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Oral Presentations

OP01 Patient Perspectives On Real-World Evidence

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ABSTRACT SUMMARY:
As stakeholders establish standards and structure for using real-world data (RWD) as evidence in regulatory and clinical decision making, patients must be the primary focus. Since the idea of RWD is new to many in the patient community, it is important to explore the patient community’s needs, concerns, and potential contributions and uses of RWE to ensure the patient voice.

INTRODUCTION:
The topic of real-world evidence (RWE) has gained considerable attention recently. As health researchers, policymakers, and regulators establish standards and structure for using real-world data (RWD) as evidence in regulatory and clinical decision making, patients must be the primary focus. Since the idea of RWD is new to many in the patient community, it is important to explore the patient community’s needs, concerns, and potential contributions and uses of RWE to ensure the patient voice is considered.

METHODS:
On 31 July 2017, the National Health Council (NHC) brought together a multi-stakeholder roundtable, with patient advocacy organizations comprising most participants. The objectives were to elicit patients’ views on RWE: 1. Definitions and uses; 2. Characteristics needed for RWE to be understood and trusted; and 3. Skillsets and tools needed by patients. The discussion and findings of the Roundtable were then turned into a white paper.

RESULTS:
Policymakers and advisory groups need to invest in significant education efforts to inform and fully include the patient community in initiatives to establish standards for RWD and to use RWE more effectively. Patients need a better understanding to both use and contribute to RWE. Patients see the possibility of using RWD to understand how a treatment works in diverse patient populations – to find someone that “looks like me” as an assurance of how a treatment might benefit them.

CONCLUSIONS:
The findings and recommendations from the Roundtable and white paper will inform efforts to provide input on discussions about uses of RWD and RWE with the patient community and policymakers such as the Food & Drug Administration (FDA) in the United States.

OP02 ‘Real World’ Experience For Health Technology Assessment In Hospitals

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AUTHORS:
Inbal Tal, Israel

ABSTRACT SUMMARY:
‘Real-World’-Experience (RWE) uses information gathered through practice prior to formal publication, to improve evaluation of innovative technologies. Twelve technologies were scored by 36 technology-assessors, using 20 parameters, including “innovation”, and “local adjustment”. ‘Low’ RWE ranking correlated with an actual decision to reject adoption. RWE provides an essential contributing assessment tool throughout all stages technology lifespan, especially at early phases.
INTRODUCTION:
Health technology assessment (HTA) is scientifically incorporating the demand, effectiveness and expedience of adopting innovative technologies, supported by evidence-based medicine. The rapid development of innovations led to an accelerated need to comprehend their benefit and satisfaction through actual utilization. ‘Real World’ Experience (RWE) in action is a source for collecting information through practice that has not yet been formally published, to identify the challenges and barriers of adoption involving considerations on significant investment and local adjustment. Aim: To assess the benefit of RWE as a tool for gathering information understanding and evaluating new technologies as candidates for public funding.

METHODS:
Twelve selected new technologies were assessed by 36 technology-assessors from the Ministry of Health (MOH) and the hospital, and were ranked using two scales: i) The contribution of using RWE to benefit the assessment mechanism; ii) The perceptual “value” of the technology.

RESULTS:
Analyzing the contribution of RWE to HTA, 67% of the technologies reviewed were recommended for adoption. ‘Low’ RWE ranking correlated with a decision to reject technology adoption. The most important “value” among all assessors on RWE was “innovation”, and among hospital assessors, the parameter “local adjustment” was cardinal. MOH assessors highlighted RWE to increase knowledge of regulators to encourage adoption. The aspect relating to economic burden received only medium ranking.

CONCLUSIONS:
RWE provides an essential contribution to HTA throughout all stages in the life of the technology, especially at early phases. It is an important methodology to gather evidence from the ongoing experience of clinicians, increasing awareness to promising innovations and amplifying the confidence for decision-making. In this new era of HTA new concepts arise on the horizon: multi-dimensional evaluations”. Expert opinion and RWE are paving the way towards better understanding of beneficial technologies, even in the absence of formal published evidence.

OP03 Optimizing The Use Of RWE In HTA: Lessons From The ICER Summit

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ABSTRACT SUMMARY:
Real world evidence (RWE) has potential to advance payers’ and HTA bodies’ evaluations of healthcare technologies by providing more relevant evidence. However, there are concerns about the quality and value of RWE. This presentation will provide specific and actionable recommendations that highlight the role that each stakeholder group can play in overcoming the challenges and realising the potential for RWE.

INTRODUCTION:
Real world evidence (RWE) is changing the overall data landscape and it has potential to advance the evaluation of real world performance (comparative effectiveness) of healthcare technologies by providing a greater quantity and quality of evidence. However, many are concerned that non-randomised RWE may be substituted for RCT data and thus increase uncertainty about effectiveness. This presentation sets out the opportunities and challenges for use of RWE by payers and HTA bodies to evaluate health care technologies.
METHODS:
Current uses, opportunities and challenges were identified via a literature review and interviews with nine experts. Interim results were discussed at the 2017 ICER Policy Summit, which brought together leaders from payer and life sciences organizations, to develop specific and actionable recommendations for the use of RWE in drug coverage and policy decision-making.

RESULTS:
RWE is utilised for multiple purposes in the US and globally, including: aiding design of drug development pathways; supporting regulatory approval decisions; monitoring safety; and informing HTA assessments and payer coverage decisions. Some stakeholders see great value in RWE and want to make greater use of these data sources, including for: drug effectiveness evaluations (including supplementing network meta-analyses); innovative study designs (including pragmatic trials); real time patient monitoring; and adaptive pathways or coverage with evidence development. However, others see numerous challenges, many of which are related to the quality and reliability of RWE sources. Acceptance of an expanded future role for RWE is not universal, and payers and developers must work together to find mutually beneficial strategies for progressing the development and use of RWE.

CONCLUSIONS:
Specific and actionable recommendations will be presented which highlight the role that each stakeholder group can play in overcoming the challenges and realising the potential for RWE.

OP04 Cardiac Implant Registries: Systematic Review Of Global Practices

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ABSTRACT SUMMARY:
The importance of cardiac implant registry (CIR) for ensuring a long-term follow-up in post-marked surveillance has been recognized and approved, but there is lack of consensus standards on how to establish a CIR. The aim of this study is to investigate the structure and key elements of CIRs 2006-2016 and to provide recommendations.

INTRODUCTION:
The importance of cardiac implant registry (CIR) for ensuring a long-term follow-up in post-marked surveillance has been recognized and approved, but there is lack of consensus standards on how to establish a CIR. The aim of this study is to investigate the structure and key elements of CIRs in the past decade (2006-2016) and to provide recommendations on “best practice” approaches.

METHODS:
A systematic search on CIR was employed in line with the PRISMA guidelines. The following databases were searched: the PubMed (Medline), ScienceDirect and the Scopus database, EMBASE. After identifying the existed CIR, an inductive approach was used to explore key elements emerging in the identified registries.

RESULTS:
The following 82 registries were identified: 18 ICD registries, 7 CRT registries, 5 pacemaker registries, and 6 Cardiovascular Implantable Electronic Device
(CIED) registries which combined ICD, pacemaker and CRT implantation data; as well as 22 coronary stent registries and 24 TAVI registries. While 71 national or local registries are from a single country, 44 are from European countries, and 9 are located in USA. The following criteria have been summarized from the identified registries, including: registry working group, ethic issues, transparency, research objective, inclusion criteria, compulsory participation, endpoint, sample size, data collection basement, data collection methods, data entry, data validation and statistical analysis.

CONCLUSIONS:
Fot HTA as well as regulatory decisions medical device registries provide a “real-world” picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. CIRs are important for regulatory decisions concerning the safety and approval issues of the medical device; for payers CIRs provide evidence on the medical device benefit and drive the decision whether the product should be reimbursed or not; for hospitals CIRs’ data are important for sound procurement decisions, and CIRs also help patients and their physicians to joint decision making which of the products is the most appropriate. However, many current CIRs are still lacking standards to inform on patient’s safety and ensuring transparency.

ABSTRACT SUMMARY:
RWE comes from real treatment settings instead of controlled clinical trials. Despite attention on RWE, it is unclear how HTA agencies use this data and how it influences reimbursement decisions. More than 3,500 HTAs from IQWiG/G-BA, HAS, NICE, SMC, CADTH/pCODR, PBAC, and HIRA from 2012-2016 were analyzed.

INTRODUCTION:
RWE comes from real treatment settings instead of controlled clinical trials. Despite attention on RWE, it is unclear how HTA agencies use this data and how it influences reimbursement decisions.

METHODS:
More than 3,500 HTAs from IQWiG/G-BA, HAS, NICE, SMC, CADTH/pCODR, PBAC, and HIRA from 2012-2016 were analyzed. RWE was defined as observational studies, retrospective database analyses, and registry studies. Usage was categorized and degree of influence was determined by analyzing agencies’ justifications of decisions. Results were stratified by agency, submission status, oncology/non-oncology, and orphan status.

RESULTS:
Use of RWE in HTA’s is low with an average of 4% (135/3503) between 2012-2016 across all agencies. HAS used RWE the most (8%), then NICE (6%), while the rest ranged between 1-4%. RWE occurred significantly more in resubmissions/reassessments than in first submissions (8% vs 3%); 82% of HAS RWE use is in reassessments/resubmissions. RWE is more prevalent in orphan drug HTAs than in non-orphan drug HTAs (6% vs 4%). One-third of RWE in HTA assessments was in oncology. Overall, RWE is used to support efficacy (49%), usage (18%), safety (17%), economic modeling (14%), long-term efficacy (7%), and validity of surrogate outcomes (2%). Only 44% of HTAs mentioned RWE in their decision-making, and most mentions were negative or neutral.
CONCLUSIONS:
Awareness of the importance of RWE is increasing, but usage in HTAs remains low. The data suggests RWE is useful in filling specific evidence gaps. RWE on efficacy, safety, utilization, long-term effect and in rare diseases can be fruitful uses in HTAs. While recent focus is on collecting RWE, the discussion should include how regulatory and HTA agencies can better integrate RWE in their decision making, enabling more effective use in the future, improving patient care and access.

METHODS:
Collaborative project • involving twenty three EUnetHTA partners, under the coordination of the French National Authority for health (HAS), • building on previous EUnetHTA methodological work, national experiences of involved partners and findings of other projects dedicated to real world data, identified through internet search, • putting together HTA bodies, and whenever possible other relevant stakeholders, in order to agree on the requirements regarding post-launch real world data to be generated.

RESULTS:
During the preparatory work, several external projects to collaborate with, or to build on, were identified. Rare diseases and innovative products were highlighted as areas of particular interest. Legal and practical challenges for cross-border collaboration included data privacy and protection rights, as well as data sources’ interoperability and comparability. The first pilot collaboration that was launched was a disease specific one, performed in collaboration with regulators. By the end of 2017, five product specific topics, for drugs and medical devices, were under consideration: four proposed by EUnetHTA partners and one by regulators. The selection criteria took into account, among others, the added value of cross-border collaboration and the feasibility of the conduct of the data collection. Reports on lessons learned and proposals for process improvement shall be compiled after each pilot and assessed at project’s midterm (mid 2018).

CONCLUSIONS:
First EUnetHTA collaboration on post-launch real world data has started. Its early results help to confirm the possible levels of collaboration and contribute to refining proposed processes.

OP06 Collaboration On Real World Data Generation: Current EUnetHTA Results

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AUTHORS:
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ABSTRACT SUMMARY:
This presentation reports on the first results of the EUnetHTA pilot project aiming at promoting cross-border multi-stakeholder collaboration in agreeing on requirements for real world data to be generated to complement initial body of evidence for a health technology, in the view of its reassessment and consequent reimbursement decision making.

INTRODUCTION:
Work package 5B of the current EUnetHTA (European network for health technology assessment) project Joint action 3 is dedicated to improving the quality of post-launch real world data that is being generated for HTA purposes. The objective of this presentation is to report on the results of this work at its midterm.
OP07 Real World Evidence: How Can It Improve Health Technology Assessment?

PRESENTING AUTHOR:
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AUTHORS:
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Chris Foteff

ABSTRACT SUMMARY:
Health Technology Assessment (HTA) considers the question of whether evaluated technologies are cost-effective in real world settings. Real world linked data could help address uncertainty may not be available, accessible or be considered low quality. Through examples from Australia we illustrate where real world data could reduce uncertainty in HTA processes.

INTRODUCTION:
Health Technology Assessment (HTA) considers the question of whether evaluated technologies are cost-effective in real world settings. As observed in HTA conducted by the Australian Medical Services Advisory Committee (MSAC), questions regarding the validity of data inputs to economic analyses that reflect real-world practice is a common reason for uncertainty on the cost effectiveness of new technologies. In addition to resource use and costs, there may be other uncertainties regarding the eligible patient population, patient management pathways and comparator selection. Our objective in this study was to present case studies from Australia where real world linked datasets could be better utilised to inform HTA conducted by the MSAC.

METHODS:
For selected therapy areas, assessment reports and public summary documents of HTA conducted by the MSAC published between January 2015 and November 2017 were reviewed. Our analysis identified HTAs where uncertainties around the inputs for health economic evaluations, as well as uncertainties in defining eligible patient numbers or current patient pathways of care were shown to exist. We then explored whether these uncertainties could have been addressed through real world linked datasets.

RESULTS:
Our preliminary investigations identified two assessments: MSAC assessment of capsule endoscopy and transcatheter aortic valve implantation - where availability of real world linked data could have addressed uncertainties around the inputs required for the health economic evaluations.

CONCLUSIONS:
Australia has a range of real world datasets with the potential to be used to inform HTA conducted by the MSAC. This can only be achieved if the datasets could be better linked and accessible for use by key stakeholders in the MSAC HTA process (e.g. industry, clinician, patient societies). Use of these data sets in HTA will enable timelier patient access to cost-effective technologies and more effective implementation and review of technologies after adoption into clinical practice.

OP08 Using Real World Data To Support National Postmarketing Surveillance

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**ABSTRACT SUMMARY:**
NPS MedicineWise’s database, MedicineInsight, collects longitudinal patient-level primary care data from Australian general practices. A series of observational studies were conducted for postmarketing surveillance and management of key health priorities. The analyses identified key gaps and potential departures from guidelines regarding medicines prescribing and medical tests ordered, suggesting MedicineInsight is a valuable tool for national postmarketing surveillance.

**INTRODUCTION:**
While medicines and medical tests are developed in a controlled, clinical trial environment, postmarketing surveillance in the real world can be challenging. MedicineInsight – a database of longitudinal patient-level clinical information from general practices in Australia – is a novel program focusing on collecting primary care data to improve postmarketing surveillance at a national level.

**METHODS:**
MedicineInsight collects de-identified clinical information from general practice information systems using data extraction tools. MedicineInsight currently includes 3.6 million regular patients of 3,300 general practitioners from 650 general practices across Australia. MedicineInsight data include longitudinal clinical information on diagnosis and medicines (dose, strength, route of administration, medication switches over time, adverse events, and allergies), and pathology testing data. A series of observational studies were developed for postmarketing surveillance of management of a range of health priorities including type two diabetes mellitus (T2DM), chronic obstructive pulmonary disease (COPD), depression and antibiotics use.

**RESULTS:**
Forty-four percent of patients with T2DM in the MedicineInsight database did not have a recorded HbA1c result and thirty-one percent did not have a recorded blood pressure reading in the previous six months. While guidelines recommend a stepwise approach to the initiation of COPD therapy, forty-nine percent of patients with COPD (with or without asthma) were prescribed dual therapy at initiation and a small number (4.5 percent) were prescribed triple therapy. Between 2011 and 2015, the annual rate of antidepressant prescribing per 1,000 GP encounters has increased by eight percent. High volumes of antibiotics were prescribed for respiratory tract infections in Australian general practice, notwithstanding guideline recommendations that antibiotics are not recommended in most cases.

**CONCLUSIONS:**
Large scale real world clinical data from general practices can play an important role for postmarketing surveillance at a national level.

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**OP09 Summary Of The 2018 HTAi Latin America Policy Forum Background Paper**

**PRESENTING AUTHOR:**
Andres Pichon-Riviere, Argentina

**AUTHORS:**
Rebecca Trowman, Canada

**ABSTRACT SUMMARY:**
The topic for the third HTAi Latin America Policy Forum is ‘defining the value of health technologies in Latin America’. This presentation will summarize the findings of the background paper that informed the discussions of the Policy Forum. It will highlight value frameworks from around the world with special focus on those suitable for use in the Latin America region.

**INTRODUCTION:**
The HTAi Latin America Policy Forum (LAPF)
will meet for the third time on 23 and 24 April in Montevideo, Uruguay. The topic chosen for this meeting is ‘defining the value of health technologies in Latin America’. Due to the differing levels of maturity in the HTA systems and approaches by countries in the region, this topic deserves specific analysis and consideration for the Latin America region.

METHODS:
A background paper is in development for the LAPF, and will be informed by a review of policy publications in scientific databases, google scholar plus other grey literature. The background paper will summarize the relevance of value frameworks around the world (building on the 2017 HTAi Global Policy Forum background paper and discussions) and will narratively synthesise key findings globally and draw out issues and experiences relevant to the Latin America region. This will be used to provoke the discussions and debates at the LAPF.

RESULTS:
This presentation will focus on summarizing the background paper that was used to inform the discussion over the two days of the LAPF, highlighting the key findings on value frameworks from the Latin America region. The presentation will also summarize the key questions for deliberation that were brought to the attention of the meeting attendees, plus the key questions that were posed for the guided breakout sessions will be presented.

CONCLUSIONS:
The presentation will provide a great opportunity for HTAi members to hear about the ‘state of the art’ methodologies for valuing health technologies in the Latin America region.

OP10 Key Messages From The 2018 HTAi Latin America Policy Forum

PRESENTING AUTHOR:
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AUTHORS:
Rebecca Trowman, Canada

ABSTRACT SUMMARY:
The HTAi Latin America Policy Forum provides a unique environment where invited senior representatives from HTA agencies and industry can discuss key issues. This presentation summarizes the key messages resulting from the discussions at the 2018 Latin America Policy Forum held in Montevideo, Uruguay.

INTRODUCTION:
The third HTAi Latin America Policy Forum (LAPF) will meet on 23 and 24 April in Montevideo, Uruguay. The format of the LAPF echoes that of the HTAi Global Policy Forum and provides a unique opportunity as a leadership meeting for senior people from public and private sector organizations using HTA. The aim of the LAPF is to provide an environment where senior people can engage in strategic discussions informed by the perspectives of their different organizations without the constraints associated with discussions of specific products or organizational policies.

METHODS:
The HTAi LPF will convene around 50 senior representatives from HTA agencies and industry active in the Latin America region. The topic that has been chosen by the organizing committee is ‘defining the value of health technologies in Latin America’ and this will be discussed over two days by attendees.
RESULTS:
This presentation will focus on summarising the key messages that resulted from the two days of discussions at the LAPF. The views reflected will balance those of the not-for-profit agencies attending and the private industry sector attendees, while respecting the ‘Chatham House’ rule (whereby no quotes will be directly attributed to any attendee). It will draw out any conclusions from the plenary sessions and the guided breakout sessions from the event. Any actions that are resulting from the event will also be summarised.

CONCLUSIONS:
The presentation will provide a great opportunity for HTAi wider membership to hear reflections on the key messages resulting from the event. This could provide an opportunity for further questions and debate surrounding the key issues to occur, such as any difference between valuing technologies in the Latin America Region with the approaches made in the European Union and North America.

INTRODUCTION:
Health systems in the Asia region seek to achieve universal healthcare (UHC) by increasing access to essential healthcare services, while reducing health inequalities and out-of-pocket expenditure. With this in mind, the discussion for the 2017 HTAi Asia Policy Forum (APF) centered around: ‘Universal Healthcare in the Asia Region: Overcoming the Barriers using HTA and Real World Data’.

METHODS:
As part of the background paper prepared to inform discussions at the APF, attendees from public sector HTA agencies from nine countries and industry attendees from eight companies were surveyed to explore issues on the barriers and challenges of establishing UHC in the region and use of real world data (RWD).

RESULTS:
Most countries used evidence-based decision-making when considering which technologies to add to healthcare benefit packages; however, this was at times inconsistently applied. Prioritization criteria included burden of disease, unmet clinical need, clinical effectiveness, cost effectiveness and affordability. The political agenda and deference to expert opinion also played a role. Although all countries reported using RWD to inform decision-making, they also reported issues including lack of capacity, poor quality data and lack of collaboration between private and public sectors, as well as a conservative approach to data-linkage. It became apparent that a disconnect had been identified, as industry overwhelmingly identified access to RWD in the region as a major issue.

CONCLUSIONS:
Discussing the differences in opinion between HTA agencies and industry led to a greater understanding of issues in the Asia region, and will lead to increased dialogue and opportunities to collaborate in the future. Building capacity in the region will assist countries to deliver on their goal of achieving UHC.

OP11 Findings From The 2017 HTAi Asia Policy Forum Survey

PRESENTING AUTHOR:
Rebecca Trowman, Canada

AUTHORS:
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Brendon Kearney, Australia

ABSTRACT SUMMARY:
The topic for the fifth HTAi Asia Policy Forum was ‘Universal Health Care (UHC): Overcoming the Barriers Using HTA and Real-World Data (RWD)’. This presentation will summarize the findings of a survey that informed the background paper and subsequent discussions of the Forum. It will highlight implementation of UHC to date and use of RWD in the Asian region.
OP12 2017 HTAi Asia Policy Forum: The Importance Of Universal Health Care

PRESENTING AUTHOR:
Sarah Garner, Switzerland

AUTHORS:
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Rebecca Trowman, Canada

ABSTRACT SUMMARY:
The 2017 HTAi Asia Policy Forum discussed how health technology assessment (HTA) may be used to help achieve UHC in the Asia region. This presentation will include an overview of the World Health Organization (WHO) presentation that was delivered at the Forum plus summarize the views from the member discussions that followed.

INTRODUCTION:
The fifth HTAi Asia Policy Forum (APF) was held in Beijing, November 2017. The topic of the meeting was ‘Universal Health Care in the Asia Region: Overcoming the Barriers using HTA and Real World Data’. This presentation will focus on the goal of achieving Universal Health Care (UHC) in the Asia region and specifically the perspective of the World Health Organization (WHO).

METHODS:
The 2017 HTAi APF had senior representatives from HTA agencies, academia, industry active in the region plus representatives from the WHO Geneva office and the Western Pacific Regional Office (WPRO). A keynote presentation was delivered by the WHO representative and there were guided breakout group discussions.

RESULTS:
UHC is a key component of the overall aims and objectives of the WHO with universal access to safe, effective, quality and affordable medicines and vaccines for all at the heart of this. Pharmaceutical spending varies widely across the Asia region and all countries in the region share common problems in attaining UHC. These include inadequate financing; inefficiencies in procurement and supply chain management; limited use of effective pricing policies and negotiations; substandard quality of medicines and widespread inappropriate prescribing and use.

CONCLUSIONS:
HTA can be used to help countries in the Asia region to achieve UHC; it is a tool to support good decision making and hence can help promote more efficient allocation of limited resources. Affordability however needs to be at the center of any decision to invest or disinvest and Incremental Cost Effectiveness Ratios (ICERs) should not be used as the sole basis of decision making.

OP13 2017 HTAi Asia Policy Forum: The Perspective Of Not-For-Profit Members

PRESENTING AUTHOR:
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AUTHORS:
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ABSTRACT SUMMARY:
Real World Data (RWD) is being used increasingly throughout the Asia region. This presentation will highlight key lessons on the use of RWD from Taiwan that was shared with members of the HTAi Asia Policy Forum plus it will summarize the views on RWD of the other not-for-profit agency attendees that were at the Forum.

INTRODUCTION:
The fifth HTAi Asia Policy Forum (APF) was held in
Beijing, November 2017. The topic of the meeting was ‘Universal Health Care in the Asia Region: Overcoming the Barriers using HTA and Real World Data’. This presentation will focus on the use of Real World Data (RWD) as a mechanism of informing HTA in the Asia region – from the perspective of the not-for-profit HTA agencies that were represented at the APF.

METHODS:
The 2017 HTAi APF had senior representatives from government and HTA agencies from 11 countries in the Asia region. This included first-time attendees from Iran, Indonesia and the Philippines. A keynote presentation on the lessons learnt from Taiwan on the use of RWD was delivered, and there were guided breakout group discussions.

RESULTS:
There are a number of registries and sources of RWD available to the HTA agencies across the Asia region. However, it was noted that the databases are resource intensive to maintain, and there are noted time lags in the data collection and release. There are examples where the data from these sources have been used to evaluate local utilisation of treatments and post-market surveillance, but it has not yet been used in pricing/reimbursement decisions.

CONCLUSIONS:
Although RWD could be a good tool for healthcare decision-making in the Asia region, it is still unclear how to do so properly. Infrastructure and human capacity, as well as law, are key factors to the successful use of RWD. Standardized methodologies, increased transparency, quality control and capacity building are essential elements to better implementing RWD in HTA.

OP14 The 2017 HTAi Asia Policy Forum: The Perspective Of Industry Members

PRESENTING AUTHOR:
Parashar Patel, United States

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ABSTRACT SUMMARY:
A key finding from the 2017 HTAi Asia Policy Forum was that industry awareness of, and access to, publically available real world data (RWD) is limited in Asia. This presentation will summarize industry views and highlight some possible reasons and solutions to the discrepancy between what RWD is available to not-for-profit agencies versus industry in Asia.

INTRODUCTION:
A key finding from the 2017 HTAi Asia Policy Forum was that industry awareness of, and access to, publically available real world data (RWD) is limited in Asia. This presentation will summarize industry views and highlight some possible reasons and solutions to the discrepancy between what RWD is available to not-for-profit agencies versus industry in Asia.

METHODS:
The 2017 HTAi APF had senior representatives from 11 pharmaceutical and medical device companies active in the region. A keynote presentation was delivered that explored the findings of the background paper and survey, and there were guided breakout group discussions.

RESULTS:
RWD is needed in all stages of the life cycle of a product, however of most import to industry is RWD to develop value propositions; informing HTA assessments; gauge market need and
demonstrating where a new technology sits within an established clinical pathway. Although the HTA agencies present at the APF stated that RWD is available in the Asia region, this was not reflected by industry members who had limited awareness and access. Whether this RWD is available for public use (and what caveats will be placed around its release); the quality of the data, whether it is longitudinal and if it includes costs were key concerns raised.

CONCLUSIONS:
There is a clear difference in the perspective of RWD between industry and HTA agencies in the Asia region. It is possible that this difference is driven by the apparent lack of publicly available data in the region and industry members comparing the use of RWD in Asia with the use in higher-income countries. This can be improved with clearer definitions, increased dialogue and multi-stakeholder collaboration in the region.

OP15 Actions Arising From The 2017 HTAi Asia Policy Forum

PRESENTING AUTHOR:
Brendon Kearney, Australia

AUTHORS:
Rebecca Trowman, Canada

ABSTRACT SUMMARY:
The HTAi Asia Policy Forum provides a unique environment where invited senior representatives from HTA agencies and industry can discuss key issues. This presentation summarizes the key messages and recommended actions resulting from the discussions at the 2017 Asia Policy Forum held in Beijing, China.

INTRODUCTION:
Universal Health Care (UHC) leads to better health, educational outcomes and productivity. However, Asian healthcare systems are experiencing huge pressures and are striving to achieve UHC. With this in mind, the HTAi Asia Policy Forum (APF) tackled: 'Universal Health Care in the Asia Region: Overcoming the Barriers using HTA and Real World Data'.

METHODS:
The HTAi APF convened forty-four senior representatives from HTA agencies and industry from Asia. Through a mixture of keynote presentations and guided group discussions, APF members spent two days grappling with the topic.

RESULTS:
There were a number of key messages from the APF, plus actions that were identified by APF members. The actions included: (i) A standardized HTA methodology for the prioritization of technologies in the Asian region should be developed to support health care systems (ii) HTAi need to define what real-world data means in the HTA glossary (iii) Members of the APF should develop a catalogue of what public and private data is available across countries in the region (iv) A policy statement that agencies can use with a common approach to the release of data needs to be developed.

CONCLUSIONS:
HTA and access to RWD were identified as essential tools to be used in achieving the goal of UHC; and this goal is should indeed be pursued in the Asia region. However, issues such as transparency and accountability of HTA; trust and collaboration between the public and private sectors are important concerns which need to be addressed in order to progress this goal. The recommendations for actions resulting from this successful Asia Policy Forum update on progress towards these identified actions will be presented.
**OP16 Decision Criteria That Influence Managed Entry Agreements**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
Managed entry agreements that target the performance of a subsidised medicine are used to address uncertainties associated with the high individual cost of clinically important medicine.

**INTRODUCTION:**
Managed Entry Agreements (MEAs) enable payers to subsidise access to new medicines while addressing uncertainties. Uncertainties may relate to the criteria for decision-making articulated in decision-making frameworks. The study’s aim was to determine if there was any association between the type of MEA and criteria considered during decision-making.

**METHODS:**
All medicines with MEAs listed on the Australian national subsidy scheme between 2012–2016 had data extracted on the types of MEA and information related to the criteria considered in decision-making for each medicine and its associated indication, a medicine-indication pair (MIP). The criteria considered in decision-making included the comparator (therapy to which it was compared), type of economic analysis, accepted value, budget impact, financial cost of supply, cost of therapy per patient, access control (such as restrictions or prior authorisation) and clinical need. Associations between types of MEA and the criteria were assessed using Chi Squared test.

**RESULTS:**
There were 87 MIPs. 56 MIPs had only financial MEAs and 32 had performance-based MEAs. Coverage with evidence development MEAs had very high ICER/QALY (74% > $50,000) and financial MEAs where performance measures were linked to reimbursement had lower ICER/QALY (13% > $50,000) but greater budget impact (33% > $80million) compared to simple financial MEAs. A statistically significant association (Cramer’s V =0.5, p=0.0007) was only found between performance-based MEAs and cost of unsubsidised therapy per patient.

**CONCLUSIONS:**
The main influence on choice of performance based MEA was provision of access to clinically important medicines with a high treatment cost for patients.

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**OP17 Value-based Pricing Of Drugs And Cost-effectiveness Of Health Care**

**PRESENTING AUTHOR:**
Dr. Afschin Gandjour, Germany

**ABSTRACT SUMMARY:**
The purpose of this study is to present a cost-effectiveness model which determines the cost-effectiveness threshold for life-extending new drugs based on the cost-effectiveness ratio of the health care system. The model suggests that the threshold value for life-prolonging new drugs is above €100,000 per life year gained in the absence of a budget constraint.

**INTRODUCTION:**
Value-based pricing of innovative new drugs defined in a narrow sense as pricing through economic evaluation requires use of a basic cost-
effectiveness threshold. The purpose of this study is to present a cost-effectiveness model which determines the cost-effectiveness threshold for life-extending innovative new drugs based on the cost-effectiveness ratio of the health care system. This study considers two scenarios depending on whether the goal of the health care system is to contain health expenditures (in agreement with a budget constraint) or the growth of health expenditures. Both scenarios are modified by a life-cycle approach, which considers changes in costs and outcomes over time after drug launch.

METHODS:
In order to estimate the cost-effectiveness ratio of the health care system we examine the period between 1896 and 2014 and use German data. To this end, we determine intertemporal differences in remaining lifetime spending and life expectancy by age and gender. In order to account for the age composition of the population, we weigh age-specific intertemporal changes in remaining lifetime spending and life expectancy by age-specific population sizes. In order to estimate life expectancy gains solely attributable to the health care system, we use aggregated data on amenable mortality.

RESULTS:
The model suggests that the threshold value for life-prolonging innovative new drugs is above €100,000 per life year gained in the absence of a budget constraint. In the presence of a budget constraint the ratio decreases to below €30,000 per life year gained. A life-cycle approach increases the threshold in both scenarios.

CONCLUSIONS:
The analysis provides new evidence on the cost-effectiveness threshold for value-based pricing of innovative new drugs. It suggests that in the absence of a budget constraint the threshold value is higher than commonly assumed in the literature.

OP18 A Patient And Caregiver-Designed Framework For Managed Access Programs

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ABSTRACT SUMMARY:
Patients with rare diseases and their caregivers see their input as critical to the successful implementation of managed access programs (MAPs), but have not yet been systematically involved in their design. Using the principles of participatory action research, researchers collaborated with patients and caregivers to design a framework for MAPs that includes aspects relating to accountability, governance, and evidence collection.

INTRODUCTION:
Reimbursement decisions on orphan drugs carry significant uncertainty, and as the amount increases, so does the risk of making a wrong decision, where harms outweigh benefits. Consequently, patients often face limited access to orphan drugs. Managed access programs (MAPs) are a mechanism for managing risk while enabling access to potentially beneficial drugs. Patients and their caregivers have expressed support for these programs and see patient input as critical to successful implementation. However, they have yet to be systematically involved in their design. The objective of this study was to explore what a framework for MAPs might look like when designed by patients and caregivers.
METHODS:
Building upon established relationships with the Canadian Organization for Rare Disorders, the project team collaborated with patients and caregivers using the principles of participatory action research. Data were collected at two workshops and analyzed using a thematic network approach.

RESULTS:
Patients and caregivers identified six aspects of an ideal MAP relating to accountability (program goals), governance (program-specific committee oversight; patient input; international collaboration), and evidence collection (outcome measures and stopping criteria; ongoing monitoring and registries). Additionally, patients and caregivers recognized that health care resources are finite and considered disease or drug eligibility criteria for deciding when to use a MAP (e.g., drugs treating diseases for which there are no other legitimate alternatives).

CONCLUSIONS:
A patient and caregiver-designed framework was created, which emphasized patient involvement and transparency. Further research is needed to examine the feasibility of this framework and roles for other stakeholders.

OP19 Are Compassionate Use Programmes Good Predictors of Clinical Benefit?

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
While compassionate use programmes (CUP) provide patients that have few therapeutic alternatives with access to products prior to marketing authorization and Health Technology Assessment (HTA), data suggests they are poor predictors of added clinical benefit. There is little agreement across HTA agencies on the value of compassionate use products.

INTRODUCTION:
In cases of high unmet clinical need, patients can access drugs prior to marketing authorization (MA) and Health Technology Assessment (HTA) through compassionate use programmes (CUP) or special access pathways (SAP). In theory, accelerated access is beneficial for patients with few therapeutic alternatives. In practice, it remains unclear if early access products actually deliver meaningful clinical benefit.

METHODS:
Twenty oncology drug-indication pairs were identified that have proceeded through a CUP or SAP in one or more countries including Canada, Australia, France, Sweden, England, and Scotland. Data was collected from regulatory and HTA websites on length of CUP or SAP, time prior to MA, time prior to HTA decision, time between MA and HTA decision, French Transparency Commission added clinical benefit (ASMR), and HTA decision. Cohen kappa scores were calculated in order to assess inter-agency agreement.

RESULTS:
Across a preliminary subset of drug-indication pairs, average duration of CUP was 139 days, average time before marketing authorization was 51 days, average time before HTA decision was 391 days, and average time between MA and HTA decision was 476 days. No products were deemed to be of major added clinical benefit (ASMR I), only 12.5% of products had important added clinical benefit (ASMR II), 37.5% of products had moderate added clinical benefit (ASMR III), 37.5% of products had minor added clinical benefit (ASMR IV), and 12.5% of products had no added clinical benefit (ASMR V). There is little inter-agency agreement in the decisions for products that have proceeded
through a CUP or SAP ($\kappa<0$), with the exception of England and Scotland ($\kappa=0.78$).

**CONCLUSIONS:**

Preliminary results suggest that CUP and SAP products accelerate access, but often only provide only moderate or minor improvements in clinical benefit. Further, there is very little agreement across HTA agencies on the value of these products.

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**OP20 When Are Nationally Available Discounts Introduced In NICE Appraisals**

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**ABSTRACT SUMMARY:**
Manufacturers often submit a nationally available discount to increase their cost-effectiveness. We reviewed all technology appraisals to NICE between October 2007 and August 2017 to determine the type of discount applied and when this was introduced in the appraisal process. Since the introduction of the current PPRS, the use of a nationally available discount has increased overall.

**INTRODUCTION:**
Offering a nationally available discount has become common to increase the chance of being recommended by the National Institute of Health and Care Excellence (NICE). Here, we review all NICE technology appraisals (TAs) since October 2007 to determine whether a national available discount was submitted, and explore when these discounts were introduced.

**METHODS:**
All TAs between October 2007 and August 2017 were reviewed. The timing of the nationally available discount submission was allocated into one of four categories: initially submitted; initially submitted but changed; introduced after submission; no submission of nationally available discount. An analysis was conducted to examine whether there was a temporal pattern in the introduction of nationally available discounts before or after January 2014, when the current Pharmaceutical Price Regulation Scheme (PPRS) came into effect.

**RESULTS:**
Before 1 January 2014, a nationally available discount was only used in the minority of cases across recommended (22% of cases) and not recommended (19%) technologies. In the period since 1 January 2014, use of a nationally available discount increased overall, but to a greater degree in technologies ultimately receiving a positive recommendation from NICE (not recommended: 19% to 39%; recommended: 22% to 59%). In the period since 1 January 2014, the proportion of technologies with a positive recommendation where implicit price flexibility during the appraisal was revealed increased (from 20/186) to 40/182.

**CONCLUSIONS:**
With the current PPRS, the majority of technologies have offered a nationally available discount, most commonly at the time of submission; however, there is increasing evidence of implicit price flexibility during the appraisal process to achieve a positive recommendation.
OP21 Value-based Pricing Of Add-on Life-extending Medicines

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
The purpose of this study is to discuss potential solutions for pricing life-extending add-on medicines in a VBP framework. Three different approaches of pricing life-extending add-on medicines under VBP are analyzed and may alleviate the associated challenges.

INTRODUCTION:
Value-based pricing (VBP) of new therapeutic entities defined in a narrow sense as pricing through economic evaluation requires use of a threshold incremental cost-effectiveness (ICER). Under such VBP scheme manufacturers have an incentive to increase drug prices up to the point where the ICER matches the threshold. For manufacturers of new life-extending add-on medicines which are used in combination therapy this leaves little room for setting a price above zero. Typical examples are add-on new cancer drugs. The purpose of this study is to discuss potential solutions for pricing life-extending add-on medicines in such a VBP framework.

METHODS:
Three different approaches of pricing life-extending add-on medicines under VBP in a narrow sense are analyzed: i) simple exclusion of the costs of baseline therapies, ii) division of the total price of combination therapy in proportion to the benefits of add-on medicines and baseline therapies compared to a less effective comparator such as best supportive care, and iii) pricing on the basis of an alternative threshold-setting framework, the efficiency frontier method used by the German Institute for Quality and Efficiency in Healthcare (IQWiG).

RESULTS:
It is shown that for pricing new add-on medicines, simple exclusion of the costs of baseline therapies from the numerator of the ICER can lead to inconsistencies in calculating the ICER. Such inconsistencies can be avoided by proportional division of the price. Using the example of a cancer indication, prices of new life-extending add-on medicines are calculated for different combinations of best supportive care expenditures and values of the threshold ICER. The conditions under which pricing according to IQWiG’s efficiency frontier method leads to the same or different drug prices are derived.

CONCLUSIONS:
High costs of baseline therapies lead to new challenges for VBP of new life-extending drugs. Depending on the framework used for VBP and the type(s) of pricing comparator(s), these challenges can be alleviated.

OP22 Value Framework And Visual Tool For Evidence-based Assessment

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ABSTRACT SUMMARY:
We developed a value framework and a visual tool to facilitate evidence informed deliberative process. It include dimensions on quality of the evidence;
The Superintendence of Social Security of Argentina with our group were working for reshape the national benefit package (PMO). Objective: To develop a value framework and a visual tool to facilitate evidence informed deliberative process.

METHODS:
We performed a review of the literature to identify the main dimensions used in other frameworks. After an initial selection of dimensions and methods we validated them with a panel of twenty HTA researchers. Selected dimensions were weighted through a Delphi method with senior researchers. A traffic light based colored scale was developed. The final framework was piloted in 55 rapid HTAs.

RESULTS:
The three dimensions included were: quality of the evidence; magnitude of net benefit (considering both benefits and adverse effects); and economic and organizational aspects (cost-effectiveness or expected budgetary impact). To classify the domain of evidence we used GRADE. The net benefit was classified as major, considerable, minor and marginal/null/uncertain, similarly to the German HTA agency (IQWiG). The domain of cost-effectiveness and budgetary impact were defined by consensus of experts taking into account the GDP per capita, catastrophic health expenditures and health budget characteristics in Argentina; and categorized as reasonable, uncertain and unreasonable. The final colored scale had five categories to summarize the assessment and as a decision aid: two poles suggesting positive or negative recommendations; and three intermediate categories where additional information is recommended before making the coverage decision. During the pilot we found the framework friendly and easy to understand. From 55 HTAs, two was categorized as positive, 24 as negative, and 29 with varying degrees of intermediate results (12 more favorable, 7 uncertain; and 10 less favorable).

CONCLUSIONS:
Developing and piloting a value framework and a user-friendly tool to facilitate evidence informed deliberative process was feasible in Argentina. Further validation and follow up are recommended to assess its applicability.

ABSTRACT SUMMARY:
The prosperity of medical innovations with scarce resources requires more precise measure of ‘added value’. Twelve innovative technologies that were controversial regarding their actual “added value” were ranked by 52 health managers on two scales: hierarchic importance (league scale) and comparative score rating (CSR), reflecting willingness-to-pay (WTP). The distribution of ranking indicated the internal agreement (IA) among the participants.

INTRODUCTION:
Technology assessment in hospital traditionally involves parameters of safety, effectiveness and costs. The prosperity of medical innovations in era of scarce resources requires more precise refined methodologies to measure ‘added value’. Aim: To reveal the added values of professionals prioritizing technologies to be adopted in hospitals.
METHODS:
Twelve innovative technologies that were discussed for adoption over 3 years, were controversial regarding their actual “added value”. Fifty-two managerial health professionals ranked these technologies on two scales: hierarchic importance (league scale) and comparative score rating (CSR), reflecting willingness-to-pay (WTP). The distribution of ranking indicates the internal agreement (IA) among the participants.

RESULTS:
There was only partial correlation between the two scales. For example, glucose-monitoring was ranked ‘highly important’ on the hierarchic (league) scale with high CSR/WTP, but with low IA. This can be interpreted as “a valuable technology but with disagreement on comprehensive adoption in the entire hospital”. The surgical robot was ranked ‘highly important’ on the hierarchic scale with low CSR/WTP, but with high IA, meaning “a valuable technology but with consensus to delay adoption in the hospital”. Overall, the participants raised 32 “values” that can be assorted into 5 clusters of significance: clinical effect (6 values), social/public dimension (8), patient-physician interaction (9), technological aspect (5) and policy-regulatory perception (4).

CONCLUSIONS:
We identified different ‘patterns’ for defining the ‘value’ of various technologies. Revealing these aspects can create a “set of values” of relative weight that may explain the added value considerations in prioritization decision-making. Interestingly, there were technologies that were ranked low, but achieved a high rating. This can be explained by individual personal-oriented added value perspectives. Using this innovative tool to incorporate social value-based scores can assist in understanding the determinants, beyond the current traditional rationing mechanism, guiding professionals while prioritizing medical technologies.

OP24 Sensitizing Researchers And Developers For Patient Needs And Value

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ABSTRACT SUMMARY:
Valuable health technologies must improve patients’ health or well-being. For sensitizing healthcare industry stakeholders for the unique perspective and values of patients, a new workshop format includes both knowledge transfer and experiential modules. The pilot program confirmed that novel learning structures integrating rational and emotional aspects may help to align researchers, marketers, or other life-science stakeholders better around patient value.

INTRODUCTION:
Valuable health technologies must improve health and well-being of patients. For sensitizing healthcare industry stakeholders for the unique perspective and values of patients, we developed a workshop format including both knowledge transfer and experiential modules.

METHODS:
The one-day pilot workshop was attended by 2 patient representatives and multidisciplinary participants from the healthcare industry (n=12) who wanted to learn about patient involvement in health technology assessment (HTA) and healthcare decision making and the implications for product development. Three content sessions covered key aspects of HTA and patient engagement and each was followed by an experiential session which aimed at experiencing the own values as a healthy person or when the diagnosis of a disease...
and the subsequent therapy decisions (including potential clinical trial participation) impact quality and length of life. The workshop concluded with the participants prioritizing their expectations for innovation and HTA as patients or as citizens.

RESULTS:
Overall, participants rated the workshop as excellent or good for knowledge and experiential sessions. Integration of both learning modalities was described as innovative, useful, and enjoyable. Participation in the clinical trial session triggered cognitive responses among the industry participants due to a strong focus on advancement of science for innovation. Otherwise, the responses of the industry participants matched those of the patient representatives well. Overall, patient perspectives were considered useful to enrich the value perceptions beyond those of industry. Emotions describing the personal experiences included despair, shock, anger, guilt, hope, and the will to live. As citizens, they emphasized expectations such as finding solutions, remaining independent, enjoying life and “giving back”.

CONCLUSIONS:
Innovative learning structures integrating rational and emotional aspects can allow researchers, marketers, or other stakeholders from the life-science industry to better understand patient perspectives. The format may be well suited for team building and alignment of team values around patient-needs.

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ABSTRACT SUMMARY:
The Scottish Medicines Consortium introduced a Patient and Clinician Engagement process in 2014, aimed at strengthening the voice of patients and clinicians in the assessment of new medicines used at the end of life and for very rare conditions. We review here the first 3 years experience.

INTRODUCTION:
In 2014 the Scottish Medicines Consortium (SMC) implemented more flexible measures in the health technology assessment (HTA) of medicines used at the end of life and for very rare conditions. We review 3 years’ experience with a Patient and Clinician Engagement (PACE) process.

METHODS:
The PACE process applies only for end of life, orphan and ultra-orphan medicines. It involves a round-table discussion to explore the added benefits of a medicine, from both patient/carer and clinician perspective, that may not be fully captured within the conventional clinical and economic case. The output is a consensus statement that is expected to have a major influence on the SMC decision.

RESULTS:
From August 2014 to August 2017, 87 submissions were assessed with the PACE process, representing 44% of all full submissions assessed in that period. Analysis of decisions shows that 67 medicines (77 per cent) were accepted and 20 (23 per cent) were not recommended. The new definitions were introduced in 2014 so historical acceptance rates
for cancer and orphan medicines combined are used as a proxy measure for comparison: from January 2011 to December 2013 the acceptance rate for cancer/orphan medicines was 48% (15/31). Data will be presented on the involvement of clinicians and patient groups to PACE and on its contribution to decision making, including key factors associated with positive and negative recommendations.

CONCLUSIONS:
The acceptance rate for new medicines used at the end of life and for very rare conditions has increased substantially since PACE was introduced. Patients, their representatives and clinicians have a greater input to HTA. Further work is needed to explore how effectively PACE captures the wider benefits of new medicines and to determine its impact on decision making.

OP26 Towards A Strategy To Involve Patients In HTA In Spain

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ABSTRACT SUMMARY:
This presentation describes the development of a strategy to involve patients in the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). The guidelines for patient involvement were developed through a research project that included a systematic search, a qualitative study, a consultation with patient organization and a consensus process.

INTRODUCTION:
In an innovative context in which new health technologies are continuously emerging, decisions must be made respecting their introduction and funding in the National Healthcare System. The aim of Health Technology Assessment (HTA) is to assess the value of those technologies for consumers, patients and carers, for the Healthcare System and, in a broader sense for society. Patient participation in HTA has emerged as an imperative to reach informed, transparent and legitimate decisions about technologies. The Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS) has developed a strategy to facilitate effective and efficient patient involvement in HTA processes.

METHODS:
Medline, Embase, Cinahl, SCI-EXPANDED, Cochrane Library, PsycINFO, Scopus and JSTOR were consulted to carry out a systematic search of the literature of papers, manuals, web pages or portals describing a strategy and/or a methodology linking HTA and patient involvement. Two reviewers performed the selection process of studies and in case of doubt or disagreement between them a third reviewer was consulted. A qualitative study was conducted to analyze the perceptions of HTA managers in the Spanish context regarding patient involvement. The aims of the study were: 1) collecting definitions of patient involvement; 2) Collecting experiences of patient involvement in HTA in the Spanish context; 3) Collecting barriers and facilitators for patient involvement in our context. A Delphi consultation was sent to patient, carers and consumers organizations. The consultation explored in 2 rounds the opinions of
this organizations related to: 1) What are the values that justify patient participation in HTA; 2) What are the methods, moments and activities in HTA in which patient participation is possible; 3) Which is the best way to operationalize patient involvement. Finally, a consensus process among the RedETS resulted in a strategy to incorporate patients in the Spanish HTA.

RESULTS:
A total of 358 references were found in the electronic databases. From those, a total of 58 references were finally included. 43 additional references were identified through manual search or through other references. 13 qualitative interviews to HTA managers and technicians were conducted. 66 patient and consumers organizations responded to the consultation in the first round and 37 in the second round. Main themes identified through literature research structured the results. In the first place, participation was framed questioning why, who and through which channels participation can be done. In the second place, participation planification was analyzed, exploring the design and procedures for patient selection and invitation, showing which are the main expected contributions of patients to HTA and what resources are needed to make participation effective. In the third place, methods for participation were identified and evaluated. Finally, methods for the evaluation of patient participation were analyzed. Results synthesize findings of the document review, complemented by the findings of the interviews and the consultation. The strategy was built through consensus taking this results as a starting point.

CONCLUSIONS:
Patient participation can be present in most all of the HTA phases and products with more or less difficulties. Therefore, a progress implementation of a patient participation strategy was recommended. A strategy was defined to incorporate patients to the normative framework of the ResETS, to design patient participation for specific reports, to choose participation methods for all ETS phases and finally to evaluate that participation. The strategy implementation requires, in the first place, the establishment of a normative framework that can make transparent the value, objectives and procedures of patient participation in the RedETS. Secondly, there is a need to define the design and methods of patient participation for the different HTA phases. Finally, it will be important to built and evaluation strategy that provides transparency on patients contributions and helps generating evidence on their impact in HTA.

OP27 Patient Engagement At Scottish Medicine Consortium Committee Meetings

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ABSTRACT SUMMARY:
From June 2017 the Scottish Medicines Consortium (SMC) has invited submitting patient groups to participate at committee meetings. This allows patient groups to answer questions from committee members or to clarify aspects of their submissions. Early feedback has been positive with patient groups believing that their voice is heard and contribution valued.

INTRODUCTION:
Since 2014 patient group representatives have been able to observe SMC committee meetings as members of the public. However, they have had no opportunity to participate in discussions on their submission on the patient experience of living with the condition under review. In 2017, to strengthen
patient engagement, we revised our processes to enable representatives from all submitting patient groups to play a bigger part in the monthly meeting.

METHODS:
The SMC Public Involvement Network (PIN) Advisory Group consulted on potential issues around patient group participation in committee meetings. Recommendations approved for implementation included; provision of comprehensive information and support to participating patient group representatives, and holding an educational session for SMC members on ‘What matters to the patient’. The process change was introduced in June 2017. Patient group representatives are invited to complete an online survey on their experience of taking part in the meeting and working with the public involvement team. Implementation is being monitored and will be evaluated in a commitment to continuous improvement.

RESULTS:
Since June 2017 fourteen patient group representatives have attended SMC meetings for the discussion of their submission. This has enabled them to answer questions from committee members and clarify points relating to their submission, if required. Early feedback has been positive with participants believing that patient engagement has been strengthened and that the patient voice was heard and valued. Patient groups expressed a willingness to participate again. The evaluation of their experience to date will be presented.

CONCLUSIONS:
SMC now involves patient group participation at committee meetings, demonstrating commitment to listening and responding to stakeholders on patient engagement. Early feedback has been positive and suggests that discussions relating to quality of life impact on patients and carers better reflect the lived experience. This ensures we are meeting our commitment to openness and transparency and strengthens patient engagement in our process.

OP28 Partnership Working To Inform Patient Engagement In HTA

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ABSTRACT SUMMARY:
To inform their participation in Scottish Medicine Consortium (SMC) assessments, patient groups highlighted a need for information from pharmaceutical companies. SMC established a multi-stakeholder short life working group (SLWG) to explore this, resulting in a new Summary Information for Submitting Patient Groups (SIP) form and guidance, which is now a standard part of company submissions.

INTRODUCTION:
The Scottish Medicine Consortium (SMC) works in partnership with patient groups and carers to capture their experiences to help inform decisions on new medicines. To better inform their participation in the SMC assessment process, patient groups highlighted a need for information from submitting pharmaceutical companies about the new medicine under review.

METHODS:
We established a multi-stakeholder short life working group (SLWG) to explore how to meet these needs. The group comprised members of the
SMC Public Involvement Network (PIN) Advisory Group, representatives of two pharmaceutical companies and the Association of British Pharmaceutical Industries, and the SMC public involvement team. The main outputs were the development of a new Summary Information for Submitting Patient Groups (SIP) form and supporting guidance document. The SIP form completed by the submitting pharmaceutical company is then shared by SMC’s Public Involvement Team, to assist submitting patient groups.

RESULTS:
The SIP form was implemented in June 2016, and following positive evaluation, became essential for inclusion with the pharmaceutical company’s new medicine submission in June 2017. Feedback has been positive, with patient groups reporting that the form includes valuable information that they may not otherwise have been able to access including the positioning of the medicine in the treatment pathway, information on dosage, administration and side-effects. The form is also completed in plain English without overly technical or marketing information. Company representatives who have completed the form state that it provides clear information on the licensed indication, enables accessible scientific evidence for patients and families/carers, and allows them to give accurate and balanced information about the medicine.

CONCLUSIONS:
Partnership working with key stakeholders has enabled SMC to provide improved information to submitting patient groups. A better understanding of a new medicine may in turn allow patient groups to participate more effectively in the HTA.

OP29 The Impact Of Individual Patient Input: Strengthening The Evidence

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ABSTRACT SUMMARY:
NICE obtains input from patients, called ‘patient commentary’, to inform committee decisions about interventional procedures, using a questionnaire sent out to patients via their clinician. A study was conducted: to capture the impact of the patient commentary on the committee’s decision-making; to explore patterns of impact; and to identify criteria that indicate when patient commentary may not be required.

INTRODUCTION:
NICE assesses the efficacy and safety of interventional procedures for use in the NHS. Since 2006, NICE’s Public Involvement Programme (PIP) has obtained ‘patient commentary’ to inform committee decisions, using a questionnaire asking patients about their experience of the procedure including benefits, disadvantages and side effects. Commentary is considered by the committee alongside other evidence. The PIP has piloted a project to: capture the impact of the patient commentary on the committee’s decision-making; explore patterns of impact; and identify criteria that indicate when patient commentary may not be required.

METHODS:
The pilot included all interventional procedures guidance started between February 2016 and
February 2017. Committee members’ views were captured using a form completed whenever patient commentary was considered. Responses were anonymised, entered into an electronic system, analysed, and correlated against ‘committee comments’ in the published guidance. After twelve months there was an unrepresentatively narrow spread of conditions, and most topics were updating previously published guidance rather than novel topics. The pilot was therefore extended by six months.

RESULTS:
Patient commentary commonly had an impact on decision-making, however no discernible patterns have yet been identified, nor criteria for when it may not be required. Key findings were: • patient commentary is equally useful for guidance updates as novel guidance • interpretation and assessment of ‘impact’ varied across committee members but the majority agreed it reinforced the other evidence.

CONCLUSIONS:
Patient commentary has a measurable impact on committee decision-making. Very occasionally it provides new evidence and routinely provides reassurance that the published evidence is substantiated by real-world patient opinion. Measuring the impact of commentary seems to have raised its profile, with more committee comments about patient issues included in guidance during the pilot than in preceding years. The project needs to be extended to identify which procedures are least likely to benefit from patient commentary and why.

OP30 From Framework To Action: Implementing Patient Engagement

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ABSTRACT SUMMARY:
This session will share lessons learned from implementing a comprehensive patient and public engagement framework (developed by Abelson et al., winners of the 2017 Egon Jonsson award) in one government agency’s HTA process. The presentation will share strategic and operational considerations for successful implementation, and early impacts of patient involvement activities on the agency’s HTA recommendations.

INTRODUCTION:
This session will share lessons learned from implementing a comprehensive patient and public engagement framework (developed by Abelson et al., winners of the 2017 Egon Jonsson award) in one government agency’s HTA process. The presentation will share strategic and operational considerations for successful implementation, and early impacts of patient involvement activities on the agency’s HTA recommendations.

METHODS:
This presentation uses a case study approach to understand the application of the framework described above.

RESULTS:
Abelson et al.’s comprehensive framework describes many different public and patient engagement activities that could be conducted at each stage of an HTA process. Health Quality Ontario has chosen to focus on engaging patients
to prioritize topics, develop an additional evidence stream on patient preferences and values, to serve on a committee that reviews the HTA, deliberates and makes recommendations, and to provide feedback on draft recommendations. Strategic considerations for these decisions included: aligning engagement activities to an evidence-focused organizational culture, and investing in engagement activities earlier in the HTA process in order to allow for sufficient consideration of the patient voice in developing recommendations. These activities have impacted the agency’s organizational culture, and evidence suggests they have also influenced recommendations for what should be publicly funded. Patient engagement activities have also led to increased feedback for the public and patients for some HTAs and the associated draft recommendations.

CONCLUSIONS:
Public agencies must make strategic decisions about how and when to invest scarce resources for patient and public engagement. Investing in direct patient engagement as an additional stream of evidence and supporting health system users to be involved in decision-making has had a significant impact on HTA deliberations and recommendations. For some HTAs, these activities have facilitated greater public engagement as well.

OP31 Tackling Representativeness: A Roadmap And Rubric

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ABSTRACT SUMMARY:
To achieve meaningful engagement, partnering with patients representative of the target patient community is important. However, the question of how to define patient “representativeness” in patient engagement remains elusive.

INTRODUCTION:
As stakeholders across the health care ecosystem embrace patient centeredness and integrate the patient voice into processes, decisions, and organizations, meaningful patient engagement has become increasingly important during drug development, regulatory product review, and value assessment. To achieve meaningful engagement, partnering with patients representative of the target patient community is important. However, the question of how to define patient “representativeness” in patient engagement remains elusive. Thus, the objective was to begin to define representativeness and its characteristics.

METHODS:
On 8 May 2017, aiming to address this issue and assist stakeholders in achieving patient representativeness in their engagements the National Health Council (NHC) convened a half-day Roundtable with key stakeholders, including representatives from patient groups, life science companies, value-assessment framework developers, payers, research organizations, and the Food and Drug Administration (FDA).

RESULTS:
Participants strongly agreed that a single target for patient representativeness cannot fit every patient engagement situation. Instead, context, including the objective of the engagement, must influence how patient representativeness is defined for any engagement activity. Moreover, the variability of patient interactions requires that stakeholders address representativeness as a process with a minimum target, rather than a fixed standard. A list of characteristics was developed.
CONCLUSIONS:
This work represents an important first step in advancing the discussion and enhancing stakeholders’ ability to meet a high target of patient representativeness for each patient engagement activity. The NHC, along with other stakeholders, will continue to contribute to this discussion and develop tools to advance the understanding and achievement of patient representativeness in engagements across health care contexts, including in drug development, product review, and value assessment. While greater representativeness improves any engagement effort, the quality of the engagement interaction is often more important. A focus on the quantity and representativeness of patients involved must never detract from the quality of the interaction.

OP32 Accelerating Evidence-To-Action Through Team Capacity Building

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ABSTRACT SUMMARY:
Evidence for Change (EFC) is a new capacity building initiative designed to support multidisciplinary health and social care teams and their public/patient peers to translate scientific knowledge to develop services and reduce health inequalities. A qualitative developmental evaluation approach was used to incrementally create EFC, whilst individual, team and service impacts were measured by adapting a five levels model.

INTRODUCTION:
Health and social care in the UK is undergoing rapidly emerging, radical change in an attempt to keep pace with new developments and increasing demands. It is widely acknowledged that the evidence-to-action gap is contributing to this problem. Therefore the goal of the Evidence for Change (EFC) initiative was to establish whether a new capacity building approach could help reduce the evidence-to-action gap by supporting multidisciplinary health and social care teams to find, analyse and translate scientific knowledge into practice, in order to tackle a predefined service issue. All teams included members of the public as equal peers and had a focus on health inequalities.

METHODS:
Using a qualitative developmental evaluation approach we worked with the participating health and social care teams to incrementally develop the EFC initiative through observations and timely stakeholder feedback. Data arising from the follow-up evaluation that involved on-line questionnaires, focus groups and interviews, was analysed against five impact levels ranging from personal to societal.

RESULTS:
All four participating teams were successful in translating knowledge into practice. Analysis of the data indicate organisational and community impacts for all projects with at least one project reaching societal level. Identified key elements leading to success included: working in multidisciplinary teams that had identified their own implementation issue; embedding developmental evaluation principles; providing skills, knowledge and support to access and interpret scientific knowledge; embedding change management and creating experiential learning opportunities.

CONCLUSIONS:
EFC, in a short period-of-time (eight months), enabled teams of health and social care providers to come together, define their practice issue, identify existing literature and implement evidence-informed decisions regarding changes to their professional practice. In addition, the process
produced unintended positive consequences that benefited the individual, the team and their working environments.

OP33 Adopting Health Technologies: NICE Approach For Evidence Into Action

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ABSTRACT SUMMARY:
NICE adoption team identify NICE health technologies guidance with significant barriers to adoption, and deliver tailored support and resources to help overcome these barriers and facilitate uptake of the guidance in practice. The presentation details the teams’ processes and approaches to achieving this and provides examples of how the team have supported the adoption of NICE health technology guidance.

INTRODUCTION:
Evidence and guidance alone do not change practice. A multitude of factors are influential upon whether a particular health technology is adopted in practice. The adoption team at NICE engages with healthcare professionals to develop specifically tailored support for the adoption of NICE health technology assessments (NICE medical technologies, diagnostics and technology appraisal guidance).

METHODS:
The NICE adoption team uses a structured process which involves engagement of healthcare professionals with experience or knowledge of the technology to identify the barriers to adoption. This information is used to: • populate the topic selection tool which presents the impact of adopting the technology under 5 headings; care pathway change, finance, difficulty to implement, education and patient acceptance. The result indicates which guidance would benefit from adoption support • plan and develop tailored solutions to address barriers to adoption which include a resource impact assessment and targeted communications • quality assure and publish tailored resources.

RESULTS:
Examples of tailored outputs include: • adoption resources sharing real world experiences of sites that have adopted the technology • NICE pilot projects, where the adoption team work closely with sites to support adoption of the technology at a local level. The team then share learning and results from the project. • engagement with national planning groups to coordinate wider scale adoption • resource impact assessments which help local cost impact of adoption to be estimated • engagement with general and specialist media • influencing national tariff.

CONCLUSIONS:
NICE’s processes have evolved to facilitate the development of a wider variety of more tailored resources, to support adoption of NICE health technology assessments guidance into practice. We will continue to engage with healthcare professionals and be responsive in our processes to ensure the packages of adoption support are tailored to need.
OP34 Building A Platform For Knowledge Translation On HTA In Brazil

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ABSTRACT SUMMARY:
We report both elements and objectives of our project to build a comprehensive knowledge translation platform for health technologies in Brazil based on evidence-informed methods developed and validated for implementation by the Brazilian Ministry of Health. The project begun in 2016 and will be fully implemented by 2020.

INTRODUCTION:
Global efforts to institutionalize the translation of scientific knowledge into action, as a tool to improve health policy outcomes are ongoing. Knowledge translation (KT) is defined as a dynamic and interactive process that includes synthesis, dissemination, exchange and ethical application of scientific knowledge to strengthen health systems and improve people’s health. However, an integration gap amongst the KT steps at the implementation level still remains. Hence, adequate mechanisms and tools are required. The construction of a national KT platform is being developed for the institutionalization of a long-term project in Brazil, including methodological and product development processes to support the systematic, transparent and balanced use of scientific research results at different levels of decision-making and deliberation in health technologies.

METHODS:
Basing ourselves on participant observation, we report our experience on developing the main elements and objectives of this encompassing project to build such national platform to support the improvement of management of health technologies within the scope of the Brazilian National Health System, via the development of robust methodological solutions to address its institutional implementation by the Brazilian Ministry of Health.

RESULTS:
This project was divided into four integrated sub-projects with interacting objectives: 1) RAPID, to develop and validate methods to produce synthesis of evidence (rapid reviews) on health technologies; 2) POPART, to develop and validate methods and tools to support and improve the social participation in decision making on the incorporation of health technologies in the Brazilian National Health System; 3) iGUIDE, to develop a framework and methodological guideline for implementation of clinical guidelines and health technologies incorporated into the National Health System, identifying barriers and implementation strategies; and 4) CONSCIO, to develop methods and tools to support the institutionalization of knowledge translation processes within the Ministry of Health and for interested groups on specific health technologies. All sub-projects include four development steps: 1) mapping, analysis and synthesis of the global evidence on methods related to its specific objectives; 2) development and validation of methods for the constitution of specific methodological guidelines; 3) capacity building activities and dissemination of developed methods; and 4) development of operational products based on the methods developed. The project begun in 2016 and will be fully implemented by 2020.

CONCLUSIONS:
This project report addresses a comprehensive platform for health technologies’ KT encompassing
the development of methodologies based on global evidence and validated for a specific context of implementation - the Brazilian Ministry of Health. Although in its initial phases, first results indicate an opportune framework to both develop and institutionalise KT for larger contexts. Monitoring and evaluation are planned to ensure that the intended results are being produced.

**OP35 Integrated Knowledge Translation in Policy Development**

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**ABSTRACT SUMMARY:**
Collaboration between researchers and decision makers is a novel approach to facilitating translation of evidence into practice. Ministries of Health in Alberta, Manitoba, and Saskatchewan adopted the integrated knowledge translation concept to collaborate with health technology assessment researchers and clinicians in developing an evidence-based guideline that formed the basis of a provincial immune globulin utilization management policy.

**INTRODUCTION:**
Immune globulin (IG) is a publicly funded blood product with high utilization rates and rapidly rising costs. Inappropriate use of IG, particularly in dose and treatment duration, is observed in about 10% of cases, and the national guidelines for IG treatment are outdated. To develop a utilization management policy for IG, the Alberta, Manitoba and Saskatchewan Ministries of Health collaborated with health technology assessment (HTA) researchers and clinicians to develop evidence-based guideline recommendations for IG treatment to inform an authorization policy for IG utilization in the provinces.

**METHODS:**
A multidisciplinary committee comprising HTA researchers and 22 physicians from seven medical specialties adapted recommendations from 43 “seed” guidelines into one locally contextualized IG guideline. HTA methods and rapid review products were used extensively to update gaps in the evidence base. The guideline recommendation document was used to develop a provincial IG utilization management policy. The challenges of achieving a methodologically rigorous guideline development process will be discussed.

**RESULTS:**
The guideline contained over 60 recommendations for IG use in different medical specialties. The health ministries used the guideline recommendations to develop an IG authorization policy. The clinician-sanctioned review criteria were used to construct a conditional reimbursement system for generating outcome data from controlled off-label IG use for conditions where evidence gaps existed, and were built into policies for benchmarking compliance.

**CONCLUSIONS:**
Three provinces successfully collaborated to develop an IG utilization management policy. The unique approach involved a credible and transparent process that incorporated key review elements for compliance benchmarking and reimbursement, promoted clinician buy-in, and created a cadre of clinical champions willing to assist in policy development and implementation. The proactive, rather than retroactive, incorporation
of clinician-sanctioned benchmarking and review criteria into policy will help bridge the know-do gap and foster a stronger, more direct link between health policy and evidence.

**OP36 Implementation Of HTA Evidence: A Case Example Of Home-based Dialysis**

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**ABSTRACT SUMMARY:**
This presentation will discuss the incorporation of an “implementation issues” review in the HTA process to identify contextual considerations that could impact the uptake of a technology, in this case, home-based dialysis modalities. The ways in which this review facilitated the implementation of the HTA recommendations by decision-makers in Canada will be discussed.

**INTRODUCTION:**
In Canada, hemodialysis offered in a clinical setting remains the most frequently used dialysis option for patients with end stage kidney disease (ESKD). An HTA on dialysis modalities for the treatment of ESKD informed optimal use recommendations that support the treatment of eligible patients with home-based dialysis treatment. This presentation will discuss i) the incorporation of an “implementation issues” review in the HTA to identify contextual considerations that could impact the uptake of home-based dialysis modalities and ii) the ways in which this review informed an implementation support plan that guided the implementation of the HTA recommendations by decision-makers in Canada.

**METHODS:**
The implementation issues review was informed by two surveys (dialysis stakeholders) and a literature review. Information on a cross-Canada landscape of implementation processes, barriers, facilitators and funding availability for dialysis was collected. The INTEGRATE-HTA context and implementation of complex interventions (CICI) framework was applied to categorize data and identify emergent factors that could influence successful implementation of the recommendations. The results were used to guide evidence-informed activities to support implementation in various Canadian jurisdictions.

**RESULTS:**
The review identified issues and strategies that may support effective implementation of home-based dialysis modalities (e.g. education for clinicians, patients, caregivers and policy-makers). Implementation considerations for patients in rural and remote settings were also identified. Reviewing implementation considerations in the HTA process in a systematic way provided an effective platform for understanding the context in which the HTA recommendations can be applied to real-world decision-making. The process also facilitated the identification of relevant stakeholders, the development of targeted knowledge mobilization activities, and the process of moving HTA evidence into practice.

**CONCLUSIONS:**
A review of implementation issues bridged the HTA recommendations to real-world implementation of the evidence. This is recommended as a key component of HTAs moving forward.
OP37 HTA Impact Assessment: Barriers & Enablers Perceived By INAHTA Members

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ABSTRACT SUMMARY:
Health technology assessment (HTA) agencies wish to ensure the impact of their work. This session presents qualitative study results to illuminate the facilitators and barriers towards assessing HTA impact among INAHTA member agencies. The social-cognitions lens is used to understand attitudes, social support, self-efficacy, barriers, and intention towards HTA impact assessment and to develop effective strategies in this area.

INTRODUCTION:
Health technology assessment (HTA) agencies wish to ensure the impact of their HTA. HTA impact assessment measures the influence of an HTA on decision-making and downstream to patient outcomes. Despite the potential to provide insights, the use of impact assessment frameworks by HTA agencies is limited. Understanding the underlying mechanisms of adopting HTA impact assessment frameworks is therefore important. Using a social-cognitions lens, this study aims to provide insight into enabling and hindering factors to the assessment of HTA impact by INAHTA members.

METHODS:
Using an interpretive description design, this cross-sectional study included semi-structured interviews among INAHTA members to gain insight into attitudes, social support, self-efficacy, barriers, and intention towards HTA impact assessment. Transcriptions were analyzed using a social-cognitions lens by two researchers using a constant comparative method to identify themes.

RESULTS:
Twenty-six of 47 INAHTA members participated. Preliminary results show that interviewees most often perceived support for assessing impact from their Ministry of Health or from agency staff. Most interviewees indicated a lack of human resources and methods and tools, and challenges to measuring impact at the right time as internal barriers. A lack of transparency and a limited impact assessment culture were perceived as the main external barriers. Interviewees reported feeling fairly confident to overcome internal barriers, but less confident to overcome external barriers. Being time-consuming was the most important disadvantage, whereas providing feedback for improvement to HTA processes and making achievements visible were the most frequent reported advantages to assessing impact.

CONCLUSIONS:
This is the first study using a social-cognitions model to understand HTA impact assessment. Although the results of this convenience sample need to be interpreted with caution, it contributes to knowledge of factors that facilitate and hinder agencies in the assessment of impact, and illuminates opportunities to develop effective strategies to support HTA agencies in this area.
OP38 Evaluating The Impact Of HTA: An Updated Review

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ABSTRACT SUMMARY:
A review of evaluations of HTA agencies was published by the Alberta Heritage Foundation for Medical Research in 2006. The review proposed a generic evaluation framework for HTA agencies and described approaches/methods used and outcomes measured. Our update of the review describes the extent to which the determinants of HTA effectiveness have since been measured by HTA agencies.

INTRODUCTION:
A review of evaluations of HTA agencies was published by the Alberta Heritage Foundation for Medical Research in 2006. The review proposed a generic evaluation framework for HTA agencies (referred to here as the 'Alberta model') and described approaches/methods used and outcomes measured. Our objective was to describe the extent to which the proposed determinants of HTA effectiveness have been measured by HTA agencies.

METHODS:
A comprehensive search of published and grey literature was performed, supplemented by targeted searches of HTA agency websites, and snowballing from included studies and evaluation reports. The outcomes measured by evaluations published since 2006 were clustered and analysed as per the topics in the Alberta model: inputs/structures; processes; outputs; impact of products; and ultimate HTA outcomes.

RESULTS:
Eight evaluations of HTA agencies were identified: four from Canada, three from the UK, and one from Europe. The Alberta model proposed outcome measures beyond HTA products and their dissemination, and there is evidence that HTA agencies in Canada, the UK and Europe are evaluating (and responding to) broader factors such as governance, staff and structure, resources, advisory committees, collaborative and contractual relationships, access to data, formulation of HTA questions, and prioritization of assessment targets.

CONCLUSIONS:
The Alberta model and the experience of HTA agencies in Canada, the UK and Europe are being used to inform a possible evaluation framework for the various government organisations that undertake HTA in Australia.

OP39 Evaluation Of Discharge Planning And Transitional Care For The Elderly

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ABSTRACT SUMMARY:
This report evaluates the effectiveness of discharge planning and transitional care aiming at reducing the readmission rate for the elderly. An umbrella review was conducted; contextual and experiential data were collected to elaborate final recommendations. An individualized discharge plan, coordination of services and follow-up performed by the same healthcare professional are established to be effective in reducing readmission.
INTRODUCTION:
According to our local data, elderly patients accounted for 60% of all emergency department hours and for 52% of patient hours on stretcher. These patients are more likely to return to the hospital following discharge. In order to meet ministerial target for length of stay of patient on a stretcher, the UETMIS-SS was requested to evaluate interventions aiming to improve the fluidity of patient trajectories in the acute care services. The objective of this health technology assessment is to evaluate the effectiveness of discharge planning and transitional care interventions aiming at reducing the readmission rate of the elderly.

METHODS:
An umbrella review was conducted following the PRISMA statement to summarize the scientific evidence. The search was conducted in five databases along with the grey literature search. Two reviewers independently performed the study selection, the quality assessment and the data extraction. To better illustrate the activities and the healthcare professionals (HCP) involved in the interventions, an analytical framework was developed. Results were summarized in a narrative synthesis. The contextual and experiential data were collected through interviews with HCP and directorates from different settings. The level of evidence was set taking into consideration the scientific, contextual and experiential evidences. A committee was then held to elaborate the recommendations.

RESULTS:
In the 8 systematic reviews included in the narrative synthesis, three models were identified: Post-discharge planning and follow-up by the same HCP was established to be effective in reducing the readmission rate. Discharge planning interventions with follow-up by non-specific HCP have been shown to be promising, while discharge planning without follow-up after the hospital discharge has shown to be ineffective in reducing the readmission rate.

CONCLUSIONS:
An individualized discharge plan, coordination of services and follow-up performed by the same HCP is established to be effective in reducing readmission rate.

OP40 Effect Of Advanced Nursing Practice On Hospital Use For The Elderly

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ABSTRACT SUMMARY:
The objective of this rapid response was to evaluate the effect of advanced practice nurse (APN)-led interventions on hospital services use for the elderly. A systematic search of the literature was conducted in 5 databases. Sixteen primary articles were identified within four systematic reviews. Comprehensive discharge planning and transitional care led by APN reduced hospital readmissions for the elderly.

INTRODUCTION:
Within the local context in Montréal, the elderly population make up more than 50% of patient hours in emergency department. To meet ministerial targets for length of stay, the UETMIS-SS was requested to conduct an umbrella review to evaluate interventions aimed at reducing health care services use for this population. Within that context, the UETMIS-SS was asked to further evaluate the efficacy of advance practice nurse (APN)-led interventions. The objective of this rapid response was to summarize the scientific literature for APN-led interventions on hospital services use.
METHODS:
An umbrella review using the PRISMA statement was conducted to review the scientific literature. Systematic searches were conducted in five databases, along with a grey literature search. Two reviewers performed the study selection, quality assessment using the ROBIS, and data extraction. The primary studies within the selected systematic reviews were extracted by two reviewers and a meta-analysis was conducted to analyze the efficacy of APN-involved in discharge planning and transitional care.

RESULTS:
From the 27 systematic reviews identified in the literature search, 4 reported data on APN-led interventions. In all, 16 primary studies were included in the 4 systematic reviews. While most studies focused on transitional care, there was heterogeneity in the components of the interventions implemented. At 6 months post-discharge, a reduction of 41% in relative risk of readmission was observed with APN-led discharge planning and transitional care with patient education, follow-up and services coordination. Studies with fewer components reported less significant results than studies with comprehensive discharge planning and transitional care. The few APN-led primary care studies identified in the systematic reviews reported inconsistent results.

CONCLUSIONS:
APN-led comprehensive discharge planning and transitional care can reduce hospital readmission rate. Several components were identified and should be considered in the discharge planning and transitional care.

OP41 Hospital-based HTA Of Static Overlays For Pressure Ulcer Prevention

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ABSTRACT SUMMARY:
We evaluated two types of advanced static overlays for pressure ulcer prevention based on a clinical pilot-test at Odense University Hospital prior to a public procurement of mattresses. Outcomes within clinical, organizational, patient and economic perspectives were included. Preliminary results indicate positive outcomes; similar clinical effect but economical savings for static overlays compared to alternating-air mattresses.

INTRODUCTION:
Pressure ulcers (PU) are common among admitted patients in developed countries and have severe consequences for patients as well as economy. At Odense University Hospital (OUH) alternating-air mattresses (AAM) are used in prevention of PU but new advanced static mattress overlays might be more effective for patients at risk of developing PU and have lower costs. Prior to a public procurement of mattresses for PU prevention, a Hospital-based HTA was carried out.

METHODS:
The HTA was nested within a clinical pilot-test at geriatric and orthopedic units at OUH, where two types of advanced static overlays were tested during six months. Prevalence of PU was investigated six months before and after the implementation. Prevalence using advanced static mattresses compared to AAM was also investigated.
in a systematic literature review. Staff attitudes were examined in a questionnaire survey and focus group interviews. Patients who had tried one of the overlays and the AAM were interviewed and economic consequences were analyzed.

RESULTS:
Preliminary results indicate no difference in the prevalence of PU between the overlays and AAM (1510 patients in pilot-test). The questionnaire survey and interviews with staff showed mixed attitudes towards the overlays but the majority preferred using the overlays due to ease of use and perceived patient comfort. Interviewed patients preferred the new overlays compared to AAM because of less noise and improved mobility. The economic analysis indicates significant savings for OUH by using either of the two overlays compared to the AAM.

CONCLUSIONS:
Both types of overlays are effective in pressure ulcer prevention and at lower cost than AAM. However, the overlays introduce challenges for the staff and clear guidelines for the selection of mattresses are needed. Overall, it is recommended that advanced static overlays are considered in the procurement of mattresses for pressure ulcer prevention.

OP42 HTA Of Colon Capsule Endoscopy In Colorectal Cancer Screening

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ABSTRACT SUMMARY:
The Danish national screening programme for colorectal cancer results in several negative colonoscopies yearly. A systematic review and meta-analysis investigated the diagnostic sensitivity and specificity of colon capsule endoscopy and showed promising results. An economic analysis investigating the consequences of including colon capsule endoscopy as a filter test, showed increased costs but reduced number of colonoscopies performed.

INTRODUCTION:
The Danish national screening programme for colorectal cancer for non-symptomatic persons aged 50 to 74 years was initiated in 2014. When the immunological fecal occult blood test (iFOBT) exceeds 100g Hgb/L, patients are offered a colonoscopy. In 2015 6.9% of the iFOBTs were positive, however 42.5% of the subsequent colonoscopies showed no cancer or abnormalities thus exposing healthy individuals for an unnecessary risk of complications. The purpose of this HTA was to investigate the I) diagnostic sensitivity and specificity of the colon capsule endoscopy (CCE) compared to colonoscopy, and II) economic consequences of including CCE as a filter test to avoid unnecessary colonoscopies in the national screening programme in the Region of Southern Denmark (RSD).

METHODS:
A systematic literature search was performed and the diagnostic sensitivity and specificity for polyps of I) all sizes, II) ≥6mm. and III) ≥10mm was determined by subsequent meta-analyses of results from the included studies. The economic consequence was based on results from the meta-analysis, registries and resource consumption in 2016. Sensitivity analyses were performed by adjusting equipment price and thresholds for colonoscopies.
RESULTS:
The literature search yielded 15 studies regarding sensitivity and specificity. The meta-analyses showed sensitivity of CCE compared to colonoscopy of 0.89, 0.87 and 0.86 for polyps in all sizes, ≥10mm. and ≥6mm., respectively, and the specificity was 0.75, 0.95 and 0.82. The total yearly cost of the existing screening programme was 2,864,072€ whereas the price including CCE was 5,690,021€. This would reduce the yearly number of colonoscopies by 1.887 (39% reduction compared to existing programme). The price per avoided colonoscopy was thus 1,498€.

CONCLUSIONS:
Meta-analyses showed acceptable sensitivity and specificity of CCE compared to colonoscopy. Including CCE as a filter test in the national screening programme was more costly, but reduced the yearly number of colonoscopies by 39%.

OP43 Robotic Or Conventional Gait Training Rehabilitation? An HTA Study

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ABSTRACT SUMMARY:
The objective is to gather evidence on overall effectiveness of three alternative technologies for gait rehabilitation in diplegic children suffered from Cerebral Palsy: robotic, conventional and joint conventional and robotic gait training. Despite robotic systems offer many benefits, the joint use of robotic and conventional therapy can produce better clinical outcomes than the separate use of the two rehabilitation techniques.

INTRODUCTION:
The purpose of this study is to gather evidence on safety and overall effectiveness of three alternative technologies for gait rehabilitation in diplegic children suffered from Cerebral Palsy: robotic, conventional and joint conventional and robotic gait training.

METHODS:
A new methodology, Decision-oriented HTA, was applied to assess the technology on clinical, technical, organizational, economic, social and ethical, legal and safety domains. This method, conceived as a hospital-based HTA tool for supporting the introduction of innovative technologies, has been implemented merging the EUnetHTA Core Model® with the Multi-Criteria Decision Analysis. In particular, the general items of the EUnetHTA Core Model® are re-formulated as performance indicators and re-placed along a decision tree structure that, from the one hand, respects the original top-down design of the EUnetHTA model (growing level of detail from domains to issues) and, from the other hand, allows obtaining a quantitative evaluation of each identified performance indicators.

RESULTS:
The multiple indicators, that have been identified for the seven domains, play important and different roles in the alternative technologies evaluation. DoHTA results showed that robotic system offers the possibility to control more accurately the exerted forces and movement trajectories than the traditional therapy. It gives the possibility to measure the task performances parameters and to receive the patient feedback simultaneously. To carry out robotic gait rehabilitation fewer therapists are sufficient compared with the conventional therapy, resulting in lower therapists’ physical workload.
CONCLUSIONS:
Despite the great perspectives that robotic offers to motor rehabilitation, it seems that robotic gait training could not provide greater benefits in terms of motor and functional recovery compared to the conventional therapy. Preliminary results, supported by most recent literature evidences, lead to the hypothesis that joint use of robotic and conventional therapy can produce better clinical outcomes than the separate use of the two rehabilitation techniques.

OP44 Hta Of 3D Videolaparoscopy: Follow Up After 12 Months Its Introduction

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ABSTRACT SUMMARY:
The objective is to evaluate the impact of 3D videolaparoscopy within the hospital setting after 12 months from its implementation at Bambino Gesù Children’s Hospital. Results of the HTA study conducted before the acquisition were compared with the clinical and management data collected after one year of clinical practice. Results confirmed previous HTA results, highlighting clinical advantages identified a priori.

INTRODUCTION:
In 2016 a HTA study was conducted in order to gather evidence on safety and overall effectiveness of performing laparoscopic surgery by using 3D videolaparoscopy (3DVL) versus 2D videolaparoscopy (2DVL) display systems in a variety of pediatric surgical procedures in order to efficiently support the final investment decision on video system to be acquired. Results showed that 3DVL might be a good alternative to 2DVL. Moreover, sensitivity analysis has also confirmed that the results associated to the best technology (3DVL) are robust; this has led to a confident decision for recommending it in Bambino Gesù Children’s Hospital (OPBG). The objective of this work is to evaluate the impact of 3DVL within the hospital setting after 12 months its introduction in clinical practice.

METHODS:
Decision Oriented Health Technology Assessment method (DoHTA), developed by HTA unit of OPBG, was applied to conduct the assessment; it provided the definition and numerical evaluation of assessment parameters through which it is possible to evaluate the performances of technologies compared. After 12 months the technology’s introduction, a comparison, based on the same assessment parameters, between the previous HTA results and the clinical and management data was carried out. Data from clinical registries concerning duration of intervention, hospital stay, surgery complications and tissue damage, were analyzed. Technical performances were evaluated through users’ surgeons’ interview (dexterity, video quality, surgeon’s comfort). To evaluate the 3DVL impact on waiting lists and operating room productivity, data from hospital management were examined.

RESULTS:
Results confirmed previous HTA results, highlighting clinical advantages identified a priori.

CONCLUSIONS:
This study provided another validation of DoHTA method and confirmed results of HTA process. It highlighted the importance of a HTA process before the acquisition of a technology for which the investment decision is not obvious, because
benefits and drawbacks of the new technology are unclear.

OP45 HTA Of A Pediatric Biplanar Low-dose X-ray Imaging System

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ABSTRACT SUMMARY:
The aim of this study is to conduct an HTA study to assess the actual advantages of an innovative biplanar low-dose X-ray imaging system compared to CT scan for particular spine’s congenital deformities. New system offers relatively low dose of radiation and the possibility of obtaining a 3D reconstruction of the bones under normal weight-bearing conditions.

INTRODUCTION:
Patients with adolescent idiopathic scoliosis frequently receive x-ray imaging at diagnosis and subsequent follow monitoring. To achieve the ALARA concept of radiation dose, a biplanar low-dose X-ray system (BLDS) has been proposed. The aim of the study is to gather evidence on safety, accuracy and overall effectiveness of a BLDS compared with CT scanning, in a pediatric population, in order to support the final decision on possible acquisition of such innovative diagnostic system.

METHODS:
The new method Decision-oriented HTA (DoHTA) was applied to carefully assess the diagnostic technology. It was developed starting from the EUnetHTA Core Model® integrated with the Analytic Hierarchy Process in order to identify all the relevant assessment aspects of the technology involved, identified from scientific literature, experts’ judgments and specific context analysis of Bambino Gesù Children’s Hospital. A weight was associated to each assessment element and the alternatives’ ranking was defined.

RESULTS:
This innovative system provides orthopedic images in standing or sitting position, being able to examine the spine and lower limbs under normal weight-bearing conditions. This system is recommended for particular clinical indications as scoliosis and other congenital deformities of the spine. It is able to acquire simultaneous posteroanterior and lateral images in a single scan without vertical distortion and with lower radiation exposure than CT scanning. 2D images acquired can be combined to obtain a 3D reconstruction scanning based on a semi-automated statistical model.

CONCLUSIONS:
The major advantages of BLDS are the relatively low dose of radiation and the possibility of obtaining a 3D reconstruction of the bones. Our preliminary results show that data on the clinical effectiveness are limited but the technical advancements of BLDS appear promising in terms of patient management and patient health outcomes associated with its use.

OP46 Redefining Youth Mental Health Services For Youths: Evidence-to-Action

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**ABSTRACT SUMMARY:**
Current service organization is not adapted for youths, particularly during transition from adolescence to adulthood. What is the efficacy of specialized youth mental health programs developed to address access, continuity and appropriateness of care issues?

**INTRODUCTION:**
Current organization of mental health services in Canada imposes a rupture during youth transition to adulthood, when severe mental health disorders start appearing. This can have a major impact on youth recovery and social integration. An HTA was initiated to evaluate the efficacy of programs targeting simultaneously adolescents and young adults to support decision making. An interdisciplinary expert committee including researchers, clinicians, managers and patients.

**METHODS:**
A systematic review of systematic reviews was conducted. Four databases were searched (MEDLINE, Embase, ASSIA and CINAHL) between 2000 and 2017. Article selection and quality assessment (ROBIS) were performed using inter rater agreement. To be included, the systematic review had to study specialized models or programs serving both adolescents and young adults. An analytical framework was constructed based on the categorisation of performance measures for early intervention by Addington et al. (2005) and the 5 dimensions of recovery of Whitley & Drake (2010). Group and individual interviews were conducted to collect contextual and experiential data.

**RESULTS:**
1054 references were identified. Following inclusion/exclusion criteria, 5 systematic reviews were selected. The majority of programs identified were developed for early psychosis. This HTA did not identify specialised programs for other types of mental illness or at-risk youth. Evidence for psychosis early intervention is emerging in regards to their efficacy on functional and clinical recovery. However, evidence has yet to be established for their impact on access. Contextual and experiential data from our organisation validated and completed scientific findings. Facilitating and constraining factors to the implementation of person-centred care model and inter-agency collaboration were identified.

**CONCLUSIONS:**
Services targeting at-risk youths should be developed in a continuum of care adapted to clinical stages so that all youths living with a psychological distress can be treated regardless of diagnostic or age. These may draw inspiration from psychosis early intervention models. Recommendations from this HTA are currently being put into action in Montreal West Island.

**OP47 Canadian Weights For The Cancer-specific Utility Instrument, FACT-8D**

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ABSTRACT SUMMARY:
A Canadian utility set for the new cancer-specific utility instrument, the FACT-8D, was obtained. Responses to a discrete choice experiment, described by the FACT-8D dimensions, were subjected to a conditional logistic regression analysis; the largest utility decrements were revealed to be pain and nausea. The inclusion of more cancer-specific dimensions may be more informative for cost-utility analyses for cancer treatments.

INTRODUCTION:
Responses to utility instruments are used to assess cancer patient outcomes. However, the dimensions of these instruments may not be sufficient to capture all the relevant information of the patient’s health. Cancer-specific utilities provide a useful alternative. Under the auspices of the Multi-Attribute Utility in Cancer Consortium, a cancer-specific utility instrument was derived from the FACT-G, a widely used quality of life measure. The new FACT-8D contains eight dimensions: pain, fatigue, nausea, sleep, work, support from family/friends, sadness, and worry health will get worse. The aim of the study was to obtain a Canadian utility set for the FACT-8D.

METHODS:
A discrete choice experiment was administered to a Canadian general population online panel. Respondents provided responses to 16 choice sets. Each choice set consisted of two health states described by the FACT-8D dimensions plus an attribute representing duration of survival. Responses were analyzed using a conditional logit model. The results were converted into utility decrements by evaluating the marginal rate of substitution between each level of the FACT-8D dimensions with respect to duration.

RESULTS:
2,228 individuals were recruited: 1,582 completed at least one choice set and 1,501 completed all choice sets. After constraining to ensure monotonicity in the utility function, the largest decrements were for the highest levels of pain (-0.39), nausea (-0.29), support from family/friends (-0.22), and work (-0.21). The decrements of the remaining dimensions ranged from -0.11 to -0.16 for their highest levels. The utility of the worst possible health state was defined as -0.64, which is considerably worse than dead.

CONCLUSIONS:
The largest impact on utility for respondents from the general population was for generic dimensions (e.g., pain and support). However, nausea also had a significant negative impact on utility. This suggests that the inclusion of more cancer-specific dimensions may be more informative for cost-utility analyses for cancer treatments.

OP48 A Contextual Model For Evaluating The Value Of Multi-Indication Drugs

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ABSTRACT SUMMARY:
An increasing number of anti-cancer medications are indicated for multiple tumors. We present a holistic framework that considers the value of multiple indications together at a product level. Application of this approach is illustrated via an example across multiple indications for a novel, targeted anti-cancer therapy (pembrolizumab) in Canada.
INTRODUCTION:
An increasing number of anti-cancer medications are indicated for multiple tumors. Existing pharmacoeconomic evaluations routinely examine the cost-effectiveness (CE) and budget impact (BI) of such drugs by indication, as and when each indication is reviewed. The impact of indication-specific conclusions on the holistic value of such medications across all indicated patients is not currently evaluated, yet is important to stakeholders including HTA agencies, payers and patients. We introduce a holistic framework that considers the value of multiple indications together at a product level. Application of this approach is illustrated via an example across multiple indications for a novel, targeted anti-cancer therapy (pembrolizumab) in Canada.

METHODS:
Previously-HTA-evaluated indication-specific CE and BI models serve as the foundation for this multi-indication model. Comparing to standard of care (SoC) per indication, the model evaluates the potential BI, clinical outcomes and CE of pembrolizumab among the individual indications along with the overall multi-indication patient population from the perspective of a third-party payer. For the contextual model, incremental costs and QALYs were weighted using indication populations derived from national incidence rates.

RESULTS:
The indication-specific incremental cost-effectiveness ratios (ICER) from CE analyses of ipilimumab-treated advanced melanoma, ipilimumab-naïve advanced melanoma, 2L NSCLC, 1L NSCLC and 4L cHL range from $52K to $163K per QALY. Accounting for the relative contributions of the various sizes of indication-specific patient populations results in an overall ICER for pembrolizumab vs. SoC of $100K.

CONCLUSIONS:
A holistic model can provide stakeholders with a tool to evaluate the overall value of multi-indication drugs. Results enable an understanding of the outcomes and economic consequences of treatment with pembrolizumab versus SoC by both individual indications and across all indications. Insights from this contextual approach will enable data from less-developed clinical trials to be considered when previously they might have gone unevaluated by decision-makers.

OP49 An Alternative Cost-effectiveness Model For Health Technology Delivery

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ABSTRACT SUMMARY:
This presentation will share the Alberta experience of using health technology assessment methods to improve health system value by determining the best strategies for delivering endovascular therapy for acute ischemic stroke. Capacity issues and challenges associated with optimal implementation strategies for the best use of existing treatments will also be discussed.

INTRODUCTION:
The cost-effectiveness of endovascular therapy (EVT) compared to tissue plasminogen activator (tPA) alone for acute ischemic stroke (AIS) has been established in the literature. However, decision-makers still face challenges of how to best deliver EVT
in a timely manner to maximize patient outcomes while minimizing the burden to the healthcare system, given that AIS has time-dependent treatment outcomes. The objective of this presentation is to report an optimization approach for improving health system value and outcomes for patients with AIS who are eligible for EVT in Alberta.

**METHODS:**

An economic model was developed to compare combinations of “mothership” (transport directly to a comprehensive stroke center [CSC] to receive tPA and EVT) and “drip-and-ship” (transport to a primary stroke centre to receive tPA, followed by transport to a CSC to receive EVT) methods across Alberta. The model considered geographical variation and searched for the best delivery methods through a pairwise comparison of all possible strategies, factoring in controlled variables including population densities, disease epidemiology, time/distance to hospitals, available medical services, treatment eligibility and efficacy, and costs. Patient outcomes were measured by functional independence. The model defined optimal strategies by identifying the transport methods that produced the highest probability of improved health outcomes at the lowest cost.

**RESULTS:**

The analysis produced an optimization map showing optimal strategies for EVT delivery. The lifetime cost per patient and likelihood of good outcomes was $291,769 and 41.82% when considering optimal clinical outcomes, and $288,025 and 41.74% when considering optimal economic efficiency.

**CONCLUSIONS:**

Our model reduces the gap that exists between health technology implementation and cost-effectiveness analysis, namely that neither fully addresses relative efficiency driven by geographical variations, which may mislead regarding system value in our setting. Implementation strategies generated in our model capture full values in terms of patient outcomes and costs.

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**OP50 Mapping A National Longitudinal Survey To The EQ-5D-3L For HTA**

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**ABSTRACT SUMMARY:**

The aim of this study is to generate a mapping algorithm between the Irish Longitudinal Study on Aging and the EQ-5D in cardiovascular disease. This will allow the temporal change in utility values to be incorporated into HTAs. To our knowledge this is the first-time mapping is being undertaken between a national longitudinal study and the EQ-5D.

**INTRODUCTION:**

The Irish Longitudinal study on Aging (TILDA) collects demographic, health, economic and social care information on more than 8,000 participants ≥50 years in Ireland, over eight years. While the EQ-5D was not collected in TILDA, detailed information was collected on each of its domains. The aim of this study is to generate a mapping algorithm between TILDA and the EQ-5D for patients with cardiovascular disease. To our knowledge this is the first attempt to map between a national longitudinal study and the EQ-5D.

**METHODS:**

Eligible patients were identified through chart review of patients attending consultant led out-patient appointments in a tertiary teaching hospital. Patients were ≥50 years, had a history of ischaemic CV disease and were able to self-report their quality of life. Consenting patients completed the EQ-5D-3L and a subset of questions from TILDA. The EQ-5D was scored using the English
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3L value set. Numerous statistical model types and covariates were explored. The preferred model was chosen based on statistical fit, predictive power and parsimony. The planned sample size was 200.

RESULTS:
A preliminary analysis was conducted on the first 50 eligible patients. The utility score was regressed on responses to TILDA questions using ordinary least squares linear regression. Coefficients for emotional/mental health, pain, limitations due to health problems, difficulty walking and difficulty bathing were included. The adjusted Rsquared was 68%. Data collection is ongoing. Results will be finalised prior to presentation.

CONCLUSIONS:
Preliminary analysis suggests that mapping between a national longitudinal survey and the EQ-5D is a possible method of generating utility values for HTA. Mapping from TILDA will allow temporal changes in utility values to be incorporated into HTAs. The examination of the relationship between utility values and the wealth of other data available in TILDA will also be possible.

OP51 Copulas in Cost-effectiveness Analysis Using Patient-level Data

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ABSTRACT SUMMARY:
Copula methods have been proposed as a way of modeling dependence between random variables. Given that cost and effectiveness are often related to each other and therefore they show statistical dependence, the use of copulas to handle uncertainty caused by sampling variation could be potentially useful when cost-effectiveness analyses are performed using patient-level data.

INTRODUCTION:
Copula methods have been proposed as a way of modeling dependence between random variables because it lies in the flexibility of the assumption on marginals. As previous authors stated, “A copula is a function which joins or “couples” a multivariate distribution function to its one-dimensional marginal distribution functions. The objective of this study was to empirically compare various copula distributions with two traditional methods, namely, the bootstrapping approach and the Bayesian approach assuming that incremental cost and life-years gained are bivariate normally distributed.

METHODS:
The patient-level data from a previously published observational study were analyzed using four copula distributions: independent, Farlie-Gumbel-Morgenstern (FGM), Frank and Clayton copulas. Using the results from the traditional methods previously published, models were compared in terms of incremental cost, incremental LYs gained and the cost-effectiveness acceptability curves (CEACs) based on the net monetary benefit (NMB).

RESULTS:
The most pronounced impact was the improvement in precision given that the confidence intervals were so much narrower for the copulas methods in comparison to the traditional methods. Consequently, the probability of being optimal derived from the Frank and Clayton copulas were close to 1.0 at a willingness to pay of CA$20,000.

CONCLUSIONS:
The results of this study demonstrate the potential impact and importance of copulas in patient-level cost-effectiveness analysis. This approach could be
particularly important in those situations where the
data suggests some kind of dependence and some
restrictions on the marginals, as observed in our
case study.

**OP52 Variation In The Implementation Of The State-transition Model In HTA**

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**ABSTRACT SUMMARY:**
In the absence of guidance, there is variation in
the implementation of the state-transition model
in HTA when estimating time spent in health
states for cancer interventions in the advanced/
metastatic setting. In addition, competing risks
are treated differently compared with the more
formal multi-state approach. Differences in model
implementation may impact on model predictions
and may lead to inconsistent decision-making.

**INTRODUCTION:**
Health economic models of cancer therapies in
the advanced/metastatic cancer setting typically
share the same structure, with three health states;
(i) progression-free; (ii) progressed disease, and (iii)
death. The time spent in these health states is weighted
according to health-related quality of life associated
with each state to estimate quality-adjusted life years
(QALYs) gained. There is variation in the way the state
transition model (STM) approach is implemented.

**METHODS:**
A review of all STM used within NICE technology
appraisals of cancer interventions in the advanced/
metastatic setting published in the last 10 years
(Oct 2007 – 2017) was conducted. The methods
identified were then implemented in a number of
datasets and compared against a more formal
multi-state model approach, which appropriately
accounts for competing risks.

