices is growing and its implementation in different areas has attracted the attention of several developers. Therefore, the need to generate a product that evaluates the functionality of such devices is necessary in order to avoid unnecessary expenses when acquiring or repairing one of these devices.

METHODS:
An interface was created with different functionalities such as the location of the coordinates in which the pointer is located, standardized graphic interface design to provide statistical data that allow an objective result for its subsequent analysis and an endless number of design possibilities.

The tests performed were of accuracy and precision where the subject was asked to follow the instructions given and observe a sequence of points, especially the points located at the ends of the monitor as these are the critical points in which there is less coincidence between the cursor and the gaze.

RESULTS:
The results obtained provided information on the performance of the tracking device. In this way, it was possible to establish that the accuracy of the ocular tracker: it was ± 12.83 pixels on the horizontal axis and ± 10.66 pixels on the vertical axis. The precision was ± 9.8 pixels on the horizontal axis and ± 14.23 pixels on the vertical axis.

This shows the use phenomenon caused due to the limited mobility of the eyes in the vertical axis in comparison to the horizontal mobility. The precision data obtained indicate that, because the movement on the vertical axis is smaller, there is a less continuous spectrum of positions on the axis, which translates to less precision.

CONCLUSIONS:
The data obtained can be used to compare with the results of the test with other eye tracking devices and thus this could serve as a tool to select an eye tracking device according to the user’s need and his economical capabilities.

VP204 Patient Safety Climate in General Public Hospitals In China

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ABSTRACT SUMMARY:
The Patient Safety Climate in Health Care Organizations (PSCHO) tool was used to measure the patient safety climate based on 4,121 employees from 54 public Chinese hospitals. The
INTRODUCTION:
As a significant component of healthcare quality, patient safety has become particularly important in China. Many hospitals have made efforts to improve patient safety. Policy makers, hospital managers, and the public have an increased interest in the current status of the patient safety climate in the hospitals of China. This study aimed to analyze the patient safety climate of general public hospitals in China and to provide the related benchmarks.

METHODS:
Using a stratified sampling method, employees from 54 public general hospitals in Shanghai, Hubei Province, and Gansu Province in China were surveyed in 2015. The Patient Safety Climate in Health Care Organizations (PSCHO) tool and the percentage of “problematic responses” (PPRs) were used to measure and analyze the patient safety climate. A Chi-square test and hierarchical linear modeling (HLM) were applied for the analysis.

RESULTS:
In the study, 4,121 valid questionnaires were collected. The psychometric analysis supported the validity and reliability of our Chinese version of the PSCHO. The overall patient safety climate was relatively good (PPR=9%) and exhibited no significant differences among the surveyed hospitals using hierarchical linear models. “Fear of blame and punishment” (65%) and “fear of shame” (20%) had the highest PPRs and were prevalent in various types of hospitals. “Provision of safe care” (16%) and “organizational resources for safety” (10%) also had notably high PPRs according to the HRO theories.

CONCLUSIONS:
“Fear of shame” and “fear of blame” are the most important barriers to the improvement of patient safety in the hospitals of China. Facility characteristics contributed somewhat to hospital patient safety climate. The initiatives to improve hospital patient safety climate are necessary and its implementation strategies need to be shared.

VP205 Implementing Electronic Records In Ambulances

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ABSTRACT SUMMARY:
Electronic Records in Ambulances (ERA) is a two-year National Institute for Health Research (NIHR)-funded study which aims to investigate and describe the opportunities and challenges of implementing electronic records and associated technology in ambulances to support a safe and effective shift to out of hospital care, including the implications for workforce in terms of training, role and clinical decision-making skills.
INTRODUCTION:
Increasingly, ambulance services offer alternatives to transfer to the emergency department (ED), when this is better for patients. The introduction of electronic health records (EHR) in ambulance services is encouraged by national policy across the United Kingdom (UK) but roll-out has been variable and complex.

Electronic Records in Ambulances (ERA) is a two-year study which aims to investigate and describe the opportunities and challenges of implementing EHR and associated technology in ambulances to support a safe and effective shift to out of hospital care, including the implications for workforce in terms of training, role and clinical decision-making skills.