**RESULTS:**
The majority of models included in the review
modelled progression-free survival (PFS) as a
single composite endpoint, accounting for the
two competing events (i.e. disease progression
and pre-progression mortality). Instead of
explicitly modelling the transitions between the
two competing risks, PFS was used directly and
extrapolated beyond the trial duration. Events in
PFS were then separated into progression or pre-
progression death using three broad approaches:
(a) assuming a proportion of PFS events are deaths;
(b) assuming a constant probability of dying in PFS
calculated from the number of deaths divided by
PFS time, or (c) assuming a probability of dying
in PFS based on the pre-progression survival
curve. Predictions produced using these different
approaches were relatively similar to those provided
by the more formal multi-state model (whereby
PFS is not used directly but estimated from the two
competing transitions) when transitions followed
an exponential distribution. However, larger
differences were observed when transitions varied
with time.

**CONCLUSIONS:**
This study emphasises the need for guidance when
constructing STMs to avoid inconsistent model
predictions and inappropriate decision-making.
OP53 Comparing Approaches To Univariate Sensitivity Analysis

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ABSTRACT SUMMARY:
The inclusion of univariate sensitivity analyses to explore the influence of different parameters on the model results is standard practice. However, there are different approaches to doing univariate analyses. We show that different methods generate different results, and address different but equally relevant questions.

INTRODUCTION:
Fully probabilistic analyses are now standard for economic models, with all parameters varied according to probability distributions. Univariate sensitivity analyses to explore the influence of different parameters on the model results are also standard. There are several approaches available, with little discussion of the merits of each or justification for the method used in any given analysis. The aim of this study was to compare three approaches to univariate sensitivity analysis using a case study.

METHODS:
We considered three univariate sensitivity analysis approaches: set one parameter at its upper and lower bounds while all others are set at their mean value; analysis of variance; and set one parameter at its mean while varying all others. We compared the approaches using an economic model of mechanical thrombectomy for the treatment of acute ischaemic stroke, considering outcomes of incremental costs, incremental quality-adjusted life years (QALYs), and net monetary benefit (NMB).

RESULTS:
For incremental costs and QALYS, the correlation between the approaches was moderate to high, with correlation coefficients between 0.46 and 0.94. For NMB the correlation between approaches was high (range 0.89 to 0.98), but some of the most influential parameters were ranked differently. Setting one parameter at its upper and lower bounds is the only method that facilitates considering direction of influence.

CONCLUSIONS:
The three approaches compared address different but relevant questions. Setting individual parameters at their bounds is effectively a systematic scenario analysis, and may be misleading to decision makers. Analysis of variance may be more simply interpreted but has disadvantages. Setting a parameter at its mean while varying other parameters bears similarity to value of information analysis. As with any sensitivity analysis, it is imperative that the uncertainty associated with each parameter is adequately captured in the model.

OP54 Strategic Behavior And The Cost-effectiveness Threshold

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Under existing supply-side theory, the cost-effectiveness threshold (λ) reflects the incremental cost-effectiveness ratio (ICER) of displaced health programmes (k). This paper advances this theoretical model to incorporate strategic behavior, demonstrating that improved population health
outcomes arise when $\lambda$ is set below $k$. This has important implications for decision making and empirical research into estimating the threshold.

**INTRODUCTION:**

In a health care system with a constrained budget, funding new health technologies displaces other services and results in health losses for other patients. Under existing theory, the cost-effectiveness threshold ($\lambda$) is set equal to the incremental cost-effectiveness ratio (ICER) of these displaced services ($k$). This paper advances existing theory to incorporate strategic behavior, demonstrating that $\lambda$ should be set below $k$.

**METHODS:**

The existing theoretical model was extended by incorporating the following assumptions:

1. The threshold is publicly stated and fixed while numerous technologies are appraised;
2. Manufacturers are strategic and ‘price to the threshold’, resulting in ICERs equal to $\lambda$;
3. Each manufacturer has a minimum ‘reserve price’, and hence ‘reserve ICER’, needed to supply the technology; 4. Some reserve ICERs lie below $k$.

**RESULTS:**

The optimal $\lambda$ is between zero and $k$. If $\lambda$ is zero, no new technologies are funded, resulting in no net population health benefit. If $\lambda$ is equal to $k$, manufacturers strategically price so the ICER equals $k$; health gains are exactly offset by health losses, such that net population health benefit is again zero. If $\lambda$ is between zero and $k$, each funded technology has positive net population health benefit. Within this region, any marginal increase in $\lambda$ has two counteracting effects: 1. Manufacturers whose reserve ICERs are now met will supply their technologies, increasing net population health benefit; 2. Manufacturers whose reserve ICERs were already met with the lower $\lambda$ will strategically raise prices, reducing net population health benefit. At the optimal $\lambda$, these two effects counteract exactly.

**CONCLUSIONS:**

When strategic behavior is considered, the optimal $\lambda$ lies below $k$. This results in improved population health outcomes compared to using the threshold implied by existing theory. This has important implications for decision making and empirical research into estimating the threshold.

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**OP55 Does Transient Anxiety Negate The Benefit Of Aneurysm Screening?**

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**ABSTRACT SUMMARY:**

Screening for abdominal aortic aneurysm has been adopted in the UK as cost effective, based upon large randomized studies. However, current models do not account for any utility decrement associated with temporary or ongoing anxiety caused by screening or surveillance. Current evidence cannot exclude an effect on HRQoL that would be sufficient to negate the benefits of screening.

**INTRODUCTION:**

Screening for abdominal aortic aneurysm is available for men aged 65 in the UK. Analysis based on large RCTs has shown it to be cost effective, but there have been changes in prevalence, treatment methods and costs since these studies, and previous analyses did not account for any disutility associated with screening. This paper considers the potential impact of anxiety on the cost effectiveness of the current NHS screening programme.
METHODS:
The cost effectiveness of the current UK aneurysm screening programme was considered in terms of net health benefit (NHB) at the current NHS willingness-to-pay threshold of £20,000 per Quality Adjusted Life Year (QALY). The level of disutility associated with ‘slight anxiety’ was obtained from published tariffs for EuroQol (EQ-5D-5L) and compared to the results of published studies of disutility associated with aneurysm screening. The minimum duration of such an effect of screening that would be required to negate the benefit was calculated.

RESULTS:
The NHB of the current screening programme is approximately 0.0044 QALY. Based upon the minimum utility decrement of 0.078 from methods for deriving utility from the EuroQol (EQ-5D-5L), a response reporting ‘slight anxiety’ as the only abnormality (i.e. health state 11112 vs. state 11111), this would equate to approximately 21 days of slight anxiety. Although there have been some studies evaluating the impact of screening on HRQoL that have shown no detrimental effect, none has been powered to demonstrate this level of short-term disutility.

CONCLUSIONS:
Based upon current methodology a short-lived period of anxiety associated with aneurysm screening would negate the estimated benefit of screening. Further studies are required that are sufficiently sensitive to detect such an effect, and to evaluate whether a strictly utilitarian approach, based upon cost-per-QALY, is in keeping with societal preferences regarding such screening decisions.

OP56 Rehabilitation Of Memory In Brain Injury: A Cost-utility Analysis

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ABSTRACT SUMMARY:
People with traumatic brain injuries (TBIs) commonly report memory impairments. Within the Rehabilitation of Memory in Brain Injury trial, a cost-effectiveness analysis examined the costs and effects of a group memory rehabilitation program for people with TBI. Our cost-utility analysis indicates that memory rehabilitation was cheaper but less effective than usual care but these findings were subject to considerable uncertainty.

INTRODUCTION:
People with traumatic brain injuries (TBIs) commonly report memory impairments which are persistent, debilitating, and reduce quality of life. As part of the Rehabilitation of Memory in Brain Injury trial, a cost-effectiveness analysis was undertaken to examine the comparative costs and effects of a group memory rehabilitation program for people with TBI.

METHODS:
Individual-level cost and outcome data were collected. Patients were randomized to usual care (n=157) or usual care plus memory rehabilitation (n=171). The primary outcome for the economic analysis was the EuroQol-5D quality of life score at 12-months. A UK NHS costing perspective was used. Missing data was addressed by multiple imputation. One-way sensitivity analyses examined the impact of varying different parameters, and the
impact of available cases, on base case findings whilst non-parametric bootstrapping examined joint uncertainty.

RESULTS:
At 12-months, the intervention was GBP 26.89 (USD 35.76) (se 249.15) cheaper than usual care; but this difference was statistically non-significant (p=0.914). At 12-months, a QALY loss of -0.007 was observed in the intervention group confidence interval (95% CI: -0.025 - 0.012) and a QALY gain seen in the usual care group 0.004 (95% CI: -0.017 – 0.025). This difference was not statistically significant (p=0.442). The base case analysis gave an ICER of GBP 2,445 reflecting that the intervention was less effective and less costly compared to usual care. Sensitivity analyses illustrated considerable uncertainty. When joint uncertainty was examined, the probability of the intervention being cost-effective at a willingness-to-pay threshold of GBP 20,000 per QALY gain was 29 percent and 24 percent at GBP 30,000.

CONCLUSIONS:
Our cost-utility analysis indicates that memory rehabilitation was cheaper but less effective than usual care but these findings must be interpreted in the light of small statistically non–significant differences and considerable uncertainty was evident. The ReMemBrIn intervention is unlikely to be considered cost-effective for people with TBI.

OP57 Removal Of IM3Ms Vs Watchful Waiting: A Cost-effectiveness Analysis

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ABSTRACT SUMMARY:
The evidence comparing the prophylactic removal of impacted mandibular third molars (IM3Ms) versus watchful waiting is very limited. However, results from our de novo economic model suggest that prophylactic removal may be the more cost-effective strategy with incremental cost-effectiveness ratios (ICERs) per quality adjusted life year (QALY) gained being consistently <£20,000.

INTRODUCTION:
Treatment options for people with impacted mandibular third molars (IM3Ms) include either removal or retention with standard care (watchful waiting). We appraised the comparative cost-effectiveness of these two strategies in a population with pathology-free or trouble-free IM3Ms.

METHODS:
We constructed an economic model with a time horizon of 50 years. Costs and quality adjusted life years (QALYs) were considered from the perspective of the United Kingdom (UK) National Health Service and discounted at an annual rate of 3.5%. The model pathways, and the assumptions underpinning the model, were determined through consultation with clinical experts and reviews of the clinical and economic literature. Clinical evidence was mainly extracted from published cohort studies undertaken in Scotland and Wales.

RESULTS:
Our model estimated the incremental cost-effectiveness ratio (ICER) per QALY gained for the comparison of prophylactic removal versus watchful waiting to be £11,741 per QALY gained for people aged 20 with asymptomatic IM3Ms. The incremental cost per person associated with prophylactic extraction was £55.71 with an incremental QALY gain of 0.005 per person. With such a small difference in costs, the level of
confidence in the utilities associated with each of the strategies gains importance. Although direct utility evidence around IM3M symptoms was lacking, suitable proxies were found and the cost-effectiveness results were robust across a range of values.

**CONCLUSIONS:**

Results from cohort studies suggest that, under the current Scottish Intercollegiate Guidelines Network and National Institute for Health and Care Excellence guidelines for watchful waiting, extraction rates for IM3Ms in the UK could be as high as 5.7% per year, meaning that the majority of people with IM3Ms will have the impacted tooth removed at some point. Given the complications that can arise with IM3Ms, our results suggest that prophylactic removal may be the more cost-effective strategy with ICERs per QALY gained being consistently £20,000.

**INTRODUCTION:**

Peripheral arterial disease (PAD) is a common condition, in which atheroma in the arteries restricts blood supply to the leg muscles. Detecting PAD early gives the opportunity to try and control associated vascular risk factors. To assess the expected costs and health outcomes associated with two alternative methods for detecting PAD, a decision modelling exercise was conducted.

**METHODS:**

A short-term model was developed to estimate the costs and diagnostic outcomes associated with introducing multisite photoplethysmography (MPPG) technology for the diagnosis of PAD in a primary care setting, compared with the current ankle-brachial pressure index (ABPI) method. A longer-term Markov cohort model, developed using best practice methods, also assessed expected costs and health outcomes over the patient lifetime, based on the short-term diagnostic results. The models were populated using a combination of evidence from the literature and expert clinical input, and results were presented from a NHS and personal social services perspective.

**RESULTS:**

The short-term model indicates that MPPG is £7 less costly per patient than ABPI. Sensitivity analysis indicates that an increase in the uptake of PAD testing in primary care with MPPG has the potential to lead to significant increased cost savings. Sensitivity analysis also shows that increased uptake, and better test performance, leads to improved outcomes with MPPG. The long-term model results suggest that improving diagnostic outcomes (increasing numbers of true positive and true negative identifications) leads to a reduction estimate the expected costs and health outcomes associated with introducing a new diagnostic test into primary care for the diagnosis of PAD. Cost-savings and improved health outcomes were demonstrated.

**OP58 Methods To Detect Peripheral Arterial Disease: An Economic Evaluation**

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**ABSTRACT SUMMARY:**
Peripheral arterial disease (PAD) is a common condition, in which atheroma in the arteries restricts blood supply to the leg muscles. Two individual economic models were developed to estimate the expected costs and health outcomes associated with introducing a new diagnostic test into primary care for the diagnosis of PAD. Cost-savings and improved health outcomes were demonstrated.
in the number of adverse cardiovascular events (MI & stroke) experienced, and is cost-saving over the lifetime of the patient.

CONCLUSIONS:
Detecting PAD in primary care is currently challenging. Improving the tests available in this setting will improve outcomes and, with an appropriate test, reduce costs. The MPPG technology has the potential capability to realise this need.

OP59 New Diagnostic Technologies? Markov Model Favours Ultrasound Post EVAR

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ABSTRACT SUMMARY:
Following endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm patients require long-term surveillance to detect complications. Computed tomography angiography (CTA) involves radiation exposure and risks contrast-induced nephropathy. Colour-duplex ultrasound (CDU) and more recently contrast-enhanced ultrasound (CEU) are proposed as acceptable, safer alternatives to CTA. The relative efficiency of surveillance strategies using CDU, CEU or CTA was assessed.

INTRODUCTION:
Following endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm patients require long-term surveillance imaging to detect complications. Computed tomography angiography (CTA), traditionally advocated after EVAR, involves repeated radiation exposure and risks contrast-induced nephropathy. Colour-duplex ultrasound (CDU) is proposed as an acceptable, safer alternative. Recently, contrast-enhanced ultrasound (CEU), a dynamic ultrasound examination utilising microbubble contrast, has been also suggested. The cost-effectiveness of surveillance strategies after EVAR using CDU or CEU were compared with CTA.

METHODS:
A Markov model (74 year-old cohort, lifetime horizon) with five strategies was generated: 1. annual CTA, 2. annual CDU, 3. annual CEU, 4. CDU and CTA at 1 year, followed by annual CDU, 5. CEU and CTA at 1 year, followed by annual CEU. Data to populate the model were obtained from systematic and structured reviews. UK NHS and Personal Social Services perspective was adopted. Costs (2015-16 prices) and EQ-5D based quality-adjusted life years (QALYs) were discounted at 3.5%. Deterministic and probabilistic sensitivity analyses were performed.

RESULTS:
CDU had the lowest expected cost (£3,791), followed by CTA (£3,828), and CEU (£4,709). CTA was dominated by CDU. Addition of CTA to CDU was not worthwhile. CEU-based strategies yielded the highest expected QALYs (6.559 and 6.560) but the incremental cost per QALY was too high (over £30,000). At willingness to pay per additional QALY up to £50,000, CDU had over 58% probability of being cost-effective, while CTA and CEU up to 42% and 4.1%, respectively. CEU strategy became cost-effective if high sensitivity and specificity rates were assumed (close to 1), for a cost-difference with CDU below £55, or for high complication incidence rates.

CONCLUSIONS:
CDU appears to be the most cost-effective option. CEU strategies produce higher QALYs but are more
expensive and might be cost-effective for higher risk patients only. Further research should consider risk-based surveillance.

**OP60 Optimising Risk-Based Screening: The Case Of Diabetic Eye Disease**

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**ABSTRACT SUMMARY:**
Eligibility for national screening programmes can be personalised according to individual risk in order to improve outcomes and reduce costs. Existing methods of economic evaluation can be adapted to identify risk thresholds and help optimise services. We describe the development of a decision model used to evaluate the cost-effectiveness of risk-based screening for diabetic retinopathy.

**INTRODUCTION:**
There is growing evidence that many people attending annual screening for diabetic retinopathy in the UK are at low risk of developing the disease. This has led to new policy statements. However, the basis on which to establish a risk-based individualised variable-recall screening programme has not yet been determined. We present a methodology for using information on an individual’s risk factors to improve the allocation of resources within a screening programme.

**METHODS:**
We developed a patient-level state-transition model to evaluate the cost-effectiveness of risk-based screening for diabetic retinopathy in the UK. The model incorporated a recently developed risk calculation engine that predicts an individual’s risk of disease onset, and allocated individuals to alternative screening recall periods according to this level of risk. Using the findings, we demonstrate a means of estimating i) a threshold level of risk, above which individuals should be invited to screening, and ii) the optimum screening recall period for an individual, based on the expected cost-effectiveness of screening and treatment.

**RESULTS:**
The cost-effectiveness analysis demonstrated that standardised screening (current practice) is the least cost-effective programme. Individualised screening can improve outcomes at a reduced cost. We found it feasible – though computationally expensive – to incorporate a risk calculation engine into a decision model in Microsoft Excel. In an optimised screening programme, the majority or patients would be invited to attend screening at least two years after a negative screening result.

**CONCLUSIONS:**
Individualised risk-based screening is likely to be cost-effective in the context of diabetic eye disease in the UK. It is expected that risk calculation engines will be developed in other disease areas in the future, and used to allocate screening and treatment at the individual level. It is important that researchers develop robust methods for combining risk calculation engines into decision analytic models and health technology assessment more broadly.
OP61 Net Value Of Treating Hepatitis C With Newly Available DAAs

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ABSTRACT SUMMARY:
This study uses an earnings-based cost-of-illness approach to estimate the net value conferred by a novel direct-acting antiviral treatment for hepatitis C in India. Results indicate that earnings preserved would exceed cost of treatment for non-cirrhotic and compensated cirrhotic hepatitis C carriers but not for decompensated cirrhotic individuals.

INTRODUCTION:
Recently developed direct-acting antiviral (DAA) treatments for HCV have been ground-breaking for their high efficacy across disease genotype and lack of severe side effects. This study uses a cost-of-illness (COI) approach to estimate the net value conferred by one of these novel drug combinations, sofosbuvir and velpatasir (SOF/VEL), recently licensed for generic manufacture in India.

METHODS:
This study considers COI from lifetime earnings lost due to disability and premature death from HCV infection. Risk of death and disability in future years is calculated using a Markov state-transition model with parameters determined from the literature. The future earnings of sampled patients are predicted using an empirical earnings model with coefficients determined from India Human Development Survey data. Costs to both the patient and secondarily-infected individuals are considered.

RESULTS:
Preliminary results suggest that curing individuals diagnosed with chronic HCV in India would preserve 37,45,803 INR in earnings per person. For non-cirrhotic (NC) and compensated cirrhotic (CC) individuals, the expected benefits associated with prevented secondary infections are worth between 1% and 41% of the value of benefits conferred to the diagnosed individual (depending on sex and extent of liver damage). Treating decompensated cirrhotic (DC) individuals with DAAs alone offers minimal earnings benefits because these individuals will likely remain disabled and unable to work without liver transplantation. Expected net benefits of treatment are substantial for NC and CC patients (ranging from 6,40,349 INR for NC women to 1,06,80,848 INR for CC men). The cost of treatment for DC individuals exceeds the expected earnings benefits.

CONCLUSIONS:
For average NC and CC individuals, the cost of treatment with Velpanat is offset by the benefits of increased future productivity. Increased earnings are not sufficient to offset cost of treatment for DC individuals but treatment may still be justified on the basis of the intrinsic value of health improvements and other treatment benefits.

OP62 Economic Evaluation Of A Provincial Back Care Pathway

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ABSTRACT SUMMARY:
We implemented and evaluated a Provincial Care pathway for early assessment and triage of
patients with back pain to determine if costs and quality differed using alternative care providers (i.e. physiotherapists/chiropractors) and models of care (i.e. primary/secondary/tertiary). Care models that used alternative care providers who have expertise in management of musculoskeletal disorders, specifically the spine, were more cost effective.

**CONCLUSIONS:**
New models of care that use the skills of physiotherapists and chiropractors to assess and triage patients with back pain adjacent to emergency departments and in the primary care sector are cost effective compared to the traditional physician-led models. The overarching intent is to use these data to enable evidence-informed policy and practice changes so that more appropriate and cost-effective care is provided to patients with back pain.

**METHODS:**
We evaluated the outcomes and cost of implementing a provincial care pathway for early assessment of patients with back pain at the 3 sites: (1) adjacent to an emergency department in a Community Hospital, (2) co-located with an orthopaedic surgeon’s clinic in a hospital, and (3) in a primary care network (PCN) with private practice physiotherapists and chiropractors. Time-Driven Activity Based Costing (TDABC) in combination with discrete event simulation was used to estimate costs.

**RESULTS:**
Costs were significantly less in the models that used hospital-based physiotherapists and in the PCN model that used private practice physiotherapists and chiropractors to triage patients. These costs ranged from $20 to manage patients identified to have low severity of back pain to $175-$200 for those with moderate to severe back pain. Models that implemented the care pathway using family physicians and surgeons to review non-surgical patients were more expensive at $339 and $514, respectively.

**OP63 Developing Australia’s Streamlined Approach to Assessing Genomic Testing**

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**ABSTRACT SUMMARY:**
There is an urgent need to develop the health technology assessment of genomic testing applications. This presentation outlines Australia’s experience with developing a Clinical Utility Card Proforma to focus and streamline the presentation of the necessary information. It builds on a pilot study in breast and/or ovarian cancer, with emphasis on a test panel incorporating BRCA1 and BRCA2.

**INTRODUCTION:**
The Medical Services Advisory Committee (MSAC) is Australia’s national health technology assessment (HTA) agency for pathology services. MSAC has developed a streamlined framework to
help appraise the health and economic value of genomic testing by enabling the assessment of testing groups of genes as well as individual genes. A recent international landscape study supports this development, showing that few genomic testing evaluation frameworks exist, and even fewer extend to the full scope of a standard HTA.

METHODS:
MSAC facilitated this development through a pilot study in breast and ovarian cancer, which evaluated specified genomic testing, including for BRCA1 and BRCA2 mutations. The pilot was successful, resulting in support for reimbursement, which was implemented in November 2017.

RESULTS:
Several key features have emerged in the resulting Clinical Utility Card (CUC) Proforma. • It relies on identifying discrete clinical contexts of affected individuals for which identifying heritable genetic abnormalities has important implications for optimising clinical management and improving health outcomes – and thus in which one or more genomic test options might have value. • It informs the consequential question of whether to also implement cascade testing of family members of those affected individuals in whom an actionable genetic mutation is detected. • For both these populations, it requests quantifiable information on both clinical validity and clinical utility using standard time-dependant metrics such as hazard ratios, relative risks and odds ratios. • This facilitates the generation of an integrated economic evaluation to help inform the decision of whether to support diagnostic genomic testing in the population of affected individuals and the possible consequential decision of whether to also support cascade testing.

CONCLUSIONS:
The CUC Proforma succinctly presents the essential information for the HTA of genomic testing. It is now being adopted for other clinical contexts such as Alport syndrome and childhood syndromes.

OP64 Review Of Economic Evaluations Of Next-Generation Precision Oncology

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ABSTRACT SUMMARY:
Our study explores the availability and scope of economic evaluations of next-generation sequencing in precision oncology. We determine which next-generation sequencing technologies have been formally evaluated in a clinical setting, review past methodologies, and identify gaps where economic evidence is of low quality or missing altogether.

INTRODUCTION:
Proponents of precision oncology report that genomic testing has the potential to reduce health system costs and improve patient health. Yet, testing also involves significant expenditures that challenge the sustainability of adopting technologies into routine practice. Our study explores the availability and scope of economic evaluations of precision oncology informed by next-generation sequencing (NGS).

METHODS:
We searched Medline (PubMed), Embase (Ovid), and Web of Science databases for English-language full-text peer reviewed articles published between 2000 and 2016. We focused our search on articles that estimated the benefit of precision oncology in relation to its costs. We excluded studies that did not undertake full economic evaluations or did not focus on NGS. We reviewed all included studies and summarized key methodological and empirical study characteristics.
RESULTS:
Fifty-five economic evaluations met our inclusion criteria. The first study was published in 2005 and the number of published studies increased steadily, from 3 studies between 2005 and 2007 to 26 between 2014 and 2016. Most studies evaluated multiplex panels (86%). Testing was frequently used to diagnose patients (24%) or predict prognosis (67%), rather than identify targeted therapies (7%). Methods varied considerably and cost-effectiveness differed according to test type, test strategy, and cancer type. Deterministic and probabilistic analyses were typically used to characterize uncertainty (92% and 72%).

CONCLUSIONS:
While the availability of economic evidence examining precision oncology increased over time, methods used often did not align with current guidelines. Future evaluations should undertake extensive sensitivity analysis to address all sources of uncertainty associated with rapidly changing NGS technologies. Further, additional research is needed evaluating the cost-effectiveness of more comprehensive next-generation technologies prior to implementing these on a wider scale.

INTRODUCTION:
Technology advances have resulted in cheaper and quicker genomic sequencing (panels, exomes, whole genomes). Uptake into clinical practice has been rapid despite limited consideration of workforce, patient safety, consent, practice standards, guidelines and cost benefit. $150M has been independently allocated to genomic initiatives by Australian state and federal governments that don’t reflect a national approach to genomics.

METHODS:
Modified HS methodology identified issues around genomic sequencing to be considered by governments regarding their support, or otherwise, before appropriate implementation and diffusion into local healthcare systems. A national jurisdictional advisory group was subsequently established that undertook extensive stakeholder consultation across Australia, including written submissions, over a four-month period.

RESULTS:
HS identified that genomic sequencing is diffusing rapidly through the health system and flagged issues of pressing concern, including: workforce requirements; education, training and literacy for the medical workforce and community; infrastructure; data; and ELSI. HealthPACT recommended a national coordinated approach to policy development across jurisdictional boundaries to ensure appropriate adoption of genomics. Stakeholder consultation confirmed overwhelming support for greater national coordination of the application of genomic knowledge in healthcare.
Five strategic priorities were developed to support appropriate integration of genomics into health care for Australians: person-centred approach, workforce, financing, services and data. Three principles underpin strategic priorities: i) application of genomic knowledge is ethically, legally and socially responsible and community trust is promoted; ii) access and equity are promoted for vulnerable populations; and iii) application of genomic knowledge to health care is supported and informed by evidence and research.

CONCLUSIONS:
HS identified significant policy, workforce, funding and sustainability issues already facing state and territory governments that would, in time, face the federal government. The National Health Genomics Policy Framework outlines an agreed high-level national approach to policy, regulatory and investment decision-making for genomics and was approved by all Australian health Ministers in November 2017.

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OP66 Tumour Profiling Tests In Early Breast Cancer: A Systematic Review

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ABSTRACT SUMMARY:
Tumour profiling tests can help to identify whether women with breast cancer need chemotherapy due to their risk of relapse, and some may be able to predict benefit from chemotherapy. We focused on four genetic tests: Oncotype DX (O-DX), MammaPrint (MMP), EndoPredict and Prosigna, and one immunohistochemistry test, IHC4, for the National Institute of Health and Care Excellence.

Tumour profiling tests can help to identify whether women with breast cancer need chemotherapy due to their risk of relapse, and some may be able to predict benefit from chemotherapy. We focused on four genetic tests: Oncotype DX (O-DX), MammaPrint (MMP), EndoPredict and Prosigna, and one immunohistochemistry test, IHC4, for the National Institute of Health and Care Excellence as part of their Diagnostic Appraisal Programme.

METHODS:
A systematic review was undertaken, including searching of nine databases in February 2017 plus other sources including a previous review published in 2013. The review included studies assessing clinical effectiveness of the five tumour profiling tests, with or without clinicopathological factors, to guide decisions about adjuvant chemotherapy in people with ER-positive, HER-2 negative, Stage I-II cancer with 0 to 3 positive lymph nodes. The PROBAST tool and Cochrane risk of bias tools were used to assess risk of bias.

RESULTS:
A total of 153 studies were included; the strength of evidence base for individual tests was varied. Results suggest all tests are prognostic for risk of relapse, though results were more varied in lymph node (LN) positive (+) patients than in LN negative (0) patients. Evidence was limited about whether tests can predict benefit from chemotherapy (available for MMP and O-DX only). Studies that assessed the impact of the tests on clinical decisions indicate that the net change in chemotherapy recommendations or decisions
pre-/post-test ranged from an increase of 1% to a decrease of 23% among UK studies, and a decrease of 0% to 64% across European studies.

CONCLUSIONS:
The studies included in the review suggest that all of the tests can provide prognostic information on the risk of relapse; however results were more varied in LN+ patients than in LN0 patients. There is limited and varying evidence for prediction of chemotherapy benefit.

OP67 Family Effects Of Receiving A Diagnosis From Genome-Wide Sequencing

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ABSTRACT SUMMARY:
This study aims to estimate the effect of obtaining a genetic diagnosis for a child’s condition on caregivers’ wellbeing. Preliminary results from a pre-/post-test survey in a sample of 44 families receiving genome-wide sequencing in British Columbia suggest that obtaining a diagnosis may reduce the impact of caregiving responsibilities on observable elements of caregivers’ lives and improve their mental health.

INTRODUCTION:
Obtaining a genetic diagnosis for a child with an unexplained condition may improve caregivers’ wellbeing by reducing prognostic uncertainty and eliminating the need to manage the child’s diagnostic odyssey. If these spillover effects are not accounted for in economic evaluations of diagnostic genome-wide sequencing (GWS) services, their cost-effectiveness may be underestimated. This study aims to estimate the effect of obtaining a diagnosis on caregiver burden for families enrolled in the CAUSES study, which is evaluating a proposed delivery model for diagnostic GWS in British Columbia, Canada.

METHODS:
One parent of each child enrolled in the CAUSES study was invited to complete a pre-/post-test online survey about 2 weeks after enrollment and 6 months after receiving the GWS results. The Caregiver Burden Scale was used to measure objective burden (the impact of caregiving responsibilities on observable elements of a caregiver’s life) and stress burden (a composite measure of the effects of caregiving on anxiety and depression). Parents also reported their child’s number and type of healthcare system encounters in a 6-month retrospective window. Pre/post means were compared using paired-sample t-tests. The effects of receiving a diagnosis were estimated using longitudinal regression analysis.

RESULTS:
44 parents completed both waves of the survey. 22 families (50%) received a diagnosis. The mean number of diagnosis-related healthcare visits declined from 3.6 pre-test to 1.8 post-test (p=0.004), while the number of non-diagnostic visits remained stable (pre-test=4.1, post-test=4.8, p=0.73). The associations between receiving a diagnosis and change in caregiver burden were not statistically significant, with a decline of 0.28 in objective burden (p=0.15; pre-test mean=3.2) and 0.27 in subjective burden (p=0.13; pre-test mean=3.1), but suggest that a significant effect may emerge once all participating families have been invited to take the pre/post surveys.

CONCLUSIONS:
Obtaining a genetic diagnosis for a child using GWS may reduce caregiver burden.
OP68 Methods For The Economic Evaluation Of Precision Medicine

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ABSTRACT SUMMARY:
We reviewed analytical frameworks valuing heterogeneity in economic evaluation, and considered their potential applications in precision medicine (PM). Five frameworks were identified, each suited to different research questions and settings. Four frameworks explicitly quantify the opportunity cost of ignoring heterogeneity, which is especially important in HTA of PM.

INTRODUCTION:
Methods that accommodate heterogeneity in outcomes are not widely used in economic evaluation. With the growth of precision medicine (PM), where choice of treatment is informed by the molecular characteristics of the patient or disease, we expect to see greater heterogeneity in effectiveness and cost of interventions. Our objective was to compare analytical frameworks for valuing heterogeneity in economic evaluation, and consider their strengths and weaknesses for applications in PM.

METHODS:
We conducted a literature review to identify papers that proposed an analytical framework for economic evaluation of a health intervention, and that placed a value on heterogeneous effects. We compared the frameworks considering the purpose of the analysis, including where in the product lifecycle the framework could be used, the types of PM interventions where the framework could be applied, and its ability to address methodological challenges of evaluating PM.

RESULTS:
Five analytical frameworks were identified: covariate adjustment methods, value of stratification, value of heterogeneity (VoH), expected value of individualized care (EVIC), and loss with respect to efficient diffusion (LED) metrics. Each framework addresses a slightly different research question, and is suited to different settings and interventions. With the exception of covariate adjustment, all focus on maximizing net benefit within certain constraints and quantify the opportunity cost of ignoring heterogeneity. Overall, EVIC is the most flexible but also the most data intensive.

CONCLUSIONS:
The ability to value heterogeneity is a critical component of economic evaluations of PM. The choice of an appropriate analytical framework will help strengthen the quality of economic evidence available to support HTA of PM technologies, informing PM adoption decisions, and supporting efficient allocation of health care resources.

OP69 Bigger-Picture Factors In Health Technology Assessment Of Diagnostics

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ABSTRACT SUMMARY:
NICE Diagnostics Assessment Programme guidance documents were evaluated to assess the “bigger-picture” factors considered during decision making, in addition to cost-effectiveness and
parameter uncertainty. Healthcare provider related factors (e.g., practicality) appeared to dominate the committee discussions for diagnostic technologies with negative recommendations, whereas both societal (e.g., patient preference) and healthcare payer related factors were mentioned in positive recommendations.

INTRODUCTION:
Diagnostic technologies are an integral part of efficient healthcare systems and directly impact patients’ experience of healthcare provision. In the UK, diagnostic technologies are predominantly assessed through cost-utility analyses by the UK National Institute for Health and Care Excellence (NICE) Diagnostics Assessment Programme (DAP), with a typical cost-effectiveness threshold of £20,000–£30,000. The objective of this study was to establish the “bigger-picture” factors also considered by the NICE DAP and to assess the impact of these factors on positive and negative recommendations.

METHODS:
All NICE DAP assessments published before September 2017 were included, and the guidance document and diagnostics assessment report were reviewed. The type of technology, disease area, adoption decision, factors contributing to decision, incremental cost-effectiveness ratio and research recommendations were extracted.

RESULTS:
Based on the 29 DAP assessments reviewed, there were 18 positive, 9 negative and 13 neutral recommendations (insufficient evidence). In addition to cost-effectiveness and parameter uncertainty, non-health related factors were also considered for decision-making and influenced a greater proportion of positive (11/18) versus negative (2/9) recommendations. The “bigger-picture” factors considered included societal factors such as patient preference (5/18 positive), impact on patient anxiety (3/18 positive) and caregiver burden (1/18 positive); and healthcare provider related factors such as implication for resourcing or service provision elsewhere in the UK National Health Service (4/18 positive, 1/9 negative), practicality (2/18 positive, 1/9 negative) and availability of required expertise (1/18 positive, 1/9 negative).

CONCLUSIONS:
Although not a substitute for clinical effectiveness and cost-effectiveness, non-health related societal factors and healthcare provider related factors not captured by the cost-utility analyses are considered by the DAP committee for decision-making. Healthcare provider related factors appeared to dominate the committee discussions for diagnostic technologies with negative recommendations, whereas both societal and healthcare provider related factors were mentioned in positive recommendations.

OP70 Evidence Synthesis With Limited Studies

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ABSTRACT SUMMARY:
A flexible elicitation framework to construct an informative prior distribution for the heterogeneity parameter in a random effect meta-analysis with limited studies

INTRODUCTION:
Pairwise and network meta-analyses using fixed effect and random effects models are commonly applied to synthesise evidence from randomised controlled trials in health technology assessment.
Fixed effect models are often used because there are too few studies with which to estimate the between-study standard deviation from the data alone. When heterogeneity is expected and inferences are required beyond the sample of studies available, then an analysis using a fixed effect model will underestimate uncertainty about the treatment effect. This research aims to provide a Bayesian approach to overcome the problem of too few studies to use a random effects model, by proposing a framework for eliciting an informative prior distribution for the between-study standard deviation in a random effects model to genuinely represent heterogeneity.

METHODS:
We developed an elicitation method using external information such as empirical evidence and experts' beliefs on the ‘range’ of treatment effects in order to infer the prior distribution for the between-study standard deviation. We also developed the method to be implemented in R.

RESULTS:
The three-stage elicitation approach allows uncertainty to be represented by a genuine prior distribution to avoid making misleading inferences. It is flexible to what judgments an expert can provide, and is applicable to all types of outcome measure for which we can construct a treatment effect on an additive scale.

CONCLUSIONS:
The choice between using a fixed effect or random effects meta-analysis model depends on the objective of the analysis and knowledge of the included studies, but not on the number of available studies. Our elicitation framework captures external evidence about heterogeneity and overcomes the often implausible assumption that studies are estimating the same treatment effect, thereby improving the quality of inferences in decision making.

OP71 Evidence Grading Systems Used In Health Technology Assessment Practice

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ABSTRACT SUMMARY:
This study originated from discussions on how to translate research findings into conclusions regarding safety and effectiveness in systematic reviews responding to requests from a provincial mechanism for introducing and diffusing publicly funded healthcare technologies. Its objective is to identify prominent and reliable evidence grading systems used in health technology assessment practice to assess quality of bodies of evidence.

INTRODUCTION:
To facilitate moving from research findings to conclusions when conducting systematic reviews (SRs) and health technology assessments (HTAs), evidence grading systems (EGSs) have been developed to assess quality of bodies of evidence and communicate (un)certainty about effects of evaluated technologies. Use of EGSs has become an essential step in conducting SRs and HTAs and those relying on review conclusions should be aware of EGSs’ potential limitations.

METHODS:
This study aims to identify EGS used in SR and HTA practice and summarize findings on their inter-rater reliability (IRR). Relevant sources were searched to identify EGSs used in recently published SRs and IRR studies of available EGSs. Members of the International Network of Agencies for Health
Technology Assessment were surveyed regarding their current approaches.

RESULTS:
Preliminary results indicate that only two conceptually similar EGSs, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and the Agency for Healthcare Research and Quality Evidence-based Practice Center Program (AHRQ-EPC) approaches, are currently used by several organization in SR and HTA practice. Both emphasize a structured and transparent method. However, results from published IRR studies suggest there is a risk for variability in their application due to researchers’ diverse levels of training and experience in using them and to the complexity and heterogeneity of evidence in SRs.

CONCLUSIONS:
Validated EGSs can play a critical role in whether and how research findings eventually are translated into practice. However, our results indicate a low level of uptake of EGSs in HTA practice. Both currently used EGSs are susceptible to misuse that allows different researchers to grade differently the same body of evidence and their performance has not been robustly explored in terms of IRR. If these results stand up to replication, one cannot rely on conclusions of published SRs, which has implications for the decisions they inform.

ABSTRACT SUMMARY:
Although individual patient data meta-analysis (IPD MA) is considered the gold standard of systematic reviews, it is not frequently included in health technology assessments (HTAs), or conducted by HTA researchers. This presentation describes our first experience with including an IPD MA in a HTA report and discusses its added value for informing an evidence-based decision-making process.

INTRODUCTION:
Although individual patient data meta-analysis (IPD MA) is considered the gold standard of systematic reviews (SRs), a recent International Network of Agencies for Health Technology Assessment (INAHTA) survey indicates that IPD MA is not frequently included in a health technology assessment (HTA), or conducted by HTA researchers. The objective of this presentation is to describe our first experience with including an IPD MA in a HTA report, discuss the added value for an evidence-based decision-making process, and advocate for expanding work in this field.

METHODS:
An overview of SRs on endovascular therapy for acute ischemic stroke included one IPD MA and six study-level SRs/MAs. Methodological quality was appraised by two reviewers independently using the tool recommended by the Cochrane IPD MA working group for the IPD MA, and the AMSTAR (A measurement tool to assess systematic reviews) for the study-level reviews. Pooled results from subgroup analyses based on access to primary patient data were compared to those reported in SRs that conducted subgroup analyses based on the published data to identify patients or clinical factors that would impact clinical outcomes.

RESULTS:
The overall findings were similar between the IPD MA and other SRs/MAs. However, when compared to aggregated data used in study-level SRs/MAs, subgroup analyses based on patient data allowed for adjustment of confounders, multiple categories

OP72 Added Value Of Using Individual Patient Data Meta-analysis

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within a subgroup, standardization of outcomes across trials, and detailed data checking. Larger sample sizes of each pre-defined subgroup permitted for more precise estimates of treatment effects. A number of methodological issues in the IPD MA were identified; particularly, no assessment of risk of bias of included trials was conducted.

CONCLUSIONS:
Access to original patient data is demanding and conducting IPD MA requires extensive resources. The advantages of having an improved quality analysis, an appropriate quantification of the effects in the analyzed subgroups, and precision of results may justify additional efforts, and may increase confidence in the decision-making process.

OP73 Problems And Promises Of Health Technologies: The Merits Of Early HTA

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ABSTRACT SUMMARY:
To inform decisions on development, adoption and/or research, 30 early (constructive) technology assessments of the (potential) value of novel health technologies were performed. Headroom, threshold, scenario, cost-effectiveness, and sensitivity analyses were performed using decision modelling. We will present our experience with performing these early assessments, as well as their feasibility and value in informing decisions.

INTRODUCTION:
Novel health technologies are being developed at a dizzying pace. The need to avoid unnecessary innovations and accelerate the adoption of valuable innovations is among the most important challenges facing healthcare systems today. To contribute to this challenge, we performed 30 so-called ‘early health technology assessments (HTA)’ over the last three years. We quantified the potential value, both in effects and cost. We will present our experience with performing these constructive assessments, as well as their feasibility and value in informing decisions.

METHODS:
We performed secondary analyses on an existing database of 30 assessments. We analyzed the phase of development, stakeholders involved, type of decision informed, and the technology’s next steps.

RESULTS:
Out of the 30 technologies, 4 (13%) were in the idea screening phase, and had not yet started the development. Here, the room for improvement (headroom) was assessed. For 16 (53%) technologies that were under development but not yet studied, we performed headroom and threshold analyses. For the 10 (33%) developed technologies where some (pilot) data were already available, scenario and/or cost-effectiveness analyses were performed. The assessments, that were commissioned by developers, clinicians or hospital managers, informed evidence-based decisions on (further) development, focus, research design or adoption in clinical practice. Preliminary results suggest that after the assessment, decisions were made to stop further development (n=2), continue outside healthcare (n=1), change the target population (n=3) or change the proposed positioning in the care pathway and/or value proposition (n=4).

CONCLUSIONS:
Stakeholders deemed an early, formative assessment useful in informing development,
research and adoption decisions, in different stages of development. Even before developing a technology, headroom analyses appeared to be feasible and useful. Consequences of the assessments mostly related to a shift in focus, which may result in more efficient research and development, as well as more valuable innovations.

OP74 Developing A Tailored Evidence Synthesis Approach for Rare Diseases

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ABSTRACT SUMMARY:
Given the paucity of high-quality evidence, debates about the effectiveness of interventions for rare diseases are common among stakeholders. Using a literature review and focus groups with key rare disease stakeholders we developed a framework to guide evidence synthesis for rare diseases. Expansion of current evidence synthesis practices will improve the quality of decision-making regarding treatments for rare diseases.

INTRODUCTION:
Few randomized controlled trials exist in the context of rare diseases. Given the paucity of high quality evidence, debates about the effectiveness of interventions for rare diseases are common among stakeholders. Our objective is to elaborate on traditional evidence synthesis methods, conceptualizing the scientific value added from alternative study designs (e.g., registry studies, case series), while specifically recognizing sources and risks of bias with each.

METHODS:
We used a literature review and focus groups with key rare disease stakeholders to better understand the perceived challenges in generating and synthesizing treatment effectiveness evidence, and to describe various research methods for mitigating these identified challenges. These data were used to inform the development of a framework to guide evidence synthesis for rare diseases.

RESULTS:
Data from our literature review and focus groups revealed three fundamental challenges in generating robust treatment effectiveness evidence for rare diseases: i) limitations in recruiting a sufficient sample size to achieve planned statistical power; ii) inability to account for clinical heterogeneity and assess treatment effects across clinical spectrum; and iii) reliance on short-term, surrogate outcomes whose clinical relevance is often unclear. Numerous solutions have been described with respect to overcoming these challenges from a research study design perspective. We found little discussion in the literature about evidence synthesis practices specific to rare diseases; however, focus group participants identified several important considerations for evaluation and synthesis of evidence, including: different standards of evidence for incremental versus transformative interventions and for stable versus progressive disease patterns, the importance of understanding natural history, and the importance of addressing patient-oriented outcomes. Framework development is on-going and is expected to be completed in the coming weeks.

CONCLUSIONS:
Expansion of current evidence synthesis practices will improve the quality of decision-making regarding the development, use, and reimbursement of treatments for rare diseases.
OP75 Tailoring Review Methods: Scope, Timescale And Needs Of Commissioners

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ABSTRACT SUMMARY:
We describe approaches for tailoring review methods to best meet commissioner requirements. This includes discussing with commissioners the trade-off between breadth of scope, level of analysis required, and timescales available. Further approaches include refining selection criteria following an initial mapping review, and use of conceptual models to identify areas for focussed review. These approaches are illustrated using case studies.

INTRODUCTION:
Commissioners of systematic reviews have differing requirements in terms of breadth of scope, level of analysis required, and timescales available. Planning a review requires consideration of the trade-off between these elements. This applies to both “rapid” reviews and “traditional” reviews with a broad or complex scope.

METHODS:
Approaches for tailoring review methods to commissioner requirements are described. These will be illustrated via case studies of reviews conducted for the NIHR Health Technology Assessment (HTA) and Health Services & Delivery Research (HS&DR) programmes and other organisations.

RESULTS:
An initial step is to discuss with commissioners the trade-off between timescales/resource available, breadth of review scope, and level of analysis; for example, broad overview of many studies or in-depth analysis of a narrower set. Where the evidence base is unknown, one option is to undertake an initial mapping review to assess the volume and type of evidence available. This may assist in refining the selection criteria for the main review, to prioritise the most relevant evidence. In complex reviews, a further option is to develop a conceptual model (logic mode) with input from commissioners and experts, to help identify factors which may influence outcomes. This can enable design of focussed mini-reviews (not necessarily exhaustive) around each factor. These methodological approaches will be illustrated through three case studies including an HTA on cannabis cessation (trade-off of breadth versus depth); a review of yoga and health (initial mapping to refine selection criteria); and a rapid review of congenital heart disease services (conceptual model to identify areas for focussed reviews).

CONCLUSIONS:
Different approaches may enable discussion with review commissioners around the trade-off between scope, methods and timescales, in order to tailor the review method to best meet commissioner requirements within the timescales available.

OP76 A Tool to Optimize Evidence-Informed Health Systems Guidance: AGREE-HS

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ABSTRACT SUMMARY:
Health systems struggle to use evidence-informed approaches to get the right health technologies to those who need them. A research program was initiated to develop a tool to support the development, reporting, and appraisal of health systems guidance (HSG). Validity and usability testing indicate that AGREE-HS can be used to improve HSG quality and identify high quality HSG for implementation.

INTRODUCTION:
A common challenge across health systems is the appropriate use of evidence in decisions about how to get the right health technologies to those who need them and more generally strengthen health systems. Of key concern is the lack of supporting tools and resources to guide the development and quality appraisal of health systems guidance (HSG) to address challenges related to both implementation strategies and broader health systems governance, financial and delivery arrangements. Using poor quality evidence or ignoring existing high-quality evidence syntheses can lead to decisions that are ineffective, harmful, or use resources inefficiently. To address this problem, we developed a tool to support the development, reporting and appraisal of HSG.

METHODS:
A critical interpretive synthesis was conducted to identify factors related to HSG quality. Based on the results and input from international stakeholders, a draft tool called the Appraisal of Guidelines for Research and Evaluation—Health Systems (AGREE-HS) was developed. A face validity study was conducted to evaluate the tool’s content and structure and the tool was applied to 85 HSG documents to assess its usability and measurement properties.

RESULTS:
Thirty international stakeholders completed the face validity study. Results indicated that the content and structure of the tool were appropriate; most respondents agreed that the AGREE-HS would be useful to guide the development (73%), reporting (70%), and appraisal (90%) of HSG. Ten participants completed the usability survey and provided positive feedback. Initial assessment of AGREE-HS measurement properties indicates strong internal consistency and moderate inter-rater reliability.

CONCLUSIONS:
High quality HSG is key to getting the right health technologies to those who need them and to strong health systems. The AGREE-HS can be used by HSG developers to optimize the quality and implementability of their recommendations and by decision-makers to appraise and select high quality HSG for implementation.

OP77 Conducting Rapid Assessments: Lessons From 25 Years Of Good Practice

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ABSTRACT SUMMARY:
This presentation describes the evolution of rapid assessment (RA) products over a 25-year relationship between a policy maker and an arms-length HTA agency to quantify the effects of this partnership on the RAs produced, and to identify elements
contribution to their relevance and impact, or not. The aim is to contribute to emergent research around methodological approaches to RAs.

**INTRODUCTION:**
The Health Technology Assessment (HTA) Program at the Institute of Health Economics (IHE) has conducted rapid assessments (RAs) for 25 years. The presentation draws on this experience to chart the evolution of RAs over a 25-year relationship between a policy maker and an arms-length HTA agency to quantify the effects of this partnership on the RAs produced.

**METHODS:**
The number, types, and methodological attributes of RAs produced over a 25-year partnership with a single requestor were reviewed. The reasons for developmental changes in RA products over time were charted to document the push-pull tension between requestor needs and HTA best practice. The elements contributing to the relevance and impact, or not, of the RAs were also identified.

**RESULTS:**
Results demonstrated the dynamic relationship required for HTA researchers to meet best practice and requestor needs. As literature search spans lengthened and data analyses became more complex, limitations were imposed on RAs to fulfill the requirements of timeliness, utility, and best practice. Adaptations were driven by requestor, researcher, and the external policy environment. Facilitators of RA utility for HTA requestors include: asking focused, well-articulated questions; specifying the request’s purpose; providing detailed information about local context and other relevant issues; and understanding the risk of bias associated with RAs. Considerations for HTA doers include: assembling a team using a triage process; involving requestors throughout RA development; negotiating deliverables and timelines using a HTA product matrix; transparently reporting methods; narratively describing methodological issues; and internally reviewing the draft RAs.

**CONCLUSIONS:**
RAs are a useful component of HTA programs. To keep these products relevant and useful, HTA agencies must allow RAs to evolve according to need, but with grounding in good practice. Negotiating the line between rigor and relevance is a key skill for HTA agencies. Having the right team is helpful.

**OP78 Code Of Ethics: Missing Cord In The Evidence-To-Action Connection?**

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**ABSTRACT SUMMARY:**
A strong ethical culture will foster the trust of stakeholders, strengthen collaboration, improve implementation of recommendations and benefit society. This is the importance of developing a code of ethics to guide conduct and detail standards of professional practice expected of HTA practitioners affiliated to HTAi and related agencies.

**INTRODUCTION:**
Ethics is a set of moral principles that guide our behavior when it affects others.HTAi acknowledges the fundamental values of "service, collaboration, professionalism and integrity, transparency, accountability". Ethical conduct balances self-interest with consequences of that behavior for others. Unethical behavior has serious personal consequences and in the case of HTA practitioners it can damage stakeholder trust and thereby hinder implementation of evidence by policy makers. Compliance with regulation alone may not suffice in building stakeholder confidence. There is need for individuals and agencies to develop a ‘culture of integrity’ at all levels in the HTA process above and beyond compliance with the law. A strong ethical culture will foster trust of stakeholders,
strengthen collaboration, improve implementation of recommendations and benefit society. This is the importance of developing a code of ethics to guide conduct and detail standards of professional practice expected of HTA practitioners affiliated to HTAi and related agencies.

METHODS:
I will argue for the development of a detailed code of ethics for HTAi and related agencies. To do this, I will explain how the code of ethics gives guidance and informs the users (HTA practitioners), and how they can guide stakeholders in the HTA processes. The public relations benefits of a code of ethics will also be discussed. I will explain why having a mere list of seven words as “values” is not sufficient guidance to professionals with diverse backgrounds who are collaborating in a multidisciplinary team.

RESULTS:
The role of a code of ethics in helping professionals to choose their actions well is an effective way to integrate ethics in HTA, safeguard the integrity of HTA processes, and improve evidence implementation by stakeholders.

CONCLUSIONS:
HTAi should develop a detailed code of ethics for its membership.

OP79 A Meta-framework To Inform Health Inequalities In Systematic Reviews

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ABSTRACT SUMMARY:
Presents a theory-led meta-framework to i) facilitate identification and understanding of when, why and how interventions may impact on socio-economic health inequalities, ii) identify data to extract and inform a priori analysis on what factors are associated with differential effects across socio-economic groups, and iii) help reviewers hypothesise the likely applicability of their review findings across disadvantaged populations.

INTRODUCTION:
Recent equity review guidance encourages reviewers to consider whether it is likely that their findings may impact on health inequalities. Much of the guidance assumes that health inequalities have either already been identified as the focus of the review, or that reviewers are able to recognise if and how health inequalities matter. However, our experience is that this is not necessarily true. Furthermore, theorising if and how health inequalities matter is not normally integrated into the HTA review process. This presentation describes a novel approach to the development of a theory-led meta-framework to inform health inequality considerations in systematic reviews. The meta-framework aims to increase the usefulness of systematic reviews in informing and implementing changes to practice.

METHODS:
Following the best-fit framework synthesis approach, a meta-framework was generated by ‘deconstituting’ concepts from theories relating to complex interventions and socio-economic health inequalities into a single framework. Feedback was sought from health inequality experts and reviewers.

RESULTS:
Complex intervention theories identify four domains and key factors that may influence effectiveness; intervention design, implementation, context and participant response. Applying an equity lens, socio-economic health inequality theories identify key factors and mechanisms associated with these domains that may lead to differential effects across disadvantaged populations.
**CONCLUSIONS:**
The meta-framework has the potential to i) facilitate the identification and understanding of when, why and how interventions may impact on socio-economic health inequalities, ii) promote a theory-led approach to incorporating health inequalities in systematic reviews iii) help reviewers identify data to extract and inform a priori analysis on what factors are associated with differential effects, iv) help reviewers to decide whether it is likely that their review findings may have the potential for an intervention to indirectly widen or narrow socio-economic health inequalities, even when evidence of an impact in the primary research is lacking.

**OP80 Reconciling Ethical And Economic Notions Of ‘Value’ For HTA**

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**ABSTRACT SUMMARY:**
Economic evaluations of morally challenging health technologies often rely on health outcomes of ambiguous social and ethical value. We use the case of non-invasive prenatal testing to explore how a capabilities approach to economic evaluation may be able to reconcile economic and ethical value frameworks, and contribute to holistic policy decision-making by resolving conflicts between ethical and economic analyses.

**INTRODUCTION:**
Different disciplinary frameworks in the field of Health Technology Assessment (HTA) may hold different, and potentially contradictory, assumptions about a technology’s value or optimal use. For example, economic analyses may be based on outcome measures that are socially controversial or ethically problematic. This can result in economic and ethical evaluations that are difficult to reconcile, leaving HTA short of its goal to provide policy decision-makers with a holistic assessment of technology. We use the case of non-invasive prenatal testing (NIPT) to explore whether the capabilities approach can be used to align economic and ethical concepts of value in assessments of morally challenging health technologies. The capabilities approach is an economic framework which bases wellbeing assessments on a person’s abilities, rather than their expressed preferences.

**METHODS:**
To develop concepts for capabilities relevant to NIPT, we started with Nussbaum’s capabilities framework, and conducted a directed qualitative content analysis of interview data from 27 Canadian women with personal experience of this technology.

**RESULTS:**
We found that eight of Nussbaum’s ten capabilities related to options or choices that women valued in the context of NIPT, and identified one new capability, Care Taking. NIPT has a meaningful impact on women’s capabilities, and capabilities concepts can capture the value of NIPT without relying on health outcomes of ambiguous social and ethical value. A capabilities approach may help reconcile ethical and economic value frameworks for NIPT.

**CONCLUSIONS:**
The capabilities approach can contribute to economic evaluations of morally challenging health technologies that better reflect patient preferences and ethical concerns, and may contribute to more holistic HTAs. It provides a framework within which policy analysts from diverse disciplines can communicate about the social and ethical value
of morally challenging health technologies. Future research should focus on operationalizing the capabilities approach for use in evaluations of NIPT and other morally challenging health technologies.

OP81 Identifying Ethical Aspects In Social Services – A Guideline

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ABSTRACT SUMMARY:
The Swedish National HTA-organization, SBU, are responsible for assessments within the social services since 2015. In comparison with health-care, social services have somewhat different ethical values. SBU have developed an adapted guideline for identifying ethical aspects in projects on social services. In the presentation the guideline will be presented and differences in relation to the health-care guideline will be highlighted.

INTRODUCTION:
The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), evaluates since 2015, also the social services. Assessment of ethical aspects of a technology is an important component of health technology assessment (HTA). However, in distinction to the health services where substantial work has been done to present guidelines to identify ethical aspects through the work of Hofmann, EUneHTA and others, no parallel work has been made for the social services. Hence, the need to develop a guideline adapted to the specific ethical values of the social services. In the presentation the guideline will be presented and differences with health-services guidelines will be emphasized.

METHODS:
The guideline was developed based on the SBU framework for systematic identification of ethical aspects of health care technologies. As the legal aspects are central, the intentions and ambitions of the Social Services Law was a point of departure. Furthermore, the guideline was adapted to the particular target groups in the legislation, for which the services have different ethical goals: children and adolescents, people with disabilities, people with drug abuse and elderly people. A pilot review of the guideline has been made by ethicists, and other experts within the field.

RESULTS:
The guideline consists of twelve items with sub-questions, short explanations, and a concluding overall summary. The items are organized into four different themes: the effects of the intervention related to the social services goals, its compatibility with ethical norms/values in the social services, structural factors with ethical implications, and long term ethical consequences of using the intervention.

CONCLUSIONS:
The guideline for identifying ethical aspects of social care technologies or interventions will guide the SBU work process, but also inspire and present insights to the social services and others interested in interventions and ethical aspects.
OP82 Ethical Challenges Related To Engaging Patients And The Public In HTA

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ABSTRACT SUMMARY:
This abstract considers the risk and benefits to patients and members of the public who participate in health technology assessment activities. Drawing on our experience engaging patients in HTA, we provide suggestions for ensuring these activities protect all participants.

INTRODUCTION:
It is widely recognized that the incorporation of patient and public perspectives can enrich health policy decision-making. Methodological and practical advice on engaging patients and the public has proliferated in recent years, with many HTA agencies working to formalize their processes in this area. However, despite growing enthusiasm for patient and public engagement, many ethical issues remain unaddressed including: balancing risks and benefits to participants, recruitment methods, reimbursement for time spent participating, representation, and information disclosure.

METHODS:
In this critical analysis, we draw on our collective experiences engaging with patients and public in the context of HTA. We use principles from two theories, a) research ethics and b) participatory governance, to analyze these challenges. The purpose of this analysis is to explore the ways in which risks and benefits to patient and public participants might be balanced in HTA activities.

RESULTS:
We begin by describing some ethically challenging experiences we have faced when soliciting views and values from patients and members of the public, some anticipated and some unexpected. These challenges include unexpected disclosures of information, navigating power differentials when working with vulnerable populations, eliciting information about potentially traumatizing experiences, and fairly representing controversial and conflicting opinions. We offer examples about what types of patient engagement activities may subject participants to unreasonable risk, and suggest some guiding principles to help plan ethical patient and public engagement activities.

CONCLUSIONS:
Patient and public engagement requires more than just procedural methodological expertise- it also requires the ability to identify and analyze relevant ethical issues. We posit that health technology assessors have a moral obligation to ensure that the risks of patient and public engagement activities do not outweigh the benefits. We call upon the HTA community to engage in thoughtful deliberation about what can be learned from experiences within HTA and in other contexts.

OP83 Thinking Explicitly About Ethical Issues: Lessons From CADTH HTA

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AUTHORS:
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ABSTRACT SUMMARY:
A critical comparison of ethics analyses for four HTAs revealed that an axiological approach helped to spur ethical reflection, but was insufficient for analysis and presentation and that explicit discussion of ethical issues can help to ensure robust deliberation. Ethics analyses create space to challenge underlying assumptions, raise issues about the value of technologies, and help integrate the results.

INTRODUCTION:
While methods for ethics analysis in HTA exist, there have been relatively few applications and assessments of these methods. CADTH began to include an explicit analysis of ethical issues within its HTAs in 2015. To examine some of the differences among ethics analyses, we critically compared the conduct and contribution of the analysis of ethical issues for four CADTH health technology assessments.

METHODS:
Two experts in ethics in HTA examined ethics analyses conducted by CADTH for four technologies: dMMR testing for colorectal cancer, treatments for obstructive sleep apnea, dialysis for end-stage liver disease, and HPV screening for cervical cancer. The methods of analysis and presentation of results, extent to which the ethics analysis was used in committee deliberations was gathered via meeting notes, recommendation documents, and discussion, and were summarized narratively.

RESULTS:
The amount of literature explicitly discussing ethical issues pertaining to particular technologies varied and was not predicted by the age and maturity of a technology. The axiological approach proved a helpful starting point for ethical reflection, but was not sufficient for analysis and presentation. Explicit discussion of ethical issues identified the need for additional information to ensure robust deliberation. Committee members expressed the belief that ethics analysis “brought together” individual sections of the HTA.

CONCLUSIONS:
While many methods exist for ethics analysis, ethics expertise is required to identify and explicitly discuss the complete range of ethical issues relevant to a particular HTA. Ethics analyses create space to challenge assumptions underlying the clinical and economic evidence, raise issues about the value of technologies, and help to integrate the HTA results.

OP84 Professional Ethics At Neonatal Intensive Care Units

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ABSTRACT SUMMARY:
Ethical challenges at the limit of viability (weeks 23 to 24 of gestation) at neonatal intensive care units in Austria stem in uncertainty, best interest, and fairness issues. The presence of moral dilemmas and the role for clinical ethics (and ethics committees) need to be recognized in order to avoid moral distress and improve team cohesion in Austrian NICUs.

INTRODUCTION:
At the backdrop of their particular socio-cultural, religious, and legal context, neonatal intensive care unit (NICU) professionals encounter many ethical challenges especially when it comes to interventions at the limit of viability (weeks 23 to 24 of gestation). We explored the challenges in the Austrian NICU context.

METHODS:
A mixed methods approach was applied. First, a comprehensive systematic literature search was conducted to gather the available evidence.
Secondly, interviews with the heads of the departments for neonatology of five perinatal care centres and a clinical ethicist were conducted to gather data specific to the Austrian neonatal context. Data from the systematic literature search as well as the interviews were analysed separately and subsequently integrated into a literature review.

RESULTS:
Challenges connected to uncertainty, best interest, and fairness were the main sources of moral dilemmas. The main causes of uncertainty were a) the imprecision of baseline and outcome data of extremely premature (EP) babies, b) the lack of empirical data on what it is to live through the experience of active or palliative treatment at NICU, and c) the obscurity of what the right course of action is. Further ethical challenges come in when attempting to discern the fair course of action that is in the best interest of the EP baby. The goal of neonatal medicine is to minimize undertreatment as well as overtreatment and avoid gestational ageism. NICU professionals attempt to save each baby that has reasonable chances for meaningful survival and let go the one that does not in order to prevent unnecessary harm.

CONCLUSIONS:
We concluded that the presence of moral dilemmas as well as the role for clinical ethics (and ethics committees) need to be recognized in order to avoid moral distress and improve team cohesion in Austrian NICUs.

ABSTRACT SUMMARY:
Potential sources of epistemic injustice are identified in evidence-based decision-making processes, as implemented by the National Institute for Health and Care Excellence in the UK. Examples will be given and categorised as relating to processes of generation or interpretation of evidence, or relating to the methods of implementation of decision-making processes.

INTRODUCTION:
Examples of epistemic injustice have been identified in the field of healthcare, including testimonial and hermeneutical injustices and forms of epistemic exclusion. This paper considers potential injustices that may be embodied in current evidence-based practice (EBP) as applied in the decision-making processes of the National Institute for Health and Care Excellence (NICE) in the UK.

METHODS:
Possible injustices in NICE processes were identified through consideration of published guides to methodology, practical examples and personal experience of decision-making committees. Examples were categorised as relating to the generation or interpretation of research evidence, or to the implementation of decision-making processes.

RESULTS:
Potential sources of injustice in the generation of evidence included unwarranted exclusion criteria within randomized controlled trials, mismatch between health needs and research funding and selective reporting of outcome measures. Interpretations that include generalizations, extrapolation or particular perspectives may also produce injustices. Implementation of decisions based upon EBP demonstrate an asymmetry in power and credibility that favours specific commercial, political and academic interests. A particular concern is epistemic exclusion of subgroups, based upon demographic, disease or

OP85 Epistemic Injustices In Evidence-based Healthcare Decision-making

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treatment characteristics. This may particularly occur where such groups are disadvantaged by disinvestment that is a consequence of guidance, but has not been explicitly considered as part of the decision-making process.

CONCLUSIONS:
NICE states that it seeks to achieve distributional justice based upon principles of procedural justice, rather than a strictly utilitarian approach. In practice, many decisions are primarily based upon cost utility analysis, with a willingness-to-pay threshold that is inflated for a variety of considerations relating to additional aspects of utility, egalitarian or other consideration, which may not be considered in relation to disinvestment decisions. This focus on high cost and high technology investment decisions results in potential exacerbation of health inequalities and epistemic exclusion.

INTRODUCTION:
Management of new-onset diabetes is important to achieve metabolic stabilization, minimise acute complications, and to provide insulin therapy, diabetes education and psychological support. A health technology assessment (HTA) was conducted to determine if an outpatient setting could be effective and safe for new-onset diabetes in children, and how it can be implemented in our paediatric center.

METHODS:
A systematic search on initial management (outpatient versus in-hospital) of diabetes in children was performed in multiple databases and grey literature. Practice guidelines (CPGs), systematic reviews (SRs), randomized controlled trials (RCTs) and non-randomized comparative studies (NRCSs) published up to August 2017 were identified. Telephone interviews with key informants from two children’s university teaching hospitals were performed to collect information on outpatient initial management models and issues related to their implementation. An interdisciplinary group of experts from our paediatric center collaborated in this project.

RESULTS:
According to 5 CPGs, hospitalization would not be required for children without acute complications at time of diagnosis or after initial treatment of ketoacidosis if outpatient care facilities, resources, and education are available. Results from one SR and 7 NRCSs suggested that outpatient initial management is associated with good metabolic control (glycated haemoglobin) and is as safe as the inpatient care model, based on rate of hospital admissions, severe hypoglycemia, and ketoacidosis episode. However, few data regarding treatment adherence, knowledge acquisition, and emotional adaptation were identified. Outpatient education programs can be successfully provided on several consecutive or non-consecutive days after diagnosis as reported by two children’s university teaching hospitals.

OP86 Outpatient Initial Management Of New-onset Diabetes In Children

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ABSTRACT SUMMARY:
A hospital-based HTA was performed to evaluate the effectiveness and safety of outpatient initial management of children with new-onset diabetes. Evidence suggested that this service organization model is effective and safe although knowledge regarding psychosocial and behavioral factors and about experiences of children and their parents in the initial management of diabetes should be increased.
CONCLUSIONS:
Although data on effectiveness and safety are scarce and of low-quality, outpatient management of newly diagnosed diabetes, uncomplicated or stabilized, is recommended in children. However, data on children and their families should be collected as part of the implementation evaluation in order to enhance its efficacy and the quality of the patient and families’ experiences.

OP87 Nitrous Oxide As Sedation Regimen In Children - How To Assess Safety?

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ABSTRACT SUMMARY:
We have performed an HTA for nitrous oxide as sedation regimen in children. Our main outcomes were effectiveness and safety. However, one important concern was long-term safety for the health personnel who perform repetitive procedures throughout their career. We here discuss our approach to address this outcome in a systematic way in an HTA otherwise designed for a different population.

INTRODUCTION:
Children who undergo short, painful procedures at hospitals are given different kinds of pain relief (analgesics), often in combination with drugs for relaxation (sedatives). Nitrous oxide (N₂O) is a drug administered for pain relief and relaxation, it is applied by inhalation and its effects are analgesic, anxiolytic and sedative. It is used in several countries, but is not normally used as a sedation method for children in Norwegian hospitals, although widely used in maternity wards during labour. Our aim was to evaluate the effectiveness and safety of this sedation regimen in children. However, we also wanted to assess safety for health Personnel after repetitive or long-term exposure.

METHODS:
We performed a systematic review on effectiveness and safety of nitrous oxide for sedation in children. For evidence on efficacy and safety of the children, only randomized controlled trials (RCT) were included. For safety of health personnel we also accepted other study designs. For all endpoints, we presented the evidence in summary of finding tables.

RESULTS:
We retrieved 22 randomized controlled trials on effect or safety of the children undergoing sedation with nitrous oxide. Effect were hospital procedure satisfaction or characteristics, and pain. Safety was reported as acute adverse events. None of the RCTs reported evidence on safety for health personnel. We are currently exploring different ways to systematically assess safety for health personnel within the form of an HTA otherwise designed for a different population.

CONCLUSIONS:
Assessing safety of new technologies, methods or procedures in HTAs is a crucial point. However, assessing the long-term safety of the health personnel should also be included, but evidence will often not be retrieved through literature search designed for the patient group, and long-term safety data is in general difficult to retrieve for exposure to novel technology. We will discuss our approach to this challenge.
OP88 Reduction Of Biologics In Rheumatoid Arthritis: A Systematic Review

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ABSTRACT SUMMARY:
This systematic review assesses the effectiveness and safety of reducing the dose of biological drugs in patients with rheumatoid arthritis at low disease activity, compared to standard dose treatment. Clinical outcomes data were collected and summarized in meta-analysis of standardized mean difference or relative risk. Most outcomes were non-significant.

INTRODUCTION:
Reduction of biologics after reaching low disease activity rheumatoid arthritis has been tested in clinical trials. The aim of this systematic review is to assess the effectiveness and safety of the reduction of biologics drugs in patients with rheumatoid arthritis in low disease activity.

METHODS:
The protocol of this review is registered at PROSPERO (CRD42017069080). We searched MEDLINE, Embase, Scopus and The Cochrane Library for randomized controlled trials that reduced or spaced the dose of biologics in patients at low disease activity or remission state compared with maintenance. Two researchers selected studies, extracted the data and assessed the risk of bias of the studies. Random effects meta-analyses by DerSimonian & Laird method were calculated considering intention to treat analysis to obtain the standardized mean difference (SMD) or relative risk (RR) and 95% confidence interval (CI). Quality of evidence will be assessed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE).

RESULTS:
From 725 retrieved records, seven studies were included. Compared to regular doses, reduction of biologics significantly increased the health assessment quality (SMD=0.20; 95% CI: 0.04 0.37; I²= 3.5%). No difference was observed for low disease activity (RR=0.83; 95% CI: 0.68, 1.03; I²= 71.3), serious and non-serious adverse events; disease activity scores; patient global assessment and radiographic progression.

CONCLUSIONS:
Preliminary results show no differences in clinically relevant outcomes from reduction of biologics compared to regular doses. As a limited number of studies is available, the certainty of evidence is limited and need to be monitored to better inform patients and clinicians.

OP89 Oral Miltefosine For Cutaneous Leishmaniasis

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ABSTRACT SUMMARY:
The mini-HTA evaluate oral Miltefosine is an efficient and safe alternative for cutaneous leishmaniasis treatment. The results were presented at the National Commission for Technology Incorporation (CONITEC) in October 2016. Regulatory barriers are preventing the inclusion in the Brazilian public system, despite the drug had been authorized for the use in visceral leishmaniasis in dogs.
INTRODUCTION:
Cutaneous leishmaniases is a public health problem in developing countries. For decades, the treatment is managed through intramuscular or intravenous route with a moderate adverse events follow-up. Oral miltefosine is an alternative to populations affected by the disease. Brazilian clinical trials were used for authorization by the Food and Disease Administration (FDA). Therefore, the purpose of this mini-HTA is assess the efficacy of oral miltefosine only or associated with other drugs versus meglumine antimonate.

METHODS:
The mini Health Technology Assessment (mini-HTA) was elaborated based on Brazilian Ministry of Health Guideline. The search was made from August to September, 2015 on MEDLINE, The Cochrane Library, Science Direct and Centre for Reviews and Dissemination databases, using MeSH terms “Leishmaniasis, Cutaneous”, “miltefosine” and “meglumine”.

RESULTS:
From 88 articles, 6 matched the inclusion criteria after reading the full text. The clinical trials showed cure rates in six months ranging from 58.6 to 87.9\% in the miltefosine group, and from 53.3 to 93.7\% in the meglumine group, RR=1.12, (95\% CI: 0.85 – 1.47) favourable to miltefosine. In relation to security, miltefosine showed adverse events of minor severity with gastrointestinal symptoms. Teratogenic effects can be monitored and avoided with contraceptive methods for women with childbearing age with the disease.

CONCLUSIONS:
We recommend the introduction of miltefosine as the first line of treatment. These results were presented at the National Commission for Technology Incorporation (CONITEC) in October 2016. The absence of register in Brazilian regulatory agency (ANVISA) are preventing the inclusion in the health public system, despite the drug had been authorized by the Ministry of Agriculture for the use in visceral leishmaniases in dogs.

OP90 Do Patients With Open Fractures need Urgent Surgery?

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ABSTRACT SUMMARY:
Calling in staff and preparing the operating room for an urgent surgical procedure is a significant draw on hospital resources and disrupts care of other patients. It has been common practice to treat open fractures on an urgent basis. HTA methods can be applied to examine this prioritization of care, just like they can be applied to acquisition of drugs.

INTRODUCTION:
Calling in staff and preparing the operating room for an urgent surgical procedure is a significant draw on hospital resources and disrupts care of other patients. It has been common practice to treat open fractures on an urgent basis. HTA methods can be applied to examine this prioritization of care, just like they can be applied to acquisition of drugs and devices.

METHODS:
Our center completed a rapid systematic review of guidelines, systematic reviews, and primary clinical evidence on urgent surgical debridement and stabilization of open fractures of long bones (‘urgent’ being defined as within 6 hours of the injury) compared to surgical debridement and reduction performed at a later time point. Meta-analyses were performed for infection and non-union outcomes and the GRADE system was
used to assess the strength of evidence for each conclusion.

RESULTS:
We found no published clinical guidelines for the urgency of treating open fractures. A good systematic review on the topic was published in 2012. We found 6 cohort studies published since completion of the earlier review. The summary odds ratio for any infection in patients with later treatment was 0.97 (95% CI 0.78-1.22, 16 studies, 3,615 patients) and for deep or “major” infections was 1.00 (95% CI 0.74-1.34, 9 studies, 2,013 patients). The summary odds ratio of non-union with later treatment was 0.95 (95% CI 0.65-1.41, 6 studies, 1,308 patients). There was no significant heterogeneity in any of the results (I² = 0%) and no apparent trends in the results as a function of study size or publication date. We graded the strength of each of the conclusions as very low, because they were based on cohort studies where the treating physician could elect immediate treatment for patients with severe soft-tissue injuries or patients at risk of complications. This raises the risk of spectrum bias.

CONCLUSIONS:
Default urgent scheduling patients with open fractures for surgical debridement and stabilization does not appear to reduce the risk of infection or fracture non-union. Based on this information, our surgery department managers no longer schedule patients with open fractures for immediate surgery unless there are specific circumstances necessitating it.

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ABSTRACT SUMMARY:
This study compares and discusses results from an IPD meta-analysis vs standard aggregate data meta-analysis of RCTs of exercise cardiac rehabilitation in chronic heart failure. Given the limitations of current trial level meta-analysis, access to individual data from several RCTs offers a timely and important opportunity to revisit the question of which CHF patient subgroups benefit most from exercise-based rehabilitation.

INTRODUCTION:
Traditional meta-analyses synthesise aggregate data obtained from study publications or study authors, such as a treatment effect estimate and its associated uncertainty. An increasingly important approach is the meta-analysis of individual participant data (IPD) where the raw individual-level data are obtained for each study and used for synthesis. This study compares and discusses results from an IPD meta-analysis vs standard meta-analysis of randomized controlled trials of exercise cardiac rehabilitation in chronic heart failure (CHF).

METHODS:
Based on a previous systematic review, the Exercise Training Meta-Analysis of Trials for Chronic Heart Failure (ExTraMATCH II) identified and collected IPD from RCTs that compared exercise rehabilitation with a non-exercise control and a minimum follow-up of 6 months. For this abstract, the outcome of interest was all-cause mortality. Original IPD were checked for consistency and compiled in a master dataset. Standard meta-analytic models were used for aggregate data whilst two-stage and one-
stage approaches, accounting for the clustering of participants within studies, were planned for statistical analyses of IPD.

RESULTS:
Overall 33 RCTs were included in the original systematic review, whereas within the ExTraMatch II project, IPD on all-cause mortality were obtained from 17 RCTs in approximately 3,700 patients. From aggregate data there was no significant difference in pooled mortality (RR 0.92, 95%CI 0.67 to 1.26). IPD analysis revealed 701 events across exercise and control group. Our ongoing IPD analyses will allow us to examine how patients’ characteristics (e.g. age, NYHA class, ejection fraction) modify treatment benefit.

CONCLUSIONS:
Given the limitations of current trial level meta-analysis evidence in CHF, access to individual data from several RCTs offers a timely and important opportunity to revisit the question of which CHF patient subgroups benefit most from exercise-based rehabilitation.

OP92 Non-Opioid Therapy For Pain Management – HTA In A Time Of Crisis

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ABSTRACT SUMMARY:
Guidelines recommend optimizing non-opioid alternatives for pain management, before a trial of opioids. However, these guidelines do not provide evidence on the effectiveness of non-opioid alternatives, thus leaving a gap for those attempting to put the recommendation into practice. This presentation will discuss the role of HTA to fill the evidence gaps, and help put evidence into action.

INTRODUCTION:
North America is facing a public health epidemic – the opioid crisis, part of which, is attributed to the inappropriate use of opioids in pain management. As such, the 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain recommends optimizing non-opioid pharmacotherapy or non-pharmacological therapy to treat chronic pain, before a trial of opioids. However, the Guideline itself is not designed to provide evidence on the effectiveness of these non-opioid alternatives, leaving a gap for those attempting to put the recommendation into practice.

METHODS:
In collaboration with its partners, including clinicians and policymakers, the Canadian Agency for Drugs and Technologies (CADTH) identified the gaps in evidence and developed an action plan to bridge the evidence gaps to support the optimization of non-opioid alternatives in pain management.

RESULTS:
Since the release of the Guideline, CADTH produced over 20 Rapid Response reports that synthesize and appraise evidence on non-opioid alternatives in the management of a wide range of pain, both acute and chronic. Additionally, CADTH has also reviewed evidence on multidisciplinary pain treatment programs, and is developing environmental scan reports on the availability and access to non-pharmacological treatments for pain in Canada, and on drugs for emerging non-opioid pain. Further, CADTH developed knowledge mobilization tools based on the evidence reviews. The evidence reviews and tools are used as a resource by CADTH partners, including the Coalition of Safe and Effective Pain Management and McMaster University National Pain Center.
CONCLUSIONS:
This presentation will discuss the role of HTA and CADTH to fill the gaps in evidence for a crucial clinical practice guideline recommendation in a time of public health crisis, and help put the evidence into action. It will present the evidence synthesized by CADTH on various non-opioid alternatives for pain management, while highlighting the remaining gaps in evidence. Understanding the evidence on non-opioid alternatives will inform clinical and policy decisions and potentially reduce inappropriate use of opioids in pain management.

INTRODUCTION:
A large number of randomised controlled trials (RCTs) have been conducted to assess the effects of surgical interventions for the treatment of women with stress urinary incontinence (SUI). The aim of this study was to gather all available evidence on the clinical effectiveness and safety of all relevant surgical interventions for SUI.

METHODS:
RCTs were identified from existing Cochrane systematic reviews and literature searches based on the Cochrane Incontinence Group Specialised Trials Register. Eight surgical interventions were assessed. Primary outcomes (cure rate and improvement rate at 12 months) were assessed by means of a network-meta analysis (NMA). Data on adverse events were collected and analysed using pair-wise meta-analyses. Risk of bias was assessed using the Cochrane risk-of-bias tool.

RESULTS:
The NMA included 121 RCTs (105 for cure; 64 for improvement). Some of the included trials had small sample sizes, short follow-up periods and high or unclear risk of bias for most domains. The NMA results indicate that traditional sling and retropubic mid-urethral slings (MUS) were more likely to resolve incontinence symptoms. The surface under the cumulative ranking curves confirmed this with traditional sling and retropubic MUS being the most likely treatments to result in the highest proportion of women cured (89.4% and 89.1%, respectively), while transobturator MUS, retropubic MUS and anterior repair showed the highest proportion of women with an improvement in SUI symptoms (85.5%, 83.1%, 72.1%, respectively). However, the credible intervals around the estimated odds ratios from the NMA showed some degree of uncertainty. Data for adverse events were limited and provided little evidence of a difference between interventions.

CONCLUSIONS:
Retropubic MUS and transobturator MUS, across all the available interventions, appear to be most
OP94 Prioritization Of Outcomes In Health Technology Assessment

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ABSTRACT SUMMARY:
The selection and prioritization of outcomes is often conducted by HTA authors or clinicians; a standardized approach to involve patients has not been established so far. We analyzed to what extent the preferences for hemodialysis-related outcomes differed between various stakeholders in the treatment of chronic kidney disease. A transparent discussion on important outcomes considering all stakeholder preferences should be contemplated.

INTRODUCTION:
In Health Technology Assessment (HTA) the effects on patient-relevant outcomes are used to evaluate the benefits and harms of medical interventions. The selection and prioritization of outcomes is often conducted by HTA authors or clinicians; patient involvement is often postulated, but no standardized approach has been established so far. We analyzed (i) which methods to prioritize outcomes exists and (ii) to what extent the preferences for hemodialysis-related outcomes differed between various stakeholders in the treatment of chronic kidney disease.

METHODS:
(i) A descriptive review was performed to identify studies assessing preferences for outcomes in health conditions. A standardized data extraction was performed and study characteristics between prioritization methods were compared. (ii) We compared preferences of stakeholders involved in outcome prioritization (patients from a self-help group, clinicians and HTA authors) with those of a large reference group of hemodialysis patients. All groups assessed the importance of 23 outcomes by means of a discrete visual analog scale. We used descriptive statistics to rank outcomes and compare the results between groups.

RESULTS:
(i) The methods identified were aligned into three method groups: multi criteria decision analysis, rating or ranking and utility eliciting. The number of outcomes assessed by method group varied. (ii) We received questionnaires from 49 self-help group patients, 19 nephrologists, 18 HTA authors and 4518 hemodialysis patients. Only three outcomes were ranked within the top 7 outcomes by all four groups: safety, health related quality of life and emotional state. The ratings by HTA authors and the large patient group showed the least concordance.

CONCLUSIONS:
A dominant method most suitable for utilization in evidence syntheses was not identified. Preferences of stakeholders differ to a varying extent from those of a large reference group of hemodialysis patients. A transparent discussion on important outcomes considering all stakeholder preferences should be contemplated.
**OP95 Are Patient-Reported Outcome Measures Meeting Today’s Standards?**

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**ABSTRACT SUMMARY:**
This review examines the pedigree of a sample of patient-reported outcome (PRO) measures used as primary or secondary endpoints in trials and discussed in Food and Drug Administration approved product labels between 2003 and 2014. The author’s found that PROs can provide patient-centered data useful for health technology assessment, however, patient-reported information is not inherently patient-centered.

**INTRODUCTION:**
Over the past decade, health technology assessment (HTA) agencies have become interested in improving the patient-centeredness of their assessments. A common approach has been to prioritize patient-reported outcomes (PROs), often describing PROs as patient-relevant or patient-oriented. However, it is often unclear whether and to what degree PRO measures (PROMs) truly reflect what is important to patients. This review examined the pedigree of a sample of measures used as primary or secondary endpoints in trials and discussed in Food and Drug Administration (FDA) approved product labels between 2003 and 2014.

**METHODS:**
We examined all 26 PROs included in chapters 1 (Office of Microbial Products) and 2 (Office of Drug Evaluation I) of the FDA’s Pilot Clinical Outcome Assessment (COA) Compendium. Three reviewers independently searched PubMed and Google to identify publications or other relevant materials related to method and stage of measure development where patient engagement took place.

**RESULTS:**
Among 26 evaluated PROMs, we were unable to locate any information on development or validation for 12 (patient diary=9; rating scale=3). Among the remaining 14 PROMs, 5 did not include any evidence of patient engagement (questionnaire=1; patient diary=2; rating scale=2); 3 engaged patients during concept elicitation or psychometric validation only (disease-specific questionnaires=3); and 6 engaged patients during both concept elicitation and cognitive interviewing (disease-specific questionnaires=6). PROMs either previously qualified or submitted for qualification by FDA were more likely to include patient engagement.

**CONCLUSIONS:**
PROs can provide patient-centered data useful for HTA, however, patient-reported information is not inherently patient-centered. This study found that only a minority of sampled PROMs engaged patients during both concept elicitation and cognitive interviewing. To facilitate patient-centered HTA, manufacturers should ensure that PROMs incorporated into clinical trials measure concepts important to patients. Similarly, HTAs should request data on development and validation of all outcome measures incorporated into trials.

**OP96 Standardising PREMs Collection To Drive Service Improvement In Wales**

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ABSTRACT SUMMARY:
Working with patient groups we developed a universal set of PREMs questions for use across Wales. We will invite patients using secondary care services to complete these and patient outcome surveys via an electronic platform. Standardised collection of experience data will allow us to benchmark and target service improvement initiatives. Triangulation with outcome data will support the prudent healthcare.

INTRODUCTION:
Co-production relates to patients and health professionals working in equal partnership with shared decision-making. Patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) are increasingly being used to involve patients and measure quality. We set out to develop a set of universal experience questions for use across Wales. These will be used in various settings including on the National electronic PROMs and PREMs platform which is already collecting outcome data across Wales with over 7,000 responses received to date.

METHODS:
Patient experience leads and clinical leads were invited to a workshop to discuss standardised PREMs collection in Wales, with all health boards and trusts represented. It was agreed that quantitative patient experience data collection while limited, would be a pragmatic way to collect responses from a large cohort. It was agreed a previously developed set of PREMs questions could be adapted to provide a set appropriate for use in all Healthcare settings. Patient focus groups were held and the number of questions reduced to those the patients thought were most important. Wording was improved and an additional question added.

RESULTS:
Working with stakeholders we have developed and agreed a set of Universal PREMs questions. These have been added to the National electronic platform with collection commencing imminently. This will allow patients accessing secondary care in Wales to provide PREMs and PROMs responses.

CONCLUSIONS:
Development of a standardised set of PREMs has allowed us to initiate collection on a National basis. Addition of PREMs to the electronic platform provides a unique means of collecting large volumes of data consistently to allow us to benchmark across and within organisations. It will allow experience teams to target improvement initiatives and identify good practice. Together with outcomes responses, data will be used to measure experience of care with in Wales.

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OP97 Digital Home Services: Overcoming Critical Barrier In Early Decision Making

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ABSTRACT SUMMARY:
There is a lack of adoption and diffusion of health innovations needed to drive the implementation of important breakthroughs in value-based health care. To stimulate organizational changes, decision-makers need to see potential benefit at an early stage. The aim of this study was to assess the potential effects of digital home-based care and compared to current care.
INTRODUCTION:
There is a lack of adoption and diffusion of health innovations needed to drive the implementation of important breakthroughs in value-based health care. To stimulate organizational changes, decision-makers need to see potential benefit at an early stage. The aim of the present study was to assess the potential effects of a conceptualized intention to provide digital home-based care and compare it to the current provision of such care. The new intervention aims to strengthen the municipality’s care services by offering a digital communication platform to recipients of home-based health services and their dependents. The platform is designed to be implemented nationally and is in line with home service needs identified in several white papers.

METHODS:
An interdisciplinary team united to determine and quantify potential effects of the project. Effects of the digitalised service were distinguished in priced quantitative, unpriced quantitative and qualitative effects. A 10-year present value calculation with a calculation rate of 4% was used for the estimates. A risk analysis was also carried out.

RESULTS:
The present value calculation resulted in estimated savings equal to 1 649 000 euro, with present value investments costs of 53 000 euro over 10 years. This resulted in net present value per invested euro in the public sector equal to 3 euro. Overall assessment of uncertainty related to the intervention’s socio-economic profitability was deemed average. Based on data quantified estimates from the conceptual phase, the project succeeded in the decision-making and funding needed to proceed into the next developmental phase of the project.

CONCLUSIONS:
The present approach to early assessment may provide much desired decision support in an early innovation phase when data is still missing. Our experience is that early stakeholder involvement and the early assessment and quantification of value gains is of utmost importance to overcome the critical barriers to organization health innovations.

OP98 Assessment Of Mobile Health Apps In Hospitals

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ABSTRACT SUMMARY:
A generic tool for fast-track assessment of mobile health apps, including collection of user experiences and analysis of system log data, was developed and tested to ensure high user satisfaction, continuous development and successful implementation in hospitals. Preliminary results show that the tool is easy to use, relevant and applicable in a busy clinical setting.

INTRODUCTION:
Increasingly mobile health apps are used to improve the delivery of healthcare, target communication between patients and healthcare professionals (HCPs) and ensure the active involvement of patients. To provide high satisfaction among patients and HCPs and to ensure optimal content and implementation of mobile health apps, continuous assessment is needed. The aim was to develop and test a generic tool for fast-track assessment of mobile health apps in hospitals.

METHODS:
A scoping review of literature published in English from 2007-2017 on how to assess mobile health apps was carried out. Assessment of the literature
was performed by two reviewers independent of each other, and the results constituted the basis for the tool. The tool was tested in three clinical departments (obstetrics, endocrinology, respiratory medicine) working with apps and subsequently adapted according to the results.

RESULTS:
5122 articles were identified and screened. The review process resulted in a total of 22 relevant articles covering methods used and topics included in the assessment of health apps. Few validated instruments were found. Based on the literature, the tool contains: • A guide on how to carry out a fast-track assessment in hospitals • A 40-item questionnaire covering patients experiences • An interview guide covering HCPs experiences • Suggestions for use and analysis of system log data Preliminary results show that the tool is easy to use and gives valuable information about the use and implementation of the apps and the satisfaction of users, concerning for example content, features and technical stability (n = 12 HCPs and 287 patients).

CONCLUSIONS:
A tool for fast-track assessment of mobile health apps, including collection of user experiences and analysis of system log data, was developed to ensure continuous development and implementation in hospitals. Further testing is needed, but preliminary results suggest that it is easy to use, relevant and applicable in a clinical setting.

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ABSTRACT SUMMARY:
While mHealth has been rapidly becoming the emerging and promising solution for its use in the health system in Vietnam, availability of mHealth-related published information remains scarce and scattered, specifically on the continuity and expansion of mHealth interventions. This study assessed the factors that hindered the sustainability of recent mHealth initiatives in Vietnam.

INTRODUCTION:
In the recent years, mHealth has been quickly becoming the emerging and possible solution in Vietnam where the health system is poor and health service provision is inadequate. Nevertheless, there is limited published information describing to what extent the sustainability of such mHealth solutions has been confronted in the Vietnamese context. This study reviewed the available projects and interventions to evaluate the factors that challenge the sustainability of mHealth initiatives in Vietnam.

METHODS:
Multimodal scoping study was designed to collect information data from various sources: published literature, government reports, unpublished literature, conference presentations, online documents, and key informant interviews. Relevant mHealth initiatives were identified and selected through electronic searches and informal discussions with key stakeholders. Collected data was charted and classified by thematic analysis. Challenges of the sustainability of mHealth were discussed by the utilization of the strengths, weaknesses, opportunities, and threats (SWOT) techniques.
RESULTS:
Nineteen mHealth initiatives with relevant information and available data were collected, covering the period from 2010 to 2017. Fourteen (74%) were primarily funded by external donors, one (5%) was government supported, and four (21%) were self-funded projects. Five (26%) were on-going, and fourteen (74%) were completed at the time of data collection. Four (21%) out of the completed initiatives were continuing to use materials, infrastructure, and technology to engage end-users.

CONCLUSIONS:
Lack of government’s intention, no electronic medical record standardization, no legislation relating to mHealth, in combination with complicated governmental procedures and bureaucracy, and particularly high percentage of external funding are among the biggest challenges to mHealth interventions and projects in Vietnam. It is crucial for project managers of future mHealth initiatives to build strong relationships with the Vietnam government and advocate for their mHealth initiatives in order to promote sustainability.

OP100 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 overall performance of EHR implementation at Bambino Gesù Children’s Hospital by applying the DoHTA method. 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.

INTRODUCTION:
The adoption of electronic health record (EHR), which contain large volumes of aggregated longitudinal clinical data, guarantees substantial benefits, including a better care, improved safety issue and decreased clinical risks. However, it is also associated with significant costs and large technical and organizational impacts. For these reasons, it is important to conduct a comprehensive evaluation of health care delivery outcomes. The purpose of the study is to gather evidence on safety and overall effectiveness of EHR implementation at Bambino Gesù Children’s Hospital.

METHODS:
Decision-oriented HTA method was applied to assess the technology on clinical, technical, organizational, economic, legal, ethical and safety domains. It is a new implementation of the 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, to each of which was attributed a weight proportional to the impact that this criterion provides to achieve the purpose of the decision problem. Finally, the alternatives’ ranking was defined. A subgroup of these indicators has been included in a checklist form for the evaluation of six EHR implementation projects. This checklist was used as a tool by each involved professional during demo sessions.

RESULTS:
The assessment took into consideration all the recommendations about the benefits and disadvantages of EHR. 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. Its implementation resulted in important organizational outcome such as EHR configuration, learning curve and training; usability was the main technical characteristics of the technology taken into account. Finally, legal aspects on privacy and data security assumed a key role.

CONCLUSIONS:
A detailed technology’s evaluation has permitted hospital’s decision-makers to knowingly assess its introduction in the hospital.

OP101 Hospital-based Health Technology Assessment At UW Medicine

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ABSTRACT SUMMARY:
University of Washington Medicine has developed and implemented a new Health Technology Assessment Program: Smart Innovation. Smart Innovation balances patient outcomes and fiscal impacts to achieve optimal outcomes for patients and the hospital system as a whole. The program replaces a fragmented and inconsistent system with a streamlined and evidence-based process for adopting new medical technologies.

INTRODUCTION:
New medical technologies are an important part of delivering innovative healthcare, however, expanding use of medical technology is a major contributor to rising costs. The increase in medical spend is related to new technologies being rapidly developed, marketed and adopted; and are often incorporated into health systems with little evidence. They also come with higher prices when compared to existing technologies.

METHODS:
We describe how UW Medicine has designed, and developed a new hospital-based health technology assessment (HB-HTA) program, Smart Innovation. Smart Innovation will replace a fragmented and complex set of purchasing and coverage-decision processes. The program will streamline the decision-making process for new medical technologies and balance quick turnaround with rigorous evidence standards. The program is also being developed in collaboration with UW Medicine’s Value Analysis team, an evidence-based purchasing team and MedApproved, a new centralized software program for medical purchasing at UW Medicine.

RESULTS:
Smart Innovation has been reviewing technologies during its first year and has received encouraging results. For example, by adopting a new liver ablation technology, UW Medicine has estimated improved patient outcomes by reducing the number of procedures and adverse events; as well as saving approximately $8,000 per patient. Additionally, The Smart Innovation program has achieved projected cost avoidance from deciding not to adopt uncertain or investigational technologies. For example, by not adopting a new bladder cancer screen, our models indicate UW Medicine will avoid spending $1.5 million per year.

CONCLUSIONS:
Smart Innovation is proving to be an effective program for reviewing and making critical
healthcare policy decisions that is having significant fiscal and patient improvements for UW Medicine. As the program continues to grow and become embedded into UW Medicine, its impacts will become even more valuable and system-wide.

OP102 Multiple Criteria Decision Analysis In The Field Of Hospital-based HTA

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ABSTRACT SUMMARY:
Integration of the principles of Multiple criteria decision analysis (MCDA) in the structure of mini-HTA report gives the opportunity to make comparative assessment of implementing new health technologies based on standardized criteria; determine the priority for implementation of new evaluated health technologies; avoid the influence of subjective factors on the managerial decision-making in hospital.

INTRODUCTION:
One of the main tools for Hospital-Based Health Technology Assessment (HB HTA) is the preparation of a mini-HTA report. Despite the high value of the results of mini-HTA reports for hospital decision-makers, the classical mini-HTA report does not allow direct comparison of several health technologies among themselves.

METHODS:
Based on the analysis of international experience of using the principles of MCDA in the field of HB HTA, we created and approved our own managerial decision-making model which includes five standardized multiple criteria. The value (weight) of each criterion was defined as the arithmetic mean obtained as a result of interviewing hospital decision-makers and HTA expert group.

RESULTS:
Five standardized multiple criteria were included in the structure of mini-HTA report. These criteria present the main results of assessment of the viability of implementing new HTs in hospital practice and contain the following: 1) Novelty/innovation; 2) Comparative clinical effectiveness and safety; 3) Relevance (demand); 4) Economic effectiveness; 5) Payback period. We conducted the modeling of various options of HTA results by using multiple criteria, which allowed us to determine the threshold values of the evaluated health technologies (HTs) corresponding to their priority for implementation: 1) High priority - HTs are recommended for implementation; 2) Medium priority - HTs can be recommended only if there are sufficient financial resources in hospital; 3) Low priority - HTs may be recommended only if there are strong reasons for their need.

CONCLUSIONS:
Integration of the principles of MCDA in the structure of mini-HTA report gives the opportunity to 1) make comparative assessment of implementing new health technologies based on standardized criteria; 2) determine the priority for implementation of new evaluated health technologies; 3) avoid the influence of subjective factors on the managerial decision-making in hospital.
OP103 Early Realistic Assessment Of Technologies In Hospitals (EARTH)

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ABSTRACT SUMMARY:
We propose a model for early assessment in hospitals (EARTH) with the aim of improving hospitals' investment decisions and resource allocation during development of innovative technologies. How a hospital can add rigour to decision making on which technologies to pursue for further development and usual clinical testing is demonstrated.

INTRODUCTION:
Hospitals increasingly make decisions concerning early development of and investment in innovative medical technologies (IMTs) that are not yet ready for usual clinical testing. At present, decisions are often made without applying a formal early assessment process in order to ensure selection of the most promising candidates for further development, thereby avoid misallocating public resources. Examples of IMTs are an app for early discharge postnatally or telemonitoring for patients with diabetic foot ulcers. This study conceptualizes and presents a novel model for EARly Realistic assessment of innovative medical Technologies in Hospitals (EARTH).

METHODS:
The development of EARTH was based on results from a qualitative interview study exploring early assessment models in eleven organisations and a literature review of twenty-four models. The findings, combined with an appraisal of the models holding the most promise for hospital decision makers, led to EARTH.

RESULTS:
Eleven early assessment principles for EARTH were identified and used to create a guideline for performing and organising early assessment. The guideline consists of an analysis track and a decision track supported by three templates. In the analysis track, an impact case, a risk analysis and a “critical questioning” procedure are key elements, while in the decision track, an “evidence threshold” for “go” to usual clinical testing is essential.

CONCLUSIONS:
Based on input from early assessment models in private companies, and with insights from behavioural economics EARTH, a model for early assessment in hospitals, is proposed. EARTH demonstrates how a hospital can add rigour to decision making on which IMTs to pursue for further development and usual clinical testing. EARTH exhibits several desirable features relevant for early assessment, compared to traditional assessment models applied in hospitals today. We thus believe that early assessment carries the promise of improving hospitals’ investment decisions and qualify resource allocation during development.

OP104 Moving Forward Hospital-based HTA: Public Procurement Of Innovation

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ABSTRACT SUMMARY:
Catalan Health Services aims to optimize healthcare services through innovative solutions that encompass both innovative technologies and new processes of care. Answering this aim, the Hospital Clinic of Barcelona is participating in an Innovative Pilot Program to optimize the efficiency in the management of Aortic Valve Stenosis using an adaptation of the methods and knowledge from HB-HTA.

INTRODUCTION:
Innovation procurement is a key enabler to improve the quality and efficiency of public healthcare services driving innovation from demand side to meet concrete public healthcare provider needs. Catalan Health Services (CatSalut) aims to optimize healthcare services through innovative solutions that encompass both innovative technologies and new processes of care. Answering this aim, the Hospital Clinic of Barcelona (HCB) is participating in an Innovative Pilot Program to optimize the efficiency in the management of Aortic Valve Stenosis (AVS) using an adaptation of the methods and knowledge from HB-HTA.