METHODS:
Our study includes a scoping review of relevant issues and a baseline assessment of progress in all UK ambulance services in implementing EHR. These will inform four in-depth case studies of services at different stages of implementation, assessing current usage, and examining context.

RESULTS:
The scoping review identified themes including: there are many perceived potential benefits of EHR, such as improved safety and remote diagnostics, but as yet little evidence of them; technical challenges to implementation may inhibit uptake and lead to increased workload in the short term; staff implementing EHR may do so selectively or devise workarounds; and EHR may be perceived as a tool of staff surveillance.

CONCLUSIONS:
Our scoping review identified some complex issues around the implementation of EHR and the relevant challenges, opportunities and workforce implications. These will help to inform our fieldwork and subsequent data analysis in the case study sites, to begin early in 2017. Lessons learned from the experience of implementing EHR so far should inform future development of information technology in ambulance services, and help service providers to understand how best to maximise the opportunities offered by EHR to redesign care.

VP206 Health Technology Assessment And Health Literacy

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ABSTRACT SUMMARY:
This study aims to investigate the level of health literacy through the questionnaire survey (The European Health Literacy Project-Q47) and interview. The results could be used as a practical strategy for improving dissemination of research results for HTA agencies.

INTRODUCTION:
In the development of health technology, patients get a wide range of medical benefits. However, most of the information is actively pursued, and health technology information is being delivered to patients with relevant knowledge. For those with low levels of health literacy, information delivery may be relatively alienated. Therefore, to use reasonable public health information for the general public, it is necessary to acquire basic data for the production of health information and a communication system based on an objective and scientific basis.
METHODS:
The health literacy survey was conducted with a nationwide sample of 1,000 adults from November 1, 2016 to November 18, 2016. To measure health literacy, the instrument labelled HLS-EU-Q47 was derived from the conceptual model. The conceptual model integrates three health relevant areas (health care, disease prevention, health promotion) and four information processing stages (assess, understand, appraise, apply) related to health relevant decision making and tasks. Data were collected with self-administered questionnaires using a 4-point self-report scale to measure the perceived difficulty of selected health relevant tasks.

RESULTS:
The level of general health literacy (HL) of Korea was 34.4 points (perfect score: 50), health care 34.7, disease prevention 35.5, and disease prevention 33.2. The HL of Korea was higher than that of eight European countries (Austria, Bulgaria, Germany (North Rhine-Westphalia), Greece, Ireland, Netherlands, Poland, and Spain) and Japan. For the four indices, threshold values were set, dividing the scores into four categories: ‘inadequate,’ ‘problematic,’ ‘sufficient,’ and ‘excellent’ health literacy. In general, sufficient and excellent groups are more than the limited HL (inadequate + problematic) group, but the limited HL group was 41.9 percent. HL was also analyzed by respondents’ socio-demographic and socio-economic characteristics.

CONCLUSIONS:
Health technology assessment (HTA) agencies need to disseminate research results in consideration of health literacy for efficient information diffusion. Also, it is necessary to develop it as one of the important agenda for HTA. At national policy level, in order to establish evidence-based patient-centered health care, it can be set as a major policy task for public health and equity improvement through enhancement of health literacy between health provider and health user.

VP207 The Adoption Of Non-Invasive Prenatal Testing Technology In China

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ABSTRACT SUMMARY:
Physicians have favorable perceptions of non-invasive prenatal testing (NIPT). This study aimed to identify the factors associated with the adoption of NIPT by obstetricians and gynecologists (OB/GYN). One hundred and sixty-seven OB/GYN were surveyed in China. The results have shown OB/GYN’s adoption of NIPT was positively associated with HTA evidence, communication, promotion, and physician’s benefits, and negatively associated with ethical concerns of NIPT.