METHODS:
The first step was to identify unmet needs, main bottlenecks and problems in the comprehensive management of AVS (from primary care to hospital discharge). Innovative technologies, solutions and health care organization were proactively scanned through literature review and professional expertise. Lists of solutions were proposed through an inclusive stakeholder participation process.

RESULTS:
A new healthcare model was proposed to be evaluated in the next 3 years based on an integral, transversal and multidisciplinary management of the AVS (named MITMEVA). For each new proposed solution, the management, workstreams, expected impact and key performance indicators (based on stakeholder information demands) were defined. To test the potential of the proposal, a theoretical modeling of the economic, clinical and process impacts of implementation was performed based on available scientific evidence, local professional and economic data. This analysis shows more QALY, less adverse effects and cost with the new proposed model.

CONCLUSIONS:
HB-HTA usually recommends for/against investments. In the era of value based procurement, HB-HTA can also help in developing a PPI project and in testing proactively its potential impact in healthcare, which will be later tested in real life. Therefore, moving ahead HB-HTA to hospital innovative procurement is another way for HTA to push for the implementation and testing of high value innovative technologies.

OP105 Disinvestment Toolkit: Patients Involvement In Disinvestment Activities

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ABSTRACT SUMMARY:
An effort jointly performed by HTAi IG on disinvestment and Early Awareness, EuroScan network and INAHTA is aiming to elaborate a toolkit that could aid organizations and individuals on the steps to be developed when considering disinvestment activities. This chapter refers to patients’ involvement and disinvestment. The whole toolkit will be presented to the society in HTAi 2017 meeting.
INTRODUCTION:
Patients are the people who with their informed consent receive medical interventions. It is important, therefore, that patients have an understanding of interventions and their potential as a treatment for their condition. Patients are becoming more informed about their health care and the treatments that are available to them. At a population level, the potential benefits and harms of treatments need to be regularly assessed. This is part of healthcare decision making at a policy level about what treatments are publically available. As technology develops and old methods are replaced by new and evidence-based interventions and procedures, healthcare payers look to streamline their payment schedules and disinvest in old technologies and procedures. Some users of health care are reluctant to let go of outmoded methods, so disinvestment is best achieved through transparent processes. Successful engagement with key stakeholders of health care, engaging with payers, health service administrators, clinicians and patients, can facilitate implementation of disinvestment processes.

METHODS:
To assist in this process, HTAi Interest Groups and EuroScan have come together to develop the following key points to consider in the involvement and engagement of clinicians, patients, and the public in the disinvestment of services and technologies.

RESULTS:
The best time to involve clinicians and patient representatives is right at the beginning of the process. Clinicians and patients can make valuable contributions as advisory committee members. The disinvestment processes may be led by clinicians, payers, or independent organisations. This will likely influence commitment of clinicians to the process.

CONCLUSIONS:
Broader consultation with clinicians, patients and the public in the development and consideration of draft reports and recommendations can increase the transparency of the disinvestment process. Consultation is an important means of obtaining buy in. Feedback needs to be seen as taken seriously and explanations given for any changes made, or not made to the report and its recommendations.

OP106 Displacement Of Care Due To The Introduction Of Expensive Surgical Interventions

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ABSTRACT SUMMARY:
High-value interventions may be displaced to accommodate the introduction of new technologies. Identifying such displacement effects and studying the underlying mechanisms (the pathway from new technology to opportunity costs) might inform future decision-making. We interviewed 36 stakeholders to study possible displacement effects of introducing three surgical interventions, including robotic surgery, LVAD, and endovascular aneurysm repair into Dutch hospital care.

INTRODUCTION:
In the Netherlands health care is restricted by budgetary limits, necessitating choices in care. Higher value interventions may be displaced to accommodate the introduction of new technologies. Identifying such displacement effects and studying the underlying mechanisms
(the pathway from new technology to opportunity costs) might inform future decision-making.

METHODS:
We developed an analytical framework using desk research and pilot interviews. Thereafter, we applied the framework to study the potential displacement effects of introducing three surgical interventions, including robotic surgery, Left Ventricular Assist Device, and endovascular aneurysm repair into Dutch hospital care. A total of 36 semi-structured interviews were conducted with relevant stakeholders in the hospital field. The interviews covered the introduction process, reimbursement of the technology, challenges in the introduction and decision-making processes, and undesirable outcomes such as rationing and displacement. Finally, we systematically identified relevant themes and topics from the interviews, using Atlas.ti.

RESULTS:
The introduction of the interventions could not causally be linked to displacement of high-value care. Part of this was explained by the Dutch financing system, which is rather complex in order for displacement effects to become clearly visible or traceable. It appeared that in times of budgetary pressure, hospitals primarily reduced accessibility. However, rationing was not directly related to individual technology disinvestment decisions. Rather, we identified several forms of rationing in response to cumulative cost pressures. We found that hospital directors play a central role as they determine the strategic set of investments that may displace potentially higher value care.

CONCLUSIONS:
The opportunity costs of cost-increasing health technologies are not directly visible as displaced care. However, we noticed decreased accessibility to and on occasions lower quality of care. More effort should be taken to prevent displacements effects, for example by fostering transparency of spending decisions. This could eventually lead to more legitimate decision-making.

OP107 The Stakeholders Involvement Strategy Of The Horizon Scanning In Korea

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ABSTRACT SUMMARY:
How to involve various stakeholders in the horizon scanning system is very important. In Korea, we identified stakeholders that should be considered at each stage of the horizon scanning system, and confirmed their feasibility by establishing strategies for their participation and roles. It is very important to engage various stakeholders, collect divergent opinions and make scientific and rational decisions.

INTRODUCTION:
As science advances, the number of newly developed health technologies increases, and as a cycle of ‘development - permit - dissemination - proper usage – deterioration’ of health technology become shorter, the importance of the horizon scanning system to identify promising health technologies and evaluate their potential impacts is increasing. How to engage and collect opinions from various stakeholders in this search process is very important. The purpose of this study is to develop a strategy to involve various stakeholders in all steps of the horizon scanning system in Korea.

METHODS:
The horizon scanning system consists of five steps: identification, filtration, prioritization, assessment, dissemination. We identified the stakeholders to be considered at each stage, and examined who would be involved and how. In addition, they planned how to converge and apply their opinions, and confirmed their feasibility by
actually participating in the horizon scanning system.

RESULTS:
In the identification stage, developers and health professionals, consumers is proposed to suggest new and emerging health technologies information. In the filtration stage, the person in charge of licensing was involved and judged based on appropriateness, innovativeness, possibility of market entry. In the prioritization phase, experts from eight to ten related fields (clinical, health technology and drug, policy, methodologies, patient organizations, etc.) participated and judged according to seven evaluation items (burden of disease, clinical impact, innovativeness, economic impact, acceptability, social impact, and evidence) based on information form. In the assessment stage, clinical and methodological experts of up to four persons were participated in the health technologies selected as the promising health technology, and the potential impact on the technology was evaluated by the seven evaluation items (unmet needs, improved patient health, health equity aspects, changed medical behaviors, acceptability in the aspect of patient and clinical condition, changes of medical cost, and social, ethical, political, and cultural impacts) and the comprehensive technology. The final report was delivered to relevant industries before the dissemination and collected feedback on the results (with particular emphasis on accuracy of data on the technology).

CONCLUSIONS:
In the horizon scanning system for new and emerging health technologies, there are many stakeholders according to national healthcare system, policy, environment, etc., and it was confirmed that there were divergent opinions depending on each position. In addition, as time changes in one country, the standards of social value judgment may change. It is therefore very important for the horizon scanning system to engage various stakeholders, collect their opinions, and make scientific and rational decisions.

OP108 From EML To HTA, And From Reimbursement To Pricing Decision-making

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ABSTRACT SUMMARY:
This oral presentation will depict the challenges for incorporating robust HTA for systematic priority setting in three different countries: Colombia, Ukraine and the U.S. Although all health systems face the need to efficiently allocate finite resources for health care, many are moving from Essential Medicines Lists (EML) to HTA approaches to inform reimbursement or pricing (while others are not). Why?

INTRODUCTION:
All health systems face the challenge of managing finite resources to address unlimited demand for services. In many countries priority-setting and resource-allocation decision-making has been inconsistent and unstructured. In these cases the lack of coherence between limitless promise and limited resources leads to implicit and covert rationing through waiting lines, low quality, inequities, and other mechanisms. Over the past decades different countries have established specialized HTA organizations aimed at better informing health care policies and clinical practice. Although the first technology assessment institution, although not exclusively health related, was the Office for Technology Assessment (OTA), HTA is not current nationwide practice in the U.S. Nevertheless, there are more than 50 agencies in operation in over 30 countries to assist systematic priority setting, specially in HICs. The cases of Ukraine, Colombia and U.S. represent different features of the need for systematic PS. Ukraine is moving from National EML to more dynamic HTA use to update its publicly funded benefits package; Colombia established a few years ago nationwide HTA, but is currently attempting to use HTA for
Pricing & Reimbursement; and the U.S. on the other hand has PCORI and is trying to promote competition to reduce price inflation, but there is no interest on implementing broader HTAs. Nevertheless, even in countries where formal HTA activities are ongoing, and in most LMICs, rationing still occurs as an ad hoc, haphazard series of non-transparent choices that reflect the competing interests of governments, donors and other stakeholders. Henceforth there is the opportunity to closer review why the state of development for HTA varies so much according to setting.

METHODS:
Retrospective policy analysis using a framework for the ”drivers” for the inception of HTA was used in these three cases. For details of the framework see: Castro, et al. 2016 https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/emergence-of-drivers-for-the-implementation-of-health-technology-assessment/1CDBB66445DDE2978D4926CBBD6A824D

RESULTS:
Through a qualitative approach, ten ”drivers” previously emerged with the ability to help or hinder HTA development were used to assess the difference of HTA development in the USA, Colombia and Ukraine (i.e. availability and quality of data, implementation strategy, cultural aspects, local capacity, financial support, policy/political support, globalization, stakeholder pressure, health system context, and usefulness perception). It seems policy/political and financial support, as well as stakeholder pressure, cultural aspects and health system context were the most prominent drivers to induce or prevent institutional development of HTA in different countries.

CONCLUSIONS:
It seems this framework may be of help for comparing institutional development of HTA in different countries. It seems policy/political and financial support, as well as stakeholder pressure, cultural aspects and health system context were the most prominent drivers to induce or prevent institutional development of HTA in different countries. Further research is needed to test these preliminary findings.

OP109 Comparison Of The Health System Establishment Periods In 88 Countries

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ABSTRACT SUMMARY:
Great efforts have been made to health system building and strengthening worldwide. However, it is still unclear which health system is appropriate for different countries. Based on 19 indicators in 88 typical counties, this study aimed to systematically compare the social, economic, demographic and health characteristics of the establishment periods between National Health Service and Social Health Insurance counties.

INTRODUCTION:
Health system reform is considered a tough issue worldwide. Great efforts have been made to health system building and strengthening. However, it is still unclear which health system is appropriate for different countries. This study aimed to systematically compare the characteristics of the establishment periods between 88 counties of National Health Service(NHS) and Social Health Insurance(SHI).
METHODS:
48 NHS countries and 40 SHI countries with data availability were selected. The establishment years of current health systems and other 18 indicators in economics, society, population and health during establishment periods were collected. Comparison between NHS and SHI was conducted by descriptive analysis of every indicator.

RESULTS:
Most NHS countries were established during the cold war, while SHI had been set up since the cold war ended. The median of GDP per capita, urbanization rate and aging rate of SHI were 1535 in current dollars, 58.2% and 9.8%, respectively; compared with 1387, 41.2% and 4.7%, respectively of NHS. NHS countries had a less total population, lower mortality rate and elderly dependency ratio, while the birth rate and children’s dependency ratio were higher. SHI countries showed a higher expectancy life and lower mortality rate in infant and children. NHS countries spent less in total health expenditure with a lower proportion in GDP. The median of health expenditure per capita of SHI and NHS were 188 and 131 in current dollars, respectively. There was little difference among maternal mortality rate, public and private health expenditure proportion.

CONCLUSIONS:
NHS and SHI countries had different characteristics during the health system establishment periods. NHS was established earlier than SHI overall, so that SHI revealed higher levels in economic and social development. Health outcomes of NHS countries were slightly lower than SHI ones, while health expenditure was more in SHI countries. Specific social, economic, demographic and health conditions should be considered when countries building their own health systems.

OP110 Use Of Multi-criteria Decision Analysis In Insurance Decision-making

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ABSTRACT SUMMARY:
We used MCDA to assist a panel of stakeholders to decide ‘whether to list dipeptidyl peptidase IV (DPP-4) inhibitor, compared with sulfonylurea, on the insurance formulary’. Ten quantifiable decision criteria and three contextual decision criteria were identified. The final score support the inclusion of DPP-4 inhibitor. The use of MCDA supported existing reimbursement decision-making process by adding consistency and transparency.

INTRODUCTION:
With a fixed budget, insurance decision makers are facing pressures to improve accessibilities of medical innovations and to increase transparency of decision-making processes. This study aims to support existing drug reimbursement decision-making process in China by adding consistency and transparency through multi-criteria decision analysis (MCDA).

METHODS:
(i) MCDA tool: A systematic review and two rounds of experts counseling (12 experts from insurance authorities, academics, and industry) were conducted to identify the decision criteria. Weights of the criteria were obtained using analytic hierarchy process. (ii) the MCDA tool was tested by deciding ‘whether to list dipeptidyl peptidase IV (DPP-4) inhibitor, compared with sulfonylurea, on the insurance formulary’. (iii) Evidence was collected through rapid HTA. The concise
summaries of the evidence were presented in a grading form to inform judgments and scoring of alternatives on each criterion. (iv) Linear additive model was used to calculate the final weighted score for each alternative. Single factor sensitivity analysis and a fortnight re-measurement were used to deal with uncertainty.

RESULTS:
Ten quantifiable criteria, belonging to five aspects (disease impact, comparative effectiveness, type of benefit, economics, quality of evidence), and three contextual criteria (fairness and access, reasonable application, ensure supply) were identified. The varied weights given by stakeholders expressed their different judgments of the relative importance of criteria. For example, the weight given to “comparative effectiveness” by academics was 0.31, more than three times of that given by industry stakeholders. The final score (DPP-4 inhibitor 87.28 vs sulfonylurea 71.68) support the inclusion of DPP-4 inhibitor.

CONCLUSIONS:
The MCDA assistant tool explicitly depicted the underlying values held by reimbursement decision makers. The combined use of MCDA, HTA and the structured evidence grading form could promote the consistency and transparency of reimbursement decision-making processes in China.

ABSTRACT SUMMARY:
The citizen panel in the Netherlands aims to identify values and criteria for reimbursement decisions, to optimize the legitimacy of governmental policies. After three full weekends of deliberation, the 24 participants were unanimously willing to make explicit trade-offs, and to recommend reimbursement of some services at the expense of not reimbursing others. They identified 16 distinct criteria for doing so.

INTRODUCTION:
The Ministry of Health in the Netherlands is increasingly confronted with public criticism on its reimbursement decisions. The citizen panel aims to identify the values and criteria that the Dutch population considers relevant regarding these decisions. By doing so, the citizen council aims: i) to enable the Ministry to better take into account the preferences of the Dutch population; ii) to stimulate the societal debate on these decisions, to create awareness among the Dutch population; iii) to explore options for a structured inclusion of citizens in decision-making and thereby increasing the legitimacy of decision making.

METHODS:
During three weekends in 2017, 24 citizens discussed with each other on the values and criteria they find important in reimbursement decisions in the Netherlands. They did so on the basis of eight cases, e.g. expensive medication for a rare disease, hip replacement for the elderly, and orthodontic care for children. The participants had the opportunity to inquire with experts in health economics, ethics and reimbursement decisions. We compared values and preferences of the participants before and after the panel, using quantitative and qualitative research methods.

RESULTS:
The participants often had fierce debates, and did not always agree. Their values and preferences changed over the course of the three weekends. At the end of the citizen panel participants were
unanimously willing to make explicit trade-offs, and to recommend reimbursement of some services at the expense of not reimbursing others. Overall, they identified 16 distinct criteria and underlying values. As most important criteria, they considered medical necessity, severity of disease, effectiveness, evidence, and the relation between costs and benefits.

CONCLUSIONS:
Conclusions including full results will be reported in a Manifest and a background document. This will be discussed with main stakeholders in the beginning of 2018, and will result in an advice to the Ministry. All end products will be available at the time of the HTAi conference.

INTRODUCTION:
NICE’s strategic review of its public involvement offer included a survey with stakeholders to explore how NICE can continue to deliver high quality, meaningful public involvement in a rapidly-changing environment.

METHODS:
NICE staff, committee lay members and an external academic ran the project and designed an online survey. The survey was open for two weeks. A purposive sample, recruited through various communication channels, was invited to participate. The sample comprised: • external individuals involved in NICE work • NICE committee and Board members • NICE staff The survey included qualitative and quantitative questions, covering the ‘who’, ‘when’, ‘how’ and ‘what’ of NICE’s public involvement approaches.

RESULTS:
The survey yielded 684 responses, which were stratified by stakeholder type. Overall the responses indicated that: • the suggested stages for involvement are all important, but on a sliding scale: ‘defining outcomes guidance should consider’ is most important, and ‘helping committee chair recruitment’ is least important. • different perspectives are needed: ¬ - individual treatment or care decisions should incorporate views of directly affected people ¬ - population-based public health decisions need the views of citizens. Quality improvement suggestions included: • seeking feedback on people’s experiences of care, using clear, structured approaches including focus groups, interviews, surveys, social media • increasing communications about NICE’s work, specifically about involvement opportunities and use of patient evidence • using data on people’s experiences equally with academic evidence • providing education and training on involvement to NICE staff and the general public • partnership working with other organisations to enhance engagement. A focus group with key stakeholders used the survey findings to shape the subsequent public consultation document.
CONCLUSIONS:
There was consensus that public involvement is necessary throughout guidance development, however the type of person involved and nature of participation should vary across the development stages. Project challenges included managing diametrically opposing views, and the associated implications for engagement.

OP113 Iramuteq Analysis of Trastuzumab’s Public Consultation in Brazil

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ABSTRACT SUMMARY:
In Brazil, the “Sistema Unico de Saude” (SUS) is a public health system that has universal coverage, comprehensive care, and principles like community participation. We developed a typology of social representations on the contributions to the national HTA agency’s public consultation to Trastuzumab for initial breast cancer in Brazil. We report findings from using IRAMUTEQ for such public consultation analysis.

INTRODUCTION:
In Brazil, the “Sistema Unico de Saude” (SUS) is a public health system that has universal coverage, comprehensive care, and principles like community participation (1). The incorporation, update or exclusion of new health technologies (2) is done by the National Committee for Technology Incorporation (CONITEC), which issues reports on the incorporation of technologies and submits them to public consultations, which is the main mechanism of public involvement and an opportunity to influence the decision to access and coverage to new health Technologies (2). Our study aimed to investigate a typology of social representations on the contributions from 2012 to the CONITEC’s public consultations to the incorporation of Trastuzumab for the treatment of initial breast cancer in Brazil. REFERENCES 1. Lei Nº. 8080/90, de 19 de setembro de 1990. Dispoe sobre as condições para a promocao, protecção e recuperacao da saúde, a organização e o funcionamento dos serviços correspondentes e da outras providencias. Diario Oficial da Uniao, Brasilia, Brasil. Pub. L. No. 8080/90 (SEPTEMBER 20, 1990) 2. Ministerio da Saude do Brasil; Secretaria de Ciencia, Tecnologia e Insumos Estrategicos; Departamento de Gestao e Incorporacao de Tecnologias em Saude. Entendendo a Incorporacao de Tecnologias em Saude no SUS : como se envolver. 1st ed. Brasilia: Ministerio de Saude, 2016.

METHODS:
Our study deployed a mixed-methods approach to semi-quantitatively analyze the social representativeness and corpus composition of all the public consultation contributions for the recommendation of the Trastuzumab’s incorporation for treatment of initial breast cancer within SUS, as well as the authors’ qualitative analysis of the IRAMUTEQ software as a potential effective and efficient tool to semi-qualitatively analyse such public consultations. All contributions were included (127 contributions, from several Brazilian states) and organized into a single corpus, which was submitted to 5 types of analyzes (classical lexical analysis, analysis of group specificities, descending hierarchical classification; similitude analysis and word cloud), performed by “IRAMUTEQ” software (Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires), which allows different forms of statistical analysis on textual corpus and tables of individuals by words (1). REFERENCES 1. Camargo BV, Justo AM. IRAMUTEQ: um software gratuito

RESULTS:
The general corpus consisted of 114 texts, separated into 685 text segments (TS), with use of 79.12 percent of total TS (684). The analyzed content was categorized into four classes: Class 1 – Patient Representations/ Advocacy (186 ST-34.3 percent); Class 2: Pharmaceutical Industry/ Advocacy (181 ST-33.4 percent); Class 3: Health Professionals (81 ST-14.9 percent); and Class 4: Individual Contributions (94 -17.3 percent). Class 1 corpus consisted mostly of contributions made from a breast cancer patient association/ advocacy report, which focused mainly on lay expertise terminology. We observed a proximity in corpus between Classes 2 and 3, showing a potential approximation between the pharmaceutical industry's and health professionals' contributions, to whom the main word occurrences related to health technologies. Class 4 corpus focused on improvement and individual need, as well as in corpus referring to SUS.

CONCLUSIONS:
From our findings, we observed: 1) a potential similarity in contributions of health professionals and pharmaceutical industry; 2) how lay expertise might affect the contributions of patients individually and within advocacy and patient organisations; and 3) the uses and limitations of IRAMUTEQ as potentially effective and efficient tool to semi-qualitatively analyse health technology assessment public consultation contributions.

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ABSTRACT SUMMARY:
While efforts to engage ‘the public’ in HTA exist, the goals remain unclear. This may be attributable to the lack of a shared definition of ‘the public’. Using mixed methods, we arrived at the following definition: “A non-aligned community member with no commercial or professional interest in the HTA process and not a patient or member of a stakeholder group”.

INTRODUCTION:
Increasingly, HTA organizations have instituted mechanisms for involving patients in assessment and review processes. The reasons are obvious – to understand the ‘patient experience’ with a disease and ensure that patient perspectives are considered during deliberations about the value of new treatments. More recently, there have been efforts to engage ‘the public’ in HTAs and HTA-informed decision-making processes. However, the goals of these efforts have not been well-articulated. This may be attributable to the lack of a shared definition of ‘the public’. The objective of this study is to develop a common understanding of the term ‘the public’ within the context of HTA.

METHODS:
• A survey of HTA organizations • A systematic review • Consultation with HTAi’s Special Interest Group on Patient and Citizen Involvement • A workshop comprising representatives from patient organizations, industry, and HTA bodies in Canada.

RESULTS:
In many HTA processes, the terms ‘public’ and ‘patients’ are synonymous. Definitions found in scholarly articles vary and depend on the rationale for involving the public in a particular issue. Through consultations, it became clear that, in the context of HTA, the definition depends

OP114 The Public’s Role In Understanding The Value Of Health Technologies

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on understanding what is missing from current deliberations around the value of new health technologies. There was consensus among workshop participants that 1) ‘patients’ and ‘the public’ are not the same, 2) the role of ‘the public’ may be to ensure societal values are reflected in HTAs and HTA-informed decision-making processes (e.g., serving an audit function), and 3) a legitimate definition of ‘the public’ could be: “A non-aligned community member with no commercial or professional interest in the HTA process and not a patient or member of a stakeholder group”.

CONCLUSIONS:
Consensus on the use of the terms ‘patient’ and ‘public’ will support rigorous, evidence-based public and patient engagement in HTA. The proposed definition indicates a way forward in this debate.

OP115 Conditions And Factors Influencing Application Of Patient Preferences

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ABSTRACT SUMMARY:
Patient preferences are gaining importance in different stages of the drug life cycle, including HTA. Multiple HTA bodies are performing patient preference studies and are exploring how they can be used in their evaluations. In this crucial stage, we had discussions with stakeholders on applications of patient preferences and investigated factors and conditions influencing the utility of patient preference studies.

INTRODUCTION:
To identify factors that influence the utility of patient preference studies in decision making by Health Technology Assessment (HTA) bodies, regulators and industry. In parallel, it was sought to identify the current applications of patient preferences in decision making and to investigate the conditions in which patient preferences are most valuable.

METHODS:
A systematic literature search was conducted in five scientific databases. In addition, publicly available documents of national and international health agencies and patient-centred initiatives were included. Semi-structured interviews (n=143) were conducted with several stakeholders in 7 European countries and the US. Focus group discussions (n=8) were conducted between September 2017 and January 2018 with HTA representatives, regulators, industry representatives, and patients from the United Kingdom, Sweden, Romania and Italy.

RESULTS:
A total of 742 publications were retrieved and 85 were included. Major factors influencing utility of patient preference studies according to the literature include cognitive burden, question framing, and the willingness of patients to participate. Evidence exists on the possible
applications of patient preferences in decision making, but evidence on their actual inclusion in decision making was limited. Patient preferences were mostly found to be used in ideation, benefit-risk assessment and Health Technology Assessment (HTA). Conditions under which patient preferences were found to be more useful include uncertain benefit-risk balance, new technologies, rare diseases, and unmet medical needs. Results of the focus group discussions (n=8) will be presented at the HTAi 2018 meeting, paying special attention to the HTA focus group.

CONCLUSIONS:
Although application of patient preferences in decision making is limited, they are gaining importance in ideation, benefit-risk assessment and Health Technology Assessment (HTA). However, many conditions and contextual factors have to be taken into account when designing and conducting a patient preference study in order to obtain valuable results that can be used in evaluations.

OP116 Implementing Lung Cancer Screening: The Participant Perspective

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ABSTRACT SUMMARY:
It is unclear how lung cancer screening can be best implemented. In this study we investigate the preferences of those people who are eligible for screening and find that there is great potential for novel screening technologies and that a screening based on low-dose CT must take into account the participant perspective to maximize attendance.

INTRODUCTION:
Lung cancer screening can reduce cancer mortality. Most implementation studies focus only on low-dose computed tomography (LDCT) and clinical attributes of screening and do not include preferences of potential participants. In this study we evaluated the perceived value of screening programs based on LDCT, breath analysis (BA), or blood biomarkers (BB) according to the perspective of the target population.

METHODS:
A multi-criteria decision analysis framework was adopted. Criteria were selected based on interviews and a panel session. Criteria weights were elicited from a thousand persons from the Dutch general population using SWING weighting. Performance data for the screening modalities was obtained from clinical trials and expert opinion. Parameter uncertainty about clinical performances was incorporated probabilistically, while heterogeneity in preferences was analyzed by investigating subgroups with cluster analysis.

RESULTS:
The identified criteria were location of screening (weight=0.18, SD=0.16), mode of screening (0.17, SD=0.14), sensitivity (weight=0.16, SD=0.13), specificity (weight=0.13, SD=0.12), waiting time until results (weight=0.13, SD=0.12), radiation load (weight=0.13, SD=0.12), and duration of screening procedure (weight=0.10, SD=0.09). The mean overall values of the policies under consideration were 0.58 (CI: 0.57 to 0.59), 0.57 (CI: 0.56 to 0.59), and 0.44 (CI: 0.43 to 0.45) for BB, BA, and LDCT, respectively. Seventy-seven per cent of respondents preferred BB or BA. For most subgroups, the overall values were similar to those of the entire sample. BA had the highest value for respondents who would have been eligible for earlier screening trials.
CONCLUSIONS:
There is much variation in what value people attach to attributes of lung cancer screening. BB and BA seem valuable to participants because they can be applied in a primary care setting. Although LDCT still seems preferable given its strong and positive evidence base, for implementation it is important to take non-clinical attributes into account to maximize attendance.

OP117 Stakeholder Perspectives On Patient Preferences In The Drug Life Cycle

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ABSTRACT SUMMARY:
Even though today there is an increased focus on the patient perspective in the drug life cycle, the use of patient preferences in HTA is limited and unstructured. This large, European based, qualitative research identified stakeholders' desires, expectations, concerns and requirements regarding the measurement and use of patient preferences towards integrating patient preferences in the drug life cycle.

INTRODUCTION:
Today, there is an increased focus on the patient perspective in the drug life cycle. However, little is known about stakeholder perspectives towards integrating patient preferences in the drug life cycle. This study aimed to explore stakeholders' desires, expectations, concerns and requirements regarding the measurement and use of patient preferences throughout the drug life cycle.

METHODS:
This study used a four-step approach. First, 16 exploratory interviews were conducted. Second, a literature review consulting scientifically published and other publicly available documents was performed. Third, 143 semi-structured interviews were conducted with stakeholders (patients, informal caregivers, patient representatives, physicians, regulators, reimbursement agency representatives, health technology assessment representatives, industry representatives, academics) from Sweden, Romania, Italy, the United Kingdom, the Netherlands, Germany, France and the United States. Fourth, 8 focus groups with different representatives from the same stakeholder groups were designed.

RESULTS:
The exploratory interviews revealed a general agreement among stakeholders on the value of using patient preferences in all stages of the drug life cycle. The literature review showed that patient preferences could be used in HTA (e.g. to inform about benefit-risk trade-offs and to prioritize HTA topics). The 143 semi-structured interviews indicated that although the majority of HTA representatives support using patient
preferences for HTA, they also raise a need for scientifically strong methods as well as a clearer view on the quality criteria for patient preference studies. Concerns of HTA representatives included concerns related to the novelty of patient preference research and related to the methods for measuring patient preferences.

CONCLUSIONS:
Although the use of patient preferences is desired by stakeholders, their needs and concerns have to be addressed before patient preferences can be integrated throughout the drug life cycle.

OP118 Women’s Preferences And Perspectives On Cervical Cancer Screening

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ABSTRACT SUMMARY:
Participation in Cervical Cancer Screening (CCS) is influenced by a multitude of barriers and facilitators governed by the preferences, values, and beliefs of women. This presentation will discuss the findings from a Patient Perspectives and Experiences review for a CADTH Health Technology Assessment on HPV Testing for Primary Cervical Cancer Screening.

INTRODUCTION:
Cervical cancer screening (CCS) is conducted through multiple testing modalities including Papanicolaou smears and more recently, HPV Testing. Participation in CCS is influenced by a multitude of barriers and facilitators governed by the preferences, values, and beliefs of women. This presentation will discuss the findings from a Patient Perspectives and Experiences review for a CADTH Health Technology Assessment on HPV Testing for Primary Cervical Cancer Screening.

METHODS:
A systematic literature search yielded 4864 citations published from January 1, 2002 to November 1, 2017. 106 eligible studies were analyzed using the qualitative meta-synthesis methodology.

RESULTS:
The social location, circumstances and resources available to women significantly influence how they negotiate the factors that influence their CCS participation. Some of the factors we identified are Emotions, Understanding Personal Risk, Logistics, and Multiple Roles of Women. In this presentation, we will discuss how these factors interact with a woman’s social location to influence women’s choices and preferences about engaging in cervical cancer screening. Specifically, we describe an analysis that conceptualizes social location as a balancing fulcrum, which changes the force exerted by factors acting as incentives and disincentives. Women who experience social and material deprivation may find that disincentives are harder to overcome than women who have access to ample social and material resources. More incentives in quantity and strength would tip the balance in favour of incentives and increase CCS participation. This presentation will also describe how incentives and disincentives were operationalized in the context of a patient perspectives and experiences review for a health technology assessment.

CONCLUSIONS:
Women’s decisions to participate in CCS is influenced by many factors. The way women negotiate these factors is closely related to their personal circumstances and the availability of social, material, and financial resources.
OP119 Appraising Qualitative Research For Qualitative Evidence Syntheses

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ABSTRACT SUMMARY:
Over 100 appraisal tools have been developed to assess the quality of qualitative studies. We offer information to help appraisers determine the most suitable tool for appraising the rigour of qualitative research included in a qualitative evidence synthesis. This presentation will offer a discussion on the characteristics of tools available for assessing the quality of studies in qualitative evidence syntheses.

INTRODUCTION:
The growth of the evidence-based policy movement sought to determine how to better assess and incorporate qualitative evidence in clinical practice and policy development. The question engendered was not whether qualitative research is valuable but how researchers can enhance its rigour. From this discussion arose over one hundred appraisal tools for the quality appraisal process of qualitative studies. For those without a deep familiarity with the qualitative research paradigm, navigating through the breadth of tools to find the most suitable tool for the task is a cumbersome process. This presentation will review the descriptive characteristics of available quality appraisal tools for assessing the quality of primary qualitative studies in qualitative evidence syntheses (QES). This presentation will also offer a critical discussion on the use of reflexivity as a de facto quality criterion, and how methodological reporting may influence the application of quality criteria in QES.

METHODS:
We conducted a systematic search to identify quality appraisal tools of qualitative research designed for use in QES. This search built upon the work of Santiago-Delefosse and colleagues by extending their search to 2016.

RESULTS:
We identified 8 appraisal tools intended for use in the quality appraisal process of a QES. We provide a description of the structure, content, objectives, and philosophies of tools followed by considerations concerning their historical antecedents, common patterns regarding structure, content, and purpose, and the implications of these patterns on the QES process.

CONCLUSIONS:
Quality appraisal of qualitative research is an important step in QES, and there have been a proliferation of tools for this purpose. By providing an overview of available tools detailing their intent and strengths, this presentation will assist those engaging in QES to choose an appropriate tool for their work.

OP120 Rapid Qualitative Reviews: A Scoping Review Of Guidance And Examples

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ABSTRACT SUMMARY:
Increasing requests to include qualitative evidence
as part of HTA have given rise to an emerging field of methodological development: rapid qualitative reviews. Through our scoping review we searched for existing guidance and publicly available examples. We determined that several agencies are producing rapid qualitative reviews, and there is a corresponding need to develop methods that balance rapidity and rigour.

INTRODUCTION:
Decision-makers are increasingly recognizing the usefulness of qualitative research to inform patient-centred policy decisions, and are accordingly increasingly demanding qualitative evidence as part of health technology assessment (HTA). In the context tight HTA timelines, a new form of evidence synthesis has emerged – rapid qualitative reviews. The need for rapidity requires either an increase in resources or, more commonly, a compromise in rigor, yet guidance on appropriate compromises for qualitative reviews is lacking.

METHODS:
In order to inform de novo guidance, we conducted a systematic scoping review to identify existing guidance and published examples of rapid qualitative reviews. We searched Medline and CINAHL using medical subject headings and keywords related to “rapid reviews” and “qualitative” research, and screened the 1,771 resultant citations independently in duplicate. Additionally, we searched the grey literature and solicited examples from our contacts and other evidence-synthesis organizations. We summarized included guidance and reviews using the Search, Appraisal, Synthesis, Analysis (SALSA) framework to identify abbreviations in the review process.

RESULTS:
We found no guidance documents specific to rapid qualitative reviews. We found one published peer-reviewed rapid qualitative review, and several more (>10; grey literature search in process) through our organizational contacts. While methods to abbreviate the process are poorly reported, an abbreviated literature search (years and databases searched) and the use of a single reviewer appear common.

CONCLUSIONS:
A number of agencies are producing rapid qualitative reviews however our review identifies the urgent need to develop and explore methods for the synthesis of qualitative research that balance rapidity and rigour.

OP121 Experiences With Using The GRADE-CERQual Approach In Systematic Review

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ABSTRACT SUMMARY:
CERQual provides a method for assessing confidence of evidence from qualitative reviews. Drawing on practical experiences the presentation gives examples of applying CERQual and discussing its strengths and limitations. Though time-consuming to learn, CERQual can facilitate the use of qualitative evidence in decision-making and encourage more uniform reporting of qualitative research. This may increase the impact of qualitative reviews.

INTRODUCTION:
There are many approaches to synthesis of qualitative studies. The GRADE-CERQual approach (Confidence in the Evidence from Reviews of Qualitative research) provides a transparent method for assessing the confidence of evidence from reviews of qualitative research. This presentation aims at giving examples of applying CERQual,
METHODS:
This presentation draws on practical experiences with the conduction of three qualitative systematic reviews using the CERQual approach. The reviews differ in aim and field of research.

RESULTS:
The three CERQual reviews to be discussed in this presentation are: 1) Emergency departments and mental health patients - Purpose: Uncovering knowledge in a project on merging emergency departments to include both somatic and psychiatric patients. 2) Parental responses to severe or lethal prenatal diagnosis – Purpose: Providing physicians with knowledge on a patient group from their daily clinical practice. 3) Patients’ experiences with home mechanical ventilation – Purpose: Disseminating important knowledge from a national project to an international audience.

CERQual strengths: • Presents complex and large amount of knowledge in a clear way • Pools knowledge from different studies into common outcome measures across studies • Presents an assessment of the quality and strength of outcome measures • The clear presentation makes it useful in decision making CERQual weaknesses: • Time consuming to conduct the reviews • Simplification of qualitative research, missing out on context and nuances.

CONCLUSIONS:
CERQual represents a useful tool to facilitate the use of qualitative evidence in clinical and political decision making. CERQual is time-consuming to learn, but a useful tool to apply when learned. CERQual may encourage a more uniform reporting of qualitative research, including assessment of confidence in findings. This may increase the impact of systematic reviews of qualitative studies.

OP122 Applications For Research Funding: How Many Peer Reviewers Do We Need?

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ABSTRACT SUMMARY:
Evidence is required to support the connection between innovation and implementation. It is therefore, crucial to select the most promising research studies to fund. Research was undertaken evaluating the influence of peer review and reviewer scores on funding decisions, and how the process might be modified to reduce the workload for stakeholders.

INTRODUCTION:
The National Institute for Health Research (NIHR) is a major funder of health research in the United Kingdom. Selecting the most promising studies to fund is crucial, and external expert peer review is used to inform the funding boards. Our aim was to evaluate the influence of different kinds and numbers of peer review and reviewer scores on Board funding decisions, and how we might modify the process to reduce the workload for stakeholders.

METHODS:
Our mixed method study included a) retrospective cross sectional analysis of funding board and
external reviewer scores for second stage applications for research funding, using Receiver Operator Characteristic (ROC) curves to quantify the influence of reviewer scores on funding decisions and b) qualitative interviews with thirty stakeholders (funding board members, applicants, external peer reviewers and NIHR staff).

RESULTS:
Analysis of ROC area for reviewers indicated that areas changed very little with increasing numbers of reviewers from 4 to 7 or more. External reviewers with clinical, methodological or patient expertise all appeared to influence Board funding decisions to a similar extent. The stakeholders interviewed valued peer review but felt it was important to develop a more proportionate process, to better balance its benefit with the workload of obtaining, preparing, reading and responding to reviews. Reviews are of most value when they fill gaps in expertise on the Board. Less than 4 reviews was felt to be insufficient but more than 6 excessive. Workload could be reduced by making reviews more focussed on the strengths and weaknesses of applications and identifying flaws which are potentially “fixable”.

CONCLUSIONS:
Stakeholders supported the need for peer review in evaluating funding applications. Our results suggest that four to six peer reviews per application is optimum, depending on the expertise needed to complement that of advisory boards.

ABSTRACT SUMMARY:
National health research funders are accountable to the public with regard to the societal impact of the research, including HTA, that they fund. We present the results of reducing research waste to ensure societal responsible research, both at international as national level. It was concluded that more focus on societal impact assessment is needed.

INTRODUCTION:
National health research funders are accountable to the public with regard to the societal impact of the research, including HTA, that they fund. Failing to do so, not only can negatively affect public trust in the allocation of resources to funding agencies but can also lead to public mistrust in science.

METHODS:
We present the results of reducing research waste to ensure societal responsible research, both at international as national level. In the Netherlands, the National Organization for Health Research and Development (ZonMw) developed an analytical framework to assess its research programs, including the national HTA program.

RESULTS:
An evaluation of 12 national funding agencies in Australia, Europe and North America demonstrated that certain processes e.g. how research questions are prioritised or decided are not transparent. At international level, health funders believe that they have a joint responsibility not just to seek to advance knowledge, but also to advance the practices of health-related research and research funding. In the Netherlands, ZonMw (HTA) research programs perform well regarding addressing societal relevance (e.g. stakeholder participation) and reasonably well on scientific quality (e.g. international cooperation and knowledge sharing). Efficiency (e.g. encouraging use of existing data and systematic reviews) appears to be less well developed, while integrity (e.g. preventing publication bias) is underexposed.

OP123 Translating Evidence To Action – The Role Of Health Research Funders

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CONCLUSIONS:
Although ZonMw is doing reasonably well in terms of reducing research waste, it was concluded that more focus on societal impact assessment is needed. To do so funding agencies need to collaborate with all relevant stakeholders. This is especially relevant in the field of HTA where the ambition is to move from evidence to impact.

OP124 Research Gaps In Health Technology Assessment In Brazil

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ABSTRACT SUMMARY:
Promotion of research for contribute to the resolution of the priority health problems of the Brazilian population and to the strengthening of the management of the Unified Health System, within the scope of the ATS.

INTRODUCTION:
In 2017 the Brazilian Ministry of Health (MS) through the Department of Science and Technology (Decit), in partnership with the Hospital Alemão Oswaldo Cruz (HAOC), financially supported research activities focused on the Technology Assessment area in Health (ATS) on subjects demanded by the MS technical areas. Objective: to contribute to the resolution of the priority health problems of the Brazilian population and to the strengthening of the management of the Unified Health System, within the scope of the ATS.

METHODS:
A survey of ATS research needs was carried out involving all MS sectors through internal meetings conducted by representatives of the sectors themselves. Next, the problems / needs were discussed, prioritized and transformed into research lines in a workshop held in partnership between Decit and HAOC. Following this, a specific public call was made in ATS contemplating the prioritized research lines. This call was launched and the submitted research projects were judged and selected through a committee of experts in the field. The approved projects were contracted and when the project execution deadline the research results were presented and discussed by the researchers in a final seminar for representatives of the MS technical areas.

RESULTS:
A total of 135 research gaps were surveyed, of which 42 lines of research were included in the research call after the prioritization workshop and the search for evidence in the literature. The call involved an amount of one million reais and through the judgment and selection of the submitted proposals, 17 research projects were financed, among which were two systematic reviews, 7 rapid reviews and 8 economic evaluation studies.

CONCLUSIONS:
The promotion of research promoted in MS has enabled the search for scientific evidence to support public policies and decision making in health services.
OP126 Does SDM Influence Patients’ Adoption Of Drug-eluting Stents In China?

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ABSTRACT SUMMARY:
This study examines patients’ participation in decision-making in relation to the clinical application of DES and analyzes the impact. A cross-sectional survey was conducted in 15 hospitals from 3 provinces in China, and 179 patients completed the questionnaire. Patients’ level of SDM was found to be an important predictor of patients’ satisfaction with decision-making processes and adoption of DES.

INTRODUCTION:
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 examines the current situation of patients’ participation in decision-making in relation to the clinical application of drug-eluting stent (DES) and analyzes the impact of patients’ involvement in decision-making on patients’ adoption of DES, with a view to providing research outcomes to guide clinical practice.

METHODS:
A cross-sectional study was conducted from July to December 2016 in selected hospitals in Fujian Province, Sichuan Province, and Shanghai in China. Patients with coronary heart disease completed a survey which contained the 9-item Shared Decision-Making Questionnaire (SDM-Q-9) about satisfaction with decision-making processes and questions on DES. Data were analyzed with cluster analysis, correlation analysis, multivariate logistic regression, and multivariate liner regression.

RESULTS:
179 patients with coronary heart disease from 15 hospitals in the three regions completed the questionnaire. There were good validity and reliability for SDM-Q-9 with Cronbach’s $\alpha$ as 0.96 and intra-class correlations 0.59-0.79 (all p<0.01). Among these respondents, 42.1% adopted DES, 83.4% were supportive of SDM and 61.33% thought they had better communication with physicians regarding decision-making. Patients’ level of SDM involvement was found to be positively associated with their satisfaction with the decision-making process (P<0.001) and their adoption of DES (P<0.05). Also, satisfaction with shared decision-making regarding treatment was positively associated with adoption of DES (P<0.001).

CONCLUSIONS:
Most of the patients with coronary heart disease preferred SDM, and SDM was found to be an important predictor of patients’ satisfaction with decision-making processes and adoption of DES. Better communication between physicians and patients is needed in order to improve patients’ satisfaction and promote the appropriate use of drug-eluting stent technology in China.
Governments face considerable challenges in making fair and sustainable drug funding decisions. In cancer, expenditure on drugs has risen dramatically compared to other areas of healthcare due to costly new cancer drugs and a growing/ageing population. Public input can assist policy makers in drug funding policies that are regarded as fair, reflect citizens’ values, and are socially acceptable.

METHODS:
The project’s objective was to engage Canadians through a series of deliberative public engagement events or to generate recommendations that could inform cancer drug funding decisions. The study combined the strengths of two well-established models: the McMaster Health Forum’s citizen panels (www.mcmasterhealthforum.org) and the deliberative public engagement approach developed by Burgess and O’Doherty (www.cangage.ca). Six panels were held across Canada in 2016, with a total of 139 participants. Recommendations were grouped thematically, with transcript analysis identifying where participants’ views converged and diverged.

RESULTS:
In order to achieve greater value for money, participants accepted the need to make tough funding decisions, including the potential to cease/scale back funding for some currently funded drugs. Recommendations included: the review and regular re-review of approved using ‘real-world’ evidence on effectiveness and cost-effectiveness; that priority be given to treatments that restore patients’ independence, mental health, and general well-being; that processes for ensuring transparency of decision-making processes, decisions and their rationales are implemented; and that people with similar needs should receive the same care regardless of where in Canada they live.

CONCLUSIONS:
The deliberative events provide a set of baseline perspectives on what participants collectively thought made for good, trustworthy decisions about funding for cancer drugs in a fair and sustainable way. Next steps would be to move from event-based public engagement to a more sustained model, e.g. a ‘standing’ public panel or incorporating the public into existing decision-making processes.

OP128 Evaluating The NPS MedicineWise Medicines Information Phone Service

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ABSTRACT SUMMARY:
NPS MedicineWise’s service Medicines Line provides evidence-based information and advice to consumers with enquiries related to their medicines. A mixed-methods evaluation found that contact with the service improved consumer
knowledge, confidence and decision-making in relation to their medicines. The service was also perceived to be trustworthy, efficient, evidence-based and beneficial to others as a mechanism for reporting adverse drug reactions.

INTRODUCTION:

NPS MedicineWise’s pharmacist-delivered phone line service Medicines Line aims to provide evidence-based medicines information to consumers. We evaluated outcomes of the Medicines Line, including common consumer enquiries and resultant decision-making, and explored motivations for seeking medicines information.

METHODS:

The evaluation involved conducting paper-based and telephone surveys with a sample of 200 Medicines Line callers, and semi-structured telephone interviews with a subset of 20 callers. Quantitative data was analysed using SPSS. Qualitative data was thematically analysed manually.

RESULTS:

Preliminary analysis found that the majority of callers thought the Medicines Line had improved their knowledge (ninety-six percent), confidence (eighty-two percent) and decision-making (eighty-nine percent). The most common reasons for calling the Medicines Line were enquiries about side effects or medicine compatibility. The most commonly enquired about medicines were antidepressants (twenty percent), analgesics (thirteen percent) and antibiotics (nine percent). Questions about sertraline accounted for thirty-six percent of antidepressant enquiries. Interview themes regarding motivations for using the service included trust; efficiency and convenience; specialised drug knowledge; and as a mechanism for reporting adverse drug reactions to help others stay safe from medicine-related harm. Medicines Line was perceived to be especially useful as an alternative to GP or specialist consultations, where consumers had a non-urgent enquiry about a medicine; and as a service to provide medicines information in remote communities.

CONCLUSIONS:

These results indicate that pharmacist-delivered medicines information telephone services are an effective and efficient way of handling medicines enquiries. Medicines information telephone services are effective in improving health literacy, by increasing callers’ knowledge and confidence to source evidence-based medicines information and make informed decisions about their medicines. This evaluation has identified knowledge gaps in medicine side effects and antidepressant use. Identifying knowledge gaps through this evaluation may be useful in informing future health professional education programs, community campaigns and shared decision-making resources.

OP129 Health Economic Analysis Of Genomic-Guided Lymphoid Cancer Management

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ABSTRACT SUMMARY:

Decision-making in personalized oncogenomics is challenged by uncertainty of outcomes related to ‘real world’ performance. We have used various methods to address this in the context of lymphoid cancer in British Columbia. Cost effectiveness results using decision analytic models are quantified using probabilistic sensitivity analysis. Similarly, public tolerance for such uncertainty
will be captured using discrete choice experiment methods.

INTRODUCTION:
Decision-making in personalized oncogenomics may be challenged by statistical and structural uncertainty of outcomes, particularly when technologies have not been evaluated in Phase 3 clinical trials. We have used various methods to analyze uncertainty with respect to cost effectiveness evaluations and preference-based assessments of genomics-informed treatments for the lymphoid cancers in British Columbia.

METHODS:
Economic (Markov) models that incorporate probabilistic sensitivity analyses using Monte Carlo methods have been used to investigate the cost-effectiveness of molecularly-guided treatments for the most common lymphoid cancers. A discrete choice experiment (DCE) is underway to elicit preference-based values for genomics-informed treatment decision-making from patients and the general public.

RESULTS:
Incremental cost-effectiveness ratios (ICER) varied for different cancer types: $214,650 (CAD) ($190,088 USD) per quality-adjusted life year (QALY), with 95% confidence interval (CI) of $204,087–225,226 ($160,540–177,169 USD) for relapsed/refractory Hodgkin’s lymphoma; $198,804/QALY ($156,384 USD) (CI: $74,681–1,248,140 [$58,746–981,821]) for molecularly-guided treatment of diffuse large B-cell lymphoma; and $145,504/QALY ($114,457 USD) (CI: $129,977–165,539 [$102,243–130,217 USD]) for treatment of 17p deleted chronic lymphocytic leukemia over 5-year horizon. For all modeled diseases, large CIs around mean ICERs were observed due to uncertainty regarding ‘real-world’ performance. Analysis of patient focus groups for the DCE revealed that participants valued actionable results that would lead to changes in their care management. They accepted uncertainty regarding test results. Discussions about willingness to pay for testing revealed a lower tolerance for uncertainty related to treatment decision-making than for disease prognosis.

CONCLUSIONS:
The use of genomics-guided treatments to treat common lymphoid cancers may be accompanied by a significant increase in overall healthcare expenditures. Evidence of cost-effectiveness and patient/public preferences can be used as inputs into the decision-making process. Future work will refine these models to reflect changing technologies, and DCE results used to predict expected uptake of molecularly-guided testing for lymphoid cancer management.

OP130 Economic Evaluation Of Cervical Cancer Screening In LMIC Countries

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ABSTRACT SUMMARY:
We performed a systematic review to evaluate the economic aspects of cervical screening conducted in low-and-middle income countries. We included 30 studies, 26 of which used mathematical models, and found HPV DNA testing, starting at age 30 years or older and repeated at 5-year or longer intervals, was the most cost-effective strategy in most of the settings.

INTRODUCTION:
The unequal expanding of cervical screening
(CS) using pap smear (PS) has reduced both the incidence and mortality of cervical cancer in high-income countries since 1940s, leaving low-and-middle income countries (LMIC), which lack sustained CS strategies, suffering from heavy disease burden. Optimizing population-based CS policies is becoming more complex due to the expanding range of screening technologies available. We performed a systematic review to evaluate the economic aspects of CS conducted in LMIC.

**METHODS:**
We conducted an exhaustive literature search of medical and biological databases. We include primary economic evaluations, published from January 2006 to December 2016, which examined the costs and effectiveness of CS in women of LMIC, compared with alternatives, either no screening or screening using alternative tests, as well as starting age and intervals. Data were extracted as costs and consequences of CS and control. Descriptive analyses were conducted for the huge heterogeneities in the CS tests and the methodology of economic evaluations. Methodological qualities of included studies were evaluated using Drummond’s checklist.

**RESULTS:**
Thirty studies, 26 of which used mathematical models, were included. Five categories of CS tests (HPV DNA, visual inspection with acetic acid (VIA), PS, liquid based cytology, sequencing screening using two tests) were suggested as cost-effective, under the criterion that incremental cost-effectiveness ratio was less than three times of GDP per capital. HPV DNA was most frequently suggested (15/30), followed by VIA (8/30) and PS (6/30). The most frequently suggested starting age was 30 years old (13/24) and once in five years (7/14). All but two included studies were judged as qualified economic evaluations.

**CONCLUSIONS:**
HPV DNA testing, starting at age 30 years or older and repeated at 5-year or longer intervals, is the most cost-effective strategy in most of the settings. We suggested the introduction of HPV DNA testing to the CS programs in LMIC.

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**OP131 Treating Differentiated Thyroid Cancer: A Cost-effectiveness Analysis**

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**ABSTRACT SUMMARY:**
We assessed the cost-effectiveness of lenvatinib and sorafenib for the treatment of differentiated thyroid cancer (DTC) after radioactive iodine. Using list prices, compared with best supportive care, cost-effectiveness results for both treatments were >£50,000 per quality adjusted life year gained. However, these results may be of limited value to decision-makers if lenvatinib and sorafenib are available at discount prices.

**INTRODUCTION:**
Differentiated thyroid cancer (DTC) is a rare form of thyroid cancer. Most patients require treatment with radioactive iodine. Treatment for DTC that is refractory to radioactive iodine (RR-DTC) is often limited to best supportive care (BSC). We assessed the cost effectiveness of lenvatinib and sorafenib for the treatment of RR-DTC.
METHODS:
We constructed an economic model with a time horizon of 40 years. Costs and quality adjusted life years (QALYs) were considered from the perspective of the United Kingdom National Health Service (NHS) and discounted at an annual rate of 3.5%. The model pathways, and the assumptions underpinning the model, were determined through consultation with clinical experts and reviews of the clinical and economic literature. Clinical data were derived from the SELECT (lenvatinib versus BSC) and DECISION (sorafenib versus BSC) trials. Health-related quality of life data were only collected during the DECISION trial, and these were limited.

RESULTS:
It was not possible to compare the cost effectiveness of lenvatinib with sorafenib. This was primarily because the risk profiles of the patients in the BSC arms of the SELECT and DECISION trials did not appear to be comparable. Using list prices, the incremental cost effectiveness ratios (ICERs) for the comparisons of lenvatinib versus BSC and sorafenib versus BSC were £65,872 and £85,644 per quality adjusted life year (QALY) gained respectively. Deterministic sensitivity analyses results for both comparisons were >£50,000 per QALY gained. Compared to BSC, the probability of lenvatinib and sorafenib being cost effective at a threshold of £50,000 per QALY gained was <5.4% and <0.05% respectively.

CONCLUSIONS:
Using list prices, compared with BSC, cost effectiveness results for both treatments were >£50,000 per QALY gained. However, these results may be of limited value to decision-makers if lenvatinib and sorafenib are available at discount prices, as in the UK NHS.

OP132 Assessment Of Outpatient Chemotherapy For Cancer Patients In China

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ABSTRACT SUMMARY:
Qualitative analysis, questionnaire survey and comparison of medical expenses based on propensity score matching were performed with the data obtained from 2 hospitals to assess the outpatient chemotherapy for patients with malignant neoplasms in China.

INTRODUCTION:
There is rising morbidity and mortality of malignant neoplasms in China. As inpatient chemotherapy is the mainstay treatment for these patients, it poses overcrowding problem and heavy economic burden in the cancer hospitals oncology departments in general hospitals. Outpatient chemotherapy has been introduced by some hospitals to improve the current situation in recent years. This study sought to assess the effects of outpatient chemotherapy to improve quality of cancer care.

METHODS:
Two Tertiary hospitals (Grade-A) specialized in oncology with outpatient chemotherapy services were chosen as the sample sites. Focus group discussion was used to gather the qualitative data from the hospital managers and medical staffs responsible for outpatient chemotherapy in the hospitals. 36 questionnaires were collected from the medical staffs who worked at the departments.
of outpatient chemotherapy in 2 hospitals. 100 outpatient chemotherapy cases and 100 inpatient chemotherapy cases was collected from the 2 hospitals. One complete chemotherapy cycle was used as the unit to analyze the characteristics of patients and compare the expenses. propensity score matching was used to reduce the imbalance of baseline characteristics.

RESULTS:
The qualitative analysis revealed that the implementation of outpatient chemotherapy improved the efficiency of hospital (e.g., turnover of beds), fulfilled the demand of patients, and reduced the average hospitalization days and the medical expense. The lack of medical insurance coverage and the lack of clinical guidelines were the obstacles for the development of outpatient chemotherapy. In the questionnaire survey, we also found out the favorable responses of reducing hospital beds stress (100%), reducing expense (94.4%), improving the convenience of seeking chemotherapy services (91.7%), improving the patient satisfaction (86.1%), improving the information construction (88.9%), improving the hospital efficiency (97.2%), enhancing the risk management (83.3%), improving the hospital reputation (91.7%), and reducing the waste (94.4%). After the propensity score matching, the mean medical expense of inpatient chemotherapy and outpatient chemotherapy was CNY12478.2 vs. CNY2212.5 (p<0.05) for one hospital and CNY15920.8 vs. CNY10071.77 (p<0.1) for another.

CONCLUSIONS:
The implementation of outpatient chemotherapy improves the efficiency of hospital and reduces the medical expenses. To disseminate and scale up the practice, the medical insurance policy and clinical guidelines should be formulated.

OP133 Using Scenario Studies To Inform Orphan Drug Coverage

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ABSTRACT SUMMARY:
Four empirically-grounded scenarios of possible futures relating to coverage decision-making for expensive orphan drugs for rare disease were deployed in focus groups with decision-makers from four Canadian provinces. Key policy challenges identified by decision-makers included the need to coordinate approval and reimbursement processes, develop new licensing and pricing frameworks, and evaluate new governance frameworks for public and patient engagement.

INTRODUCTION:
Due to the high cost of orphan drugs for rare diseases (DRDs) the use of standard cost-effectiveness thresholds within health technology assessment (HTA) can result in negative reimbursement recommendations. Together with uncertain evidence regarding the effectiveness of some DRDs, this causes a dilemma for public payers because rare disease patients typically have limited treatment options. Our objective was to identify a diverse range of current and future challenges concerning coverage decision-making on DRDs, to explore them with decision-makers, and to develop policy recommendations.

METHODS:
Using a ‘scenario-study’ framework, we constructed four empirically-grounded scenarios
of possible futures relating to decisions on orphan drug coverage for rare diseases. These scenarios were then deployed in four focus groups with decision-makers from four Canadian provinces to explore how they might respond to current trends and future challenges in this area. Transcripts of the focus group discussions were analysed using a qualitative research methodology.

RESULTS:
The focus group discussions indicated a need to coordinate the regulatory approval (federal) and reimbursement (provincial) processes for DRDs in Canada. Relatedly, decision-makers identified a need to develop alternative licensing and pricing frameworks for DRDs where evidence concerning efficacy is lacking. Given the highly political nature of coverage decisions, we also found the need to evaluate new forms of governance that involve publics and patients in diverse components of the coverage decision making process.

CONCLUSIONS:
Current budgetary, regulatory and coverage processes in Canada cannot cope with the proliferation of expensive DRDs. These findings stand to be of particular interest in both Canadian and European contexts where medicines are regulated by a centralized body, but coverage decisions are made at a decentralized level. Further, this project is serving the dual benefit of advancing the fields of HTA and health policy research through methodological innovation in the form of scenario studies.

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ABSTRACT SUMMARY:
This study is first to assess the impact of pCODR decisions on the access to new cancer drugs in Canada’s public drug plans. Data from CADTH and Health Canada were obtained and analyzed. Study found a pressing needed to reduce access barriers due to negative pCODR recommendations and delay in inclusion of positive recommended drugs to provincial drug plan.

INTRODUCTION:
The CADTH pan-Canadian Oncology Drug Review (pCODR) plays an important role in public reimbursement decision-making for oncology drugs in Canada. This study is the first to assess the impact of pCODR decisions on the access to new treatment for cancer in Canada’s public drug plans.

METHODS:
We studied all oncology drugs that received an approval from Health Canada and were reviewed by the pCODR from inception till 26th Sept, 2017. The data was obtained from the www.cadth.ca and Health Canada. Data such as drug indication, submission type, submission date, recommendation date, and final recommendation, and subsequent provincial funding status was extracted and analyzed. Impact was evaluated by analyzing the percentage of drug submissions with assessment outcome (+recommendation rate and conditional recommendation rate) and time taken for the final decision (recommendation gap). Percentage of drugs included in public formulary after +recommendation by pCODR (coverage rate) and the gap in days from +recommendation to subsequent coverage in provinces (coverage gap) was also assessed.

RESULTS:
Among 119 drugs reviewed by pCODR, the +recommendation rate was 8% with nine
applications comprising seven drugs for six indications receiving +recommendation and genitourinary tumor type receiving maximum +recommendations. Whereas conditional recommendation rate was 52% with 62 applications of 45 drugs for 46 indications receiving a conditional recommendation and lymphoma & myeloma tumor type receiving maximum conditional recommendations. The average recommendation gap for positive and conditional recommendations was 180 and 172 days, respectively. Coverage rate for drugs with +recommendation was 100% for all provinces except 89% for Newfoundland and Labrador (NL), and 67% for Prince Edward Island (PEI). Among the provinces, PEI had a maximum of 361 days and SK has the minimum of 165 days coverage gap for drugs receiving subsequent inclusion in drug plan after +recommendation.

CONCLUSIONS:
Despite Health Canada’s approval only a fraction of oncology drugs receive positive pCODR recommendation. Furthermore, provincial drug plans take their own time to include these in the reimbursement formularies. While health technology assessment is crucial for appropriate allocation of limited resource, efforts should also be made to reduce access barriers, particularly to oncology drugs, caused by negative recommendations and subsequent delays in the inclusion of positively recommended drugs in provincial formularies.

INTRODUCTION:
Health care systems around the world struggle with high prices for new oncological drugs. The purpose of this study is to contribute to the ongoing policy debate on high cancer drug prices. To this end, this study conducts a thought experiment and calculates how much health expenditures would increase if a cure for cancer through pharmaceutical treatment were made available.

METHODS:
As its underlying method this study uses a cause-elimination life-table approach and employs German data. In order to account for the age distribution of the population, the study weights age-specific increases in remaining life expectancy by age-specific population sizes.

RESULTS:
Based on the cause-elimination life-table approach and accounting for the age structure of the population, curing cancer in Germany yields an increase in average remaining life expectancy by 2.65 life years. Based on the current ‘exchange rate’ between money and health for new oncological drugs, which is on average €101,493 per life year gained (€39,751/0.39 life years), we would need to pay €275,473 over the lifetime of an individual in order to obtain the gains in life expectancy from cancer elimination. Dividing this figure by current lifetime health expenditures yields a ratio of 2.08, which represents a multiplier of current health expenditures.

CONCLUSIONS:
Eliminating cancer at the current ‘exchange rate’ between money and health would increase total
health expenditures in Germany 2.08-fold or by 108%. A cure for cancer would therefore require a drastic reduction of non-health consumption. Implications for incentivizing future R&D are discussed.

**OP136 Full Texts vs. Conference Abstract Data: How Does The Message Change?**

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**ABSTRACT SUMMARY:**
We assess whether the findings of our systematic review of diagnostic test accuracy would change with including conference abstracts. Our findings suggest that the test accuracy results would not alter substantially by including conference abstracts. Work is ongoing to evaluate whether the assessment of heterogeneity and risk of bias would alter, given the limited methodological reporting from conference abstracts.

**INTRODUCTION:**
High quality evidence for test accuracy can be scarce. We assessed the test accuracy of two tests (Actim Partus and PartoSure) for the prediction of preterm birth. Twenty published full-text papers were included whilst conference abstracts were excluded. Since systematic reviews of diagnostic tests on other topics may need to rely on data from conference abstracts, we test whether the findings of our review would change with conference abstracts included.

**METHODS:**
Conference citations previously excluded (n=108) were re-screened for inclusion using the following criteria: 1) the diagnostic test was Actim Partus or PartoSure 2) test accuracy data of preterm delivery within 7 days was reported 3) the population was women with signs/symptoms of preterm labour with intact membranes Relevant test accuracy data were extracted and used to calculate sensitivity and specificity. Pooled sensitivity and specificity for each test were run using data from full-text papers and conference abstracts combined. These values were compared with the pooled sensitivities and specificities produced for the systematic review using full-text papers only.

**RESULTS:**
Preliminary, pooled sensitivities of the 16 full-text Actim Partus studies and 16 full-texts and two abstracts were 0.77 (95% CI 0.68, 0.83) and 0.76 (95%CI 0.69, 0.83) respectively whilst pooled specificities were 0.81 (95%CI 0.76, 0.85) and 0.80 (95%CI 0.75, 0.84) respectively. Preliminary, pooled sensitivities of the four full-text PartoSure studies and four full-texts and three abstracts were 0.83 (95%CI 0.61, 0.94) and 0.82 (95%CI 0.65, 0.92) respectively, whilst pooled specificities were 0.95 (95%CI 0.89, 0.98) and 0.96 (95%CI 0.94, 0.97) respectively.

**CONCLUSIONS:**
Our findings suggest that the test accuracy results would not alter substantially with the inclusion of conference abstracts. However, work is ongoing to investigate how the assessment of heterogeneity and risk of bias across studies would alter, given the difficulties associated with limited methodological reporting from conference abstracts.
OP137 Adjacency Operators Across Concepts: Impact On Precision And Retrieval

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ABSTRACT SUMMARY:
While adjacency operators typically result in greater precision than the ‘AND’ operator alone, they are typically used to combine text words (TW) within individual concepts (patient* adj3 anxiety), rather than across concepts (diabetes adj3 metformin). This study investigates how using adjacency operators to combine TW searches across concepts impacts retrieval, recall and precision in systematic review searches.

INTRODUCTION:
The objective of database searches for Systematic reviews (SRs) is to retrieve all relevant material within each database, resulting in high recall and low precision. Section 6.4.2 of the Cochrane Handbook recommends that searches for SRs be designed according to the following structure: the controlled vocabulary terms and text words for each concept are combined with the Boolean ‘OR’ operator. Sets for each concept are then combined with the ‘AND’ operator, resulting in a set where each reference contains at least one term from each concept. While the Cochrane Handbook concedes that, when available, the use of adjacency operators results in greater precision than the use of the ‘AND’ operator alone, they are typically used to combine text words within individual concepts (patient* adj3 anxiety), rather than across concepts (diabetes adj3 metformin). Objective: to investigate how the use of adjacency operators to combine text word searches across concepts impacts retrieval, recall and precision in SR searches.

METHODS:
The original Medline searches within a sample of SRs were re-executed for the purpose of calculating recall and precision. Once replicated, the structure of the original strategies were modified using adjacency operators (3 degrees of adjacency were tested: adj10, adj5 and adj3) to combine text word searches across concepts. Recall and precision of the original and modified searches of each SR were calculated and compared.

RESULTS:
Preliminary results indicate that while the use of adjacency operators across concepts does not consistently result in the same sensitivity as the original searches (average decrease from 4.6% to 11.1%), impact on recall is significant (average decrease from 35.2% to 51.2%).

CONCLUSIONS:
Considering that the number of references retrieved has been identified as one of the main variables impacting the time needed to conduct a SR, the use of adjacency operators across concepts could conceivably accelerate the evidence-to-action connection.

OP138 Using Text Mining To Identify Domains Of Wellbeing To Extend The QALY

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ABSTRACT SUMMARY:
The ‘Extending the QALY’ project led by the School of Health and Related Research at the University of Sheffield aims to develop a new generic measure of quality of life. This paper will describe how text mining was used alongside a purposive sampling approach to the identification of domains of wellbeing from the literature.
INTRODUCTION:
The Extending the QALY project aims to develop a broad generic measure of quality of life for use in the economic evaluation of health technologies in health and social care. The objective was to identify domains of wellbeing which are important to patients but are not covered by the current measure. One of the early stages is a review of qualitative literature around wellbeing and quality of life. An innovative approach was used, combining purposive sampling and complementary text mining.

METHODS:
A decision was taken to search for qualitative reviews of wellbeing/quality of life in one condition from each category in the WHO’s International Classification of Diseases (ICD-10). This approach retrieved a representative sample; but concerns persisted about missing reviews spanning multiple conditions. To complement the condition-specific data, a separate literature search was conducted in order to identify reviews of qualitative literature on wellbeing with no disease or condition specified but excluding those already retrieved. The results of this broader search were examined using text mining software in order to identify which domains of wellbeing were reported.

RESULTS:
Preliminary findings suggest that the purposive approach was an effective method of identifying domains of wellbeing which are of importance to patients. The complementary text mining did not reveal any completely new domains not previously identified however, the results confirmed that the domains selected would be relevant across a wider range of conditions, and may inform the weighting they receive in the final version of the measure.

CONCLUSIONS:
For projects where the scope is too broad for conventional review methods, text mining provides a useful complementary method to purposive sampling of the literature.

OP139 Not Using Data From ‘Failed’ Primary Research Undermines HTA Reporting

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ABSTRACT SUMMARY:
Availability of primary evidence is a source of bias which can undermine the conclusions of an Health Technology Assessment (HTA) report. This often occurs because attempts to generate primary evidence gave been partially successful. We discuss how rich qualitative evidence from ‘failed’ clinical trials should be incorporated into HTA reports, allowing information beyond the bounds of meta-analysis.

INTRODUCTION:
The reliability of HTA is built on accessing evidence systematically to inform conclusions and recommendations. However, the availability of primary evidence is a source of bias which can undermine an HTA. This omission is often because attempts to generate primary evidence have not been completely successful. Where partial evidence exists, ignoring it constitutes avoidable bias. Taking the Hip Op trial as an example (a study of developmental dysplasia of the hip (DDH)) we consider how despite lack of quantitative outcomes data, rich information was obtained which should inform HTA in this area.

METHODS:
The Hip Op trial was an open label trial comparing early against late surgery in the management of developmental dysplasia of the hip. In parallel, a qualitative study attempted to explore the experience of parents of children with DDH.

RESULTS:
The trial protocol called for recruitment of 636 children, but due to changes in clinician
equipoise and service configuration only 29 could be recruited. The trial was stopped early. While baseline data for the 29 children was available, no estimate of effect was attempted due to a lack of outcome data. However, the qualitative data was rich, representing the biggest qualitative sample worldwide on this topic. It reflected the patient experience, and shows a clear preference towards early intervention, despite the absence of quantitative evidence.

CONCLUSIONS:
The qualitative work here gives a clear indication that parents have a strong preference. This is data which would not be captured in traditional HTA reports, which tend to focus on quantitative data and meta-analysis. This is however information which is important to patients - and should inform clinicians and payers. We discuss how HTA do-ers should make efforts to find this data from 'failed' primary research and incorporate it into their reports; and how HTA do-ers could be alert to this situation.

INTRODUCTION:
For patients with symptomatic coronary artery disease (CAD), refractory to medical therapy, there are two treatment options: percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG). To elicit patients’ preferences in this scenario may be relevant for the decision making since there is more than one viable treatment option and physicians may value them differently than patients. In this study, we aimed to elicit, rank and rating attributes that may be considered important.

METHODS:
Attributes were selected after a systematic review and face-to-face interviews with patients with CAD and cardiologists. The outcomes selected were stroke, peri-procedural death, long-term survival, post operative infection, atrial fibrillation, myocardial infarction, renal failure, repeat CABG, repeat PCI, postprocedural angina, length of stay, incision scar, pseudo aneurysm and heart failure. These attributes were ranked and rated by participants according to relative importance of attributes. Importance was defined by answering the following question: “how much are you worried about this attribute when you are facing a decision between coronary revascularization treatment options?”

RESULTS:
We enrolled 22 cardiologists and 54 patients. Notably, patients presented discomfort when encouraged to cite possible complications and claimed that they had not spoken to their physicians about them. The peri-procedural death and renal failure were ranked as the most important outcome by physicians and patients respectively. Incision scar was considered as the least important for both groups. There was significant difference for renal failure, long-term survival and periprocedural death. It is worth noting that “repeat PCI”, a very common outcome in clinical trials, was considered one of the least important for patients (13th out of 14) and for physicians (10th out of 14).
CONCLUSIONS:
Patients and physicians value attributes related to CAD treatment differently. Repeat PCI has a limited importance in stakeholders’ perspective. These findings must be considered in future guidelines.

OP141 A Patient-Reported Outcome Measure For Haemorrhoidal Disease

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ABSTRACT SUMMARY:
We developed a core outcome set (COS) and a patient-reported outcome measure (PROM) for haemorrhoidal disease treatment. The PROM can be used in clinical trials as the primary outcome evaluating treatment effectiveness from the patient’s perspective.

INTRODUCTION:
Treatment options for haemorrhoidal disease (HD) include conservative treatment (e.g. laxatives), Rubber Band Ligation, and more invasive surgical treatment options. Outcomes reported in clinical trials evaluating treatment effectiveness are heterogeneous, making comparisons difficult. Moreover, clinical outcomes, such as recurrence, complications and symptoms, do not fully represent the relevant benefits and harms of treatment to the patient. We therefore developed 1) a core outcome set (COS) for HD treatment, and 2) a patient-reported outcome measure (PROM) evaluating symptoms and impact on daily life.

METHODS:
Literature review established outcomes most commonly used in studies evaluating HD treatment. A Delphi study with health professionals and patients was conducted to rank and discuss the outcomes in terms of importance and completeness and reach consensus on a COS. In addition, individual patient interviews (n=15) were held to gain insight into patient experiences with HD and treatment. A panel of experts subsequently developed a PROM that focused on the core outcomes. Face and content validity were assessed (n=10) using a retrospective verbal probing technique.

RESULTS:
Recurrent symptoms, complications and treatment satisfaction were the primary focus for health professionals, while patients were more concerned with overall impact on daily life. Patients ranked blood loss, pain and itching as the most bothersome symptoms. A PROM was developed consisting of seven items covering three domains: severity of symptoms, impact on daily life, and treatment satisfaction (if applicable). The questions and response options were clear to patients and content validity was good. The questionnaire took approximately three minutes to complete.

CONCLUSIONS:
We developed a COS and a PROM for HD treatment. The PROM can be used in clinical trials as the primary outcome measure evaluating treatment effectiveness from the patient’s perspective. It can also support shared decision-making regarding individual treatment pathways in clinical practice. A psychometric validation study is currently underway.
OP143 Conceptualizing Patients’ Experience With Atrial Fibrillation

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ABSTRACT SUMMARY:
This presentation describes the development of a patient-centered conceptual model of the atrial fibrillation patient experience in a United States-based sample. The model, based on the Andersen model of healthcare utilization, was developed by interviewing patients, physicians, pharmacists, and nurses.

INTRODUCTION:
Conceptual models (CMs) are useful tools for researchers and health technology assessment bodies to understand the interplay among environmental characteristics (e.g., health care system), patient characteristics, health behaviors, and patient outcomes. The objective of this pilot study was to elicit perspectives of patients with atrial fibrillation (AF) and health care providers (HCPs) to develop a patient-centered CM of the AF patient experience in a US-based sample.

METHODS:
We developed two preliminary versions of the Andersen model of healthcare utilization (standard and patient-friendly versions) based on the published literature and the help of a patient advisor. For example, instead of describing “predisposing characteristics,” the patient-friendly CM describes, “what is it about me, or other afib patients” that could impact disease or outcomes; “enabling resources” is swapped for “helpful resources,” and “perceived need” is changed to “what impacts whether I believe I need to be treated.” Five patients from an online patient community and 10 HCPs from the University of Maryland Medical System provided feedback on the preliminary models. Audio recordings of interviews were transcribed verbatim, analyzed, and findings incorporated into a revised CM.

RESULTS:
Interviewee additions under “what impacts whether I believe I need to be treated” included: absence of symptoms and fear of experiencing an AF episode; under “helpful resources” suggested additions include resources for navigating insurer formulary/benefits. Suggested additional outcomes of interest include anxiety, bruising, and shortness-of-breath. While patients found the patient-friendly version easy to understand, HCPs required explanation of standard-version headers, for example ‘predisposing characteristics’ and ‘enabling resources,’ which had been adapted in the patient-friendly version.

CONCLUSIONS:
Soliciting input from stakeholders ensures CMs are pragmatic, reflect the “real-world” experiences of patients and HCPs, and incorporate variables or other considerations not currently described in published literature. Researchers can utilize CMs to aid in selection of variables for observational studies.

OP144 Health Economics In Clinical Practice Guidelines: The Know-Do Gap

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ABSTRACT SUMMARY:
A review of recent literature highlighted an under-recognized know-do gap among guideline developers in using health economics information and expertise in guideline development. The advantages and potential limitations of applying health economics to guideline development are discussed, as well as areas where developers can better utilize health technology assessment researchers and health economists to improve the quality of guidelines.

INTRODUCTION:
Clinical practice guidelines (CPGs) are an ideal implementation mechanism for promoting effective clinical practice, but without due consideration of costs they may do more harm than good and become a source of inefficiency. The Alberta Guideline Adaptation Program sought current best practice for incorporating economic information into CPGs to better leverage health technology assessment (HTA) and health economic expertise in its guideline development program.

METHODS:
A comprehensive, systematic review of published and grey literature was undertaken to: • catalogue theoretical frameworks and practical methods for incorporating economic information into CPGs and forecasting the post-implementation economic impact of CPGs; • summarize current methods for evaluating the economic impact of CPGs; • identify barriers and facilitators to incorporating economic information into CPGs.

RESULTS:
Rigorous economic analyses were infrequently incorporated in CPG development. While a selection of guidance documents and CPG manuals published between 2001 and 2017 by leading CPG developers emphasized the health economist’s role and the importance of incorporating economic evidence into CPGs, few provided adequate guidance on the best way to do this. There is no agreement on how best to monitor the economic impact of CPGs. Analysis of a sample of over 100 studies published between 2005 and 2013 identified the three main methods currently used to assess the post-implementation economic impact of CPGs: pre-test/post-test cost analyses, mapping studies, and modelled cost-effectiveness studies. The key elements of each study type were summarized and compared.

CONCLUSIONS:
The review highlighted the under-recognized know-do gap among developers with respect to using health economics information and expertise in CPG development. It identified the advantages and potential limitations of applying health economics to CPG development, as well as areas where developers can better utilize HTA researchers and health economists to improve the quality of guidelines and better document the resource implications and feasibility of the interventions they recommend.

OP145 The Release Of The Fourth Edition CADTH Economic Guidelines – A Year In Review

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ABSTRACT SUMMARY:
In March 2017, CADTH released the 4th edition of the Guidelines for the Economic Evaluations
of Health Technologies. In this presentation, the implementation of the Guidelines will be discussed, approaches taken to facilitate the adoption of the guideline statements presented, and tools to assist users and doers to ensure use of cost effectiveness information in health care decision making.

INTRODUCTION:
In March 2017, CADTH released the 4th edition of the Guidelines for the Economic Evaluations of Health Technologies. As part of the update a few notable changes were made to topics such as: discount rate, target population, modeling, effectiveness, analysis, and the theoretical foundations for the Guidelines. In this presentation, the implementation of the Guidelines will be discussed, approaches taken to facilitate the adoption of the guideline statements presented, and tools to assist users and doers to ensure the use of cost effectiveness information in health care decision making described.

METHODS:
Given some of the changes made to the Guidelines, CADTH identified the need to engage stakeholders early in preparation for the release of the 4th edition. Feedback on topics was sought from various stakeholders (researchers in the field, industry, patient groups, decision makers) throughout the process. As well, suggestions for tools to support the understanding and implementation of the Guidelines were noted by CADTH. To further support to use of the Guidelines, CADTH committed to undertake a number of activities, including: workshops for decision makers and researchers; worked examples to illustrate the approaches; and, development of tools to assist in the use of recommended methods. Updates to submission guidelines for drug submissions to correspond with the Guidelines are ongoing.

RESULTS:
The final version of the Guidelines was greatly influenced by the stakeholder feedback received, with focus on the request for greater clarity. Whilst efforts to increase acceptance and adoption of the guidelines are ongoing, we present preliminary findings with respect to engagement with stakeholders and adoption of new guidance in drug submissions.

CONCLUSIONS:
The plan to engage stakeholders is continuing to be effective. As such, there has been general acceptance for the changes and an interest in seeking education and tools to assist with implementation of the Guidelines.

OP146 Expanding Cost-effectiveness Analysis: Measures And Methods

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ABSTRACT SUMMARY:
This study identifies and defines potentially useful expansions to traditional cost-effectiveness analysis (CEA) used as a part of health technology assessment (HTA) and discusses how they can be operationalized. Novel elements--beyond health gain and cost-offsets--include uncertainty reduction, value of hope, real option value, insurance value, and scientific spillovers. Alternatives for measuring and aggregating these elements are proposed.

INTRODUCTION:
Since the seminal paper by Weinstein and Stason in
The recommended approach for comparing costs and benefits in health technology assessment (HTA) has been the use of the incremental cost-effectiveness ratio (ICER) using the metric of the cost per quality-adjusted life year (QALY) gained, thus allowing comparisons across different technologies. The purpose of this study was to (i) identify and define potentially useful expansions to traditional cost-effectiveness analysis (CEA) used as a part of health technology assessment (HTA) and (ii) discuss how they can be operationalized to support a more comprehensive economic evaluation.

**METHODS:**
Our analysis—grounded theoretically in expected utility maximization—posits that economic value assessment should address three key questions: 1) what are the elements of value?; 2) how are they measured, evidenced, and valued?; and 3) how are they aggregated and judged to reach a decision on value? Current proposed approaches to value frameworks are critiqued in relation to these questions.

**RESULTS:**
Recently proposed value frameworks each have serious shortcomings as measures of value. An expanded framework, incorporating a wider range of the elements of value, is proposed. In addition to the core value drivers of health gain and cost-offsets, we propose that seven other elements deserve consideration: some more common ones (e.g., productivity and impacts on other sectors), and some less recognized ones related to information and the value of knowing (i.e., uncertainty reduction, value of hope, real option value, insurance value, and scientific spillovers). We discuss how they could potentially be included in HTA, exploring alternative ways to measure and aggregate these—from monetizing them via net monetary benefit to their inclusion in multi-criteria decision analysis or in a deliberative process.

**CONCLUSIONS:**

The elements of value for HTA need to be expanded beyond health gain and medical cost-offsets, but there is no one best way to scale, score, and weight these elements. There are, however, alternative ways in which they can be operationalized in reaching decisions, and these approaches are likely to be complementary.

**OP147 Clinical Pathway Of Stroke Therapy Based On 534 Acute Patients**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
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” can improve the medical outcome in these samples.

**INTRODUCTION:**
Actually one observes increasing work loads for the hospital staff (nurses, doctors) during the last 10 years by an average increase of 30% more hospitalized stroke patients. Owing to the larger number of patients and the coincidental reduced length of stay of the stroke patients cause an increasing work load. 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 outcome were measured according the classic neurological tools.

RESULTS:
On the basis of the following neurological clinical tools the medical outcome was mapped: NIHSS (National Institut of Health Stroke Scale), mRS (modified Rankin Scale), FIM (Functional Independence Measure), FAM (Functional Assessment Measure), 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 these samples. Additionally, one gets first positive hints that clinical pathway treated stroke-patients have positive benefits during the HTA-analysis.

ABSTRACT SUMMARY:
This study analyzed the medical costs of long-term care in private health care facilities in Shanghai and evaluated the influence of non-for-profit status of the facilities on their medical costs of long-term care. The results of the study provides evidences and information for regulation and surveillance of Shanghai Social Medical Insurance authorized long-term care facilities in Shanghai.

INTRODUCTION:
To facilitate the development of private long-term care to meet the needs of an ageing population, Shanghai Social Medical Insurance (SSMI) authorized many private health care facilities for their long-term care. Our study aims to evaluate the influence of non-for-profit status of private health care facilities on their medical costs of long-term care in Shanghai.

METHODS:
All data related to inpatients discharged from every private SSMI long-term care facilities in 2016 were extracted from the information system of the Shanghai Municipal Medical Insurance Office. Multilevel linear regression models were used to compare total daily medical costs between private, non-profit SSMI long-term care facilities and private, for-profit SSMI long-term care facilities.

RESULTS:
The study showed that 20,777 inpatients were discharged from 54 private SSMI long-term care facilities. Non-profit SSMI long-term care facilities had more female inpatients, more inpatients aged 80 or older, more inpatients with basic medical insurance for urban employees (BMIUE), and more inpatients with primary diagnoses of four surveyed diseases than did for-profit SSMI long-term care facilities. The average total daily medical cost in private SSMI long-term care facilities was 930.91 yuan. The cost was higher in for-profit facilities than in non-profit ones, even after controlling for inpatient characteristics, size of long-term care facilities, and types of diseases.
CONCLUSIONS:
The high burden of medical costs of private SSMI long-term care facilities will limit the public's access to them. Possible patient selection and supplier-induced services in private, for-profit SSMI long-term care facilities should be supervised and regulated.

OP149 Survival Rates And Costs In Hepatocellular Carcinoma With Cirrhosis

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ABSTRACT SUMMARY:
This article intends to generate real world evidence such as survival rates and medical costs to support the importance for early detection of primary hepatocellular carcinoma patients and this evidence will contribute for further the cost effectiveness analysis of the national liver cancer surveillance program.

INTRODUCTION:
Early detection of primary hepatocellular carcinoma (PHC) patients with cirrhosis is critical to enhance PHC patients' survival rates and to save medical costs. The study aimed to generate real world evidence to support the importance for early detection of PHC patients and this evidence will contribute for further the cost effectiveness analysis of the national liver cancer surveillance program.

METHODS:
A retrospective analysis was performed on 98,275 PHC patients with cirrhosis in the National Center Cancer Registry from 2005 to 2014 linked to the Korea National Health Insurance claims database. The hazard ratio (HR) of mortality within 5 years and medical costs for the patients were compared by surveillance, epidemiology, and end results (SEER) stage.

RESULTS:
There were differences in survival rates and medical costs depending on their characteristics including sex, age at diagnosis, SEER stage and types of initial treatment of cancer. The HR of mortality within 5 years of the PHC patients with distant stage versus local stage was 3.36 with 95% Confidence Interval (95% CI: 3.33 – 3.38) which is higher than those of the patients with regional stage (HR: 1.93, 95% CI: 1.92 – 1.95). The estimated annual medical cost was USD 38,208 with Standard Deviation (SD) 54,399 for localized stage but USD16,345 (SD: 42,377) for distant stage.

CONCLUSIONS:
If PLC patients with cirrhosis were detected at early stage, their survival rates would be clinically better with a big saving for medical costs than if they were detected at distant stage. This result itself highlights that importance of the national liver cancer surveillance program. Future studies are indicated to apply these quantitative results into the cost-effectiveness analysis of the Korean national liver cancer surveillance program.

OP150 Acquired Immune Deficiency Syndrome Benefit Package: A Financial Review

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ABSTRACT SUMMARY:
In 2010, the Philippine National Health Insurance Corporation introduced the Outpatient HIV/AIDS Treatment package to cover for the necessary health expenses of diagnosed patients. This study aimed to reassessed the package to determine if it has been able to improve the financial risk protection of patients and, using evidence-based research, what are the necessary revisions that must be made.

INTRODUCTION:
The Philippines has an increasing number of newly diagnosed cases of Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS). Most Filipinos are also dependent on out-of-pocket (OOP) expenditure to finance their health needs. In 2010, the Philippine National Health Insurance Corporation (PhilHealth) introduced an Outpatient HIV/AIDS Treatment (OHAT) package for patients to cover for necessary basic expenses. The objective of this study is to review the OHAT package in terms of financial risk protection specifically amount of OOP incurred and package support value.

METHODS:
The study was divided into two different phases: (i.) patient surveys (PS) and (ii.) facility costing surveys (FCS). PS focused on information from enrolled and non-enrolled patients specifically their current financial needs and expenses, while the FCS reviewed actual cost breakdown per treatment hub of package inclusions.

RESULTS:
The calculated maximum support value of the package in 2015 was at 267 percent. The median patient OOP is PHP 4,700.00 (USD 92.75) but can be as high as PHP 392,000.00 (USD 7,737.03) per year mostly due to treatment for opportunistic infections (OIs) which are currently not included in the package. High OOP was also due to non-uniform coverage of services across different hubs; there was no consensus among providers on what specifically should be included in the package. This reflected a variety of support value with some hubs falling below patient expenditure.

CONCLUSIONS:
The current OHAT package if properly implemented is sufficient to cover basic yearly needs of patients. However, non-uniform implementation and variation in prices of services per treatment hub means that coverage is not always sufficient in all areas and can cause continued high OOP payment by patients even with insurance coverage. Furthermore, coverage of OI’s as the main driver of increased OOP should be explored.

OP151 Weathering The Development To Adoption Storm: NICE Safe Harbours

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ABSTRACT SUMMARY:
Getting technologies adopted in the UK healthcare system can be time-consuming and complex. The National Institute for Health and Care Excellence Office for Market Access (NICE OMA) has developed a novel approach, as safe harbour engagement framework, to enable greater and more coordinated dialogue between life sciences companies and healthcare system stakeholders on market access issues.

INTRODUCTION:
Getting technologies adopted in the UK healthcare system can be time-consuming and complex. The National Institute for Health and Care Excellence Office for Market Access (NICE OMA) has developed a novel approach to enable greater and
more coordinated dialogue between life sciences companies and healthcare system stakeholders on market access issues.

METHODS:
When establishing NICE OMA, interactions were carried out with life sciences trade associations and key healthcare system stakeholders to explore challenges in market access landscape. Feedback highlighted that dialogue with NICE and other stakeholders is often limited and occurs in high-risk situations; indicating a need for greater and more coordinated dialogue between industry and multiple healthcare system stakeholders outside of formal processes.

RESULTS:
The approach developed is a safe harbour engagement framework which enables NICE OMA to facilitate interaction between life sciences companies and key healthcare system stakeholders; this collaborative approach promotes shared understanding of aspects that will allow innovative technologies to reach patients faster. It brings together multiple organisations in a safe environment where ideas can be exchanged between participants, allowing organisations to think beyond their own area of interest and to work collaboratively. Companies have used the engagement framework flexibly to engage at different stages along the development to adoption journey. Feedback indicates that companies have benefitted from channelling discussions through NICE to bring together key leaders from different organisations, as well as the neutral facilitation of discussions. Healthcare system partners have gained insights/knowledge that hadn’t been apparent beforehand. Patient and clinical representatives have appreciated the opportunity to provide views to a broad range of stakeholders often early in the development of the technology.

CONCLUSIONS:
The NICE OMA safe harbour engagement framework has been well-received to date. Further feedback will be sought to understand the impact in helping to optimise the market access journey.

OP152 Level Of Agreement On EUenetHTA Joint Action 3 Early Dialogues

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ABSTRACT SUMMARY:
This analysis aims to describe if the EUenetHTA Joint action 3 (JA3) early dialogues process modified the commonality across European HTA bodies. During the first four JA3 early dialogues 46 HTA bodies’ positions were identified: full or partial agreement was reached 45 times and only one disagreement was observed. The high commonality observed may be facilitated by the EUenetHTA process.

INTRODUCTION:
A recent article reported a high level of commonality across European Health Technology Assessment bodies’ (HTABs) positions in former parallel scientific advice procedure. Since 2017, the EUenetHTA joint action 3 (JA3) offers a new early dialogue process involving a higher number of European HTABs. The present analysis aims to describe if the JA3 process modified the level of agreement across HTABs.

METHODS:
A descriptive analysis of the written
recommendations provided during every JA3 early dialogues coordinated by the French National Authority for Health (HAS) until November 2017 was conducted. The level of commonality for each HTAB position identified was assessed globally and by domain (population, comparator, outcomes, study design and health economics) and classified as follows: “full agreement” if all HTABs had the same position, “partial agreement” if more than half HTABs had the same position and “disagreement” in all other cases.

RESULTS:
Four JA3 early dialogues were performed until November 2017: two in oncology, one in neurology and one in metabolic disorders. Between 5 and 9 HTABs from 11 European countries participated. A total of 46 positions were identified in these 4 early dialogues: 10 on population, 5 on comparator, 15 on outcomes, 4 on study design and 12 on health economics. Full agreement was reached for 28/46 positions, partial agreement for 17/46 positions and only one disagreement was observed. The level of full agreements was highest for questions on comparators (5/5) and population (9/10) and lower for questions on health economics (6/12).

CONCLUSIONS:
Although the JA3 process substantially increased the number of HTABs participating in the early dialogues, this descriptive analysis suggests that the level of agreement remains very high. This may be facilitated by the high level of dialogue and coordination between HTAB ensured by the EUnetHTA process.

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ABSTRACT SUMMARY:
Since the launch of a new EMA-EunetHTA Parallel Consultations in July 2017, EunetHTA Early-Dialogue (ED) Secretariat has received 14 requests for parallel consultation/multi-HTA. Among the 14 applications, 3 have been cancelled, 5 have been considered as eligible by the ED Working Party for a consolidated recommendation and 10 have pursued individual consultations involving volunteered HTA bodies and EMA.

INTRODUCTION:
In the context of EUnetHTA JA3, EMA-EUnetHTA Parallel Consultation program was launched in July 2017, making EUnetHTA the one-stop-shop for HTA bodies’ (HTAB) involvement in parallel advice on evidence-generation plans.

METHODS:
A EunetHTA Early-Dialogue (ED) Secretariat, has been based at the French National Authority for Health (HAS). Applicants submit a request for an ED to the EUnetHTA ED secretariat (multi-HTA ED) or in parallel to EUnetHTA and EMA (Parallel Consultation, PC). All submissions are reviewed by the ED Working Party (EDWP) composed of representatives from six HTABs experienced in EDs. PC can follow two pathways: the consolidated PC (PCC) which involves the participation of the EDWP, the outcome being a common recommendation and the individual PC (PCI) where individual HTABs participate on a voluntary basis, the outcome being individual recommendations from each HTAB. The choice between the two pathways is made by the EDWP based on defined prioritization criteria. All PCs follow a well-established procedure available online.
RESULTS:
As of November 2017, 14 requests have been received including 11 demands for PC and 3 for multi-HTA ED. Requests concern following disease areas: Onco-haematology (8), Neurology (3), Immuno-inflammation (1), ophthalmology (1), Vaccine (1). Among the 14 applications, 3 have been cancelled, 5 have been considered as eligible by the EDWP for a multi-HTA or PCC and 10 have pursued PCI pathway. Most of them are still ongoing but will be finalized at the time of the HTAi conference.

CONCLUSIONS:
The number of requests for parallel consultation/multi-HTA in the first few months demonstrates the significant interest expressed by drug developers. Building on the success of previous processes established in Europe, the launch of the PC and the EUnetHTA single gateway has reinforced alignment between HTAB as well as coordination with EMA.

OP154 Industry And Clinician Views Of Medtech Innovation Briefings

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ABSTRACT SUMMARY:
Medtech Innovation Briefings (MIBs) provide fast flexible summaries of novel and promising technologies. Surveys of core users and technology manufacturers were conducted to understand views and opinions of MIBs. There was a high level of awareness of MIBs and positive views on the impact of MIBs on access and uptake by the healthcare system. Stakeholders provided feedback for future development.

INTRODUCTION:
The National Institute for Health and Care Excellence Medtech Innovation Briefings (MIBs) are commissioned by NHS England and designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical, digital or diagnostic technologies. MIBs are fast flexible summaries of single technologies that are intended to be responsive to commissioners needs for information about innovative technologies. MIBs include a description of the technology, how it’s used and its potential role in the treatment pathway. They also include a review of relevant published evidence and likely costs. As a relatively new product the format of MIBs continues to evolve and in 2016 a more streamlined evaluation template was introduced. To ensure MIBs continue to meet users’ needs a study was conducted to understand the opinions and requirements of core stakeholders and to identify key areas for future development.

METHODS:
An initial cross-sectional online survey with NHS staff who were potential users of MIBs was carried out in December 2015. A second round of online and mailout surveys were circulated between November 2016 and May 2017 to medical technology manufactures and an additional group of NHS staff. Descriptive analysis was used for all quantitative data and qualitative data was summarised using thematic analysis.

RESULTS:
106 Medical professionals and 42 manufacturer representatives participated in the surveys. More than half of clinicians were aware of MIBs and thought that raising awareness and visibility should be a future priority. Manufactures regarded MIBs as having a positive or mixed impact on innovation, access, or uptake by the healthcare system.

CONCLUSIONS:
Stakeholders are using MIBs in a variety of ways and there was and a range of suggestions for their
future development particularly regarding moving from single technology evaluation to simultaneous assessment of similar technologies.

OP155 From Health Technology Assessment To Medicare Listing In Australia

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Australian Government decisions to subsidise new medical services under Medicare are usually supported by a Health Technology Assessment (HTA), carried out through the independent Medical Services Advisory Committee. Linking HTA to clear and established government consideration and implementation processes has achieved timely outcomes for public funding of new technologies, which in turn has achieved timely outcomes for patients and doctors.

INTRODUCTION:
Medicare is Australia’s universal health care program. A key component is payment of patient benefits for privately rendered professional services listed on the Medicare Benefits Schedule (MBS). Australian Government decisions to list new services on the MBS are usually supported by a Health Technology Assessment (HTA), carried out through the processes of the independent Medical Services Advisory Committee (MSAC). After MSAC recommends public funding of a medical service, there is a structured government approval process encompassing consideration of MSAC’s advice and financial implications. The Department of Health (DoH) then implements the new listing on the MBS. The timeliness of these processes is greatly enhanced by the DoH working alongside MSAC in a complementary fashion, from the very outset of a new application being submitted for consideration.

METHODS:
While MSAC’s evidence gathering and advisory processes are always independent, the DoH’s role includes: • Assessing new applications against MSAC’s Process Framework to determine an application’s suitability and appropriate HTA pathway. • Providing a point of contact for applicants. • Providing policy advice to MSAC, including the early identification of any implementation issues. In addition to regulatory processes, implementation requires the DoH to consult with the medical profession and other government departments, to communicate details of the new listing as well as to discuss any implementation issues.

RESULTS:
Of applications for new medical services eventually supported by MSAC between July 2014 and June 2016 (n=18), the average period of time from MSAC recommendation to MBS listing was 11.9 months.

CONCLUSIONS:
Linking HTA to clear and established government consideration and implementation processes has achieved timely outcomes for public funding of new technologies in Australia, which in turn has achieved timely outcomes for patients and doctors.

OP156 10 Years’ Experience Of New Health Technology Assessment In Korea

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ABSTRACT SUMMARY:
It has been 10 years of New Health Technology
Assessment (NHTA) establishment. The aim of this report is to recollect last 10 years of NHTA and suggest the future of NHTA system.

**INTRODUCTION:**

New health technology assessment (NHTA) system was established in 2007 and is conducted by the National Evidence–Based Healthcare Collaborating Agency (NECA) in Korea. NHTA is a system to introduce safe and effective health technologies to medical field. The purpose of NHTA can be defined as 1) to protect the health rights of people, 2) to manage the health insurance budget efficiently. The aim of this report is to recollect last 10 years of NHTA and suggest the future of NHTA system.

**METHODS:**

We performed the statistical analysis of assessment results. Also, we reviewed the systemic change of NHTA. And we suggest the future of NHTA system that beyond the evidence-based HTA.

**RESULTS:**

Total 2,122 technologies were applied for the NHTA. Among them, around 1,800 technologies are assessed and 1,100 (61.1% of assessment) technologies are introduced to medical field. Most of applied technologies are related to medical field (96.2%), and some are dentistry (1.5%) and traditional medicine (2.0%). About half (48.2%) of technologies are applied by non-medical agencies such as medical device company. More than 80% of applied technologies are accompanied by medical devices (1,562 technologies). This result indicates that NHTA are closely related to industry. Some important changes to enhance the conveniences of medical industry are arisen during 10 years. Representative change is the unified assessment system. In unified assessment system, medical device approval and NHTA are conducted simultaneously to reduce the time required for market introduction of new medical devices. Another representative change is the conditional approval system. Conditional approval system is conditional introduction of health technology into the market and support evidences generation regarding the safety and the effectiveness. Since its conditioned, technologies can be used only in selected medical institutions for limited periods (3 years). Although it is obvious that the systematic literature review is the best methodology to seek the scientific evidences of health technology, it has limitation that some technologies may not be assessed including newly developed technologies and health technologies related to rare diseases, due to lack of literature evidences. To overcome the limitation, we try to introduce the value-based HTA beyond the evidence-based HTA. In 2017, we performed a research to develop the methodology of value-based HTA. And in 2008, we are planning to conduct the pilot project to settle down the value-based HTA in NHTA system.

**CONCLUSIONS:**

During 10 years after the NHTA system established, many systemic changes are occurred to yield to demand around the system. And the system will be changed consistently as the environment changes. However, we will try to keep the core purpose of the system that is protecting the health right of people in Korea.

**OP157 Quo Vadis Romanian HTA?**

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**ABSTRACT SUMMARY:**

Applying HTA in Romanian healthcare system is a new and unique approach by using a scorecard as a tool for rapid assessment of drugs. However, pros and cons of this approach are identified and results in terms of number and type of drugs reimbursed during the period of implementation (2014–2017).
INTRODUCTION:
Romanian healthcare system is struggling to use a more transparent approach in evaluating health care technologies for more than 10 years. Even though, not a systemic and satisfactory approach was implemented till present to evaluate health technologies. The objective of the presentation is to present the characteristics of the HTA system used by the Romanian healthcare authority as well as the consequences of the drug assessments by using the actual Romanian HTA evaluation framework, from the initiation, May 2014 till end of year 2017.

METHODS:
The drug reimbursement context and the healthcare legislation regarding HTA evaluation were studied. A critical appraisal of the scorecard was conducted, taking into consideration general principles of the Health technology assessment. A descriptive analyse covering the assessment drug reports issued by the National Agency for Drug and Medical Devices (NADMD) issued between May 2014 and December 2017 was presented, together with the decision made by the Ministry of Health and the Romanian government.

RESULTS:
During the analysed period of time, more than 10 updates of the reimbursement list were implemented by the Ministry of Health. By November 2017, more than 180 drugs (new INN, new indications or fix dose combinations) were included in the reimbursement system with conditional or unconditional reimbursement; more than 230 reports were assessed by the NADMD. While the new drugs reimbursed between May 2014-November 2017, in most part, demonstrated cost savings, a lot of new innovative drugs proposed to be evaluated were rejected since the drugs had no comparators on the Romanian market and their cost have been considered with negative impact on the healthcare budget.

CONCLUSIONS:
The rapid HTA assessment has many strengths, by using a proper scorecard. Limitations and weakness of the actual scorecard were identified, mainly regarding the lack of a basic budget impact analysis which must include at least the direct healthcare cost, as well as the imported results of different healthcare environments that are not matching the Romanian context. Opportunities to implement a more rapid and accurate HTA evaluation are identified since the scorecard could be updated in order to address the HTA general principles.

OP158 Overview Of The Technologies Assessment For Multiple Sclerosis In SUS

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ABSTRACT SUMMARY:
The CONITEC provides technical support to SUS in decision-making process. This study describes CONITEC’s assessments of submissions for incorporation, disinvestment or alteration of treatment for MS. From 2012-2017 ten technical reports about health technologies incorporation of treatment for MS were produced. The CONITEC recommended 50% of the requests and resulted in profound change in current clinical guideline.

INTRODUCTION:
The National Committee for Health Technology Incorporation (CONITEC) in the Brazilian Public Health System (SUS) has a structured process for the incorporation, disinvestment or alteration of different health technologies into SUS and to
provide technical support to decision-making process. Since its creation, CONITEC has received several submissions for incorporation of medicines and update of clinical guideline for multiple sclerosis (MS). Nowadays, more than 12 different therapies currently available to treat MS and the Brazilian clinical guideline, which last updated in 2015, offers 6 medicines to treat MS, divided into 1st, 2nd and 3rd line of treatment. The purpose of this study is to describe CONITEC’s assessments of applications for incorporation, disinvestment or alteration of medicines for MS.

METHODS:
A case study method was used and information about the health technologies reports developed by CONITEC’s Executive Secretariat in response to the applicants in the period 2012 to 2017 was retrieved from CONITEC database.

RESULTS:
Ten technical reports on health technologies for MS were produced by CONITEC during this period. This number represents 3.7% of the external submissions for incorporation of technologies for several clinical conditions in SUS. Six medicines were evaluated and the most submissions were made for incorporation (6), followed by alteration of treatment lines (3) and disinvestment (1) and 50% of them were not recommended. The main reasons were low or unproven efficacy, high budget impact and inadequacy of the proposal with the evidence presented. The CONITEC’s favorable recommendations implied a profound change in the current clinical guideline and impact on the SUS.

CONCLUSIONS:
MS is considered a rare disease in Brazil but there is significant pressure by society to provide better treatments options that impact the MS scenario. The recent CONITEC assessments have led to a revolution in the treatment of MS in Brazil that is in the process of being updated.

OP159 Shared Decision Making At Public Tertiary Hospitals In China

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ABSTRACT SUMMARY:
This study revealed the shared decision making in tertiary public hospitals in China and the influencing factors of shared decision making, indicating that shared decision making with deficits. Implementations should be taken to improve the shared decision making. Hospitals and physicians should provide more opportunities to encourage patients to participate the decision-making.

INTRODUCTION:
In china, more than 90 percent of outpatients go to public hospitals for medical treatment. Tertiary hospitals are mainly responsible for the treatment of serious illness, so shared decision making is very important in tertiary public hospitals. Despite surveys reporting that physicians are aware of what shared decision making is and have positive attitudes towards its use, implementation into clinical practice remains challenging. This study revealed the shared decision making in tertiary public hospitals in China and the influencing factors of shared decision making, improving patient-perspective on shared decision making.

METHODS:
An outpatient experience survey was discharged from public hospitals in Shanghai, China between July and August 2017. 47 tertiary public hospitals in Shanghai were selected, with the total number of 1174 patients. Outpatient experience was self-
reported based on 8 questions including 2 shared decision-making questions. Logistic model was used to analyze the influencing factors of the shared decision makings. Person correlation for the relationship between shared decision and other three patient experiences with physician services.

RESULTS:
Out of 1174 participants, 706 (63.49%) patients strongly agreed the question “Physician provided detailed information regarding the treatment plan including alternative treatment”. 715 (62.24%) patients strongly agreed the question “Physician considered the patient’s preferences and situations when making treatment decisions”. Residence, health condition were the influencing factors of the shared decision making. Shared decision making was strong positive related with physician-patient communication and physicians’ care, while was moderately related with physicians’ respect.

CONCLUSIONS:
However, this study indicated shared decision making with deficits. Implementations should be taken to improve the shared decision making.

OP160 Enhancing Innovation Through HTA: Experience From South Australia

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ABSTRACT SUMMARY:
A robust statewide HTA program overseen by SAPACT was implemented to support equitable access to safe, clinically effective and cost-efficient health technologies. It utilises best available evidence to guide decision-making for dis-/investment in health technologies; improve patient safety and clinical outcomes. Focusing on clinical engagement, information-sharing and system-wide capacity building, the program is well integrated with benefits and challenges.

INTRODUCTION:
Access to new technologies was previously variable across SA Health and limited to individual requests. The statewide HTA program provides assessment of high-cost/ high-risk technologies/those with system-wide impact.

METHODS:
Local hospital networks and clinicians refer technologies to SAPACT for assessment. Independent comprehensive HTA reports are developed using internationally recognised evidence and critical appraisal methodologies. Clinical and economic systematic analyses are utilised with extensive clinical consultation to develop recommendations for an approved new technology. Requirements fitting models of care and appropriate credentialing are considered. For approved technologies, SAPACT may also develop audit criteria and seek implementation reports on clinical outcomes.

RESULTS:
The HTA framework is successfully adopted across SA Health, increasing the incorporation of evidenced-based decision making for use of high cost and high-risk health technologies. Over 35 evidence evaluations for high-risk and high-cost health technologies were conducted for a broad range of treatment interventions. SAPACT develop and utilise HTA Decision-making Criteria for transparency on Committee’s considerations. The program recommends adoption of technologies and rejects a number or requested re-submission due to safety concerns or lack of effectiveness. SAPACT has also given recommended temporary approval through adoption under clinical evaluation to inform investment decisions. A key component is
working with clinicians to define specific treatment criteria and patient selection. SAPACT continues to strengthen relationships with all stakeholders, increase patient input through the development of public summary documents for technologies and improve monitoring and reporting of clinical outcomes.

CONCLUSIONS:
The program is very productive and positively received. The success of the HTA program is underpinned by engagement with clinicians, hospital networks and consumers. The completion of SAPACT HTA reviews and the publication of the SAPACT Decision Making Criteria, increased the credibility of decisions supporting enhancements in patient care and cost efficient for the state government.

OP161 Relationship Between Appropriateness And Arthroplasty Recommendation

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ABSTRACT SUMMARY:
We examined relationships between validated measures of surgical ‘appropriateness’ constructs and surgeon recommendation for total knee arthroplasty (TKA) in osteoarthritis (OA) patients. Multivariable logistic regression demonstrated that knee symptoms, prior non-surgical OA management, readiness for surgery and TKA expectations were significantly and independently associated with TKA recommendation. Our further research will evaluate predictive validity for patient-reported TKA outcomes.

INTRODUCTION:
We examined relationships between measures of TKA ‘appropriateness’ constructs and surgeon TKA recommendations in people with knee OA. Although TKA is highly effective, 15-30% of recipients report little or no symptom improvement and/or dissatisfaction. More appropriate selection of surgical candidates may improve both patient outcomes and health care resource use, but no validated appropriateness criteria exist currently in Canada.

METHODS:
Patients with knee OA ≥30 years referred for surgical consultation at two large joint arthroplasty centres in Alberta, Canada were invited to participate. Participants completed a standardized pre-consult questionnaire, which included socio-demographics and validated measures of appropriateness constructs for TKA: knee symptoms, non-surgical management, patient readiness for and expectations of TKA, net patient benefit. Post-consultation, surgeons were asked to confirm knee OA and their recommendation. We used multivariable logistic regression to examine the relationship between measures of appropriateness constructs and receipt of surgeon TKA recommendation.

RESULTS:
Of 3,009 patients approached, 2,360 completed the questionnaire and 2,064 (69%) were confirmed eligible at surgical consultation (mean age 65.7 years, SD 9.1; 58.6% female); 1,495 (72.4%) were recommended for TKA. The likelihood of receiving TKA recommendation was independently
associated with knee symptoms (OR/unit increase in pain intensity 1.19 (95%CI=1.11-1.27); prior non-surgical OA management (OR for prior knee injection 1.53 (95%CI=1.21-1.94), readiness for surgery (OR if definitely/probably willing to undergo TKA 3.03 (95%CI=1.99-4.59); TKA expectations (OR outcome ‘very important’: ability to perform daily activities 1.40 (95%CI=1.04-1.88); straighten the knee/leg 1.42 (95%CI=1.13-1.80); participate in exercise/sports 0.75 (95%CI=0.58-0.98).

CONCLUSIONS:
In our cohort of patients with confirmed knee OA consulting a surgeon for TKA, appropriateness constructs were significantly associated with receipt of a TKA recommendation. Research is ongoing to evaluate the predictive validity of these measures for patient-reported outcomes associated with TKA.

OP162 Access To Biologics In Regional And Remote Australia

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ABSTRACT SUMMARY:
Australians living outside of metropolitan areas tend to have shorter lives, higher levels of disease and poorer access to health services. A geographical analysis of biologic drug utilization confirms that non-metropolitan populations access fewer intravenous treatments compared to subcutaneous treatments. A reimbursed subcutaneous treatment option in ulcerative colitis could increase the number of people with access to treatment.

INTRODUCTION:
The concept of remoteness is an important dimension of policy development in Australia. According to the Australian Institute of Health and Welfare, Australians living outside of metropolitan areas tend to have shorter lives, higher levels of disease and poorer access to health services. Infliximab and vedolizumab, administered via intravenous (IV) infusion, have been reimbursed for the treatment of moderate-to-severe ulcerative colitis (UC) since December 2014 and August 2015 respectively. This analysis estimates the impact on the number of regional and remote patients with improved access to treatment following reimbursement of a subcutaneous (SC) biologic, adalimumab (ADA), in December 2016.

METHODS:
Ex-wholesaler unit sales were classified according to the Australian Standard Geographical Classification Remoteness Structure to obtain remoteness distributions for each biologic for 2015 and 2016. A weighted geographical distribution for the IV biologics was obtained using moderate-to-severe UC prescription numbers. The geographical distribution for ADA observed in other indications was applied to a hypothetical population. Holding the number of patients living in major cities constant, a second population was constructed based on the IV distribution. The difference between the two populations was calculated for each regional and remote classification.

RESULTS:
Major cities account for 67.5 percent of ADA utilization versus 87.9 for IV biologics; regional areas 30.3 versus 11.6; and remote areas 2.2 versus 0.5. With a reimbursed SC treatment option for UC, it is estimated that 2.4 times more regional, 3.2 times more remote, and 10.5 times more very remote Australians would have access to biologic treatment.

CONCLUSIONS:
The availability of a reimbursed SC treatment option for moderate-to-severe UC should improve equity of access to effective treatment for people living...
with UC in regional and remote areas of Australia. Further investigation of the geographic utilization of biologics in UC would be informative once ADA has been reimbursed for several years.

OP163 EUnetHTA JA3 Relative Effectiveness Pilots: Pharma Company Experience

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ABSTRACT SUMMARY:
The experience with one of the first relative effectiveness assessment (REA) pilots in EUnetHTA Joint Action 3 will be comprehensively reflected upon from a pharmaceutical manufacturer perspective. Potential measures to further improve the EU-collaboration on REA will be proposed.

INTRODUCTION:
More than 50 HTA agencies evaluate the clinical value of medicines in Europe resulting in duplication of work for HTA agencies and manufacturers and lengthy and variable time to reimbursement for patients across Europe. A consistent, single European HTA of the relative clinical effectiveness of medicines can become a key element in ensuring patients get equitable and timely access to care in Europe. EUnetHTA is responsible under Joint Action 3 (JA3, 2016-2020) to pilot more than 30 Relative Effectiveness Assessments (REAs) of medicines. First EUnetHTA JA3 REA pilots are now being completed and Roche, with its participation the REA pilot for Alectinib, has gathered relevant experience.

METHODS:
The goal of this analysis is to summarize and reflect upon the experience with one of the first EUnetHTA REA assessments in JA 3. Drawing on the experience of the authors and the earlier experience gathered in JA2 REA pilots, potential process improvements will be proposed.

RESULTS:
The Alectenib assessment demonstrates that EUnetHTA processes have improved compared to JA2. The timing of the assessment is aligned with the regulatory EMA process. It has been possible to adjust the duration of the scoping phase to a shortened regulatory approval process. There is an increased commitment at the end of a growing number of EUnetHTA members to use the reports in national HTA, pricing and reimbursement processes. At the same time, the pilots so far have identified areas that could benefit from further refinement e.g. the active engagement of patient group representatives and clinical experts, rules and principles related to the handling of confidential information. Participation in the JA3 REA pilot has provided the manufacturer with unique opportunities to strengthen internal processes, to avoid the duplication of work in the HTA submission process and to internally align between the global, regional and national organization.

CONCLUSIONS:
Based on the limited number of REA pilots for medicines it is too early to draw final conclusions on the state of EU-level collaboration in this field. But first signals are positive. The active involvement of clinical experts and patient organizations seems of critical importance to advance activity in this field. Interim evaluations are recommended to assess progress, and capture learnings for future pilots.
**OP164 Hospital Budget Impact Of High-cost Drugs: The Case Of Nusinersen**

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**ABSTRACT SUMMARY:**
Hospital Garrahan provides multidisciplinary care for a large cohort of children with spinal muscular atrophy (SMA). Budget impact of nusinersen treatment of eligible patients made financing unaffordable. Collaboration with the central level for negotiation of an expanded access program based on risk-sharing was proposed and implemented.

**INTRODUCTION:**
Nusinersen is an orphan drug for SMA recently approved for marketing. Its high cost, striking but limited evidence of efficacy, and strong demand by media and patient organizations have generated a health policy conflict. We analyze the flaws of available evidence on nusinersen and its budget impact at a pediatric hospital, and report a collaborative strategy for drug procurement and financing.

**METHODS:**
Nusinersen is the highest-cost drug assessed by our HB-HTA program so far. At the time of our assessment, only interim-analysis data of the pivotal randomized trial submitted to FDA for approval and the EMA report containing unpublished final results were available. These secondary sources and other published phase II results were appraised. As a referral hospital we concentrate most of the 300 SMA patients in our country. Hospital budget impact estimation included drug and hospitalization costs for the first and following years. The HTA report was submitted to the Ministry of Health to address this financing issue.

**RESULTS:**
The available evidence of efficacy raised serious methodological and clinical uncertainties. First-year treatment cost per patient was estimated in Argentine $13.008.688 (US$752.000, 10% of Pharmacy annual drug budget). Hospital budget impact (70 eligible patients) was $910.608.160 (US$52.000.000, 18% of total annual hospital budget). Our recommendation was to contact central level authorities to resolve both drug financing and patient access by negotiating a shared-risk approach for an expanded access program, allowing further data collection for reassessment after 12 months. This in turn fostered mutual collaboration and consensus within the health system where several lawsuits were demanding drug coverage. Negotiation with the industry was initiated by the ministry.

**CONCLUSIONS:**
This case is a clear example of forthcoming ultra-high-cost drugs unaffordable by hospital budgets. Their acquisition opportunity cost is a health policy matter requiring to display collaborative coping strategies with ministries and other stakeholders including industry.

**OP165 The Effectiveness Of NOAC And VKA: Observational Study In Japan**

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**ABSTRACT SUMMARY:**
Our study evaluated the long-term effectiveness of NOAC and VKA in patients with NVAF using the Japanese National Insurance Claims Database (NDB) between April 2010 to December 2015, included Diagnosis, Medical treatment, Medicine Usage. Our study showed no significant to clinical effectiveness between NOACs and VKAs.
INTRODUCTION:
Non-vitamin K antagonist oral anticoagulant (NOAC) is approved as anticoagulant for minimizing the risk of recurrence like Stroke or transient ischemic attack (TIA) in patients with non-valvular atrial fibrillation (NVAF). Previous study clarified the clinical effectiveness of NOACs by clinical trial and long-term follow-up clinical research. However, no significant difference was found between NOACs and VKA for clinical effectiveness by nationwide claim database. Our study evaluated the long-term effectiveness of NOAC and VKA in patients with NVAF using the Japanese National Insurance Claims Database (NDB). 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 98.1% of the medical institutions in Japan. The insured medical treatment was based on medical practice determined by the Central Social Insurance Medical Council. It could be claimed for medical treatment in accordance with criteria for institutional structure or patients’ comorbidity. In the Japanese healthcare delivery system, insured people may visit any hospital or clinic at any time. Therefore, the NDB has claim information with the cross-medical institutions nationwide. Those data are consistent and can be used to follow patients receiving long-term care across institutions.

METHODS:
Our study use the Japanese National Insurance Claims Database (NDB) between April 2010 to December 2015. NDB include Diagnosis, Medical treatment, Medicine Usage, Device Usage, reimbursement expenditure. We developed the standard datasets for cost-effectiveness analysis and generate patient episode dataset based hospitalization and out-patients after discharge. Our study used extracted at 10% random dataset for analysis. Main diagnosis is NVAF (I48.x) and congestive heart failure: CHF (I50.x). total number of insurance claim is 6,045,196, excluding younger than 15-year-old. We identified people with NOACs and VKAs based on Anatomical Therapeutic Chemical (ATC) classification code. We identified people with a first-time purchase of a NOACs and VKAs. Endpoint and variable of outcome is stroke or ischemic stroke (I63.0-I63.9, I64.9), transient ischemic attack (TIA) (G45.0-G45.9). The comorbidity index is thrombosis (I74.0-I74.9), lung embolism (I26.0-I26.9), acute myocardial infarction (I21.0-I21.9, I23.0-I23.9), Atherosclerosis (I70.x-I71.x,I73.9) diabetes (E10.x,E11.x), hypertonien (I10.x-I13.x,I15.x), COPD (J44.x), valve diseases (I05.x-I06.x, I34.x-I35.x), and CHA2DS score. Payment variable is reimbursement per patient and treatment days.

RESULTS:
The number of NOACs and VKAs are 1,399 and 5,274 patients, respectively. The rate of older than 85-year-old patients is 6.5%(NOACs) and 9.9%(VKAs). The comorbidity index of Atherosclerosis and Diabetes showed that NOACs were higher than VKAs. Endpoint of (ischemic) stroke and TIA were no significant difference between NOACs(12.6%) and VKAs(12.3%). Treatment days from of NOACs is 3 months shorter than VKAs, but the reimbursement payment of NOACs is more 1.6 higher than VKAs.

CONCLUSIONS:
Our observational study using national insurance claim database showed no significant to clinical effectiveness between NOACs and VKAs. Our study supported several previous observational studies using nationwide administrative claim database.

OP166 How Responsive Is Industry To Value Based Procurement (VBP)?

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**ABSTRACT SUMMARY:**
EU directive on public procurement strives to stimulate innovation and seeks for methodologies to implement a quality/cost based Most Economically Advantageous Tendering (MEAT). The MEAT Value-Based-Procurement is a framework, compiling best practices and based on layers and considering value from different perspectives. The first EU pilot testing the feasibility to use the MEAT’s framework/tool at our university hospital is presented.

**INTRODUCTION:**
EU directive (2014/24) on public procurement strives to stimulate innovation and seeks for methodologies to implement a quality/cost based Most Economically Advantageous Tendering (MEAT). MedTech Europe launched the MEAT Value-Based-Procurement initiative: a framework, compiling best practices and based on layers covering from outcomes/costs and considering value from different perspectives as proposed by the HTAi policy forum. The process and results from the first EU pilot testing the feasibility to use the MEAT’s framework/tool at our university hospital is presented.

**METHODS:**
The pilot included different types of technologies: high volume (underpads, diapers) and highly specialized (TAVI). Companies were invited to participate following standard procurement rules. Criteria, metrics (i.e. measurement units) and weights were defined, using multidisciplinary teams. In parallel, companies were asked to do the same justifying their criteria selection. Information provided by companies was reviewed; scores for products performance were obtained through regression analysis. Challenges and feasibility of implementing a MEAT process in real life were identified through face-to-face meetings.

**RESULTS:**
The process was valued by companies and our procurement organization. Nevertheless, level of information provided by companies was not homogeneous either in quantity or quality. There was a greater coincidence between the criteria proposed by HCB and companies in the outcomes/costs layer, nevertheless relative weights differed. The challenges to provide value propositions and robustness of information differed across technologies and size of companies. Implementing the MEAT Value-based-Procurement framework/tool requires additional expertise, buy-in and is more time consuming. For identifying relevant and valuing some criteria knowledge gathered from HB-HTA is an asset.

**CONCLUSIONS:**
MEAT is an opportunity to value technologies ahead of price. While extra time and knowledge is needed, a learning curve exists. MEAT value-based-procurement facilitates a more comprehensive value and a full cost of care consideration and can lead to economic most advantageous purchasing.

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**OP167 Recommendations On HTA Guidelines For Medical Devices**

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ABSTRACT SUMMARY:
There is an increasing trend to evaluate the impact of medical devices within various health and social care systems. The International Federation of Medical and Biological Engineers (IFMBE) convened two structured focus group sessions to develop recommendations to address the gaps in HTA guidelines for devices. The proposed recommendations aim to provide a more integrated approach in medical device assessments.

INTRODUCTION:
There is an increasing trend to evaluate the impact of medical devices within various health and social care systems. Existing HTA guidelines can benefit from the contribution of the biomedical and clinical engineering community working in all stages of the product lifecycle. Our study objectives were to: i) review current HTA medical device guidelines; ii) develop recommendations to address the identified gaps in the guidelines from a biomedical and clinical engineering perspective; and iii) to reach a consensus on the proposed recommendations.

METHODS:
A grey literature search of HTA agency websites was conducted to identify, review, and summarize current HTA methods guidelines for medical devices. The International Federation of Medical and Biological Engineers (IFMBE) then convened two structured focus group sessions to develop recommendations to address the gaps in these guidelines. A modified Delphi survey is underway to enhance and achieve consensus on the proposed recommendations. Respondents include biomedical and clinical engineers involved in the design, development, implementation, maintenance, and assessment of medical devices.

RESULTS:
Seven HTA guidelines for medical devices were identified. Our review indicated that gaps exist in the guidelines as the methods described to conduct clinical, ergonomic, and economic evaluations were not specific enough for devices. None addressed the shorter product lifecycle, and one guideline only discussed issues in use. The proposed recommendations centered on the medical device characteristics and functionality. To ensure their comprehensiveness, they were organized by the product lifecycle, clinical evaluation, user issues, and costs and economic evaluation.

CONCLUSIONS:
As the medical device characteristics and functionality are unique, current HTA methods may not accurately reflect the conclusions of their assessment. Recommendations proposed by the IFMBE focus group aim to address the existing gaps and to provide a more integrated approach in medical device assessments. Final recommendations from the Delphi survey will be presented.

OP168 Delivering Health Technology Management Through Decision Modelling

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ABSTRACT SUMMARY:
This paper examines two health technology management (HTM) case studies, each highlighting how model-based analyses can support HTM, moving us towards more balance in our analytic work between new and existing in-use technologies.

INTRODUCTION:
With intense pressure on health care budgets, the need is for disinvestment in low-value technologies...
and possible re-investment in higher value alternatives. Some refer to this as health technology management (HTM), a process of analysis and evidence-informed decision making throughout a technology’s life-cycle. The primary challenge is not conceptual – stakeholders typically endorse an HTM approach – but rather operational. For example, the search for potential disinvestment topics is challenging. Our hypothesis is that disease-based modelling of pathways, undertaken by multidisciplinary teams (analysts, clinicians, policy-makers, patients, etc.), can effectively facilitate HTM, including disinvestment decision-making.

METHODS:
This paper examines two HTM case studies, each highlighting how model-based analyses can support HTM, moving us towards more balance in our analytic work between new and existing in-use technologies. The first case considered people with uncomplicated symptomatic gallstones or cholecystitis, comparing a more conservative approach with immediate cholecystectomy (the current standard of care). The second, in the context of diabetic retinopathy screening, explored a less frequent approach (biennial) compared to the current standard of annual screening.

RESULTS:
The first case study indicates potential for the conservative approach to deliver significant cost savings but also highlighted significant uncertainties in cost-effectiveness. Given these uncertainties, a pragmatic multicentre trial has now been commissioned to address this question. The retinopathy model identified scope for biennial screening in low-risk individuals to generate significant cost savings for negligible reductions in health outcomes. This policy is now being pursued in the UK.

CONCLUSIONS:
The case studies demonstrate the value of decision modelling as a method to inform technology management decisions and to focus the research agenda around them. The ultimate objective of economic evaluation should be to inform reallocations of resources that improve population health in the face of resource scarcity.

OP169 Usability Evaluation Of A Portable Dry-Electrode ECG Device In Vietnam

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ABSTRACT SUMMARY:
As cardiovascular disease is now the leading cause of death in Vietnam, there is an urgent need of affordable and convenient cardiovascular care and services at primary care level. This study evaluated the usability of a portable dry-electrode electrocardiography (ECG) device in supporting ECG service delivery in Vietnam.

INTRODUCTION:
According to the Vietnamese Cardiovascular Association, one-fifth of Vietnam’s population is suffering from cardiovascular disease (CVD) – now the leading cause of death in the country that accounts for about one-third of total deaths every year. Yet affordable and convenient solutions to monitor and detect CVDs remain limited and
not available nation-wide. This study aimed to investigate the usability of a portable dry-electrode electrocardiography (ECG) device, paired with a mobile phone, in supporting ECG service delivery in Vietnam.

METHODS:
An evaluation study was designed to combine a portable dry-electrode ECG device to measure and a mobile phone to receive and record ECG signals. Healthy young college students were invited to participate in the study. Three rounds of ECG measurement were administered for each of the participants. Usability of the device was assessed through the reliability of the measures and feasibility of use during intervention. Standard error of measurement (SEM) and intra-class correlation coefficient (ICC) estimations were used for reliability, while structured questionnaire administered before and after measures was used for feasibility assessments.

RESULTS:
A total of 234 participants enrolled in the study. No major difference was found in SEMs between trials 1 and 2 (4.96% [90%CI 4.61-5.37]) and 2 and 3 (4.14% [90%CI 3.85-4.48]). A slight improvement was observed in ICC of trials 2 and 3 (0.95 [90%CI 0.94-0.96]) in comparison to one of trials 1 and 2 (0.94 [90%CI 0.92-0.95]). The SEM and average ICC of all trials were 3.41 [90%CI 3.17-3.69] and 0.96 [90%CI 0.95-0.96] respectively. 45% of participants thought the device would be suitable for their parents while 69% thought the device would benefit their grandparents the most.

CONCLUSIONS:
High consistency of measures demonstrated that the device is reliable to provide ECG service delivery. The study also showed great potential of device usage in primary health care of Vietnam.

OP170 Regulatory & HTA Considerations In Alzheimer’s Disease

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ABSTRACT SUMMARY:
This presentation will summarise the key lessons from the first year of ROADMAP’s Regulatory and HTA expert advisory group and identifies the next steps that are need to prepare Europe’s healthcare systems for a disease-modifying drug in Alzheimer’s disease.

INTRODUCTION:
There has been a move towards the development of disease-modifying agents in Alzheimer’s disease (AD) and it is likely that early disease-modifying treatments will initially be offered to people who have positive AD markers and mild cognitive impairment (MCI). Consequently, disease-modifying drugs will have distinctive features as compared to currently licenced symptomatic treatments, which makes the implications of these new agents for regulatory and health technology assessment (HTA) processes unclear.

METHODS:
The ROADMAP (real-world outcomes across the AD spectrum for better care) project provides the foundation for a European data platform for real-world evidence in AD and established an expert advisory group (EXAG) consisting of regulatory and HTA experts. This presentation will summarise the key lessons from the first year of ROADMAP’s EXAG and identifies the next steps that are required to prepare Europe’s healthcare systems for a disease-modifying drug.
RESULTS:
The EXAG identified a need for establishing the rationale and justification for the selection of priority outcomes in pre-clinical AD and MCI; establishing accepted outcomes for defining prevention of AD or delayed AD onset; exploring modern technology that could assist in testing cognition that could easily be used in clinical practice, establishing the caregiver-relevant outcomes (quality of life, loss of income, carer time) that are important to capture; and found that not all evidence to support modelling assumptions can be generated through RCTs, making the case for using real-world evidence.

CONCLUSIONS:
Many of the challenges that the EXAG identified can be solved by generating better real-world data in AD. There is a clear need to agree on the outcomes that will facilitate and inform regulatory and HTA decision-making. Once the gaps in the availability of outcomes in AD will be closed, we will be one step closer towards being ready for a disease-modifying drug.

OP171 Does Parallel Regulatory-HTA Reviews Affect Time To HTA Decisions?

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ABSTRACT SUMMARY:
In this study, HTA performance were examined in terms of their outcome and timing by looking at how 103 drugs that gained regulatory approvals from Australia, Canada and Europe in 2013-2015 were assessed by relevant HTA agencies in 2014-2016. In Australia, the TGA/PBAC parallel process proved to be beneficial for reducing time between regulatory approval to first HTA decision.

INTRODUCTION:
Timely recommendation by HTA agencies for drug reimbursement is critical to ensure patient access to medicines of therapeutic value. In this study, HTA performance were examined in terms of their outcome and timing by looking at how 103 drugs, that gained regulatory approval from 2013 to 2015, were assessed by HTA agencies from 2014 to 2016.

METHODS:
Products must have received regulatory approval from one of the following regulatory agencies: EMA (Europe), Health Canada (Canada) and TGA (Australia). The first HTA recommendations were then collected from PBAC (Australia), CADTH (Canada), HAS (France), IQWiG (Germany), SMC (Scotland) and TLV (Sweden). The HTA decisions were classified as: positive, positive with restrictions, negative and multiple.

RESULTS:
84 drugs were approved in Europe before Australia and Canada. Of the studied HTA agencies, PBAC had the highest percentage of products recommended within a year from regulatory approval (93 percent). In addition, Australia had the shortest median time between first regulatory submission by any of the three agencies and HTA recommendation (553 days) as compared to Europe (616 days) and Canada (722 days). This can be attributed to the TGA/PBAC parallel process. However, Australia has the highest proportion of products receiving a negative PBAC recommendation (62 percent).

CONCLUSIONS:
Majority of drugs were first submitted to Europe but the time from regulatory submission to HTA decision was the fastest in Australia. This can be
attributed to the TGA/PBAC parallel review process, which showed its benefit in reducing the overall time. Parallel review process is also available in Canada however, it is not utilized as frequently by companies as in Australia.

OP172 Do Expedited Regulatory Pathways Affect Time To HTA Decision?

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ABSTRACT SUMMARY:
In this study, the effects of FRPs (expedited and conditional pathways) were investigated in terms of their HTA outcome and timing. Generally, the expedited pathways were associated with an increase in positive recommendations and shorter time between regulatory approval and HTA recommendation as compared to standard pathways.

INTRODUCTION:
In an effort to speed the assessment of new medicines while maintaining the quality of the regulatory review, facilitated regulatory pathways (FRPs) have been introduced in many countries. In this study, the effects of FRPs (expedited and conditional reviews) were investigated in terms of their influence on HTA outcomes and timing.

METHODS:
HTA recommendations issued between 2014 and 2016 were collected from CADTH (Canada), HAS (France), IQWIG (Germany), SMC (Scotland) and TLV (Sweden) for 90 internationalised medicines (new active substances approved between 2012 and 2016 by all five regulatory agencies). The HTA decisions were then classified into the following categories: positive, positive with restrictions, negative and multiple.

RESULTS:
Of this cohort of internationalised medicines that received a HTA recommendation, 31 percent in Canada and 28 percent in Europe were approved via a FRP. With the exception of Scotland, expedited medicines were more likely to be appraised within a year from regulatory approval and had a shorter median time between regulatory approval to HTA recommendation than standard medicines. The largest difference was seen in Sweden, where medicines were 66.5 days faster than standard pathways when it underwent the expedited pathways. There were generally a higher proportion of positive and positive with restrictions recommendations when expedited pathways compared to standard pathways were used, with Germany showing the largest proportional difference (31 percent) between the two pathways.

CONCLUSIONS:
Medicines being designated for an expedited review pathway show a reduced time from regulatory approval to HTA decision. Although this finding suggests an alignment between regulators and HTA on which medicines there is a need to expedite the time to HTA decision, it cannot be assessed from this data whether the reduced time from approval to HTA decision is attributed to the company strategy, HTA review time or both and further investigation would be required.
OP173 Eligibility Criteria For “Accelerated Access” Approval: A Global Survey

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ABSTRACT SUMMARY:
Eligibility for inclusion of a new medicine into an Early Access to Medicines Scheme (EAMS) and the respective type of EMAS varies across countries. An international survey of HTA stakeholders aimed to map eligibility criteria such as evidentiary, monitoring & funding requirements for inclusion of new medicines into these schemes, across countries and across different types of schemes available internationally.

INTRODUCTION:
Several Early Access Schemes (EAS) exist aiming to accelerate patient access to new, potentially life-saving therapies. While some information exists on key schemes and their modalities, such as the ATU in France, EAMS in England and the Early Temporary Reimbursement in Belgium, the determinants that drive adoption of a new medicine under an EAS remain unclear. We aimed to map eligibility criteria for inclusion of new medicines into the different EAS available across countries.

METHODS:
HTA stakeholders across 23 countries globally were invited via email to complete a web-survey with questions on; a) items that define product eligibility for EAS designation, b) standards for minimum level of evidence, monitoring, and additional evidence generation for early access products, and c) funding arrangements for these products across settings.

RESULTS:
Fourteen responses from 10 countries (including Belgium, England, France, Japan and Mexico, among others) demonstrated that “Unmet clinical need” was paramount for EAS designation across all countries and types of schemes, followed by “Phase-III trials underway” and “Serious condition” for Compassionate Use Programme (CUP) and Named Patient Programme (NPP) inclusion (21% and 20% of respondents respectively). “Measures in place to monitor risk” was key for CUP and NPP designation (43% and 27% of respondents respectively), followed by “Innovative product designation” for CUP and “Scientific opinion” for NPP eligibility (14% and 23% of respondents respectively). “No specific monitoring requirements” exist in Germany and Austria, whereas “Reporting of adverse events” is crucial in France, England, Japan and Spain. NPP eligible products are mainly funded at a negotiated price and CUP designated products are largely provided by manufacturers free-of-charge (i.e. England, Scotland, Germany).

CONCLUSIONS:
Eligibility criteria/requirements and funding arrangements for early access vary considerably across settings and their respective EAS. Information from a larger sample of countries is required for an all-encompassing mapping of the early access products’ characteristics.

OP174 Development Of A Formal Priority-setting For The Philippine Government

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ABSTRACT SUMMARY:
The lack of institutional mechanisms in the Philippines has led to a less than optimal allocation of financial resources. A six-step priority setting process to facilitate the assessment of new interventions was developed for the Philippine Health Insurance Corporation (PhilHealth). The proposed priority-setting process has been approved and is the current policy in PhilHealth.

INTRODUCTION:
The lack of institutional mechanisms in the Philippine Health Insurance Corporation (PhilHealth) for rationalizing spending has led to a less than optimal allocation of financial resources. The study’s objective is an explicit and systematic priority setting process of selecting new interventions for PhilHealth through identification of relevant literature evidence on the themes under study, then subjecting these to stakeholder and expert consultations.

METHODS:
The qualitative study followed a problem-solving approach to policy analysis. Bardach’s Eightfold Path, supplemented by a World Health Organization (WHO) guideline on policy analysis, provided the framework. Eightfold path recommends that the analysis proceed by (i) defining the problem, (ii) assembling the evidence, (iii) constructing the alternatives, (iv) selecting the criteria for identifying the best alternative, (v) projecting the outcomes, (vi) confronting the trade-offs, (vii) making the decision and (viii) disseminating the results.

RESULTS:
A six-step priority setting process to facilitate the assessment of new interventions for PhilHealth coverage was developed. The process is governed by seven accountability-based principles and four explicit criteria to evaluate interventions. Additionally, the study provided proof of concept for conducting local cost-effectiveness and budget impact analyses as key inputs to a national systematic priority-setting process.

CONCLUSIONS:
This study recommended four criteria and a seven-step process for priority setting to be adopted and an overarching set of principles that will guide the conduct of such activities. The proposed priority-setting process was approved by the PhilHealth. The same process was adopted by the Department of Health (DOH) in the draft administrative order for Health Technology Assessment. This study stimulated research projects for economic evaluations of health interventions.

OP175 A National Perspective On Criteria And Methods For Resource Allocation

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ABSTRACT SUMMARY:
The Quebec Health and Welfare Commissioner recently employed six complementary methods to elicit citizens’ values and concerns regarding publicly funded services. Citizens expressed clear viewpoints regarding decision-making (DM) criteria and processes for resource allocation and shared several expectations regarding appropriateness of care.
**INTRODUCTION:**
Decisions about which health and social services to include in the publicly funded services basket are complex. Several criteria need to be taken into account in decision-making (DM), as well as ethical, economic and organizational issues. Nowadays a global consensus supports the view that citizens’ values and preferences must guide DM. To elicit these values and concerns regarding publicly funded services, the Quebec Health and Welfare Commissioner recently conducted a vast public consultation on the population viewpoints. Parts of this consultation targeted criteria for DM, approaches to assess new or current services and perspectives on appropriateness of care.

**METHODS:**
Various consultation methods were used in complementary steps: a representative population survey (n=1850), six regional focus groups (n=62), a call for briefs (n=52) for groups that wished to share their views, consultation meetings (n=35) with diverse stakeholders and a call for personal accounts (n=2633). It also held five deliberation sessions (18 citizens and 9 experts) over the course of the project on major related issues.

**RESULTS:**
The need to ensure the appropriateness of covered services was one of the strongest themes emerging from the consultation. Citizens want that the appropriateness evaluation be carried out under certain conditions: transparently, in explicit DM processes, using criteria that are clear and adaptable according to the disease or problem. The whole evaluation process needs to be well documented, showing clearly the data used and rejected, so that they can understand the decision and see on what basis it is supported. Among the usual criteria for DM, those related to cost are less valued whereas others are considered incomplete.

**CONCLUSIONS:**
Citizens have clear viewpoints and expectations regarding DM criteria and processes for resource allocation. Decision-makers must take them into account to ensure that the basket of insured services is representative of social values and preferences.

**OP176 A Framework To Integrate Knowledge For Fair And Reasonable Decisions**

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**ABSTRACT SUMMARY:**
A pragmatic framework building on the A4R and reflective multicriteria was designed and piloted, aiming at fair and reasonable decisions on coverage or implementation of healthcare and social services. The framework stimulates integration of all forms of knowledge conveyed through scientific, consultative, and deliberative methods and processes, thereby promoting healthcare and social services systems that are relevant, equitable and sustainable.

**INTRODUCTION:**
Fair and reasonable decisions on coverage or implementation of healthcare and social services requires integration of all forms of knowledge conveyed through scientific, consultative, and deliberative methods and processes. Objectives of the study was to develop a pragmatic methodology to integrate such diversity.

**METHODS:**
A conceptual framework integrating all forms of knowledge that fulfills the needs of health
and social technology assessment (HSTA) for reasonable and fair decision was developed building on: 1) the principles of the Accountability for Reasonableness (A4R) framework (publicity, relevance, appeal and enforcement); 2) the principles of pragmatic reflective multicriteria (universality of systems objectives, clarity of reasoning, knowledge integration, systems transformation) and 3) a consultation at an HSTA agency to identify existing processes, methods and expertise (e.g., ethics, economics, mixed methods).

RESULTS:
The framework directly supports the development of HSTA knowledge products falling under the mandate of the agency and includes three modules: 1) a consultative and decision process interactive grid, 2) a methodology portal to generate, collect, analyse and synthesize evidence (scientific, experiential and contextual) and 3) an interpretative multicriteria grid encompassing criteria necessary to evaluate the contribution of interventions to the relevance, equity and sustainability of healthcare and social services, along with a methodology to present most relevant synthesized data for each criteria, and a tool to elicit recommendations emerging from the deliberative process thus supported. The framework is also designed to facilitate training and project development, and ensure quality within the agency.

CONCLUSIONS:
Expertise of HSTA agencies can be leveraged into integrative methodologies and processes that supports reasonable decisions conducive to relevant, equitable and sustainable healthcare and social services systems. Agile development through piloting and iterative improvement of such framework is envisioned to increase agencies capacities to support enlightened priority-setting.

OP177 Identification Of Technologies Of No Or Low-added Value

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ABSTRACT SUMMARY:
An effort jointly performed by HTAi IG on DEA, IG on ethics, EuroScan network and INAHTA is aiming to elaborate a toolkit that could aid organizations and individuals on the steps to be developed when considering disinvestment activities. This chapter refers to identification activities and disinvestment. The whole toolkit will be presented to the society in HTAi 2018.

INTRODUCTION:
Use of technologies has no or low added value when it is harmful and/or is deemed to deliver no health gain for its cost, being a not efficient health resource allocation. We synthetized the state of the art of methods for identifying candidate technologies for disinvestment and proposed a framework for executing this task, which comprises seven basic approaches; eleven triggers and thirteen methods grouped in embedded and ad-hoc methods.

METHODS:
We synthetized the state of the art of methods for identifying candidate technologies for disinvestment and proposed a framework for executing this task, which comprises seven basic approaches; eleven triggers and thirteen methods grouped in embedded and ad-hoc methods. We searched systematic reviews (SR) on disinvestment and compare methods used for identifying
potential candidates. On the basis of this evidence, we proposed a new framework for identifying these technologies. Ten SR were retrieved and methods of 29 disinvestment initiatives were compared.

RESULTS:
A new framework for identifying potential candidates was proposed which comprises seven basic approaches based on the wide definition of evidence provided by Lomas et al.; eleven triggers adapted from Elsaugh’s proposal and thirteen methods for applying these triggers which were grouped in embedded and ad-hoc methods.

CONCLUSIONS:
Identification methods have been described in the literature and be tested in different contexts. Context is crucial in determining the not to do practices as they are described in different sources.
**Poster Displays**

**PD01 IPC For Prevention Of VTE: An Economic Analysis**

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**ABSTRACT SUMMARY:**
Total hip and knee arthroplasty patients are at risk of venous thromboembolism (VTE). Guidelines recommend 10-35 days of pharmacoprophylaxis, but this may induce bleeding, resulting in increased healthcare costs. This study assessed whether using intermittent pneumatic compression (IPC) for VTE prophylaxis is associated with reduced healthcare costs compared to anticoagulants.

**INTRODUCTION:**
Total hip and knee arthroplasty patients are at risk of venous thromboembolism (VTE). Guidelines recommend 10-35 days of pharmacoprophylaxis, but this may induce bleeding, resulting in increased healthcare costs. This study assessed whether using intermittent pneumatic compression (IPC) for VTE prophylaxis is associated with reduced healthcare costs compared to anticoagulants.

**METHODS:**
Studies related to VTE and prophylaxis in THKA were identified by a structured search of the PubMed database. VTE incidence and cost data were Australia specific or, if not available, taken from other developed healthcare systems. A Markov model was used to estimate the incidence of deep vein thrombosis (DVT), pulmonary embolism (PE), death, post-thrombotic syndrome, as well as minor and major bleeding and heparin-induced-thrombocytopenia, to assess the budget impact of different VTE prophylaxis strategies.

The time horizon was one year, low-molecular-weight-heparin (LMWH) was used as the reference intervention, and effectiveness data were obtained from meta-analyses.

**RESULTS:**
A total of 102,459 THKA were performed in Australia in 2015. The 12-day incidence of DVT and PE using LMWH prophylaxis were 4.48% and 0.25%, respectively, with minor and major bleeding occurred in 9.9% (within 12 days) and 1.9% (within 10 days) of the patients, respectively. The incidence of VTE was not different between LMWH and IPC after THKA. The model estimated that the total cost of post-operative care for THKA was AU$101.7 million in 2015. A 1%-point change from LMWH to IPC prophylaxis (n=1025 patients) would reduce the total healthcare costs by $317,361 per year (or $310 per patient), primarily through reduced bleeding events (~72 minor and ~3 major bleeds). Sensitivity analysis including 500 simulations demonstrated a likelihood of 100% for IPC to reduce both costs and bleeding events compared to LMWH. Similarly, a 1%-point change from dabigatran and rivaroxaban to IPC also resulted in total healthcare savings of $320,580 and $702,584 per year, respectively, with two-thirds and 99% of the simulations favoured IPC over dabigatran for bleeding and cost savings, respectively.

**CONCLUSIONS:**
Using IPC for VTE prophylaxis after THKA has the potential to substantially reduce total healthcare costs compared to anticoagulants, primarily through reduced bleeding events. IPC is suitable for all patients, but may be particularly cost-effective in the immediate postoperative period or in patients at high-risk of bleeding.
PD02 Cost-effectiveness Threshold And Price Negotiations

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ABSTRACT SUMMARY:
This study evaluated the influence of the cost-effectiveness threshold in price negotiations. There is enough information to establish that the lack of standard method to define the threshold associated to the high values defined around the world end up giving manufactures a way to justify premium-prices for new drugs. Well-defined thresholds can help price negotiations, as observed.

INTRODUCTION:
Medical innovations have made great contributions to people’s survival and quality-of-life. Nevertheless, the healthcare systems are showing difficulties in funding premium-priced new drugs. Some ways to improve affordability in healthcare are to rapidly approve generics and biosimilars, ensure the approval of me-toos, encourage clinical trials that measure value and facilitate the collection of information. Also, a well-established threshold can support the sustainability of the system and become a tool for price negotiation. The objective of this study is to evaluate the role of the threshold in price negotiations.

METHODS:
An electronic search on Medline, Lilacs and ScienceDirect was conducted and complemented by references of included studies, Google Scholar and conference abstracts.

RESULTS:
It has been suggested that companies take the price of other approved drugs for the same diagnostic, in a process described as reference pricing, to enforce higher prices for their new products and this has led to increasing costs for cancer drugs over the years. The lack of a standard method for the definition of the threshold in association with the high value set by the World Health Organization (WHO), on three GDP per capita/DALY, gave manufacturers a way to justify higher prices, especially in low- and middle-income countries. In 2007, Thailand determined a threshold of 100.000 THB/QALY, equivalent to 0.8 GDP per capita that, in time, became a powerful instrument for price negotiation. Researches showed, through opportunity cost approaches, that even high-income countries would not be able to afford a threshold as high as WHO’s recommendation.

CONCLUSIONS:
Although the Health Technology Assessment agencies function is to make recommendations about funding of technologies and not determine prices, the recommendation issued through a well-designed threshold can influence companies to lower their prices “voluntarily” to improve the chance of incorporation and increase their market shares.

PD03 Limitations Of Utility-Adjusted Outcomes In Health Economics

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ABSTRACT SUMMARY:
This study evaluated the limitations of the use of utility-adjusted outcomes in economic evaluations and decision making. Despite many reported limitations, one seems especially important to health economics: the apparent impossibility of comparisons between different strategies for different conditions through a league table.

INTRODUCTION:
The quality-adjusted outcomes have been broadly used in the health economics. Their appeal is in the possibility to unify measures of mortality and morbidity and to compare between a wide range of technologies. The objective of this study was to assess the limitations of the use of utility-adjusted outcomes in economic evaluations.

METHODS:
An electronic search on Medline, Lilacs and ScienceDirect was conducted and complemented by references of included studies, Google Scholar and conference abstracts.

RESULTS:
The most widespread utility-adjusted unit is the quality-adjusted life year, which is not necessarily the best measure of outcome for all diseases since its values might be difficult to obtain in practice; it might be age discriminatory; the instruments used to uncover utilities have different sensibilities; it is a challenge to evaluate if a difference in utilities is clinically relevant even if it is statistically significant; and comparisons between areas are only logical if the utility is calculated with the same method. Time is our ultimate scarce resource, which might be why technologies that extend time of life in end-of-life scenarios can have higher thresholds, as in England. There is no reason to believe that an equal variation at different levels of utilities represent the same value in terms of preferences (a variation between 0.1 and 0.2 might be different in terms of preference from a variation between 0.8 and 0.9). For the same utility gains, societies seem to favor poorer health conditions compared to better health conditions.

CONCLUSIONS:
The use of utility-adjusted outcomes in league tables might not enable the system to issue recommendations when the health states are very different in terms of utilities, because the threshold might actually be different for different health states. Nevertheless, they might be the best approach to measure effectiveness in economic evaluations so far.

PD04 Cost-utility Of Quetiapine For Schizophrenia: A Systematic Review

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ABSTRACT SUMMARY:
This study compared the cost-effectiveness profile of quetiapine to other antipsychotic drugs for the treatment of schizophrenia through a systematic review. Despite its relatively great market share, none of the studies favored quetiapine compared to all other drugs. There seems to be a trend favoring olanzapine and risperidone over quetiapine around the world.

INTRODUCTION:
Schizophrenia is a chronic debilitating condition characterized by disorders in thought, affect and behavior. Its prevalence is around 0.3 to 1% in the world. The pharmacological treatment is based on antipsychotic drugs, but their efficacy is limited, culminating in discontinuation of treatment, relapses and readmissions in health services. Quetiapine was initially approved for use in 1997 in the USA. The drug has moderate affinity for D2 and 5-HT2A receptors and high affinity for H1 receptors.
The aim of this study is to conduct an assessment of cost-utility of quetiapine for schizophrenia around the world.

METHODS:
Cost-utility studies of head-to-head comparisons of quetiapine against other antipsychotic drugs for the treatment of patients with schizophrenia and related disorders were included, irrespective of the diagnostic criteria used. An electronic search on Medline, Lilacs, Center for Reviews and Dissemination, The Cochrane Library and PsycINFO was conducted and complemented by references of included studies, Google Scholar and conference abstracts. Monetary values were converted to PPP-USD for the same base-year of the study.

RESULTS:
Six economic evaluations were included, representing four countries and a multi-centric analysis. Comparisons between quetiapine and twelve more antipsychotic drugs were found. Three studies found quetiapine to be dominated by risperidone and other three found it to be more expensive and more effective with ICER values of 36,535, 8,786 and 127,600 USD/QALY. Three studies found quetiapine, in comparison to olanzapine, to be dominated, one found it to be dominant and two studies found it to be more expensive and more effective with ICER values of 139,699 and 224,000 USD/QALY. The reports were considered of reasonable quality. Yet the diversity of contexts might influence the results.

CONCLUSIONS:
In general, there seems to be a trend favoring olanzapine and risperidone over quetiapine. None of the studies favored quetiapine over all the other drugs.

PD05 Influence Of Economic Data In The Incorporation Of Medicines In Brazil

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ABSTRACT SUMMARY:
The process of incorporation of technologies into the Brazilian public health system is assisted by the National Commission for the Incorporation of Technologies in SUS (CONITEC). This work evaluated the influence of economic data on the recommendations issued by CONITEC. Economic evaluations appear to be a secondary criterion for CONITEC’s recommendations.

INTRODUCTION:
Since 2011, the process of incorporation of technologies into the Brazilian public health system (SUS) is assisted by the National Commission for the Incorporation of Technologies in SUS (Conitec). The present work collected data of effectiveness, safety, cost-effectiveness, budget impact and other criteria from Conitec’s reports to determine the influence of economic evaluations on issued recommendations.

METHODS:
Data was collected from drug recommendation reports published by Conitec between 2012 and 2016 and organized in a Microsoft Excel® spreadsheet. The association of the incremental cost-effectiveness ratio (ICER) and the chance of incorporation was assessed through a binary logistic regression in R®.

RESULTS:
266 reports were issued by Conitec between 2012 and 2016. Data was collected from 169
reports that evaluate requisitions of incorporation of new medicines. Of these, there were ninety-nine recommended the incorporation. The most common ATC classes analyzed were immunosuppressants (thirty-four drugs), other antineoplastic agents (sixteen drugs) and direct-acting antivirals (fifteen drugs). Of the seventy negative recommendations, thirty-five were due to cost-effectiveness, thirty-one due to efficacy, twenty-nine due to safety, forty due to the budget impact, and thirty-two associated to other reasons. In general, the reports were considered to be of poor quality. Only 21.9 percent of the reports had ICERS. The binary logistic regression analysis did not present a statistically significant difference for the influence of the ICER on the recommendation decision with outcomes reported in life years gained (OR = 0.9999732; 95% CI = 0.9999304 to 1.000016) or quality-adjusted life years (OR = 0.9999789; 95% CI = 0.9999321 to 1.000026).

CONCLUSIONS:
Economic evaluations appear to be a secondary criterion for Conitec’s recommendations. Despite this, they are commonly used to justify non-incorporation of drugs into the public system.

PD07 Cost-utility Analysis Of Therapies For Type 1 Diabetes In Brazil

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ABSTRACT SUMMARY:
Type 1 diabetes should be treated with association of different types of insulin. Among the alternatives, only human insulin and rapid-acting insulin analogues are available through Brazilian Public Health System. However, T1D population still cannot access long-acting insulin analogues and pumps through SUS. Bargaining power in economic analysis seems to produce more realistic estimates, since centralized purchasing is economically sustainable.

INTRODUCTION:
Type 1 diabetes (T1D) should be treated with an association of different types of insulin. Among the alternatives in Brazilian market, only human insulins and rapid-acting insulin analogues are available through the National Public Health System (SUS). Our aim is to calculate the incremental cost-utility ratio of the alternatives for T1D treatment in Brazil compared to human insulin.

METHODS:
A cost-utility analysis was performed using a Markov model to simulate diabetes chronic complications and variations. Final outcome was cost/quality adjusted life years (QALY). Time horizon was lifetime. Direct medical costs covered by SUS were included. We applied the bargaining power of Ministry of Health to insulins’ price. Univariate and multivariate sensitivity analyzes were performed.

RESULTS:
Among the alternatives, the only that proved to be cost-effective, below the willingness to pay threshold, was the association of NPH insulin and rapid-acting insulin analogues. The incremental cost-utility ratios were R$ 8,600 for the association of NPH insulin and rapid-acting insulin analogues, R$ 106,000 for association of long-acting and rapid-acting insulin analogues and R$ 186,500 for insulin pump.

CONCLUSIONS:
The main advantage on cost-utility analysis was using bargaining power on drugs prices to produce more realistic estimates of resource use, since centralized purchasing is an economically sustainable strategy in Brazil. Association between
analogues had the best results, even though slightly higher than the threshold for developing countries. As a limitation, we did not consider potential bargaining gains in defining the cost of pump and disposables. Thus, if these discounts were also adopted for pumps that could bring more favorable results.

**PD11 From Scientific Assessment (mini-HTA) To Real Life Assessment**

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**ABSTRACT SUMMARY:**
To present the differences between the results from a mini-HTA of Negative Pressure Wound Therapy and its subsequent implementation in real life in a Community Hospital.

**INTRODUCTION:**
From scientific assessment (mini-HTA) to real life assessment: the case of Negative Pressure Wound Therapy (NPWT) in a Community Hospital. The NPWT consists of a board that is connected to an exudate extraction device generating a vacuum. This therapy replaces conventional wound healing therapy. Three years ago, NPWT was assessed by the HTA Committee, which recommended its monitored introduction to check if mini-HTA results were the same as real life implementation and to analyze its impact on the organization of nursing care.

**METHODS:**
From March 2015 to February 2016, all patients carrying NPWT were monitored, an economic model for the associated activity was created and a follow-up sheet was administered by the departments of Traumatology, Surgery, Surgical Block and Nursing Supervisors.

**RESULTS:**
The NPWT has been used in 21 cases, 6 of surgery and 15 of Traumatology. The use of NPWT was less than expected by mini-HTA (50 to 21 cases). The results from real life are aligned with the evidence from the reviewed scientific literature. Nevertheless, 90% of cases of surgical infection achieved a better resolution of the wound than showed by scientific literature. Appropriateness is reached in diabetic foot and managing infections, while grafting indications needs improvement. The use of NPWT for surgery is cost saving in our hospital; while for the other indications is not clear.

**CONCLUSIONS:**
The use and impact of NWPT in real life deviates somehow from mini-HTA results. Nevertheless, these deviations are towards a positive impact in health care since it improves patient outcomes, helps to realign appropriateness and save costs in some indications. This result could be an indicator of the conservative approach traditionally adopted when performing mini-HTA.

**PD12 Economic Benefit Of Workplace Health Promotion: What Has Been Proven?**

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**ABSTRACT SUMMARY:**
Workplace health promotion is an important
instrument for maintaining the health of employees. More and more frequently, however, the question of economic benefits is also being raised - the economic benefits for businesses for employees and for the society. To what extent reliable scientific results are available were analysed in this paper.

INTRODUCTION:
Maintaining people’s ability to work is a priority in many European countries. Through healthier and more motivated employees, companies should benefit from lower absenteeism and increased productivity. The public sector expects savings in health care costs, an increase in the employment rate and avoiding early retirement. The employees benefit from improving their health and well-being. The aim of the study is to investigate whether there is scientific economic evidence for the benefit of workplace health promotion.

METHODS:
Systematic literature search in electronic databases and hand-search for systematic reviews, meta-analyses and economic studies with predefined inclusion and exclusion criteria.

RESULTS:
Literature search provided two meta-analyses (with 84 primary studies), three systematic reviews (with 36 primary studies) and one model calculation (with 6 included primary studies). There are relatively few economic studies available to prove the economic benefit, often with inadequate methodological quality. Most of them are conducted in USA, only few are from Europe mainly from Scandinavia. The available studies show a positive return on investment for companies however with a width range. Benefits for the health and social services have also been proven in a model calculation.

CONCLUSIONS:
The positive results must be interpreted with caution. Firstly, there is a lack of good primary studies on the effectiveness of measures on which economic analyses could be based; secondly, the methodological quality and comparability of economic analyses can still be improved and thirdly, the transferability of the results is often limited due to different health care systems.

PD13 An Introduction To Risk Factors Of Caesarean Section

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ABSTRACT SUMMARY:
In this study, we chose 67,349 medical records of the maternal women, including 28,900 medical records of caesarean section (CS) from 30 tertiary public hospitals in Shanxi province during 2014-2016. we focus on the clinic indications for CS and explore the risk factors of CS by the methods of logistic regression for controlling and reducing CS rate suitably.

INTRODUCTION:
In recent decades, the remarkable increase in the rate of caesarean section (CS) in both developed and developing countries have been observed by us, especially in China, the rate of CS has been a new higher peak. However, the real reason that leads to this phenomenon are uncertain. In this study, we analyze the clinic indications for CS and explore the risk factors of CS in tertiary public hospitals in Shanxi province, China.

METHODS:
In this study, we chose 67,349 medical records of the maternal women, including 28,900 medical records of CS from 30 tertiary public hospitals in Shanxi province during 2014-2016. The clinic
indications description for CS were adopted by the method of descriptive statistical analysis. The risk factors of CS were explored by the method of logistic regression.

RESULTS:
The overall rate of CS was 42.91% in 30 sample tertiary public hospitals in Shanxi province, China. Besides those women by the caesarean delivery on maternal request, the top ten clinic indications for CS include uterine scar (10.45%), eclampsia (7.71%), premature rupture (6.73%), fetal distress (5.92%), the oligohydramnios (5.37%), obstructed labor (4.50%), disproportion (4.11%), breech (2.86%), pregnancy complicated with hypertensions (2.22%) and pregnancy complicated with diabetes (2.16%). Significant risk factors for CS in the logistic analysis were: age $\geq 35$ years (OR =2.9; 95% CI: 2.44 to 3.44), maternal women with multiple fetuses (OR=3.95, 95% CI:3.42 to 4.55), intrapartum complication (OR=8.94, 95% CI:8.05 to 9.92), the pregnancy complications (OR=5.29, 95% CI:4.95 to 5.65). The age of maternal women, the multiple fetuses, the intrapartum complication, and the pregnancy-related complications, existed significant influence on CS ($P<0.001$).

CONCLUSIONS:
Due to the higher rate of CS, the maternal women should select suitable and scientific delivery modes based on the delivery indications. To decrease the CS rate, we should first decrease the rate of CS on maternal request. Appropriate policies and guidelines should be considered to accomplish the goal. It is beneficial that CS rate reduction and medical resources will be the benefits if vaginal delivery is chosen by maternal women.

PD14 Telemonitoring For Chronic Obstructive Pulmonary Disease

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ABSTRACT SUMMARY:
In this study, the clinical effectiveness of telemonitoring for chronic obstructive pulmonary disease (COPD) was investigated. The use of telemonitoring for COPD was unlikely to result in statistically significant improvements in health outcomes. However, in the subgroup analysis, telemonitoring longer than 6 months reduced the exacerbation rates. To clarify the impacts of telemonitoring for COPD, further researches are needed.

INTRODUCTION:
Chronic obstructive pulmonary disease (COPD) is characterized by irreversible or poorly reversible airflow obstruction in the lung. Self-management strategies are becoming more important in the treatment of COPD. In this study, the clinical effectiveness of telemonitoring for COPD was investigated.

METHODS:
To conduct systematic review, we searched MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials and CINAHL up to March 2016. We selected randomized controlled trials (RCT) comparing telemonitoring with control for COPD. We analyzed dichotomous data as risk ratio (RR), and continuous data as mean difference (MD) or standardized mean differences (SMD) while using random-effects models for meta-analysis. Critical outcomes were COPD exacerbation, quality of life and all-cause mortality.
RESULTS:

Twenty-four RCTs were included. As a result of meta-analysis, there were no variables showing statistically significant results between two groups. Exacerbation rates (6 studies) were not different between two groups (RR: 0.67, 95% CI: 0.31 - 1.42). Due to the moderate degree of the heterogeneity among studies (I square = 67%), subgroup analysis was performed. Intervention duration could be the one of the factors describing the heterogeneity. No differences between two groups were found for exacerbation period (6 studies; MD: 0.12, 95% CI: –1.18 - 1.43) and number of exacerbation (6 studies; MD: -0.76, 95% CI: –0.32 - 0.07). Also, quality of life (10 studies) did not show any differences between two groups (SMD: -0.17, 95% CI: –0.41 - 0.07). Finally, mortality (5 studies) was not different between two groups (RR: 0.80, 95% CI: 0.48 - 1.35).

CONCLUSIONS:

The use of telemonitoring for COPD was unlikely to result in statistically significant improvements in health outcomes. However, in the subgroup analysis, telemonitoring longer than 6 months reduced the exacerbation rates. To clarify the impacts of telemonitoring for COPD, further researches are needed with the well-defined intervention and outcome variables.

PD15 Radiofrequency Ablation In The Inoperable Recurrence Thyroid Cancers

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ABSTRACT SUMMARY:
The aim of this study is to evaluate the effectiveness and safety of radiofrequency ablation for inoperable recurrent thyroid cancers. In conclusion, radiofrequency ablation is a safe and effective treatment for reducing the volume of tumors and alleviating tumor-related symptoms in high-risk patients with locally recurrent thyroid cancer.

INTRODUCTION:
The aim of this study is to evaluate the effectiveness and safety of radiofrequency ablation for inoperable recurrent thyroid cancers.

METHODS:
We conducted Systematic Review of scientific literature by searching the Ovid-Medline, Ovid-Embase, Cochrane Library up to 12 December 2016. We identified 200 studies through electronic search of databases including duplicated 41 studies. Additionally, we identified 7 guidelines related radiofrequency ablation for treating thyroid cancer through websites.

RESULTS:
We finally identified 5 studies and 7 guidelines. According to the guidelines, the evidences of radiofrequency ablation for thyroid cancer were not sufficient, but it was recommended as an alternative to topical treatment for local recurrence or localized thyroid papillary cancer. Especially, it was recommended to apply to patients who had difficulty in surgical resection. A systematic review was conducted 5 studies including 119 patients with 160 tumor lesions. We evaluated complications, survival rates, recurrent rates, nodule volume, thyroglobulin level, symptom relief associated with radiofrequency ablation. The overall complication rate was 10.1% (12/119), including voice change (dysphonia), second degree skin burn. No patient experienced a life-threatening during the follow-up period. Although some patients reported a burning sensation, pain, neck regional discomfort after ablation procedure were relieved by reducing Radiofrequency power or stopping the ablation for several second. The survival rate after Radiofrequency ablation was 99.2% (118/119).
during the follow-up period (1 to 49 months). One patient who underwent lung resection died of respiratory failure. The recurrence rate was 0~42.9%. The mean nodule volume reduction rate was 50.9~98.4%, completely disappear rate was reported 0~93.9%. The thyroglobulin level was reduced after radiofrequency ablation. A study was reported 63.6% patients’ symptom relieve. In 1 study, 63.6% of patients were reported to have relieved symptoms due to discomfort due to tracheal compression.

CONCLUSIONS:
The Radiofrequency ablation is a safe and effective treatment for reducing the volume of tumors and alleviating tumor-related symptoms in high-risk patients with locally recurrent thyroid cancer.

INTRODUCTION:
Pulmonary Hypertension is a silent disease and its diagnosis often occurs when it is already at an advanced stage. Pharmacological treatment of Pulmonary Arterial Hypertension (PAH) can be performed with: (a) calcium channel blockers, (b) phosphodiesterase-5 inhibitors, (c) prostanoids, (d) endothelin-receptor antagonists and (e) soluble guanylate cyclase stimulator. The use of Riociguat was approved in Brazil by the National Sanitary Surveillance Agency on October 5, 2015 for PAH use. The objective was to perform a systematic review (SR) of the efficacy of pharmacological treatment of Pulmonary Arterial Hypertension comparing Riociguat with other available medications or with placebo.

METHODS:
Following the steps described in the PRISMA guideline, a search for randomized controlled clinical trials was conducted in which Riociguat was used alone or in combination with other therapies, in databases MEDLINE, LILACS, Web of Science, Science Direct, Cochrane Library Wiley and in the gray literature (Google Scholar, Capes Bank of Theses and Clinical Trials). EndNote and Mendeley were used as reference managers. Outcomes analyzed were: death, 6-minutes walking distance (6MWD), WHO functional class (improvement, stabilization or worsening), hemodynamic variables (pulmonary vascular resistance, cardiac index, pulmonary-artery pressure), clinical worsening, hospitalization and quality of life.

RESULTS:
467 articles were obtained, remaining 379 after the duplicated articles withdrawal. After exclusion by title and abstract by two independent reviewers, 47 studies remained. Through the gray literature, 6 studies were obtained, counting 53 studies for full article reading, and the eligibility criteria were verified. Five studies were selected to compose the SR. Compared with placebo, Riociguat showed improvements in 6MWD, pulmonary vascular resistance, WHO functional class and time to
clinical worsening, also maintained after one year of use. Subgroup analysis was performed comparing of treatment-naive patients and patients on background PAH-targeted therapy.

CONCLUSIONS:
This work may be used as a management and decision support tool, based on the same rationality that involves a Health Technology Assessment, contributing to quality the decisions to be taken in relation to the incorporation of new technology.

PD17 Analysis On Supply-side Of Rural Clinics Under Hierarchical Medical

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ABSTRACT SUMMARY:
The purpose of this study was to use Cobb-Douglas function to quantitatively analyze the resource supply and service output of rural clinics based on the theory of supply-side, to study the influence of the supply of various resources on the medical service output.

INTRODUCTION:
In 2015, the Chinese government put forward the theory of “supply side reform” to deal with the problems of economic and social development. In 2016, the establishment of health work policy “focusing on grassroots level” and the implemented of hierarchical medical system put forward higher requirements on the bottom of primary health care system: the rural clinics. The development of rural clinics relies on investment of health resources from government. Based on the supply-side theory, to study the impact of various types resources on the medical services output of rural clinics.

METHODS:
This cross-sectional survey was conducted between October to November 2015 in Shandong province, PR China. Based on the supply-side theory, according to the Cobb-Douglas production function, combined with the actuality of rural clinics, establish the output function model of medical service: LnY = C + α LnK + β LnF + γ LnH + ε. OLS method was used to estimate the α, β, γ in the model.

RESULTS:
2012-2014, the elastic coefficient of the main kinds resources for supplying fixed assets, the basic medicine subsidy and human resources were 0.11, 0.218 and 0.495; The reduction of human resource made the maximum contribution for the decrease of the health service output, the contribution rate was 92.62 percent. In 2012-2014, the elasticity coefficient of the fixed assets increased slightly, the elasticity coefficient of the basic medical subsidy decreased obviously, and the elasticity coefficient of human resources increased first and then decreased.

CONCLUSIONS:
The development of rural clinics is in the condition of scale benefits diminishing on Shandong province. Human resource is the most important power producer. The lack of human resources has become the main reason for restricting the development of rural clinics. Financial investment is insufficient to promote the development of rural clinics and the impetus is constantly weak.
PD18 Cost-effectiveness Of Extracorporeal Life Support In Cardiogenic Shock

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ABSTRACT SUMMARY:
Cost-effectiveness analysis of Venoarterial extracorporeal life support (ECLS) in the perspective of the Brazilian public health system (SUS), based on a decision tree, and supplemented by probabilistic sensitivity analysis (PSA). Incremental cost-effectiveness ratio (ICER) for ECLS was Int$ 62,215 per averted in-hospital death; in PSA, ECLS probability of being cost-effective was 27%, considering willingness-to-pay of 3 times Brazilian GDP/capita.

INTRODUCTION:
Venoarterial extracorporeal life support (ECLS) is increasingly used in patients during cardiogenic shock, due to favorable results in this very high-risk scenario. However, it is a costly intervention, that requires heavy financial investment and specialized human resources.

METHODS:
Cost-effectiveness analysis to evaluate ECLS in the perspective of the Brazilian public health system (SUS) in the population of adult patients with cardiogenic shock. A decision tree comparing ECLS and usual care was built, using efficacy data from a systematic review of literature, and cost data from SUS reimbursement values. Impact of parameter variability and uncertainty were ascertained with deterministic and probabilistic sensitivity analysis.

RESULTS:
Usual care resulted in 30% probability of survival, at an average cost of 3,000 international dollars (Int$); the strategy that includes ECLS resulted in 62% survival rate, and average cost of Int$ 23,000, with incremental cost-effectiveness ratio (ICER) of Int$ 62,215 per averted in-hospital death. Results were sensitive to device cost, and survival difference between strategies. In probabilistic sensitivity analysis, ECLS was consistently more costly and more effective than usual care; based on a willingness-to-pay of 3 times Brazilian GDP per capita (Int$ 45,000), there was 27% probability of ECLS being cost-effective.

CONCLUSIONS:
ECLS has the potential to increase survival for cardiogenic shock, but would significantly increase costs; in the Brazilian public health system, ICER per averted in-hospital death is 4.1 times the domestic GDP per capita.

PD19 Evaluation On Compensation Mechanism Reform Of Primary Health Facility

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ABSTRACT SUMMARY:
In this study, a self-designed index evaluation system was applied to evaluate the pilot reform of the compensation mechanism of primary health facilities in Zhejiang Province through quantitative and qualitative data. The results show that the policy has good operability, acceptability, fairness and sustainability. We need to strengthen information system construction, financial support and performance wage reform in future popularization.

INTRODUCTION:
In order to solve the problems of inefficiency of original compensation mechanism of primary health institutions and low enthusiasm of medical staffs, Zhejiang Province created new reform method of combining the main responsibility of government with the regulating role of market, linking funding compensation with service performance in four pilot regions. This study evaluates the design and implementation of this reform and provides recommendation for policy popularization.

METHODS:
Quantitative data were obtained from the health department in the pilot regions by filling in the pre-designed questionnaire. Data were double-entered and double-checked by Epidata 3.0 and analyzed with SPSS 20.0. Qualitative Data were collected by conducting focus group interviews on three types of stakeholders: leaders in charge of reform, directors of primary healthcare institutions and medical staffs. We evaluated the effect of the reform based on our pre-designed evaluation index system.

RESULTS:
In terms of the scientific nature of policies, this reform focuses on building an internal market for primary health institutions, which has good scientific features. In terms of the implementation of policies, this reform has strong operability with a sound information platform, scientific standardization of working equivalent and scientific performance evaluation system. Different stakeholders fully recognize this policy illustrates its high degree of acceptability. The settings of adjusting coefficient and policy-type subsidies enhance the fairness of policies. Pilot regions adopt measures such as establishing reform risk fund and setting purchase cap to evade risks and ensure the sustainability of the reform.

CONCLUSIONS:
For policy popularization, the following points are highlighted. 1. It’s necessary to strengthen the construction of medical information system; 2. All regions should measure and formulate standardization of work equivalent based on their actual conditions; 3. The government should provide sufficient funds to deal with incremental risks attributed to the reform; 4. total control of the distribution model should be broken to ensure the principle of more pay for more work.

PD20 'Where’s Waldo?’ Incorporating Patient Aspects Into Rapid Reviews

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ABSTRACT SUMMARY:
Describes early experiences of incorporating qualitative literature into rapid reviews of non-medicine health technologies in order to explore patient issues. Two technologies currently being examined by the Scottish Health Technologies Group (SHTG) for the National Health Service in Scotland were used to pilot this work; transoral robotic surgery and point of care testing for sore throat.
INTRODUCTION:
Patient and social aspects form a key domain within health technology assessments (HTAs) but are less well established in rapid HTA. Patient aspects can add value to HTAs by aiding in interpretation of variations in intervention effectiveness or providing context on the impact of interventions on patients’ lives. This poster describes initial experiences of incorporating patient aspects into rapid HTAs for the Scottish National Health Service.

METHODS:
Two rapid reviews explored using qualitative literature to understand patient issues relating to transoral robotic surgery (TORS) for head and neck cancer and point-of-care testing (POCT) for sore throat, respectively. Literature searches identified qualitative studies or systematic reviews of qualitative studies using two search filters: one for patient perspectives and another for qualitative study designs.

RESULTS:
Neither project identified qualitative literature specific to the exact question posed in the review. In these early experiences of incorporating qualitative literature into rapid HTAs, the TORS project focused on patient treatment experiences (radiotherapy or open surgery) and outcome preferences. The literature for the sore throat POCT review identified only one applicable study which described issues around patient confidence in diagnosis and their preference for avoiding antibiotics where possible. Pragmatic decisions on study selection were required in the TORS review due to the large volume of literature identified. This may be an issue for future rapid HTAs attempting to incorporate qualitative evidence.

CONCLUSIONS:
Patient aspects can be incorporated into rapid HTAs using systematic and pragmatic approaches to identifying and synthesising qualitative literature. Decisions on the most important patient aspects should be made in response to findings and uncertainties arising from clinical and cost-effectiveness literature. This is a challenge in the short timescales of rapid HTA.

PD22 Behavioral Factors Mediating Between Socioeconomic Status And Obesity

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ABSTRACT SUMMARY:
This study investigates the association between socioeconomic status (SES) and obesity mediating by behavioral factors. The data was obtained from the China Health and Nutrition Survey. A variety of statistical models were used to investigate the association. Several behavioral pathways for different SES groups leading to obesity were simulated. Changes in SES may create some offsetting risks.

INTRODUCTION:
China has the largest obese population in the world and its prevalence is increasing faster and faster. The researchers are investigating in the association between the socioeconomic status (SES) and obesity in several ways. However, SES may not only play a direct impact on obesity but influences health behaviors which, in turn, affect obesity. The mediating factors have been rarely studied. This study investigates the association between SES and obesity mediating by behavioral factors among adults in China.
METHODS:
The longitudinal data including 110449 individuals was obtained from the eight waves of the China Health and Nutrition Survey from 1991-2011. The outcome of obesity was measured using Body Mass Index (BMI). The SES factors include education and income (low, medium and high). Mediating factors include alcohol consumption, smoking status, diet and physical activity. A variety of statistical models were used to investigate the association between SES and obesity. Age/gender-adjusted prevalence of obesity was calculated and multiple-logistic regression was used.

RESULTS:
To some extent, SES influenced BMI directly, positively in men and inversely in women, respectively. SES may also operate through behavioral factors. These associations were not always straightforward, and changes in SES might create some offsetting risks. Behavioral factors including alcohol consumption, smoking status, diet and physical activity were associated with SES indicators in all groups. In addition, the prevalence was higher in urban areas than rural areas in China. Several pathways for different SES groups leading to obesity were simulated.

CONCLUSIONS:
Higher SES groups are more likely to have higher BMI compared to lower SES groups. Different SES groups have different significant mediating risk factors. The pathways between SES and obesity are complex. This study suggests that it is necessary to apply different interventions to different SES individuals especially focused on the disadvantaged populations according to their different behaviors and preference.

PD24 Data Collection By Patient Groups To Provide Patient Input

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ABSTRACT SUMMARY:
CADTH's Common Drug Review and pan-Canadian Oncology Drug Review programs incorporate perspectives and experiences from patients and family members. Despite resource and timing challenges, patient groups often gather primary data to provide to CADTH as 'patient input', including experiences of individuals who have received the drug under review. Groups use multiple different approaches to gather the perspectives shared.

INTRODUCTION:
CADTH’s Common Drug Review and pan-Canadian Oncology Drug Review programs incorporate perspectives and experiences from patients and family members who might be affected by the resulting funding recommendation. Perspectives are provided by patient groups who use different approaches to gather patient input.

METHODS:
We analyzed a random sample of 93 patient input submissions, drawn from a sampling frame of 532 submissions given to CADTH between June 2010 and June 2016. We looked at how groups described their information gathering methods in the original submissions or the published Clinical Guidance Reports.
RESULTS:
Approaches were categorized according to whether they involved primary (n=86) or secondary data collection (n=130) and further sub categorized according to how data was collected. Primary data included: personal experiences, as described by the submission’s author (n=16); surveys conducted specifically for the submission (n=34); and new interviews of patients and family members on disease and drug experiences (n=36). Half (47/93) of the patient input submissions included experiences of one or more patients who had received the drug under review. Secondary data included: published literature (n=31); existing surveys (n=27); past conversations with patients and family members (n=36); experiences of patient group staff interacting with patients and family members (n=19); and advice from clinical experts (n=17). Many patient input submissions (68 out of 93) reported multiple approaches to collect data. Use of two approaches was most common (37 out of 93) with five or six approaches used in three of 93 submissions.

CONCLUSIONS:
Despite resource and timing challenges, many patient groups gather primary data to share with CADTH and find individuals with experience of the drug under review.

PD25 Principal Component Approximation: Medical Expenditure Panel Survey

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ABSTRACT SUMMARY:
Patient-reported outcomes (PRO) are important. However, there are large numbers of PROs generated in survey data. It is difficult to have a proper overview of the PROs. Principal component (PC) analysis has been used to summarize major trajectories. We developed methods to 1) understand the major sources of variances and 2) interpret the PCs in survey data.

INTRODUCTION:
Principal component analysis (PCA) is important to summarize data or reduce dimensionality. However, one disadvantage of using PCA is the interpretability of the principal components (PCs), especially in a high-dimensional database. This study aims to analyze the patterns of variance accumulation according to PCA loadings and to approximate PCs with input variables from sample data sets.

METHODS:
There were three data sets of various sizes used to understand the performance of PC approximation: Hitters, SF-12v2 subset of the 2004 to 2011 Medical Expenditure Panel Survey (MEPS), and the full set of 1996 to 2011 MESP data. The variables in three data sets were first centered and scaled before PCA. PCs approximation was studied with two approaches. First, the PC loadings were squared to estimate the variance contribution by variables to PCs. The other method was to use forward-stepwise regression to approximate PCs with all input variables.

RESULTS:
The first few PCs represented large portions of total variances in each data set. Approximating PCs using stepwise regression could efficiently identify the input variables that explain large portions of PC variances than approximating according to PCA loadings in three data sets. It required few numbers of variables to explain more than 80% of the PC variances.

CONCLUSIONS:
Approximating and interpreting PCs with stepwise regression is highly feasible. Approximating PCs can help 1) interpret PCs with input variables, 2)
understand the major sources of variances in data sets, 3) select unique sources of information and 4) search and rank input variables according to the proportions of PC variance explained. This is an approach to systematically understand databases and search for variables that are highly representative of databases.

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**PD26 Principal Component Approximation: Canadian Health Measures Survey**

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**ABSTRACT SUMMARY:**
Patient-reported outcomes (PRO) are important. However, there are large numbers of PROs generated in survey data. It is difficult to have a proper overview of the PROs. Principal component (PC) analysis has been used to summarize major trajectories. We developed methods to 1) understand the major sources of variances and 2) interpret the PCs in survey data.

**INTRODUCTION:**
Principal component analysis (PCA) is used for dimension reduction and data summary. However, principal components (PCs) cannot be easily interpreted. To interpret PCs, this study compares two methods to approximate PCs. One uses the PCA loadings to understand how input variables are projected to PCs. The other uses forward-stepwise regression to determine the proportions of PC variances explained by input variables.

**METHODS:**
Two data sets derived from the Canadian Health Measures Survey (CHMS) were used to test the concept of PC approximation: a spirometry subset with the measures from the first trial of spirometry and full data set that contained representative variables. Variables were centered and scaled. PCA were conducted with 282 and 23 variables respectively. PCs were approximated with two methods.

**RESULTS:**
The first PC (PC1) could explain 12.1% and 50.3% of total variances in respective data sets. The leading variables explained 89.6% and 79.0% of the variances of PC1 in respective data sets. It required one and two variables to explain more than 80% of the variances of PC1 respectively. Measures related to physical development were the leading variables to approximate PC1 and lung function variables were leading to approximate PC2 in the full data set. The leading variable to approximate PC1 of the spirometry subset were FEV0.5/FVC (%) and FEV1/FVC (%).

**CONCLUSIONS:**
Approximating PCs with input variables were highly feasible and helpful for the interpretation of PCs, especially for the first PCs. This method is also useful to identify major or unique sources of variances in data sets. The variables related to physical development are the variables related to the most variations in the full data set. The leading variable in the spirometry subset, FEV0.5/FVC (%), is not well studied for its application in clinical use.

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**PD27 A Case Study Of Equity In Health From Zhejiang Province, China**

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ABSTRACT SUMMARY:
Equity in health has attracted broad attention worldwide, and China is no exception. We measure and analyze the equity of health needs and absent rate of health services. We find that the poor have more urgent health needs and higher absent rate of inpatient services compared with the rich. Based on the results we provide suggestions for decision making.

INTRODUCTION:
Equity is the core of primary care. The issue of equity in health has become urgent and China has attached increasing attention to it. With rapid development of economic and great change of the policy on medical insurance, the pattern of equity in health has changed a lot. Reform of healthcare in Zhejiang province is at the forefront of China, studies on Zhejiang are of great significance to the whole country. This paper aims to measure the equity in health from the perspectives of health needs and health seeking behavior, and provides suggestions for decision making.

METHODS:
Household survey was conducted in August 2016. A sample of 1000 households, 2807 individuals in Zhejiang was obtained with the multi-stage stratified cluster sampling method. Descriptive analysis and Chi-square test were adopted in the analysis. The value of concentration index was used to measure the equity.

RESULTS:
This study finds that the poor have more urgent health needs and poorer healthy situation compared with the rich. The utilization of outpatient service was almost equity whilst the utilization of hospitalization was pro-rich (the rich use more). Individuals with employer-based medical insurance use more outpatient services than those with rural and urban medical insurance. Compared to the rich, there were more people in the poorer income groups who didn’t use inpatient services due to financial difficulties. The issue of equity in health has attracted broad attention in the world, and China is no exception. We measured and analyzed the equity of health needs and absent rate of health services. We find that the poor have more urgent health needs and high absent rate of inpatient services compared with the rich. Based on the results we provide suggestions for decision making.

CONCLUSIONS:
Income level and medical insurance may well explain the equity of outpatient and inequity of hospitalization. In view of the pro-rich inequity of hospitalization, more financial protection should be provided for the poor.

PD28 A Systematic Review Of Patients’ Preference For Diabetes Medications

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ABSTRACT SUMMARY:
This study did a systematic review of discrete choice experiments to investigate patients’ preference for outcome, process and cost in noninsulin diabetes medications.
INTRODUCTION:
This study did a systematic review of discrete choice experiments to investigate patients’ preference for outcome, process and cost in noninsulin diabetes medications.

METHODS:
A systematic review was conducted by searching MEDLINE, EMBASE to identify DCEs investigating patients’ preference for type 2 diabetes mellitus treatments. Attributes were classified into outcome, process and cost attributes to assess their relative importance. A reporting quality assessment was applied to all studies. Inclusion criteria were: Empirical preference studies focus on type 2 diabetes mellitus treatment, DCE methodology, noninsulin diabetes medications and English article published from January 2012 to September 2017.

RESULTS:
We identified 5 studies (N=3146 patients) that elicited patients’ preference for noninsulin diabetes medications. All studies get more than 3 scores on the PREFS (Purpose, Respondents, Explanation, Findings, Significance) 5-piont scale. Most attributes were related to outcome (81%), followed by cost (11%) and process (8%). The most commonly applied outcome attribute was “blood glucose control (HbA1c)”; the most frequently used in process attributes was “daily dosing schedule” and “monthly out-of-pocket cost” was the most commonly used cost attributes. The relative importance of outcome attributes was ranked highest in 71% of the cases where it was included, followed by cost (29%). The attributes and attribute levels used in discrete choice experiment were identified by literature review, patient focus group, and expert interviews.

CONCLUSIONS:
This systematic review of DCEs was the first review conducted to investigate preference and relative importance in terms of outcome, process and cost attributes for noninsulin diabetes medications. The outcome was the most important attribute to type 2 diabetes mellitus followed by cost, the process attribute was less important in almost all the studies. These results will help clinicians and providers in conducting future studies of patient preference for type 2 diabetes mellitus treatments.

PD29 Effectiveness Of Physical Rehabilitation In Advanced Cancer Patients

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ABSTRACT SUMMARY:
This article intends to evaluate the efficacy of supervised-exercise rehabilitation in cancer patients. Exercise may have beneficial effects on fatigue and be effective to improve muscular strength for advanced cancer patients: Leg press, Bench press, Abdominal crunch, Back. Furthermore, exercise interventions compared with control interventions have a positive effect on overall quality of life.

INTRODUCTION:
Due to the increase of cancer survival, more effective cancer patients’ management system is needed. This article intends to evaluate the efficacy of supervised-exercise rehabilitation in advanced cancer patients.

METHODS:
A systematic search of electronic databases, including MEDLINE, EMBASE and the Cochrane Library, as well as three domestic databases from inception to 3 July 2017, was performed. Two
reviewers independently screened all references according to selection criteria. The Cochran Risk of Bias (RoB) for randomized controlled trials (RCT) and Risk of Bias for Non-randomized studies (RoBANS) were used to assess quality of literature. Data from randomized controlled trials and pre-post studies were combined and meta-analysis was performed.

RESULTS:
A total 11 studies were included. 4 studies were randomized controlled trials and the remaining 7 studies were pre-post studies respectively. Meta-analyses were performed by study design. For RCT meta-analyses, exercise interventions showed little reduction in fatigue than control group with standardized mean difference (SMD), −0.62 and 95% Confidence Interval (95% CI: −0.87 – 0.37). In meta-analyses for pre-post studies, exercise interventions resulted in improvements in muscular strength from baseline to follow-up: Leg press (mean difference (MD): 12.13, 95% CI: 5.90 - 18.35); Bench press (MD 4.81, 95% CI: 0.85 - 8.77); Abdominal crunch (MD 6.48; 95% CI: 2.01 to 10.96); Back (MD 5.18; 95% CI: 1.59 - 8.77). Exercise interventions have a positive impact on quality of life measured by EORTC-QLQ-C30 from baseline to follow-up (MD 9.86, 95% CI 1.56 -18.34).

CONCLUSIONS:
Exercise may have beneficial effects on fatigue and be effective to improve muscular strength for advanced cancer patients based on existing studies. However, the positive results must be interpreted cautiously because of the heterogeneity of studies. More studies are needed to further investigate how to sustain positive effects of exercise over time.

PD30 Cost-effectiveness Of Stereo-Electroencephalography For Refractory Epilepsy

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ABSTRACT SUMMARY:
Stereo-electroencephalography (SEEG) has been shown to be a valuable tool to define the epileptogenic zone. We undertook a meta-analysis on the effectiveness and safety of the stereo-electroencephalography, and a cost-effectiveness analysis based on decision modelling from the Spanish National Health Service perspective. Stereo-electroencephalography is a cost-effective technology in patients with refractory epilepsy considered for surgery when compared to no stereo-electroencephalography intervention.

INTRODUCTION:
Stereo-electroencephalography (SEEG) has been shown to be a valuable tool to the anatomo-electroclinic definition of the epileptogenic zone (EZ) in some patients with medically refractory epilepsy considered for surgery. In Spain, many of those patients are not offered this diagnostic procedure. The objective of our HTA report was to evaluate the effectiveness, safety and cost-effectiveness of SEEG to define the EZ in patients with refractory epilepsy considered for surgery compared to no SEEG intervention, i.e., remaining with further antiepileptic drugs.
METHODS:
We undertook a systematic review with meta-analyses on the effectiveness and safety of SEEG. A cost-effectiveness analysis was conducted using a Markov model which simulates the costs and health outcomes of individuals for a lifetime horizon from the perspective of the Spanish National Health Service (NHS). The effectiveness measure was quality-adjusted life years (QALYs). We ran extensive sensitivity analyses, including a probabilistic sensitivity analysis.

RESULTS:
The EZ was found in 92% of patients who underwent SEEG, 72% were eligible for epilepsy surgery and 33% were free of seizures after surgery (47% of those who received surgery). Any complications related to insertion and monitoring of SEEG and the subsequent intervention occurred in 1.3% of patients. In the base case analysis, SEEG led to higher QALYs and healthcare costs with an estimated incremental cost-effectiveness ratio (ICER) of 10,368 EUR per QALY. The sensitivity analyses showed that the results of the study were robust.

CONCLUSIONS:
SEEG is a cost-effective technology in patients with refractory epilepsy considered for surgery when compared to no SEEG intervention.

ABSTRACT SUMMARY:
The therapy using molecular-targeted (MTT) and monoclonal antibodies (MA) are examples of new therapeutic technologies, with high impact on costs. MTT and MA were identified with regular annual use, and were evaluated in relation to total drug expenditure.

INTRODUCTION:
The therapy using molecular-targeted (MTT) and monoclonal antibodies (MA) are examples of new therapeutic technologies, in search of greater clinical effectiveness and reduction of adverse effects in the fight against highly frequent diseases. Generally, new technologies impact in high costs. OBJECTIVES: evaluate the financial impact generated by the use of molecular-targeted and monoclonal antibodies therapies in the teaching Hospital de Clínicas, Porto Alegre, Brazil.

METHODS:
The first 60 higher monetary spending drug items of the last 12 months were analyzed. From them, drugs which fit in the categories under study and have been regularly used were identified. The monthly expenditures with each item were tabulated and compared with the total expenditures on drugs, in order to calculate the budgetary impact. The major groups of diseases treated with each agent were analyzed.

RESULTS:
Two MTTs agents (gefitinib and infliximab) and three ACMs (rituximab, basiliximab and abciximab) were identified. The highest expenditure items, respectively, per year, were the oncological medicine gefitinib (US$ 72,228.80), followed by immunosuppressives basiliximab (US$ 97,138.50) and infliximab (US$ 77,534.90), the oncological rituximab (US$ 72,228.80) and the platelet aggregation inhibitor abciximab (US$ 54,090.10) corresponding to, respectively, 10.4%, 9.3%, 7.5%, 7.0% and 5.3% of total drug expenditure per year (US$ 13,403.300). Trastuzumab, bortezomib and imatinib were often used, but directly supplied by
the public system, in a way that didn’t impacted directly in the hospital budgetary management.

CONCLUSIONS:
The MTT and MA have important budget impact and are mainly used to treat some types of cancer, cardiovascular disease and immunosuppressive therapies. These aspects should be considered in the management of drugs in hospitals of high complexity.

PD33 Incorporation Of New Medicines In Brazil: A Descriptive Analysis

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ABSTRACT SUMMARY:
This work reports a descriptive analysis of the recommendations on incorporation of new medicines in Brazil issued by the National Commission for the Incorporation of Technologies in SUS. Data suggest that the economic evaluation is secondary to the decision of incorporation. It was not possible to determine an implicit cost-effectiveness threshold.

INTRODUCTION:
Health Technology Assessment (HTA) is important to the rational decision in healthcare systems. In Brazil, HTA is carried out by the National Commission for the Incorporation of Technologies in SUS (Conitec), which issues reports with recommendations. This work aims to describe these recommendations and the factors influencing them.

METHODS:
A descriptive analysis was conducted on Conitec’s reports of incorporation of medicines between 2012 and 2016. The reports are freely available at: http://conitec.gov.br/decisoes-sobre-incorporacoes. The medicines were classified according to the ATC system.

RESULTS:
128 reports were assessed. Most requests were issued by the pharmaceutic industry (N=72; 47,3%), followed by the Ministry of Health (N=63; 41,4%). More reports issued by the Ministry of Health had positive recommendations compared to manufacturers (N=22 vs. N=50; \(\chi^2=30.231, df=1, valor-p=3.836e-08\)). Other antivirals were the most common class with requisitions (N=16), followed by TNF-\(\alpha\) inhibitors (N=14) and selective immunosuppressants (N=12). Other antivirals had the most positive recommendations (N=12; 75%), followed by TNF-\(\alpha\) inhibitors (N=7; 50%) and selective immunosuppressants (N=7; 58,3%). The difference was significant (\(\chi^2=88.65, df=63, valor-p=0,0183\)). TNF-\(\alpha\) inhibitors was the class with the most negative recommendations (N=7; 50%), followed by monoclonal antibodies (N=6; 66,6%).

62 reports contained economic assessments. 54 presented ICER data and 57 presented the budget impact. 23 reports showed data indicating dominance of the medicine, but only 5 of these were recommended for incorporation. Drugs for cancer have been recommended despite high ICER values. Decision makers accepted all the recommendations issued by Conitec.

CONCLUSIONS:
Data suggest that the economic evaluation is secondary to the decision of incorporation. The pharmaceutical industry is the largest applicant for the incorporation of medicines, but these requests are significantly less accepted than those made by the Ministry of Health. Conitec’s recommendations are well-accepted by policy-makers. It was not possible to determine an implicit cost-effectiveness threshold.
PD34 São Paulo Congenital Heart Corrections: Three-Years’ Assist Registry

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ABSTRACT SUMMARY:
São Paulo State Voluntary Pediatric Cardiovascular Surgery Multicenter «ASSIST» Registry analyzes of 1842 patients surgical practice performance and outcomes within a federal-state joint strategic public policies research. Morbi-mortality related factors elicited critical points and allowed improvement actions. Excluding age and intrinsic procedure complexity, identified outcome modifier factors can be manageable aiming to increase patient safety and program resolubility or performance.

INTRODUCTION:
Death from congenital heart disease (CHD) can be avoided, contributing to reduce infant mortality. Objective: To identify the profile of patients undergoing CHD surgical correction in three São Paulo State hospitals, and morbidity and mortality factors.

METHODS:
«ASSIST» Voluntary Pediatric Cardiovascular Surgery Multicenter Registry was created in 2014 through a PPSUS* project, a federal-state joint strategic public policies research grant, coordinated by InCor-HCFMUSP-SP and Ribeirão Preto’s Hospital das Clínicas, both linked to the São Paulo University Medical School.

RESULTS:
We analyzed 1842 patients, average age of 1.2 (0.4-8.6) years, 50.9% male. The procedures complexity was classified by RACHS-1: 18.2% RACHS1, 25.5% RACHS2, 41.2% RACHS3, 9.6% RACHS4 and 5.4% RACHS5-6. Overall hospital mortality was 12.2% and its preoperative risk factors were: age <30 days (OR=1.7 p=0.012) and ICU admission (OR=3.3 p=0.001). Intraoperative mortality increased with RACHS> 4 (OR=5.3 p<0.001), lactate and vasoactive drug index at the end of surgery (OR=1.0 p<0.001) and (OR=1.0 p<0.001), respectively. Postoperatively, further mortality modifiers were cardiac dysfunction (OR=3.4 p=0.001), sepsis (OR=3 p=0.001), need for surgical or hemodynamic re-intervention (OR=6.2 p<0.001), cardiorespiratory arrest (CPR, OR=24.9 p<0.001) and renal failure (OR=5.4 p<0.001). Observed morbidities were: 16.2% cardiac dysfunction, 7.1% arrhythmia, 5.9% pneumonia, 5.9% pneumothorax, 4.2% pleural and pericardial effusion, 10% required mechanical ventilation> 7 days, 13.2% late sternal closure, 2.8% had wound infection, 3.7% neurological alterations, 2.3% diaphragmatic dysfunction, 11.5% CPR, 3.2% renal failure, 4.5% sepsis, 55.1% length of hospital stay> 5 days with 45.8% postoperative hospital admission> 15 days and 6.1% needed surgical or hemodynamic re-intervention.

CONCLUSIONS:
The ASSIST’s information generated was of great importance in the São Paulo State CHD surgical treatment practice evaluation. Morbi-mortality related factors elicited critical points and allowed improvement actions. Excluding age and intrinsic procedure complexity, identified outcome
modifier factors can be manageable aiming to increase patient safety and program resolubility or performance.

PD35 Patient Engagement In Rapid Cycle Health Technology Assessments

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ABSTRACT SUMMARY:
A review of published literature, both internationally and nationally, was conducted to identify processes in place to incorporate PE in HTAs, as well as, emergence of new theories and strategies for PE. Currently, the HTA team at the Centre for Clinical Epidemiology and evaluation (C2E2) is applying a mixed-approach PE scheme (involvement and collaboration) in a rapid-cycle HTA project.

INTRODUCTION:
To create a standardized process for Patient Engagement (PE) within a ninety-day rapid cycle Health Technology Assessment (HTA).

METHODS:
A review of published literature, both internationally and nationally, was conducted to identify processes in place to incorporate PE in HTAs, as well as, emergence of new theories and strategies for PE. Interviews with stakeholders and experts in the field of PE within British Columbia (BC) were conducted to consult and review the proposed process for PE in rapid cycle HTAs.

RESULTS:
In analysis and assessment of published tools to navigate PE within HTAs, and in consideration of stakeholders’ guidance and expertise, a process for PE in rapid cycle HTAs was designed. This process includes a mixed-approach to PE to include patients both at the level of “involvement” and “Collaboration” based on the International Association for Public Participation spectrum of public participation (IAP2 Spectrum). Approval by the UBC Research ethics board was obtained to keep any PE documents within the research grounds to protect the privacy and confidentiality of patients. Input from PE is incorporated into the feedback provided to the multidisciplinary team, to incorporate these findings in any adjustments made in the design of the economic model, as well as any other components such as the budget impact analysis, investigation of implementation barriers, and interpretation of findings throughout the different stages of the HTA Process.