INTRODUCTION:
Non-invasive prenatal testing (NIPT) is reported to be effective in detecting trisomy 21 (Down syndrome), 18, and 13. Physicians have favorable perceptions of NIPT because NIPT has shown higher sensitivity and specificity and lower miscarriage compared with invasive prenatal diagnosis techniques. Therefore, it is important to understand the adoption behavior of providers towards NIPT and reasons why individual physicians adopt or recommend NIPT. This study aimed to identify the factors associated with the adoption of NIPT by obstetricians and gynecologists (OB/GYN).
METHODS:
A cross-sectional study was conducted from July 2016 to October 2016 in Fujian Province and Shanghai and Sichuan Province in China. Gynecologists and obstetricians (N=167) working on prenatal screening completed a self-reported questionnaire. Following the Roger’s diffusion model, multivariable logistic regressions were performed separately on five aspects of influencing factors, including physicians’ perceived attributes of innovations, communication channels, nature of the social system, the extent of change agents’ promotion efforts, and physician benefits.

RESULTS:
Most of the specialists had a positive attitude (53.20 percent) toward NIPT and wanted to adopt it (57.00 percent), while 93 (58.90 percent) physicians had already adopted NIPT in their clinical practice. OB/GYN’s adoption of NIPT was positively associated with strength of HTA evidence (P=.03), perceived communication frequency with colleagues (P=.04), OB/GYN colleague’s adoption before their own adoption decision (P=.07), hospital competition (P=.06), hospital teaching status (P=.02), perceived for-profit genetic testing company’s promotion (P<.001), perceived clinical practice skill improvement (P=.03), and perceived better practice skill improvement (P=.008). However, the adoption behavior towards NIPT has a negatively borderline significant trend on provider’s perceived ethical concerns of NIPT (P=.06).

CONCLUSIONS:
This study demonstrated multiple factors influencing the diffusion of non-invasive prenatal testing (NIPT). The information can help health policy makers encourage appropriate use of NIPT.

VP208 Informing An Economic Model For Hyperhidrosis: A Clinical Survey

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ABSTRACT SUMMARY:
As part of a clinical and cost-effectiveness study of alternative treatments for hyperhidrosis, a survey of UK dermatologists was conducted. The results indicate a wide variation in treatments typically administered. This variation highlights the lack of evidence-based guidance underpinning practice and the importance of clinical surveys as a complement to usual data collection methods.

INTRODUCTION:
Hyperhidrosis is characterised by uncontrollable excessive sweating, which occurs at rest, regardless of temperature. As part of a wider study exploring the clinical and cost effectiveness of alternative treatments for primary hyperhidrosis, a survey of United Kingdom (UK) dermatologists was conducted to gain a better understanding of current clinical practice in the area and inform economic model inputs.

METHODS:
The survey was conducted by means of an online survey tool, “Qualtrics”. It was circulated to members of the British Association of Dermatologists. Topics covered included treatments typically administered, medication dosages prescribed, effectiveness of treatments, adverse events related to treatments and resource use associated with individual treatments.
RESULTS:
Forty-five respondents from forty-two different dermatology units completed the survey. The majority of clinicians (83 percent) prescribed more than one medication - most commonly oxybutynin and propantheline bromide. The next most commonly reported treatments were: iontophoresis, botulinum toxin and curettage.

Respondents were asked to indicate dosage, frequency and details about follow-up visits related to medication use. Doses prescribed were largely consistent with British National Formulary (BNF) recommendations. For other treatments, dermatologists were asked to indicate duration of the procedure, job title of the treatment provider and details about monitoring visits. Results were similar to the findings from the literature and previously conducted interviews with clinicians.

Respondents were asked to indicate the dropout rates for each type of treatment due to lack of effectiveness and adverse events. Dropout rates were relatively high for both reasons.

CONCLUSIONS:
The results highlight the wide range of treatments for hyperhidrosis currently administered by dermatologists across the UK, and the variation in current clinical practice. This variation highlights the lack of evidence-based guidance underpinning practice and the importance of clinical surveys as a complement to usual data collection methods.

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ABSTRACT SUMMARY:
Despite rapidly becoming the emerging and practicable solution for health systems in low-resource settings, most mHealth interventions are still in urgent need of vigorous proof to show their efficiency and productivity in public health and healthcare systems. This study assessed the use of two-way Short Message Service (SMS) in disease surveillance in improving health staff engagement and quality of the work.

INTRODUCTION:
Along with the exponential growth of technology, the use of mobile devices in health, or mHealth, has been quickly becoming a viable practice to strengthen health systems, especially in low-resource settings. Nevertheless, the majority of mHealth interventions are pilot efforts which mostly lack robust design and evidence about the use of mHealth in public health. This study assessed the use of a bi-directional Short Message Service (SMS) in disease surveillance in Vietnam and aimed to bring evidence in improving engagement of health staff as well as the quality of reporting.

METHODS:
Eighty health staff from forty communes of Hoa Binh and Hung Yen provinces were trained and participated in two 6-month pilots: one with one-way, and one with a bi-directional SMS system for assisting in error screening, and reminder and feedback provision to report two diseases: influenza and diarrhea using cell phones. After
each examination and checking-in onto the paper logbook, participants reported the case by texting an SMS to a designated number and made notes of successfully reported cases. A central data repository server was set up to collect SMS reports, and aggregate reported patient data. Engagement of health staff and quality of the reporting work were assessed by the evaluation of the qualitative questionnaires, and the comparison of the texted SMS reports to the patient logbooks.

RESULTS:
With the use of a two-way vs one-way SMS system, participants were 4.6 times more likely (95 percent Confidence Interval, CI 3.93-5.44, p< .001) to send correctly formatted text reports, and 3.4 times more likely (95 percent CI 2.72-4.33, p< .001) to have precise information in their texted messages. Results also revealed that while their position, age, or gender of participants did not statistically influence the results, ethnicity and management roles did.

CONCLUSIONS:
The study showed that the use of a bi-directional SMS-based reporting system both significantly improved participants engagement in the reporting protocol, and greatly enhanced their reporting quality. The study demonstrated that robust evidence of a practical utilization of SMS in a disease reporting system to replace the traditional paper-based one has great potential for a scale-up and national-wide implementation.

ABSTRACT SUMMARY:
Scottish Medicines Consortium (SMC) has developed an advisory group to provide strategic guidance for patient and public involvement. The public involvement network (PIN) advisory group has provided advice which has strengthened relationships with patient groups and helped to ensure that the views of patients, carers, and members of the public are effectively used to inform HTA decision making.

INTRODUCTION:
Following a review of public involvement activities, the Scottish Medicines Consortium (SMC) executive group agreed to the establishment of a new public involvement network (PIN) advisory group. This group was developed to strengthen SMC’s relationships with patient groups and ensure that the views of patients, carers, and members of the public effectively inform SMC health technology assessment processes. The PIN advisory group also provides a forum for patient and carer groups to engage constructively and productively with SMC staff to further develop and shape all aspects of SMC public involvement work.

METHODS:
The PIN advisory group was established in June 2015 and meets three times per year. Membership includes four patient group partners nominated through the umbrella organisations. The group also includes all three SMC public partners (volunteer members of the public), an area drug and therapeutics committee (ADTC) representative from one region of Scotland, four SMC representatives including a committee member who is a clinical expert, and the SMC public involvement team. Both group members and SMC executive jointly contribute to setting the agenda for meetings. All recommendations made by the group are considered by SMC executive, which, upon approval, directly influence SMC processes and strategy to continuously develop and strengthen patient and public involvement.

VP210 Establishing An Advisory Group For Patient And Public Involvement In HTA

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RESULTS:
The PIN advisory group has provided input to SMC resulting in a range of improvements to patient involvement processes during 2015/16 including:

- development of new public involvement training resources, including online videos and events, including an annual national training event;
- early embargoed release of SMC decisions to submitting patient groups;
- introduction of PACE (patient and clinician engagement) mentors to help prepare patient groups for taking part in the PACE process; and
- revision of patient group presentations at SMC to prevent duplication of PACE (patient and clinical engagement) statement.

CONCLUSIONS:
The PIN advisory group has provided advice to SMC which has strengthened our relationships with patient groups and helped to ensure that the views of patients, carers, and members of the public are effectively used to inform HTA decision making.