CONCLUSIONS:
Currently, the HTA team at the Centre for Clinical Epidemiology and evaluation (C2E2) is applying the proposed mixed-approach PE scheme in a rapid-cycle HTA project. Patients at the involvement level will include those with direct and personal experience of the topic under evaluation, whereas engagement at the collaboration level will be in partnership with two external members of the public, identified as Patient Partners (PP).
PD36 Scoping Of Interventions Of The Philippines’ Most Burdensome Diseases

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ABSTRACT SUMMARY:
This study provides a comprehensive list of candidate interventions - 745 spanning from primary to tertiary prevention - for priority-setting in the Philippines to attain universal health coverage. Interventions were triangulated from a comprehensive literature review search and interviews with medical societies. This study serves as the foundation for building a larger evidence base for service coverage decisions.

INTRODUCTION:
In 2016, Global Burden of Disease (GBD) data was used to identify the top twenty percent of disease causes in the Philippines, which happened to account for eighty percent of the burden, following the Pareto principle. This study follows from that initial work, aimed at creating a list of cost-effective interventions recommended for priority-setting to achieve universal health coverage (UHC).

METHODS:
A comprehensive literature review search was done, from global sources such as the Disease Control Priorities (DCP) for Developing Countries Project and World Health Organization’s (WHO) Choosing Interventions that are Cost-Effective (CHOICE), and local sources such as clinical practice guidelines (CPGs). Forty-seven local experts from thirty-eight medical societies were also consulted on the applicability, appropriateness, adaptability, feasibility of implementation, ability to maintain fidelity, ease of dissemination, and sustainability of selected interventions in the Philippine setting. Resource requirements were then derived using the WHO OneHealth Tool, CPGs, and key informant interviews.

RESULTS:
A list of 745 interventions categorized by life stages and by level of intervention with estimates of cost-effectiveness was produced, from these, fifty seven percent had cost-effectiveness studies. Primary interventions were found to be the least costly for the pregnant women, newborn, infant, adolescents, adults, and elderly life stages while tertiary interventions were found to be the least costly for children.

CONCLUSIONS:
The interventions are potential targets for inclusion by policymakers. Additional factors to consider are: the appropriateness of the context in which the cost-effectiveness study was conducted, the feasibility of conducting primary HTA locally, the local costs of the intervention, and the need to act quickly before the policy window closes.

PD37 Effects Of Exercise And Education Intervention In Elderly

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ABSTRACT SUMMARY:
The aim of the study was to assess effects of
multi-intervention, which utilizes a combination of exercise and education for improving the health of elderly individuals residing in local communities, based on a systematic review method.

INTRODUCTION:
In 2015, Korea newly launched Korea Preventive Services Task Force (KPSTF) to provide community guidelines in field of preventive medicine and public health, based on rigorous assessment of existing evidence, and this study conducted as part of the project in 2016. The aim of the study was to assess effects of multi-intervention, which utilizes a combination of exercise and education for improving the health of elderly individuals residing in local communities, based on a systematic review method.

METHODS:
Five international and eight domestic databases were searched up to June, 2016. Two or more reviewers independently participated in the process of literature selection, assessing risk of bias, and data extraction.

RESULTS:
A total of 35 pieces of literature, including 25 RCT and 10 non-RCTs, were selected finally. Among the 25 RCTs, 11 could be utilized for quantitative analysis for the amount of physical activity as consequences of physical activity practices. The results showed physical activity of intervention was significantly more than that of control (SMD 0.13, 95% CI 0.02–0.24, I²=47.0%). In subgroup analysis, the following factors positively affected to increase the amount of physical activity in elderly: 1) adding to incentives and other supplemental intervention programs, 2) intervention period of three months or longer, 3) offering a structured exercise program, 4) existing a supervisor during the exercise program, 5) providing the exercise intervention at local community facility, not in households, and 6) including the education/counselling program contents about physical activity.

CONCLUSIONS:
The study findings suggest that, while multi-interventions of exercise and education/counselling produce significant effects in increasing physical activity of elderly individuals who are healthy or pre-frail. Further research should identify the effects of intervention according to each type of control group, which this present study could not consider, due to lack of evidence.

PD38 Approach For Estimating The Ethical Relevance Of Health Technologies

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ABSTRACT SUMMARY:
Estimating the relevance of ethical aspects before preparing a health technology assessment (HTA) report can help contracting agencies and contractors better estimate the resources required. By conducting a preliminary search and applying the Hofmann questionnaire, ethical aspects can be identified that allow inferences on the ethical relevance of health technologies and on the resources required for handling ethical aspects.

INTRODUCTION:
The ethical relevance of health technologies can vary greatly. No standards exist on how to estimate the resources required for handling ethical aspects in HTA reports, and without ethics experts, this is a difficult task. Our aim was to develop an approach that, before an HTA report is produced, enables non-experts to estimate the relevance of
health technology-related ethical aspects and the resources required for handling these aspects.

METHODS:
We searched for approaches for capturing and presenting ethical aspects in HTAs using the following information sources: the NHS HTA database, HTAi Vortal, the EUnetHTA core model, the final report of INAHTA’s working group on handling ethical issues, and Pubmed. The approach outlined above was developed using content analysis and was tested using examples.

RESULTS:
Seven theoretical approaches for capturing ethical aspects were identified. We then developed an approach that should preferably allow a universal (topic- and user-independent) assessment of ethical relevance. After a preliminary search on ethical aspects of the health technology under assessment, the short form of the Hofmann questionnaire is applied by one ethics expert and one non-expert. The ethics expert can be replaced by a second non-expert if he or she has sufficient experience with the questionnaire. The objective is to classify the relevance of ethical aspects into those with no relevance or slightly or clearly increased relevance. The results of the questionnaire are consented and the relevance of ethical aspects estimated.

CONCLUSIONS:
By identifying health technology-related ethical aspects at an early stage in the production of an HTA report, their relevance as well as the resources required can be estimated and consequences for the various options of handling ethical aspects in the production of the report can be derived.
Pubmed. An approach for handling ethical aspects was developed on the basis of the data identified.

RESULTS:
HTA producers currently use different approaches for identifying ethical aspects, such as systematic literature searches, qualitative interviews, and expert opinions. Our approach unites these different approaches. Depending on the estimation of ethical relevance (no increased, slightly increased, and clearly increased relevance), a step-by-step approach for handling ethical aspects is suggested in the production of HTA reports. A systematic literature search alone will not identify unpublished technology-related ethical aspects. To capture those unpublished aspects with a slightly or clearly increased relevance, we also recommend applying the Hofmann questionnaire, potentially involving patients and other affected persons.

CONCLUSIONS:
The current testing of our approach will show whether it is confirmed as an appropriate approach for the transparent, systematic and pragmatic handling of ethical aspects in HTA reports, while taking the technology-related relevance of these aspects into account. First results will be presented.

PD40 GEL Versus HES In Expanding Blood Volume: A Meta-analysis And CEA

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ABSTRACT SUMMARY:
This study did a meta-analysis and cost-effectiveness analysis of Succinylated gelatin (GEL) versus Hydroxyethyl starch (HES) in expanding blood volume.

INTRODUCTION:
This study aimed to evaluate the effectiveness and cost-effectiveness of succinylated gelatin (GEL) and hydroxyethyl starch (HES) in expanding blood volume, from the perspective of providing evidence-based information for clinical decisions.

METHODS:
PubMed, Cochrane Library, EMBASE database were searched for collecting head to head randomized controlled trials comparing GEL and HES from year 1946 to year 2017. For the meta-analysis, the Jadad measuring scale was used to do quality assessment. A decision tree model was developed to compare the cost-effectiveness of GEL versus HES. The cost, probability and QALY inputs parameters were from critical literature review, clinician focus group and analysis of retrospective real-world data from two hospitals. The uncertainty was evaluated by using one-way sensitivity analysis with Tornado approach.

RESULTS:
A total of 8 RCTs (N= 354 patients) were identified. Meta-analysis showed there was no significance difference in terms of platelet count after operation [SMD = -0.21, (95%CI: -0.47~0.04)], hemoglobin concentration after operation [SMD = 0.09, (95%CI: -0.41~0.23)], intraoperative blood loss [SMD = 0.16, (95%CI: -0.18~0.50)], postoperative heart rate [SMD = 0.23, (95%CI: -0.77~0.32)] and postoperative central venous pressure [SMD = -0.21, (95%CI: -0.47~0.04)]. The results of decision tree model analysis showed the minimum cost of GEL and HES were ¥263.89 (exchange rate: US $ 1 for ¥6.64) and ¥485.26, respectively, and the incremental cost–effectiveness ratio was -1316000/QALY. One-way sensitivity analysis showed that the GEL total treatment cost was the most sensitive factor.
**CONCLUSIONS:**

GEL and HES have comparable effects in terms of platelet count after operation, hemoglobin concentration after operation, intraoperative blood loss, postoperative heart rate and postoperative central venous pressure, but GEL treatment is less expensive than HES. Considering some limitations, a larger-scale high quality RCT and real-world evidence studies are required for further validation of the findings.

**METHODS:**

HsTnI for rule-in and rule-out of AMI in the ED is being evaluated using the EUnetHTA Core Model® framework for health technology assessment. The hsTnI HTA assessment will be completed with real-world evidence derived from a multicenter observational study which has been designed to be conducted in 12 Italian EDs, enrolling 6000 patients with chest pain of suspected cardiac origin, aiming to provide data from the Italian context on clinical, organizational and economic aspects of the use of the test in the ED. Endpoints of the study include: time lapses related to diagnosis, admission, treatment and discharge of patients; number of tests performed; and number of patients diagnosed with AMI.

**RESULTS:**

Initial results from a literature review confirm the usefulness of the hsTnI assay in diagnosing AMI. Generated real-world data will be collected, analyzed and integrated to existing evidence to assess the utility of the test in real contexts, providing details relevant for organizational aspects of the use of the test in the ED.

**CONCLUSIONS:**

The use of hsTnI could improve diagnosis of AMI by allowing a faster ruling-in or ruling-out, and reducing inappropriate hospitalizations. Furthermore, this technology could represent an opportunity to reduce overall costs for the healthcare system.
PD42 Safety And Cost-effectiveness Of Platelet-rich Plasma For Chronic Wound Healing

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ABSTRACT SUMMARY:
Platelet-rich plasma (PRP) gel is increasingly used for chronic wound healing. We undertook a meta-analysis on the effectiveness and safety of PRP and a cost-effectiveness analysis based on decision modelling from the Spanish National Health Service perspective. PRP is not a cost-effective technology in patients with diabetic foot ulcers as compared to standard care.

INTRODUCTION:
New therapeutic strategies have been established in chronic wound healing procedures, such as the use of platelet-rich plasma (PRP). There is currently still uncertainty about the effectiveness, cost-effectiveness and real safety of PRP in promoting chronic wound healing and what specific types of chronic wounds can benefit most from its use.

METHODS:
Systematic review of available scientific literature on the effectiveness, safety and cost-effectiveness of PRP compared to placebo, standard care or alternative topical therapies for the treatment of chronic wounds in adults. Overall effect size was estimated through a meta-analysis. A cost-effectiveness analysis was conducted using a Markov model which simulates the costs and health outcomes of individuals for a 5-years horizon from the perspective of the Spanish National Health Service (NHS) for the PRP versus standard treatment in patients with diabetic foot ulcers. The effectiveness measure was quality-adjusted life years (QALYs). We ran extensive sensitivity analyses, including a probabilistic sensitivity analysis.

RESULTS:
16 RCTs and 4 observational studies were included for the effectiveness and safety meta-analysis. The primary outcome was the proportion of chronic wounds completely healed: 143 patients out of 334 (42.8%) were cured in the standard treatment arm and 251 patients out of 375 (66.9%) in the PRP arm, RR 1.68 (95% CI 1.22 to 2.31). It was unclear whether there was a difference in the risk of infection (RR 0.53, 95%CI 0.10 to 2.71) or adverse events (RR 1.05, 95%CI 0.29 to 3.88) between PRP and standard care. Three studies were considered for the cost-effectiveness analysis. In the base case analysis, PRP led to higher QALYs and healthcare costs with an estimated incremental cost-effectiveness ratio (ICER) of 41.767 €/AVAC.

CONCLUSIONS:
PRP treatment is more expensive and more effective than standard treatment. The estimated ICER is above the acceptability threshold in Spain.
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ABSTRACT SUMMARY:
The National Institute of Health is proposing to the Ministry of Health and to the National LEA Commission a new evidence and value-based procedure for updating the health benefit package (“Livelli Essenziali di Assistenza” - LEA) for the Italian NHS.

INTRODUCTION:
In Italy, the central government sets the health benefit package (denominated “Livelli Essenziali di Assistenza” - LEAs) of the National Health System (NHS), which must be provided to all residents. In 2004, the Italian Ministry of Health established a new technical body, the National LEA Commission, responsible for updating LEAs.

METHODS:
Recently, the Ministry has commissioned to the National Institute of Health (NIH) the development of a new value-based procedure for updating the health benefit package for the Italian National Health System (NHS), supporting the National LEA Commission. A review and comparison of value frameworks and decisional models was performed in order to select a framework and a model that can be applied to the Italian context, design an administrative process for the update procedure, and propose approaches for: (i) the assessment of services currently included in the health benefit basket and of those planned to be incorporated, (ii) the process of appraisal and decision-making to be adopted by the Commission.

RESULTS:
The NIH designed an evidence and value-based administrative process for the procedure for updating LEAs, and provided methodological documents for (i) the assessment of services currently included in the health benefit basket and of those planned to be incorporated, (ii) the process of appraisal and decision-making to be adopted by the Commission.

CONCLUSIONS:
The NIH is proposing to the Ministry of Health and to the National LEA Commission a new evidence and value-based procedure for updating the health benefit package for the Italian NHS. This procedure is entering a pilot phase in which potential gaps can be identified and minimized for its subsequent implementation.

PD44 Multi-comparator ICER: A New Framework For Cost-effectiveness Analysis

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ABSTRACT SUMMARY:
Estimating a multi-comparator ICER accounting for the changes in clinical practice following the introduction of a new technology may provide a more comprehensive assessment of value than only considering traditional measures of cost-effectiveness.

INTRODUCTION:
Current practice in cost-effectiveness analysis (CEA) involves the estimation of the incremental
cost-effectiveness ratio (ICER) between a new intervention and one alternative comparator reflecting the standard of care. As this focuses on pairwise comparisons, rather than considering the whole range of available alternatives at any given time, this method fails to capture the full impact of bringing the new intervention to market.

METHODS:
A multi-comparator ICER (MC-ICER) evaluating the impact of the new technology on patients treated with all comparators used in clinical practice, rather than a theoretical ‘second-best’ alternative only, was estimated. This can be achieved by weighting the incremental costs and benefits for each comparator by its change in market share to generate an MC-ICER. This is shown using a stylized example with three comparators.

RESULTS:
The traditional ICER against the second-best alternative was $200,000 per QALY, while the estimated multi-comparator ICER is $133,548 per QALY, corresponding to a 33% decrease. This reflects the fact that patients who switch to the new intervention are not only those who had been previously treated with one particular comparator, as is assumed in a traditional CEA. The difference between the traditional ICER and the MC-ICER depends on how the new intervention impacts on the uptake of each comparator.

CONCLUSIONS:
Results show that, when comparator selection was made excluding dominated and extendedly-dominated alternatives, the MC-ICER, produced using the method described above, is lower than the traditional ICER comparing the new intervention to the second-best comparator. This captures the fact that patients may switch to the new intervention not only from the second-best comparator, but from the whole range of alternative treatments. Such patient movements determine the real impact, or opportunity cost, of the new intervention on the healthcare system and, therefore, should be captured in CEA alongside traditional one-way ICERs.

PD45 Surgical Care Of Stress Urinary Incontinence: Economic Evidence Review

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ABSTRACT SUMMARY:
To explore and understand the economic modeling evidence base around the management of patients with SUI using surgical treatments, a systematic review of economic evaluations was conducted. Seventeen studies met the inclusion criteria and were included in the final review. There is limited, robust model-based economic evaluation evidence to inform the cost-effectiveness of surgical treatments for the management of SUI.

INTRODUCTION:
Stress urinary incontinence (SUI) is a distressing and common condition, which affects more than 30% of women. To explore and understand the economic modelling evidence base around the management of patients with SUI using surgical treatments, a systematic review of economic evaluations was conducted.

METHODS:
The review work was conducted in accordance with the Centre for Reviews and Dissemination’s guidance for undertaking reviews in health care. The following databases were searched in March 2017: MEDLINE, MEDLINE In-Process,
EMBASE, HIMC, NHS EED and the CEA registry. Two researchers undertook the screening of titles and abstracts identified through the searches. No restrictions were placed on the publication timeframe or the study country.

RESULTS:
Seventeen studies met the inclusion criteria and were included in the final review (nine US; four UK; three Canada; and one in the Netherlands). The populations, interventions, and comparators were generally well defined. Very few studies were informed by literature reviews and few used synthesized clinical evidence. Although the comparators in individual studies had potential differential effects on long-term quality of life and resource use, most of the studies used relatively short time horizons (< 3 years). Univariate sensitivity analyses were reported in all studies, but less than half characterized all uncertainty using probabilistic sensitivity analysis. Very few studies incorporated patients’ health-related quality of life data, and only four studies used social tariff values.

CONCLUSIONS:
There is limited, robust model-based economic evaluation evidence to inform the cost-effectiveness of surgical treatments for the management of SUI. Many of the recent publications did not satisfy essential methodological requirements such as using clinical evidence informed by a systematic review and evidence synthesis; highlighting the need and importance of robust modelling to estimate the cost-effectiveness of these treatments, fully characterise the uncertainty in the evidence base and inform the value of future research.

PD47 Implanted Hypoglossal Nerve Stimulation For Obstructive Sleep Apnea

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ABSTRACT SUMMARY:
The hypoglossal nerve stimulation devices produce a tongue contraction to alleviate the symptoms of mod-severe obstructive sleep apnea patients. The objective of this work is to evaluate the effectiveness and safety of this group of devices for a preliminary assessment of its possible inclusion in a National Health System.

INTRODUCTION:
The hypoglossal nerve stimulation (HNS) produces a tongue protrusion for the treatment of mod-severe obstructive sleep apnea (OSA). It is one of the emerging health technologies prioritised to assess its possible inclusion on the Spanish NHS. The objective of this study is to evaluate the efficacy and safety of this system in the treatment of OSA.

METHODS:
It was performed an early assessment. The searched databases were: PubMed, WOS, Tripdatabase, Dynamed, Cochrane Library and ICTR. Clinical studies of OSA patients treated with HNS published until 01 March 2017 were reviewed. Outcomes considered were: AHI (Apnea Hypopnea Index) ODI (Oxygen Desaturation Index) ESS (Epworth sleepiness scale) and AE (adverse events).
RESULTS:

Four devices of HNS were founded: Inspire™, HGNS®, Aura6000™, and Nixoah™. We found two randomised controlled trials (RCT). The Inspire™ RCT showed significant results on mean differences on AHI (-16.9, 95% CI -24.7 to -9.0); ODI (-15.1, 95% CI -22.7 to -7.5) and ESS (-4.5, 95% CI -7.5 to -1.4) in 46 patients, after one week of follow-up. The HGNS® RCT showed non-significant differences on AHI (Device active 22.1 ± 5.2 vs Control 29.7 ± 6.2), ODI (11.4 ± 4.1 vs 19.5 ± 5.2) and ESS (9.8 ± 1.0 vs 14.1 ± 2.5) in 21 patients at 6 months. A systematic review that included 6 cases series (3 with HGNS®, 2 with Inspire™ and 1 with Aura6000™) without device subgroup analysis and 7 cohorts studies (6 with Inspire™ and one with Aura6000™) showed significant differences comparing AHI, ODI and ESS results to before treatment values. Major AE reported from the studies varied from 4 to 4.5%. No study with Nixoah™ was found.

CONCLUSIONS:

Inspire™ seems to be an effective option for OSA patients although the evidence is scarce and of low quality for all HNS devices. It would be necessary further well-designed studies.

ABSTRACT SUMMARY:

The OTL38 agent is a folate analogue conjugated to a near-infrared fluorescent dye which together with a specific imaging system can help the surgeon to visualise diseased tissue in cytoreductive surgery for ovarian cancer. The objective of this work is to know the effectiveness and safety of OTL38 in ovarian cancer surgery.

INTRODUCTION:

Ovarian cancer (OC) has the highest mortality rate of all gynecologic malignancies. Completeness of cytoreductive surgery is a key prognostic factor for survival. To differentiate clearly between malignant and healthy tissue is essential for achieving complete cytoreduction. Using current approaches, this differentiation is difficult and can lead to incomplete tumour removal. OTL38 is a folate analogue conjugated to a near-infrared fluorescent dye which has high specificity and affinity for folate receptor alpha (FRα) expressed in OC. OTL38 together with a specific imaging system can help the surgeon to visualise diseased tissue. The objective of this work is to know the effectiveness and safety of OTL38 in OC surgery.

METHODS:

Early assessment of OTL38 identified through the Early-Awareness and Alert-System, “SINTESIS-new technologies”, of AETS-ISCIII. The searched databases were: PubMed, WOS, Tripdatabase, Dynamed, Cochrane Library and ICTRP. Clinical studies using the OTL38 in cytoreductive surgery in OC published until September 2017 were reviewed.

RESULTS:

Only one publication, supported by industry, was retrieved. The study assesses the pharmacokinetics and tolerability of OLT38 in 30 healthy people randomised into 4 groups with different doses and a control group. The study also analyses the percentage of cytoreduction in 12 OC patients. Infusion of 0.025, 0.05 and 0.1 mg/kg OTL38 doses was associated with mild adverse events which did not require intervention. The 0.2 mg/kg dose was
associated to adverse events of moderate severity. In OC patients, 0.0125mg/kg dose was considered the optimal dose with mild adverse events. OTL38 accumulated in FRα-positive tumours and metastases allowed the surgeon to resect an additional 29% of malignant lesions which were not detected using standard inspection and palpation methods.

CONCLUSIONS:
The OTL38 is an emergent health technology, which could help in cytorreductive surgery for ovarian cancer. However the evidence is scarce and it would be necessary to continue further studies.

INTRODUCTION:
It is established that the current cost effectiveness HTA paradigm does not appropriately value rare disease technologies. Social willingness-to-pay (SWTP) has been suggested to be higher for rare disease technologies, its inclusion into existing HTA framework could better reflect social preferences (SP) and enable a more equitable evaluation of rare disease technologies. Our study aims to estimate SP and SWTP for a rare disorder, CLN2 disease. <40 children live in the UK with this severe and debilitating disease with an average life expectancy of around 10 years.

METHODS:
Relevant attributes for CLN2 disease were developed and validated by literature review and focus groups with patient’s primary caregivers. An elicitation survey (DCE WTP and RS-WTP) was developed using the selected attributes and levels of each attribute. The survey instruments and attributes/levels were tested and validated in a pre-pilot survey (n=103) and a subsequent pilot survey (n=286) of the UK general population. Information about CLN2 disease was provided to respondents and their understanding of the disease was tested including assessment of framing effects. The main survey with the general UK population (n≈4,000) is ongoing.

RESULTS:
826 people were contacted, of which 286 completed the DCE, 113 abandoned the survey before the DCE and 92 abandoned after the DCE. There were no significant differences in characteristics of respondents completing the DCE and those starting but not completing the DCE. Median survey completion time was 20 minutes with 90% participants completing in a single sitting. Median score for the understanding test was 3 (Min=0 and Max=4). Incoherencies in WTP estimates were analysed enabling us to introduce relevant modifications and select the most appropriate attribute levels.
**CONCLUSIONS:**

DCE and RS-WTP potentially are appropriate methods for assessment of social preferences. The selected attributes/levels for the experiment in CLN2 disease have been validated in this pilot.

**PD50 Helping Innovators Navigate Policy And Regulatory Processes**

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**ABSTRACT SUMMARY:**

This presentation describes the development of resources to help innovators to navigate policy and regulatory systems to have their technologies adopted; preliminary feedback suggests these were valued by innovators.

**INTRODUCTION:**

As part of a national aging and technology network, AGE-WELL, our group works to promote the understanding of potential policy and regulatory hurdles among innovators and decision-makers. This presentation describes the development of resources to help innovators to navigate policy and regulatory systems to have their technologies adopted.

**METHODS:**

We created a policy primer that highlights considerations for innovators during the innovation process (from development to implementation). The content of the policy primer was developed by identifying resources through the Canadian Agency for Drugs and Technology in Health Grey Matters search tool, and in consultation with legal and regulatory consultants. By surveying AGE-WELL technology-developing projects, (n=15) we characterized the technologies being developed within the network. Survey questions included: intended end-user/purchaser of the technology and past/anticipated facilitators/barriers in their innovation process. The policy primer and survey data were combined to create tailored innovation maps with considerations for each technology being developed within the network. These materials were used to develop a beta website where users can receive information relevant to various innovation stages, as it pertains to their technology. We gained feedback about our materials via surveys and interviews with AGE-WELL technology developers.

**RESULTS:**

The tailored innovation maps and website were seen as helpful resources for understanding policy and regulatory processes required for technology adoption. Technology developers expressed interest in gaining further access to these resources. Innovators desired additional resources about demonstrating value and measuring technology effectiveness.

**CONCLUSIONS:**

We developed resources to help guide technology innovators through policy and regulatory processes; preliminary feedback suggests these were valued by innovators. Next steps include refining the website and releasing these resources to innovators beyond the AGE-WELL Network.

**PD51 The Economic And Fiscal Impact Of Vaccination In Italy**

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ABSTRACT SUMMARY:
The aim of this study is to assess the social value of some immunization programs in the adult working population for three diseases. This objective is split in two minor sub objectives: i) To explore the social cost of the 3 diseases ii) To develop a model to estimate the fiscal impact of vaccination programs.

INTRODUCTION:
The investigation of the clinical and economic impact of poor health states, functional to the assessment of health technologies, is traditionally focused on the identification, measurement and valorisation of direct health care costs needed to provide care, as well as productivity costs associated with the diseases and their treatments. However, especially in contexts characterized by a large role for public sector in funding welfare, such an approach carries the risk to disregard potentially relevant costs beard by the public sector, outside the healthcare systems. Indeed, when the assessment is carried out under the perspective of the public sector, it is possible to quantify the effect of poor health states looking not only at the consumption of healthcare resources, but also at their effect in terms of early retirement and management of temporary and permanent disability. As a matter of fact, disability has a cost for the public sector which is both direct (pensions/allowances to be corresponded the sick person) and indirect (changes in consumption patterns affecting revenues from VAT). The aim of this study is to assess the value of some immunization programs in the adult working population for three diseases, namely invasive pneumococcal disease (IPD), influenza (FLU) and herpes zoster (HZ). This objective is split in two minor sub objectives: i) To explore the social cost of the 3 diseases ii) To develop a model to estimate the fiscal impact of vaccination.

METHODS:
The analysis has adopted the perspective of the public sector. The epidemiologic data have been extrapolated from the literature. The social costs and the fiscal impact have been represented with a simulation model putting together data concerning the losses of productivity, by using the human capital approach as well as reduced revenues for the public sector resulting from the decrease in income taxes. Data refer to an Italian population aged 50-64. The losses of productivity have been estimated by using data related to the number of days out of work and average salaries provided by the Italian National Institute for Statistics (ISTAT) and the Italian National Security Institute (INPS) The fiscal impact has been estimated by applying to the number of days out work the related reduction in the total income taxes as resulting from the Italian taxation system. Montecarlo simulation has been conducted in order to account for the variability and to check the robustness of results.

RESULTS:
Concerning FLU, assuming 2 mln infected, the total expected impact is € 1 bln including losses of productivity and fiscal impact with the latter estimated at € 160 mln. As per IPD, considering 90,000 infected, the total impact is € 150mln with the fiscal impact being € 25mln. Finally, in the case of HZ (and related complications), assuming 7000 infected, the total impact is € 4 mln with €630,000 resulting from a decrease in fiscal taxation.

CONCLUSIONS:
Our results show that the social costs deriving from three infectious diseases have a major economic impact. Moreover, decision makers should also consider the fiscal impact given by the reduction in income perceived from individuals experiencing poor health.
PD53 Efficacy And Safety Of Nicotinamide In Hemodialysis Patients

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ABSTRACT SUMMARY:
This is a systematic review of randomized controlled trials addressing the efficacy and safety of Nicotinamide in hemodialysis patients. The primary outcome was changed in serum phosphorus level. All included RCTs showed statistically significant reduction in mean serum phosphorous, calcium-phosphorus product level in treatment arm as compared to placebo. Nicotinamide was found to be effective in the management of hyperphosphatemia.

INTRODUCTION:
Hyperphosphatemia is a most common problem in dialysis patients. Phosphorus imbalance in dialysis patients increases the risk of developing the bone mineral disorder and cardiovascular mortality. Randomized Controlled Trials (RCTs) presented variable findings concerning the reduction of phosphorous level in nicotinamide user. So, this systematic review is aimed to explore the efficacy and safety of nicotinamide in hemodialysis patients.

METHODS:
This systematic review was conducted by adhering to the PRISMA guidelines. Study for inclusion was identified by running the suitable keywords in databases including PubMed, Embase, and Cochrane central from inception to 31st October 2017. Cochrane risk of bias tool was used to judge the quality of included RCTs. The change in serum phosphorus level was the primary outcome, while the change in other biochemical parameters including serum calcium, calcium-phosphorus product level, iPTH, platelets, lipid profile parameters, and the safety profile was considered under secondary outcomes. Review Manager (RevMan v5.3) was used for statistical analysis.

RESULTS:
Finally four articles were qualified for inclusion in this study with a total of 274 participants of which 136 were in the treatment group. All studies were of high quality. All the included studies showed statistically significant reduction in mean serum phosphorous, calcium-phosphorus product level in the treatment arm at the end point of the study, while the reduction in the placebo group was not statistically significant. Among other biochemical parameters analyzed, only High-Density Lipoprotein (HDL) was found to be significantly increased from baseline to the endpoint of the study in the nicotinamide group, while the placebo group showed no significant change. Thrombocytopenia was the most commonly reported adverse event in the treatment group followed by diarrhea.

CONCLUSIONS:
Nicotinamide was found to be effective in the management of hyperphosphatemia in hemodialysis patients. The safety profile was found to be satisfactory.

PD54 Associated Factors Renal Graft Loss Using Real-world Evidence In Brazil

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ABSTRACT SUMMARY:
This study describes associated factors with graft loss in kidney transplantation patients who received deceased donor organ and who used maintenance immunosuppressive regimens in SUS. The real-world evidence in fifteen years of follow-up in Brazil.

INTRODUCTION:
Renal transplantation is considered a cost-effective treatment compared to dialysis and represents a significant percentage of public health resources. Post-transplant treatment requires the use of three immunosuppressive drugs. The immunosuppressive regimens consists of a corticosteroid, a calcineurin inhibitor (cyclosporine or tacrolimus) and an antiproliferative agent (azathioprine or mycophenolate mofetil) and also by sirolimus or everolimus. In Brazil, the Unified Health System (as known as Sistema Único de Saúde - SUS) is responsible for 95% of all kidney transplants performed, as well as ensuring access to immunosuppressive drugs. Therefore, there is a huge and growing economic impact caused by the distribution of these drugs in SUS. We evaluated the factors associated with kidney graft loss in patients who received deceased donor organ and used maintenance immunosuppressive regimens in SUS, in fifteen years.

METHODS:
We analyzed a nationwide cohort of kidney transplant recipients from January 2000 to December 2015 developed through deterministic-probabilistic linkage of SUS administrative databases: Hospital Information System (SIH/SUS); Subsystem for High Complexity Procedures (SIA/ SUS) and the Mortality Information System (SIM). Graft loss was defined as death or dialysis for more than three months. All regimens included corticosteroid. We used Cox proportional hazards model to evaluate the factors associated with progression to graft loss.

RESULTS:
In total, 18,333 patients were included; 58.5% used tracolimus+ mycophenolate, 11.7% cyclosporine+mycophenolate, 8.9% tacrolimus+azathioprine, 5.5% cyclosporine+azathioprine and 15.4% received other immunosuppressive regimens (sirolimus+mycophenolate, everolimus+mycophenolate, tacrolimus, mycophenolate, cyclosporine, azathioprine) . Most patients were male with a median age of 46 years. A higher risk of graft loss was associated with the use of tracolimus+ mycophenolate (HR=1.069; 95% CI, 0.999–1.146), sirolimus+mycophenolate (1.395;1.150 -1.692), tracolimus (monotherapy ) (1,468;1,239 -1,739); mycophenolate (monotherapy) (1,297;1,126 - 1,493), male gender (1.144; 1.072–1.221), an additional year of age (1.010; 1.007–1.013), a median dialysis period greater than 38 months (1,266; 1.182 - 1.356), a diagnosis of diabetes (1.211; 1.071–1.367) and a diagnosis of arterial hypertension (1,209; 1.134– 1.288) as the primary cause of chronic kidney disease.

CONCLUSIONS:
Among other factors, the use of mycophenolate, tacrolimus, tacrolimus+ mycophenolate and sirolimus+ mycophenolate was associated with worse graft survival. The choice of drug therapy is one of the few factors that influence survival amenable to direct action by health professionals. Therefore, the results of this study are important and should be disseminated aiming to better outcomes for kidney transplant patients and the sustainability of SUS.
PD55 Diagnostic Accuracy Of The Line Probe Assay Technique (LPA) Compared To The Sensitivity Test In Liquid and Solid Media-based Techniques

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ABSTRACT SUMMARY:
A rapid reviews for assess the accuracy of the Line Probe Assay (LPA) technique for the detection of resistant tuberculosis compared to the sensitivity test in liquid and solid media-based techniques.

INTRODUCTION:
Antimicrobial resistance is a serious public health problem at the global level. The sensitivity test in liquid and solid media-based techniques is traditionally used in Brazil for the diagnosis of resistant TB. However, the time required for the diagnosis of this test is, on average, 60 (sixty) days, a period considered to be very high, especially considering certain vulnerable populations (street dwellers), since the long time to the result of the test makes it difficult to establish a second contact between the health institution and the individual, resulting in people without access to diagnosis and appropriate treatment. The LPA technique often replaces the use of the sensitivity test in many countries, being considered of low time for the diagnosis, ranging from 24 to 48 hours.

METHODS:
To assess the accuracy of the Line Probe Assay (LPA) technique for the detection of resistant tuberculosis compared to the sensitivity test in liquid and solid media-based techniques.

RESULTS:
Three systematic reviews with meta-analysis were selected. The interventions evaluated the Line Probe Assay (LPA) technique compared to the conventional drug sensitivity test. The evaluated tests showed good performance as rapid screening tests for resistance to rifampicin in high prevalence sites. However, although the test results for resistance to isoniazid showed good specificity, there was a high variability in sensitivity estimates.

CONCLUSIONS:
This study reinforces the idea that the technique may contribute to the previous diagnosis, and this is a probable strategy to control the disease, especially in vulnerable populations that are more likely to be affected by tuberculosis. For a broader analysis of the benefit of the technique, further studies are suggested.

PD56 Economic Evaluation Of Dalbavancin In European Countries

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ABSTRACT SUMMARY:
The aim of this study was to develop a spending predictor model for evaluating the direct costs
associated with the management of ABSSSI from NHS perspective of Italy, Spain and Romania. The preliminary results highlight that the introduction of dalbavancin could generate a significant reduction in the term of length of stay with no incremental cost from the NHS perspective.

INTRODUCTION:
Dalbavancin is a new innovative long-acting antimicrobial treatment allows the clinicians to endorse early discharge program for patients suffering from Acute Bacterial Skin and Skin Structure Infections (ABSSSI). The aim of this study was to develop a spending predictor model for evaluating the direct costs associated with the management of ABSSSI from the National Health Service (NHS) perspective of Italy, Spain and Romania. The main purpose is to compare the hospitalization and drug costs due to the treatment of ABSSSI patients treated with standard antibiotics therapy or innovative long-acting treatment dalbavancin.

METHODS:
A decision-analytic model was performed to evaluate the diagnostic and clinical pathways of ABSSSI patients in the hospital, based on clinicians expert opinion. The standard of care scenario was compared with dalbavancin scenario. The epidemiological and cost parameters were extrapolated from national administrative databases (hospital information system) and from a systematic literature review for each Country. Only direct costs in the National Payer's perspective were considered. Probabilistic Sensitivity Analysis (PSA) and One-way sensitivity analysis (OSA) were performed to check the robustness of the model assumptions.

RESULTS:
Overall, the model estimated an average annual number of patients with ABSSSI equal to around 50,000 in Italy, Spain and Romania. The introduction of dalbavancin reduced the length of stay of, on average, 3.3 days per ABSSSI patient. From the economic point of view, dalbavancin did not incur any additional cost from the NHS perspective with homogenous results between countries. The PSA e OWA demonstrated the robustness of the results.

CONCLUSIONS:
The preliminary results highlight that the introduction of dalbavancin could generate a significant reduction in term of length of stay with no incremental cost from the NHS perspective. This model could represent a good tool for policymakers to provide information on the early discharge approach in the ABSSSI management.

PD58 Cost-effectiveness Of Quinolone For Acute External Otitis In Brazil

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ABSTRACT SUMMARY:
This study is a systematic review and cost-effectiveness of quinolone versus polymyxin B, neomycin and steroid combined for treatment of acute external otitis. In this case, effectiveness is not measured by life years. The incremental cost-effectiveness ratio was BRL 136.25 (USD 42.15). Thus, quinolone was considered a cost-effective alternative in Brazil.
fluocinolone. The aim was to evaluate the proportion of cure and cost-effectiveness of quinolone versus polymyxin B, neomycin and steroid combined (PNS) for acute external otitis from the perspective of the Brazilian Public health system.

METHODS:
A systematic review was conducted using the Medline, Cochrane Library, CRD and Lilacs databases. Studies evaluating quinolones versus PNS in the treatment of acute external otitis were included. A cost-effectiveness model was made using a decision tree, considering the direct cost of treatment. Univariate sensitivity analysis was conducted, considering the confidence interval of clinical outcomes and a 15 percent variation in cost.

RESULTS:
The proportion of cure in up to 10 days was 70.1 percent with quinolone and 60.4 percent with PNS (p = 0.004). The treatment costs were BRL 16.22 (USD 5.02) with quinolone and BRL 3.04 (USD 0.94) with PNS. The incremental cost-effectiveness ratio was BRL 136.25 (USD 42.15) per cure in up to 10 days for quinolone in relation to PNS. This value was more sensitive to clinical outcomes, ranging from BRL 95.48 (USD 29.54) to BRL 254.25 (USD 78.65) for cure with quinolone and from BRL 90.77 (USD 28.08) to BRL 262.57 (USD 81.23) for cure with PNS. These values should be considered with caution because acute external otitis is resolved within a few days and treatment effectiveness is not measured by life years.

CONCLUSIONS:
There are few studies on therapeutic alternatives available in Brazil. Through the available evidence, there is a lack of results on the effects attributed to each drug. Considering the higher effectiveness, low cost and rational use of antibiotics, quinolone is considered a cost-effective alternative for acute external otitis in Brazil.

PD59 Formulation And Disclosure Of Information On Technologies In Health

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ABSTRACT SUMMARY:
This study reports the experience of formulation and disclosure of information on technologies in health more judicialized in Brazil. In a meeting with experts was argued and elaborated an appropriate format of the document directed towards policymakers, patient, professional health and other stakeholders. The availability of these documents represents a strong link between evidence and actions in health.

INTRODUCTION:
The Brazilian public health system (SUS) provides technologies based on the best available scientific evidence. However, there is a large number of lawsuits against the government for access to non-standard technologies, a phenomenon called “Judicialization of the right to health”, which disrupts the system’s operating logic. The aspect of judicialization that most impacts the health system is that involving unregistered technologies in the country without scientific evidence of superiority comparing to the alternatives already offered. The aim of the study reported experience of National Committee for Health Technology Incorporation in the Brazilian Health System (CONITEC), of mitigate the effects of the judiciary, with has elaboration of informative documents about technologies directed towards policy-makers, patient, users...
METHODS:
The main judicialized technologies in the country were identified and then, a meeting with experts was realized to discuss a more appropriate format for these documents. After defining the format, a review of the literature was carried out to identify the best available evidence of those health technologies.

RESULTS:
A question-and-answer (QA) format document was drawn. The PRs addressed information on the use of the technology for a specific clinical condition. Health registry and price in Brazil, if it has already been evaluated by CONITEC and its respective recommendation, as well as strategies of care and therapeutic alternatives available in the SUS. Their content has been adapted to a lay language and all of the documents were made available on the CONITEC’s website in the “Law and Health Section”.

CONCLUSIONS:
The availability of QA represents a strong link between evidence and actions in health. For, they enable broad access to quality information for the lay public and stakeholders who seek information to support evidence-based decision-making.

PD61 HTA Regional Network In The Central Region Of Brazil: Survey In 2016.

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ABSTRACT SUMMARY:
A survey was conducted with stakeholders from the hospitals and training/research institutions in Federal District, Brazil and 35% (25/70) questionnaires were answered. Fifteen institutions were cited among the interviewees as a potential to build the HTA network. Twelve of them produce rapid review and clinical guidelines. The challenges were training and organizing HTA units in the hospitals.

INTRODUCTION:
The Federal District has about 2.9 million inhabitants and the public health system is focused on medical specialties with one university hospital and 20 regional hospitals. This ecosystem is favorable for fostering HTA to improve the efficiency and effectiveness of health care. The objective is to identify institutions to structure an HTA network to support Decision-Oriented Evidence in public health system.

METHODS:
A survey was conducted with stakeholders from the hospitals and training/research institutions in Federal District. An online questionnaire (Google docs) was developed to identify the potential and capacity of institutions to analyze and/or produce clinical and economic evidence. Two HTA seminars were held to spread the knowledge about HTA and to increase the stakeholders’ answers.

RESULTS:
35% (25/70) questionnaires were answered. Fifteen institutions were cited among the interviewees as a potential to build the HTA network. Twelve of them produce rapid review and clinical guidelines, and only three are making an organized priority...
setting or their assessment were demanded by the hospital manager. The challenges were training and adherence of decision makers to organize HTA units in the hospitals.

CONCLUSIONS:
An executive group was created and defined the strategy to support the implementation of HTA units as part of the HTA National Network (REBRATS) and a regulation proposal was elaborated to touch decision makers to activate the HTA Network in Federal District.

PD65 The Acquisition Of Eculizumab By Judicial Proceeding In Brazil

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ABSTRACT SUMMARY:
Since 2009 in Brazil eculizumab was the most expensive drug requested by judicial proceeding. This study assesses the regulatory situation and the scientific evidence of eculizumab. Although licensed in FDA and EMA since 2007, the manufacturing company requested its license only in 2017, obligating the Brazilian government to import the drug at high prices.

INTRODUCTION:
Eculizumab is a monoclonal antibody indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) or with atypical hemolytic uremic syndrome (aHUS). In Brazil, in recent years the drug was the most expensive and requested through court orders obliging public health managers to import it from the USA. From 2012 to 2016, approximately 424 million dollars were spent on eculizumab. The purpose of this study is to assess the regulatory situation and the scientific evidence on safety and efficacy of eculizumab.

METHODS:
A literature search was conducted on PubMed, The Cochrane Library, and CRD databases, on September 2017, and surveys were conducted on websites of regulatory agencies.

RESULTS:
In 2007, the use of eculizumab was approved by FDA and EMA. In Brazil, despite its acquisition through judicial proceedings since 2009, the manufacturing company requested its license only in 2017, after several meetings with the government, when the company agreed to license the drug at approximately half the price of the imported product. The efficacy of eculizumab in PNH patients was assessed in one randomized and placebo-controlled study, in a single arm study and in a long-term extension study. The drug reduced hemolysis and the need for transfusions, although the studies had methodological problems. The efficacy of eculizumab in the treatment of aHUS was assessed in four prospective open-label controlled studies, in two long-term extension studies, and in one retrospective study. Eculizumab normalized platelet count and reduced the need for plasmapheresis, although the studies have no control group. Eculizumab was well tolerated with no meningococcal infections since patients were immunized.

CONCLUSIONS:
Some companies have no interest in licensing their products in Brazil since their acquisitions by judicial
proceedings are more lucrative. This situation promotes the litigation and irrational prescription of drug and also obligates the Brazilian government to import the product.

PD66 Indirect Comparison For The Treatment Of Metastatic Melanoma

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ABSTRACT SUMMARY:
The objective of this study is to perform an indirect comparison to measure the effect of Vemurafenib plus cobimetinib compared to Dacarbazine based on the results of trials with the same comparator (Vemurafenib). We present an indirect comparison and discuss the value of this tool when comparator curves are not similar even though inclusion criteria between trials are the same.

INTRODUCTION:
Vemurafenib plus cobimetinib (VC) for the treatment of metastatic melanoma was requested to be included in the National Formulary in Uruguay. The standard of care for this disease in the country is Dacarbazine. There is no head to head trial published that assessed the effect of VC versus Dacarbazine. The objective of this study is to perform an indirect comparison to measure the effect of VC compared with Dacarbazine based on the results of trials that included both treatments versus the same comparator (Vemurafenib).

METHODS:
We searched Pubmed and Cochrane for trials comparing VC and Dacarbazine independently to Vemurafenib. Trials were assessed in terms of risk of bias, similarity of interventions and inclusion and exclusion criteria and comparability of characteristics of Vemurafenib arm. We performed an indirect comparison by Bucher method.

RESULTS:
From the search we retrieved two studies that met the selection criteria: a randomized clinical trial that assessed VC versus Vemurafenib plus placebo and another one assessing Vemurafenib versus Dacarbazine. Both studies were similar in terms of methodological quality, characteristics of inclusion and exclusion criteria and comparability of vemurafenib arms. However, the comparison of overall survival and progression free survival curves of Vemurafenib arms were quite different between trial. Overall survival at 9 month was 81 percent and 55 percent, progression free survival was 30 percent and 15 percent respectively. The indirect comparison showed hazard ratio and CI 95 percent for overall survival 0.24 (0.14-0.48), for progression free survival 0.13 (0.09-0.19) and Grade 4 adverse events 0.15 (0.02-1.29).

CONCLUSIONS:
The treatment with VC improved overall survival and progression free survival compared to Dacarbazine. Severe adverse events were less frequent in the combined therapy. However, the differences in Vemurafenib curves increases the doubts about the accuracy of the indirect estimators of overall survival and progression free survival.
PD67 Strengthening And Accelerating HTAs Through Artificial Intelligence

PRESENTING AUTHOR:
Randy Goebel, Canada

ABSTRACT SUMMARY:
In using a novel approach to the usual methodology in HTA, the poster will outline the conceptual design of artificial intelligence in such a project.

INTRODUCTION:
Rising costs and rapidly increasing findings from research in healthcare are driving the demand for comprehensive information to inform the allocation of resources. Health Technology Assessments (HTA) apply rigorous processes to provide high quality synthesize information to policymakers and healthcare payers. HTA involves combining through large amounts of research publications to systematically evaluate the properties, effects, and impacts on a topic of interest.

METHODS:
The time and resources required to complete a full HTA are often demanding. There is an opportunity to apply high-performance computing (inclusive of Artificial Intelligence and machine learning disciplines) to HTA. This project applies high computing technology to create a research synthesis tool to support HTA and then develop a service that integrates as much relevant data as possible to strengthen HTA. This is a joint project that brings expertise in the areas of health technology, machine learning, information technology and innovation.

RESULTS:
In this phased project, we will present the gathered information from HTA subject matter experts and other stakeholders for a research synthesis tool. This will be presented on a broader concept of the project.

CONCLUSIONS:
This will inform the design of the research synthesis tool which covers the HTA process end to end (literature search, screening titles and abstract, data extraction, quality assessment, and analysis). The collaborators include Alberta Innovates, Alberta Machine Intelligence Institute (Amii), University of Alberta, Cybera, and PolicyWise. Alberta Innovates, who is an accelerator and innovator of research in the province of Alberta, Canada, is the primary source of funding for this project.

PD68 Using Clinical Data To Evaluate The Uptake Of New Anticoagulants

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ABSTRACT SUMMARY:
The utility of administrative claims for pharmacovigilance is limited by a lack health information. Analysis of clinical practice data offers a potential solution. Data from the MedicineInsight program were used along-side administrative claims to evaluate the uptake of direct-acting oral anticoagulants and their impact on warfarin use. This provided insight into medicines use not available from claims alone.

INTRODUCTION:
Understanding how new medicines affect
the use of established ones is important for pharmacovigilance. Administrative claims are typically used to evaluate the impact of new medicines, but their utility is limited by a lack of health information. Data triangulation with clinical practice records is a potential solution, but centralized sources of health information are rare. We demonstrate how MedicineInsight, a centralized repository of clinical information on over 4 million Australian patients from over 600 general practices, can be used in conjunction with claims data to provide insights into medicine use not possible using administrative claims alone. The effect of new direct-acting oral anticoagulants (DOACs) on warfarin use in Australia is given as an example.

METHODS:
Data on warfarin and DOACs were extracted from the MedicineInsight repository and two sources of administrative claims; one containing provider records and the other patient records. For each data source, claims or prescriptions were summed every month, producing a sequence of warfarin and DOAC use spanning seventeen (2000–2017) and eight years (2010–2017) respectively. Interrupted time series analysis was used to quantify DOAC uptake and its impact on warfarin use.

RESULTS:
Qualitatively similar patterns of DOAC uptake and warfarin use were observed in both the claims data and MedicineInsight’s clinical practice data. Following their introduction, prescriptions and claims for DOACS increased abruptly. A decrease in warfarin use followed, suggesting a large number of patients switching from warfarin to DOACs. MedicineInsight data indicated that >60% of patients were switched to DOACs for an indication related to atrial fibrillation and that males with fewer co-morbidities were the most likely to be switched.

CONCLUSIONS:
Repositories of clinical data such as MedicineInsight are an important pharmacovigilance tool, providing a richer understanding of the impact of new medicines than claims data alone.

PD69 The Impact Of Judicialization Of Soliris® On Brazilian Health System

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ABSTRACT SUMMARY:
The analysis of judicialization of Soliris® in the period 2010-2016 demonstrates the impact of judicial decisions on the public budget. It also shows that technical advice in Health Technology Assessment (HTA) for judges is an important tool to the Judges for decision-making that are clinically, economically and ethically safe in lawsuits filed to ensure medicines, especially high-cost ones.

INTRODUCTION:
Eculizumab (Soliris®) is a drug used to treat the atypical hemolytic-uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). From 2010-2016, several judicial decisions obliged the Brazilian Ministry of Health (MoH) to buy the drug. This had a severe impact on the public budget and demonstrated the need to disseminate knowledge about Health Technology Assessment (HTA) among judges. The objective of this work is to identify the profile of the plaintiffs in the lawsuits, which led to the acquisition of eculizumab during this time.

METHODS:
This is a cross-sectional descriptive study using
as input data the information available in MoH management reports.

RESULTS:
In the period under review, we identified 514 lawsuits, of which 376 (73 percent) in the Federal District, 46 (9 percent) in the State of São Paulo, and the remainder from several other Brazilian states. It was found that a single law firm filed 361 lawsuits, representing 70 percent of the total. In 27.13 percent of the cases, there was no doctor’s name. 32.4 percent of the prescriptions originated from private doctors and 31.2 percent from the Brazilian Public Health System (SUS). In 2016, the spending on Soliris® was BRL 624.6 million (i.e. USD 193.7 million) to serve 364 patients.

CONCLUSIONS:
For almost a decade, the strategy of selling the drug came through judicialization. Only in March 2017, it was registered in Brazilian regulatory agency, but its incorporation into SUS has not yet been requested to the National Committee for Health Technology Incorporation (CONITEC). The Judiciary does not perceive the distortions caused by such judicialization, despite the evident concentration of lawsuits by a law firm in a state. Thus, it is important that judges understand that technical advice on HTA is an important tool for guiding decision-making in lawsuits filed do ensure medicines, especially related to high-cost.

PD70 Cost-effectiveness Of Deep Brain Stimulation For Epilepsy In Australia

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ABSTRACT SUMMARY:
Deep brain stimulation (DBS), which uses an implantable device to modulate brain activity, is an adjunctive treatment for partial-onset seizures in patients with medically refractory epilepsy. We studied the cost-effectiveness of DBS compared to medical therapy alone in the Australian healthcare system, and found DBS to add meaningful QALY gains at a cost-effective lifetime ICER of $40,951 per QALY gained.

INTRODUCTION:
Deep brain stimulation (DBS), which uses an implantable device to modulate brain activity, is an adjunctive treatment for partial-onset seizures in patients with medically refractory epilepsy. Our objective was to perform and exploratory cost-utility analysis of DBS in conjunction with medical therapy compared to medical therapy alone, using latest clinical data and costs for the Australian healthcare system.

METHODS:
A deterministic five-state Markov model was used to project treatment response and outcomes over the patients’ lifetime, based on 5-year data from the recent SANTE DBS trial and drug outcome data identified through literature search. Costs were based on 2017 data for the Australian healthcare system, and response-specific utilities derived from published literature. We estimated the lifetime discounted incremental cost-effectiveness ratio (ICER) in Australian dollars per quality-adjusted life-year (QALY) for patients 36 years of age, 55% of whom were male. Costs and effects were discounted at 5% per annum. The robustness of projections was evaluated through scenario and sensitivity analyses.

RESULTS:
Under assumed continued treatment benefit, DBS was projected to add 3.48 QALYs over the patients’
lifetime, at increased cost of $142,304 ($244,408 vs. $142,304), resulting in an ICER of $40,951 per QALY gained. Reducing the analysis horizon to 20 years increased the ICER to $49,803. Increasing DBS generator life from 3 to 6 years decreased the ICER to $23,956 per QALY. Longer follow-up periods and younger treatment age were associated with greater cost-effectiveness. Results were sensitive to assumptions about health state-specific utility estimates and long-term treatment effect.

**CONCLUSIONS:**
Our exploratory findings suggest that DBS is a cost-effective treatment strategy for patients with medically refractory epilepsy in the Australian healthcare system. DBS therapy might meaningfully improve patient outcome at a health-economic profile that compares favorably to other well-accepted therapies. Consideration of indirect costs would further add to this value proposition.

**PD71 Evidence-Informed Decisions in Mental Health – A Broader Role For HTA?**

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**ABSTRACT SUMMARY:**
Timely access to reliable and relevant evidence to inform clinical and policy decisions in mental health care is crucial. The role of HTA in the identification and assessment of evidence on existing and emerging treatments and how HTA can be leveraged to increase mental health awareness and guide evidence-informed implementation activities will be discussed.

**INTRODUCTION:**
Research evidence on existing and emerging treatment approaches in mental health continues to evolve. Within a changing research landscape, timely access to reliable and relevant evidence to inform clinical and policy decisions in mental health care is crucial and HTA may be a tool which can help bridge this gap. This presentation will discuss i) the role of HTA in the identification and assessment of evidence on existing and emerging treatments for mental illness and ii) how evidence derived from HTA can be leveraged to increase awareness around mental health and engage a broad spectrum of relevant stakeholders in evidence-informed implementation activities.

**METHODS:**
As a Canadian HTA organization, we support healthcare decisions of jurisdictions across Canada through evidence synthesis and knowledge mobilization (KM). A cross-functional Mental Health and Addictions Working Group (WG) was established to identify, lead, and coordinate activities and initiatives related to mental health and addictions across Canada.

**RESULTS:**
This presentation will focus on how the WG i) reviewed internal HTA processes and products to identify gaps and opportunities for improving relevance, reach and implementation of evidence on mental health topics ii) engaged and partnered with external organizations in the mental health area to improve the uptake of relevant evidence and address the evidence needs of Canadian decision-makers and iii) contributed to internal HTA organizational culture for increased awareness around mental health and addiction.
CONCLUSIONS:
Examples of activities, impact and lessons learned through our focused yet flexible approach to KM and implementation of mental health HTA evidence will be discussed.

PD73 Identification Of Influencing Factors On The Distribution Of CT And MR

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ABSTRACT SUMMARY:
The comparison with the OECD countries on the distribution of CT and MRI was used to reveal the allocation status in China. Bivariate Pearson correlation analyses and fixed regression model help to identify the influencing factors on the distribution of CT and MRI.

INTRODUCTION:
Though the widespread use of Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) in China, few studies explore the influencing factors on their distribution. The study aims to fill the gap.

METHODS:
Five provinces with the whole 66 cities in China were selected as the sample sites. A questionnaire survey was conducted to collect data. To examine how the distribution of CT and MRI were associated with socio-demographic and health system factors, we conducted both bivariate Pearson Correlation Analyses, and fixed effects regression analyses, which were chosen based on Hausman test.

RESULTS:
Compared with the OECD countries, both the absolute number and the number of CT and MRI per million population in the study provinces were lower, but the growth rates were higher in 2005/2006—2013. Both socio-demographic (e.g., population and GDP) and health system factors (e.g., numbers of hospitals, health professionals, hospital beds, outpatient and inpatient visits) had significant, positive correlations with the number of CT and MRI. For the CT distribution, two of the variables (i.e., number of health professionals and number of inpatient visits) had the largest correlation coefficients (0.75 and 0.72 respectively). These two variables also had the largest correlation coefficients (0.72 and 0.71 respectively) for the MRI distribution. The regression results confirmed that these two variables had the largest impact on both the CT and MRI distribution.

CONCLUSIONS:
Despite a rapid growth in recent years, China still had fewer CT and MRI than OECD countries. The distribution of CT and MRI in China were significantly affected by health system factors, especially the number of health professionals and the number of inpatient visits.

PD74 Systematic Review Of Cost-effectiveness Of General Cervical Screening

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AUTHORS:
Ping Zhou, China
ABSTRACT SUMMARY:
Economic evaluations of general cervical cancer screening strategies was systematically searched between January 2006 to December 2016 in Cochrane Library, Medline, Embase, Web of science,CBM.

INTRODUCTION:
Compared with developed countries, there are more new cases and deaths that occur in developing countries every year. The high-cost of the vaccine has severely hindered its use and now screening is still the main way to reduce the burden of cervical cancer in developing countries. This study aims to assess the economic value and cost-effectiveness of general cervical screening strategies and provide reference for the implementation of cervical cancer screening strategies.

METHODS:
The literature about economic evaluations of general cervical cancer screening strategies including VIA/VILI,PAP smear, liquid-based cytology and HPV DNA testing with different screening frequency was systematically searched between January 2006 and December 2016 in Medline, Embase, Biosis, ISI Web of Science, Cochrane Library and CBM ,the quality of the literatures was evaluated, descriptive analysis was used to systematically evaluate the economy of screening strategy for cervical cancer.

RESULTS:
A total of 19 literatures were included into the study according to the inclusion criteria and exclusion criteria. There were 17 articles got a score of over 13 in literatures quality evaluation. Markov model was used to estimate the cost effectiveness in 13 of 17 articles. The main outcomes indicators these articles used the number of positive patients, the cumulative incidence/mortality of cervical cancer, and the life saving years.

CONCLUSIONS:
For middle and low-income countries and regions, VIA/VILI screening strategies would be the most cost effective choice, especially when can’t afford public health expenditure. HPV DNA screening strategies can be considered if the economic conditions permit.

PD75 Cost-effectiveness Of Cervical Cytology And HPV DNA Testing For Cervic

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
This study aims to evaluate the cost effectiveness of general screening strategies from government perspectives, to provide decision-making reference for the implementation of cervical cancer screening strategies.

INTRODUCTION:
This study aims to evaluate the cost effectiveness of general screening strategies from government perspectives and provide decision-making reference for the implementation of cervical cancer screening strategies.

METHODS:
A decision tree model was used to estimate the cost effectiveness of the various screening strategies. Decision tree models, operated by using data based on the literature review, expert interview and local investigation, are used to represent the sequence of chance events and decisions that occur during 5 years. We estimated the cost-effectiveness of three screening strategies (Pap smear every three years;TCT testing every three
years and HPV DNA testing every five years) for women above 30 years-old, and screening efficacy, coverage, cost, and screening regular review rate were varied in sensitivity analyses.

RESULTS:
Compared with no screening, the cost to exactly diagnose one histopathology positive case of Pap smear every three years, TCT testing every three years and HPV DNA testing every five years was 5.32 million yuan, 7.70 million yuan and 4.01 million yuan respectively. The CE ratios of these strategies to detect one positive cases was 2485 yuan, 8844 yuan and 1415 yuan and the average cost of a single screening was 36.35 yuan, 101.60 yuan and 154.70 yuan. Thus when considered from the accuracy and cost-effectiveness, HPV DNA testing every five years would be recommended at current price. According to the one-way sensitivity analysis, the cost of the screening test had a great effect on the cost-effectiveness results.

CONCLUSIONS:
This CEA indicates that HPV DNA testing could be a cost-effective screening alternative for large-scale organized screening.

PD76 The Value Of Continuous Lateral Rotation Therapy In The ICU

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ABSTRACT SUMMARY:
Our study estimates the value of Continuous Lateral Rotation Therapy (CLRT) beds compared to standard care in mechanically ventilated patients from a healthcare sector perspective and a societal perspective. We find that CLRT is highly cost-effective from both perspectives. Value of Information analysis further supports the results, and Return on Investment analysis shows a break-even point within 5 months.

INTRODUCTION:
Mechanical ventilation in the intensive care unit (ICU) increases the risk of hospital-acquired conditions (HACs) such as ventilator-associated pneumonia (VAP) and pressure injuries (PrI). Continuous lateral rotation therapy (CLRT) has been shown to reduce VAP and PrI incidence, but the value of switching to CLRT over standard care is presently unknown. We evaluate the cost-effectiveness of CLRT beds compared to standard care in ICUs and determine the return on investment (ROI) associated with its implementation.

METHODS:
A Markov model was constructed to predict health state transitions from the time of ventilation through 28 days using the healthcare sector perspective. Daily transition probabilities were extrapolated from prospective clinical studies comparing CLRT with standard care. Costs were estimated in 2014 USD. Utility scores were extracted from the published literature. Cost per quality-adjusted life-years (QALYs) was calculated and sensitivity analyses were conducted. A secondary analysis from a societal perspective with a one-year time horizon included the costs of patient and caregiver lost productivity. ROI analysis was performed to estimate the net benefit and break-even point of the investment. Value of Information analysis was performed to determine whether further research is warranted.
RESULTS:
From both perspectives, CLRT was dominant. From the healthcare sector perspective, the expected cost for CLRT per patient was $47,165 compared to standard care at $49,258 per patient, showing that CLRT saves cost per patient. The expected effectiveness of CLRT per patient was 0.0418 QALYs compared to 0.0416 QALYs for standard care. CLRT was dominant in 99.94% of Monte Carlo simulations. CLRT also reached the break-even point after 5 months. Expected Value of Perfect Information was equal to 0.019, indicating little value of additional evidence at the current level of parameter uncertainty.

CONCLUSIONS:
CLRT is highly cost-effective compared to standard care by preventing ventilator-associated infections and PrIs in an ICU setting.

PD77 Methodology To Assess A Predictive Test For Breast Cancer Recurrence

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ABSTRACT SUMMARY:
A clinical and economic assessment of Prosigna®, a 50 gene test for predicting breast cancer recurrence, was conducted for the purpose of applying for subsidy. Methodology using linked evidence for diagnostic tests was developed to assess a predictive test for the first time by our group. The methodology and clinical assessment outcomes are presented.
CONCLUSIONS:
Despite the absence of direct evidence, a modified linked evidence approach can be used to determine prognostic and predictive effectiveness of a test. The proportion of patients impacted by treatment recommendations, depends on prior management practices.

METHODS:
This technology was identified by the early Awareness and Alert System, “SINTESIS-new technologies” of AETS-ISCIII. An early assessment was conducted. The searched databases were: PubMed, CRD, and Cochrane Library. Clinical studies using the procedure published in any language until 29 September 2017 were reviewed.

RESULTS:
An open-label, randomized trial in paediatric cataract patients (age: 0–2 years) was retrieved. Twelve patients underwent minimally invasive capsulorhexis, while 25 patients received the standard treatment. Regarding efficacy, a transparent regenerated biconvex lens was found in 100% of eyes three months after surgery, but wasn’t found in the control group. 100% of capsular openings healed within one month after surgery in the experimental group, but not in the control group. Both groups increased their visual acuity parameters without significant differences. Regarding safety, children receiving the standard technique had a higher incidence of corneal oedema (8% in the intervention vs 30% in the control group), anterior chamber inflammation (17% vs 74%), additional laser capsulotomy (0% vs 84%) and increased visual axis opacification (4% vs 84%).

CONCLUSIONS:
The minimally invasive capsulorhexis in children’s cataract seems to be a promising new procedure. Preliminary efficacy results were good and safety profile was better than standard treatment. However, it would be necessary to continue further studies to confirm these results.

PD78 Minimally Invasive Capsulorhexis In Children’s Cataract

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ABSTRACT SUMMARY:
The objective of this work is to assess the efficacy and safety of minimally invasive capsulorhexis to promote lens regeneration in children’s cataract. An early assessment of this technology was conducted. The minimally invasive capsulorhexis seems to be an effective therapy with a good safety profile in children’s cataract.

INTRODUCTION:
The minimally invasive capsulorhexis is an incision in the anterior capsule in the peripheral zone for cataract extraction. It allows reducing the size of the lesion, ensuring a better transparency of the visual axis, preserving the capsule almost intact and a layer of lenticular epithelial cells. The procedure could have a potential regenerative effect of the lens in a natural way. The objective of this study is to assess the efficacy and safety of minimally invasive capsulorhexis to promote lens regeneration in children’s cataract.
PD79 Poor Design And Reporting Impacts The Value of Current Systematic Reviews

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ABSTRACT SUMMARY:
In this study, we evaluated the quality and transparency of reporting of systematic reviews on prostate artery embolisation, a topic of considerable interest in urology. We identified nine existing reviews, eight published within 12 months, all with significant quality concerns. It appears that despite recent efforts to reduce waste and increase the quality of systematic reviews, considerable limitations still exist.

INTRODUCTION:
Systematic reviews are useful for identifying gaps in research, setting priorities for future research, and informing clinical practice and public policy decisions. However, appropriate methods are needed to ensure that systematic reviews are of suitable quality in order to maximise their potential to achieve impact. The aim of this study was to evaluate the quality and transparency of systematic reviews conducted on prostate artery embolization (PAE), a topic of considerable interest in urology.

METHODS:
We conducted a cross-case analysis. Existing reviews were identified through a systematic search of four biomedical databases (Cochrane Library, York CRD, Embase, Medline) from inception up to 8 December 2016. Systematic reviews that evaluated the safety and effectiveness of PAE to treat benign prostatic hyperplasia were included. Included reviews were critically appraised using the AMSTAR tool, and were scored against the PRISMA criteria.

RESULTS:
From 536 search results, nine relevant systematic reviews were identified, of which eight were published in 2016. None of the included reviews were prospectively registered on PROSPERO. The median AMSTAR score was 4 of 11 (range 0-7). The most common methodological concerns were related to comprehensive searches (33%), inclusion of grey literature (0%), and evaluation of publication bias (0%). Reviews adequately reported a median of 17 of 21 items (range 6-19) against the PRISMA checklist.

CONCLUSIONS:
Despite the availability of robust guidelines for conducting systematic reviews, methodological limitations in reviews of PAE are prolific, leading to considerable heterogeneity. There is also a significant duplication of effort, which can be prevented by prospectively registering systematic reviews on PROSPERO. Reducing duplication and increasing methodological quality are imperative to reducing waste in urological research.

PD80 Implantation Of Multilayer Flow Modulator Stents: Systematic Review

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ABSTRACT SUMMARY:
Implantation of multilayer flow modulator stents
Implantation of multilayer flow modulator stents (MFMS) is a treatment for aortic aneurysms by reducing turbulence in the aneurysm sac causing sac thrombosed while maintaining side branch patency. The objective of this review is to pool the result of MFMS in terms of the safety and effectiveness.

METHODS:
Two reviewers independently selected the articles which reported MFMS when used in accordance to the instructions for use (IFU) to treat aneurysms using 8 Korean databases, MEDLINE, EMBASE, and Cochrane Library. Data was collected regarding the safety outcomes based on adverse events and for the effectiveness outcomes based on stability of aneurysm, technical success, survival, and re-interventions.

RESULTS:
Using strategic search, a total of 95 articles were searched and 15 articles were finally included in this review which met the inclusion criteria. Fifteen studies consisted of all single arm trials, which were 6 case series and 9 case reports including 110 patients. There were 4 deaths within 30 postoperative day and 3 procedure-related deaths in a total of 39 surgery or stent-related adverse events. Although postoperative aneurysm diameter and volume were inconsistently reported, aneurysm tended to be stable by making sac thrombosed. Technical success of deployment was achieved in all patients and the rate of side branch vessel patency was 96.6 ~ 100%. In addition, re-interventions were conducted in 17 patients mostly because of endoleaks.

CONCLUSIONS:
On the basis of current data, MFMS is a safe and effective treatment for aneurysm patients, especially high risk patients for open surgical repair when IFU was adhered. However, long-term data on its sustained effectiveness and comparative studies are needed.

PD81 General Practitioner Training Strategies Based On Systematic Review

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ABSTRACT SUMMARY:
Use systematic review method to describe the range of strategies for training General practitioners and how the authors have assessed these strategies. We found post-graduation education and on-the-job education are two effective strategies in the transitional period of the construction of general medical system under the current national conditions in China.

INTRODUCTION:
In the course of the reform of the existing medical and health service system in China, in order to meet the people’s growing demand for health
care and rehabilitation, it is urgent to strengthen the construction of community health service. And in order to meet the needs of community health service personnel construction, we need to develop general practice education to train general practitioners who are engaged in community health service work. So how to train a large number of qualified general practitioners for granted is the key issue. The objective of our study is to describe the range of strategies for training General practitioners and how the authors have assessed these strategies.

METHODS:
Search words were chosen by both health policy experts and search coordinators after discussion and pilot. What was searched included 4 electronic databases of China and other countries. Any study of implemented strategies to train General practitioners was included. Pre-designed data extraction form was used for collecting strategies and study methods of the included studies. Then the extracted information was analyzed and described.

RESULTS:
A total of 65 studies were included. In terms of the study objective, 50 studies aimed to describe strategies and 15 ones are to evaluate effectiveness of the strategies. All strategies could be categorized into 4 groups based on the general practitioner training system of China, school education, Post-Graduate Medical Education, on-the-job education and continuing education. Most of the studies evaluating effectiveness were retrospective analysis of longitude data.

CONCLUSIONS:
All of the four strategies have good effects on general practitioner training, especially post-graduation education and on-the-job education are two effective strategies in the transitional period of the construction of general medical system under the current national conditions in China.

PD82 E-Health Coverage: Lessons From A Remote Monitoring Assessment

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ABSTRACT SUMMARY:
Remote monitoring (RM) of implantable cardiac defibrillator (ICD) is a clinical approved practice but its deployment is still limited in France. We therefore conducted a health technology assessment to support its coverage. Focusing on individual, technical, clinical and organizational minimal requirements, we defined guidelines to transpose the benefits of RM, from trials to the French practice.

INTRODUCTION:
Remote monitoring (RM) of implantable cardiac defibrillator (ICD) is one of the e-health technologies that has demonstrated clinical benefits without any additional risk. However, ICD RM practice is still limited in France due to barriers ranging from organization constraints to the lack of medical fees. The French National Authority for Health (HAS) therefore planned an e-health technology assessment (e-HTA) to support its coverage.

METHODS:
We conducted a systematic review to select randomized controlled trials (RCT) assessing efficacy and safety of ICD RM compared to conventional follow-up. In these trials, we also mapped the RM process to analyze interactions between patients, RM systems, health professionals and care environment. Technical specifications of
RM systems were also collected from providers. Cardiologist representatives were asked about current clinical practices on ICD follow-up. E-health French legislation was also taken into account.

RESULTS:
The analyse of the 7 selected RCT confirmed the benefits of RM compared to conventional follow-up. Similar care pathways for patients were identified in the RM arms. Process specificities were considered minor and technical equivalence between RM marketed devices was confirmed. Nevertheless, in most of the studies, we noticed the lack of details on alerts management and tasks sharing between health professionals. On this basis, HAS defined guidelines in order to transpose the benefits of RM from these trials to the French practice. We recommended a total of thirty-six key points describing the minimal requirements for patients, technological providers, medical and RM centers.

CONCLUSIONS:
E-health technologies create new and faster interactions between patients, clinicians, care environments and information systems. In practice, their major potential in modernizing the health care system appears as new opportunities to explore. In this changing context, e-HTA should be conducted according to this global approach, to support the deployment of efficient solutions.

PD83 The Analysis Of Treatment Patterns & Cost In Acute Ischemic Stroke

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ABSTRACT SUMMARY:
The Analysis Of Treatment Patterns & Cost In Acute Ischemic Stroke Using 2015 National In-patient Sample Dataset of South Korea.

INTRODUCTION:
Acute ischemic stroke(AIS) is one of major cause of death and it is very important to treat patient timely for recovery to minimize disabled. Despite of its severity, there is no sufficient analysis of cost and treatment trends of AIS in Korea. This study aimed to show characters of AIS and compare the cost of approved therapy [recombinant tissue plasminogen activator(rt-PA), mechanical thrombectomy(MT)], also validate the revised reimbursement guideline using National In-patient Sample(NIS) dataset.

METHODS:
This study extracted Cerebral Infarction patient who were treated with as solutions of AIS treatment out from 2015 NIS dataset. General information of AIS was shown national-wide patterns by frequency-analysis in age, sex, treatment method. The average cost comparisons among therapies and were assessed.

RESULTS:
The total cases were 635 [547 single (313 rt-PA, 234 MT and 88 Dual)]. 66.3% of cases was over 65(58% of men, 78% of women). Length of stay (LOS) 13.60 days for single therapy (11.87 days for rt-PA, 15.91 days for MT) versus 15.99 days for dual therapy (rt-PA + MT). The cost per case averaged $7,196 for single therapy ($4,463 for rt-PA, $10,788 for MT) versus $10,476 for dual therapy.

CONCLUSIONS:
This study is the first to show treatment patterns of AIS from 2015 NIS dataset in Korea. Since the cost burden is similar for the rest of the patients except for the single treatment with rt-PA, this study supports that the revised guideline is suitable for AIS treatment because it allows additional devices when the first therapy fails. For value-based AIS treatment, a continuous multidisciplinary approach is needed.
PD84 Hostile Anatomic Neck Of AAA Patients And EndoAnchor Cost Analysis

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ABSTRACT SUMMARY:
Complications are significant higher in patients with hostile aortic neck for endovascular repair to treat Abdominal Aortic Aneurysm. EndoAnchors enables the patients with hostile neck to have endovascular repair by enhancing proximal fixation. This study is to figure out the population size for hostile neck in Korea and cost-effectiveness for EndoAnchor based on real-world data.

INTRODUCTION:
Failure at the proximal neck for EVAR (Endovascular Aortic Repair) in AAA (Abdominal Aortic Aneurysm) is more common in the presence of unfavorable proximal neck anatomy. In patients with hostile neck, EndoAnchors provide proximal fixation and reduces potential type I endoleak or endograft migration. However, the population size for AAA patients with hostile anatomic neck among Korean is unknown and cost-analysis with regard to EndoAnchors has not been established.

METHODS:
To figure out the population size of AAA patients with hostile neck anatomy, retrospective medical chart review was conducted from 4 major medical centers. Hostile proximal aortic neck was defined as any or all of neck length <10 mm, neck diameter >28 mm, infrarenal neck angulation >60°, > 50% of circumferential thrombus, > 50% of calcified neck, and conical neck. Cost-analysis on EndoAnchor use for treatment purpose was conducted based on Korean National Health Insurance Claims dataset (HIRA-NIS 2015).

RESULTS:
210 patients’ anatomic data treated with EVAR were included. 130/210 (61.9%) met the criteria for a hostile aortic neck and 32 (15.2%) patients had multiple hostile anatomy parameters. Endograft migration was reported in 4 (1.9%) patients and intra or post-op type I endoleak was reported in 21 (10.0%) patients. Based on 1-year claims data, 1,607 patients were treated with EVAR in 2015 and the annual average medical costs for open repair were USD16,151. Given the patients with type I endoleak or endograft migration needs open repair if not treated with EndoAnchors, the estimated annual costs for patients treated with EndoAnchor were USD 2,234,321 and those for patients without EndoAnchor were USD 2,595,508, therefore USD 361,187 can be saved annually.

CONCLUSIONS:
The population size with hostile aortic neck in Korea was comparable with those in western countries. Economically, EndoAnchor is a cost-saving treatment for type I endoleak and migration after EVAR from Korean payer.

PD85 Testing Search Filters To Retrieve Economic Evaluations In Embase

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ABSTRACT SUMMARY:
The objective was to identify the best performing search filters to retrieve health economic evaluations,
by comparing sensitivity, precision and specificity of the cost-effectiveness analysis (CEA) filter to six published filters in Ovid Embase. Compared to the CEA filter, the six published filters are still performing well. Researchers should agree on levels of performance before choosing search filter.

INTRODUCTION:
Health technology assessments (HTAs) are increasingly used by Norwegian health authorities as the evidence base when prioritizing which health care services to offer. HTAs typically consist of a systematic review of the effects and safety of two or more health care interventions, and an economic evaluation of the interventions, based on systematic literature searches in bibliographic databases. Objective: To identify the best performing of seven search filters to retrieve health economic evaluations used to inform health technology assessments (HTAs), by comparing the cost-effectiveness analysis (CEA) filter to six published filters in Ovid Embase, and achieve a sensitivity of at least 0.90 with a precision of 0.10, and specificity of at least 0.95.

METHODS:
In this filter validation study, the included filters’ performances were compared against a gold standard of economic evaluations published in 2008-2013 (n=2,248) from the National Health Service Economic Evaluation Database (NHS EED), and the corresponding records (n=2,198) in the current version of Ovid Embase.

RESULTS:
The CEA filter had a sensitivity of 0.899 and precision of 0.029. One filter had a sensitivity of 0.880 and a precision of 0.075, which was closest to the objective. The filter with lowest sensitivity (0.702) had a precision of 0.141.

CONCLUSIONS:
Developing search filters for identifying health economic evaluations, with a good balance between sensitivity and precision, is possible but challenging. Researchers should agree on acceptable levels of performance before concluding on which search filter to use.

PD86 Arthroplasty Register Of The Brazilian Orthopaedic Institute INTO

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ABSTRACT SUMMARY:
Registers may hinder evolution and progress by deterring the introduction of new surgical method and implants. This study of case described the development process of an institutional arthroplasty register. The study aims were to describe the development process of the Brasilian Instituto Nacional de Traumatologia e Ortopedia Arthroplasty Register INTO-AR and to rank the INTO-AR according to international.

INTRODUCTION:
Instituto Nacional de Traumatologia e Ortopedia (INTO) is a center of excellence in the treatment of diseases of the locomotor system and reference in the articulation of Brazilian public policies. The Institute is also a technical cooperation partner of the Comissão Nacional de Incorporação de Tecnologias (CONITEC). Thus, the INTO’s Health Technology Assessment Unit developed its institutional arthroplasty register INTO-AR, following international models and with aim to assess all technologies that are involved with this surgery. The study aims were to describe the development process of the INTO Arthroplasty Register INTO-AR and to rank the INTO-AR according to international level.
METHODS:
This study of case described the development process of an institutional arthroplasty register. A systematic review of studies that related some registers arthroplasty data were done to know the quality and the content of these data. We perform search at MEDLINE and Center Cochrane Collaboration databases, beyond sites, journals and gray literature about orthopaedic surgery. The specialists from the specialized care knee and hip institutional centers also participated of the development process to select the studies and to define the specific data would be collected by INTO-AR.

RESULTS:
INTO-AR presents electronic multidisciplinary forms to fill out by Institute professionals according to the patient assistance flow since the preoperative, operative and immediate postoperative period until the follow-up of the surgery. Orthopedic surgeons, nurses, physiotherapists and other professionals can collect patient data until a replacement. Implants data can also describe like size, brand, lot, manufacturer and others. It allows monitoring the prostheses. The INTO-AR can evaluating patient-reported outcome measures by patients questionnaires which included both generic, Short Form-6 Dimensions SF6D, and disease-specific, Ontario and McMaster Universities Osteoarthritis Index WOMAC, Knee Society Score KSS, Harris Hip Score, to patient assessment. The INTO-AR ranking was done by Rolfson’s feature levels and characteristics. We ranked it like between level II and level III because the costs are not included.

CONCLUSIONS:
INTO-AR has the potential to generate information for the assessment of technologies about arthroplasties, implants failure and surgical techniques, collaborating with the decision process. Registers provide crude monitoring and are not suitable for detailed analyses regarding clinical outcome, but they provide important information which can identify problem and are a basis for further in-depth analyses.
**Poster Presentations**

**PP01 Estimating Prostate Cancer-Specific Mortality From Databases**

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**ABSTRACT SUMMARY:**
Cancer-specific mortality is an important parameter for decision models. Using data from a population-based cancer registry in Ontario, we tested two classification algorithms to estimate prostate cancer (PC)-specific mortality: 1) calculate PC-specific mortality using ICD10 codes for PC mortality and 2) include also codes for ‘other cancers’. The cumulative incidence of PC-specific mortality was substantially different between the methods.

**INTRODUCTION:**
Cancer-specific mortality is an important parameter for decision models where its over-/underestimation can affect significantly the outcomes. This information is obtained most commonly from public reports. This study evaluates two classification algorithms to estimate prostate cancer (PC)-specific mortality in Ontario, Canada.

**METHODS:**
The cohort included all Ontario incident PC cases diagnosed in 2004-2013. Two classification algorithms to define PC-specific mortality were tested: 1) cause of death coded as C61 (ICD-10 code for PC), used in Canadian public reporting; and 2) C61 plus ICD-10 codes for any other cancer, used in the US public reporting. We used the cumulative incidence function to estimate the incidence of PC-specific mortality under competing risk framework.

**RESULTS:**
The study cohort included 90,815 PC patients. The mean (SD) age at diagnosis was 67.6 (9.6) years. The mean (SD) follow-up duration was 4.5 (2.8) years, and 15,167 patients (16.7%) died within 10 years. Among patients that died from ‘other cancers’, 22% had stage III-IV PC at diagnosis. Using Methods 1 and 2, 37.9% and 59.4% of deaths were considered PC-specific, respectively. The 6-year cumulative incidence of PC-specific mortality was 6.3% and 9.7% with Methods 1 and 2 respectively.

**CONCLUSIONS:**
Based on past reports, only 6-10% of patients with PC develop second primary tumors. Therefore, it is likely that in most cases the ‘other cancer’ diagnosis as a cause of death in death certificates is indicative of a metastatic disease. The effect of this type of misclassification can be significant. Future validation studies should derive more accurate algorithms.

**PP02 Cost-effectiveness Of Tamoxifen For Breast Cancer Treatment In Ghana**

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**ABSTRACT SUMMARY:**
Adjuvant treatment improves breast cancer survival. The study sought to evaluate the cost-effectiveness of Tamoxifen for the adjuvant treatment of breast cancer among pre-and-peri-menopausal women in Ghana using a Markov model. Data was from published literature and expert opinion. Tamoxifen was cost effective compared to no treatment at an incremental cost effectiveness ratio of GHC 666.15(USD 150) per QALY gained.
INTRODUCTION:
In recent years, unlike developing countries, developed countries has seen an increased in the survival of women diagnosed with breast cancer and this has been attributed to early detection through screening and best treatments such as adjuvant systemic therapies with medications like tamoxifen. The burden of breast cancer in Africa, including Ghana is among premenopausal women, with mean age of 46 years at diagnosis. However, survival among these women is low due to reasons such as inability to afford treatment including tamoxifen, an older but cheaper and effective adjuvant therapy. This study therefore sought to assess the cost effectiveness of tamoxifen compared to nothing for the adjuvant treatment of early breast cancer among pre-and-peri-menopausal women in Ghana to inform funding decisions.

METHODS:
A Markov model was developed using TreeAge pro to incorporate effectiveness, costs and utility data. Effectiveness of tamoxifen, rate of events and utility weights were derived from published literature. Resource utilization and costs were estimated from Ghanaian clinical expert, national health insurance scheme tariffs and medicines. The analysis was conducted from the perspective of the payer.

RESULTS:
Patients on tamoxifen incurred additional costs compared to those who received nothing. The key driver of costs was the cost of tamoxifen. However, these costs were offset by the QALY gained: 3.51. The incremental cost effectiveness ratio (ICER) was GHC 666.15 (USD 150) per QALY gained. In line with the effective measure commonly used in developing countries, the ICER per DALYs averted was GHC 219.96 (USD 50). The results were sensitive to variations in the utility weights and the cost of tamoxifen. There were no significant difference between the ICERs of premenopausal and peri-menopausal women in a subgroup analysis.

CONCLUSIONS:
Compared to no treatment, tamoxifen therapy is highly cost-effective for the adjuvant treatment of breast cancer among pre-and peri-menopausal women in Ghana. The results can be applied to other African countries with similar resource use and treatment protocols.

PP03 Evidence Synthesis In Spasticity In Children

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ABSTRACT SUMMARY:
The objective was to evaluate the relative efficacy and safety of different BoNT-A to manage spasticity in children, based on a systematic literature review and Bayesian network meta-analyses. Our analyses suggest that abobotulinumtoxinA offers a comparable or favourable efficacy on tone, spasticity, functional outcomes and tolerability versus onabotulinumtoxinA, in the management of children with lower limb spasticity.

INTRODUCTION:
Botulinum toxin type A (BoNT-A) is used in the management of lower limb spasticity in children, which affects more than 2.5 million of children worldwide. BoNT-A aims to improve active function and to prevent or delay future musculoskeletal complications. The objective was to evaluate the relative efficacy and safety of different BoNT-A to
manage spasticity in children, in the absence of head-to-head evidence.

**METHODS:**
A systematic literature review was conducted in March 2016 to identify all relevant randomised controlled trials. The evidence base was synthesized by means of Bayesian network meta-analyses. Scenario analyses included standardized mean differences (SMD). The endpoints were: Modified Ashworth Scale (MAS), Tardieu scale-spasticity grade and Goal Attainment Scale (GAS) [SMD only] at 12 weeks post-injection, and any adverse events.

**RESULTS:**
Thirty-eight studies were identified, 10 of which met the inclusion criteria for quantitative synthesis. For MAS, abobotulinumtoxinA 15U/kg/leg was significantly better compared to onabotulinumtoxinA 4U/kg/leg (-0.99 [-1.49; -0.50]), onabotulinumtoxinA 4U/kg/leg + casting (-0.81 [-1.30; -0.32]) and numerically (although not statistically significantly) better than onabotulinumtoxinA 8U/kg (-0.70 [-1.64; 0.22], Pbetter=93%). For GAS, abobotulinumtoxinA 15U/kg/leg was numerically better than onabotulinumtoxinA 12U/kg/leg. On Tardieu scale-spasticity grade, abobotulinumtoxinA was comparable to other treatments. AbobotulinumtoxinA 15U/kg/leg showed the highest SUCRA value on MAS and GAS. On tolerability, abobotulinumtoxinA was found to have comparable or fewer adverse events) than onabotulinumtoxinA 4U/kg/leg.

**CONCLUSIONS:**
Our analyses suggest that abobotulinumtoxinA offers a comparable or favourable efficacy on tone (measured by MAS), spasticity (Tardieu scale-spasticity grade), functional outcomes (GAS) and tolerability versus onabotulinumtoxinA, in the management of children with lower limb spasticity. The results must be interpreted in the context of the heterogeneity of the evidence base and sparse evidence base.

**PP04 Co-constructing Recommendations With Patients And Health Professionals**

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**ABSTRACT SUMMARY:**
We engaged both patients and health care professionals in a multi-method approach in order to advise on the structures and processes that facilitate informed and shared decision-making regarding implantable cardioverter defibrillator replacement. We show how literature review, a field evaluation and expert consultation enabled the co-construction of recommendations in partnership with patients and professionals.

**INTRODUCTION:**
Decision-making about replacement or modification of an implantable cardioverter defibrillator (ICD) must be patient-centered and clinically appropriate. We engaged both patients and health care professionals in a multi-method approach in order to recommend structures and processes that facilitate informed and shared decision-making.
METHODS:
A systematic literature review (2000 to 2016) was performed focusing on the patient’s perspective and the optimal organization of structures and processes for decision-making. A province-wide field evaluation based on medical chart review was carried out to provide ‘real world’ evidence in Québec’s six ICD implanting centers (1 July to 31 December, 2016; N=418). Patients and health care professionals reviewed the findings of the review and field evaluation and deliberated recommendations in an anonymous manner by electronic mail. A joint meeting focused on proposed recommendations concerning shared decision-making.

RESULTS:
The patients provided feedback on the literature review based on their ICD experience, and highlighted the need for better and more interactive decision aids, clinical information, and time and a private space for sensitive discussions. The field evaluation underlined the variability of treatment choices at the time of replacement and that more than 1 in 10 patients had undergone ICD deactivation. Proposed recommendations focus on multi-disciplinary, integrated follow-up of patients and outline best practice for incorporating patient wishes and life objectives when discussing treatment options. The multi-round consultation process allowed both patients and professionals to co-construct recommendations with our evaluation team.

CONCLUSIONS:
This multi-method approach enriched our interpretation of literature and ‘real world’ data and facilitated identification and prioritization of important themes. Partnership with both patients and clinicians added a new and energizing dynamic to our evaluation and recommendation processes. We acknowledge the contribution of the members of the Patient Committee and the Advisory Committee.

PP05 Developing Equity In Remote Locations Through Telediagnosis

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ABSTRACT SUMMARY:
This study has evaluated the results of a telemedicine system in remote public hospitals in Paraguay, in order to show how the response capacity of the local integrated health service delivery networks has been improved by providing access to tertiary level diagnostic services by specialists.

INTRODUCTION:
Clinical background: Populations living in remote areas did not have access to specialist care and quality diagnostic services and thus depended on the low response capacity of their local health system. There were subsequent equity issues between urban and rural populations. In this context the telediagnosis applications should be directed towards developing better equity in the provision of services in remote locations without access to specialists. This study has evaluated the results of a telemedicine system in remote public hospitals in Paraguay, in order to show how the response capacity of the local integrated health service delivery networks has been improved by providing access to tertiary level diagnostic services by specialists. Objective: this study aims to evaluate the utility of telemedicine as tool for developing better equity in the provision of services in remote locations.
METHODS:
Descriptive study, where the results using telemedicine for diagnosis in remote public hospitals were evaluated as tool to improve access to diagnostic services countrywide between 2014-17. For these purposes, type and frequency of pathology diagnosed was determined.

RESULTS:
A total of 311,562 telediagnoses were performed in 57 hospitals. The 191,435 ECG diagnosis performed in the 55 hospitals were mainly normal (62.1%), unspecified arrhythmias (12.5%), and sinus bradycardia (10.4%). 115,924 teletomography tests were performed in 12 hospitals, where 54.4% corresponded to head as a consequence of accidents (motorcycles) and cerebrovascular diseases, 13.8 % chest, and the rest the other anatomical regions. Regarding the 4,184 EEG tests performed, antececdents of seizure (54.3%), evolutionary controls (14.0%), and headache (11.5%), were mainly diagnosed. The 19 ultrasound studies corresponded to prenatal controls.

CONCLUSIONS:
Despite the results of the telediagnosis implemented in the public health to develop better equity in the provision of services in remote locations, a widespread use-assessment should be analyzed before this tool is adopted.

PP06 HER2 Evaluation By CISH And SISH In Breast Cancer: A Meta-analysis

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ABSTRACT SUMMARY:
This systematic review and meta-analysis summarizes the evidence and evaluates the sensitivity and specificity of two new techniques (CISH and SISH) used to identify breast cancer patients with HER2 overexpression in comparison to the reference standard, FISH. The results show equivalence between tests, and a potential benefit regarding sensitivity or specificity of CISH when examining studies enriched with equivocal samples.

INTRODUCTION:
Molecular techniques play a critical role in identifying breast cancer patients with overexpressed human epidermal growth factor receptor-2 (HER2). New bright field techniques such as chromogenic in-situ hybridization (CISH) and silver in-situ hybridization (SISH) have emerged to overcome some of the challenges associated with the reference standard, fluorescence in-situ hybridization (FISH). We conducted a literature review and synthesis to characterize the accuracy of HER2 tests, and inform decisions about test selection.

METHODS:
We searched MEDLINE and EMBASE databases using these eligibility criteria: studies evaluating invasive breast cancer samples which examined agreement between CISH or SISH, and FISH, and reported sensitivity, specificity, or concordance. We performed a bivariate meta-analysis of sensitivity and specificity using a generalized linear mixed model in Stata. We used likelihood ratio tests from meta-regression to compare accuracy between HER2 tests.

RESULTS:
The search identified 4,475 articles, of which 31 were included. A total of 13 studies (43%) evaluated dual-colour SISH, 12 single-colour CISH, and 6 dual-colour CISH. The summary estimates for sensitivity and specificity were, respectively, 0.97 (95%CI 0.83-0.99) and 0.99 (95%CI 0.96-1.00) for single-colour CISH, 0.98 (95%CI 0.92-0.99) and
0.98 (95% CI 0.91-0.99) for dual-colour CISH; 0.92 (95% CI 0.86-0.95), and 0.96 (95% CI 0.91-0.98) for SISH. Significantly higher specificity was reported for single-colour CISH than SISH (chi-square 4.12; p=0.04), while dual-CISH had higher sensitivity than SISH (chi-square: 4.63; p=0.03). These differences were not maintained when studies with cohorts enriched with equivocal samples were excluded.

CONCLUSIONS:
The agreement between new bright field tests (SISH and CISH) and FISH is high (>92%). Indirect comparison of HER2 tests indicate that overall CISH performance exceeds that of SISH. However, low agreement between SISH and FISH in equivocal cases affects these comparative estimates. The pooled estimates from this meta-analysis can help inform future HER2 test selection decisions.

INTRODUCTION:
Microfracture (MF) has been the main intervention in symptomatic articular cartilage knee defects. Autologous chondrocyte implantation (ACI) has looked promising, but was not recommended by the UK National Institute for Health and Care Excellence (NICE) in 2015 due to the short-term follow-up data from trials.

METHODS:
Most long-term data comes from observational studies. We provided new unpublished analyses to NICE based on survival data of these studies, with appropriate caveats. They included: a large ACI study by Nawaz with useful subgroup data by osteoarthritis Kellgren-Lawrence stage and previous repair attempts; a very large MF study by Layton, and a small RCT by Knutsen indicating MF was as ‘good’ as ACI. A Markov model explored the cost-effectiveness of ACI vs. MF. Different scenarios were explored: ACI or MF as a first procedure, followed by ACI or MF in those needing a second repair. A NHS England perspective was adopted. Health outcomes were expressed as quality-adjusted life-years (QALYs).

RESULTS:
The revised base-case analysis, used a list price of £16,000 for cells, used ACI failure data from Nawaz with no previous procedures for ACI, and pooled MF failure data from two studies - Saris and Knutsen. ACI was more expensive but provided more QALYs. The incremental cost-effectiveness ratio comparing ACI then MF with MF then ACI was £8,000 per QALY. Various sensitivity analyses were conducted assuming a threshold of £20,000 per QALY; previous repair attempts reduced success of ACI (£22,000 per QALY); reducing cell costs, ACI improved its cost-effectiveness; and limiting intervention to patients with higher Kellgren-Lawrence score did not appear cost-effectiveness.

CONCLUSIONS:
The final NICE guidance published in October 2017 approved the use of ACI for patients who had no

PP08 Health Technology Assessment Of Autologous Chondrocyte Implantation

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ABSTRACT SUMMARY:
Autologous chondrocyte implantation (ACI) has looked promising, but was not recommended by the UK National Institute for Health and Care Excellence (NICE) in 2015 due to the short-term follow-up data from trials. We provide new unpublished analyses to NICE based on survival data of some long-term observational studies to determine the cost-effectiveness of ACI compared with microfracture (current practice).
previous knee repairs, for people with minimal osteoarthritic damage to the knee, and for people with articular defects of over 2cm².

**PP11 Would A HST Be Approved in England Under The New NICE Guidance?**

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**ABSTRACT SUMMARY:**
In 2017, NICE updated its guidance for HST appraisals, introducing an ICER threshold of £100,000 per QALY, and a ‘QALY modifier’ weighting QALYs gained by the size of gain. This research found that it may become more difficult for HSTs to get recommended by NICE under the new guidance, even with the QALY modifier.

**INTRODUCTION:**
In April 2017, the National Institute for Health and Care Excellence (NICE) updated its guidance for highly specialised technology (HST) appraisals, whereby it would automatically fund technologies for very rare diseases that fall below a threshold of an incremental cost-effectiveness ratio (ICER) of £100,000 per quality-adjusted life year (QALY). In addition, NICE proposed to introduce a ‘QALY modifier’, weighting QALYs gained by the size of gain, which will advantage treatments that offer greater QALY gains.

**METHODS:**
We reviewed all technologies reviewed through the NICE HST process until November 2017 and assessed whether additional QALYs may be awarded, and subsequently result in ICERs below the new NICE threshold.

**RESULTS:**
Six products (eculizumab, elosulfase alfa, ataluren, migalastat, eliglustat, and asfotase alfa) have been through HST process. Within the appraisal documents, most analyses were cost consequence analyses with no ICERs reported. The estimated cost per patient per year ranged from approximately £100,000 to £400,000 (listed prices). Of the six technologies, three resulted in at least ten incremental QALYs (eculizumab, elosulfase alfa and asfotase alfa). From the information in the public domain, it is unclear whether this would result in ICERs below £100,000 per QALY.

**CONCLUSIONS:**
It may become more difficult for HSTs to get recommended by NICE under the new guidance, which requires cost-effectiveness analyses, whereas previously there was no official ICER threshold. The additional weighting of QALYs may be insufficient to meet an ICER threshold of £100,000 per QALY.

**PP12 Selection Of Non-Drug Medical Technologies For Evaluation In Singapore**

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**ABSTRACT SUMMARY:**
The demand for health technology assessment (HTA) generally far exceeds the resources available to
INTRODUCTION:
The demand for health technology assessment (HTA) generally far exceeds the resources available to perform HTA, thus topic selection processes are often applied to prioritise topics for technical evaluation. This study outlines the process followed by the Agency for Care Effectiveness (ACE) to select non-drug medical technology topics for HTA in Singapore to inform subsidy decisions in the public healthcare system.

METHODS:
An annual call for topics for subsidy consideration from public healthcare institutions was held in 2017. After filtering out topics which did not fall within ACE’s remit for HTA, a checklist was completed for each topic to consider the clinical need, clinical benefits, organisational feasibility, and international subsidy status of the proposed technology. A need score was then generated, with higher scores indicating higher clinical need. The annual budget impact to the government to subsidise the technology was also considered. Technologies with a high need score and high budget impact were proposed for evaluation, and presented to a clinical decision-making committee to agree on final topics for evaluation.

RESULTS:
A total of forty-six applications were received. After filtering, thirty-eight topics remained, of which eighteen were proposed for evaluation in view of their high annual costs and high need scores. After the Committee’s deliberation, one topic was further excluded as HTA was unlikely to have a material effect on the technology’s subsidy decision. The remaining seventeen topics will inform ACE’s non-drug medical technology HTA work plan in 2018.

CONCLUSIONS:
A topic selection process to prioritise non-drug medical technologies for evaluation to inform subsidy deliberations has been developed in Singapore. This process is important to better direct limited resources to evaluate health technologies that truly need HTA to assist policy decision-making. The process will be modified overtime to make it more fit-for-purpose as stakeholder needs change.

PP13 Australia’s Commitment To Making Consumer Friendly HTA Summaries

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ABSTRACT SUMMARY:
The Australian Government has implemented an initiative to support consumer understanding of health technology assessments by developing consumer friendly public summary documents of assessments. Ensuring consumers information needs are met, particularly around explaining decisions to fund or not fund services, is important as it promotes disclosure and transparency in the Australian health assessment and funding process.

INTRODUCTION:
The Australian Government relies on a rigorous health technology assessment (HTA) process to inform its decisions to fund health-related goods and services through Medicare, the Australian Government’s universal health care program. The independent Medical Services Advisory Committee (MSAC) is responsible for advising the Government about what medical services should be funded on Medicare. MSAC provides summaries of its recommendations through ‘public summary documents’ published on the MSAC website (www.m sac.gov.au). These documents outline MSAC’s
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HTA of a medical service. Feedback has indicated that the documents are difficult to understand for consumers, who often have very little knowledge of HTA processes. The Australian Government has implemented an initiative to support consumer understanding of MSAC’s assessments by developing consumer friendly public summary documents (CFPSDs).