INTRODUCTION:
Currently treatments for HCV infection in Kazakhstan include pegylated interferon alpha, ribavirin, the protease inhibitors boceprevir, telaprevir and simeprevir. A new scenario of therapy for HCV infection is being established with the approval. The aim of this study is to evaluate the long-term health outcomes and the willingness to pay of new anti-HCV treatment from the Kazakhstan societal perspective.

METHODS:
The morbidity-mortality model was developed to estimate the HCV-infection process in a theoretical cohort. The Markov process considered 12 health states (F0, F1, F2, F3, F4), SVR, decompensated cirrhosis, HCC, transplantation (1 year and years later), HCV-related death and death from other causes) and 36 transition probabilities. The model was fed with data from national and international literature. The effectiveness of the new treatment strategies was hypothesized taking into account a data of clinical trials of new HCV-drugs that now will be available in Kazakhstan.

RESULTS:
The cohort of subjects with chronic HCV in 2015 approximately to 70,000 patients, of these about 2,500 patients F3-F4 are treated with drug therapy. Cumulative cases of HCV-related diseases who succeed in preventing by the increased effectiveness of new treatments amounted to 12,214 after 7 years, 38,082 after 17 years, 63,856 after 27 years. The direct net medical costs, after the cost of the drug, amounted to $4,62, $18,07 and $36,78 millions after 7, 17 and 27 years respectively, and $41,78, $238,02 and $137,95 attributable to indirect costs avoided, for the same time horizons. Furthermore, it was estimated that each patient treated with new drugs achieves a reduction of expenditure of about $11,750 in terms of treatment...
of direct costs, and $4,156 in terms of indirect costs.

CONCLUSIONS:
This model is the first attempt to estimate the saving that use of new anti-HCV drugs would cause, which may increase the Kazakhstan healthcare willingness to pay for the acquisition of such new drugs. An important share of the cost per treated patient can be balanced with the reduction of direct and indirect costs caused by the greater effectiveness of new treatments.

VP212 Value Of Comparing real World Outcomes To Health Technology Assessment

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
The listing of new services onto the Medicare Benefits Schedule (MBS) in Australia is dependent on assessment of evidence by Health Technology Assessment (HTA) methods. A new process that tests the assumptions in HTAs against real world use after listing is important for improving the quality of the HTA process.

INTRODUCTION:
Australia utilises Health Technology Assessment (HTA) to assess new services proposed for funding under the Medicare Benefits Schedule (MBS). Until recently, once a service was listed onto the MBS, there was no regular monitoring mechanism to ensure that the service was being used in practice consistent with evidence on effectiveness. The Medical Services Advisory Committee (MSAC) which advises on reimbursement of diagnostic, therapeutic interventions and services funded by Medicare in Australia has recently implemented a monitoring process for items listed on the MBS. The aim is to examine whether services are used in the real world as they were proposed to the MSAC.

METHODS:
The Department of Health in Australia collects data on services on the MBS. Utilisation data at a timepoint 1-2 years after listing is compared to the predictions made in the original HTA package. This analysis focuses on demographics and distribution of patient uptake and service charges by provider.

RESULTS:
To date, five reviews have been undertaken, this has showed utilization estimates on par (n=1), lower (n=3), and higher (n=1) than predicted. In some instances, the deviation from predicted reflected high utilization in particular geographic regions. Epidemiological data did not reveal a high prevalence of disease in this area. Variations in provider charging behavior were identified in all of the five reviews. In one case utilization was at 15 percent of the rate predicted. MSAC hypothesised that as the service is an invasive surgical treatment that occurred in hospital, patient preference for the procedure may be much lower and effectiveness less certain than presented in the HTA which included evidence from trials involving patient volunteers. This process is still in its early stages but is already detecting issues.

CONCLUSIONS:
Henceforth, a pathway for follow-up will follow each review – specifically: a) compliance, b) no further action, c) amendment to the descriptor for the service, d) continued monitoring, or e) formal review. Greater scrutiny of utilization estimates is required, particularly for co-dependent technologies where maximizing patient numbers may financially favor industry sponsors. This feedback process is important for important for improving the quality of the HTA process.
VP213 Satisfaction Survey Of National Essential Medicines System In China

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ABSTRACT SUMMARY:
China launched the National Essential Medicine Policy (NEMP) for primary care organizations in 2009. This study aimed to understand the perceptions of primary care workers in regard to the impacts of the NEMP. A questionnaire survey was undertaken in 791 primary care workers from 42 randomly selected community health centers in four provinces in China.