METHODS:
The Department of Health has worked closely with the Australian Government’s Health Consumer Consultative Committee to refine what information should be included in a CFPSD. CFPSDs summarise the outcomes from MSAC’s HTA in plain language. They also include additional useful guidance for consumers about the post-MSAC process and what this means for consumers, particularly when a service has not been supported for Medicare funding by MSAC. Options for alternative funded treatments are outlined where possible and pathways to reassess the evidence are simply explained.

RESULTS:
50 percent of MSAC PSDs are being adapted into CFPSDs and these are expected to be published in early 2018. The process has been commended by consumers and it is possible that the initiative could be expanded over time.

CONCLUSIONS:
Australia is committed to involving and assisting consumers in understanding the MSAC assessment process. The CFPSDs have demonstrated that HTA summaries can be produced for a consumer audience.

PP14 Development Of The EUnetHTA Standards Tool For Registers In HTA

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ABSTRACT SUMMARY:
A post-launch evidence generation tool is being developed including a quality standards tool for Registers in HTA. The first draft version of the tool structure, which is going to be piloted during the forthcoming months, is presented. There is a clear growing availability and requirement for RWD for HTA. A robust tool can provide a relevant basis for excellent evaluations.

INTRODUCTION:
Bridging gaps between registry-holders, HTA-producers and users is one of the EUnetHTA Joint Action 3 aims. In this context, a post-launch evidence generation tool is being developed including a quality standards tool for Registers in HTA. The Standards tool for registers in HTA will enable, among others, register owners to consistently collect high quality register data, and HTA agencies, accordingly, to use proper register data collected by others as evidence for their assessments. The objective is to present the first draft version of the tool structure, which is going to be piloted during the forthcoming months.

METHODS:
A review and description of the currently available
first version (November 2017) sections, items and criteria for HTA studies.

RESULTS:
The tool is divided in three sections; "Methodological information", "Essential Standards" and "Additional Requirements". The first section enables users to analyse not only the ability of the registry to answer to research questions but also to check the registry transparency. The second section encloses the essential elements of good practice and evidence quality (therefore all of them must be met for getting an HTA use). Finally, the third section includes elements of good practice and evidence quality useful to consider in planning and evaluating registries for specific purposes. Although suggestions are defined, the third section item requirements could depend on the individual HTA agency perspectives and needs.

CONCLUSIONS:
There is a clear growing availability and requirement for real world data for health technology assessment. A piloted and robust registries standards tool for HTA can provide a relevant basis to improve both the evidence generation but also to make more trustful and excellent evaluations.

ABSTRACT SUMMARY:
Employing principles and methods from well-established sociotechnical fields such as participatory design may help HTA teams in the production of formal, rigorous ‘practice-based evidence’. Drawing on a literature review and experiences using participatory design for a large scale health IT project, we present an overview of how participatory design approaches may inform the production of qualitative evidence in HTA.

INTRODUCTION:
To address local workability, cross-setting variation, and clinician and patient perspectives, HTA practitioners and health system decision-makers incorporate varying forms of qualitative evidence into evaluations of novel health technologies. Employing principles and methods from long-established sociotechnical fields such as participatory design (PD) may help HTA teams in the production of formal, rigorous ‘practice-based evidence’.

METHODS:
We draw on a theoretical review of foundational PD literature and experiences using PD for a large-scale health information technology project to summarize principles and strategies for the effective introduction and evaluation of new technologies in healthcare.

RESULTS:
HTA may benefit from observing some of the core commitments of PD: (a) Ensuring that technologies enhance rather than detract from the quality of working life; (b) Fostering democratic engagement in the implementation and evaluation of technologies; and (c) Proceeding via direct partnership with technology users. These are practical commitments stemming from the recognition that technology implementation entails re-configuring existing practices and social arrangements. The experts of this existing milieu are the people on the ground, who may reject or underutilize technologies that they perceive as
impractical, ill-adapted to their needs, or having negative consequences on their work. At the same time, PD recognizes that local activities occur within larger systems and that effective technology introduction also requires attention to macro-politics (e.g. governance challenges, competing priorities). PD employs a diversity of methods (e.g. ethnography, focus groups, workshops, interviews) to develop evidence that is holistically informed.

CONCLUSIONS:
Many of the challenges that HTA faces, both in terms of evidence production and translation, have been encountered before in PD. Given that decision-making around health technologies necessarily involves consideration of many forms of qualitative evidence, there is value in producing and evaluating such evidence in carefully designed manner – a challenge to which fields like PD can lend a wealth of experience.

PP16 Turning Tide On Antibiotic Use With Consumers And Health Professionals

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ABSTRACT SUMMARY:
NPS MedicineWise implemented a series of nation-wide educational interventions for consumers, general practitioners (GPs) and community pharmacies to reduce antibiotic use in Australian primary care. Surveys have demonstrated improvements in consumer and GP knowledge and time series analysis has shown reduced antibiotic prescribing at a national level.

INTRODUCTION:
Many countries have a national antimicrobial resistance strategy. In Australia, primary care is especially important because this setting encompasses a high proportion of antibiotic use. While antibiotic use reduced during the 1990s, it began to increase again in the mid-2000s. In response, in 2009, NPS MedicineWise implemented a series of nation-wide educational interventions for consumers, general practitioners (GPs) and community pharmacies aiming to reduce excessive antibiotic use.

METHODS:
For consumers, a social marketing approach was used including strategies that leveraged collectivism, nudge theory, celebrity endorsement and co-creation. Channels included social, print, radio and other media, as well as practice waiting rooms and pharmacies. For health professionals, interventions included face-to-face education, audits, comparative prescribing feedback, case studies and point-of-care materials. Consumer and GP surveys were conducted periodically to evaluate changes in knowledge and behaviour. National Pharmaceutical Benefits Scheme claims data were analysed using a Bayesian structural time series model to estimate the cumulative effect of interventions comparing observed and expected monthly dispensing volumes had interventions not occurred.

RESULTS:
The consumer survey results indicated more people are aware of antibiotic resistance (seventy-four percent in 2017 versus seventy percent in 2014), the minority requesting/expecting antibiotics for upper respiratory tract infections (URTIs) (twenty-two percent in 2017). Although, people underestimate the usual symptomatic duration for URTIs and are more inclined to expect antibiotics beyond
that timeframe. Compared with non-participants, GPs who participated in the program reported more frequent discussions about hand hygiene (ninety versus eighty-two percent) and proper use of antibiotics with patients (ninety-five versus eighty-eight percent). Between 2009 and 2015, for antibiotics commonly prescribed for URTIs, there was an estimated fourteen percent reduction in prescriptions dispensed for concessional patients.

CONCLUSIONS:
GPs and consumers have responded positively to national programs. Sustaining and building on the improvements will require continued education and further innovation.

PP17 Comprehensive Evaluation Of A Technology With Expanding Indications

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ABSTRACT SUMMARY:
We have implemented a comprehensive approach to inform decision-makers on optimal use of a disruptive transcatheter technology with expanding indications. Evidence from a field evaluation (2013-2017) were combined with literature review results to establish provincial standards for practice, in collaboration with an expert committee. We continue to evaluate patient characteristics, processes of care and outcomes in relation to the standards.

INTRODUCTION:
The use of transcatheter aortic valve implantation (TAVI) is evolving. Our cardiovascular evaluation unit is implementing a comprehensive approach to inform decision-makers on optimal use of TAVI, including the development of quality standards. We are implementing a multifaceted evaluation framework in collaboration with clinical stakeholders.

METHODS:
Our unit has carried out a continuous field evaluation in collaboration with the clinical teams at all 6 TAVI centers in Québec for the past 4 years (1 April 2013 – 31 March 2017), with regular feedback to the teams and sharing of results with each individual center. Hospital documentation was reviewed according to established national quality indicator definitions. Field evaluation data were combined with the results of systematic literature review to establish provincial standards for practice, through a deliberation process by an interdisciplinary committee of clinical experts from each center. Systematic surveillance of the literature is ongoing.

RESULTS:
In the period 2013-2017, use of TAVI in Québec was limited to very elderly patients with significant comorbidities at high risk of operative mortality. We observed improvements in both processes of care (e.g. documentation of risk scores) and clinical outcomes (e.g. 30-day and 1-year mortality) over time. Our consensus standards recognize the potential value of TAVI for patients at moderate operative risk, identify uncertainties and recommend best practices for patient evaluation and clinical decision-making about choice of treatment.

CONCLUSIONS:
A comprehensive, long-term evaluation process
of TAVI with feedback to centers is associated with improvements in processes of care and outcomes. In the present context of expanding clinical indications, we will continue to evaluate patient selection, processes and outcomes according to the newly-established provincial quality standards. This iterative approach facilitates continued evidence generation and decision-making for optimal use of an evolving intervention. We acknowledge the contribution of the members of the Advisory Committee.

PP18 An Access Evidence IT Solution Within A Pharmaceutical Company

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ABSTRACT SUMMARY:
Roche developed an innovative Access Evidence IT Solution to increase collaboration and effective access evidence knowledge management and sharing within the company as well as enable sharing of access evidence with external stakeholders. The platform internally called #TAg was rolled out October 2017. Uptake has so far been positive.

INTRODUCTION:
During 2014 Roche tested whether the EUnetHTA HTA Core Model® was a useful, exhaustive and relevant value framework to promote efficiencies in scoping, storing and sharing HTA evidence within a pharmaceutical company. The conclusion was positive and Roche decided to build a cloud based IT platform to store all relevant HTA evidence to support global and regional market access activities, tagged with metadata according to the HTA Core Model®. To develop an innovative, user-friendly platform that promotes efficiencies and knowledge sharing across the organization. Eventually this platform may also be used by external stakeholders to access relevant HTA evidence.

METHODS:
In order to better equip global functions, regions and affiliates in a major pharmaceutical company with user-friendly and fast access to product-relevant HTA and payer evidence as well as access evidence plans, an easy-to-use IT-based platform was needed. The platform, internally called #TAg, is a central repository of information to support market access activities and promote collaboration between Affiliate, Region and Global teams. The platform uses metadata to label all types of evidence and uses the HTA Core Model® domains to categorize the evidence.

RESULTS:
The platform #TAg was developed throughout 2016/2017 and officially launched on 1 October 2017. Within the first 30 days the platform has been readily accepted by affiliates, regions and global functions through significant use uptake as measured by user registration and download activities. In addition #TAg was used successfully in a pilot project for a submission to an external HTA body.

CONCLUSIONS:
A complete knowledge management system for HTA evidence is important for driving efficiency in scoping, storing and disseminating access evidence information within a pharmaceutical company. #TAg has so far proved a good start on such a system with further development expected in the coming years.
PP19 Opioid Poisoning Deaths: A National Picture

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ABSTRACT SUMMARY:
Opioid poisoning deaths are at record levels. Using anonymised routine linked data we sought to find out if people who die of opioid poisoning use medical emergency services prior to death. Eighty-seven percent of opioid poisoning decedents (n = 112/129) attended the emergency department in the three years prior to death, with over half attending more than three times.

INTRODUCTION:
The factors associated with opioid poisoning death are poorly understood. We performed a retrospective autopsy study of decedents of opioid poisoning in Wales in 2015. Using anonymised linked data, we describe demographic characteristics, patterns of emergency service utilisation, and clinical presentation prior to death.

METHODS:
Decedents of opioid poisoning in Wales in 2015 were identified from the Office of National Statistics (ONS) mortality dataset. Records were linked with the Emergency Department Dataset (EDDS) by the National Welsh Informatics Service (NWIS); and held in the Secure Anonymised Information Linkage (SAIL) databank. The data were accessed and analysed in the SAIL gateway.

RESULTS:
Age at death ranged from eighteen to seventy-eight years, with a mean age of forty-two years. Average male age was forty-one years and average female age was forty-four and a half years. Seventy-six percent of decedents were men (n = 98/129). Eight-seven percent of decedents (n = 112/129) attended the emergency department in the three years prior to death; eighty-nine in the previous year, ninety-nine in the previous two years and 112 in the previous three years. Eighty-four percent of male and ninety-three percent of female decedents attended the ED in the three years prior to death. In total 665 attendances were made, half of which involved conveyance by ambulance. Attendances per individual ranged from one to sixty, with over half of decedents attending more than three times. Diagnostic codes were mostly missing or non-specific, with only six and a half percent of attendances representing twenty-seven decedents, coded as drug related.

CONCLUSIONS:
Matching previously published data, we found that fatal opioid poisoning is preceded by a period of high emergency health service utilisation. On average decedents were in their fifth decade and more likely to be male than female. Attendances varied widely, with men less likely to attend than women.

PP20 Assessment Of The First Software Combined With Telemonitoring Support

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ABSTRACT SUMMARY:
The French National Authority for Health assessed the first software combined with telemonitoring support. This assessment highlighted some specificities but showed that randomised clinical trials are feasible to demonstrate the clinical benefit for this medical device. To help manufacturers to build their application dossier for reimbursement, a specific guide to connected medical devices has been developed by HAS.

INTRODUCTION:
More and more software programs, including those with medical device status, aiming to facilitate management of diabetic patients, are coming in the market. In France, their coverage requires a positive opinion from the French National Health Agency (HAS) dedicated committee. To understand the utility of these products for patients, real-life experiments are in progress. Since the evaluation principles are similar for all medical devices, it was important to find out with this first connected software if specific methods or evaluation criteria are necessary.

METHODS:
After obtaining CE marking, the manufacturer submitted his dossier argued on clinical data and technical performance to HAS. HAS assessed the dossier submitted by the manufacturer and the opinion of stakeholders (professionals and patient associations) in order to determine the actual clinical benefit of this software. At the same time, HAS set technical features in particular to secure patient data and limit access to only those involved in telemonitoring. Terms of prescription and use of this connected software had also been defined.

RESULTS:
Two feasibility studies and one randomized controlled trial were analyzed. Specific clinical data demonstrated that the risk-benefit balance was positive in type 1 diabetic patients.

CONCLUSIONS:
In addition to the need to keep personal data confidential and to integrate the technology in the organization of healthcare, this assessment shows that randomised clinical trials are feasible and necessary to demonstrate the clinical benefit of connected software. However, specificities exist; in particular, linked to data collection methods and to the scope in terms of healthcare organization that should be taken into account. A specific guide to connected medical devices for industry has been developed by HAS to help them build their application dossier for reimbursement. The second step for HAS is to develop guidelines on the specificities of the assessment of these connected devices.

PP21 Reassessment Of Cochlear Implantation For Children In Kazakhstan

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ABSTRACT SUMMARY:
This presentation covers developments in the provision of cochlear implantation services for children in Kazakhstan following an HTA report prepared for the Ministry of Health. There were improvements in availability of screening services and a standard protocol, and a decrease in the age for implantation. Progress in rehabilitation post-implantation has been more limited.

INTRODUCTION:
Cochlear implantation (CI) is a standard technology for the management of children with sensorineural hearing loss. In the Republic of Kazakhstan (RK),
CI was introduced in 2007. In 2012, a report for the Ministry of Health (MoH) of the RK, considered the effectiveness of CI, age of implantation, use of clinical protocols, and availability of audiological screening and rehabilitation services. We assessed the influence of the report findings on the provision of medical care in the RK for children with sensorineural hearing loss.

**METHODS:**

Information was collected in a survey of all RK health regions on issues related to CI, audiological screening and rehabilitation. Administrative data relevant to provision of CI in the RK were obtained from the MoH. Data obtained were compared with those available for preparation of the 2012 report.

**RESULTS:**

The proportion of medical organizations with equipment to provide audiological screening had improved, from 29 percent in 2012 to 90 percent in 2018. The proportion of children under two receiving CI increased from 12 percent to 36 percent, while that for children over five years decreased from 48 percent to 17 percent. A clinical protocol for CI in children was developed by a center in the MoH. Progress with post-CI rehabilitation of children was limited by a lack of specialists in the health regions. The proportion of school-age children with implants who have attended general schools remains low.

**CONCLUSIONS:**

The findings of the HTA report had a positive influence on availability of screening services and a protocol for CI. The average age of children receiving an implant has decreased, though it is still higher than in other countries. The need for improvements in post-CI rehabilitation and placement of children with implants in general schools is recognised but these await further resources.

**PP22 How Do Health System Leaders Use Evidence To Inform Action?**

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**ABSTRACT SUMMARY:**

This presentation will share results from a series of interviews with executives from a variety of US health care delivery systems. The executives described how they obtain evidence and use it in decision-making. With this information, we can make HTA reports more relevant and actionable for end-users.

**INTRODUCTION:**

The US Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) program sponsors the development of systematic reviews to inform clinical policy and practice. The EPC program sought to better understand how health systems identify and use this evidence.

**METHODS:**

Representatives from 11 EPCs, the EPC Scientific Resource Center, and AHRQ developed a semi-structured interview script to query a diverse group
of 9 Key Informants (KIs) involved in health system quality, safety and process improvement about how they identify and use evidence. Interviews were transcribed and qualitatively summarized into key themes.

RESULTS:
All KIs reported that their organizations have either centralized quality, safety, and process improvement functions within their system or have partnerships with other organizations to conduct this work. There was variation in how evidence was identified, with larger health systems having medical librarians and central bureaus to gather and disseminate information and smaller systems having local chief medical officers or individual clinicians do this work. KIs generally prefer guidelines, especially those with treatment algorithms, because they are actionable. They like systematic reviews because they efficiently condense study results and reconcile conflicting data. They prefer information from systematic reviews to be presented as short digestible summaries with the full report available on demand. KIs preferred systematic reviews from reputable entities and those without commercial bias. Some of the challenges KIs reported include how to resolve conflicting evidence, the generalizability of evidence to local needs, determining whether the evidence is up-to-date, and the length of time required to generate reviews. The topics of greatest interest included predictive analytics, high-value care, advance care planning, and care coordination. To increase awareness of AHRQ EPC reviews, KIs suggest alerting people at multiple levels in a health-system when new evidence reports are available and making reports easier to find in common search engines.

CONCLUSIONS:
Systematic reviews are valued by health system leaders. To be most useful they should be easy to locate and available in different formats targeted to the needs of different audiences.

PP23 Evolution Of National Drug Evaluation Processes In Singapore

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ABSTRACT SUMMARY:
The Agency for Care Effectiveness (ACE) was established in August 2015 as the national health technology assessment agency in Singapore. Since its establishment, ACE has developed technical evaluation processes and decision-making frameworks to support drug subsidy deliberations for public healthcare institutions. This presentation will summarise the evolution of drug evaluation during ACE’s first two years, and its anticipated future direction.

INTRODUCTION:
The Agency for Care Effectiveness (ACE) was established in August 2015 as the national health technology assessment (HTA) agency in Singapore to guide health policy, drive appropriate use of treatments and inform subsidy decisions. Since its establishment, ACE has developed technical evaluation processes and decision-making frameworks to support drug subsidy deliberations for public healthcare institutions. This presentation will summarise the evolution of drug evaluation during ACE’s first two years, and the anticipated future direction as the remit of the agency expands.

METHODS:
Core processes and methods for drug evaluation, including topic selection and systematic assessment of clinical and economic evidence, were developed by drawing upon methodologies from overseas HTA agencies with contextualisation
to the local setting. Processes were also established to increase stakeholder engagement during drug evaluations, encourage transparency and consistency of decision-making, and enhance the credibility and quality of the resulting HTA products. Value-based pricing processes were implemented in parallel to improve cost-effectiveness and inform appropriate prices for drugs under evaluation.

RESULTS:
From January 2016 to August 2017, ACE completed 26 evaluations of 38 drugs, leading to positive subsidy recommendations for 22 drugs. Guidance documents for 14 of these topics were published on ACE’s website to promote transparency of decision-making and guide appropriate prescribing behaviours. Increased stakeholder involvement throughout the evaluation process was pivotal in improving the real-world applicability of ACE’s assessments.

CONCLUSIONS:
Efforts will be made to further evolve ACE’s methods and processes to meet demand as awareness and understanding of HTA increases in the local clinical community. This will ensure ACE’s work remains relevant and in line with international HTA developments, while addressing the needs of all local stakeholders.

ABSTRACT SUMMARY:
This was a retrospective cohort study for the identification and valuation of resources using a microcosting methodology in real world data for a sample of 81 patients selected from a Brazilian’s teaching hospital’s ischemic heart disease clinic. The perspective of this study was that of the health service provider.

INTRODUCTION:
In Brazil, cardiovascular disease accounted for 28% of deaths in 2013 with an estimated prevalence of 5 to 8% in adults over 40 years of age. Health care costs have quadrupled in the last decade, reaching US $125 billion in 2013, of which 44% paid by the public system. The objective of this study was to estimate the direct costs associated with the inpatient stay for myocardial infarction in a public teaching hospital from the perspective of the service provider.

METHODS:
We used a bottom up microcosting methodology for collecting data from computerized hospital records and patients’ hospital bills. The costs included salaries of health professionals, medications, consumables, laboratory and diagnostic tests performed during hospitalization and maintenance expenses. Mean, standard-deviation, median and total costs were calculated. The costs were presented as mean and median values in Brazilian currency and converted to US dollars by the exchange rate.

RESULTS:
A total of 81 patients were included in this study. The mean population age was 60 ± 10.6 years, the follow-up period were 107 ± 2.6 months; 54% were male, 84% had hypertension, 36% had diabetes, and 12% had previous cerebrovascular accident. During follow-up, there were 101 hospitalizations for myocardial infarction, of which 57 with intensive care unit (ICU) days. The total cost with hospitalizations was US $ 177,288, of which 52% were the health professionals costs. The average
cost for hospitalization was US $ 1,755 (median US $1,221). However, the average reimbursement paid by the public system was US $ 1,188 (median US $1,044) per hospitalization, generating a deficit of 32% for the hospital.

CONCLUSIONS:
These results may indicate the necessity of reviewing the public reimbursement policies for the service providers in Brazil. Besides that, these data may also serve as input for the economic evaluation in coronary artery disease.

PP26 Facial Palsy therapy: Can Novel ‘Smart Spectacles’ Help People Smile?

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ABSTRACT SUMMARY:
One third of people diagnosed with acute onset facial paralysis (facial palsy) end up with permanent disabilities; these can include an inability to smile. Guidelines recommend tailored facial exercises (TFEs); but not many patients can access this specialist therapy. ‘Smart spectacles’ (linked to a smartphone) could deliver TFEs to more people. A national study is reported on this new technology.

INTRODUCTION:
In the United Kingdom (UK), 23,000 people annually are diagnosed with facial palsy (acute onset facial paralysis). For nearly one third this will result in a permanent disability, including in some the inability to smile. In addition to initial pharmacological therapy, guidelines recommend tailored facial exercise (TFE) therapy repeated every day. However, not all patients are currently able to access such specialist physical therapy. ‘Smart specs’ (using miniaturised sensors in the frames to measure facial movement) are currently being developed. Linked to a smartphone, these could allow people to practice TFEs discreetly, provide immediate feedback, and supply data on outcomes to the patient and their clinician.

METHODS:
Modelling of introduction of Facial Remote Activity Monitoring Eyewear (FRAME) into treatment pathways for patients with facial palsy. This included: (i) review on effectiveness of TFE therapy; (ii) national surveys (medical staff, facial therapy specialists and patients) to gather data on access to TFE therapy; (iii) Delphi Exercise to identify consensus on key outcome measures; (iv) economic modelling to estimate cost-effectiveness and determine a range of acceptable costs for the technology. In parallel, research to examine target markets to inform product development, and production of integral commercialisation plan.

RESULTS:
Searches short-listed ten studies to add to the three included in 2011 Cochrane review. Surveys indicate approximately 13% eligible UK patients access personalised TFE therapy. Estimated annual expenditure on hospital treatments for facial palsy patients is currently >£80 million compared with <£0.5 million on TFE therapy. Patients with permanent defects can suffer a loss of up to two quality-adjusted life years (QALYs).

CONCLUSIONS:
Findings from this study, particularly in relation to costs and benefits, will inform the design of a subsequent RCT. A novel wearable technology
could make a major difference to people’s lives, as well as generating potential efficiencies for healthcare.

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**PP27 A Prototype Patient Advocate Decision Aid For Oncology HTA**

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**ABSTRACT SUMMARY:**
Patient advocates have a critical role in HTA processes but often lack time and resources to survey the complex field of relevant interventions. We present a prototype tool providing structured information on published efficacy, safety, and quality-of-life results within several oncology indications. Patient representatives can use this resource to evaluate evidence while taking into account known heterogeneity and patient preferences.

**INTRODUCTION:**
Patient advocates need to process vast amounts of information to accurately and effectively represent heterogeneous patient groups and make meaningful contributions to HTA decisions. Although a wealth of data is available from a variety of sources, it is not often curated in user-friendly ways. Patient representatives have frequently requested tailored resources that allow them to mine the existing literature in preparation for their engagements. Developing such resources constitutes a complex challenge that requires contributions and scrutiny from multiple stakeholders.

**METHODS:**
We previously developed the Continuous Innovation Indicators™ (CII), an evidence-based tool to assess treatments for 12 solid tumors (freely available at www.scoringprogress.com). The foundation of the CII is a rigorous assessment of published evidence for increased overall survival. Based on feedback from patient advocates, we are expanding the framework to include information on adverse events and other patient-centered outcomes for selected prototype indications.

**RESULTS:**
We present a novel, flexible framework that combines evidence of efficacy with published results on other outcomes that matter to patients. Menus and outputs are designed to facilitate dialogue between advocates, clinicians, and HTA professionals. By allowing the user to adjust settings based on known heterogeneity among subpopulations, the tool’s output can be used to inform discussions about the value of new interventions for defined patient segments.

**CONCLUSIONS:**
Patient representatives must frequently identify knowledge gaps in the literature before their HTA engagements and leverage this information to conduct surveys among their constituents. Our new patient advocate decision aid can support this process and facilitate a better understanding of the value of new innovations for diverse subgroups. A better definition of target populations will help to achieve balance between patient access and budget impact of new treatments. We seek feedback on our prototype from all stakeholders to further improve and maximize utility of this tool.
PP28 Overview Of Reviews In HTA- Opportunities And Challenges In Supporting

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ABSTRACT SUMMARY:
HTA often considers both clinical and economic evidence, with clinical findings incorporated as model parameters in cost-effectiveness analyses. With proliferation of systematic reviews (SRs), a case can be made to consider overview of SRs. Limited guidance exists on how to incorporate such evidence into economic evaluations. Although this represents an opportunity towards greater efficiency, challenges exist.

INTRODUCTION:
SRs are often conducted to inform clinical parameters as they are highest on the evidence hierarchy. However, with growth in SRs publication, overview of SRs have grown increasingly common. Recent experiences in incorporating clinical parameters from overviews into cost-effectiveness analysis are described through two case studies: interventions for obstructive sleep apnea; and diagnostic strategies for pulmonary embolism.

METHODS:
An overview of SRs was used to inform model parameters in the economic evaluations. Issues and challenges in adopting this approach were considered.

RESULTS:
When considering appropriateness of clinical inputs, trade-offs exist among fitness-for-purpose, credibility and consistency. This was particularly pertinent when multiple studies exist as was observed for the OSA treatment model in which both a unstratified network meta-analysis and stratified conventional meta-analysis could inform model parameterization. In such circumstances, exploration of different parameters through scenario analyses permit an assessment of the impact of methodological variations between SRs. The definition of parameter distributions is necessary to support probabilistic analyses and may be particularly challenging with correlated parameters (e.g., sensitivity and specificity for diagnostics tests). Correlations are rarely reported in pooled clinical estimates and additional re-analyses at the individual study-level may be required.

CONCLUSIONS:
In selecting clinical parameters from published SRs for cost-effectiveness analysis, the data must be fit-for-purpose in addressing the decision-problem. When multiple SRs exist, the selected clinical parameter value for the reference case should be credible and consistent, with appropriate scenario analysis conducted on estimates from alternative sources. Overviews of SRs may not always provide all the necessary data parameters and re-analyses may be required.

PP29 Evaluating Supplementary Search Methods: Outcomes To Measure. And Why

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ABSTRACT SUMMARY:
In a recently published review of supplementary search methods, we proposed that researchers could usefully record time taken to search and present outcome values in similar way to existing studies, to facilitate generalisability of outcomes, where appropriate. We also discuss the idea of linking literature search effectiveness to study value.

INTRODUCTION:
In a recently published review of supplementary search methods, we proposed that researchers could usefully record time taken to search and present outcome values in similar way to existing studies, to facilitate generalisability of outcomes, where appropriate. We also discuss the idea of linking literature search effectiveness to study value. In this vignette, we discuss which outcomes we believe are important to measure and why. We discuss this in the context of the review of supplementary search methods and using a recently submitted evaluation of contacting study authors for context.

METHODS:
In a recently completed systematic review, we contacted 82 study authors to ask three questions. We aimed to measure the following outcomes when contacting study authors: -Effectiveness: determined as number of contacts compared to number of replies; -Efficiency: i) time to make contact and ii) time between contact and reply. We determined this in hours, minutes and seconds, in line with other studies; -Cost: determined by comparing the efficiency of contacting authors with the effectiveness; and -Value: determined by reading and comparing the published studies with the replies received to see if any unique data was identified.

RESULTS:
-Effectiveness: 38 answers were received from 82 possible contacts; -Efficiency: In total, author contact took 6 hours, 54 minutes and 25 seconds across 39 weeks. Replies were received across 0-39 days (median 14 days). -Cost: Cost for staff time was £80.33 or £2.11 per e-mail reply received. -Value: We were able to identify value in author replies for each of the questions asked.

CONCLUSIONS:
In a recently published review of supplementary search methods, and a linked evaluation of the effectiveness of contacting study authors, we suggest outcomes that should be measured to determine effectiveness of literature search methods. We conclude that measuring these outcomes demonstrate both effectiveness and value.

PP30 The Effectiveness And Safety Of TAs And SR For Small HCC

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ABSTRACT SUMMARY:
This network meta-analysis based on Bayesian framework was used to compare the effectiveness and safety among radiofrequency ablation (RFA), microwave ablation (MWA), high intensity focused ultrasound (HIFU) and surgical resection (SR) for the patients with small hepatocellular carcinoma (HCC) and to support clinical decisions on appropriate therapies for the patients.

INTRODUCTION:
There has been long debates on whether thermal ablation (TA) can achieve the same effect as surgical resection (SR) and which kinds of TAs is better in treatment of small Hepatocellular Carcinomas (HCCs). Our study aim was to compare
the effectiveness and safety among radiofrequency ablation (RFA), microwave ablation (MWA), high intensity focused ultrasound (HIFU) and SR for the patients with small hepatocellular carcinoma and to support clinical decisions on appropriate therapies for the patients.

METHODS:
Eligible references, from January of 2010 to December of 2016, were searched and selected from Embase (Ovid SP), Pubmed and The Cochrane Central Register of Controlled Trials (The Cochrane Library) according to criteria. Network Meta-analyses based on Bayesian-framework were used to compare 1-year, 3-year and 5-year overall survival (OS) rates and incidence rate of major postoperative complications among TAs and SR for the patients with small HCCs. The function of BayesDiagnos was applied to estimate diagnostics and fitting detection for Bayesian models.

RESULTS:
There were 4 randomized controlled trials (RCTs) and 34 non-randomized controlled trials (NRCTs) with 8778 patients included in the study. Network Meta-analyses showed that there were no significant differences among SR, RFA, MWA and HIFU in 1-year OS rate for the patients with HCC≤5.0 cm, but SR had significantly higher 3-year OS rate (OR =1.19) and 5-year OS rate (OR =1.66), compared to RFA. The analyses also showed that there were no significant differences among SR, RFA, MWA and HIFU in 1-year OS rate and 3-year OS rate, and among SR, RFA and MWA in 5-year OS rate for the patients with HCC≤3.0 cm. The SUCRA value demonstrated that SR ranked the first (SUCRA5cm=75.6%; SUCRA3cm=73.2%) and RFA ranked the second (SUCRA5cm=70.3%; SUCRA3cm=66.5%) in 5-year OS rate. Furthermore, HIFU ranked the first (SUCRA5cm=2.6%; SUCRA3cm=18.5%) and RFA ranked the second (SUCRA5cm=34.1%; SUCRA3cm=27.7%) in safety.

CONCLUSIONS:
RFA can be used as an alternative treatment for small HCC not suitable for SR and as an alternative therapy for HCC≤3.0 cm other than SR. But our study should be interpreted carefully because of some study limitations, such as less RCTs and no long-term outcome.

PP31 What Does It Mean To Assess The Impact Of PPe In HTA?

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ABSTRACT SUMMARY:
Patients and public engagement (PPE) brings legitimacy to health technology assessments (HTA) and their contributions help make more meaningful health decisions. Many HTA agencies have formalized their processes in this area. However, measuring impact is complex and while efforts have started, progress has been slow. We explore the concepts of PPE impact and impact evaluation in the context of HTA.

INTRODUCTION:
The practice of engaging patients and the public (PPE) has spread worldwide, with many health technology assessment (HTA) agencies formalizing their processes in this area. PPE in HTA bring legitimacy and their contributions help make more meaningful health decisions. Since finite and valuable resources are dedicated to this work along with other competing priorities, understanding and assessing the impact of engaging patients and the
public is important. However, measuring impact is complex and while efforts are beginning to gain traction, progress has been slow. We explore and clarify the concepts of PPE impact and impact evaluation in the context of HTA.

METHODS:
Using qualitative concept analysis, we reviewed the scientific literature and national HTA agency documents for references to impact and impact evaluation related to PPE in HTA and related fields. Textual excerpts providing clarification on the terms impact or impact evaluation were extracted from these documents. We organized and integrated our findings using adapting “the best fit framework” approach. Our findings draw on literature from evaluation and other disciplines to complement our understanding of how PPE impact has been interpreted and operationalized in HTA.

RESULTS:
The evidence to date provides limited guidance on the conceptual underpinnings of impact and even less on what impact evaluation of PPE in HTA might look like. We offer preliminary conceptualizations for these terms, drawing on a range of disciplines. Meanings were constructed around concepts related to both the value of engagement as well as from engagement in the context of HTA. Recurrent and potential terms linked to impact and impact evaluation are presented.

CONCLUSIONS:
Gaps in understanding and conceptual fuzziness have hindered efforts to assess the impact of PPE in HTA to date. We believe this empirical investigation and clarification of key concepts will move the field of impact and PPE in HTA forward.

PP33 Systematic Review Of Cost-effectiveness Studies Of Melanoma Treatments

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ABSTRACT SUMMARY:
This systematic review identifies published cost-effectiveness studies for treatments for metastatic melanoma (MM). Fourteen studies were identified, the majority funded by pharmaceutical industry. There is considerable variation in the modelling approaches and assumptions. None were considered transferable to the Irish setting. Construction of a de novo cost-utility evaluation in the Irish setting will commence in 2018.

INTRODUCTION:
Many new treatments for metastatic melanoma (MM) have been authorised in recent years, but their relative efficacy and cost-effectiveness is unknown in many jurisdictions. As part of a scoping review for a health technology assessment of treatments for MM in Ireland, a systematic review (SR) of published cost-effectiveness studies (CES) of treatments for MM was undertaken.

METHODS:
MEDLINE, EMBASE, EconLit and the Cochrane databases were searched using a search strategy including recommended filters for economic evaluations. Reference checking of included studies was conducted and abstracts from 2013-2016 from ISPOR, ESMO and ASCO were hand searched. Reporting was assessed using the CHEERS checklist. Quality was assessed using the Philips checklist. Transferability to the Irish setting was examined using the EUnetHTA Transferability Tool economic evaluation domain.
RESULTS:
The SR is reported in accordance with the PRISMA guidelines. The search was conducted on 9th August 2017 and identified 583 records. Abstracts (n=33) and full CES (n=14) were included in the final qualitative synthesis. The majority of full CES were cost-utility analyses (n=12) funded by pharmaceutical manufacturers (n=8) with either a Markov (n=6) or partitioned survival (n=5) approach taken. There was marked variation in model structure (time horizon, cycle length, health states defined), approach to evidence synthesis and survival extrapolation. Only one study adopted a systematic approach to the identification of parameter inputs. None of the models were considered transferable to the Irish setting, mainly because of inappropriate comparators, preferences and modelling of health care resource use and costs.

CONCLUSIONS:
The reporting of CES is inadequate in many instances and thus assessing quality and transferability is challenging. None of the identified CES were compliant with the Irish reference case and therefore were not considered transferable to the Irish setting. Construction of a de novo cost-utility evaluation in the Irish setting will commence in 2018.

ABSTRACT SUMMARY:
We performed an economic evaluation of a randomized trial comparing the use of implantable loop recorder to empiric pacemaker insertion in the management of older adults (age>50 years) with bifascicular block and syncope over two years, from the perspective of a Canadian publicly funded health care system.

INTRODUCTION:
For patients with bifascicular block and syncope of unknown origin, different American Heart Association guidelines give Class 2A recommendations for two management: the implantable loop recorder (ILR) and empiric pacemaker insertion (PM). Equipoise reflected in guidelines may contribute to uncertainty in management and inefficient resource use. The objective of this analysis is to determine cost-effectiveness of the ILR compared to PM in the management of older adults (age>50 years) with bifascicular block and syncope over two years, from the perspective of a Canadian publicly funded health care system, in the Syncope: Pacing or Recording In The Later Years (SPRITELY) trial.

METHODS:
Resource utilization data was collected throughout the trial, and unit costs were assigned (2017 Canadian dollars). Utility was measured at baseline and annually with the EQ-5D-3L. Quality adjusted life years (QALYs) were calculated as area-under-the-curve, and adjusted for baseline imbalances in utility. Confidence intervals for the incremental cost effectiveness ratio were generated with non-parametric bootstrapping.

PP34 A Cost-utility Analysis Of The Syncope: Pacing Or Recording Trial

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RESULTS:
Mean cost in participants randomized to PM was $9,759, compared to $13,453 in participants randomized to ILR. The ILR strategy resulted in 0.020 QALYs more than the PM strategy. The incremental cost effectiveness ratio was $186,553 (95% CI: -831,950 - 1,191,816) per additional QALY. In 1000 bootstrapped replicates, the cost of the ILR strategy was always greater than that of the PM strategy. At the threshold of $50,000 per additional QALY, the probability that the ILR strategy is the cost-effective option is 0.504.

CONCLUSIONS:
ILR costs were greater than PM costs, with little difference in QALY outcomes over two-years. Findings are generalizable to patients similar to SPRITELY participants, from the perspective of the Canadian health care system. However, practice pattern variation and payment systems inhibit generalizability to other countries. Future analysis will explore cost and QALY outcomes in countries that participated in the SPRITELY trial.

INTRODUCTION:
The National Oral Health Policy (NOHP) – “Smiling Brazil” was launched in 2004, with the goal of reorienting the model of oral health care in the Unified Health System. Up to then, this area was impaired by limited access and curative procedures. The NOHP aims to reorganize Primary Health Care in Oral Health, expand and qualify Specialized Care and add fluoride in the public water supply. This review will bring a reflective view of NOHP evaluation.

METHODS:
This review work searched for evidence on the Bireme and Google Academic bases, with the keywords “Evaluation” and “National Oral Health Policy” in October 2017. The search was limited to full texts in Portuguese, English and Spanish. After reading the titles, the abstracts and finally the complete texts, the articles that did not correspond the evaluation objective of the NOHP were excluded.

RESULTS:
Of the 381 initial articles found, 15 were selected as subjects of this study. The majority reported advances in the quality and scope of oral health care with expanded access and provision of services, such as preventive actions, health education, fluoridation of the public water supply and an increase in population coverage. There was also an improvement in the main indicators, in resolution, financial investments and epidemiological surveys. Moreover, few studies showed improvement in user satisfaction. Conversely, difficulties were pointed out in overcoming the traditional care model, in training and professional appreciation. Challenges included the need to expand access to fluoridated water, increase coverage, build a more comprehensive care network and reduce regional disparities.

CONCLUSIONS:
After 13 years, advances and challenges in the quality and comprehensiveness of oral health care provided.
observed in the quality and comprehensiveness of oral health care in Brazil. There is evident improvement in indicators, however there remains a lack of access and resolution in the actions, with a large number of regional discrepancies.

PP36 Early Diagnosis And Treatment Of Psoriatic Arthritis

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ABSTRACT SUMMARY:
This study estimates the cost-effectiveness of screening tools for psoriatic arthritis in Canada. It evaluates the economic and clinical repercussions of implementing a screening program that is focused on identifying early disease. This study compares, through mathematical simulation, the Canadian current practice versus this hypothetical preventive program.

INTRODUCTION:
Screening of Psoriatic Arthritis (PsA) is expected to identify patients at earlier stages of the disease. Early treatment is expected to slow disease progression and delay biologic therapy. This study estimates the cost-effectiveness of screening tools for PsA in Canada.

METHODS:
A Markov model was built to estimate the associated costs and Quality-Adjusted Life-Years (QALYs) of screening tools for PsA for patients with psoriasis using topical treatment. Screening tools included were the Toronto Psoriatic Arthritis Screening Questionnaire (ToPAS), the Psoriasis Epidemiology Screening tool (PEST), the Psoriatic Arthritis Screening and evaluation (PASE), and the Early Psoriatic Arthritis Screening Questionnaire (EARP). Health states were defined by disability levels as measured by the Health Assessment Questionnaire (HAQ), and state transition was modelled according to annual disease progression. Screening was assumed to be effective during a 2-year sojourn period. Incremental cost-effectiveness ratios (ICERs) were estimated based on health-state-specific costs and utilities. A probabilistic analysis was undertaken to account for parameter uncertainty. All results were compared to the commonly cited cost-effectiveness threshold of $50,000 per additional QALY.

RESULTS:
Screening with ToPAS represents cost savings compared to 'no screening' and EARP, with a total cost of $30,706 and 17.291 QALYs. PEST extendedly dominates PASE and is more costly and more effective than ToPAS with an ICER of $312,398. Results are most sensitive to test sensitivity and specificity, HAQ progression, and average HAQ score at diagnosis and start of biologic therapy. A scenario analysis tested screening efficacy for a 1-year period before diagnosis. ToPAS remains the cost-effective alternative.

CONCLUSIONS:
Screening is cost-effective compared to no screening at the commonly used cost-effectiveness threshold of $50,000. Value of information analyses will be useful to determine the need to collect further information around test accuracy parameters.
**PP37 Economic Evaluations Assessing Lyme Disease Burden: A Scoping Review**

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**ABSTRACT SUMMARY:**
This review characterized the body of literature on economic evaluations assessing the healthcare costs of Lyme disease (LD), and the cost-effectiveness of LD interventions. Our review highlighted the heterogeneity in LD economic evaluations, and the need for future research on attributable LD healthcare costs associated with long-term sequelae and cost-effectiveness of emerging interventions to provide evidence supporting policy decision-making.

**INTRODUCTION:**
Lyme disease (LD) is an increasingly common vector-borne disease in North America. While mostly treatable, misdiagnosed or untreated LD can result in debilitating long-term sequelae and excessive healthcare usage. The objective of this review was to characterize the body of literature on economic evaluations assessing the economic burden of LD and the cost-effectiveness of LD intervention strategies.

**METHODS:**
We followed Joanna Briggs Institute scoping review methodologies. We systematically searched terms related to LD, economic evaluations, costs, and cost-effectiveness in bibliographic databases (MEDLINE, EMBASE, PsycINFO, and Cochrane Library) and grey literature using the Canadian Agency for Drugs and Technologies in Health (CADTH)’s Grey Literature Tool, up to October 2017. Primary economic evaluations reporting LD costs or cost-effectiveness of human interventions were included. Studies from Canada, the United States (US) and Europe were included.

**RESULTS:**
We screened 555 non-duplicated titles and abstracts; and included 18 economic evaluations (10 costing studies; 8 cost-effectiveness analyses (CEA)). Costing studies were conducted from the US (n=5) and Europe (n=5), while CEAs were conducted from the US (n=7) and Canada (n=1). Most CEAs were conducted prior to 2003 (88 percent), likely related to the lack of novel interventions. CEAs from healthcare payer (63 percent) and societal (25 percent) perspectives compared vaccination/no vaccination strategies (37 percent) and antibiotic treatment strategies (63 percent). Meanwhile, the number of costing studies have increased since 2003. Costing studies from healthcare payer (10 percent) and societal (60 percent) perspectives included diagnostic testing costs (30 percent) or overall healthcare costs (70 percent). There was zero costing studies assessing the attributable costs of LD from a healthcare payer perspective.

**CONCLUSIONS:**
Our review highlights the heterogeneity of economic evaluations in LD. Future research on attributable LD healthcare burden from long-term sequelae and cost-effectiveness of emerging interventions will strengthen our understanding of LD.

**PP38 Jurisdictional Pre-submission Advice: Effect On Submission And Outcome**

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ABSTRACT SUMMARY:
Local jurisdictional HTA scientific advice is an important component for companies seeking reimbursement. Pre-submission advice from five jurisdictions across 12 companies have been evaluated. Pre-submission advice taken at the jurisdiction level influenced the submission companies make to agencies, but products which underwent pre-submission advice seemed more likely to have restrictions then for those that did not seek advice.

INTRODUCTION:
Early scientific advice in regard to HTA is an important component in the development of new medicines and is actively being encouraged. But of equal importance is the pre-submission advice companies can take at the local jurisdiction level. This study has evaluated the type of advice and impact on time taken and outcome of the HTA decision.

METHODS:
Information was collected from 12 companies on products which had an HTA decision in the following jurisdictions Canada, Australia, Germany, France and England between 2008 -2017. The number of products per jurisdiction were 40, 41, 42, 46 and 34 respectively. Companies provided information on, if and where local jurisdictional scientific advice was taken as well as providing information on timing for each of the relevant HTA decisions and the influence of the advice on the submission and impact on the final label recommendation.

RESULTS:
Pre-submission advice taken at the jurisdictional level varied from 78 percent of the products assessed in Australia to 37 percent of those assessed by France. The timing of the advice was usually as the product was being reviewed by the regulatory agency with the exception of England, were it was taken from key opinion leaders and focused on payer information. The advice provided influenced the submissions made for over 70 percent of the products, with the exception of France where it was only for 55 percent. Products that took pre-submission advice showed a lower proportion receiving reimbursement as per regulatory label in all jurisdictions, except Canada.

CONCLUSIONS:
Pre-submission advice taken at the jurisdiction level is important as it influences the submission companies make to agencies, but the outcome for products which underwent pre-submission advice seemed more likely to have restrictions then those that did not. This maybe because companies are more likely to seek advice for products where the reimbursement outcome may not be certain.

PP39 Health Technology Assessment And Aging: Moving Evidence To Action

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ABSTRACT SUMMARY:
HTA of aging-related technologies presents particular challenges and opportunities to which countries are exploring diverse responses. We
report on our previous HTAi 2016 and 2017 panel sessions, to highlight international examples of evidence to action for health and aging innovation and explore questions and make recommendations relevant to how HTA can best meet the needs of an aging population.

INTRODUCTION:
With the rapid increase in technologies and innovations to support a growing aging population in many countries, HTA of aging-related technologies warrant special consideration. Building on our efforts at HTAi 2016 and 2017, this presentation will highlight themes generated from two previous HTAi international collaborations with an aim of continuing to build interest and capacity in HTA for aging-related technologies in an international ecosystem responsive to local needs and global opportunities.

METHODS:
Researchers from the Canadian research network in technology and aging (AGE-WELL) collaborated with international panelists at HTAi 2016 and HTAi 2017 to explore interests in HTA focused on aging. International panelists shared the current state of aging and HTA in their respective countries. At both sessions, opportunities were provided for participants to rate the importance of themes identified by the panelists.

RESULTS:
At the 2016 session, the two most highly ranked themes were: i) identifying unmet needs of older adults in society that could be met by technology—how can HTA help?; and ii) engagement of older adults and caregivers. These two themes became the starting point for the panel discussion in 2017. At this session, the highest ranked themes were: i) identification of challenges in HTA and aging; ii) approaches to advancing the effectiveness of HTA addressing technology and aging; and iii) development of an aging-related interest group in HTAi.

CONCLUSIONS:
International collaborations have identified a number of recommendations to consider for HTA and aging-related work including developing a good mutual awareness and understanding of barriers and opportunities; the importance of co-creating solutions with patients, health care providers, researchers/innovators, and funders; and the identification of a suite to methods and tools that can help accelerate the technological innovation in care delivery.

PP40 HTA Evaluations Of Combination Drugs: Positive Reimbursement Solutions

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ABSTRACT SUMMARY:
Health Technology Assessments (HTA) for combination oncological therapies are increasingly common. France and UK have approved combination therapies via standard HTA processes. The complexity and high cost of these therapies create challenges, as does involvement of multiple companies. Potential solutions include multiple-criteria decision-making and indication-specific pricing. Collaboration between decision-makers and industry is also essential to successful HTA for combination therapies.

INTRODUCTION:
Health technology assessments (HTA) for combination drug therapies in oncology are
increasingly common. Companies face multiple challenges when determining their economic value due to their complexity and high cost, while payers must balance the need for these vital innovations with sensitivity to rising costs. The study objective was to evaluate the current HTA frameworks in Europe and identify the potential barriers/solutions to reimbursement of brand-on-brand (BoB) combination therapy.

METHODS:
A targeted literature review of HTA agency websites was undertaken to identify any literature/guidance relating to HTA decision-making for combination oncology therapies in France, Germany, Sweden, and the UK.

RESULTS:
In France and UK, BoB HTA decisions reflect clinical- and cost-effectiveness. Combination therapies have been accepted for use in France and UK, for example, dabrafenib plus trametinib, and are assessed through standard HTA processes, exemplifying that positive reimbursement is not unattainable where there is an unmet need and high clinical value. Despite this flexibility, many will fail to prove their cost-effectiveness, resulting in delays or arbitrary pricing decisions. Potential solutions are the use of the ‘efficiency frontier’, as typified by the German HTA system, giving more ‘scope’ to expensive innovations; or the Swedish HTA approach, which applies variable cost-effectiveness thresholds according to therapeutic area, disease severity, and social criteria. Other possibilities include indication-specific pricing, multiple-criteria decision analysis, and net monetary benefit with willingness-to-trade weights. One likely issue to arise is when different companies are involved, necessitating co-operation. In this scenario, a simplistic solution would be arbitration of the division of the combined price, circumventing the need for HTA agencies to make changes to decision-making criteria.

CONCLUSIONS:
Constructive debates and collaboration between industry and decision-makers are vital to achieve a harmonized HTA process for high-cost combination therapies which offer advanced benefits and improved safety outcomes, whilst satisfying HTA bodies and providing better access for patients.

PP41 Toward Rules For Stakeholders’ Involvement In Regional HTA Units

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ABSTRACT SUMMARY:
Patient involvement in HTA is a best practice standard. The term patient can be expanded to include multiple stakeholders (i.e. health services users, caregivers, citizens). Implementation of this standard in regional HTA units should be based on explicit rules and processes. In an advisory committee including users, caregivers and citizens, we co-constructed rules for involving patients in regional HTA units.

INTRODUCTION:
Health services users must participate in HTA activities. Users, caregivers, and citizens have the practical experience of healthcare and social services. HTA outputs are more useful when values and preferences of patients, caregivers, and citizens are taken into account. Despite this, the best methods of stakeholders’ involvement, timing for doing so, selection of participants, and the type of users to recruit depending of methods and contexts
remain unspecified. Herein, an involvement policy has been developed to formalize the participation of users, caregivers and citizens in the services offering of a regional HTA unit.

METHODS:
A steering committee composed of stakeholders (i.e. user, caregiver, citizen, User Experience Service representative, manager, provincial HTA body representative, HTA unit members) was constituted to discuss user involvement in a regional HTA unit. A preliminary vision statement emerged from this committee, and included objectives and principles for users, caregivers, and citizens participation. This statement was deliberated using a Delphi consensus method. Three rounds of deliberations were needed to reach a strong consensus.

RESULTS:
Four objectives and four principles that should underlie the development of an involvement policy reached consensus. Participants agreed that users, caregivers, and citizens should 1) propose principles of involvement for each HTA projects, 2) co-realize evaluations with HTA professionals, 3) contribute to evaluation processes and 4) be involved in some management decisions of regional HTA units. Four principles to formalize users, caregivers and citizens’ involvement in regional HTA units also emerged. These principles were about utility and feasibility of involvement as well as on ethical and methodological considerations.

CONCLUSIONS:
Users, caregivers, and citizens must participate in the activities of regional HTA units. Each of them have different roles and can contribute to evaluation processes. Their involvement in HTA activities is warranted for co-producing better evaluation more adapted to users’ needs in healthcare and social services.

PP42 How IO Drugs Changed The Landscape Of Non-small-cell Lung Cancer

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ABSTRACT SUMMARY:
A look at how immuno-oncology drugs have reshaped the landscape of non-small-cell lung cancer.

INTRODUCTION:
In April 2015, nivolumab became the first checkpoint inhibitor approved to treat non-small-cell lung cancer (NSCLC). Shortly thereafter, pembrolizumab was approved, thus changing the NSCLC landscape.

METHODS:
Using the Context Matters data model and prices from the joint Context Matters/IHS Markit PriceCurrents platform, we evaluated regulatory, reimbursement, and pricing data (where available) for NSCLC in Australia, Germany, France, the United Kingdom (UK), Canada, Scotland, the European Union (EU), and the United States (US). Data used was from January 2009 through June 2017. Excepting the US, pricing data was excluded for trametinib, gemcitabine, alectinib, and necitumumab, and partially excluded for ramucirumab, docetaxel, and bevacizumab, due to lack of market access.

RESULTS:
Since nivolumab’s regulatory approval, NSCLC reimbursement decisions, which had previously
peaked at 24 in 2013, increased to 45 in 2015 and to 87 in 2016. The rate of positive decisions dropped from 60% in 2014 to 52% in 2015 and to 49% in 2016, despite increases in key clinical measures. The rate of decisions that: included significant primary outcomes vs a comparator went from 7 in 2014 to 15 in 2016; evaluated overall survival as a primary outcome went from 0 during 2011-2014 to 10 in 2016. Prices increased from January 2015 through June 2017: the average price-per-mg for NSCLC treatment increased from $1.78 to $3.57 in Australia, €2.25 to €3.2 in Germany, £1.58 to £2.68 in the UK, $5.88 to $16.19 in the US, and €1.31 to €3 in France.

**CONCLUSIONS:**
The prices of newer NSCLC drugs have doubled the average treatment’s cost-per-mg. This possibly correlates with the decrease in positive decisions and the increase in overall decisions, pointing to a greatly altered NSCLC landscape, which, because of a lack of market access in several other key new therapies, is largely driven by immuno-oncology drugs.

**METHODS:**
MACBETH was applied in helping INTO to evaluate two drugs (Rivaroxaban and Enoxaparin), taking into account drugs benefits and risks, through a series of interviews and decision conferences attended by INTO stakeholders that acted as evaluators in the model-building process, supported by M-MACBETH DSS (www.m-macbeth.com). Following MACBETH preference elicitation process, the evaluators were asked to make qualitative pairwise comparison judgements of difference in value between stimuli for constructing quantitative value and weighting scales. These scales allow measuring the relative value of the drugs on each evaluation criterion, separately and globally. The value measurement process was informed by a literature review and meta-analysis of randomized clinical trials with a critical appraisal of the evidence.

**RESULTS:**
We report a model-structure with eight criteria, hereafter presented by decreasing order of their weighting: Death from any cause, Clinically significant bleeding, Proximal deep vein thrombosis, Distal deep vein thrombosis, Existence of antidote, Thrombocytopenia, Comfort and Costs.
and Comfort. From the value model developed and after performing sensitivity and robustness analyses, Rivaroxaban was considered a robust option for thrombosis prophylaxis, under the MACBETH value framework and at the light of a simple additive aggregation of those eight criteria.

CONCLUSIONS:
This study shows how a value measurement socio-technical framework, combining MACBETH with scientific evidence within a participatory group evaluation process, can support health technology assessment in an user-friendly and effective way. MACBETH facilitates transparent and robust decision-making in the face of complex evaluation problems that the scenario hospital often faces.

INTRODUCTION:
Long-acting insulin analogues have been reported in patients with type 1 diabetes mellitus who exhibit important oscillations of their daily blood glucose, although the therapeutic benefits are lacking. The aim of this study was to evaluate the effectiveness and safety of the insulin analogue glargine compared detemir to support health decision-making.

METHODS:
Systematic review with meta-analysis of observational studies (cohort and registry), available in the MEDLINE (Pubmed), Latin American and Caribbean Health Sciences (LILACS), EMBASE and Cochrane Library databases (accessed August 2017), including research in the electronic journal Diabetes Care and gray literature. Several combinations of terms were used, including disease terms, interventions and type of study. The results evaluated were: glycated hemoglobin, weight gain, occurrence of severe hypoglycemia, total insulin dose and fasting capillary glycemia. Methodological quality was assessed using the Newcastle scale. The meta-analyses were performed in the Review Manager® 5.2 software in the random effects model. Protocol, number CRD42017054925, in the International Prospective Register of Ongoing Systematic Reviews.

RESULTS:
A total of 705 publications, 8 cohort studies were included. The quality of included studies was classified as alta. In the meta-analysis the results for episodes of severe hypoglycemia (p = 0.002), measurements of fasting capillary glycemia (p = 0.01) and weight gain (p = 0.001) were favorable for detemir. The glycated hemoglobin endpoint (p = 0.58, heterogeneity = 89%) revealed high heterogeneity and no statistically significant difference between groups, showing no difference between the interventions for glycemic control.

CONCLUSIONS:
Although some results are favorable to detemir, it was not possible to identify significant differences.
in effectiveness and safety between the two analogues evaluated, requiring new long term studies and better quality of methodological studies.

PP45 Efficiency Evaluation Of Village Clinics In Shandong Province

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ABSTRACT SUMMARY:
In China, the village clinic is the most basic unit of the rural tertiary medical and health service system, which is an important institution to ensure the rural health work carried out successfully. Using output oriented BCC model in data envelopment analysis to evaluate the efficiency of 202 village clinics in Shandong province, PR China.

INTRODUCTION:
In China, the village clinic is the most basic unit of the rural tertiary medical and health service system, which is an important institution to ensure the rural health work carried out successfully. However, because the village clinic is located in remote rural areas, the information is difficult to obtain, and the related researches are less.

METHODS:
The research group adopts multistage stratified random sampling method. In 2015, according to the economic level in Shandong Province, randomly selected the cities of Ji’nan, Weifang, Linyi, Dongying, Dezhou, Binzhou. According to the same principle, 3 counties were selected in each city, 3 townships were selected in each county, and 3~5 village clinics were selected in each township. Use the questionnaire compiled by the research group to conduct investigation. It eventually investigated 248 village clinics. According to the purpose of the study and data quality, this study was finally included in 202 village clinics for analysis. Using output oriented BCC model in data envelopment analysis to evaluate the efficiency of 202 village clinics in Shandong province, PR China.

RESULTS:
The proportion for DEA effective unit in 202 villages in Shandong Province was 10.40 percent, and the average efficiency of technical efficiency, pure technical efficiency and scale efficiency were 0.53, 0.63 and 0.82 respectively. The proportion of medical services efficiency and public health service efficiency for DEA effective unit was 8.9 percent, the average technical efficiency of the average was 0.42 and 0.44, pure technical efficiency was 0.51 and 0.60, the scale efficiency of the average was 0.84 and 0.71.

CONCLUSIONS:
The overall efficiency of village clinics in Shandong Province is low. The level of management and technology is low; although the village clinic construction has been achieved a certain level, but caused a higher management costs; the current basic public health service assessment system is defective.
**PP46 When Composite Measures Or Indices Fail: Data Processing Lessons**

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**ABSTRACT SUMMARY:**
Patient-reported outcomes are important for trials and clinical assessment. Many of them could not be observed with one measurement or a single variable. Therefore composite measures or indices are necessary. We aim to demonstrate the occasions when researchers may induce bias to their composite measures or indices while processing data.

**INTRODUCTION:**
Index mining is a new discipline that aims to search for the composite measures or indices most relevant to the contexts or outcomes. After reviewing three frailty indices and principal component (PC)-based indices, we hereby show certain occasions that can lead to ineffective indices, which consist of bias or fail to represent the theories.

**METHODS:**
We reproduced and reviewed the three frailty indices in Cigolle et al. (2009) and the 134689 PC (principal component) -based indices in Chao and Wu (2017). The impact of aggregating the input variables on the final indices was analyzed using forward stepwise regression.

**RESULTS:**
Several methods to combine the input variables were related to ineffective projection of information onto the indices. The most common causes leading to ineffective summation of input variables were shown in three examples involving different types of input variables, which were positively or negatively correlated or uncorrelated to the outcome. Ineffective indices were created often because of the summation of redundant information or uncorrelated variables.

**CONCLUSIONS:**
The creation of ineffective indices can be avoided if the relationships between input variables and outcomes are properly scrutinized. The creation of composite measures and indices is still a discipline under active development. The three examples we identified are the mistakes that may be repeated unintentionally and need to be addressed with explicit rules. Chao and Wu (2017) proposed a reporting guide for the creation of composite measures. They recommended conducting a proper review of index objectives, data characteristics, and data limitations before creating composite measures or indices.

**PP47 Defining The Needs And Preferences Of Patients With Dry Eye Disease**

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**ABSTRACT SUMMARY:**
We outline a research process for determining the factors of importance to patients suffering from moderate/severe dry eye disease (DED) and then quantifying their preference structures to identify the most patient-relevant outcomes. The results
will inform future clinical trial design in DED and discussions with HTAs and regulators on product attributes that matter and are of most value to patients.

INTRODUCTION:
Dry eye disease (DED) is a common condition that significantly impacts patients’ quality of life. Previous studies have explored the impact of DED on patients’ lives qualitatively; however, patients’ preference structures have not been thoroughly explored quantitatively.

METHODS:
A targeted literature review and social media listening project guided design of a discussion guide for in-depth patient interviews (n=12). These, in turn, guided construction of a quantitative questionnaire administered to moderate to severe DED patients, forty per country in Australia, Germany, US & UK (total n=160). Patients’ preference structures were explored through an online survey using a self-explicated conjoint methodology, because of its high respondent-friendliness. Additionally, we administered the EQ5D-5L instrument to determine the health states/utilities of patients. Reaction to a hypothetical novel treatment was further obtained to check for convergent validity with the self-explicated conjoint. Finally, we asked respondents to rate the ease and relevance to them of the questionnaire.

RESULTS:
Qualitative research uncovered important patient perspectives that were built into the quantitative survey. For example: patients seek medical advice when their symptoms are not improving. Patients’ lives are most affected by sensitivity to light, itchy and tired eyes and an inability to perform computer/screen work. However, of most concern/worrying to them is that their DED will get worse and they go blind. Results from the quantitative preference research will also be shared and its implications for future clinical trials in DED outlined. The results of the patient research and preference study are to be shared with HTA bodies and regulators through the early dialogue scientific advice process.

CONCLUSIONS:
A process of using qualitative research to determine what matters to patients and then quantification through respondent-friendly preference research can identify outcomes that are most patient-relevant, to inform future drug development strategies.

PP48 Caregiver Perceptions And Experiences Of Diagnostic GWS

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ABSTRACT SUMMARY:
We present findings of a qualitative study on caregiver perceptions and experiences of receiving or not receiving a diagnosis following genome-wide sequencing, within a wider service delivery evaluation. The evaluation included a family survey and we thematically analysed the free-text comments using Nvivo. We found differences between caregivers’ anticipated versus reported effects of a diagnosis following genomic testing.

INTRODUCTION:
The objective of this qualitative analysis was to explore caregiver perceptions and experiences...
of receiving or not receiving a genetic diagnosis following genome-wide sequencing (GWS) for children with suspected genetic disorders.

METHODS:
One caregiver of each child completed an online survey two weeks after enrolling in the CAUSES study, beginning in January 2016, and again about six months after receiving the GWS results. The survey covered the caregivers’ experiences and quality of life and children’s healthcare resource utilization and provided open-ended questions for comments. A thematic analysis of the free-text comments data from the follow-up survey completed by 20 families who had received a diagnosis with their GWS results and 22 who had not received a diagnosis was performed using NVivo v11.4.2.

RESULTS:
Caregivers from both groups expressed similar experiences of negative socioeconomic effects of caregiving, particularly related to employment and time burden. Caregivers who did not receive a diagnosis with the GWS results were generally hopeful of receiving a diagnosis in the future, and reported expectations of positive benefits from receiving a diagnosis in future both in terms of access to additional resources and positive psychological effects. The absence of a diagnosis was a source of anxiety for many caregivers. By contrast, caregivers who had received a diagnosis reported positive, neutral as well as negative psychological effects of the knowledge that was gained; no participants commented on the consequences for access to additional services or other socio-economic effects.

CONCLUSIONS:
Our findings suggest that caregivers may have high expectations for what a diagnosis can provide to them and their families, which may not be fully met once a diagnosis is obtained. The results underpin the importance of patient-centred communication of genomic testing so that families can set realistic expectations of what having a diagnosis would bring them.

PP49 Assessing Values In National And Regional Governance Of E-health

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ABSTRACT SUMMARY:
Norwegian Centre for E-health Research is commissioned to assess e-health within an HTA framework. This project aims to explore: 1. The use of HTA (for assessing) 2. Value-based governance of e- and m-health strategies. By conceptualizing, comparing and contrasting governance practices, the purposes are: 1. Contribute to transparency and adjustment of values in e-governance. 2. Capacity building for HTA of e-governance.

INTRODUCTION:
Globally, countries are investing substantially in e-health. Failures of programs to achieve valuable economic, clinical and societal outcome are increasingly reported. Unsuitable governance models may be one explanation. Research on governance models’ usefulness for realization of valuable outcomes is incomplete and scattered. Our goal is to fill this gap by producing knowledge on e-governance in Norway. Hypotheses: 1. Co-governance and Relational Coordination will positively impact the realization of valuable outcome. 2. Multilateral stakeholder dialogue and collaboration, including health service delivery perspective, have been proposed to innovate HTA. This will improve the relevance of HTA e-governance research.
METHODS:
1. Systematic Review of e-governance in healthcare
2. Participatory observations, in depth interviews/ focus groups
3. Document retrieval and analyses
4. Creation and support of arenas for dialogue between stakeholders on values and governance
5. Analyses of co-produced value adjustments
6. Analyses of the usefulness of the Scientific Dialogue Approach for changing HTA paradigms

Study populations
1. Governmental bodies responsible for innovation of EHR in Norway
2. Regional and municipal authorities and management responsible for implementation of EHR
3. The leaders of different levels at a municipal “Health House” established as a hybrid between primary and specialist health services.

RESULTS:
The project runs between January 2018 - 2022. Expected findings:
1. Diverging and common values
2. Diverging governance models
3. Diverging attitudes towards “best governance practices”
4. Diverging levels of trust
5. Different world views, belief-systems and individual values
6. Attitudes towards consensus building or conflict
7. Experiences to feed into the discussion of stakeholder dialogue as an HTA approach.

CONCLUSIONS:
We expect:
1. To present results from the systematic review and preliminary findings from the first phases of participatory observations.
2. That results from the overall project will have high impact on the Norwegian governance models of e-health.
3. Publications in high impact scientific journals.

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ABSTRACT SUMMARY:
The literature has explored the use of TDABC to measure costs related with health technologies in microcosting studies. This research applied TDABC to measure the cost of Extracorporeal circulatory membrane oxygenation (ECMO) in Brazil. A gap of U$68,708 between the cost and the public reimbursement was identified.

INTRODUCTION:
Extracorporeal circulatory membrane oxygenation (ECMO) is a technology that allow to recover adults in cardiorespiratory failure with encouraging results, but is not available at Brazilian universal public health system (SUS) due to high implementation costs. Time-driven Activity based costing (TDABC) is applied to measure process in an economic perspective identifying opportunities to turn process more efficient, through the reduction of resources used in each activity. The literature has explored the use of TDABC to measure costs related with clinical procedures and technologies in microcosting studies, identifying opportunities to improve the process turning it more efficient. This research measures the real costs to implement ECMO in Brazil to compare with the public current public reimbursement system.

METHODS:
This study applied TDABC using data from 6 patients to measure costs of ECMO intervention considering the public perspective from Brazil. In sequence, standard price payed by SUS was used to estimate the current reimbursement amount received by the hospital for ECMO procedure. Cost variable analysis were conducted to understand

PP50 Microcosting With TDABC Applied On Brazilian HTA System

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when and how patients in ECMO are using hospital resources. Cost data were collected from an academic public hospital, using an average of 18 months (2016-2017) for the department costs.

RESULTS:
The real cost varied between $30,677 and $161,076 and the average was $88,304. Most representative resource in costs was medical staff, in special for the three survivor patients, being the ECMO equipment the second highest cost. The ECMO activities were fragmented in: before implantation of ECMO, period using ECMO, intensive care post ECMO and rehabilitation, being the period in ECMO the most expensive, in special by the payments of nurses and physicians. The SUS average was U$19,596, which shows that exist a difference of U$68,708 between the real ECMO cost and the public reimbursement in Brazil.

CONCLUSIONS:
A critical element of propagation of ECMO in Brazil and reimbursement by public health system is the high cost and especially out of date standard payments by the Ministry of Health. Effort to implement a trustworthy method to guide decisions of SUS for the adoption and financing new technologies is essential to contribute for the optimization of public health policies in a country with a universal health system and limited resources dedicated to health sectors.

Mitchell Levine, Canada

ABSTRACT SUMMARY:
The present systematic review of the literature is the initial step of updating Canada’s budget impact analyses (BIAs) guidelines for new drug submissions to provincial public and private payers. Guidelines published from 2007 to 2017 in different jurisdictions such as UK, United States and Australia were reviewed and new recommendations were abstracted and listed.

INTRODUCTION:
Budget impact also referred as resource impact, is the financial change in the use of health resources adding a new drug to the formulary or adopting a new health technology. The first Canadian budget impact analyses (BIAs) guidelines was published by Patented Medicine Prices Review Board (PMPRB) in 2007. An update for PMPRB BIAs guidelines was recommended to reflect the changes in the pharmaceutical environment over last decade, and countries like England, United States, and Australia updated their BIAs guidelines recently. The main objective of the present study was a comparative review of BIAs model structures published in different jurisdictions as the initial step of updating Canada’s BIAs guidelines.

METHODS:
BIAs guidelines were searched in databases such as MEDLINE, EMBASE, Cochrane, and the gray literature including regulatory agencies websites. Data was abstracted based on determined key items in a standard BIAs model and new recommendations were compared to each other, respectively. The main focus of the review was preparing a list of new recommendations which was not included in PMPRB BIAs guidelines.

RESULTS:
Eleven guidelines were reviewed in detail. The results showed that there are different methodologic recommendations for most BIAs analytical framework and data input aspects based

PP51 Updating Canada’s Pharmaceutical Budget Impact Analysis Guidelines

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on different countries’ healthcare financing system and the payers’ requirements. A reference case model recommendation was set up describing the most up-to-date method of conducting a comprehensive budget impact analysis.

CONCLUSIONS:
The present literature review is the initial step of updating Canada’s PMPRB BIA guidelines. This study presents a comparative review of BIAs model key elements among different guidelines and provides a list of relevant practical recommendations for the improvement of Canadian BIAs guidelines. The new methodologic advancements and recommendations collected as a part of PMPRB BIAs guidelines update proposal which was provided to Canada’s experts and policy makers for their opinion and feedback.

INTRODUCTION:
In England, 7% of men and 9% of women have severe obesity (BMI≥35kg/m2), with increased premature mortality and obesity related diseases risk. Despite the substantial health and economic burden, evidence syntheses regarding the most efficient treatment pathway are lacking. Compared to clinical-effectiveness data, little guidance exists regarding the unique challenges of reviewing, synthesising and in particular presenting findings from cost-effectiveness systematic reviews.

METHODS:
The REBALANCE evidence synthesis, incorporates a systematic review of economic evaluations of weight loss interventions for BMI≥35kg/m2. A bespoke online data extraction form was created to retrieve and store data. Standard checklists were used to quality assess the studies. Findings were tabulated and a narrative synthesis of cost-effectiveness provided, focusing on the key policy questions.

RESULTS:
Over 2000 abstracts were identified, and 47 studies included. Bariatric surgery (28 studies) is highly cost-effective, often generating cost savings alongside health benefit. Drug therapy (3 studies) and lifestyle interventions (16 studies) generate mixed results, driven in part by the poor quality of the studies. Many challenges exist for data synthesis in economic evaluation. The differing health systems internationally, with differing currencies further complicates the process. Different frameworks for analysis generate differing results. Economic evaluation alongside RCTs without longer term extrapolation offers little benefit in evaluating a chronic disease such as obesity, yet 7 studies used this as their analysis framework. Decision models with poorly justified and wildly varying assumptions regarding time horizon, weight regain and included disease health states further increase uncertainty in estimated ICERs and limit cross study comparability.

PP52 Challenges Of Cost-effectiveness Systematic Reviews: REBALANCE Study

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ABSTRACT SUMMARY:
The REBALANCE study included a systematic review of economic evaluations of weight loss interventions for BMI≥35kg/m2. Systematic reviews of complex economic evaluations pose unique challenges. Poor study quality, heterogeneous definitions of interventions and comparators, poorly justified model assumptions, different health systems and frameworks for analysis all complicate synthesis of findings. We suggest methods for improved reporting of systematic review results.
CONCLUSIONS:
Bariatric surgery is highly cost-effective for treating severe obesity. However poor study quality rendered it difficult to draw clear conclusions regarding lifestyle interventions. We propose methods for reporting systematic review results in a manner that best communicates the key messages to decision makers.

PP53 New Medical Device Law: Germany’s Experience With Refund Restrictions

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ABSTRACT SUMMARY:
New medical devices (MD) of high risk classes or new scientific concepts are being evaluated versus alternatives by the Federal Joint Committee. Out of 19 MDs, 6 were rated as having no potential benefit which may lead to exclusion from reimbursement by the statutory health insurance. Manufacturers need to revise their study concepts to fulfill the demand for robust evidence.

INTRODUCTION:
Since 2005, new hospital examination and treatment methods (NUB) were reimbursed by hospital individual supplementary fees as long as they were not sufficiently covered by a DRG. In 2016, the NUB procedure was decisively changed by legal norm §137h SGB.V to evaluate medical devices (MD) of high risk classes, particularly invasive, or new theoretical-scientific concepts versus treatment alternatives by the Federal Joint Committee (G-BA). Hospitals and manufacturers have to submit detailed information on the application of the MD and the scientific evidence to G-BA along with a NUB application. This assessment may lead to exclusion of the method from reimbursement by the statutory health insurance (SHI).

METHODS:
The to date published MD consultation submissions, assessments and G-BA resolutions were analyzed regarding evaluation criteria, treatment potential and study obligation.

RESULTS:
In 2017, 19 procedures were reviewed by G-BA with respect to §137h. 2 ultra-controlled high-intensity focused ultrasound (HIFU) indications were regarded as having potential benefit but not sufficient evidence yet, thus respective studies have to be initiated. 3 procedures were regarded as eligible according to §137h but not yet evaluated. 6 procedures (ultra-controlled HIFU in 5 indications, targeted lung denervation in COPD) were rated as having no potential benefit, while 8 procedures were regarded as not eligible according to §137h.

CONCLUSIONS:
Initially put into place for high risk class and primarily invasive devices, consultations and assessments under §137h show that there is some uncertainty around applicability criteria. The majority of those procedures which fell under the assessment law failed to be granted potential benefit as treatment alternative. Currently consultations are ongoing which could possibly lead to the exclusion of these methods from the performance spectrum of the SHI. Manufacturers should revise their study concepts in order to fulfill the specific demand for robust evidence.
**PP54 Effectiveness And Costs Analysis Of Mobile Phone App Healthcare**

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**ABSTRACT SUMMARY:**
The mobile phone is used to support healthcare and public health interventions, also are a useful and easy method for collection of data for healthcare research. This study aims to assess the effectiveness and analyze costs before and after the inclusion of type 2 diabetic patients in a mobile phone app health care program.

**INTRODUCTION:**
Smartphones have been one of the success stories of the last decade. Recently, apps are being used to promote, manage and provide medical and healthcare education. By the way, the mobile phone is used to support healthcare and public health interventions, also are a useful and easy method for collection of data for healthcare research. In addition, apps have shown successful use of support telemedicine and remote healthcare in developing nations. This study aims to assess the effectiveness and analyze costs before and after the inclusion of type 2 diabetic patients in a mobile phone app health care program.

**METHODS:**
The mobile phone app health care program is available for Android and IOS system, is used to manage the behavior changes and to improve patients’ adherence to pharmacotherapy. The patients followed up is done through a specialized telephone monitoring center, made up a physician, nurses, nutritionists, and psychologists, which provide constant monitoring and guidance health actions. A retrospective study was conducted considering data before (2016) patients (29) were included in the mobile phone app health care program and twelve months later (2017). Data were collected from medical records, including physician visits, hospitalization, medical and laboratory exams. The cost analysis was taken the private healthcare group perspective and was performed considering the micro-costing method.

**RESULTS:**
98% of patients had reduction or maintenance of glycated hemoglobin levels, reaching the therapeutic goal (glycated hemoglobin less than 7%). The costs analysis show a 25% total costs saving, due to a 23,14% reduction in the number of physician visits, 32,80% decrease in hospitalizations and 34,47% cutback of medical and laboratory exams.

**CONCLUSIONS:**
The mobile phone app health care program can facilitate and improve diabetes care, especially controlling and managing the use of health resources.

**PP55 HTA And High Cost Innovative Therapies - Focus On Cancer Drugs**

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**ABSTRACT SUMMARY:**
High-cost innovative therapies are considered as high-risk investments in the reality of limited health care budgets. The objective is to identify similarities and differences in the methods and processes in HTA of CT. Making coverage decisions based on
HTA recommendations control the technologies introduction into the healthcare system, thus properly adjusted approach for CT assessment is needed.

**INTRODUCTION:**

High-cost innovative therapies are considered as high-risk investments in the reality of limited health care budgets. HTA facilitates evidence-based decision making that relies on robust assessment of the clinical cost-effectiveness of the technology that is often not available for the expensive cancer therapies (CT).

**METHODS:**

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 CT. A cross-sectional web-based survey was conducted between September 2013 and May 2015. We received responses from 161 HTA organizations based in 39 countries.

**RESULTS:**

HTA of CT is mainly performed by agencies in South America (38.46 percent), Australia (37.05 percent) and Europe (36.07 percent), followed by agencies in North America (20.00 percent) and Asia (16.67 percent). Logically the agencies in high income countries produce more assessments of CT (40.23 percent), which in 34.43 percent they determine as innovative technologies compared with 10.00 percent of the units based in middle income countries and active in CT assessment (11.11 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 (50.00 percent), government agencies (42.11 percent) and professional organizations (40.00 percent). HTA bodies that assess CT distribute recommendations (37.50 percent) nationally and they are mainly addressed to private health care providers (66.67 percent).

**CONCLUSIONS:**

Making coverage decisions based on HTA recommendations control the technologies introduction into the healthcare system that is why it’s very important this tool to be properly adjusted to the specific needs of CT assessment.

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**PP56 Have A Drug Replacement An Impact On Hospital Treatment? A Discussion**

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**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 for drug product changes.

**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. 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.
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 latter 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 from 2,300 € to 6,420 € and depend on the frequency of prescription and the complexity of the product.

CONCLUSIONS:
This Health Technology Assessment 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.

PP57 Grading The Quality Of Evidences In HTA Process

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ABSTRACT SUMMARY:
In HTA processes, the lack of literature evidence on Medical Devices, is a common issue. This has led to develop a mathematical model, based on GRADE system, to weight the relevance of each assessment element used to inform the decision-making processes. In this way different level of evidence would result in different weights modulating the final decision.

INTRODUCTION:
In decision-making processes, HTA plays an important role ensuring the adoption of effective technologies, translating scientific evidence into decisions. Bambino Gesù Children’s Hospital developed a new method which integrates EunethTA Core Model with MCDA enabling decision makers to make a more informed decision between different alternatives. This approach is able to quantify the assessment parameters, which were defined by literature evidences, or by expert opinion when lacking evidences. MCDA results (i.e. decision tree of assessment elements, weights’ systems and numerical values of the technologies’ performances) are derive from judgements’ expression by experts. It means that indicators are weighed by the same weight system; either they are supported by strong literature evidences or, on the contrary based only on expert opinion. The objective of this work is to use the GRADE approach to weight the relevance of each indicator starting from its source of information, because different level of evidences should result in different weights.

METHODS:
A Grade level was associated to each judgement value of performance indicators and a normal probability function was built with the standard deviation inversely proportional to GRADE level to describe the possible dispersion of the judgement due to the different levels of evidence that support each indicator. The higher the GRADE value, the lower the standard deviation associated. A Montecarlo simulation was carried out to evaluate
the expected value of technologies’ performances modulated by GRADE level.

RESULTS:
Four Gaussian distributions were built and associated to four GRADE levels. When an indicator has a low Grade level, its performance value will vary in a broader way according to the linked Gaussian distribution.

CONCLUSIONS:
This approach showed the importance of applying GRADE system to indicators’ sources of information, because it can modify the overall computation of parameters’ weights and performance, proportionally to their robustness.

PP58 Hasty HTA: Delivering HTAs Under Severe Time Constraints

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ABSTRACT SUMMARY:
Health technology assessment (HTA) is a time-consuming and resource-intensive decision support tool. Completing urgent HTAs in tight timelines poses challenges for quality and relevance to the decision maker. We consider some of the critical issues and suggest how agencies might best manage HTAs under these conditions.

INTRODUCTION:
Health technology assessment (HTA) is a resource-intensive decision support tool, typically structured around a set of defined domains. Sometimes urgent requests for HTAs arise that may be subject to very short timeframes, creating unique challenges. This study aims to describe some of the options for carrying out a ‘hasty HTA’, and the impact of those options.

METHODS:
We recently completed a HTA for the Department of Health in Ireland, with a strict two month deadline. We considered the impact of the short timeline using the project management triple constraint framework whereby the quality of a project is constrained by cost, scope and schedule.

RESULTS:
When delivering HTAs within short timeframes, the schedule is an inflexible constraint. Providing interim advice pending a full assessment may be a precedent, or may not be possible if capital expenditure is entailed. Additional staff should enable research to be completed faster, although economies of scale may not apply fully. Frequently such resources are not readily available. The reduction of scope through the omission of domains offers the best prospect of facilitating a short timeframe. Scope may also be reduced through a less comprehensive analytical approach, but this creates risk for accuracy. Curtailing data collection and analysis is likely to increase uncertainty in the findings. Risk management is important as comprehensive quality assurance may not be possible.

CONCLUSIONS:
Carrying out HTAs in short timeframes has implications for content, approach and potentially quality. Agencies must consider how they can meet the needs of the decision maker without overly compromising on accuracy or relevance. Due to resource constraints, the best approach is likely to be judicious changes to the scope to remove assessment elements that are unlikely to have a substantive impact on the decision.
**PP59 Evaluating Reimbursement Applications With Decision-oriented Evidence**

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**ABSTRACT SUMMARY:**
It is not uncommon for clinical trials to be designed specifically to inform a reimbursement decision. However, such cases can pose challenges to the evaluation of a health technology in relation to limited evidence, external validity concerns and duration of follow-up. This presentation will describe some of these challenges through a detailed case analysis of a recent technology evaluation.

**INTRODUCTION:**
Our research group recently evaluated a minimally invasive surgical procedure in order to inform a reimbursement decision. The application for funding was designed around the study selection criteria from a single pivotal randomised controlled trial (RCT). The aim of this study review was to evaluate the safety and effectiveness of this minimally invasive surgical procedure, and document challenges faced in evaluating a technology based on a highly targeted population.

**METHODS:**
A systematic literature search of 4 biomedical databases was conducted (PubMed, Embase, Cochrane library, York CRD) up to 8 August 2017. Specific elements related to the population were patient age, together with level and duration of pain. Primary effectiveness outcomes included pain, patient reported quality of life scores, mortality and adverse events. The included RCTs were critically appraised against the Cochrane risk of bias tool. Meta-analysis was not possible due to the limited availability of evidence with consistent outcomes.

**RESULTS:**
From 4,718 search results, only the pivotal RCT specifically met the inclusion criteria, and demonstrated favourable safety and effectiveness of the procedure; however, the sample population included in the trial had limited external validity to the proposed reimbursement population and follow-up was limited to 6 months. As a result, the selection criteria were broadened to better reflect the manner in which the service may be provided in broader clinical practice, and capture longer-term safety concerns. Four additional RCTs were included, which provided contradictory results.

**CONCLUSIONS:**
The results of this review identified two important issues in evaluating a health technology where the assessment has been focused to the results of a single trial. In particular, the generalisability of a trial is defined by the demographic distribution of the sample, not the selection criteria. Designing the review selection criteria around the selection criteria for a single trial can have consequences for a funding decision.

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**PP60 Producing Qualitative Syntheses In HTA: Challenges From Canary Islands**

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ABSTRACT SUMMARY:
This joint presentation from an HTA agency and an academic methodologist examines challenges that arise when seeking to produce qualitative evidence synthesis to inform decision making. Practical and methodological issues relating to the quality of, and confidence in findings from, the synthesis product are explored. The value of GRADE-CERQual and use of accompanying Evidence to Decision frameworks is examined.

INTRODUCTION:
With heightened awareness of the value of patient and provider perspectives to decision making Qualitative Evidence Synthesis (QES) is increasingly used within an HTA context. Acceptability, feasibility and implementation can all be addressed by synthesis of qualitative research. Concerns have been raised about the quality of the synthesis product, especially when conducted within a constrained time window. How can we test the validity of qualitative studies and assess confidence in synthesised qualitative findings, particularly when time is tight?

METHODS:
A brief examination of issues relating to production and use of qualitative evidence synthesis (QES) identified from within the Canary Islands HTA agency will identify practical and methodological challenges. How can existing approaches address wider patient, social, organizational and ethical considerations that inform HTA? The potential for use of Evidence To Decision frameworks and approaches such as GRADE CERQual (a transparent method for assessing the confidence of evidence from reviews of qualitative research) will be briefly examined.

RESULTS:
This presentation will identify potential gaps between the needs of a small HTA agency and the methodological support and tools required to address these gaps, based on experience of conducting QES to date. Issues identified are particularly relevant to other small HTA agencies but also generalise to larger agencies and guideline producers worldwide. Pragmatic solutions are suggested. A future research agenda for potential methodological and applied research is outlined and current GRADE-CERQual development initiatives briefly shared.

CONCLUSIONS:
Despite significant progress in developing methodologies for integrating QES within HTA decision making, substantive challenges remain. Observations derived from this small HTA agency can inform further developments across all HT.

PP61 Time Horizons Used In Economic Models For Drugs To Treat Lung Cancer

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ABSTRACT SUMMARY:
Between 2007 and 2017 the time horizons of economic models used in NICE appraisals of drugs to treat non-small cell lung cancer have risen from 5 to 20 years. During the same period, model overall survival estimates have become progressively more reliant on projections rather than trial data. The consequence is increasing uncertainty around model cost effectiveness results.
INTRODUCTION:
The National Institute for Health and Care Excellence (NICE) reference case stipulates that the time horizons for economic models, developed to generate cost effectiveness estimates, should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. We explored how the time horizons of economic models submitted to NICE as part of Single Technology Appraisals (STAs) of therapies used to treat stage III or IV non-small cell lung cancer (NSCLC) have changed over time. We also explored how changes were related to the availability of trial overall survival (OS) data.

METHODS:
Time horizon details were extracted from NSCLC STAs with guidance published on the NICE website between 2007 and 2017. Further details of the main trials that were used to provide clinical evidence to populate the NSCLC models were also extracted. Relationships between variables were explored.

RESULTS:
Between 2007 and 2011, the time horizons used in company models were either 5 or 6 years. However, since 2011, time horizons have risen steadily to 20 years in 2016 and 2017. The length of time that OS data from the trials underpinning STAs have been available has varied between 9 months (2016) and 42 months (2010), with no clear trend. The net result of these two phenomena is that the proportion of OS in the economic models generated by parametric functions, rather than directly relating to trial data, has tended to rise over time (minimum: 46% [2007], maximum: 95% [2016]).

CONCLUSIONS:
Time horizons of models used to project cost effectiveness estimates for new drugs to treat NSCLC have increased since 2010 and model OS estimates are becoming progressively more reliant on survival projections rather than clinical trial data. This has resulted in growing uncertainty around model cost effectiveness results.

PP62 A Guide To Report And Review Innovative Indices Or Composite Measures

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ABSTRACT SUMMARY:
Patient-reported outcomes are important for trials and clinical assessment. Many of them could not be observed with one measurement or a single variable. Therefore, composite measures or indices are necessary. We aim to propose a guide to help researchers to better understand the assumptions imposed by indices and avoid generating the bias while processing data.

INTRODUCTION:
Composite measures and indices are used in medical research to represent certain concepts that cannot be measured with one variable. They can be used to predict outcomes or serve as outcomes in trials. The creation of innovative indices is important to increase publications and secure research funding. However, some assumptions and problems are prevalent among indices. We aim to develop a reporting guide and an appraisal tool for indices based on the issues we identified.

METHODS:
We reproduced the three frailty indices in Cigolle et al. (2009) and 134,689 principal component-based indices. We reviewed the index assumptions, bias introduced by data processing, relationships between input variables. We interpreted the indices with input variables.

RESULTS:
We identified four major issues to be addressed in a reporting guide: constraints imposed by index
creation on the input variables, data processing without evidence base, indices poorly linked to input variables, and relatively inferior predictive power. We demonstrated a flow diagram and a checklist to report and review these four issues related to innovative indices.

CONCLUSIONS:
A reporting and critical appraisal tool for innovative indices is lacking and needed. These four issues that need to be explicitly considered are previously neglected. This guide is the first attempt to improve the quality and generalizability of innovative indices. This guide can be used to lead further discussion with other experts and review committees.

INTRODUCTION:
In the Philippines, medicines are procured at higher rates in government hospitals. The prices of essential medicines have high variability, which causes a significant portion of Filipino’s out-of-pocket expenditures just for medicines. The study’s objective is to determine the factors associated with the variation in drug pricing among public hospitals.

METHODS:
The study was a mixed-methods, case-control study among 57 hospitals. Two tools were developed based on: (i) Management Sciences for Health (MSH)’s Rapid Pharmaceutical Management Assessment and (ii) World Health Organization (WHO)’s Good Pharmaceutical Practices. The dependent variable is a drug price reference ratio of a preselected drug basket. Examples of factors studied are: (i) preference for generics, (ii) procurement type, and (iii) time out of stock.

RESULTS:
Hospitals with proper procurement planning and performance monitoring are expected to decrease the price ratio (R = -0.030). However, from the interviews, forecasting is still not robust enough. Past consumption (91%) remained to be the most frequently used for procurement planning. Few hospitals took into consideration other factors such as morbidity, mortality, and patient demographics. The expertise of hospital’s procurement staff increases a hospital’s mark-up. This is because, from the interviews, members and hospital units do not meet eye to eye to ensure accountability and coordination across units in planning and implementing the procurement procedures.

CONCLUSIONS:
By having a forward-looking procurement plan, forecasting can be more efficient. Potential lies in finding mechanisms where nearby hospitals could participate in pooled procurement. Pooled procurement could have an impact on reducing prices by capturing economies of scale, provided this is operated efficiently and transparently.

PP63 Factors Influencing Drug Prices Among Philippine Public Hospitals

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ABSTRACT SUMMARY:
The high prices of essential medicines causes a significant portion of Filipino’s out-of-pocket expenditures. The study’s objective is to determine the factors associated with the variation in drug pricing among public hospitals. Results showed that proper procurement planning and performance monitoring decrease the price ratio. Coordination among the procurement staff decreases the mark-up of drugs.
PP64 Price Negotiations With Stratified Cost-effectiveness Analysis

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ABSTRACT SUMMARY:
Price negotiation has become an integral step between pharmaceutical licensing and reimbursement. Economic evaluation guidelines increasingly emphasise the need to conduct stratified analysis but the interpretation of such analyses in informing price negotiations is unclear. A framework for such decisions is presented and illustrated by a recent economic evaluation of treatment for osteoporosis.

INTRODUCTION:
Price negotiation has become an integral step between pharmaceutical licensing and reimbursement balancing the aims of decision-makers and manufacturers – population health and profit maximization. Economic evaluation guidelines increasingly emphasise the need to conduct stratified analysis but the interpretation of such analyses in informing price negotiations is unclear. A framework for such decisions is presented.

METHODS:
Options for funding without price negotiation include funding only in patient groups (strata) with positive incremental net benefit (INB) (Stratification) or funding across all strata if total INB is positive (NoStratification). A decision maker could negotiate price such that INB is positive in all strata (All_CE). Alternatively, decision makers could negotiate price such that the INB across all strata is equal to the INB under Stratification (Equal_INB). This would ensure full coverage without any loss in population health. The impact of these options on INB and profit is assessed using a recent economic study of zoledroic acid (ZA) in the treatment of osteoporosis patients unable to tolerate oral bisphosphonates. In addition, the potential impact of changes to the initial price is assessed.

RESULTS:
Based on current prices, the required price reduction for ZA is 12% for All_CE and 3% for Equal_INB. INB per patient was $261, $164, $261 and $514 for Stratification, NoStratification, Equal_INB and All_CE respectively. Manufacturer profits per patient were $825, $1491, $1395 and $1141 respectively. However, if the initial drug price was 50% higher, the INB under both Stratification and Equal_INB would be $6 and the price reduction required for Equal_INB would be 30% (5% higher than the original price).

CONCLUSIONS:
When conducting pharmaceutical price negotiations involving stratified economic evaluation, decision makers need to consider both the INB of different reimbursement strategies and potential price manipulation. Given the latter, decision makers should only consider comprehensive funding when treatment is cost effective in all patient strata.

PP65 Coordinated Implementation And Evaluation Of Promising Stroke Therapy

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ABSTRACT SUMMARY:
We demonstrate how evaluation of a promising therapy is being carried out at the same time as its limited, early implementation. Field evaluation at all four specialized centers using thrombectomy for ischemic stroke in our province and ongoing literature surveillance are being employed to develop recommendations to optimize use, in collaboration with an expert clinical committee.

INTRODUCTION:
One important objective at the Institut d’excellence en santé et en services sociaux (INESSS) is to guide the implementation of promising new technologies into Québec’s healthcare system. A comprehensive evaluation framework was recently developed that takes into account the dynamic and iterative nature of the life cycle of such technologies. This framework is presently being used to inform the decision-making process concerning use of thrombectomy for ischemic stroke.

METHODS:
A field evaluation has been conducted since April 2016 in all four of Québec’s specialized tertiary stroke centers. This real-world evidence is communicated regularly to the clinical teams as well as decision-makers. A systematic literature surveillance is also ongoing, with results being shared amongst clinical experts on our interdisciplinary advisory committee. On the basis of the generated evidence from these sources, recommendations to optimize structures, processes of care and clinical outcomes will be developed, in collaboration with the interdisciplinary committee.

RESULTS:
Thrombectomy has been shown to be safe and effective for treating ischemic stroke in the randomized trial setting in high-volume, expert centers. Real-world evidence from Québec indicates increasing use of this new technology but with wide variation across health regions. Observed times to treatment appear favorable for patients admitted directly to tertiary centers, but inter-hospital transfer is associated with important increases in delays from first door to thrombectomy. The documentation of 90-day outcomes is problematic, especially for patients transferred out of tertiary stroke centers prior to discharge. Uncertainties raised in the literature include patient selection criteria and optimal processes of care during prehospital and inter-hospital phases of the patient’s trajectory.

CONCLUSIONS:
The ongoing comprehensive evaluation of thrombectomy for ischemic stroke in Québec is a concrete example of how the use of an innovative, disruptive technology can be optimized. We acknowledge the contribution of the members of the Advisory Committee.

PP66 Hospital Cleaning, Detergent Or Disinfectant-Detergent? A Rapid Review

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ABSTRACT SUMMARY:
A review of the evidence on routine cleaning of noncritical healthcare surfaces with a low-level disinfectant-detergent showed no benefit in Healthcare Acquired Infection rates over cleaning using detergent only. Furthermore, the use of quaternary ammonium compound-based disinfectant-detergents may induce sporulation or and microbial resistance.

INTRODUCTION:
Healthcare Associated Infections (HAIs) are
potentially preventable and an important reason to maintain a clean healthcare environment. However, European and American guidelines do not concur - European guidelines recommend using neutral detergent, whilst American guidelines recommend using detergent or hospital-grade disinfectant-detergents for the routine cleaning/decontamination of noncritical healthcare environmental surfaces. Objective: To compare the effectiveness of disinfectant-detergents versus detergents and quaternary ammonium compounds (QAC) (active ingredient of many disinfectant-detergents) versus chlorine-based disinfection (CBD) in routine decontamination of noncritical healthcare surfaces on rates of HAI.

METHODS:
A rapid review of systematic reviews. Search terms: keywords and controlled vocabulary terms for the concepts of 'healthcare environmental surfaces' AND ('QAC-based disinfectants' OR 'disinfectant-detergents' OR 'decontamination') AND ('environmental contamination' OR 'colonisation' OR 'HAIs'). Filters: systematic reviews/guidelines/technology reports. Databases: Cochrane library, PubMed. Grey literature: HTA, guideline websites. Screening: Inclusion criteria = systematic reviews of disinfectant-detergents versus detergent OR QAC versus CBD in the healthcare environment on rates of HAIs. Exclusion criteria = cleaning/disinfection of body surfaces or disinfection of invasive medical devices. Quality assessment: not conducted. Data extraction: using a proforma.

RESULTS:
Searches resulted in 356 titles. Screening gave 94 abstracts, 64 full texts for evaluation, (58 excluded) and six reviews for inclusion. All reviewers cautioned that the evidence is low-level, methodologically poor, subject to confounding and didn’t address adverse outcomes. They identified twelve relevant primary studies. Five primary studies compared disinfectant/disinfectant-detergents with detergent. They found no difference in HAI rates/acquisition of methicillin-resistant Staphylococcus aureus. Seven studies compared QAC with CBD disinfection: five demonstrated CBD was superior to QAC, reducing Clostridium difficile infection rates in outbreak contexts; QAC may induce sporulation and microbial resistance; two were laboratory studies.

CONCLUSIONS:
Low-level evidence suggests no advantage in using disinfectant-detergents for routine cleaning; chlorine-based disinfection is superior to QAC-based in reducing clostridial infections; QAC agents may induce sporulation and/or microbial resistance.

PP67 Validity Of A Questionnaire Assessing Patient Medication Experiences

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ABSTRACT SUMMARY:
The PESaM-questionnaire is a promising tool to provide more scientific evidence regarding the patient’s perspective in health technology assessments and reimbursement decision-making regarding (expensive) medications, but can also support shared decision-making and appropriate use of medication at the individual patient level.
INTRODUCTION:
The Patient Experiences and Satisfaction with Medications (PESaM-) questionnaire was recently developed. It consists of two disease-specific modules, evaluating drug treatment for idiopathic pulmonary fibrosis (IPF) and atypical hemolytic uremic syndrome (aHUS), a generic module applicable to any medication, and a patient expectations module. This study assessed the validity and reliability of the generic module in a large sample of patients in the Netherlands.

METHODS:
In 2017, the PESaM-questionnaire was sent out to IPF patients on pirfenidone or nintedanib, aHUS patients receiving eculizumab, and patients using advagraf after kidney transplantation. The generic module consists of 16 items related to the domains effectiveness, side-effects and ease of use, and assesses patient experiences regarding impact of the medication on daily life and health, and satisfaction. Mean scores for each domain were calculated using a scoring algorithm. Content validity, construct validity, and reliability were assessed using recommended methods.

RESULTS:
Patients (n=188) completed the generic module of whom 48% used pirfenidon, 36% nintedanib, 11% advagraf, and 5% eculizumab. Content validity was established. Expected associations between patient experiences, satisfaction, and quality of life (QoL) were generally confirmed, demonstrating construct validity. For example, a moderate to strong positive association was found between patient experiences and satisfaction with side-effects (correlation coefficient 0.625, p<0.05), and low (positive) associations were found between patient experiences and QoL. Importantly, the PESaM-questionnaire was able to discriminate between patients using different medications. Intraclass correlation coefficients, for test-retest reliability, ranged between good and excellent for most domains.

CONCLUSIONS:
The PESaM-questionnaire is a promising tool to provide scientific evidence regarding the patient’s perspective in health technology assessments and reimbursement decision-making regarding (expensive) medications, but can also support shared decision-making and appropriate use of medication at the individual patient level. Further research will assess the questionnaire’s responsiveness and generalisability of results to other patient populations.

PP68 Urinary And Fecal Collection Devices: A Cornerstone For Autonomy

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ABSTRACT SUMMARY:
HAS has assessed the actual clinical benefit of the medical devices for urinary and fecal drainage and collection. The devices recommended can fit different situations of use and take individual preference in account. The expected benefits are a better access to the necessary devices for homecare and a reduction of health expenditure due to misuse, complications or hospitalizations.

INTRODUCTION:
To stay at home, to have social interaction or to work, people having urinary retention or having uncontrolled urine or feces leakages, need specific medical devices (MDs). In France, these MDs for urinary and fecal drainage and collection 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 low resistance to unnecessary or wasteful spending. Furthermore, a periodic update of the list is required whereas it has not been done for more than 10 years.

METHODS:
In 2016, HAS assessed the actual clinical benefit of these MDs using a standard HTA method (systematic literature review, opinions of health professionals and patients’ representatives). Manufacturers were asked to provide technical specifications on their MDs.

RESULTS:
The lack of professional guidelines and well-conducted comparative clinical trials has to be pointed out; among 516 identified publications screened, only seven recommendations, one technological review and one randomized controlled study were selected. Despite it, according to users’ experience (patients and caregivers), HAS defined for each generic description: specific indications, minimum technical specifications and, when applicable, conditions of prescribing and use. This assessment took into account the individual preferences, the role of the natural carers and the conditions, providing opportunities for patients to improve and update their self-care and rehabilitation skills.

CONCLUSIONS:
This HAS assessment of medical devices for urinary and fecal drainage and collection provides a cornerstone for the enhancement of the access to the necessary devices for homecare. The expected benefits are an improvement of the quality of life and a reduction of health expenditure due to misuse, complications or hospitalizations.

PP69 Prostatic Artery Embolisation For Benign Prostatic Hyperplasia

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ABSTRACT SUMMARY:
Prostatic artery embolisation (PAE) was introduced in the 1970s to control major bleeding after prostate surgery. The procedure was noticed to improve the lower urinary tract symptoms of benign prostatic hyperplasia (BPH) and in 2010, PAE was first investigated as an alternative treatment for BPH. This rapid health technology assessment examines the clinical effectiveness of PAE for patients with BPH.

INTRODUCTION:
Prostatic artery embolisation (PAE) was introduced in the 1970s to control major bleeding after prostate surgery. The procedure was noticed to improve the lower urinary tract symptoms of benign prostatic hyperplasia (BPH) and in 2010, PAE was first investigated as an alternative treatment for BPH. A rapid health technology assessment was carried out to inform our hospital’s decision on introducing this procedure.

METHODS:
The rapid HTA investigated the safety and clinical effectiveness of PAE for patients with BPH. The PICO elements were: Population- Patients with symptomatic BPH Intervention- PAE Comparator- Conventional management Outcomes- Adverse effects, clinical outcomes The NHS Centre for Reviews & Dissemination databases, Cochrane Database of Systematic Reviews, and PubMed (MEDLINE) were searched for systematic reviews and HTA reports.

RESULTS:
Eight systematic reviews from the most recent
two years were found. The primary evidence base consists of two randomised controlled studies of PAE versus transurethral resection of the prostate (TURP), one matched pair analysis of PAE versus open prostatectomy in patients with large prostates, and several non-comparative studies. The comparative studies showed patients had better International Prostate Symptom score, quality of life and reduced prostate volume with TURP and open prostatectomy from 1 to 24 months. With respect to adverse events, embolised patients had more adverse events than controls, particularly acute urinary retention and post-embolisation syndrome. However, controls had more abnormal ejaculation; and adverse effects from surgery naturally only occurred in controls.

**CONCLUSIONS:**

PAE appears to be a promising technology lacking long term outcomes. It has potential for patients who are not fit or not keen on surgery, or who may have large prostates, but who are still vascuarily suitable for embolisation. It would be suitable to carry out under clinical research conditions to clarify the incremental benefits of the technology and which patient groups are best served by the procedure.

**ABSTRACT SUMMARY:**

High-cost oncological combination therapies present challenges to Health Technology Assessment (HTA) agencies; the value of new drugs must be rewarded but many older drugs cannot be discounted. Inter-country variability in HTA processes affects patient access and reimbursement outcomes. In Italy, multiple assessment criteria and managed access agreements provide a partial solution. Concerns remain about budget impact and transparency in decision-making.

**INTRODUCTION:**

Health technology assessment (HTA) must adapt to support the changing health system landscapes and improve access to valuable innovation under budgetary constraints. This is exemplified by the pricing and reimbursement of high-cost combination therapies increasingly used in oncology. Variability exists in current HTA practices across different countries, resulting in discrepancies in reimbursement outcomes and patient access. Using Italy as a case study, the objective was to assess the challenges faced by HTA agencies in the negotiation of pricing and reimbursement of combination therapies.

**METHODS:**

A targeted literature review of Italian HTA agency websites was undertaken to identify any literature/guidance relating to HTA decision-making for combination oncology therapies.

**RESULTS:**

In Italy, there is no fixed cost-effectiveness threshold and decisions are based on multiple criteria. Managed market entry agreements are extensively used; price-volume agreements and drug registries are common. While this framework allows flexibility and avoids the rigidity of incremental cost-effectiveness ratio thresholds, it has raised concerns about transparency and budget impact. Combination therapies are not given specific concessions; however, market...
access for a combination of a new high-cost drug with an existing one is complex, particularly if the drugs are manufactured by different companies. The added value provided by the new drug in the combination should be rewarded while the older product benefits from the increased volume of use. The price of the older drug cannot be lowered unless the pricing and reimbursement contract is expiring or a new indication/formulation is pending, presenting a challenge to both pharmaceutical companies and HTA agencies.

CONCLUSIONS:
Combination therapies pose a challenge for HTA agencies. In the Italian system this is partially mitigated by the use of multiple criteria for decision-making and managed access agreements. However, these approaches have also led to concerns about a lack of transparency in decision-making.

INTRODUCTION:
Interventions and services for people with mental health problems can have broad remits: they are often designed to treat people with a variety of diagnoses. Furthermore, addressing mental health problems can have long-term implications for economic, social and health outcomes. This represents a challenge for health technology assessment, for which long-term trial data can be lacking. In this review, we sought to identify how analysts have tackled this problem. We reviewed the methods used to extrapolate costs and outcomes for the purpose of economic evaluation, where long-term trial data are not available.

METHODS:
We conducted a systematic review of the medical and economic literature evaluating long-term costs and outcomes for mental health interventions and services designed to treat or prevent more than two mental health conditions. We searched key databases including MEDLINE, Embase, PsycINFO, CINAHL, and EconLit. Two authors independently screened citations. Articles were excluded if they reported within-trial analyses or employed a time horizon of less than 5 years.

RESULTS:
The search identified 829 unique records. No papers could be included in the review.

CONCLUSIONS:
This review highlights the lack of research and understanding available to inform the appraisal of broad mental health interventions. In light of our findings, we consider the reasons for this lack of information and review relevant literature on the subject. Potential barriers to research in this context include: i) challenges in understanding the value of broad mental health services, such as the mental and physical health nexus, intersectoral costs and benefits, and interpersonal impacts, ii) methodological difficulties, such as data availability, patient heterogeneity, and the challenge of extrapolation, and iii) parity

PP71 Long-term Evaluation Of Broad Mental Health Interventions: A Review

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ABSTRACT SUMMARY:
Interventions and services for people with mental health problems can have broad remits. However, methods for the long-term economic evaluation of such services are underdeveloped. Supported by a systematic review, we discuss the challenges and barriers to research in this context and make recommendations for future strategies.
of esteem. We make recommendations for resolving this problem with regard to funding, data collection, modelling methods, and outcome measurement.

PP72 HRQoL Of Patients With Heart Failure Measured By The EQ-5D-3L And 5L

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ABSTRACT SUMMARY:
This study assessed HRQoL in heart failure patients using the EQ-5D 3L and 5L, and compared the measurement properties of this tool in the same sample. The findings suggest that when the patients have intermediate options to rate, they can report health status more accurately, corroborating with what was found in the literature.

INTRODUCTION:
Heart failure (HF) occurs frequently in elderly population. The recurrent symptoms are fatigue and dyspnea, but emotional symptoms also occur, such as sadness and fear. This study aims were twofold: 1) To assess the health-related quality of life (HRQoL) in a sample of patients with HF 2) to assess and compare the measurement properties of the EQ-5D-5L and the EQ-5D-3L descriptive systems in the same patient sample.

METHODS:
HF patients were recruited and interviewed at the outpatient clinic of a public hospital in Rio de Janeiro, Brazil. The sample HRQOL was measured using both EQ-5D descriptive systems (EQ-5D-3L and 5L). Patients were also asked to complete the MOS Social Support Survey Scale (MOS-SSS), as well as to disclose socio-economic and clinical information. The sample HRQOL distribution was described and characterized resorting to central tendency and dispersion values. The 3L and 5L descriptive systems were compared regarding, their redistribution properties, ceiling and floor effects, discriminatory power.

RESULTS:
Forty-nine patients were interviewed between September 2014 and November 2015. The sample HRQoL distribution appears to be slightly skewed towards left (mean < affected = most = the = regarding = population = general =
the = sim = very = is = research = in =
found = data = state = a = such = rate =
options = intermediate = have = they =
when = status = health = their = accurately =
more = report = can = patients = that =
indicate = may = activities, which = usual =
dimension = 24.49% = 5L vs. = 38.78% =
3L (e.g. = 14.29% = of = effect = ceiling =
on = reduction = significant = was = there =
systems = descriptive = and = between =
comparison = samples. = patient = other =
findings = with = consistent = which =>

CONCLUSIONS:
The results may serve as a basis for further research of cost-utility, also associated with other data and studies in literature. Consistently with literature, our findings show that EQ-5D-5L appears to improve on its 3-level counter-part by reducing the ceiling and improving discriminatory power.
PP73 Communication With Parents At Neonatal Intensive Care Units

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ABSTRACT SUMMARY:
Communication strategies of choice options to parents at the limit of viability (weeks 23 and 24 of gestation) have a possible impact on the way parents decide and hence also on the outcomes of EP infants. The main factors were institutional, personal, and informational biases as well as challenges with parental understanding, and the process of information giving.

INTRODUCTION:
Finding an agreement with parents of an extremely premature (EP) infant at the limit of viability (weeks 23 to 24 of gestation) via a shared decision-making procedure is one of the key tasks of neonatal intensive care units (NICUs). We explored the communication strategies and their possible impact on outcomes.

METHODS:
A mixed methods approach was applied. First, a comprehensive systematic literature search was conducted to gather the available evidence. Secondly, interviews with the heads of the departments for neonatology of five perinatal care centres and a clinical ethicist were conducted to gather data specific to the Austrian neonatal context. Data from the systematic literature search as well as the interviews were analysed separately and subsequently integrated into a literature review.

RESULTS:
Professional biases, challenges with parental understanding, and the process of information giving were identified as the main communication-related aspects of shared decision-making possibly influencing outcomes. Based on the literature as well as interviews, NICU professionals are prone to several types of biases: institutional, personal, and informational. Institutions create self-fulfilling prophecies by recommending active/palliative care based upon their institutional statistics, yet those vary considerably among high-income countries. Obstetricians are more reluctant to intervene actively than NICU professionals are, and labelling an EP infant by the gestational week was shown to skew the estimates for survival. Furthermore, parental understanding varies with parents and thus requires a personal approach, while the process of information giving is subject to framing bias and other cognitive biases.

CONCLUSIONS:
Communication strategies of choice options to parents have an impact on the way parents decide and hence also on the outcomes of EP infants. For that reason, it is important to address the impact of communication in guidelines as well as in in-house trainings for NICU professionals.

PP74 An Economic Evaluation Of The NSQIP® Pilot Project In Alberta, Canada

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ABSTRACT SUMMARY:
Many quality improvement interventions were initiated and implemented as a result of NSQIP® data recommendations. These interventions appear
to be effective and cost-saving for Alberta Health Services. The cost-savings would be even larger if NSQIP® was prolonged in the pilot sites and/or expanded to other sites across the province.

INTRODUCTION:
There is little evidence in Canada on benefits of utilizing NSQIP as a quality improvement (QI) tool to reduce costs and improve care in surgery. Five acute care facilities in Alberta adopted the National Surgical Quality Improvement Program (NSQIP®) in 2015 for a pilot project. We analyzed the healthcare costs and savings associated with QI interventions initiated and implemented within this pilot project.

METHODS:
The cost-savings of NSQIP® were estimated from the start of the pilot project to the end of 2017 using this formula: Gross cost-savings = N * (p1 – p2) * unit cost, where N was the number of surgical patients after the intervention, p1 was the probability of event occurrence (within 30 days of surgery) before the intervention, p2 was the probability of event occurrence after the intervention, and unit cost is healthcare cost per event. To calculate the net cost-savings, we deducted the entirety of the pilot project costs of NSQIP® and its interventions from the gross cost-savings.

RESULTS:
The QI initiatives initiated by the surgical site teams utilizing NSQIP® data recommendations have reduced surgical complications and improved overall quality resulting in significant impacts clinically and economically. The gross cost-savings of NSQIP® were estimated at $11.4 million. Subtracting the costs of NSQIP® and its interventions ($2.6 million) from the gross, the net cost-savings were $8.8 million. The return on investment ratio was 4.3, meaning that every $1.00 invested in NSQIP® would bring $4.30 in returns. The probability for NSQIP® being cost-saving was 95%.

CONCLUSIONS:
QI interventions initiated and implemented within the NSQIP® pilot project appear to be effective and cost-saving for Alberta. It is anticipated that these cost-savings would be even larger if NSQIP® as a QI tool in surgery was prolonged in the pilot sites and/or expanded to other surgical sites across the province.

PP75 Genetic Testing For Bladder And Kidney Cancer: An Interactive Evidence

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ABSTRACT SUMMARY:
Much research and commentary has touted genetic and molecular testing to improve the management of urological cancer. We created an interactive graphical tool to help policymakers examine current research, identify prevailing trends, and prioritize research efforts. The 828 included abstracts indicated that diagnosis and prognosis are the most common purposes, and the field is in an exploratory phase.

INTRODUCTION:
Recently, voluminous research and commentary have touted genetic and molecular testing to improve the management of urologic cancer. The purposes of such testing include screening, risk assessment, diagnosis, prognosis, pharmacogenetics, and monitoring (e.g., recurrence, predicting treatment response). An interactive graphical tool (“evidence map”) would help policy makers examine the current state of research, identify prevailing trends, and prioritize research efforts.
METHODS:
A professional information specialist searched MEDLINE/EMBASE for articles published in 2010 or later that primarily focused on genetic/molecular testing and either kidney or bladder/urothelial cancer. Two research analysts classified all relevant abstracts regarding to cancer type, genetic marker(s), clinical purpose(s), assay methods, publication type, and author country/region. We created an interactive map using HTML5 and JavaScript.

RESULTS:
We identified 4,731 articles, 828 (18%) of which met our inclusion criteria. Our map has interactive filters (left side) which allow flexible selection of articles and automatic updating of the counts (right side). For example, one can quickly redraw the map to focus only on U.S./European systematic reviews and meta-analyses. Research on bladder/urothelial cancer focuses on both diagnosis and prognosis, with some interest in monitoring (see figure). In kidney cancer, research on prognosis outweighs research on diagnosis. Overall, research on genetic/molecular markers is in an exploratory phase, e.g., for kidney cancer prognosis alone, 173 empirical studies considered hundreds of different markers.

CONCLUSIONS:
Assessing prognosis is a common purpose of genetic tests for both bladder/urothelial and kidney cancer. Increased research on the monitoring of bladder/urothelial cancer may be due to its high recurrence rates, whereas lower interest in genetic tests to diagnose kidney cancer may be due to effective imaging tests. For policy makers, evidence maps can inform decisions about the scope of commissioned systematic reviews as well as the targets for recommendation statements. Interactive features allow maps to be redrawn to align with users’ specific interests.

PP76 Providing Information About Rheumatoid Arthritis Guideline In Brazil

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ABSTRACT SUMMARY:
Academic detailing is a strategy to provide information with the intent of changing health professionals’ prescribing behavior. This project describes the physicians’ perception regarding the academic detailing program about the Clinical Protocols and Therapeutic Guidelines of Rheumatoid Arthritis and the Specialized Component of Pharmaceutical Service medicines request process in the National Health System of Brazil.

INTRODUCTION:
Specialized Component of Pharmaceutical Service (SCPS) is a strategy to access high cost medicines in the National Health System (NHS) of Brazil, to ensure integrality of medical treatment whose lines of care are defined in the Clinical Protocols and Therapeutic Guidelines (CPTG). To access the SCPS, the physician has to give to the patient a filled form, following some requirements and the CPTGs. In order to improve the rational prescription and facilitate patients’ access to medicines, we visited physicians and presented key information regarding the CPTGs of Rheumatoid Arthritis (RA) and the SCPS medicines request process, then, we sought to know their perception.
**METHODS:**
Specialized Component of Pharmaceutical Service (SCPS) is a strategy to access high cost medicines in the National Health System (NHS) of Brazil, to ensure integrality of medical treatment whose lines of care are defined in the Clinical Protocols and Therapeutic Guidelines (CPTG). To access the SCPS, the physician has to give to the patient a filled form, following some requirements and the CPTGs. In order to improve the rational prescription and facilitate patients’ access to medicines, we visited physicians and presented key information regarding the CPTGs of Rheumatoid Arthritis (RA) and the SCPS medicines request process, then, we sought to know their perception.

**RESULTS:**
Specialized Component of Pharmaceutical Service (SCPS) is a strategy to access high cost medicines in the National Health System (NHS) of Brazil, to ensure integrality of medical treatment whose lines of care are defined in the Clinical Protocols and Therapeutic Guidelines (CPTG). To access the SCPS, the physician has to give to the patient a filled form, following some requirements and the CPTGs. In order to improve the rational prescription and facilitate patients’ access to medicines, we visited physicians and presented key information regarding the CPTGs of Rheumatoid Arthritis (RA) and the SCPS medicines request process, then, we sought to know their perception.

**CONCLUSIONS:**
The physicians, who were mostly specialists, already had knowledge about CPTG and prescription practices of SCPS’s medicines even though, they showed interest in the visits to review and improve their knowledge and clinical practice.

**PP77 The Use Of HTA With Focus On Affordability And Value For Money: The BC**

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**ABSTRACT SUMMARY:**
A critical appraisal of included studies and economic model was used to assess the clinical and cost-effectiveness of the group Electronic Monitoring Systems for hand hygiene compliance against observation audits. This is a classic situation where the technology might be clinically effective; however, when the evidence was applied to the specific local circumstances, the cost-effectiveness differed greatly between settings.

**INTRODUCTION:**
This health technology assessment (HTA) was conducted to inform policy in the management of health technologies with a focus on affordability. In 2017, group Electronic Monitoring Systems (EMS) with aggregate feedback for hand hygiene (HH) compliance were evaluated against direct observation audits, the current standard of practice in BC.

**METHODS:**
A critical appraisal of included studies and economic model was used to assess the clinical and cost-effectiveness of the new technology.

**RESULTS:**
The clinical effectiveness analysis suggested that EMS had a positive impact on HH compliance.
ranging from 5-20% absolute improvement, leading to an absolute reduction of 1.2-1.96 MRSA infection per 10,000 patient-days. A cost-effective analysis (CEA) was tailored for the acute (ACF) and residential care facilities (RCF). Our analysis resulted in an ICER of $48,852 in ACF and $160,258 in RCF per incident MRSA case avoided. The difference in ICERs between the two settings was due to the lower baseline infection rate in residential care facility which led to small number of cases avoided. Under the current costs, the projected 10-year incremental budget impact in BC is $29.2M for ACFs and $38.5M for RCFs, even when taking into account the decrease in resources necessary to perform direct observation audits.

CONCLUSIONS:
This is a classic situation where the technology might be clinically effective; however, when the evidence was applied to the specific local circumstances, the cost-effectiveness differed greatly between settings. It is also a clear case of a technology that is sold at a single price but with different value for money depending on the potential benefits of each setting of application, which led to a substantial budget impact to replace direct observation by electronic monitoring. The application of this HTA was delivered to senior decision makers within a Province-wide structured process for priority setting for ultimate policy recommendations.

PP79 Treating Radioiodine-Refractory Thyroid Cancer: A Systematic Review

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ABSTRACT SUMMARY:
We assessed the clinical effectiveness of lenvatinib and sorafenib for the treatment of differentiated thyroid cancer that is refractory to radioactive iodine. Using systematic review methods, we identified 2 randomised trials, 13 systematic reviews and 9 observational studies. It was not possible to reliably compare the clinical effectiveness of both treatments. However, versus placebo, both treatments resulted in improved efficacy.

INTRODUCTION:
Thyroid cancer is a rare cancer. Differentiated thyroid cancer (DTC) accounts for ~94% of all thyroid cancers, and most patients require treatment with radioactive iodine. Treatment for DTC that is refractory to radioactive iodine (RR-DTC) is often limited to best supportive care (BSC). We assessed the clinical effectiveness of lenvatinib and sorafenib for the treatment of RR-DTC.

METHODS:
We searched five electronic databases (1999-2017) to identify relevant randomised controlled trials (RCTs), systematic reviews and observational studies. We extracted data on a range of clinical outcomes from the included studies. We assessed the feasibility of undertaking an indirect comparison to compare lenvatinib versus sorafenib.

RESULTS:
The clinical review identified 2 RCTs (SELECT: lenvatinib versus placebo; DECISION: sorafenib versus placebo), 13 systematic reviews and 9 observational studies. Comparative evidence (from RCTs) showed treatment with lenvatinib or sorafenib improved median progression-free survival versus placebo. Overall survival (OS) data, adjusted for crossover, only demonstrated
a statistically significant improvement for patients treated with lenvatinib versus placebo. Objective response rates for both treatments were increased versus placebo. Both treatments were associated with adverse events and dose reductions with both treatments were commonly required. Quality of life (QoL) data were collected only in the DECISION trial. It was not appropriate to compare lenvatinib with sorafenib due to differences in trial/participant characteristics, the risk profiles of patients in the placebo arms and because the proportional hazard assumption was violated for five of the six survival outcomes available from the two key trials.

CONCLUSIONS:
It was not possible to reliably compare the clinical effectiveness of lenvatinib with sorafenib. Versus placebo, both treatments resulted in improved efficacy. Research should include further examination of the effectiveness of lenvatinib and sorafenib (including QoL) and their optimal positioning in the treatment pathway.

INTRODUCTION:
We conducted an assessment on the interventions done between 2012 and 2014 to improve the treatment of homeless people with pulmonary tuberculosis in the Federal District of Brazil. The HTA were not ordered by policymakers, and it was based on the evidence-based National theoretical model compared with local interventions indicated in focus group, semi-structured interviews and in secondary data produced by the Health Secretariat. The results demonstrated that the implementation of interventions was unsatisfactory. Our objective is to present the process of feedback for policymakers and the Health Secretariat of State, particularly its challenges.

METHODS:
The feedbacks were categorized as: (i) an executive abstract with key messages (i.e.: underreporting of cases in the surveillance system; lack of primary care; underestimation of the health problem) reported to policymakers involved with the surveillance and healthcare systems; (ii) oral presentations in eight meetings organized by the research group and local policymakers.

RESULTS:
The feedbacks were categorized as: (i) an executive abstract with key messages (i.e.: underreporting of cases in the surveillance system; lack of primary care; underestimation of the health problem) reported to policymakers involved with the surveillance and healthcare systems; (ii) oral presentations in eight meetings organized by the research group and local policymakers.

CONCLUSIONS:
The feedback of an HTA not ordered by policy makers can be a challenge. Mainly, we demonstrated a negative result on research done with a vulnerable population and a neglected result. In the meantime, professionals discussed barriers to the implementation of tuberculosis control and surveillance.

PP81 Engagement Of Health Care Professionals In HTA With Negative Results

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ABSTRACT SUMMARY:
We describe the feedback of HTA with negative results to policy makers and professionals that were involved with homeless population with pulmonary tuberculosis. The engagement of healthcare managers was a challenge mainly when HTA is not ordered by policy makers and when demonstrated
disease such as tuberculosis. In the meantime, it was an opportunity for professionals of the surveillance system to discuss the implementation challenges of tuberculosis control in the homeless population.

PP82 HTA Of Drugs For Ultra Rare Diseases: Is The Type Of Evidence Unique?

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ABSTRACT SUMMARY:
Drugs for ultra-rare diseases are considered by some HTA agencies to be a unique category under the umbrella of drugs for rare diseases. We examine the type of evidence used to inform HTA of drugs for ultra-rare diseases at CADTH and compare them to those used to inform HTA of drugs for other rare diseases.

INTRODUCTION:
Drugs for rare diseases (DRD) face unique hurdles in acquiring robust and high-quality clinical evidence. A discussion regarding drugs for ultra-rare diseases (DURD) has emerged encouraging a distinct consideration for this group of drugs. Some HTA agencies, including NICE, have adopted this approach. We aim to empirically assess the evidence base used to inform the HTA of DURD compared to DORD.

METHODS:
Two reviewers (GJ and WA) independently and in duplicate screened all submissions made to CADTH since 2004 and until 2016. Submissions of drugs targeting diseases with a prevalence of 50 or less per 100,000 people were included. Withdrawn, under consideration at the time of the review, and original submissions of resubmissions were excluded. DURD were defined as treatments targeting diseases with a prevalence of 1 or less per 100,000 people. We extracted relevant clinical evidence characteristic from each submission, including the number of studies used to inform HTA, study size, study types, and type of comparator. We used the Mann-Whitney U test and odds ratio to compare continuous and categorical data, respectively.

RESULTS:
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CONCLUSIONS:
Our results suggest that a DURD defined at a prevalence of 1 or less in 100,000 people show a different clinical evidence base than DORD and may be considered a unique category.
PP83 Early Assessment Of Proof-of-Problem To Guide Health Innovation

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ABSTRACT SUMMARY:
We applied an approach to early HTA that focuses on assessing the problems and needs underlying a certain health technology innovation.

INTRODUCTION:
In the fast-paced world of health technology innovation, early HTA gained recognition as a tool to help prioritize and steer the development of those innovations that potentially add value. Much of early HTA seems technology-driven; a certain novel technology is introduced and the focus is on assessing its expected cost-effectiveness. We argue that a first step in assessing innovation would be to derive proof-of-problem through combining evidence from literature and stakeholder engagement. We applied this approach to a novel surgical instrument aimed to facilitate meniscus surgery.

METHODS:
First, we identified a broad scope of stakeholders in meniscus surgery (i.e. meniscectomy). Through interviewing them we derived key problems in meniscectomy as-is, and determined which outcomes matter most. We used stakeholder and literature input to quantify the room for improvement in current meniscectomy. Together with stakeholders we interpreted the problem quantification and conducted an early assessment of the proposed surgical innovation. Finally, we made use of this early stakeholder engagement to uncover possible barriers and facilitators to the innovation’s implementation.

RESULTS:
While all stakeholders were enthusiastic about the innovation, there was a shared perception that there is little room for improvement in meniscectomy at present. Put differently; the innovation poses a great solution to problems that may not exist. In addition, by involving a broad range of stakeholders we were able to identify barriers and facilitators to future implementation early on, such as surgeons’ preferences.

CONCLUSIONS:
We conclude that the innovation’s value may lie with applications outside of meniscus surgery. Regarding methodology, we showed how a shift of focus from solution to problem definition provides a different perspective on an innovation’s potential value, borne out of needs not currently met. In doing so, early HTA is in a unique position to help navigate the stream of health technology innovation before actual development of the innovation.

PP84 Functional Recovery Of The Elderly Following Hip Fracture Surgery

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ABSTRACT SUMMARY:
Our study examined the functional recovery and factors associated with regained mobility at
12-month post discharge from Changi General Hospital (CGH) following hip-fracture surgery in the elderly. 35% of patients regained their pre-fracture NMS at 12-months follow-up. New mobility score at 3 months predicts better one-year mobility outcomes. This study warrants further research on utilisation of community rehabilitation services within 3-months post-discharge.

INTRODUCTION:
Hip fractures are among the most common causes of disability in the elderly. The magnitude of functional recovery following hip surgery varies widely, with heterogeneity of tools used to measure mobility outcomes. Our study examined the functional recovery and factors associated with regained mobility at 12-month post discharge from Changi General Hospital (CGH) following hip-fracture surgery in the elderly.

METHODS:
This prospective cohort included 329 consecutive elderly (≥65 years old) with unilateral fragility hip-fracture who underwent surgery at CGH from December-2014 to November-2015 as part of an orthogeriatric hip fracture programme. Thirty patients who died within 12 months were excluded from analysis. Pre- and post-fracture functional mobility were assessed using the Parker’s New Mobility Score (NMS). Primary outcome was the proportion of patients who regained pre-fracture NMS at 12-month post discharge. Wilcoxon’s rank sum test and multiple logistic regression model were performed.

RESULTS:
The mean age was 80 years old (SD=7.3), 72% female, 76% received subacute rehabilitation at a community hospital; 82% were able to get about the house without an aid (pre-fracture NMS≥3) and 43% were independently mobile (pre-fracture NMS 7-9). Mean NMS at 3, 6 and 12-month follow-up visits (3.5, 4.1 and 4.4 respectively) were statistically significantly lower than mean pre-fracture NMS of 5.9 (p <0.005). 35% of patients regained their pre-fracture NMS at 12-months follow-up. A lower proportion of patients with good pre-fracture NMS (7-9) regained mobility at one year compared to those with poor pre-fracture NMS (0-6) (28% vs. 42%, p=0.07). Multivariate regression analyses showed that regained pre-fracture mobility at one year is significantly associated with pre-fracture NMS (OR= 0.57, P=0.000) and NMS at 3-months (OR=1.62, P=0.000).

CONCLUSIONS:
New mobility score at 3 months predicts better one-year mobility outcomes. This study warrants further research on subsequent utilisation of community rehabilitation services, fear of falling and other psycho-social factors which may influence regained mobility within 3-months post-discharge from the acute hospital to further improve functional recovery.

PP85 Including Patient Perspectives In Health Technology Assessment Reports

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ABSTRACT SUMMARY:
We describe involving two members of the public in a Health Technology Assessment. Our systematic
INFORMATION:
Public involvement in health technology assessment (HTA) projects is increasingly recognised as being an essential component of the entire research process but how that involvement is reflected in the published reports of individual projects varies widely. We describe our experience of involving two members of the public in a complex HTA assessing the clinical and cost-effectiveness of surveillance imaging following endovascular abdominal aortic repair (EVAR).

METHODS:
A systematic review of randomised and non-randomised studies of diagnostic imaging technologies in adults undergoing surveillance following EVAR for abdominal aortic aneurysm (AAA). Currently, no patient support groups targeted solely at EVAR patients exist. Two patient representatives who were currently undergoing EVAR surveillance were, therefore, recruited from the NHS Scottish Health Research Register (SHARE) to become project advisors. The patient representatives attended face-to-face and telephone meetings where they were able to comment on the project and share their personal, lived experiences of being a patient undergoing EVAR surveillance.

RESULTS:
Two non-randomised comparative studies and 25 cohort studies were identified for inclusion in our review. Data reported in these studies included clinical outcomes, such as mortality and re-intervention rates. By contrast, the patient representatives described patient-centred issues, such as anxiety, continuity of care, and the quality of patient and health professional communication. In our HTA report, we supplemented the clinical information provided by the studies included in the systematic review with the patient perspective data with the aim of informing clinical practice. We also invited the patient representatives to contribute to writing the plain language summary.

CONCLUSIONS:
Identifying members of the public to become advisors to our project was challenging and time consuming; however, both patient representatives provided data that supplemented the HTA project findings and provided invaluable insights for those who design and deliver EVAR surveillance protocols.

PP86 Impact Of HTA On Drug Price Negotiations: Canada

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ABSTRACT SUMMARY:
This research investigated the role of HTA recommendations on drug price negotiations (in Canada, these are conducted by separate agencies). The role of HTA-reported ICERs in price negotiations was specifically examined. Key findings include the observation of major differences between oncology and non-oncology drugs. For all drugs, negotiations were initiated despite conventionally-unacceptable ICERs.

INTRODUCTION:
Subsequent to review by Canada’s two central health technology assessment (HTA) agencies, confidential drug prices are negotiated by the pan-Canadian Pharmaceutical Alliance (pCPA) on
behalf of public drug plans. This analysis is the first to examine characteristics of drugs considered for negotiation, and the duration of negotiations, from inception in 2011 to August 2017. The objectives were to identify how HTA recommendations impacted price negotiations, and in particular the role of health economics in the process.

**METHODS:**
The dataset contained 208 drug-indications from the pCPA archives: those with a decision to negotiate (155) or a decision not to negotiate (53). Data were abstracted from the publicly-maintained websites of the respective agencies; descriptive statistics were conducted.

**RESULTS:**
There was close but imperfect alignment between the health technology assessment (HTA) agency listing recommendation and the pCPA’s decision to negotiate. The incremental cost-effectiveness ratio (ICER) of negotiated drugs (as estimated by HTA agencies) approached $200K/QALY for oncology drugs, but was closer to $100K/QALY for non-oncology drugs – revealing that negotiations would require a substantial discount to achieve conventionally ‘acceptable’ value-for-money. ICERs were influential to non-oncology drug recommendations (and were increasingly used to set pCPA negotiation targets) but did not appear to influence oncology drug HTA recommendations. The time period required to initiate negotiations was dramatically shorter for oncology versus non-oncology drugs (53 versus 263 days), and also differed markedly between therapeutic areas. The time period for pCPA activities was surprisingly similar for drugs recommended without a price condition and for those conditional on a price reduction.

**CONCLUSIONS:**
These findings revealed an implicit prioritization pattern at the pCPA, as well as the evolving role of health economics in Canada’s two-stage reimbursement process.

PP87 How Does A Patient Access Scheme Affect SMC Decision-making?

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**ABSTRACT SUMMARY:**
A look at how the inclusion of Patient Access Schemes affects reimbursement decisions made by the Scottish Medicines Consortium.

**INTRODUCTION:**
Patient Access Schemes (PAS) are used to obtain market access for drugs when they might otherwise not be able to gain reimbursement. In Scotland, in particular, PAS are used to improve the cost-effectiveness of drugs and to enable patients to receive access to cost-effective, innovative medicines.

**METHODS:**
We used the Context Matters data model to look at reimbursement decisions for the Scottish Medicines Consortium (SMC), from 2009-2016. We excluded non-submissions and abbreviated submissions, and separated initial submissions from resubmissions. We then looked at decision trends for submissions with and without a PAS.

**RESULTS:**
At the time of the analysis, 392 initial reimbursement decisions had been made across 65 disease conditions. Of those decisions, 31% included PAS. By therapeutic area, ophthalmology decisions were the most likely to include PAS (59%), while endocrine/metabolic decisions were the least
likely to include PAS (5%). For initial submissions that did not include a PAS, 69% (n=269) received positive decisions compared with 71% (n=123) of submissions that did include a PAS (p=0.75). For resubmissions that did not include a PAS, 64% received positive decisions (n=52) compared with 79% of resubmissions that did include a PAS (n=48) (p=0.08). Of the initial submissions that included PAS but received negative decisions (n=35), 71% had greater clinical efficacy/effectiveness than their comparators but had either lower or uncertain cost-effectiveness (54% and 17%, respectively), and 14% had insufficient clinical evidence.

CONCLUSIONS:
Upon initial submission, the inclusion of a PAS makes a drug as likely to receive a positive reimbursement decision as a negative decision, but including a PAS possibly improves the chances of receiving a positive decision in subsequent resubmissions. When a submission includes a PAS, the company must still prove a drug’s cost-effectiveness in addition to its greater clinical efficacy.

ABSTRACT SUMMARY:
The medication delivery is one of the interventions most common in the clinical practices. It is one of the activities of major importance and one of the most critical ones in the intensive care units. So, it requires the direct involvement of the nurses and the high precision infusion pumps in order to increase the infusion accuracy.

INTRODUCTION:
The medication delivery is one of the interventions most common in the clinical practices. So, it requires the direct involvement of the nurses and the high precision infusion pumps in order to increase the infusion accuracy. Any mistake in the medication delivery process can lead to the medication error, resulting in the adverse events with considerable increases in the hospital stay length and cost. Research studies should analyze more this area in emerging countries, as their realities differ many times deeply from the realities of developed countries, where most of the literature of this area has been developed. This research study analyses this area in Brazil, a leading emerging country. Anyway, the incorporation of these technologies in health services have clashed in two major problems: the uncertainties of its effectiveness in reducing the adverse drug event rates related to the dose errors during the infusion and the high cost of their inputs. Question: How are drug library infusion pumps cost-effective to reduce the adverse drug event rates? Objectives: To analyze the cost-effectiveness and to calculate the incremental cost-effectiveness ratio of the use of intelligent drug library infusion pumps to reduce the adverse drug event during the intravenous medication delivery to the pediatric and the neonatal patients.

METHODS:
Cost-effect based on the decision-tree framework, considering two scenarios as baseline case: the reference one, which uses the conventional infusion pumps to make the intravenous medication delivery with the volume greater than
60 ml, and an alternative one, which uses the drug library infusion pumps. The analysis is with the Unified Health System (Brazil’s publicly funded health care system) perspective. The Monte Carlo simulations addressed the uncertainties of the framework. The effectiveness measure avoided the adverse drug event.

RESULTS:
The drug library infusion pumps are more cost-effective than the conventional infusion pumps. The probabilistic analysis showed the drug library infusion pumps to be more cost-effective than the conventional ones, ratifying what had already been revealed by acceptance curve, which demonstrated that the drug library infusion pumps are more likely to be cost-effective compared to the conventional infusion pumps (with a minimum of the incremental cost-effectiveness of USD 1.501,28).

CONCLUSIONS:
The study demonstrated that the use of the drug library infusion pumps in the pediatric and the neonatal intensive care unit can improve the results for the adverse drug event reduction strategy.

PP89 Living-Lab Concept: An Innovation Hub For Elderly Residential Care

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ABSTRACT SUMMARY:
Many countries face the challenge of ageing populations. ‘Living labs’ can provide real-life test and experimentation environments where users and producers co-create innovations and large-scale data can be collected. Strategic establishment of a cluster of residential settings providing 24/7 living labs plus an innovation hub is described to generate new technologies, blueprints for data capture, and ethical and organisational guidelines.

INTRODUCTION:
Many countries face the challenge of an ageing population. Development of suitable technologies to support frail elderly living in care homes, sheltered housing or at home remains a concern. Technology evaluation in real-life conditions is often lacking, and randomised controlled trials of ‘pre-designed’ technologies are expensive and fail to deliver. A novel alternative would be ‘living labs’- real-life test and experimentation environments where users and producers co-create innovations and large-scale data can be collected.

METHODS:
Living labs and Data Driven Research and Innovation (DDRI) Programme: the goal is to use data driven analytics and insights to support technology development for independent living, healthy ageing and more cost-effective care. Cluster of residential settings providing 24/7 living labs plus innovation hub. DDRI also encompasses private vehicles (e.g. sensors in cars) to enable elderly to drive safely for longer. Collaborations have been established with Universities in England, Scotland and Ireland and with international industry partners.

RESULTS:
HTA projects underway to: 1) develop machine learning algorithm from non-intrusive sensor data to build a well-being representation for individual residents/citizens; 2) evaluate innovative
interventions for good sleep environment and nutritional support; 3) establish ethics framework to ensure that needs of residents, families and staff are embedded in design, communication, and evaluation of future DDRI projects. In addition: a) fifteen interdisciplinary doctoral fellowships are in place; b) six universities are working closely with individual living lab settings; and c) an innovation hub has been established in one care home for horizon-scanning and strategic technology selection and implementation.

CONCLUSIONS:
Over the next 5 years, a national network of 20 residential Living Labs with over 1,500 participants will be established. Generation of new user-led technologies, blueprints for capture of individual data at significant scale, and ethical and organisational guidelines will be developed. Intelligent mobility via data capture/feedback in vehicles will be established.

PP90 The Value Of MCDA Use On Health Technology Decision-making Process

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ABSTRACT SUMMARY:
The use of MCDA in HTA studies offers a comprehensive technique for decisions which different criteria and stakeholders should be engaged. A systematic review was conducted. The increase of studies on MCDA and healthcare point to the possibility to add different criteria, engaging people with different known level, and turning information transparent.

INTRODUCTION:
The use of Multicriteria decision analysis (MCDA) in Health Technology Assessment (HTA) studies has been more common due the fact that MCDA offers a comprehensive technique for decisions which different criteria and stakeholders should be engaged. Although how MCDA contributes to the HTA decision making process is an issue to be investigated. A systematic review was carried in order to provide an overview of the benefits identified in MCDA applications for the strategic HTA decision making process.

METHODS:
A systematic review developed by Philip Wahlster et al. (2014) was updated. The papers were analyzed with the purpose to answer how MCDA is being connected with traditional HTA and to identify opportunities through the MCDA application. 965 papers were found and at the end 43 articles were selected because are detailing MCDA application oriented to tactical and strategic decision making process. All the review flow was conducted by 2 researchers.

RESULTS:
Considering the period, the number of studies tends to increase, 76% were published between 2014 and 2017. About MCDA methodology, 10 used Analytical Hierarchy Process (AHP), 4 multi attribute theory, and others refer the methodology like only “MCDA”. 17 studies also included health technology economic analysis, in special Cost Effectiveness, safety and technological innovation. The authors discuss MCDA adds value since it allows engage different stakeholders at the decision making process (22).

CONCLUSIONS:
The increase of studies on MCDA and healthcare point to the possibility to add different criteria, engaging people with different known level, and turning information transparent. Although, in comparison with other technical areas, the use of MCDA in healthcare is more focused on achieve
the decision about adding the new technology and to show how to engage stakeholders than to explain how to develop the algorithms and methodologies.

PP91 Economic Evaluation Of Treatments For Acute Ischemic Stroke In Italy

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ABSTRACT SUMMARY:
The aim is the assessment of the cost-effectiveness of mechanical thrombectomy (MT) with the SolitaireTM Revascularization Device (stent retriever) for the treatment of acute ischemic stroke (AIS) in patients with large vessel occlusions (LVOs), comparing MT plus intravenous tissue plasminogen activation (MT plus IV t-PA) versus IV t-PA alone, in Italy.

METHODS:
A Markov model was used to simulate costs and benefits of MT plus IV t-PA and IV t-PA alone over a 5-year time horizon and considering the perspective of the Italian National Health Service (NHS). Results are reported in terms of Incremental Cost Effectiveness Ratio (ICER). Deterministic and probabilistic sensitivity analyses are carried out in order to test the robustness of the results.

RESULTS:
Total costs of MT plus IV t-PA and IV t-PA alone are equal to €31,798 and €34,855 respectively. The MT allows incremental QALYs for 0.77, determining a dominant ICER. The utilities associated to the mRS health states are the parameters with the highest impact on the results. Multiway sensitivity analyses determined a 90% probability of dominance.

CONCLUSIONS:
MT plus IV t-PA for AIS patients with LVO is cost-effective in the Italian context achieving better results, both in terms of efficacy and in terms of resource consumption.
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ABSTRACT SUMMARY:
Patient preference together with multi-criteria decision analysis (MCDA) can be used for value-based technology assessments but correlations in preference data have been largely ignored. This study explores the use of copula’s for fitting this type of data and finds them flexible and appropriate for the task. We recommend the reporting of copula parameters in preference studies.

INTRODUCTION:
Preference elicitation studies have been proposed together with multi-criteria decision analysis (MCDA) models for value-based and patient-centered healthcare decisions. Until now, correlations between attribute weights have been largely ignored. Copulas are a flexible method for fitting multivariate distributions and this study aims to explore their use for fitting multivariate preference distributions.

METHODS:
We fitted copulas to public preference data for seven attributes of lung cancer screening. Maximum likelihood estimation was used to fit marginal density distributions for each attribute. A vine copula was used to capture dependencies. We compared Monte Carlo samples from the copula to samples obtained with normal, beta, and Dirichlet distributions.

RESULTS:
Most fitting methods estimated mean attribute weights and standard deviations well (mean differences ≈0). Copulas had the lowest differences in skewness and kurtosis compared to the dataset (0.6 and 4.5, respectively), while the normal distributions had the highest difference (2.3 and 8.4, respectively). The multivariate normal distribution had the highest log likelihood (17843) and the Dirichlet distribution had the lowest (809). The multivariate normal distribution had a lower Frobenius norm than the copula (0.0 compared to 0.1). The MCDA assumptions were met best by the Dirichlet distribution (100%) while the normal distributions yielded negative weights in 23% of samples.

CONCLUSIONS:
Using a large dataset, we have illustrated that copula functions are a flexible and appropriate approach for fitting multivariate preference distributions. We recommend the reporting of copula parameters in preference studies and recommend further research into the application of copulas in personalized healthcare.

PP93 HTA Role In coreHEM, A Multi-Stakeholder Core Outcome Set Project

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ABSTRACT SUMMARY:
The coreHEM Initiative is a project that used a multi-stakeholder consensus process (including patients, clinicians, payers, HTA representatives, and industry representatives) to determine a core outcome set for gene therapy in hemophilia. The use of a core outcome set with relevant and consistent outcomes can increase the predictability and consistency of technology assessment.

INTRODUCTION:
Hemophilia gene therapy trials demonstrate a “cure” could be achievable, changing disease
management. coreHEM aims to develop multi-stakeholder consensus around a clearly defined, core outcome set (COS) - a minimum set of outcomes that should be measured and reported in all clinical trials of a specific condition - that will demonstrate and allow differentiation of the effectiveness and value of gene therapy relative to the current standard of care. HTA frequently suffers from a lack of relevant, consistently reported outcomes. When uniformly implemented, COS increase the predictability and consistency of appraisals, coverage, and reimbursement decisions by payers and HTA agencies.

METHODS:
A COS was developed using a modified Delphi process, including online surveys and an in-person consensus meeting. A literature review and key informant interviews were used to create an initial list of outcomes for voting. Participants (patients, including representatives from the National Hemophilia Foundation and the World Federation of Hemophilia, healthcare providers, payers, HTA agencies, regulators and industry representatives) condensed and prioritized the list by rating each outcome on a scale of 1 (not important to include) to 9 (essential). Participants could also suggest outcomes for voting. Outcomes were eliminated from consideration if <70% rated the outcome from 7-9, unless the patient stakeholder group average score was ≥7.

RESULTS:
After two Delphi rounds, there was consensus on three outcomes: frequency of bleeds, factor activity level and duration of expression. Additional outcomes in the domains of pain, physical functioning, emotional functioning, resource use, and perceived health status will be included. Adverse events of interest were evaluated and will be separately reported.

CONCLUSIONS:
Including the coreHEM COS in clinical development programs will ensure that relevant, consistent outcomes are available for decisions by HTA agencies, clinicians and patients. This should result in faster access to novel, high-value therapies for appropriate patients.

PP94 Canadian Cost Utility Analysis For Treatment Of Osteoporosis

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
The objective of this study was to identify the optimal osteoporosis treatment based on a women’s age and fracture history. A cost utility analysis was conducted using a Markov model. Based on a threshold of $50,000 per QALY, alendronate is the optimal therapy for osteoporotic women who can tolerate oral bisphosphonates regardless of age or fracture.

INTRODUCTION:
The objective of this study was to conduct an independent analysis to identify the optimal osteoporosis treatment based on a women’s age, fracture history and their ability to tolerate oral bisphosphonates adopting the practices recommended in the recently revised Canadian economic guidelines.

METHODS:
A Markov model was developed which allowed conduct of a cost utility analysis comparing alendronate, etidronate, risedronate, zoledronic acid, denosumab and no pharmacotherapy. Analysis incorporated data on the fracture risk, and the associated costs, mortality and disutility and the effect of treatment. Stratified analysis was conducted based on a women’s age and fracture history. Expected values were obtained through probabilistic analysis with methodological and
structural uncertainty assessed through scenario analyses.

RESULTS:
For all patient strata, risedronate, etidronate and denosumab were subject to dominance. In comparison with no therapy, alendronate was either dominant or was associated with a low incremental cost per QALY (ICER) – range $4,676 to $6,471. In comparison with alendronate, zoledronic acid was either dominated or associated with a high ICER – range $535,881 to $2.7 million.

CONCLUSIONS:
Based on a threshold of $50,000 per QALY, alendronate is the optimal therapy for osteoporotic women who can tolerate oral bisphosphonates regardless of age or fracture history.

INTRODUCTION:
São Paulo city in Brazil implement social and healthcare for homeless people with pulmonary tuberculosis since 2007. We conducted an assessment on the interventions realized with data of 2015 based on National theoretical model and an overview of systematic reviews. The HTA was ordered by National policymakers. The results demonstrated that the interventions were satisfactory. The municipal secretariat implemented actions improving the National recommendation and adopted incentives for increase adherence of treatments. Our objective is to describe the feedback process for Health Secretariat of municipality.

METHODS:
The feedbacks were categorized as: (i) an executive abstract with key messages (i.e.: 97% of notified cases underwent sputum smears; 18.9% of hospitalized cases for social causes; 58.5% of cases were cured) reported to policymakers involved with the surveillance program; (ii) three meetings were organized jointly by the research group and local policymakers: project phase (2) and results phase (1).

RESULTS:
In 2016, we conducted the meeting to present the results. Thirty-nine professionals involved in the primary care team working on the streets (34.87%) and the Tuberculosis Surveillance and Control Program (5.13%) were present. The main barriers presented by the professionals were issues of human resources (i.e.: suboptimal professional staff, two groups of different social organizations responsible for health care). The main facilitators presented by professionals were: (i) homeless-peers as health care workers; (ii) network between primary care and surveillance programs; and (iii) periodic training.

CONCLUSIONS:
We have an huge acceptance, but despite the positive results, it was a opportunity to discuss of the sustainability of incentives to adherence of treatment adopted by the policymakers.
treatment adopted by the policymakers, such as meal allowance, housing support to improve social conditions of the homeless people.

PP96 Which Data For Dual Mobility Cups In Hip Arthroplasty?

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ABSTRACT SUMMARY:
The French National Authority for Health (HAS) has assessed prospectively the actual benefit of all the dual mobility hip implants marketed in France. Most of them have been qualified for reimbursement by the national health insurance system. A brand name follow up will be realized for the next five years before their reassessment.

INTRODUCTION:
The dual mobility concept was invented to prevent post-operative hip dislocation. It has been used for 40 years, but demonstrative data are limited and many designs are available. In France, many implants for hip arthroplasty are reimbursed by the national health insurance system through a generic description that corresponds to a class of products having the same indications and technical features (designs, coatings, types and systems of fixation). Dual mobility cups were one of them until 2017. The ministry decided to set up the assessment of each design of dual mobility cup, marketed in France for their reimbursement.

METHODS:
Manufacturers concerned submitted to the French National Authority for Health (HAS) medico-technical application dossiers with technical characteristics and clinical data available. HAS has assessed prospectively the actual benefit of these implants.

RESULTS:
Sixteen companies marketing 42 kinds of dual mobility cups associated with 22, 28 or 32 mm femoral heads and cementless or cemented fixations have submitted dossiers. Their demands were argued on non-specific and specific clinical data. For few implants with non-specific clinical data, arguments to demonstrate the equivalence towards others implants were not accepted for the reimbursement. For other implants, the specific data available were only low quality studies. No randomized controlled trial has been identified. When the risk/benefit balance was acceptable, the implants were approved for reimbursement and HAS required post-launch data to assess safety on real life on the dislocation rate and the long-term survival of these implants.

CONCLUSIONS:
All the dual mobility cups marketed in France have been assessed by the French HTA Authority. Most of them have been approved for reimbursement, despite of low level of evidence. The brand name inscription enables a specific follow up and the analysis of a post-approval study results in five years.

PP97 Delineating Key Components Of Community Paramedicine Programs

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ABSTRACT SUMMARY:
This presentation will describe key components of currently existing community paramedicine programs in Australia, Canada, the United Kingdom, and the United States, using a framework originally developed in Australia, to inform policymaking on the design, development, and implementation of community paramedicine programs in the province of Alberta, Canada.

INTRODUCTION:
Population growth, epidemiological and demographic transition, and a shortage of healthcare workers are affecting health care systems in Australia, Canada, the United Kingdom (UK), and the United States (US). Community paramedicine (CP) programs provide a bridge between primary care and emergency care to address the needs of patients with low acuity but lack of access to primary care. However, how to capture the key characteristics of these programs and present them in a meaningful way is still a challenge. The objective of this presentation is to identify and describe the characteristics of currently existing CP programs in the four countries to inform policy-making on CP program development in Alberta.

METHODS:
Information was obtained from systematic reviews, health technology assessments, general reviews, and government documents identified through a comprehensive literature search. The characteristics of the CP programs are described using a framework originally developed in Australia with three categories: 1) the primary health care model, 2) the health integration model (in Australia, called the substitution model), and 3) the community coordination model.

RESULTS:
In general, Australia emphasizes rural/remote paramedics, whereas Canada, the UK, and the US implement expanded paramedic practice within different environments including rural, remote, regional, and metropolitan settings. Extended care provider programs have been intensively investigated and widely implemented in the UK. While the identified CP programs vary in terms of program components, designation of providers, skill mix, target population, and funding model, the majority of these CP programs fall under the primary health care category of the Australian framework.

CONCLUSIONS:
Transitioning from hospital-based to community-based health care requires careful consideration of all key factors that could contribute to future program success. Delineating key components of CP programs using the Australian framework will help Alberta decision-makers design, develop, and implement appropriate CP programs that adequately address local needs.

PP98 Are Multi-attribute Utility Instruments Reflecting QoL In Cancer?

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ABSTRACT SUMMARY:
Empirical evidence suggests that some MAUIs are more sensitive than others in reflecting the quality of life (QoL) in particular disease areas. A systematic
literature review on the mapping methods used to determine utilities from cancer-specific instrument was conducted. The literature suggests that differences exist between MAUIs in their capacity to capture the QoL dimensions of the cancer-specific instruments.

**INTRODUCTION:**

Health state utilities measured by the generic multi-attribute utility instruments (MAUIs) differ. Empirical evidence suggests that some MAUIs are more sensitive than others in reflecting the quality of life (QoL) of patients in particular disease areas. Additionally, in order to estimate utilities based on cancer-specific health-related quality of life instruments (CSQoLs), a number of mapping functions have emerged. Although it is common practice to apply a CSQoL instead of a MAUI in clinical trials, CSQoL cannot be used to estimate utility values for economic evaluations. Mappings based on MAUIs that are not sensitive to changes in cancer patients’ QoL may result in misleading approximations of utilities that could affect allocation of resources. The study objective is to explore the validity and sensitivity of the major MAUIs to variation in the QoL measured by cancer-specific instruments. We aim at investigating (1) the sensitivity of the general MAUIs scores to changes in the CSQoL, and (2) whether particular dimensions of the general instrument are more sensitive.

**METHODS:**

A two stages systematic literature review is conducted. First, an update of the review done by McTaggart-Cowan et al. (2013) on the mapping methods used to determine utilities from cancer-specific instrument. Second, an analysis of studies that measure the relationship between CSQoLs and general MAUIs.

**RESULTS:**

The literature suggests that differences exist between MAUIs in their capacity to capture the QoL dimensions of the CSQoLs. Additionally, the main challenges in building an appropriate mapping function for deriving utilities values from CSQoL are identified.

**CONCLUSIONS:**

In the context of Health Technology Assessment and cost-effective analysis, it is crucial to carefully select and report the CSQoL and MAUI involved in the estimation of the additional benefits. Policy makers need to be awarded of the sensitivity of the instruments to changes in QoL in relation to the CSQoL dimensions QoL.

**PP100 Rapid Evidence Assessment In Hospital Health Technology Assessment**

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**ABSTRACT SUMMARY:**

A systematic review was performed to evaluate the appropriateness of REA products for HB-HTA unit. Evidence suggested that rapid reviews appear to be a more robust methodology for HB-HTA producers than Mini-HTA, and could be probably more useful to support health decision making in local context.

**INTRODUCTION:**

Systematic review (SR) is the most valid and reliable scientific evidence to evaluate the effectiveness of healthcare interventions. However, substantial resources and months are required to conduct such a review. Most hospital-based health technology assessment (HB-HTA) units don’t have time and academic team to produce SR. Rapid
evidence assessment (REA) may represent, in this local context, an interesting avenue. The aim was to evaluate characteristics of REA and their impacts on healthcare decision making.

METHODS:
A SR was performed in several databases and grey literature to search data on REA including Mini-HTA and rapid reviews methodologies through March 2017. Data selection, extraction and quality assessment were performed by two independent researchers. Outcomes were about REA’s methodology including question, search strategy, inclusion criteria, study selection, data extraction, quality assessment, critical appraisal and impacts on decision making.

RESULTS:
Twelve publications on REA have been included. More similarities were found in the methodology between rapid review and SR than with Mini-HTA. Shortcuts in performing rapid reviews included evaluation scope, number of databases, gray literature websites, studies design mainly SR, reviewers number, critical appraisal and production time (3 to 6 months). Study selection and data extraction by two independent reviewers in rapid reviews were seen in 34 to 38% and 10 to 22%, respectively. Furthermore, assessment quality was optional. Although it is performed within a short timeframe (2 months), methodology to conduct Mini-HTA is not well defined in the literature. The scope is mainly to support decision making in the introduction of new medical devices. Impacts of REA on local health decision making process are not well documented.

CONCLUSIONS:
Methodology to conduct REA is quite diverse. According to the data available, rapid reviews is a more robust methodology for HB-HTA producers than Mini-HTA. Although impacts were not well reported, rapid reviews could be more useful to support health decision making in local context.

PP101 Anti-TNF Pivotal Studies: Psoriatic Patients’ Nebulous Data

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ABSTRACT SUMMARY:
Usually, the first choice for systemic drug treatment for moderate to severe psoriasis is methotrexate. So, novel drugs for psoriasis should ideally be studied in a population that did not respond to this treatment. This poster investigated the profile of patients enrolled in pivotal anti-TNF (infliximab, adalimumab and etanercept) phase III, randomized, controlled trials regarding the use of previous drugs.

INTRODUCTION:
Health systems’ guidelines and dermatology associations advise that the systemic drug treatment for moderate to severe psoriasis should be initiated with synthetic immunosuppressive or immunomodulatory drugs such as methotrexate, cyclosporine and acitretin. The Brazilian Ministry of Health recommends methotrexate as the first choice. Therefore, novel drugs for psoriasis should ideally be studied in a population that did not respond to this treatment. Our objective was to investigate the profile of patients enrolled in pivotal anti-TNF (infliximab, adalimumab and etanercept) phase III, randomized, controlled trials regarding the use of previous drugs, especially methotrexate.
**METHODS:**
Revision of published data of three pivotal studies (1 with infliximab, 1 with adalimumab and 1 with etanercept) evaluating the treatment of plaque psoriasis in adults.

**RESULTS:**
Forty three percent of patients included in the infliximab study had received methotrexate previously to study entry. This information is not available in the adalimumab study, in which a “non-biological systemic treatment” group was created to include all synthetic immunosuppressive or immunomodulatory drugs used (23% of patients where in this category). In the etanercept study, the information is even less clear. Patients using systemic drugs or phototherapy were grouped in the same category, with 25% of patients entering the study without using any of these as previous therapy. Efficacy was not assessed according to previous use of systemic treatment.

**CONCLUSIONS:**
Pivotal studies supporting the commercialization approval of anti-TNFs (infliximab, adalimumab and etanercept) for psoriasis treatment included patients who did not use prior recommended systemic medications, which impairs the translation of efficacy results to real life patients. The efficacy of anti-TNFs in these real life patients may be less relevant than demonstrated in the studies, since the results were influenced by data from patients who were naive of the usual systemic treatments.

**AUTHORS:**
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**ABSTRACT SUMMARY:**
Through early stakeholder engagement and focused discussions about existing deprescribing interventions, we developed an approach to developing and adapting a local deprescribing intervention in Care Homes that is cognisant of contextual considerations.

**INTRODUCTION:**
Deprescribing - process reducing or stopping drugs when the balance of benefits and harms may no longer be in a person’s interests is a key aspect of managing multimorbidity and polypharmacy in older people. Several deprescribing interventions have been developed (e.g. in Australia and Canada), although significant challenges for successful implementation remain. Through key stakeholder consultation in the Care Home setting in the South West of England, we take the initial steps to develop a context-informed deprescribing approach. Engaging stakeholders from the outset gains insight into acceptability, feasibility, and relevance of deprescribing interventions developed elsewhere informing co-production of an effective, implementable approach.

**METHODS:**
Consultation workshops were held with two groups of stakeholders: 1) Care Home residents and their families; 2) Care Home staff and health care professionals (GPs, medical specialists, pharmacists, nurses, allied health professionals). Focus groups were held with each group separately, to understand perspectives on deprescribing in general; contextual considerations; and perspectives on deprescribing interventions developed in other countries. A combined focus group then considered components of a deprescribing intervention for Care Homes. Qualitative data were audio recorded, transcribed, and thematically coded.
RESULTS:
Participants described the nature of local relationships, dynamics, structures, and resources, as important considerations in the development of a deprescribing approach in Care Homes. Perspectives and concerns around deprescribing among the stakeholder groups varied although the importance of eliciting local stakeholder feedback in the early stages of developing a deprescribing intervention was a common thread.

CONCLUSIONS:
Early engagement and co-production are crucial in developing an approach to deprescribing in Care Homes. The combination of stakeholder involvement and qualitative research is important for developing an effective, contextually relevant intervention as the balance between interests can be incorporated into the approach. Leveraging the experience in other countries is a novel and valuable step.

PP103 The Significance Of Stakeholder Involvement And Early Support Methodol

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ABSTRACT SUMMARY:
Procurement is one tool for the public sector to acquire need-based, innovative and effective solutions. To succeed in purchasing services that succeed in improving patient’s outcomes and optimise cost of care, the process must be accompanied with tools for early decisional support. The present review identified tools for early decisional support that address risks and stepwise health care management support.

INTRODUCTION:
Procurement is one tool for the public sector to acquire need-based, innovative and effective solutions. To succeed in purchasing services that succeed in improving patient’s outcomes and optimise cost of care, the process must be accompanied with tools for early decisional support. Documenting the effects of health care innovation is therefore fundamental when dealing with prioritizing adequate technology. The aim of the present study was to review the literature to identify early assessment methodology applicable to innovative procurement processes.

METHODS:
A scoping review was performed in January and February 2017 with the objective of selecting literature reporting on early assessment of health innovation. Methods for early assessment of health innovation were identified with the aim of investigating whether the methods change depending on where in the innovation process (development, introduction, and early diffusion) they are applied, and if the literature pointed to dominant methods. Next, critical elements of the innovative procurement process were identified, and methods relevant to the need-based phase of procurement were assessed.

RESULTS:
In total 1064 articles met the search strategy. Based on predefined inclusion and exclusion criteria, 39 articles were included in the study. When viewed in the light of innovative procurement, stakeholder insight was an important source of data in early assessment of potential benefits of health innovation. Such data can be applied in scenario analysis to provide necessary outcome overviews and direct and accelerate the procurement process. Further, various simulation and analysis methods may be used in new ways to increase the impact.
of the scarce availability to data in early innovation phase.

CONCLUSIONS:
The present review identified tools for early decisional support that address risks and step-wise health care management support. Information based on the present review will also be addressed in Panel 26 "Accelerating Value Based Health Care with Innovative Procurement and Early Decisional Support".

PP104 Australian Government Support Of The Bariatric Surgery Registry

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
The Australian Government currently supports a number of clinical quality registries including the Bariatric Surgery Registry (BSR). Bariatric surgery is currently subsidised by the Australian Government and service utilisation is increasing at a rapid pace. When long-term data becomes available, the BSR will inform a health technology assessment review of current and emerging bariatric surgery services in Australia.

INTRODUCTION:
The Australian Government currently supports a number of clinical quality registries including the Bariatric Surgery Registry (BSR). Bariatric surgery is subsidised by the Australian Government through the Medicare Benefits Schedule (MBS), a key component of Australia’s universal health care program. The decision to support the BSR was influenced by recommendations from the Medical Services Advisory Committee (MSAC), following their review of MBS-listed bariatric services in 2011. MSAC deduced that bariatric surgery was a valuable intervention and likely to be cost-effective, but noted that long-term data on outcomes was lacking.

METHODS:
The BSR was initiated by the Obesity Surgery Society of Australia & New Zealand in 2012 and is operated by Monash University. The Australian Government commenced financial support of the BSR in 2014. The aim of the BSR is to monitor the safety and quality of bariatric surgery in Australia. The BSR will also supply long term outcome-based data for bariatric surgery patients, including safety, weight and diabetes outcomes.

RESULTS:
Enrolment of relevant hospitals and surgeons in the BSR has steadily increased since inception in 2012. By 30 June 2017, the BSR reported enrolment of nearly 30,000 participants. Australian use of bariatric surgery services continues to increase at a rapid pace, with a 64 percent increase in MBS services for primary bariatric surgery between the 2013-14 and 2016-17 financial years. It is estimated that about half of the 2016-17 MBS services for bariatric surgery were captured by the BSR.

CONCLUSIONS:
Clinical quality registries are a valuable source of data for both clinicians and governments. When long-term data becomes available, the BSR will inform a HTA review of current and emerging bariatric surgery services. This review will provide a sound basis for decisions on future government funding for bariatric surgery.

PP107 Cost-effectiveness Of Therapeutic Drug Monitoring In Patients With IBD

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ABSTRACT SUMMARY:
The approach involving the therapeutic drug monitoring showed to be more cost-effective than a clinically-based approach in the management of patients affected by a bowel inflammatory disease experiencing a loss of response to infliximab.

INTRODUCTION:
Empirical dose intensification and therapeutic drug monitoring (TDM) of infliximab (IFX) trough levels (ITL) and antibody (ATI) assays are recognised approaches for managing the loss of response (LoR) in inflammatory bowel disease (IBD) patients.

METHODS:
Consecutive IBD patients, experiencing LoR, were clinically managed according to a TDM algorithm. A historical group of empirically treated patients, for whom sera for ITL and ATI assays were collected, served as the control group. Clinical outcomes 12 weeks after the therapeutic interventions were compared between the two groups. A cost-minimization analysis was performed to compare the economic impact of these two approaches.

RESULTS:
Ninety-six patients were enrolled prospectively and compared with 52 controls. The two cohorts were similar in characteristics and the distribution of TDM results. In the prospective cohort, however, we observed less IFX dose escalations compared with controls (45% versus 71%, p=0.003). Also, more patients were switched to a different anti-TNFα in the prospective cohort than in the control one (25% versus 4%, p=0.001). The percentages of patients achieving a clinical response at 12 weeks were 52% and 54% for the prospective and control groups, respectively. By cost analysis, we estimated a savings of 15% if the TDM algorithm was applied. Such results imply that at least 25% of the optimizations in the retrospective cohort could be avoided without any clinical repercussion. Thus, if the therapeutic monitoring had been performed using the theoretical algorithm, it would allow a saving of €128,648.13 (~15%, Chart 2) over the 12 weeks of treatment considering the sample of 145 patients, namely around €887/patient.

CONCLUSIONS:
In our population, applying a TDM algorithm for LoR to IFX resulted in less dose escalations, without loss of efficacy, compared with empirical adjustment. In addition, the TDM approach was cost-effective.

PP108 Novel Approaches For Fair And Reasonable Value-based Recommendations

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ABSTRACT SUMMARY:
INESSS has developed novel approaches to support fair and reasonable value-based recommendations for innovative technologies, in a context of promise and uncertainties. The methodological development was an iterative process supported by the use of the preliminary approach for the assessment of several technologies. The experience is positive and stakeholders confirm its relevance to support fair and reasonable recommendations.

INTRODUCTION:
Stakeholders from the innovation field in Québec (Canada) have collectively stressed the need to formalize the process for evaluating innovative technologies in the province. In the context of
innovation, and more so for non-pharmaceutical technologies where the pace of development is rapid and the lifecycle short, evidence supporting the added value can be limited and uncertainties are common. Therefore, pragmatic approaches are needed to guide recommendations and to assure that the process is rigorous, transparent and fair.

METHODS:

Inspired by international experiences, the Institut national d’excellence en santé et services sociaux (INESSS) has developed a novel framework, where four types of recommendations are possible (introduction, refusal, limited or conditional introduction). The starting point is an evaluation of the technology’s added value, for the patient, the population and the healthcare system, and the identification of uncertainties. The value of addressing uncertainty with further research is assessed, based on the value-of-information theory, and the distinct characteristics of medical devices are taken into account (e.g., learning curve effect, irrecoverable costs and incremental innovation). Those elements interact to support the formulation of recommendations by INESSS’ advisory committee.

RESULTS:

The development of the framework was an iterative process supported by the use of the preliminary framework for the assessment of several innovative technologies. Challenges with its use were identified, and led to methodological and operational improvements. So far, the experience with the framework is positive and stakeholders confirm its relevance to support fair and reasonable recommendations for innovations.

CONCLUSIONS:

In the rapidly changing landscape of innovation, HTA has to adapt to the challenges of assessing technologies in a context of promise and uncertainties. The framework developed by INESSS is a tool for supporting timely and fair value-based decision-making, which will benefit the healthcare system, and the patients and population it serves.

PP109 Use Of Speech Recognition In Medical Reports: A Systematic Review

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ABSTRACT SUMMARY:

Speech recognition is increasingly used in medical reporting. A systematic review of systematic reviews has been conducted to identify advantages and weaknesses of this technology, as well as barriers and facilitators to its implementation.

INTRODUCTION:

Speech recognition is increasingly used in medical reporting. The aim of this article is to identify in the literature the advantages and weaknesses of this technology, as well as barriers and facilitators to its implementation.

METHODS:

A systematic review of systematic reviews has been conducted in PubMed, Scopus, Cochrane Library and Center for Reviews and Dissemination up to August 2017. The grey literature has also been consulted. The quality of systematic reviews has been assessed with the AMSTAR checklist. Inclusion criteria were to use speech recognition for medical reporting (front or back-end). A Survey has also been conducted in Quebec, Canada, to identify the dissemination of this technology in this province, as well as the factors of success or failure in its implementation.

RESULTS:

Five systematic reviews were identified. These reviews indicated a high level of heterogeneity across studies. The quality of the studies reported
was generally poor. Speech recognition is not as accurate as human transcription but can dramatically reduce the turnaround times for reporting. In front-end use, medical doctor need to spend more time for dictation and correction than with human transcription. With speech recognition major errors can be up to three times more frequent. In back-end use, a potential increase in the productivity of transcriptionist is noted.

CONCLUSIONS:
Speech recognition offers some advantages for medical reporting, the main one being a reduction in turnaround times. However, these advantages are challenged by an increased burden for medical doctor and risks of additional errors in medical reports. It is also hard to identify for which medical specialties and which clinical activities the use of speech recognition will be the most beneficial.

INTRODUCTION:
Impacted third molars (I3Ms) are blocked from fully erupting; many I3Ms are asymptomatic, however there could be pain and pathological changes. Historically, I3Ms were removed prophylactically. Current UK options include either retention with standard care (watchful waiting), or removal due to pathological changes. We conducted a systematic review of the prophylactic removal of asymptomatic impacted mandibular third molars (IM3Ms) compared with standard care.

METHODS:
We searched five electronic databases from 1999 onwards. Inclusion criteria: randomised and non-randomised trials, observational studies, and systematic reviews (SRs) comparing the prophylactic removal of IM3Ms with standard care or studies assessing the outcomes of either approach; outcomes included pathology associated with retention, post-operative complications, adverse effects of treatment and health-related quality of life. Two reviewers independently screened all titles and/or abstracts, applied inclusion criteria to potentially relevant publications, and quality assessed and data extracted the included studies. No meta-analysis or network meta-analyses were undertaken.

RESULTS:
11,373 references were screened; 13 studies (four cohort studies and nine SRs) were included. One cohort study investigated the prophylactic removal of asymptomatic IM3Ms in comparison with standard care and retention, two investigated the prophylactic removal of asymptomatic IM3Ms, and one studied the retention and standard care of asymptomatic IM3Ms. Two studies reporting surgical complications found no serious complications, however one study reported intense pain and post-operative infection. Pathological changes due to retention of asymptomatic IM3Ms were reported by three studies. Nine SRs of the management of third molars were reported by three studies. Nine SRs of the management of third molars were included in this review, however none focused solely on IM3Ms.
CONCLUSIONS:
Consistent with previous systematic reviews, we found no RCT data to support or refute the prophylactic removal of asymptomatic IM3Ms, despite extensive searching of the literature. The review however did identify evidence from two longitudinal studies demonstrating the outcomes when asymptomatic IM3Ms are left in situ.

PP111 Toward Healthy Coagulation In Hemophilia

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ABSTRACT SUMMARY:
Recent advances in hemophilia healthcare have compelled a need for new goals and approaches to disease management beyond the current minimal treatment approach that considers only the level of replacement clotting factor. We describe the development of a stepwise milestone model toward normal hemostasis and cure that accommodates the treatment goals of treaters and patients alike.

INTRODUCTION:
Healthcare advances in hemophilia have led to near-normal life expectancies in a disorder previously associated with early death. Unlike other disorders where the therapeutic goal is to restore deficiencies to normal levels, prophylaxis in hemophilia is used to achieve a plasma level of FVIII >1%, such that severe hemophilia may be reduced to a moderate/mild phenotype. With the development of new therapies, treatment goals are evolving from on demand treatment or prevention of bleeds to one where the risk of bleeding is minimal/absent. To accelerate this development, a new treatment paradigm is needed, with consensus from key stakeholder communities, to facilitate a shared vision for the future of hemophilia healthcare.

METHODS:
A panel of hemophilia providers, patient advocates, and industry representatives convened to develop a new treatment model that establishes specific treatment milestones and target outcomes in a stepwise fashion, culminating in a progressive definition of cure.

RESULTS:
To represent the collective experience of hemophilia patients and treaters around the world, the following treatment milestones were defined based on optimized outcomes: (1) Sustain Life – prevention of premature death; (2) Minimal Joint Impairment – improved quality of life; participation in activities of daily living; (3) Freedom From Spontaneous Bleeds – ability to engage in low-risk activities; (4) Attainment of ‘Normal’ Mobility – participation in work, career, and family life without restriction; (5) Able to Sustain Minor Trauma – more unrestricted lifestyle; (6) Ability to Sustain Major Surgery or Trauma Without Additional Intervention – no dependency on specialized healthcare; (7) Normal Hemostasis

CONCLUSIONS:
With milestones for disease management leading toward normalized hemostasis, this treatment model provides a vision to improve hemophilia care for all patients. And by providing achievable outcomes, the community – patients, treaters, and their industry partners – has a clear path to achieve that goal.
PP112 Cost-utility And Budget Impact Of Proton Therapy In Medulloblastoma.

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ABSTRACT SUMMARY:
Cost-utility and budget impact of proton beam therapy in pediatric medulloblastoma were estimated, under the Brazilian public health system perspective. A lifetime microsimulation model was built to compare proton with photon therapy. Proton therapy in the base case scenario was not cost-effective in a 1 GDP per capita (U$8,649,95)/QALY threshold, and the incremental budget impact was estimated at U$109,713,790.91,76.

INTRODUCTION:
Medulloblastoma is the most common malignant brain tumor of childhood, accounting for approximately 20% of all primary central nervous system tumors under 19 years of age. Survivors often have treatment-related sequelae that significantly compromise quality of life. The potential advantage of proton-to-photon radiation therapy is the better dose distribution, reducing the occurrence of adverse effects. The study objective was to develop cost-effectiveness and budget impact analyses comparing the proton beam vs photon therapy for pediatric patients with medulloblastoma.

METHODS:
The Brazilian health system perspective was adopted in the analyses. To evaluate the cost-effectiveness of the proton beam therapy, a lifetime microsimulation model was developed comparing scenarios of equipment lifespan and number of patients treated.

The base case parameters were 50 patients and 20 years of equipment lifespan, while the alternative scenarios were 100 and 150 patients with 10 and 15 years of equipment lifespan, respectively. The capital costs of photon radiotherapy such as maintenance, training, infra-structure and acquisition were raised at the Brazilian National Cancer Institute. Implementation and maintenance costs of proton beam therapy were obtained from the Emergency Care Research Institute (ECRI) database. The effectiveness measure used was quality-adjusted life year (QALY).

RESULTS:
The base case incremental cost-effectiveness ratio (ICER) was U$34,590.53/QALY. For the willingness to pay threshold of 1 GDP per capita/QALY (U$8,649,95), proton therapy incorporation would be cost-effective for at least 150 treated patients. However, the Brazilian health system databases reported 54 pediatric patients with medulloblastoma treated in 2014. The equipment lifespan and other variables had limited weight when varied in the sensitivity analysis, without significant changing in model outputs. At the end of 20 years, the incremental budget impact was U$109,713,790.91,76.

CONCLUSIONS:
Under the Brazilian base case scenario, using proton beam therapy to treat pediatric medulloblastoma was not a cost-effective option considering a 1GDP per capita/QALY threshold. The budget impact analysis showed very high incremental values for the national public health system.

PP113 Towards A Systemic Approach Of Value Judgment In HTA

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ABSTRACT SUMMARY:
Since HTA is a value-laden process, some authors have proposed the elicitation of implicit value judgments (VJs), to clarify the role ethics may play in HTA. A conceptual analysis of VJs, as a specific speech-act, was used. VJs are intrinsically embedded in decision-making and this is why implicit VJs can be identified at every decision-steps in the HTA process.

INTRODUCTION:
The fact that HTA is a value-laden process is recognized in the literature. This is one of the reasons for promoting a better integration of ethics in HTA processes. Although what is meant by value-judgment (VJ) and how it can be used in HTA is not clear for some authors; others have proposed the elicitation of implicit VJs, to make them more explicit, as one way for clarifying the role ethics may play in HTA. In order to clarify what is a VJ, a conceptual analysis is needed to distinguish it from a factual-judgment and see how they diverge on certain aspects and converge on others.

METHODS:
The distinction between VJs and factual-judgments was debated in the fifties. At the core of the philosophy of language was a distinction between factual-scientific assertions about facts, considered objective, and VJs on what is right/wrong-good/bad, considered subjective. In speech-act theory these distinctions were treated as two different operations: assertive and evaluative. A conceptual analysis of VJs, considering them as specific speech-acts, was used for clarifying/deciphering the role of VJs in HTA.

RESULTS:
VJs are intrinsically embedded in decision-making since they are the reasons justifying decisions. This is why implicit VJs can be identified at every decision-steps in the HTA process. Assessment is usually considered objective while appraisal seems subjective. Since VJs are entrenched in the decisions taken throughout the assessment process, the results are not completely objective. Ethical analysis also distinguishes two types of VJs, those based on normative criteria and those based on various degrees of value actualization. Furthermore, since evaluation requires criteria based on a rational process, VJs are not totally subjective.

CONCLUSIONS:
Elicitation of VJs in HTA is one way of integrating ethics in HTA and offers decision-makers a more thorough picture of the ethical issues involved in their decision.
ABSTRACT SUMMARY:

Patients, family practitioners (FPs), and researchers co-conceptualized and co-designed a tool to support self-management and lifestyle changes for knee osteoarthritis (KOA) patients. With input from stakeholders and the evidence base, this co-designed tool may help bridge the gap between clinical knowledge of KOA management and its application within a patient’s daily life and communication with their FP.

INTRODUCTION:

There exists a gap between evidence for reducing risk of knee osteoarthritis (KOA) progression and its application in patients’ daily lives. We aimed to bridge this gap by identifying patient and family physicians (FPs) self-management priorities to conceptualize and develop a mobile-health application (m-health App). Our co-design approach combined priorities and concerns solicited from patients and FPs with evidence on risk of progression to design and develop a KOA self-management tool.

METHODS:

Parallel qualitative research of patient and FP perspectives was conducted to inform the co-design process. Researchers from Enhancing Alberta Primary Care Research Networks (EnACT) evaluated the mental models of FPs using cognitive task analysis through structured interviews with four FPs. Using grounded theory methods, patient researchers from Patient and Community Engagement Research (PaCER) interviewed five patients to explore patient perspectives about needs and interactions with primary care. In three co-design sessions, relevant stakeholders (n=4 patients; n=5 FPs; n=13 researchers) participated to: a) identify user needs with regard to KOA self-management; and, b) co-conceptualize and determine design priorities and functionalities of an m-health App using a modified nominal group process.

RESULTS:

Priority measures for symptoms, activities and quality of life from user perspectives were determined in the first two sessions. The third co-design session with our industry partner resulted in finalization of priorities through interactive patient and FP feedback. The top 3 features were: 1) symptoms graph & summary, 2) information and strategies, and 3) setting goals. These features were used to inform the development of a minimum viable product.

CONCLUSIONS:

The novel use of co-design creates directive dialogue around the needs of patients, highlighting contrasting views that exist between patients and FPs, and emphasizing how exploring these differences might lead to strong design options for patient-oriented m-health apps. Characterizing these disjunctions has important implications for operationalizing patient-centered health care.

PP116 Health Utilities And Neglected Conditions: A Chagas Disease Study

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ABSTRACT SUMMARY:

Health-related quality of life and utility measures are scarce for neglected conditions as Chagas Disease. EQ-5D was employed to assess utility values in different subgroups of chronic Chagas Disease. The obtained measures from these patients were lower than normative values for the Brazilian population.
INTRODUCTION:
Chagas disease (ChD), also known as American trypanosomiasis, is a neglected tropical disease caused by the protozoan parasite Trypanosoma cruzi. About 6 to 7 million people worldwide are estimated to be infected, most in Latin America. Health-related quality of life (HRQoL) and utility measures are still poorly employed for assessment of ChD life-time impairments. HRQoL Brazilian published data showed that cardiac subgroup of patients have worse scores than other ChD chronic groups. For the time being utility scores are not available yet for ChD population. The present study aims to assess quality of life (QoL), as utility scores, of patients with chronic Chagas Disease.

METHODS:
This is a cross-sectional study. Data were collected from 183 outpatients with chronic ChD in a reference center in Brazil. Information pertaining to socio-demographics, clinical status, and quality of life were collected using self-administered questionnaires. Utilities were obtained by the European Quality of Life – 5 Dimensions (EQ-5D) questionnaire. Comparisons were made between clinical subtypes and population normative values. Continuous variables were compared using t-test or ANOVA, and categorical variables were compared using Chi-square test. Associations between QoL and patient characteristics stratified by demographics, clinical status were identified by linear regression models.

RESULTS:
Most subjects were female (61%). The average age of men was 53.3 years and women 56.6. When analyzing the EQ-5D utility scores, it was observed that the results were lower for cardiac patients (0.610 – 95%CI 0.582-0.638) in comparison to indeterminate form patients (0.659 – 0.632-0.687). When comparing patients with the general population of the same age and sex, patients with ChD showed lower utility scores than normative values (0.624 – 95%CI 0.596-0.652).

CONCLUSIONS:
Chronic ChD causes a negative impact on quality of life, physical functioning, as well as psychosocial function, with the impairment becoming worse in cardiac patients.

PP117 Real-life Cost-Of-Illness Studies for HTA: Methodological Challenges

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ABSTRACT SUMMARY:
Given the limitations of health administrative data, there exist a number of practical challenges when estimating the healthcare costs of infectious diseases. We use a costing analysis of pneumococcal disease as a case study to explore the unique aspects of this therapeutic area and some solutions to the challenges it presents.

INTRODUCTION:
Decision-makers, such as the Canadian National Advisory Committee for Immunization (NACI) increasingly consider economic evidence for immunization programs. Predicting benefits and costs requires evidence of burden of disease; however, high quality cost-of-illness studies for infectious diseases are limited. Large health administrative datasets provide a unique opportunity to conduct population-based costing studies using real life data; however, infectious diseases present unique challenges in accomplishing this objective. Using Streptococcus pneumoniae as a case study we will discuss key challenges and possible solutions.
METHODS:
Using a pathogen-based approach, we conducted a retrospective population-based cohort study in Ontario, Canada of patients with one of the 3 common manifestations of S. pneumoniae infections: pneumonia, otitis media and invasive pneumococcal disease. We identified infected subjects using ICD-10 codes as well as linked laboratory data from local public health agencies. Infected subjects were matched with uninfected subjects from the general population using hard- and propensity score- matching on age, sex, income quintile, urban/rural residence, comorbidities and costs prior to index date. Attributable costs represented the mean difference in costs between the infected subjects and their matched pairs.

RESULTS:
We identified five key challenges: (1) identifying exposed cohort (i.e., infected subjects), for both pathogen- and syndrome-based costing studies, (2) defining an accurate index date, (3) minimizing residual confounding when matching to unexposed (i.e., uninfected) subjects, (4) defining an appropriate follow-up time, (5) deciding on the most suitable costing framework (e.g. phase-of-care, statistical methods). Using costing data in model-based economic evaluations requires further considerations (e.g. identification of subgroups).

CONCLUSIONS:
Given the limitations of health administrative data, there exists practical challenges when applying traditional costing methodologies to infectious diseases. Nevertheless, the use of these datasets provides an exceptional opportunity to obtain accurate estimates of the economic burden associated with specific infections.

PP118 Cardiac Safety Of Trastuzumab For Metastatatic Breast Cancer

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ABSTRACT SUMMARY:
We conducted a systematic review of randomized controlled trials to access the cardiac safety of trastuzumab (T) in the treatment of metastatic breast cancer. In first line treatment, patients using T had three times higher risk of developing cardiac adverse event. There were no difference between T users and non-users in treatment after metastatic breast cancer progression.

INTRODUCTION:
Metastatic breast cancer (MBC) is considered incurable. Trastuzumab (T), a monoclonal antibody that blocks HER-2 is used in combination with other chemotherapies or as monotherapy to treat various stages of breast cancer, including MBC. The aim of this study was to evaluate the safety of T as first line treatment or after progression in women with MBC.

METHODS:
We conducted a systematic review of randomized controlled trials. We searched the databases: MEDLINE (Pubmed), LILACS, Cochrane Library and EMBASE (accessed November 2016) and performed manual search. The methodological quality assessment was performed using the Cochrane Collaboration risk of bias tool. We adopted the
random effects model for meta-analysis. The results were presented as relative risk (RR) with 95% confidence intervals (p <0.05), I² and p value for heterogeneity.

**RESULTS:**
The search retrieved 2238 publications. After eligibility criteria assessment we included five studies on T in the first line treatment (T n=493; no-T n=492) and two studies on T after progression (T n=226; no-T n=226). In general, studies presented moderate quality. Five were funded by the pharmaceutical industry. Regarding first line treatment, the group of patients that used T had three times higher risk of developing cardiac adverse event compared to the group that did not use T (RR=3.3; 1.52-7.29; I²=0%, p=0.39).

The continuity of T after progression revealed no difference between the groups regarding the risk of developing cardiac adverse event (RR=5.31; 0.62-45.49; I²=0%, p=0.62).

**CONCLUSIONS:**
The evidence regarding the higher risk of cardiac adverse event with T as first line treatment for MBC is robust and this should be taken into account when balancing risks and benefits of treatment. The evidence for continuation of T after MBC progression is week and more studies are needed to confirm the findings.

**PP119 How Much Evidence is Enough For Action – ‘Adaptive Approach’ Helps?**

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**ABSTRACT SUMMARY:**
In order to make strategic plans for hepatitis C elimination in Taiwan, certain evidence and estimates about the disease distributions are needed however they may not be as precise as preferred. We have used an adaptive approach that so far is the pragmatic way to move plans forward yet without sacrificing the quality of decisions.

**INTRODUCTION:**
Aimed for hepatitis C elimination by 2030, Taiwan has set up a mid-term goal of “over 50% of patients are treated by 2025.” Among various aspects of evidences that are needed, the target number to be treated was difficult to estimate with certainty due to great geographical heterogeneity of hepatitis C prevalence and lacking of nation-wide large scale prevalence survey.

**METHODS:**
A broad estimate of number of patients to be treated with high uncertainty was firstly calculated and reimbursement criteria were set for year 2017 given limited data and treatment budget. In the meanwhile, various sources and approaches to estimate the target number to be treated and to identify the high prevalence areas were collected and synthesized for future planning through systematic review for published data and consulting experts for unpublished data. An expert panel was consulted for the level of confidence and completeness of the evidence. A plan for using real-world data to reduce the uncertainty after initial actions of national program was also in place.

**RESULTS:**
8,000 patients who fulfilled the reimbursement criteria were firstly treated in 2017 as planned. Based on the collected data, the strategic steps were identified and the treatment target, namely 200,000 patients to be treated during 2018 to 2025, was then set for appropriate action plans. National registry infrastructure is planned for supporting future policy modification.
CONCLUSIONS:
Hepatitis C elimination is an important public health task and it requires immediate actions. The expected expenses are high, yet the number of patients is difficult to estimate with precision. How to deal with this uncertainty (financially and on care program design) will be the most challenging part. An adaptive approach (“evidence”-“action”-“more evidence”-“modified action”) could be the pragmatic way to move forward the plan without sacrificing the quality of decision-making.

PP120 A Qualitative Analysis On The Methods In Health Technology Assessment

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ABSTRACT SUMMARY:
The contribution that HTA can make to informed policy and decision-making, particularly in developing and emerging countries, is constantly evolving. In our setting, HTA involving oncologic therapies was more prevalent. Certification in quality management systems and appropriation of “real world data” to produce HTA reviews have improved our results.

INTRODUCTION:
Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. The “Grupo de Avaliação de Tecnologias em Saúde” (GATS) is a multidisciplinary group specialized in assessing the technical, economic and ethical issues of a health intervention or health technology working in a private, nonprofit healthcare organization located in the city of Belo Horizonte, Brazil.

METHODS:
To describe the research methods used, including novel methods for conducting HTA as rapid reviews and the use of “real world data”. All HTA reviews produced by the GATS from 2015 to 2017 were included in this study. The GATS is composed by eight physicians, one librarian and one administrative assistant. A qualitative analysis describing the evolvement of the processes used to produce HTA reviews from 2015 to 2017 was performed. The reviews were analyzed individually and classified into the following groups: oncologic therapy, devices, laboratory tests, non-oncology drugs, guidelines and medical procedures.

RESULTS:
From 2015 to 2017, 1,026 HTA reviews were produced. The demands involved the assessment of oncologic therapies (33%); medical procedures (22%); non-oncologic drugs (18%); devices (13%); laboratory tests (9%) and guidelines (6%). The assessments were produced using “rapid reviews” templates. Two studies, involving the assessment of medical devices, were produced using “real world data” extracted from an administrative databank. The processes involved in the production of the HTA reviews were certified by the ISO 9001:2015.

CONCLUSIONS:
The contribution that HTA can make to informed policy and decision-making, particularly in developing and emerging countries is constantly evolving. In our setting, HTA involving oncologic therapies was more prevalent. The certification in quality management systems, as the ISO 9001:2015, and the appropriation of “real world data” to produce HTA reviews have enriched our
results and helped us to better allocate healthcare resources and define long sustainable healthcare policies.

PP121 Relationship Of Self-Reported Sleep Condition With Diseases

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ABSTRACT SUMMARY:
Self-reported outcome is considered to be useful to understand physical and mental conditions in daily life. We examined the relationship of self-reported sleep condition with diseases based on an analysis of health insurance claims database with annual medical check-up data. Our results suggest that sleep condition is associated with various chronic diseases as well as mental disorders.

INTRODUCTION:
Self-reported outcome is considered to be useful to understand physical and mental conditions in daily life. Sleep condition is an important factor related to healthy lifestyle and work productivity, as well as to diseases. We examined the relationship of sleep condition with lifestyle and diseases based on self-reported sleep.

METHODS:
A Japanese employee-based health insurance claims database with annual medical check-up data was used. Individuals were questioned about sleep condition as: “Do you get enough rest by sleeping?” in medical check-up. The prevalence of diseases and medical check-up data were compared between those who answered “Yes” or “No”.

RESULTS:
Among 1,310,157 individuals who answered about sleep condition, 540,564 (41.3 percent) answered “No”. The female ratio was around 38 percent for both answers, and the average age was lower for those who answered “No” (45.3) than “Yes” (47.3). Matched individuals for same examination year, sex, and age were 536,218 in each group. Individuals diagnosed with sleep disorder were 8.7 percent of those who answered “No”, representing the highest relative risk (RR)(1.64), followed by other anxiety disorders (1.47), and depressive episode (1.45), with statistical significance. Other diseases diagnosed in >200,000 of total individuals (“Yes” and “No”) were: vasomotor and allergic rhinitis, disorders of refraction and accommodation, acute upper respiratory infections, gastritis and duodenitis, and acute bronchitis, which showed significantly higher RR for those who answered “No”, 1.09, 1.02, 1.11, 1.17, and 1.13, respectively. RR of other diseases of liver (1.13), diabetes (1.12), hypertension (1.08), and disorders of lipoprotein metabolism and other lipidaemias (1.06) were also significantly higher for those who answered “No”.

CONCLUSIONS:
Sleep condition is suggested to be associated with various chronic diseases as well as mental disorders. Therefore, self-reported outcome should be a useful tool to understand health-condition, prevent onset and progression of diseases, and evaluate patient-centered care.

PP122 A Quick CEA Of PFO Closure On Korean Patients With Cryptogenic Stroke

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ABSTRACT SUMMARY:
This is the best available evidence so far in Korea for the economic evaluation of the PFO closure procedure for the patients with cryptogenic stroke history.

INTRODUCTION:
Patent Foramen Ovale (PFO) is an open hole in heart between right and left upper chambers. It may contribute to the risk of stroke so the closure is considered as a secondary prevention to the patients who had a cryptogenic stroke. Recent evidences published on the effectiveness of PFO closure including a publically funded prospective study on the effectiveness of PFO closure for prevention on recurrent stroke or transient ischemic attack (TIA) in selected Korean patients with cryptogenic stroke. The objective of this study is to examine cost effectiveness of PFO closure procedure using the existing evidences.

METHODS:
Available clinical data from the aforementioned Korean prospective study and other recent multicenter trials such as CLOSE trial both were funded by public bodies. The cost data was obtained from the current Korean fee schedule in the National Health Insurance (NHI). Utility data was extracted from the local research in stroke patients. Using these data, a cost effectiveness analysis model based on 20 year Markov modeling on (1) PFO closure with antiplatelet therapy and (2) oral anticoagulants only therapy was compared.

RESULTS:
The initial analysis showed PFO+antiplatelet has 7.13 million KRW more cost with 1.27 higher utility which corresponds to an ICER of 5.6 million KRW per QALY. The implicit Korean threshold for ICER is 25 million KRW for non-cancer drugs so it seems the PFO+antiplatelet therapy is cost effective in the Korean setting.

CONCLUSIONS:
Since this study used some transition probabilities from the foreign source, there might be some uncertainties in the Korean setting. However, this is the best available evidence so far in Korea for the economic evaluation of the PFO closure procedure and hence, a careful selection of patients with cryptogenic stroke history and application of PFO closure may benefit the public payer in Korea.

PP123 Triangulate, Converge, Assess, And Recommend (TCAR): Evaluation Method

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ABSTRACT SUMMARY:
Methods to assess evidence and to use that evidence to inform practices and policies are under developed in the area of social services. A taskforce was implemented to address this and to propose a method that may be more appropriate for the social sciences. A method to triangulate scientific, contextual and experiential of data is proposed.

INTRODUCTION:
Methods to assess evidence and to use that evidence to inform practices and policies are under developed in the area of social services. Although health professions have developed robust methods in recent decades to collect, analyze and
synthesize scientific evidence and to inform clinical recommendations, the use of these methods often remains difficult in social services. A taskforce was implemented to address this and to propose a method that may be more appropriate for the social sciences.

**METHODS:**
The project was comprised of four steps: (a) performing a qualitative review of discussions between experts, (b) designing a cognitive map of the data, (c) conducting a systematic literature search, and (d) comparing the data from the meetings with experts with the scientific literature. These steps were completed using the grounded theory approach. In order to test the method developed, focus groups were then conducted and four case studies were used to assess the evidence and provide recommendations for youths with mental health problems and for elderly care.

**RESULTS:**
Although robust scientific data remain crucial when developing recommendations for practice, results showed that these data are incomplete if considered alone, and that contextual (circumstances in which the intervention is delivered) and experiential data (how the intervention is perceived by stakeholders) must also be taken into consideration. A method to triangulate these three types of data is proposed. Using this technique, the value of the data is established by means of various measurements that converge towards the same result or that provide a consistent overall picture or some important nuances that need to be considered, as illustrated by the four case studies.

**CONCLUSIONS:**
The proposed method can be used to address the limitations that are inherent to the use of techniques and procedures drawn from the medical field when assessing evidence and developing recommendations for the social sciences. The case studies that the proposed method is not only a viable option to methods drawn from medicine, but also adds to the quality of the recommendations that are made and is more congruent with the epistemology of social sciences.

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**PP124 HTA And Feedback For Healthy Workplace Culture In Malaria Care In LMIC**

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**ABSTRACT SUMMARY:**
Malaria is a leading cause of deaths in LMICs. Evidence Based Care for malaria is also challenging due to lack of access to evidence for the clinical team and lack of shared decision making. We conducted a clinical practice assessment and feedback using evidence based criteria to improve workplace culture and practice in Cameroon.

**INTRODUCTION:**
Malaria is a leading cause of mortality and morbidity in children under 5 in LMIC. Management of malaria in children under five years of age is challenging. One challenge faced by clinical practice in LMIC is lack of evidence to guide practice. This challenge is further compounded by different training backgrounds of team members. In the management of malaria in Cameroon, conflicts usually arise between clinicians, lab technicians and pharmacists over diagnosis and treatment of malaria. The patient’s view is usually not considered. This leads to over diagnosis and over prescriptions for malaria in children under 5.
METHODS:
We used the JBI approach of getting research into practice to organize stakeholder meetings, assess existing evidence in malaria care, develop evidence criteria for management based on levels of evidence, assess the gamut of care for malaria, provide feedback to clinicians and re-assess practice. We used the JBI PACES and GRiP evidence implementation tools in the process to facilitate teamwork, collaboration on evidence and provide feedback.

RESULTS:
A collaborative approach to assessments and feedback including all healthcare stakeholders significantly improved workplace culture of evidence-based care and staff to staff relationship as well as staff to patient relationship. Over a period of 12 months, we reported 84% less conflicts between staff and staff and 98% less conflicts between staff and patients. For malaria management, overall criteria showed a 31% improvement in compliance best practice recommendations with evidence levels Grade 1.

CONCLUSIONS:
The project demonstrated that local leadership and evidence based care can significantly improve practice in resource limited settings.

ABSTRACT SUMMARY:
In 2010, the Philippine National Health Insurance Corporation (PhilHealth) introduced the Outpatient HIV/AIDS Treatment (OHAT) package to cover for the necessary health needs of diagnosed patients. This research aimed to assess the impact of this package using patient-focused insight to understand what health and financial needs have been met and recommend what can be further improved on.

INTRODUCTION:
The Philippines has an increasing number of newly diagnosed Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) cases. In 2010, the Philippine National Health Insurance Corporation (PhilHealth), introduced an Outpatient HIV/AIDS Treatment (OHAT) package for patients covering yearly basic expenses. The objective of this study is to review the OHAT package in meeting health needs and economic risk protection based on patient-focused perspectives.

METHODS:
The study was divided into two different phases: (i.) patient surveys (PS) and (ii.) health provider interviews (HPI). The PS included package utilizers and non-utilizers focusing on their health needs, specifically on their satisfaction with the current package coverage. The HPI focused on key personnel working at treatment hubs to gain insight on the impact the OHAT package has had on facility operations, service delivery and on patient care.

RESULTS:
A majority of patients were satisfied with the current package due to reduction of out-of-pocket (OOP) costs per year. However, continuing OOP expenditure was also the main reason for dissatisfaction. This is due to non-uniform provision of services across different hubs, mainly due to unavailability of services and health provider discretion on final package inclusions. Non-coverage of opportunistic infection
(OI) treatment and privacy issues were also noted as causes of dissatisfaction. Claim filing for the formal membership type requires employer signature for proof of contribution. Due to fear of stigma, some members create a second insurance account or to shift to an individually paying type thus driving up OOP expenses.

CONCLUSIONS:
The OHAT package has increased access to services and medications for HIV/AIDS patients in the Philippines. Despite the increasing percentage of package utilization, there is still room for improvement of the package specifically with regards to addressing privacy needs, non-uniform package inclusions and extending coverage to treatment of OIs.

PP126 Alfa-Alglucosidase For Pompe Disease: Literature Review

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ABSTRACT SUMMARY:
Alpha-alglucosidase has a beneficial effect in patients with Pompe disease despite evidence of limited quality. A systematic review found that patients treated with alpha-alglucosidase had a mortality rate five times lower than untreated (rate ratio: 0.21, 95% CI 0.11-0.41). Annual treatment cost: US$ 296,187.64 (adult patient with 70 kg) and US$ 42,312.52 (pediatric patient with 10 kg).