INTRODUCTION:
China launched the National Essential Medicine Policy (NEMP) for primary care organizations in 2009. This study aimed to understand the perceptions of primary care workers in regard to the impacts of the NEMP.

METHODS:
A questionnaire survey was undertaken in 791 primary care workers from 42 randomly selected community health centers in four provinces in China. The respondents were asked to rate the impacts of the NEMP on four domains: health workers, patients, health centers, and provision of medicines. A summed score was calculated for each domain, ranging from 0 to 100. A higher score indicates a more positive rating. Linear regression models were established to determine the socio-demographic characteristics that were associated with the four domain scores.

RESULTS:
The respondents gave a rating score of 65.61±11.76, 63.17±13.62, 66.35±13.02, and 67.26±11.60 for the impact of the NEMP on health workers, patients, health centers, and provision of medicines, respectively. Respondents from the middle income central region rated the NEMP higher than those from the eastern affluent and western poor regions. The pharmacists (?=5.457~7.558, p<0.001) and nurses (?=2.612~3.107, p<0.05) gave a more positive rating on the NEMP than their physician counterparts. A higher income was found to be associated with a decrease in the NEMP ratings. Repetitive training was a predictor of higher ratings.

CONCLUSIONS:
The NEMP has significant impacts (as perceived by the health workers) on health workers, patients, health organizations, and the provision of medicines in primary care settings. However, the impacts of the NEMP vary with regions, the nature of professional practices, and the income levels of health workers. It is important to maintain support from physicians through income subsidies and training.

VP214 Criteria That Influence The Brazilian Public Decision-Making

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ABSTRACT SUMMARY:
In Brazil, the National Committee for Health Technology Incorporation in the Brazilian public health system (CONITEC) advises the Ministry of Health about the incorporation, exclusion and alteration of health technologies in the Brazilian
public health system. Some fundamental criteria, included or not in the legislation, are involved in the decisions made by the Committee.

INTRODUCTION:
In Brazil, the National Committee for Health Technology Incorporation in the public health system (CONITEC) advises the Ministry of Health about incorporation, exclusion and alteration of health technologies in Brazilian public health system (SUS). Decision making considers multiple criteria, included or not in legislation. This analysis was the first step for a multiple-criteria decision analysis (MCDA) building. This study aims to identify criteria that influence Health Technology Assessment (HTA) for SUS.

METHODS:
Five real cases of controversial recommendations of technology incorporation made by CONITEC were reviewed by listening to the plenary recordings and reviewing committee minutes. The choice was guided by convenience, with prioritization according to CONITEC’s members, using a pre-defined standardized form. Weight in decision making was also raised and identified. Selected technologies judgments were: Trastuzumab for metastatic/advanced Breast Cancer; Fingolimod for Multiple Sclerosis; Clozapine, Lamotrigine, Olanzapine, Quetiapine and Risperidone for Bipolar Affective Disorder; Hematopoietic stem cell transplantation for Sickle Cell Disease; and Positron Emission Computed Tomography (PET-CT) for Lung Cancer and for hepatic metastasis from Colorectal Cancer.

RESULTS:
The choice of different technologies allowed verifying specific criteria used for the incorporation of each type of technology, as well as the similar criteria discussed and used by all these technology types. In addition, some identified criteria were specific to the Brazilian reality, such as: “Incorporation by other countries”, “Off-label use”. These criteria were not previously identified in studies conducted in other countries. Some criteria have been identified in all decisions, such as: efficacy, disease severity, quality and confidence in the evidences, logistic challenges for implementation, unmet needs, budget impact and treatment costs. Relative impact of cost-effectiveness was considered low.

CONCLUSIONS:
CONITEC’s recordings are an important source to understand the Brazilian decision-making process. To identify the important criteria can help to standardize and improve the HTA process.

VP215 Time To Public Reimbursement For Innovative Medicines In Canada

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ABSTRACT SUMMARY:
Drug review for marketing authorization, Health Technology Assessment (HTA), and the public reimbursement decision-making process in Canada takes approximately three years or longer on average. The review process includes many actors and a sequential process from regulatory approval (Health Canada) through HTA (CADTH and INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) followed by a final funding decision by individual jurisdictions.
INTRODUCTION:
In Canada, the drug review process and public reimbursement includes many actors and a sequential process from regulatory approval for marketing authorisation (that is, NOC issued by Health Canada) through HTA (conducted by CADTH and INESSS), negotiations conducted by pan-Canadian Pharmaceutical Alliance (pCPA), followed by a final reimbursement decision by individual jurisdictions.

METHODS:
This study is a retrospective analysis of time to marketing authorization and time to drug listing decisions by the public drug plans in Canada. Data used in this study was collected primarily from publicly available data sources and websites.

RESULTS:
Despite comparable HTA times, Canada still lags in total time to public reimbursement compared to many OECD countries. Post-NOC, Canadians wait another 1.5 to 2.0 years on average before accessing a new medicine or indication. The biggest chunk of time post-NOC is HTA, but the pCPA process adds to the overall timelines. Provinces still take more time to decide after pCPA.

CONCLUSIONS:
Despite the success of individual processes across the drug review and funding decision pathway, Canada experiences significant delays to quality listing of innovative medicines. Potential explanations for why overall time to listing remains longer in Canada could include: consecutive or sequential processes (Health Canada, HTA, pCPA, jurisdictions); processes are more concurrent and uniform in other countries, the pCPA process appears to be contributing to backlog in the system – taking longer to start negotiating, and to complete negotiations, and some provinces take still more time to list following pCPA. There are opportunities to take a holistic or integrated view and build on the strengths and successes of individual processes to reduce system level inefficiencies – explore parallel reviews and other mechanisms to improve overall timelines to public reimbursement.

VP216 Health Technology Assessment’s Balance Between Additional Data, Adoption, And Patient Access

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) bodies, hospital administrators, physicians, and patients will provide a comprehensive discussion of device HTAs using two recent examples of devices to support innovative procedures and compare those to a sample of HTAs for novel drugs and biologics. Opportunities are identified to improve current HTA frameworks and methodologies for devices while balancing patient access and appropriate use of health resources.

INTRODUCTION:
Historically, many Health Technology Assessment (HTA) bodies were developed with a focus on addressing rapidly rising drug costs and the unique need to evaluate each drug as a de novo entity. The degree to which the unique needs for evaluating technologies vis a vis drugs are reflected in distinct HTA methods and activity is to date understudied.

METHODS:
We examined HTA’s reviews of two technologies: WATCHMAN™, a device to reduce the risk of stroke in certain patients and Alair™, a procedure-based treatment for severe asthma. Both technologies
have been extensively reviewed by HTA bodies and payers in many countries. These HTA reviews are compared to a convenience sample of these HTA’s bodies reviews of drugs and qualitative differentiators between these two categories explored.

RESULTS:
The differences and similarities (for example, in rigor and necessity of evidence) between US Section 510(k) clearances, US premarket approval (PMA), and US new drug application (NDA) regulatory pathways have not been clearly understood by HTA or reflected in their methodologies employed. Additionally, emergent methodologies such as Bayesian statistical analyses may encounter challenges within technologies reviews. HTA bodies may not be cognizant of development timelines or the timelines of comparators. Finally, HTA bodies may overestimate device adoption rates.

CONCLUSIONS:
The differences in evidence requirements for regulatory approval between US 510(k), US PMA, and US NDA pathways have not been reflected in different methodological approaches within HTA bodies reviews. Opportunities and novel methods are needed for HTA bodies to derive imputed comparisons between technologies that may have inherently incongruent timelines. Finally, HTA bodies could benefit from methods to more accurately estimate projected adoption curves. Challenges exist using frameworks, paradigms, and methodologies initially established for, and commonly used for, pharmaceuticals on device evaluations; leaders of HTA methods can improve the situation by providing guidance and recommendations for more appropriate HTA methods to evaluate devices.