INTRODUCTION:
Pompe disease is a rare disease and therapies aimed at improving the function of the heart and skeletal muscles, and the quality of life of patients. This review aims to update and evaluate the safety and efficacy of alpha-alglucosidase therapy.

METHODS:
Performed search in the databases of Medline, EMBASE, Center for Reviews and Dissemination (CRD), LILACS and Cochrane. Publications of the National Institute for Health and Care Excellence (NICE) and national and international guidelines have been consulted. The quality of the evidence was assessed using the criteria of the Grading of Recommendations Assessment, Development and Evaluation - GRADE. We performed annual cost estimates of alpha-alglucosidase for the treatment of adult and pediatric patients.

RESULTS:
In a randomized clinical trial comparing alpha-alglucosidase enzyme replacement therapy (20 mg / kg) with placebo for seventy-eight weeks, the results favored alpha-alglucosidase (an increase of 28.1 ± 13.1 m in the six minute walk and an absolute increase of 3.4 ± 1.2 percent in forced vital capacity (FVC), p = 0.03 and p = 0.006, respectively). In another systematic review, it was observed that patients treated with alpha-alglucosidase had a mortality rate five times lower than untreated patients (rate ratio: 0.21; 95% CI 0.11 - 0.41). In a pediatric population with advanced disease, biweekly infusions prolonged survival and survival free of invasive ventilation. The quality of the evidence was classified as very low. Annual treatment cost: US$ 296,187.64 (adult patient with 70 kg) and US$ 42,312.52 (pediatric patient with 10 kg).

CONCLUSIONS:
Limited evidence for the treatment of Pompe disease with alpha-alglucosidase suggests efficacy in patients with some clinical conditions who do not present negative cross-reactive immune material. The balance between the limited quality of the evidence and the benefits demonstrated is favorable, especially for clinical improvement, reduction of mortality and intangible benefits.
**PP127 Issues On The Estimation Of The Opportunity Cost Threshold Value**

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**ABSTRACT SUMMARY:**
We propose Data Envelopment Analysis (DEA) as the methodology that can help to address some of the challenges of estimating the opportunity cost threshold for the efficient allocation of resources. DEA allow us to consider health location efficiency and to include several outcomes in addition to the normally used mortality.

**INTRODUCTION:**
There is no consensus on which methods to use to estimate an opportunity cost threshold for the efficient allocation of resources. Researchers have attempted to estimate an evidence-based threshold value, but only a few approaches have been considered and any estimate is currently used by policy makers. This study aims at exploring three assumptions normally applied in the threshold estimation: (1) Approaches assume that there is always a displacement involving a loss of health, however, empirical studies suggest that one of the first responses of local health care purchasers is to squeeze greater efficiency out of providers. (2) To be sure about the appropriate threshold it is necessary to know which health services purchasers are giving up to introduce a new treatment; current estimates bypass this lack of information by averaging the effects of changes in expenditure by clinical area. (3) Recent methodologies consider a single health outcome: mortality; however, health outcomes of many clinical areas may not be well reflected in mortality.

**METHODS:**
We propose Data Envelopment Analysis (DEA) as a methodology that can help to address these issues by considering efficiency to measure opportunity cost per health location, and including several outcomes in addition to mortality. This is the first time that DEA is tested in this context.

**RESULTS:**
Results suggest that the majority of health locations have the possibility of decreasing their expenditures between 1% and 15% without affecting outcomes.

**CONCLUSIONS:**
Estimation of the threshold should allow for observation of the actual level of inefficiencies as well as an ability to consider the previous capacity of health locations to respond to changes in expenditures. Moreover, it is crucial to select the appropriate set of health outcomes, such that they reflect health system priorities, otherwise, we would be estimating a threshold that does not reflect likely displacement.

**PP128 Relationship Between Hemoglobin A1c And Medical Costs**

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**ABSTRACT SUMMARY:**
The Japanese government has promoted measures
for the prevention of diabetes aggravation, affecting quality of life and medical cost. We examined the medical cost by the analysis of hemoglobin A1c (HbA1c) level based on health insurance claims database with annual medical check-up data. As a result, more expensive medical cost was observed for those having high HbA1c level.

**INTRODUCTION:**
Diabetes causes complications and collateral diseases, reducing the quality of life and rising medical cost. The Japanese government has promoted measures for the prevention of diabetes aggravation. Although glycemic control is reported to prevent the development of complications, assessment of the effects on overall medical cost is insufficient. We examined the medical cost by the analysis of hemoglobin A1c (HbA1c) level.

**METHODS:**
A Japanese employee-based health insurance claims database with annual medical check-up data was analyzed. Excess medical cost was calculated as the difference between medical cost and standard medical cost (defined as the average medical cost for individuals of same age and sex). Percentage of excess medical cost was calculated by dividing excess medical cost by standard cost, and compared between individuals with or without treatment for diabetes.

**RESULTS:**
Of 4,307,184 individuals with HbA1c data, four percent of them received treatment for diabetes. For treatment of 6.5 percent of HbA1c, excess medical cost increased to 124 percent. The medical cost increased by an additional 20.4 percent (95% confidence interval: 17.1 – 23.8) when the HbA1c level increased one percent. Treatment for less than six percent of HbA1c caused an increase consistent with the HbA1c level. The relative risk of iron deficiency anemia, unspecified of those with less than six percent of HbA1c against those with seven to eight percent was the highest, 2.15.

**CONCLUSIONS:**
An increase of medical cost for individuals with treatment for high HbA1c is likely associated with diabetic complication. The raise for individuals with lower HbA1c level may be related to anemia. Despite the younger age and healthier life of the analyzed individuals, since they were insureds by employee-based health insurance who took regular medical check-up, more expensive medical cost was observed for those having higher HbA1c level.

**PP130 Burden of Disease of HPV9 Using Administrative Data in Italy**

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**ABSTRACT SUMMARY:**
The objective of this study was to estimate the economic burden and the preventable costs associated with nine HPV-related diseases in the light of the updated vaccination strategy and the newly available 9valent generation vaccine in Italy. The total direct costs of the nine HPV-related conditions were €503.2 million of which 63.6% attributable to HPV9 genotypes hence preventable through vaccination.

**INTRODUCTION:**
Italy has recently approved the National Immunization Plan 2017-19 becoming the first country in the EU to adopt a nationwide gender-
neutral HPV vaccination programme. The objective of this study was to estimate the economic burden and the preventable costs associated with nine HPV-related diseases in the light of the updated vaccination strategy and the newly available 9valent generation vaccine.

METHODS:
An incidence-based model was developed to estimate costs of invasive cervical cancer, cervical dysplasia, cancer of the vulva, vagina, anus, penis, head and neck, anogenital warts, and recurrent respiratory papillomatosis from the Italian National Health System perspective. Secondary data were used to estimate the number of incident cases of each disease and the prevalence of HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58. Diagnoses and treatments were identified through a regional administrative archive, according to the International Classification of Diseases (ICD-9 CM). Direct medical costs were calculated on a DRG basis at 2013 tariffs. A mean national value was calculated for each DRG, weighted for the 2016 resident regional population.

RESULTS:
The total direct costs (expressed in 2017 Euro) associated with the annual incident cases of the nine HPV-related conditions were estimated to be €503.2 million, with a plausible range of €492.7–651.9 million. The fraction attributable to the HPV9 was €320.0 (range €298–€342 million), accounting for approximately 63.6% of the total annual burden of HPV-related disease in Italy.

CONCLUSIONS:
Compared to the previous analysis conducted in 2011, the introduction of a prevention strategy was an important step forward in public health in reducing incidence rates of HPV related diseases and consequent costs (from €534.5 million in 2011 to €503,2). The new HPV9 vaccine represents an important investment that could prevent approximately 64% (range 60% - 68%) of total economic burden compared to 59% in the vaccination strategies available in 2011.

PP131 Eliciting Implicit Value-Judgments In The HTA Process

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ABSTRACT SUMMARY:
Eliciting implicit value-judgments in the HTA process is one way of integrating ethics in HTA. A categorization-based analysis of published citations referring to value-judgments is proposed. The citations gathered for each category regroup different expectations on the elicitation of implicit value-judgments. This chart allows a better understanding of the expectations to the appeal for more transparency in the HTA process.

INTRODUCTION:
Eliciting implicit value-judgments (VJs) in the HTA process is one way of integrating ethics in HTA since the latter is recognized as a value-laden process. An analysis of the diversity of opinions on implicit VJs in HTA and of their role, highlights the connection there exists between VJs and the different decisions involved in the whole HTA process. Such a link is corroborated by a conceptual analysis of VJ using a speech-act philosophical approach grounded in the philosophy of language, since VJs are linked with normative speech-acts such as commands, recommendations and advices.
**METHODS:**
We propose an analysis of the published citations mentioning VJs, extracted from our systematic review on the challenges of integrating ethics in HTA. In order to do so, those quotes were categorized in a chart, the latter of which presents: (i) the different steps of decision-making in the HTA process, (ii) the description of the implicit VJs(s) and (iii) the criteria involved. This chart was elaborated with the participation of the HTA local evaluators involved as co-investigators in our research group. The final version was discussed, debated and validated by the entire research group.

**RESULTS:**
The chart shows 18 decision-making steps in the HTA process in which 20 implicit VJs can be observed. The range of such VJs encompasses the whole HTA process from the initial mandate to the agency presenting the decisional issues, to the dissemination of the final report. The published citations gathered for each category compile different expectations on the elicitation of the implicit VJs, thus making the latters more explicit.

**CONCLUSIONS:**
This chart allows a better understanding of the expectations that are at the core of the appeal for more transparency in the HTA process, since stakeholders need to understand which value-judgments the final conclusion of a report is relying on.

**PP132 The 2nd Panel On Cost-effectiveness In Health And Medicine: A Critique**

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**ABSTRACT SUMMARY:**
Twenty years ago, the “Panel on Cost-Effectiveness in Health and Medicine” published methods for conducting cost-effectiveness analyses of health technologies. Recently, a second panel was convened to update these methods. The purpose of this paper is to critique this update. We identify numerous fundamental flaws, which we recommend be addressed through revisions to the panel’s report and recommendations.

**INTRODUCTION:**
Twenty years ago, the “Panel on Cost-Effectiveness in Health and Medicine” published a landmark report setting out methods for conducting cost-effectiveness analyses (CEAs) of health technologies. Recently, a second panel was convened to update these methods. The purpose of this paper is to critique the panel’s updated report and its recommendations.

**METHODS:**
Critical review of the second panel’s report and recommendations, with reference to CEA guidelines in other jurisdictions and existing theoretical and empirical literature.

**RESULTS:**
Several chapters are authoritative, including those on ‘valuing health outcomes’ and ‘reflecting uncertainty’. However, we identify substantive issues across multiple chapters, including: 1. The ‘theoretical foundations’ chapter acknowledges the distinction between ‘welfarist’ and ‘extra-welfarist’ approaches, yet key sections - including ‘cost-effectiveness analysis’, ‘net health benefit’ and ‘net monetary benefit’ - adopt a welfarist approach only. 2. The ‘perspectives’ chapter recommends that analysts report two reference case analyses - from both the ‘health sector’ and ‘societal’ perspectives - with no consideration as to whether this is desired by decision makers. 3. The ‘discounting’ chapter contains fundamental methodological errors, and the recommended discount rate is not supported by theoretical or empirical evidence. 4. The ‘ethical and distributive considerations’ chapter does not reflect the current
state of knowledge and mischaracterizes the equity position adopted by conventional CEA; its recommendations are not based upon an explicit decision-making perspective, and are biased in favour of the beneficiaries of technologies to the detriment of patients who bear the opportunity cost of their adoption.

CONCLUSIONS:
The second panel’s recommendations contain numerous flaws. We recommend that these be addressed through revisions to the panel’s report and recommendations, rather than waiting for a “third panel” to be convened. The process for future updates must also be strengthened to include greater engagement and transparency during the writing process, as well as more thorough peer review.

PP133 Collaborative Development Of Clinical Practice Guidelines And Decision

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ABSTRACT SUMMARY:
This study presents the results of a systematic review and a qualitative study on the link between collaborative development of Decision Aids and recommendations from the Clinical Practice Guidelines.

INTRODUCTION:
The Clinical Practice Guidelines (CPG) are a set of recommendations based on a review of the best available scientific evidence. CPG have become a fundamental support for health professionals in the decision-making process in clinical practice. Decision-making is not an exclusive competence of health professionals, patients are also part of this process, so Patient Decision Aids (DAs) are interventions that complement the medical care received. Therefore, a collaborative development of CPG and DAs has been proposed, in which CPGs are proposed to be developed before DAs, and later to attempt to adapt CPG recommendations to individual patients.

METHODS:
A systematic review of the literature on studies describing a strategy was carried out, describing a strategy for linking the development of DAs to CPG recommendations and studies describing the development of DAs based on CPG recommendations. A qualitative study was also carried out to explore the perceptions of relevant stakeholders on the methodological aspects needed to integrate patient values and preferences into the CPG-based decision-making process and for collaborative CPG and HATD development.

RESULTS:
A total of 50 references were included (40 from the systematic review and 10 recommended by some experts in the area). From the synthesis of the included references and from the qualitative study, some key aspects were extracted to favor link the DAs to the recommendations of CPG developed with the GRADE system and to favor the Shared Decision Making (SDM) process, and tools for linking CPGs and DAs, among other concrete experiences of some research groups.

CONCLUSIONS:
The development of DAs derived directly from the recommendations of the CPG, through the GRADE system, could improve the SDM process at the clinical encounter. For this, is important to establish
a collaborative development of CPG and DAs could be more efficient and facilitate its implementation in clinical practice.

PP134 The Impact Of pCODR Coming Under The Remit Of CADTH – 3 Year Update

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ABSTRACT SUMMARY:
The pan-Canadian Oncology Drug Review (pCODR) was established in 2010 to bring consistent oncology drug assessments across Canadian provinces/territories but was transferred to the Canadian Agency for Drugs and Technologies in Health (CADTH) in 2014. This research finds this transfer has not affected the number of appraisals nor the likelihood of a positive recommendation for Canadian oncology drug appraisals.

INTRODUCTION:
The pan-Canadian Oncology Drug Review (pCODR) was established in 2010 to bring consistent oncology drug assessments across Canadian provinces/territories. In April 2014, pCODR was transferred to the Canadian Agency for Drugs and Technologies in Health (CADTH). This transfer comprised two phases. In phase 1, pCODR staff, processes, funding, and expertise remained intact as a program but under the government of CADTH. In Phase 2, beginning April 2015, better alignment of pCODR and CADTH evaluation criteria and review processes were explored. This research aims to see what effect the CADTH transfer has had on the number of appraisals conducted by pCODR and their recommendation rates.

METHODS:
All publically available pCODR reports were extracted up to 22nd November 2017 and the drug, indication, date and outcome were extracted. Statistical comparisons were made using Student’s t-test.

RESULTS:
96 appraisals have been conducted by pCODR, reflecting an average of 16.0/year (10 in 2012, 18 in 2013, 9 in 2014, 24 in 2015, 19 in 2016, and 20 in 2017). The rate of appraisals was similar pre-CADTH transfer (14.2/year [32 from January 2012 to March 2014]) versus post-CADTH transfer (13.7/year [56 from April 2014 to November 2017]). 78% of pCODR outcomes were positive recommendations (defined as full recommendations [10%] or restricted/conditional recommendations [68%]) with 22% not recommended. Annually, positive recommendation rates were 70% in 2012, 89% in 2013, 78% in 2014, 79% in 2015, 74% in 2016, and 75% in 2017. There were no significant differences in recommendation rates since pCODR was transferred to CADTH irrespective if the Phase 1 or Phase 2 cut-off dates were used (p=0.434 and 0.307, respectively).

CONCLUSIONS:
The number of appraisals and likelihood of a positive recommendation for oncology drugs has not been affected by the pCODR transfer to CADTH.

PP135 CEA Of Cryoballoon Ablation For PAF In China: Real-world Data Results

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**ABSTRACT SUMMARY:**
This study aims to evaluate the cost-effectiveness of CBA versus RFA in patients with drug-refractory PAF in China. A Markov model was developed. Cost and probability inputs data were obtained mainly from a real-world study in China, and propensity score matching was used to overcome retrospective bias. Results showed CBA is a cost-saving treatment with providing increased QALYs.

**INTRODUCTION:**
Paroxysmal atrial fibrillation (PAF) represents a significant economic burden to the healthcare system. Catheter ablation is a commonly adopted treatment for PAF, and cryoballoon ablation (CBA) has been recently proven to be as effective as radiofrequency ablation (RFA). This study aims to evaluate the cost-effectiveness of CBA versus RFA in patients with drug-refractory PAF in China.

**METHODS:**
A Markov model was developed to study the effects and the costs of CBA versus RFA. Cost and probability inputs data were obtained mainly from a real-world study of 85 and 284 PAF patients receiving CBA and RFA, respectively, in a tertiary hospital between July 2014 and July 2016, and propensity score matching was used to overcome retrospective bias, resulting in including 75 patients in each group. Input data gaps were closed with literature review and advisory board. A simulation was carried out for 14 cycles/years, and a discount rate of 3% was used. Then, a probabilistic sensitivity analysis was carried out with Monte Carlo approach.

**RESULTS:**
In the base case scenario, the cumulative costs incurred by the CBA and RFA groups were ¥132,222 (exchange rate: US$1 for ¥6.64) and ¥147,304, respectively. Over the 14-year period, the QALYs gained by the CBA group was 7.85 versus 7.71 by the RFA group. The incremental cost-effectiveness ratio for CBA vs. RFA was thus -¥107,729/QALY. Model results were most sensitive to the cost incurred during the first hospitalization, recurrence rate, and relative utility weights. The probability of CBA being cost-effective for willingness to pay thresholds of per capita GDP in China was estimated to be 99%.

**CONCLUSIONS:**
Compared with RAF, CBA is a cost-saving treatment with providing increased QALYs. It represents good value for money for patients with drug-refractory PAF in China. However, further evidence needs to be generated from larger-scale studies in China.

**PP136 Smartphone Intervention To Promote Healthy Lifestyles Among Teenagers**

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**ABSTRACT SUMMARY:**
PEGASO system is a Smartphone based platform that uses the user-centered design, that includes apps, wearables and games to promote healthy lifestyles among adolescents. Results from qualitative an quantitative methodology show some impact on the improvement of diet. Several challenges and opportunities are associated with the implementation of mHealth.
INTRODUCTION:
We aimed to pilot the evaluation of the PEGASO system, a Smartphone based intervention (apps/wearables/game) to improve lifestyles and its awareness.

METHODS:
Design: Before-after quasi-experimental pilot controlled study. Participants: Teenagers aged 13-16 in a 2:1 (intervention: comparative group (IG:CG)) basis from Spain, Italy and UK. IG had access for six months to apps and game and to smart sensors the last 2 months. Schools were recruited by convenience sampling. Participants in both groups undertook a) anthropometric measurements, b) diet (KIDMED), physical activity (PAQ-A) and sleep (HELENA study) validated questionnaires and c) ad-hoc lifestyles knowledge questionnaire. PEGASO, if used, continuously recorded diet and physical activity. User experience was assessed through focus groups.

RESULTS:
558 participants were included (IG:365/ CG:193); mean (SD) age: 14.8 (0.8) and 52.3% girls. At baseline, mean scores (SD) of KIDMED, PAQ-A and weekday and weekend sleep hours were 5.60 (2.41), 2.48 (0.66), 8.34 (1.07) and 9.99 (1.66), respectively. The percentage of correct answers of lifestyle’s knowledge was 65.2% (13-100%). IG and CG did not show differences for main outcome variables. At six months, a higher percentage of participants of IG reported an increase of at least one point in the adherence to Mediterranean Diet (43.8% vs. 35.4, p<0.005). No differences were observed for other lifestyles. Focus group results showed a predisposition of adolescents to use mHealth for health promotion; the system was considered to be useful and complete and personalized suggestions were positively valued. Participants reported little interest on the game and several technical issues.

CONCLUSIONS:
Although participants were motivated and excited about their involvement in the study and that PEGASO was something desirable for them, the system only showed some impact in specific areas; namely in diet and could improve some its technological features. Several challenges and opportunities are associated with the implementation of mHealth.

PP137 Colorectal Cancer Screening In The Philippines: Cost-utility Analysis

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ABSTRACT SUMMARY:
Colorectal cancer is one of the leading causes of cancer deaths in the Philippines. Diagnosis occurs usually at late stages due to low rates of early screening. This study aimed to assess the possible creation of a national benefit screening package using a model-based economic evaluation to estimate various screening measures using existing cancer guidelines.

INTRODUCTION:
Colorectal cancer (CRC) is the fourth leading cause of cancer deaths in the Philippines. In 2014, the Philippine National Health Insurance Corporation (PhilHealth) created a package covering the treatment of clinically diagnosed CRC cases. Early detection is recommended for those aged fifty and above and for high-risk individuals as symptoms usually arise at later stages of the disease leading to poor prognosis. However, most choose not to get screened due to the perceived high costs of testing. The objective of this study is to conduct a cost-utility and budget impact analysis on CRC
METHODS:
The study used model-based economic evaluation to estimate costs of various screening measures for CRC using the National Comprehensive Cancer Network Guidelines and from specialist consultations. Included in the study were public and private tertiary level hospitals from different regions. A Markov model was used with costing information from PhilHealth and probability parameters from existing literature to estimate costs. Two output measures were derived from the estimates: (i.) incremental cost-effectiveness ratios (ICER) and budget impact of each screening modality.

RESULTS:
Data Analysis is ongoing. The median cost of a Guaiac FOBT was PHP 160.00 (USD = 3.16 USD) while it was PHP 486.85 (USD = 9.62) for an immunologic FOBT. The median cost of a colonoscopy was PHP 7,400.00 (USD = 136.30) while for the FS, it was PHP 6138.34 (USD= 121.42).

CONCLUSIONS:
The median costs of screening modalities come in a varied range. Since screening will be an out-of-pocket expense, the financial burden currently falls squarely on the patient. The creation of evidence-based analysis will help create informed decision making for the national insurance provider in the face of limited resources.

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ABSTRACT SUMMARY:
We studied the cost-effectiveness of the chemoprophylaxis for Influenza A (H1N1) with oseltamivir and zanamivir for the Brazilian health care system; the model was a decision-tree and outcomes were quality-adjusted life years (QALY) and avoided H1N1 cases. With this model, we concluded that prophylaxis is cost-effective in the health care system perspective.

INTRODUCTION:
Influenza A (H1N1) virus is the most relevant virus in death by flu complications. Oseltamivir and zanamivir are used for influenza prophylaxis in epidemics. We aimed to evaluate the efficacy of chemoprophylaxis for influenza A (H1N1) for the Brazilian health care system.

METHODS:
We systematically searched the literature to identify efficacy results. Costs assessed for the system perspective were obtained from official Brazilian Ministry of Health systems and completed from medical care at a university hospital of Campinas, Sao Paulo. Model outcomes were quality-adjusted life years (QALY) with willingness to pay BRL 30,000.00/QALY and prevention of H1N1. A decision-tree model was used for calculation of cost-effectiveness incremental ratios for prophylaxis scenario, compared to no prophylaxis. Deterministic and probabilistic sensitivity analysis were used to test robustness.

RESULTS:
Prophylaxis had 70% adherence to treatment, 9% adverse events, effectiveness in avoiding H1N1 (relative risk = 0.43; 95% confidence interval: 0.33, 0.57); no evidence of prophylaxis efficacy for
complication, hospitalization and death was found. Both scenarios had 14% H1N1 attack rate, 67% of ambulatorial consult, 43% of inpatient care, 14% of deaths in hospital, 23% of intensive care where death was 40%. Utility was 0.50 during H1N1 infection, 0.23 with hospitalization, 0.195 less with adverse events, 0 for deaths and 0.885 for healthy. Cost was BRL39.42 for chemoprophylaxis; BRL12.47 for outpatient care; BRL5,727.59 for hospital admission; BRL19,217.25 for intensive care; and BRL292.05 for adverse events. Incremental cost of prophylaxis was BRL39.70 and utility increased 0.004, which mean saving of BRL2,921.14/QALY. Prophylaxis saves BRL337.84 per H1N1 case avoided. Univariate and probabilistic sensitivity analysis assure the robustness of results, with 43% probability of being of lower cost and higher effectiveness.

CONCLUSIONS:
Prophylaxis is cost-effective in the health care system perspective using utility and avoided H1N1 cases outcomes.

INTRODUCTION:
Patient-focused drug development (PFDD) recognizes the value of engaging patients throughout drug development. Life-science companies, known commonly as sponsors, aim to engage patients so that they can develop medicines that align with patient needs, resulting in better patient outcomes. However, often sponsors struggle with engaging patients in all but the most basic ways because of regulatory and legal uncertainty and lack of clear guard rails on non-promotional interactions with patients. The objective of this project was to clarify good practices in sponsor-patient engagement.

METHODS:
On 15 June 2017, to discuss issues associated with sponsor-patient interactions in drug development and identify good practices for those interactions, the National Health Council (NHC), Genetic Alliance (GA), and the Food and Drug Law Institute (FDLI) brought together 90 drug-development stakeholders from patient advocacy groups, life-science companies, professional associations, industry trade associations, academic institutions, non-profit organizations and institutes, and government agencies for a one-day public meeting to elucidate good practices in sponsor-patient interaction.

RESULTS:
The consensus good practices and examples of good and poor practices were split into six categories: i. WHAT: Defining Data on Interactions to be Collected ii. WHY: Defining the Purpose of Interaction iii. WHEN: Timing of Interaction iv. WHO: Establishing Who Interacts v. HOW: Structure of the Interaction vi. WHERE: Where Interaction Takes Place Illustrative examples will be provided for the presentation.

CONCLUSIONS:
Organizations need to have clear processes and protocols, so their engagement actions will not be questioned or misinterpreted. While more
work is needed to continue to advance this space, the good practices learned and outlined are a start to helping drive this evolution and meet the good practices identified during the meeting.

PP140 Cancer And The Burden For Social Security System: Is It Sustainable?

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ABSTRACT SUMMARY:
The aim of the study is to estimate the beneficiaries and the pension costs related to cancer between 2009 and 2015. We have analysed the database about the approved claims and the mean cost per benefit of the National Institute of Social Security. The total estimated expenditure for ND in the seven years amounted to €8.1 billion.

INTRODUCTION:
The purpose of the study is to estimate both the number and the burden of the Disability Insurance (DI) benefits provided for Neoplastic Diseases (ND) and for five cancer type, focusing on the expenditure from the social security system.

METHODS:
To estimate the current DI benefits and its cost, we analysed the databases about the DI awards and the mean cost per benefit of the Italian National Social Security Institute (INPS) for two types of social security benefits: the disability benefits (DB) for people with reduced work ability and the incapacity pensions (IP) for people without work ability. A probabilistic model with a Monte Carlo simulation was developed in order to estimate the total benefits provided and costs.

RESULTS:
Between 2009 and 2015, were estimated an yearly average of about 122,000 beneficiaries of DI for cancer. The total estimated expenditure for ND in the seven years, supported and provided by INPS for these social security benefits amounted to €8.1 billion (corresponding to the 27.4% of the total expenditure for disability provided by INPS) of which 66.7% associated with the DB and the remaining 33.3% with the IP. The percentage increase related to the costs show that DB have the most significant starting from the 2013 with 11.3% from 2013 to 2014 and 9.7% from 2014 to 2015 and IP have an increase from 2009 to 2011 with a maximum during the 2011 with a percentage difference of 7.6%.

CONCLUSIONS:
The incidence and the prevalence of the ND are bound to increase in the coming years in Italy. In order to minimize the consequences of this scenario, a rapid access to innovative treatments would reduce the costs borne by the social security system, accompanied by an improvement of the effectiveness of interventions and increase in terms of quality of life for patients.

PP141 The Irrelevance Of ICERs

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ABSTRACT SUMMARY:
The incremental cost-effectiveness ratio (ICER) is commonly used by decision makers. Despite its flaws, it remains popular due to its perceived simplicity and the ability for decision makers to calculate ICERs without specifying a cost-
effectiveness threshold. We demonstrate that these perceived advantages are misplaced, and that many common approaches for interpreting ICERS are fundamentally flawed.

**INTRODUCTION:**
The incremental cost-effectiveness ratio (ICER) is the most commonly used summary statistic in cost-effectiveness analyses of health technologies. Although the ICER has received criticism, particularly due to its undesirable statistical properties, it remains popular with decision makers. This may be because of its perceived simplicity compared to alternative measures such as ‘net benefit’, and the ability for decision makers to calculate ICERS without specifying a cost-effectiveness threshold. We demonstrate that the perceived advantages of ICERS are misplaced, and that many common approaches for interpreting ICERS are fundamentally flawed.

**METHODS:**
In depth review of methods to calculate and interpret ICERS and measures of ‘net benefit’, followed by a review of how each measure is used in practice by decision makers. We also propose a novel means for representing ‘net benefit’ on the cost-effectiveness plane, allowing for easy interpretation by decision makers.

**RESULTS:**
The ICER is more complex to calculate than measures of ‘net benefit’ and cannot be interpreted in the absence of a cost-effectiveness threshold, nullifying its perceived advantages. Common practices, such as interpreting lower ICERS as implying that a technology is ‘more cost-effective’, are fundamentally flawed; a lower ICER may be associated with higher, lower, or equal ‘net benefit’, so is uninformative as to whether a technology is more or less cost-effective. Common uses for ICERS, including their interpretation without a threshold and in sensitivity analyses (e.g. “tornado diagrams”), are entirely unsupported theoretically and may result in misleading findings.

**CONCLUSIONS:**
If the cost-effectiveness threshold is not known then ICERS cannot be used to inform decisions. If the threshold is known then measures of ‘net benefit’ are easier to calculate and interpret. It follows that decision makers should take steps to abandon ICERS and instead adopt measures of ‘net benefit’ to inform their decisions.

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**PP142 Is Insulin Therapy Important For The Quality Of Life Of Diabetics?**

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**ABSTRACT SUMMARY:**
We conducted a cross-sectional study with 401 patients with T1DM who used insulin glargine (GLA) and 179 patients who used insulin neutral protamine hagedorn (NPH) to access the influence of insulin therapy on quality of life (QoL). Sociodemographic and clinical factors explained 41.3% of QoL results – insulin therapy with either GLA or NPH was not associated with QoL results.

**INTRODUCTION:**
Quality of life (QoL) is an important health measure and is widely used to access the difference
between treatments for Type 1 Diabetes Mellitus (T1DM), since the desirable glycemic control and the minimization of episodes of hypoglycemia are fundamental aspects for a better QoL. This study aims to identify the factors associated with QoL in patients with T1DM.

METHODS:
A cross-sectional study (approved by ethics committee) was carried out in the state of Minas Gerais, with 401 T1DM patients who used insulin glargine (GLA) selected in March 2017 and 179 patients who used insulin-neutral protamine (NPH) between January and February 2014, both treated by the Unified Health System. A questionnaire with three blocks was used: A) sociodemographic data; B) clinical data and access to the service; and C) QoL by Euroqol (EQ-5D-3L). We used multiple linear regression by the forward stepwise method to access the correlation between the utilities of the EQ-5D-3L and all the explanatory variables (blocks A and B). We adopted the significance level and Confidence Interval of 95% (95% CI).

RESULTS:
Of the 580 patients evaluated, 54 percent were women, 37 percent were in the age group between 21-40 years, 53 percent reported to be non-black. Being young, very good / good health self-perception, having not been bedridden, none to three medical appointments in the last year, no hospitalization, to practice physical exercise, having between zero and three comorbidities and no severe hypoglycemia in the last 30 days were explained 41.3 percent of QoL. Insulin therapy with either GLA or NPH was not related to QoL result.

CONCLUSIONS:
The findings of this study pointed to a lack of correlation between insulin therapy and QoL of patients with T1DM. Socio-demographic and clinical factors were more important to explain the QoL of diabetics.

PP143 Systematic Review Of Abdominal Aortic Aneurysm Surveillance Imaging

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ABSTRACT SUMMARY:
We conducted a systematic review of imaging modalities used in the surveillance of patients who have received endovascular aneurysm repair for abdominal aortic aneurysm. We identified two non-randomised comparative studies and 25 cohort studies. Substantial clinical heterogeneity precluded a formal synthesis of results. No firm conclusions can be drawn with regards to the optimal surveillance strategy.

INTRODUCTION:
Endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA) is less invasive than open surgery, but may be associated with important complications. EVAR patients require long-term surveillance to detect abnormalities and direct treatments. Computed tomography angiography (CTA) has been the most common imaging modality adopted for EVAR surveillance but may be associated with repeated radiation exposure and risk of contrast-related nephropathy. Colour duplex ultrasound (CDU) and, more recently, contrast-enhanced ultrasound (CEU) have been suggested as possible, safer, alternatives to CTA.
METHODS:
A systematic review of randomised and non-randomised studies of CT and CEU and/or CDU in adults undergoing surveillance following EVAR for AAA. We searched major electronic databases, conference abstracts and ongoing studies from 1996 to September 2016.

RESULTS:
Two non-randomised comparative studies and 25 cohort studies were identified. Substantial clinical heterogeneity precluded a formal synthesis of results. Overall, the proportion of patients who required surgical re-intervention ranged from 1.1% (mean follow-up 24 months) to 23.8% (mean follow-up 32 months). Re-intervention was mainly required for thrombosis and types I, II and III endoleaks. All-cause mortality ranged from 2.7% (mean follow-up of 24 months) to 42% (mean follow-up of 54.8 months). Aneurysm-related mortality occurred in less than 1% of the participants. Strategies based on early and midterm CTA and/or CDU and long term CDU surveillance were broadly comparable with those based on a combination of CTA and CDU throughout follow up in terms of clinical complications, re-interventions, and mortality.

CONCLUSIONS:
Current surveillance practice is very heterogeneous. No firm conclusions can be drawn with regards to the optimal surveillance strategy after EVAR. CDU may be a safe alternative to CTA, with CTA reserved for abnormal/ or inconclusive CDU cases. There is a need to identify how often imaging should occur, taking a person’s individual risk of developing complications into consideration.

PP144 Social Preferences For Health Care Interventions: The SoPHI Study

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ABSTRACT SUMMARY:
The SoPHI Study was a discrete choice experiment (DCE) designed to assess social value drivers of health care interventions. Results indicate that the following attributes exert a relevant influence on social value: health state before and after intervention, age, prevalence (or “rarity”), and social willingness-to-pay (SWTP) as payment vehicle, chosen to capture social preferences including risk aversion and caring externalities.

INTRODUCTION:
Conventional cost effectiveness analyses (CEAs) are restricted in scope. Valuation is conceptually based on individual (or “selfish”) preferences for health states and the cost of health care resource use per patient. There are both normative and empirical reasons to believe that social value may however exceed satisfaction of individual (selfish) preferences. Multi-criteria decision analysis (MCDA) and social cost value analysis (SCVA) represent recently proposed attempts to capture sources of value beyond gains in length and quality of life. Both MCDA and SCVA should be informed by robust empirical evidence on the social preferences of citizens covered by a health scheme.

METHODS:
Based on prior work, a comprehensive literature review, the Swiss HTA project, and an expert
consensus on valuation principles for ultra-rare disorders, we designed the SoPHI Study as a discrete choice experiment (DCE) to assess the relative weights of selected attributes of health care interventions, their interaction and the impact of the level of information on the implications of rarity and cost (potential framing effects). After cognitive and quantitative pretests, the main survey was conducted in Switzerland and enrolled 1,501 respondents, who underwent an initial preference formation phase before participating in the DCE experiment. Attributes tested were health state before and after intervention (separately for length and quality of life), age, prevalence (or “rarity”), and social willingness-to-pay (SWTP) as the payment vehicle, which we chose in order to capture social preferences including risk aversion and caring externalities.

RESULTS:
The main survey provides support for the importance of all attributes tested, with change in remaining life expectancy, incremental cost (from a citizens’ perspective), and quality of life improvements being more relevant than prevalence and the age effect observed in the experiment.

CONCLUSIONS:
The SoPHI Study provides empirical support for the contribution to social value judgments by all attributes tested.

ABSTRACT SUMMARY:
Clinical practice guidelines (CPGs) are seen as a key vehicle for converting evidence into action. Deciding whether and how to develop CPGs is challenging. Health technology assessment (HTA) researchers used their methodological expertise to address this challenge by developing a multi-step decisional algorithm highlighting where HTA products and expertise can help demystifying these decisions.

INTRODUCTION:
Clinical practice guidelines (CPGs) are a key vehicle for converting evidence into action. CPGs can be produced by various methods: de novo, adaptation, adoption, or a combination of these. Deciding whether and how to develop a guideline can be challenging. Health technology assessment (HTA) researchers from the Institute of Health Economics developed a multi-step decisional algorithm highlighting the decision nodes in the initial phase of guideline development where HTA products and expertise can be valuable in demystifying these decisions.

METHODS:
A literature search was conducted for articles comparing methods of developing CPGs, with particular focus on finding a priori criteria for deciding when to use one method versus another.

RESULTS:
The published literature is sparse and there are no specific criteria available for deciding when to use one method of development versus another. The proposed multi-step algorithm identifies similar steps in the production of all types of CPGs: the set-up phase; establishing the need for a new CPG in consultation with a guideline development group and local stakeholders; developing research question(s); conducting searches for suitable existing guidelines; and finalizing the guideline. HTA can help set the health question(s) and identify and screen existing CPGs. When CPGs are not available, HTA methods are implemented to update
the evidence in a blend of de novo and adaptation processes by reviewing umbrella reviews, systematic reviews, and primary studies. Quality appraisal of existing guidelines and syntheses of evidence in a rapid review fashion help determine whether there are enough studies to support the guideline scope.

CONCLUSIONS:
Deciding which method of guideline development to employ requires ample methodological expertise, an intimate knowledge of the clinical practice environment, and access to detailed contextual information. The proposed multi-step algorithm shows how to successfully leverage HTA resources to support CPG production and move research evidence into practice.

PP146 Cost-effectiveness Of Nivolumab Plus Ipilimumab In Advanced Melanoma

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ABSTRACT SUMMARY:
This study was done to contribute to existing literature about cost-effectiveness of nivolumab and ipilimumab, both of which are new and expensive agents and used in first-line immunotherapies for patients with unresectable/metastatic (stage III-IV) Advanced Melanoma. The study aimed to assess if combination therapy (nivolumab plus ipilimumab) is more cost-effective compared to monotherapy (nivolumab) for these patients in the Netherlands.

INTRODUCTION:
This study was done to assess the cost-effectiveness of NIV+IPI (nivolumab plus ipilimumab) versus NIV (nivolumab alone) for treatment of previously untreated patients with AM (advanced melanoma) patients from Dutch health care perspective.

METHODS:
A Markov model was constructed with a life-time horizon. Future effects and costs were discounted at 1.5 and 4 percent, respectively. Risks of progression and death were based on PFSs (progression-free survivals) obtained from a phase III clinical trial (NIV+IPI and NIV versus ipilimumab) and conjectural OSs (overall survivals) calculated indirectly by using PFSs and OSs from another one (NIV versus dacarbazine), which were extrapolated by Weibull distribution lateron. Utility values of health states and disutility values of adverse events were derived from literature. Unit costs were taken from Dutch Diagnosis Treatment Combination Care Products Tariff, Erasmus MC prices and Dutch pharmacy purchase prices. Chronic management costs of AM and treatment costs of adverse events were calculated based on a survey done among clinicians determining necessary health care services and their utilization rates.

RESULTS:
Over life-time, on average an AM patient being treated by NIV+IPI was estimated to live 4.22 years and 2.59 QALYs (quality-adjusted life years) at a (discounted) net cost of 262,824.61 EUR, while another being treated by NIV was estimated to live 3.26 years and 2.00 QALYs at a (discounted) net cost of 195,341.79 EUR, per individual. So, the incremental cost-effectiveness ratio was 70,770.30 EUR per life year saved and the incremental cost-utility ratio was 115,533.29 EUR per QALY gained.

CONCLUSIONS:
At a willingness to pay threshold of 80,000.00 EUR per QALY gained, NIV+IPI compared to NIV may not be accepted as a cost-effective tool, from Dutch health care perspective, in order to prevent high mortality and morbidity rates of AM.
**PP147 Olaratumab With Doxorubicin For Advanced Soft Tissue Sarcoma**

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**ABSTRACT SUMMARY:**
We report results of a National Institute for Health and Care Excellence Single Technology Appraisal of olaratumab in combination with doxorubicin for advanced soft tissue sarcoma (STS) not amenable to surgery or radiotherapy. Based on available evidence, this treatment is likely to represent poor value for money when judged by cost-effectiveness criteria used in England.

**INTRODUCTION:**
The National Institute for Health and Care Excellence (NICE) invited the manufacturer of olaratumab (Lartruvo®), Eli Lilly & Company Limited, to submit evidence for the clinical and cost effectiveness of this drug, in combination with doxorubicin, for advanced soft tissue sarcoma (STS) not amenable to surgery or radiotherapy, as part of the Institute’s Single Technology Appraisal. The Peninsula Technology Assessment Group critically reviewed the submitted evidence.

**METHODS:**
Clinical effectiveness was derived from an open-label, randomised controlled trial, JGDG. The economic analysis was based on a partitioned survival model with a time horizon of 25 years. The perspective was of the UK National Health Service (NHS) and Personal Social Services. Costs and benefits were discounted at 3.5 percent per year. The company’s evidence was submitted in anticipation that olaratumab would be considered as an alternative to doxorubicin, which has been used as a first-line treatment for advanced STS. To improve the cost effectiveness of olaratumab, the company offered a discount through a Commercial Access Agreement with the NHS England.

**RESULTS:**
In the company’s submission, the mean base-case and probabilistic incremental cost-effectiveness ratios (ICERs) for olaratumab plus doxorubicin versus doxorubicin alone were GBP46,076 (USD61,403) and GBP47,127 (USD62,804) per quality-adjusted life-year (QALY) gained, respectively; the probability of this treatment being cost effective at the willingness-to-pay threshold of GBP50,000 (USD66,632) per QALY gained, applicable to end-of-life treatments, was 0.54. The respective estimates in our analysis were approximately GBP60,000 (USD79,959) per QALY gained, and the probability of cost-effectiveness was 0.21. The increase in the ICERs was primarily due to differences in extrapolation of overall survival, and drug administration costs.

**CONCLUSIONS:**
Based on the available evidence, olaratumab in combination with doxorubicin improve survival of patients with advanced STS. However, this treatment is unlikely to be cost-effective. Olaratumab is now recommended for use within the Cancer Drugs Fund.

**PP148 Your Money Or Your Life? Are Price Negotiations HTA Best Practice?**

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ABSTRACT SUMMARY:
HTA outcomes directly link to reimbursement decision-making based on manufacturer submitted prices in some markets (e.g. NICE). In others, price negotiations by a separate body follow HTA outcomes (e.g. G-BA/GKV). This research suggests that the former approach may represent a more objectively fair and transparent HTA method but the flexibility enabled through price negotiations may enable access for more therapies.

INTRODUCTION:
Many countries use Health Technology Assessment (HTA) organizations to evaluate the clinical and economic impact of new therapeutic interventions. In some markets, HTA outcomes directly link to reimbursement decision-making based on the manufacturer’s submitted price (e.g. NICE and SMC[UK]). In others, the HTA outcome leads to price negotiations with manufacturers by a separate body (e.g. HAS/CEPS[France] and G-BA/GKV[Germany]). This research compares major examples of each approach to inform a discussion on whether such price negotiations align with HTA best practice.

METHODS:
Publically-available technology assessment outcomes for G-BA/GKV, NICE and SMC (01/01/2011-31/12/2015) were extracted and compared.

RESULTS:
Of 112 G-BA benefit assessments, 45% offered no additional benefit with automatic reference pricing, 55% offered additional benefit, qualifying for price negotiations. 77% had prices negotiated, 14% had price fixed by court, and 8% withdrew from market. Of 156 NICE STAs: 51% were recommended, 17% restricted, 20% not recommended, and 12% non-submissions. Of 497 SMC appraisals: 35% were accepted, 28% restricted, 17% not recommended and 19% non-submissions. 48% and 24% of NICE and SMC positive appraisals were associated with a PAS, with 86% and 88% being simple discounts schemes, respectively.

CONCLUSIONS:
Making reimbursement decisions for new medicines based on a clear set of criteria may be the most objectively fair and transparent method of HTA. However, as the NICE and SMC examples show, although strong downward price pressure is exerted (high frequency of PASs), this may come at the cost of many therapies (~33%) being denied access. By contrast, the flexibility enabled by a distinct price negotiation phase may enable more therapies access, as shown by the G-BA/GKV example (<10% medicines withdrawn). Nevertheless, the relative effectiveness of the downward price pressures, a key determinant of HTA process effectiveness, cannot be compared due to the confidential nature of UK PAS discounts.

PP149 Features Of Accountable And Reasonable Processes For Coverage Decision

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ABSTRACT SUMMARY:
In this study, experts explored how to align specific features of coverage decision-making processes with the Accountability for Reasonableness conditions (Relevance, Publicity, Appeals, Implementation) to guide legitimised decision-making, using rare disease and regenerative therapies as a case study. Recommendations included supporting participation and deliberation, enhancing transparency, and more explicit consideration of multiple decision criteria that reflect normative and societal objectives.

INTRODUCTION:
The Accountability for Reasonableness (A4R) framework addresses the legitimacy of coverage decision processes by defining four conditions for accountable and reasonable processes (Relevance, Publicity, Appeals, Implementation). Cost-per-QALY- and multicriteria-centered processes may have distinct implications for meeting A4R conditions. The aim of this study was to reflect on how the diverse features of decision-making processes can be aligned with A4R conditions to guide legitimised decision-making. Rare disease and regenerative therapies (RDRTs) pose special decision-making challenges and offer a useful case study.

METHODS:
To support reflection on how different approaches address the A4R conditions, 34 features operationalizing each condition were defined and organized into a matrix. Seven experts from six countries explored and discussed these features during a panel (Chatham House Rule) and provided general and RDRT-specific recommendations for each feature. Responses were analyzed to identify converging and diverging recommendations.

RESULTS:
Regarding Relevance, panelists highlighted the importance of supporting deliberation, stakeholder participation and grounding coverage decision criteria in the legal framework, goals of sustainable healthcare and population values. Among 17 criteria, 13 were recommended by more than half of panellists. Although the cost-effectiveness ratio was deemed sometimes useful, the validity of universal thresholds to inform allocative efficiency was challenged. Regarding Publicity, panelists recommended communicating the values underlying a decision in reference to broader societal objectives, and being transparent about value judgements in selecting evidence. For Appeals, recommendations included clear definition of new evidence and revision rules. For Implementation, one recommendation was to perform external quality reviews of decisions. While RDRTs raise issues that may warrant special consideration, rarity should be considered in interaction with other aspects (e.g., disease severity, age, budget impact).

CONCLUSIONS:
Improving coverage decision-making towards accountability and reasonableness involves supporting participation and deliberation, enhancing transparency, and more explicit consideration of multiple decision criteria that reflect normative and societal objectives.
ABSTRACT SUMMARY:
The study aimed to explore the status and the
constraints of talent team construction of rural
primary medical institutions in China taking
Shandong province as an example. Used multi-
dimension to evaluate and analyze, such as
recruitment, training, professional mentality,
resource integration, etc. Then put forward some
strategies to improve the rural medical talent team’s
quality and quantity.

INTRODUCTION:
Rural basic medical institution played an important
role ensuring vital rural residents’ health. But the
talent team which is the core of institution faced
the low quality and quantity. How to solve this
dilemma becomes an urgent problem. The study
aimed to explore the constraints for rural primary
team building based on the multi perspective of
personnel recruitment, training, preparation of
promotion, professional mentality and resource
integration, etc. And then put forward the
strategies.

METHODS:
Based on the questionnaires and interview outline
of the task group design, multi-stage stratified
random sampling was used to collect data. We
chose Shandong province as the example which is
located the north-middle of China. And used mean,
rate, constituent ratio to descriptive the data, and
used fishbone diagram and a radar graph to show
constrains of talent team development clearly.

RESULTS:
The constraints of talent team construction were:
the recruitment policy mismatching the actual
demand, lacking of the training effect evaluation
mechanism, doctors’ low income satisfaction, the
high work pressure and risk, irrational title structure
and employment system, talent siphoned by
country-level medical institutions, and weak help
from superior hospital.

CONCLUSIONS:
The study suggested that enhance the
government’s human capital investment,
implement the Preparation filing system, strengthen
personal training and development mechanism,
raise the composition of primary titles, improve
promotion system and achieve appraising and
hiring of professional evaluation, implement high-
level, transparent salary system and job subsides,
establish medical responsibility insurance system
and compact medical consortium.

PP151 Comparison Of Patients Undergoing New Technology For Prostate Cancer

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ABSTRACT SUMMARY:
Prostatectomy X High Intensity Focused Ultrasound description

INTRODUCTION:
Prostate neoplasia affecting more than one million
people worldwide. Surgical treatments evolved
from open or video prostatectomy up to the High
Intensity Focused Ultrasound (HIFU) technique.
HIFU studies cited less costs and better quality
of life during 01 year follow-up. Objectives: To
describe a consecutive series of eligible patients,
with Gleason score 6 and 7, and compare resources
used along those three treatment techniques.
**METHODS:**
Comparative and retrospective study during the first 2017 semester, at Hospital de Transplantes de São Paulo, São Paulo city, Brazil. Consecutive eligible patients were matched by age, disease stage and profile and Gleason score 6 or 7. Resources used were assessed through medical records review and in- and out-patients visits interviews.

**RESULTS:**
Total of 152 patients were followed, 50 underwent open surgery prostatectomy, 50 a video prostatectomy and 52 HIFU. Mean age did not differ between groups, 66.6, 64.1 and 65.6 years, respectively. All patients were followed at least 3 months. Groups’ operating room average time was 4.7, 4.1 and 2.3 hours and 2.0, 1.9 and 2.0 hours in anesthetic recovery setting, respectively. Average inpatient length of stay was 2.5, 2.7 and 1.5 days respectively. Postoperatively, 09 of the 50 patients (18%) of open surgery, and 14 (28%) of video-prostatectomy, in average required 01 full-day intensive care unit, compared to only one patient (2%) of HIFU. During follow-up, same effectiveness was observed amid the 3 groups, none required re-intervention. Thus, considering the 50% economy in hours of operating room and of days of hospital stay, as well as 10 times less use of intensive care unit days when HIFU technique was compared to conventional surgeries, it is estimated the HIFU program allowed 30% costs savings.

**CONCLUSIONS:**
The HIFU program presented effectiveness and savings. The hospital can increase access to care for prostate neoplasia patients.

**PP152 Options To Approach Health Litigation In Brazil: A Policy Brief**

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**ABSTRACT SUMMARY:**
An evidence brief to better inform Brazilian law workers decision-making process concerning health technologies was developed, using SUPPORT tools from the Evidence-Informed Policy Network (EVIPNet). After defining the problem and appraising strategies to approach it, the authors described implementation barriers and solutions, considering the data available from systematic reviews. This brief can support evidence-informed decision-making in health litigation.

**INTRODUCTION:**
In Brazil, health is a constitutional right and the government is responsible for its guarantee. Brazilian Health System (SUS) is oriented by universality, equality and integrality, however citizens have been striving to guarantee the rights through litigation. This work aimed to develop an evidence brief to inform judges decision-making process concerning health technologies.

**METHODS:**
SUPPORT tools, from the Evidence-Informed Policy Network (EVIPNet), were used to develop this evidence brief. After defining and describing the
problem, a comprehensive search was conducted for systematic reviews from 2010 to 2016 in PubMed, Health Systems Evidence; Campbell; The Cochrane Library; Rx for Change, PDQ-Evidence. Nine systematic reviews were found, paired appraised and three options were defined. Evidence was summarized considering benefits, harms, resources, cost-effectiveness, uncertainties and implementation. Afterwards, implementation barriers and strategies to overcome them were described.

RESULTS:
Three strategies were found: 1. Rapid response services to support evidence-informed decision-making in health technologies decisions – even though financial reallocation is needed, to inform decision-making with educational activities and materials is described as an effective way to involve different parts; 2. Continuing education program, focused on law workers, to develop health technologies assessment abilities – continued education and educational outreach may be effective in knowledge and abilities acquisition and retention, changing professional practices. Eventual lack of interest or availability from the professionals can be addressed by involving leaders and opinion makers, as well as offering multimedia educational materials and activities adapted to the aimed public. 3. Restorative Justice Conferencing (RJC) focused on the litigation of health technologies – the use of RJC through face-to-face meeting or social councils, brings closer together the citizens and the decision-making process, including resources management. There are multiple barriers to this option (i.e. public incomprehension, interest conflicts, lack of professionals capable of conducting RJC’s and the need for legal reformulation), because of its unprecedented approach in health. Opinion leaders should be invited to facilitate the communication and the decision-making process among citizens, government and law.

CONCLUSIONS:
The evidence brief will be debated among interested parts and presented to Health Minister and State Secretaries, in order to implement the options, considering regional specificities.

PP153 Using Theory To Assist Guideline Development In Economic Evaluation

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ABSTRACT SUMMARY:
Revisions to the Canadian guidelines for economic evaluation were founded in a cohesive and appropriate theoretical framework; the social decision-making paradigm. Consideration of a consistent paradigm led to substantial changes in some guidance and provided clearer justification for existing guidance. The revised guidelines aim to facilitate decisions through placing sound economic theory as the basis for determining appropriate methodology.

INTRODUCTION:
The Canadian Guidelines for the Economic Evaluation of Health Technologies have been recently revised. As topics within the Guidelines were being reviewed the need to ensure the Guidelines were founded in a cohesive and appropriate theoretical framework with emphasis on the role of economic evaluation as an input to decision making processes was recognised. We report the theoretical paradigm which guided our thinking and the subsequent guidance which emerged.
METHODS:
Within Canada, economic evaluation facilitates health care decisions within a publicly funded system. Thus, we argue that the appropriate theoretical paradigm for this context is the social decision-making approach. It is assumed that decision-maker wish to maximise a health related outcome such as population health within an exogenous budget constraint. This aligns with the mandates of health authorities within Canada and was verified by the initial feedback received during extensive stakeholder engagement.

RESULTS:
There were several major changes within the Guidelines all of which were consistent with the adoption of a social decision-making viewpoint. Significant revisions which were guided by the theoretical paradigm related to: specification of the decision problem, requirement for stratified analysis, discount rate, handling uncertainty and the use of probabilistic analysis in the base case. In addition, the theoretical paradigm provided clearer justification for previous recommendations relating to type of analysis, comparators, perspective, time horizon, utility and cost estimation and equity.

CONCLUSIONS:
The concepts of decision-making under scarcity and the efficient allocation of resources are arguably the raison d’être for economic evaluation of health care technologies. We argue that the Guidelines are a response to the increasing adoption of paradigms more akin to clinical epidemiology than economics within the conduct of economic evaluation. The focus is to restore economic evaluation as a means of facilitating decisions through placing sound economic theory as the basis for determining appropriate methodology.

PP154 Cost-utility And Budget Impact Of Dexrazoxane In Pediatric Cancer

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ABSTRACT SUMMARY:
Cost-utility and budget impact of dexrazoxane for cardiotoxicity prevention in anthracycline-treated pediatric cancer patients were estimated, under the Brazilian public health system perspective. A lifetime Markov model was built to compare 6 different patient profile candidates to use the prophylaxis. Prophylaxis in children < 5 years old was the most cost-effective strategy, followed by treat all children.

INTRODUCTION:
Childhood cancer survival is around 80%, with cardiovascular disease as the leading cause of non-cancer-related morbidity and mortality. Dexrazoxane has been shown to prevent anthracycline-induced cardiotoxicity. Cost-utility and budget impact of dexrazoxane for cardiotoxicity prevention in anthracycline-treated pediatric oncpatients were estimated, under the Brazilian public health system perspective.

METHODS:
A lifetime Markov model was built to compare management strategies of anthracycline-induced cardiotoxicity, based on symptoms control approach and prophylactic dexrazoxane in 6 different cohorts of pediatric cancer patients: whole cohort; < 5 years old; female; radiotherapy in chest region; anthracycline dose > 300mg;
and severe health condition. Cohorts data, model states probabilities and utilities were obtained from the Children Oncology Group Study. Mortality data were extracted from Brazilian demographic databases. Direct medical costs were extracted from national cost studies and price databases (1 USD:3.36 BRL). For the budget impact analysis, time horizon of 5 years and annual market share of 10%, 30%, 60%, 80% and 100% were adopted. Target population estimates were obtained from national databases.

RESULTS:
The most cost-effective strategy was dexrazoxane given to children < 5 years old (US$1,407.44/QALY), followed by its use in the whole cancer patients cohort (US$12,895/QALY). The remaining strategies were dominated. Acceptability curves (1 GDP/capita threshold) showed a probability of 33.6% and 23.4% that prophylaxis is cost-effective for children < 5 years and for the whole cohort, respectively. The incremental budget of prophylaxis in children < 5 years and in the whole cohort was, respectively, US$2.637,917.86 and US$9,041,953.90 in the 5th-year, and US$7,386.170.00 and US$24,464,342.47 over 5-years.

CONCLUSIONS:
Dexrazoxane given to patients < 5 years old was the most cost-effective option. Considering the low difference (10%) from probability in the whole cohort, prophylaxis given to all candidates may be a feasible alternative in case of an acceptable incremental budget.

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ABSTRACT SUMMARY:
Through the telemedicine, advantageous telediagnostic systems can be developed to enhance health care of remote populations that don´t have access to specialists.

INTRODUCTION:
Through the telemedicine, advantageous telediagnostic systems can be developed to improve the health care of remote populations that don´t have access to specialists. However, evidence on how such innovation technology can enhance universal coverage of diagnostic services in rural communities are limited. The usability of telemedicine to improve the coverage of diagnostic services in public health in Paraguay was investigated.

METHODS:
This descriptive study was carried out by the Telemedicine Unit of the Ministry of Public Health and Social Welfare (MSPBS) in collaboration with the Department of Biomedical Engineering and Imaging of the Health Science Research Institute (IICS-UNA) and the University of the Basque Country (UPV / EHU) to evaluate the utility of a telediagnostic system for universal coverage in public health. For this purpose, the results obtained by the telediagnosis system implemented in 56 public countryside hospitals were analyzed and compared to a “face to face” diagnosis.

RESULTS:
The results obtained by the telediagnosis system implemented in 56 public countryside hospitals were analyzed. In that sense, 293,142 remote
INTRODUCTION:
The knowledge of hospital equipments and their proper use are essentials for the prevention of adverse events associated with their uses. The risks controls associated to medical devices and equipments have major importance to ensure patient safety and quality delivered by healthcare professionals. Monitoring equipment (ME), infusion pumps (IP) and mechanical ventilators (MV) are devices of frequent use in Intensive Care Units, being however subject to technical, human and process failures, which may pose harm and even cause death of patients. Objective: the aim of this study was to evaluate the care risks related to the use of ME, IP, and MV at an Adult Intensive Care Unit (AICU) of a public hospital in Brazil, seeking to investigate the causes and providences related to technical complaints and adverse events associated to them. We hope the outcomes may be served as basis for the facility and peers to create mechanisms able to diminish risks and increase safety and quality to the care delivered to critical patients.

METHODS:
An observational, descriptive prospective study through 12 months, based on an analysis resulting from active and passive search of processes involving hospital medical equipments use, available human resources and material resources; training program and continuing professional education; disinfection, sterilization and assembling equipments stages; and the Hospital Risks Management measures regarding the reports and the actions towards technical, human and process failures, as much as adverse events and incidents related to them. All the data collected was confronted to Brazilian current legislation and the equipment technical manuals. The root cause of every failure and adverse event were investigated.

RESULTS:
Non-conformities: deficiencies in quantity, qualification, training, and capacitation of professionals for handling devices; failure in the
disinfection process of MV accessories; absence or difficulty to access the equipments technical manuals and lack of preventive and corrective maintenance programs; in the period 75 reports on technical complaints were detected through active search (65 were related to IP, 6 to MM and 4 to MV). Only one single adverse event related to medication error with IP attributed to programming error.

CONCLUSIONS:
The failures and deficiencies in managements and knowledges about hospital equipments are able to bring conditions potentially capable to increase risks to patients as well as healthcare professionals. Reach into compliance to Brazilian’s current legislation and to technical and operational norms of hospital equipments might turns it into safer practice with more quality in healthcare specially to critical patients.

INTRODUCTION:
The probability of better outcomes in decision making can be increased through the use of frameworks and tools for evaluating quality of decision-making processes.

METHODS:
In a 2017 study, a questionnaire was sent to 16 HTA agencies to characterize their decision-making processes, identify type of frameworks and best practices used, how quality of decision making was evaluated and potential barriers. Responses were obtained from 11 HTA agencies: Australia, Belgium, Brazil, Canada (CADTH, INESS), England, Netherlands, Poland, Scotland, Spain Basque region and Sweden.

RESULTS:
Ten of the agencies use a committee, with 9 utilising primarily a mixed (qualitative/quantitative) internal decision-making system. For agencies, other than technical members, other stakeholders attended appraisal meetings varied but included industry, payers, patient/patient interest groups and lay representatives/public members. All 11 agencies had a decision framework, for 7 this was formally defined and codified. All agencies utilised cost-effectiveness threshold/range (11) and almost all used comparative effectiveness (10) and budget impact (8). Six agencies had formal assessments for assessing quality of decision making with the majority indicating that the quality of decision making can and should be measured. In general, agencies considered the occurrence of biases within their organization or their influence on the decision making as pertinent and 9 out of 11 believed that decision making could be improved. The major barrier identified was poor quality of evidence submitted as well as high uncertainty around the information.

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PP157 How Well Do HTA Agencies Build Quality Into Their Decision-making?

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ABSTRACT SUMMARY:
A 2017 survey of 11 HTA agencies to characterize their decision-making processes, identify type of frameworks and best practices, how quality of decision making was evaluated and potential barriers revealed that the majority recognize the need to improve the quality of their decision-making process but do not currently perform any formal assessments. Such evaluations would improve decision-making transparency and accountability.
CONCLUSIONS:
Currently, HTA agencies concentrate on evidence, but it is not always clear how decisions, which require human judgment and interpretation, are made around the data. The majority of agencies recognize the need to improve the quality of their decision-making process but do not currently perform any formal assessments. Performing such evaluations using appropriate available tools and measures would improve decision-making transparency and accountability.

PP158 The Art Of Collaboration In Guideline Development

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ABSTRACT SUMMARY:
The health technology assessment (HTA) researchers from the Institute of Health Economics partnered in a unique manner with provincial clinicians and stakeholders to develop and update clinical practice guidelines using an innovative adaptation method. The complexities, intricacies, and attributes for success are presented, with emphasis on the role played by HTA resources.

INTRODUCTION:
Developing clinical practice guidelines (CPGs) is a collaborative, multi-stakeholder enterprise. Over the last 13 years, health technology assessment (HTA) researchers from the Institute of Health Economics (IHE) partnered in a unique manner with provincial clinicians and stakeholders to develop and update CPGs using an innovative adaptation method. The complexities, intricacies, and attributes for success are presented, with emphasis on the role played by HTA resources.

METHODS:
A governance structure (Advisory Committee, Steering Committee, Guideline Development Group) was designed to provide adequate oversight and quick, effective decision making, facilitate progress of the activities, and provide a mechanism for involving a wide variety of participants in the guideline development processes—stakeholders who represent policy, multidisciplinary care practice, knowledge translation, and research.

RESULTS:
The HTA researchers served various functions and played multiple translation roles in the guideline development process: acting as a hub for connecting researchers with government to address relevant policy questions; liaising with committees to translate clinical queries into searchable questions for information specialists; preparing background documents and compiling discussion materials to expedite review by committees; connecting committees with external stakeholders such as the provincial CPG program; and bringing lay advisors into the final review process. Elements for success included effective communication, development and use of consistent methods, reliance on the highest quality of research evidence, willingness to contribute and share expertise, awareness of other initiatives and projects, transparency and openness, efficiency, flexibility, respect, enthusiasm, commitment, and patience.

CONCLUSIONS:
The development of CPGs requires the establishment of sophisticated multi-stakeholder collaboration and time. HTA agencies are well positioned to be an effective translation hub connecting the various stakeholders by virtue of their inherent ability to communicate in the language of policy makers, clinicians, and patients, so that all participants understand enough to add their voice to the process.
PP159 Making HTA A Common Language In Controversies: A Hidden Role For NECA

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ABSTRACT SUMMARY:
This study explored the relationship between HTA agency and various decision-making bodies in Korea by using a qualitative method. The study finding indicates that it is commonly expected for the agency to be an intermediary between government and healthcare professionals.

INTRODUCTION:
It is critical to understand the how they have used previous health technology assessment results and what expectations of policy makers and health professionals have in HTA programs for better research planning. In this study, we aimed to examine how the results were used by decision makers and explore complex relationships between National Evidence-based Healthcare Collaborating Agency and various decision-making bodies in Korea.

METHODS:
Three areas of healthcare decision where NECA has been extensively involved in were selected: prevention programs, single technology reimbursement, and clinical guidelines. We conducted in-depth interview with two or three key informants from decision making bodies in each selected area and the interview participants include clinicians and government officials. We also conducted interviews with the researchers who participated in the related researches to better capture the context. The interviews were analyzed using qualitative content analysis.

RESULTS:
Total 8 interviews with decision makers and 5 interviews with researchers were conducted and analyzed. Three main themes were revealed in the data. Firstly, it was revealed that NECA was primarily expected to be an intermediary between clinicians and government. Both government and clinicians had referred to NECA’s HTA results which are expected to be scientific and impartial, when they need to reach one another on controversial topics. Secondly, there was high need for deliberative process to resolve the conflicting interests regarding HTA results. Lastly, they wanted the HTA process to be more responsive to fast changing healthcare environment by introducing a form of rapid reviews.

CONCLUSIONS:
Lack of effective communication channels between government and healthcare providers in Korea has made a room for HTA to be a common language for both sides. It is time to give up the ‘one-size-fits-all’ approach in conducting HTA researches and tailor the research process to various needs of decision makers.

PP160 Scoping Reviews As A Tool In HTA: A Chilean Research Group Experience

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**ABSTRACT SUMMARY:**

A scoping review is a knowledge synthesis method to map concepts, types of evidence and research gaps, through systematic search to inform practice, policy making processes and further research. We used this method to map the evidence in our HTA process. Here we report our experience to open up the discussion about other methods -as inputs- for the HTA process.

**INTRODUCTION:**

A scoping review (SR) is a knowledge synthesis method guided by broad exploratory research questions to map concepts, types of evidence and research gaps, through systematic search to inform practice, policy making processes and further research. Based on the fact that the process of health technology assessment (HTA) has a number of questions, ranging from broad (i.e. international approaches to health problems) to very specific (drug efficacy), we use the SR method to systematically map the evidence related to the questions involved in our HTA process. Here we report our experience using this, to encourage the discussion about methods as inputs in the HTA process in the academic community.

**METHODS:**

Using the Joanna Briggs Institute guidelines for SR, we listed a number of relevant questions as part of our HTA process and developed a search strategy to answer them. We included one of the key aspects of this method: the optional step of consultation with relevant actors. The SR methodology allowed us to identify questions that require a traditional systematic review.

**RESULTS:**

In Chile, where resources for HTA are particularly scarce, it’s of main relevance to map disease management strategies in developed countries and the current use of health technologies based on published assessments. In this context, the SR methodology provides key information about gaps in local clinical practice guidelines, relevant alternatives to assess, models already validated and/or revised by recognized HTA agencies, published systematic reviews of the technology efficacy, among others. Saving time in these tasks, allowed us to consider the stakeholders perspective about the appropriateness the evidence provided for the decision-making process.

**CONCLUSIONS:**

The methodological approach built here, it’s aligned with international HTA organizations recommendations to avoid the duplication of efforts in order to provide relevant evidence to decision-makers, who also value the consideration of stakeholders like patient’s associations.

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**PP161 The Search For A Cost-effectiveness Standard: 1-3 Times GDP / Capita?**

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**ABSTRACT SUMMARY:**

By means of a systematic literature search, we identified 120 studies reporting original data, yielding 133 unique estimates of the value of a statistical life (VSL). Transforming the VSL estimates into a value of a statistical life year (VSLY) yields a median VSLY of €164,500 [2014] or 6.4 times GDP/capita. Results vary primarily by regional origin of data and methodology.

**INTRODUCTION:**

The evaluation of medical interventions – in particular in the context of Health Technology
Assessments – invariably implies some kind of (explicit or implicit) cost value analysis. One possible anchor might be the value of a statistical life year (VSLY). For example, the WHO proposed one to three times annual GDP per capita as a potentially useful benchmark. One way to validate benchmarks, including the WHO recommendation, is to compare them with preferences observed in empirical studies using established economic methods.

METHODS:

By means of a systematic search for literature (published between 1995 and 2015) reporting value of a statistical life (VSL) estimates based upon original research, we identified 120 studies yielding a total of 133 unique VSL estimates. We transformed VSL estimates into VSLY (Euro, year 2014), using WHO life expectancy tables, a 3% discount rate, consumer price indices for inflation adjusting, and purchasing power parities for currency conversion. A regression analysis was performed to assess the impact on VSLY of variables including regional source of data, method (stated preference, SP; contingent valuation, CV; discrete choice experiment, DCE; revealed preference, RP; wage risk, WR; other), and study design (panel; cross-sectional).

RESULTS:

Overall, the median VSLY was €164,500 (mean VSLY, €228,000) or 6.4 times GDP per capita. We found differences by regional origin of data (median VSLY / GDP per capita: North America [based on n=45 unique VSL estimates], 7.1; Europe [n=49], 5.1; Asia [n=30], 5.2) and by elicitation method (SP/CV [n=55], 4.5; SP/DCE [n=18], 5.3; RP/WR [n=49], 9.1). The absolute VSLY was highest for North America (€272,300), followed by Europe (€158,400) and Asia (€43,000). Results were primarily sensitive to discount rate.

CONCLUSIONS:

Our results suggest that the empirical willingness-to-pay for a statistical life year might be substantially higher than currently accepted benchmarks, including the WHO recommendation.

PP162 Bridging Brazil’s Know-Do GAP On Social Engagement In HTA

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ABSTRACT SUMMARY:

We outline experiences of designing, developing and implementing innovative, effective and sustainable social - patient and public - engagement methodological approaches that bridge this know-do gap in health care, research and technology assessment via the translation of evidence into real-world action in Brazil, where both public and private health systems coexist, to enable a health systems services’ delivery reform.

INTRODUCTION:

Patient engagement encompasses the idea of involving patients as full partners in their care and health-related decisions, by giving them (back) a leading role, as a more efficient, effective and sustainable process of care delivery. Evidence shows that patient engagement is linked with fewer adverse events, better patient self-management, fewer diagnostic tests, decreased use of healthcare services and shorter lengths of stay in hospitals. In fact, patients who are more active and engaged in their care more frequently report better clinical outcomes, higher quality of life, higher satisfaction with their care relationships, healthier behaviors, more effective self-management skills, treatment adherence, and may contribute to a reduction of healthcare costs and to better economically sustainable organizational processes (Graffigna &
Barello, 2016). Matching the escalating healthcare requirements to face the ongoing societal and economic challenges regarding access and coverage to (new) health technologies is not an easy task for health providers and demands innovative methodological approaches to effectively and sustainably bridge this know-do gap in health care, research and technology assessment via the translation of evidence into real-world action, especially in countries where both public and private health systems coexist. Here we outline experiences of designing, developing and implementing social - patient and public - engagement to enable a health systems services’ delivery reform.

**METHODS:**
We outline the Oswaldo Cruz Foundation ongoing experience in building effective and sustainable methodological guidelines to social engagement in health technology assessment and coverage decision-making processes for Brazil’s National Health System by presenting findings from a systematic review (CRD42017068714) designed to address its institutional implementation by the Brazilian Ministry of Health.

**RESULTS:**
By mapping effective and sustainable models and methods of social engagement in health care, research and technology assessment, we explore experienced barriers and facilitators to bridging this know-do gap on social engagement for decisions on access and coverage to (new) health technologies from a global perspective. By debating effectiveness and sustainability, we discuss how such strategies can ultimately reform health systems services’ delivery.

**CONCLUSIONS:**
This systematic review addresses a comprehensive mapping of all models and methods so far implemented, globally, to approach the know-do gap on social engagement in health care, research and technology assessment as a way of both improving the Brazilian Ministry of Health’s HTA activities and enabling a Brazilian strategy to reform health system’s services’ reform.

**PP163 The Cost Reimbursement Mismatch For Heart Transplant In Brazil**

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**ABSTRACT SUMMARY:**
We sought to investigate costs of heart transplant in Brazil, from the perspective of a transplant-center, compared to the values reimbursed by the public health system. Average and median cost for the transplant admission was USD 62,336.27 and USD 47,105.52, respectively, while the current reimbursement value is $29,675. There is a significant cost-reimbursement mismatch for heart transplantation in Brazil.

**INTRODUCTION:**
There is an important mismatch in number of heart transplants performed and patients in need of a new heart in Brazil, despite a large public transplant program providing universal health coverage for organ transplantation. It is unclear whether the limited number of heart transplants could be related to the high costs of the procedure and potential underpayment from public agencies. We sought to investigate costs of heart transplant in Brazil, from the perspective of a transplant center, and compare results to the values reimbursed by the public health system.
METHODS:
All adults heart transplants performed in an academic center from Jul/2015-Jul/2017 were reviewed. Both Absorption Costing and Time Driven Activity Based Costing techniques were used to detail costs related to the transplant index admission. Patients’ electronic records were reviewed, involved professionals were interviewed, and the hospital electronic system was queried. Costs associated with infrastructure, personnel, surgical materials, medications, laboratory and imaging were computed. Brazilian Reais were converted to US Dollars using 2016 purchasing power parity data from OECD.

RESULTS:
All 27 patients who underwent heart transplants were included. Survival at 30 days was 94%. Average and median cost for the transplant admission was USD 62,336.27 and USD 47,105.52, respectively, while the current reimbursement value is $29,675. The lowest cost accrued by the hospital was USD 21,568.90, while the highest was over USD 300,000. Almost 70% of costs were related to personnel and hospital structure and not to direct consumption of medications, exams or materials. Total cost was highly dependent on length-of-stay, particularly days spent in intensive care units.

CONCLUSIONS:
The value currently reimbursed by the public system in Brazil for heart transplants is below average costs for the procedure in a reference center. This large cost–reimbursement mismatch might limit the increase in number of transplants that is needed to meet current demands.

PP164 Identifying Complications Of Partial Nephrectomy With Physician Claims

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ABSTRACT SUMMARY:
A novel methodology is proposed for the identification of surgery complications by using physician claims and taking into account the baseline comorbidities. Complications of open, laparoscopic, and robot-assisted nephrectomies are compared. The results showed that robot-assisted nephrectomy had lower complication rates for bleeding and circulatory diseases comparing with other nephrectomies.

INTRODUCTION:
Many population-based studies identified surgical complications using Hospital Discharge Abstract Databases (DAD). With DAD, however, the complications occurred after discharge date cannot be followed-up. This study uses physician claims data to identify the complications of partial nephrectomy. The complications of open, laparoscopic, and robot-assisted nephrectomies are compared.

METHODS:
Physician claims, DAD and ambulatory care data from April 2003 to March 3 2016 were provided by Alberta Health. DAD and ambulatory care data were used to extract patients who accepted partial nephrectomy. All claims within the period 30 days before and after the surgery for the cohort were extracted from the physician claims data. The
numbers of the same ICD-9 codes before and after surgery for each patient were compared. If a number increased after surgery, this diagnosis was initially identified as a complication. All diagnoses with neoplasms were excluded. The incidences of the three surgery groups were calculated. Chi-square tests were conducted for the comparisons: laparoscopic versus open, robot versus open and robot versus laparoscopic nephrectomies.

RESULTS:
A total of 1,896 patients had partial nephrectomies during the 13 years. Among them, 1,061, 408 and 414 had open, laparoscopic and robot-assistant nephrectomies respectively. Thirteen patients who had two different nephrectomies were excluded from analyses. Among the three surgery groups, Laparoscopic group had the highest blood-related complication (ICD 9: 280-289) rate (5.15%), while open group had the highest circulatory (ICD 9: 410-486) and respiratory (ICD 9: 510-519) complication rates (9.14%, 7.26%). Other complication rates among the groups had not significant differences.

CONCLUSIONS:
A novel methodology is proposed for the identification of surgery complications by using physician claims data. Because baseline comorbidities of the patients were different, not all diagnoses after surgery should be identified as complications. Further analyses will be conducted to adjust for comorbidities and other confounders.

ABSTRACT SUMMARY:
In 2017, NICE introduced a new fast track appraisal process where cost-comparison analyses can be included for technologies that have comparable efficacy to comparator technologies already recommended by NICE. This research found that based on learning from SMC and PBAC where cost-comparison approaches have long been used, NICE may see an increase in positive recommendations.

INTRODUCTION:
For almost 20 years (1999-2017), the National Institute for Health and Care Excellence (NICE) focused primarily on cost utility analyses (CUA) for its health technology appraisals. This changed on the 01 April 2017, when a new fast track appraisal process was introduced for technologies that offer exceptional value for money. Under this process, a cost-comparison analysis can be included for technologies that are likely to provide similar or greater health benefits at a similar or lower cost to comparator technologies already recommended by NICE. This is in contrast to other jurisdictions (e.g. Scotland and Australia) that have long accepted cost-comparison analyses such as cost-minimisation analyses (CMA) when a technology has comparable efficacy to relevant comparators. This research aimed to investigate if this new approach will have an impact on future appraisals.

METHODS:
Publically available technology appraisal documents from NICE, Scottish Medicines Consortium (SMC), and Pharmaceutical Benefits Advisory Committee (PBAC) were screened (01/01/2016-01/12/2016), and the supportive economic analyses were identified and extracted.

RESULTS:
In 2016, the proportion of CMA submissions that formed the basis of technology appraisals were 0/53 (0%), 17/55 (31%) and 25/82 (30%) for NICE, SMC and PBAC, respectively. The likelihood that a technology was recommended (with or without restrictions) for those technologies that
were assessed using a CUA was 60%, 66% and 33% for NICE, SMC and PBAC, respectively, while technologies that were assessed using a CMA were associated with higher positive recommendation rates: 76% and 76% for SMC and PBAC, respectively.

CONCLUSIONS:
Incorporating a cost-minimisation approach may result in more technologies being recommended by NICE through the fast track appraisal process, whereby the likelihood of a technology having a positive recommendation is much greater than the standard appraisal process.

PP166 RedETS. 10 Years Of Economic HTA (Medical Devices) In Spain. 2006-2016

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ABSTRACT SUMMARY:
RedETS, created in 2006, is the Spanish network of HTA agencies. Quality of the full economic evaluation reports carried out by RedETS on medical devices is analyzed. The 26 economic evaluations of MD published by the RedETS accomplish most of the quality checklist aspects and are therefore exhaustive. These FEEMD have been used in the framework of decision making.

INTRODUCTION:
RedETS, created in 2006, is the Spanish network of health technology assessment agencies. The objective of this work is to describe and assess the quality of the full economic evaluation reports carried out by RedETS on medical devices (FEEMD).

METHODS:
The FEEMD were identified through the RedETS website publications database. Assessments about screening technologies were not included. The characteristics of FEEMD were analysed using a formal RedETS HTA quality checklist. The characteristics extracted were analysed through a descriptive univariate analysis.

RESULTS:
26 FEEMD were found. The publication years were distributed quite uniformly over time (approximately 2/year), although 7 were published in 2008 and 7 in 2013. 13 studies analysed cost-utility, 10 cost-effectiveness but not utility and 3 both. The most frequent Medical Devices (MD) class analysed were “In vitro diagnosis MD” (n = 8) and Class III products (8). The most frequent sources to analyse effectiveness were literature (22) and data collected through ad-hoc studies (6). The main unit costs sources were official public tariffs (14), manufacturers direct values (10) analytical accounting of one/more centres or regions (11) and DRGs (7). In relation to the modelling used, 14 evaluations performed Markov models and 7 decision trees. The perspective of 23 studies was that of the National Health System (NHS), and the rest corresponded to the perspective of a specific region (2) or social perspective (1). All studies analysing time horizons greater than 1.5 years, except for 1, applied discount rates in the modelling. All studies included a sensitivity analysis.

CONCLUSIONS:
The economic evaluations of MD published by the RedETS accomplish most of the quality checklist aspects and are therefore exhaustive. These FEEMD have been used in the framework of decision making for an efficient management of the NHS basic portfolio.
Vignette Presentations

VP01 A Disinvestment Toolkit: The Prioritization Of Technologies

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ABSTRACT SUMMARY:
An effort jointly performed by HTAi IG on disinvestment and Early Awareness, EuroScan network and INAHTA is aiming to elaborate a toolkit that could aid organizations and individuals on the steps to be developed when considering disinvestment activities. This chapter refers to prioritization activities and disinvestment. The whole toolkit will be presented to the society in HTAi 2017 meeting.

INTRODUCTION:
Candidate health technologies identified for disinvestment will require prioritization depending on the system’s capacity for dealing with the assessments or for further considerations. Compilations of low value lists, such as the National Institutes for Health and Clinical Excellence’s, “Do not do recommendations”, can serve as databases for prioritization topics. Prioritization processes can also be triggered by experience or event-based regional requests and decisions; new evidence on safety, effectiveness and cost-effectiveness, variations in clinical practice, patient or consumer voicing, discrepancies between practice and guidelines; and or time-based mechanisms, such as approval of new health technologies and reassessment five years after introduction.

METHODS:
A search of the published and grey literature was conducted to identify the current methods or tools used to prioritize potential health technologies and services for disinvestment. The description of the methods and tools identified, the prioritization criteria, and the stakeholders involved in the process were reviewed and summarized.

RESULTS:
The methods and tools used for prioritization that were identified in the literature include the PriTec Prioritization tool, nominal group technique, Program Budgeting and Marginal Analysis, consensus building, and online surveys. Further, common criteria for prioritization centered on the disease burden, possible risks and benefits, costs and cost-effectiveness, utilization, and time-based criteria. Prioritization can be conducted by health care professionals, decision makers, patients or patient groups and representative community members.

CONCLUSIONS:
The prioritization process for disinvestment candidates should be transparent and guided largely by evidence. It is highly recommended that the list of predefined criteria be developed with input from all relevant stakeholders to meet the objectives of the specific health care setting. The commonly cited basic requirements include clinical parameters, economic measures, and social, ethical or legal considerations.

VP02 Real-world Evidence (RWE) And CADTH pan-Canadian Oncology Drug Review

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ABSTRACT SUMMARY:
The CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee makes reimbursement recommendations including next steps for stakeholders. Forty-eight percent of drug reviews included a real-world evidence (RWE) request. Key areas for reasons for RWE data collection included sequencing of the drug with available therapies, uncertainty of the true magnitude of benefit/cost-effectiveness, and duration of treatment.

INTRODUCTION:
The pCODR program was established by Canada’s provincial and territorial Ministries of Health (except Quebec) to assess cancer drug therapies and make recommendations to guide drug reimbursement decisions. The pCODR Expert Review Committee (pERC) makes reimbursement recommendations, providing a rationale for the recommendation and next steps for stakeholders. The objective of this analysis was to identify reviews and reasons pERC has requested RWE data collection.

METHODS:
A retrospective analysis of pERC Final Recommendations (January 2012 – May 2017) was conducted. pERC Final Recommendations include drug information, reimbursement recommendation, rationale for recommendation following pERC’s Deliberative Framework (clinical benefit, patient-based values, economic evaluation, and adoption feasibility), next steps for jurisdictions to consider to support their funding decisions, summary of deliberations, and evidence in brief. Reviews were included if there was a next step advising the collection of RWE to reduce uncertainty in the drug under review.

RESULTS:
Out of eighty-four reviews, forty-one (forty-eight percent) included a next step to collect RWE to address a gap in the available evidence. Reasons for RWE data collection, in descending order of frequency, were to inform: sequencing of available therapies; magnitude of clinical benefit and cost-effectiveness or the true cost-effectiveness; duration of treatment and cost-effectiveness; defining the population or disease progression; quality of life; and dosage.

CONCLUSIONS:
In almost half of pERC’s recommendation there is an indication that there is a gap in the existing evidence that could potentially be addressed through the collection of RWE. This reflects the rising number of new cancer drugs, limited evidence supporting submissions (for example non-comparative studies), and newer drugs such as immunotherapies which may not have a fixed treatment duration. Further research includes development of mechanisms for RWE data collection to help inform pERC recommendations and assist stakeholders with adoption feasibility of reviewed drugs.

VP03 Emerging Good Practices For Transforming Value Assessment

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ABSTRACT SUMMARY:
Patient engagement is a transformative strategy for improving value assessment. US value-framework developers have increased engagement activities, but more needs to be learned about how to best achieve meaningful patient engagement in value assessment.

INTRODUCTION:
Patient engagement is a transformative strategy for improving value assessment. US value-framework developers have increased engagement activities, but more needs to be learned about how to best achieve meaningful patient engagement in value assessment. The objective was to glean from patient-community experiences emerging patient-engagement good practices in value assessment.

METHODS:
The National Health Council (NHC) Value Workgroup, comprised of twenty patient-organization staff and thirteen organizations, conducted a survey among and held a focus group with its members to gather experiences with value framework developers and recommendations on emerging good practices.

RESULTS:
Ten of thirteen organizations completed the survey; reporting thirteen interactions with four framework developers. Most rated experiences as good to very good. Emerging good practices included: I. Engage as early; II. Engage a range of patients; III. Leverage patient-provided information, data resources, and outreach mechanisms; IV. Be transparent; and V. Appreciate and accommodate resource constraints. Twelve of 13 organizations participated in the focus group, which produced 30 emerging good practices in four areas: I. Timing; II. Methodology and Data; III. Partnering; and IV. Characterizing Engagement.

CONCLUSIONS:
Patient engagement was limited in early value-framework development, but increased in the past two years. Patient groups report positive experiences that can serve as emerging good practices. They experienced challenges in their interactions and posed recommended good practices to mitigate those challenges. The growing pool of patient engagement experiences can be translated into good practices to advance a patient-centered, value-driven health care ecosystem. Learnings from these early experiences can help establish emerging good practices that can eventually get the field to best practices and standards over time.

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VP04 Using Systems Thinking To Develop Care Pathway For Opioid Overdose Management

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ABSTRACT SUMMARY:
Expanding the scope of HTA: Using systems thinking to develop an evidence-based care pathway for managing patients who experience a non-fatal unintended opioid-related overdose.

INTRODUCTION:
In 2016, there were 7.8/100000 opioid related deaths in Canada, with the highest rates in British Columbia and Alberta. Since the “opioid crisis” is widely recognized as a complex issue, the Alberta Health Technology Decision Process was asked to look at evidence-based care pathways for managing patients who experience an opioid-related overdose in order to support the work of a newly created provincial commission. This abstract presents preliminary findings of a systematic review of published and grey literature, as well as
recommendations for a comprehensive approach to opioid use disorder using systems thinking principles.

METHODS:
A comprehensive review of the literature describing relevant care pathways, clinical practice guidelines, and treatment programs was conducted. We searched: PubMed, The Cochrane Library, EMBASE, Web of Science, Econlit, and CINAHL using relevant controlled vocabulary terms and keywords. Grey literature was identified using these key words applied to Google®. Two reviewers independently selected documents for inclusion and used AGREE II to assess their quality. Elements of care pathways and clinical guidelines were mapped onto a generic treatment framework developed using systems thinking to identify key evidence gaps.

RESULTS:
The search resulted in 1596 titles. Of those, 166 were fully screened and 62 included in the analysis. Most of the care pathways and guidelines were narrow, focusing on one type of treatment or one type of patient population. Few addressed mental health co-morbidities, the unique needs of sub-populations such as teenagers or those in rural and remote communities, social and non-health supports, stigma, and recovery services, in general.

CONCLUSIONS:
Treatment pathways that take into account all of the health and social factors influencing post-overdose management are lacking. Their development will require the collaborative efforts of a large, more diverse group of stakeholders from within and beyond the health sector.

VP05 Developing A Process In Alberta For Assessing Companion Diagnostics

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ABSTRACT SUMMARY:
The number of indications for companion diagnostic (CDx)-drug pairs is rapidly increasing. The project objective was to develop a provincial approach to the evaluation of CDx that aligns with existing drug review processes. Findings from a pilot revealed the importance of working closely with laboratory and clinical experts throughout the review process to ensure the review reflected the local environment.

INTRODUCTION:
The number of licensed indications for companion diagnostic (CDx)-drug pairs is rapidly increasing. As elsewhere, Alberta has separate, well-established processes for reviewing drugs and non-drug technologies which need to be revisited to support consistent decision-making for CDx-drug pairs. The project objective was to develop a provincial approach to the evaluation of CDx that aligns with existing pan-Canadian and provincial drug review processes.

METHODS:
A provincial cross-sectoral, multidisciplinary CDx working group was convened and a jurisdictional scan performed to identify existing CDx review processes. A workshop with Australian, British and American representatives was held to learn about their experiences. Subsequently, a literature
review was conducted to identify scholarly articles on existing/proposed processes. Information on elements of each process, stakeholder and expert involvement, timing, and evidence expectations for biomarker and test validation was collected and analysed. A process and set of research questions were drafted and piloted through a case study of programmed-death ligand-1 (PD-L1) testing for advanced non-small cell lung cancer. PD-L1 is in extensive use investigationally and for licensed indications, is sufficiently complicated because multiple testing strategies are available, and requires a funding decision.

RESULTS:
The proposed process is designed to coincide with the pan-Canadian review of the drug and contains the following elements: clinical effectiveness (analytical and clinical validity, clinical utility, cost-effectiveness where multiple testing strategies exist), system implications (e.g., laboratory capacity, local infrastructure, clinical algorithms), budget impact on diagnostic services, new and emerging testing strategies (e.g., liquid biopsies) and policy considerations including ethical and legal factors and innovative funding options. Findings from the pilot revealed the importance of working closely with laboratory and clinical experts throughout the review process to ensure the review reflected the local environment.

CONCLUSIONS:
The proposed CDx review process appears feasible and generates the type and level of contextual information required to support decision-making in Alberta.

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ABSTRACT SUMMARY:
We present the effectiveness and ethical considerations of prenatal testing for cystic fibrosis (CF). A key challenge in assessing a prenatal test is selecting appropriate endpoints to indicate clinical effectiveness. It is suggested that for HTAs undertaken on contentious topics, ethical analysis should be undertaken first so appropriate endpoints are selected for the subsequent systematic review and the economic model.

INTRODUCTION:
Cystic fibrosis (CF) is the most common autosomal recessive disorder in Caucasians, occurring in 1:2,500–2,800 births worldwide, and is associated with a high burden of disease. In Australia, prenatal testing for CF is indicated for pregnant couples identified as carriers or when a fetus is found to have an ‘echogenic bowel’ (FEB). We aimed to determine the effectiveness of prenatal CF testing and to assess ethical dimensions. A key challenge in assessing a prenatal test is selecting appropriate endpoints to indicate clinical effectiveness.

METHODS:
A systematic review was conducted and a linked evidence approach was used to answer the effectiveness question. The literature on ethical considerations relating to prenatal testing was also reviewed.

RESULTS:
No studies were identified on the direct effectiveness of prenatal CF testing or downstream consequences. Linked evidence showed good diagnostic performance with a test failure rate of 4.5 percent. Termination of pregnancy occurred in the majority of cases where two mutations were identified in a fetus of carrier parents (155/163;
95 percent), indicating testing impacts clinical management. In FEB cases with CF, termination occurred in around 65 percent of pregnancies. Both terminating a pregnancy and having a child with CF were associated with poor short term parental psychological outcomes. Evidence indicates prenatal testing leads to a decreased number of CF-affected births. However, ethical analyses indicated that ‘informed decisions’ should have been the primary outcome of interest.

CONCLUSIONS:
Proper counselling prior to testing ensures that the aim of prenatal testing is informing reproductive choices in a non-directive way, rather than decreasing the number of CF-affected births (which is ethnically problematic). These results suggest that for HTAs undertaken on contentious topics, ethical analysis should be undertaken first so appropriate endpoints are selected for the subsequent systematic review of clinical evidence and for the economic model.

VP07 Cost-effectiveness Of Exome Sequencing For Intellectual Disability

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ABSTRACT SUMMARY:
This study uses a Markov model to estimate the cost-effectiveness of diagnostic exome sequencing (ES) for children with unexplained intellectual disability in British Columbia. Preliminary results suggest that offering ES as a first-line diagnostic test would be more cost-effective than offering it as a last resort, but that ES may not be cost-saving at its current cost.

INTRODUCTION:
Recent evaluations of diagnostic exome sequencing (ES) for children with suspected genetic disorders suggest that offering ES as a first-line diagnostic test may be cost-saving because the standard diagnostic pathway can be avoided for patients diagnosed by ES. However, these evaluations use static models that do not account for the long time period over which ongoing diagnostic care occurs and may underestimate both the cost and the diagnostic yield of standard care.

METHODS:
A stochastic cohort-level state transition model was developed to simulate the diagnostic trajectory of 1,000 patients over 10 years with unexplained intellectual disability referred to the Children’s and Women’s Health Centre in Vancouver, Canada for diagnostic assessment. For all scenarios, chromosome microarray analysis was assumed to be offered as a first-line test. Subsequently, patients in the Standard Care scenario accrued annual costs associated with standard diagnostic testing and were subject to a time-varying background probability of diagnosis, both of which were estimated from clinical research cohorts. In the two ES scenarios, ES is performed on remaining undiagnosed patients in year 1 (First-Line ES) or year 5 (Last-Resort ES), and patients with negative ES continue with standard testing.

RESULTS:
First-Line ES had an incremental cost of $1,172 per patient over Standard Care ($10,870 vs. $9,697), but resulted in 223 additional diagnoses (731 vs. 508), resulting in an incremental cost-effectiveness ratio (ICER) of $5,259 per diagnosis. Last-Resort ES had an incremental cost of $1,834 per patient and delivered 205 additional diagnoses, resulting in an ICER of $8,945 per diagnosis. ES had a >95% chance of being cost-effective at willingness-to-
pay thresholds of more than $20,000 per additional diagnosis.

**CONCLUSIONS:**
If the decision is made to fund broader access to ES, offering it as a first-line test is likely to be more cost-effective than offering it as a last-resort.

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**VP08 Description Of A Strategy To Face Judicialization Of The Right To Heal**

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**ABSTRACT SUMMARY:**
The Ministry of Health of Uruguay developed an innovative approach to face the increasing judicialization of the access to high-cost technologies. The present work addresses the evaluation of the new strategy as a useful response to the increasing demand. This strategy reduced the judicialization and helped to prioritize the inclusion of new drugs into the national formulary.

**INTRODUCTION:**
The Ministry of Health of Uruguay has a Health Technology Assessment Division that provides the decision-makers with evidence-based information on the efficacy-safety and costs of health technologies to be included in the Comprehensive Plan of Health Care. Since 2010, patients began to demand access to high-cost technologies without funding through writs of protection. Judicialization of the right to health increased rapidly from 2010 to 2014. In this context, a Technical Advisory Commission was created in 2015 in order to assess patient requests on a case by case basis. The purpose of this study is to evaluate the results obtained with a new strategy developed to face the judicialization of access to high-cost technologies.

**METHODS:**
The methodology used to evaluate the implementation of the strategy consisted in reviewing a database of the requests from October 2016 to October 2017. Demographic characteristics, technologies requested, prescription and result of the process were analyzed.

**RESULTS:**
In the study period, 654 technologies were requested for funding through this process. The population included 61.5 percent male with a mean age of 60 years old. Technologies requested were drugs (85.1 percent) and devices (14.9 percent). Requested technologies were 35 percent for cancer treatment and the rest included drugs and devices for treatment of rheumatologic, ophthalmologic, infectious, neurological and cardiovascular conditions. The six most requested technologies were: abiraterone for prostate cancer; aortic endoprosthesis for vascular aneurysm; lenalidomide, rituximab and azacitidine for onco-hematologic diseases and cetuximab for colorectal cancer and represented among all, 45 percent of total requests. The Ministry of Health has funded, by this extra judiciary path, 35.9 percent of the requests.

**CONCLUSIONS:**
This strategy was successful in reducing the judicialization of access to high cost technology in Uruguay and it helps to prioritize the inclusion of new drugs to the national formulary.
**VP09 Trastuzumab For Metastatic Breast Cancer Access Assessment In Brazil**

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**ABSTRACT SUMMARY:**
The aim of this study was to investigate if access to this technology is appropriate. Although universal access is one of Brazilian Public Health System main directives, there is evidence of a serious issue regarding its services equity.

**INTRODUCTION:**
Trastuzumab is the most recently biological therapy incorporated by Brazilian Health Ministry for HER-2 overexpressed metastatic breast cancer treatment (2012). The aim of this study was to investigate if access to this technology is appropriate.

**METHODS:**
We performed a web-based questionnaire, which received answers from October 2016 to April 2017. Oncologists that work in the care of patients with overexpressed HER-2 metastatic breast cancer were the focus of the survey. Forty-three professionals informed work location, sector (public, private or both) and trastuzumab access. This research was approved by Brazilian Ethics Committee (CAE 59076316300005260).

**RESULTS:**
Among 43 valid answers, 9 informed they work in the public sector, 10 in the private and 24 in both sectors. In total, 33 reported to work in public and 34 in private sector. We observed that 17 (51.52%) participants who work in the public sector do not have access to trastuzumab, while in private sector only 1 participant (2.94%) reported the lack of access to this technology for HER-2 overexpressed metastatic breast cancer treatment. Regarding to respondents who informed the lack of access, 6 (33.3%) work in Northeast Brazilian region, 6 (33.3%) in Southeast, 2 (11.1%) in South, 1 (5.6%) in Central-West and 3 (16.7%) did not give this information. Eleven respondents reported they do not have another treatment option for these patients, while 7 informed access only to chemotherapy without biological therapy.

**CONCLUSIONS:**
Trastuzumab is a biological therapy that can increase HER-2 overexpressed metastatic breast cancer patients overall survival by 9 months on average. The questionnaire results indicate that its access in Brazil is still irregular mainly in public sector, even five years after its incorporation by Brazilian Health Ministry. Although universal access is one of Brazilian Public Health System main directives, there is evidence of a serious issue regarding its services equity.

**VP10 Impact Of HTA On Policy And Clinical Decision-making In Korea**

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**ABSTRACT SUMMARY:**
In this study, we aimed to measure the impact of the HTA products of NECA on clinical and policy
decision by introducing a systematic framework. Total sixty-three percent of the included HTA reports were used to support clinical and policy decisions. Although most of HTA were conducted in collaboration with clinicians, the use of results by clinicians was limited.

INTRODUCTION:
Since established in 2009, National Evidence-based healthcare Collaborating Agency (NECA) has been a sole government-funded HTA institution in Korea, yet little effort has been made to systematically evaluate the influence of its products. In this study, we aimed to measure the impact of the HTA products of NECA on clinical and policy decision by introducing a systematic framework.

METHODS:
We included HTA reports published from 2009 to 2015. Among the 141 research reports published during this period, there were 67 HTA reports. We gathered data on the influence by literature and news article search, review of administrative documents and directly listening to the decision makers. The influence was categorized into three decision types: changes in clinical guidelines, administrative decision on investment/disinvestment and healthcare policy making. Whether a research was used directly in decision making or followed by subsequent researches or round-table conference was recorded to examine the knowledge transfer process.

RESULTS:
Total sixty-three percent of the included HTA reports were used to support clinical and policy decisions. Twenty-seven reports had influenced administrative decisions on investment/disinvestment. Ten provided evidence for new health policies or legislation. Eight were reflected in clinical guidelines. The impact of HTA reports published by NECA was more evident when the research was directly requested by decision-making bodies such as government institutions. Although most of HTA were conducted in collaboration with clinicians, the use of results by clinicians was limited. Definitive results were more likely to be used, but reports with competing interests had fewer impacts.

CONCLUSIONS:
HTA by NECA had impacts on rational use of healthcare resources in Korea, and NECA has established its role as an intermediary between governmental decision-making bodies and clinicians. However, more continuous approaches rather than one-time HTA research are needed for HTA on controversial topics to have impacts on decision making.

VP11 Institutionalising Health Technology Assessment In Romania

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ABSTRACT SUMMARY:
Romania has limited experience and expertise in the use of Health Technology Assessment (HTA) to support evidence-informed policy decision-making. We present the key findings of a landscape analysis, describe the institutional models proposed to enable the development of technical capacity, and highlight some of the challenges to establishing the regulatory framework needed to support effective institutionalisation.

INTRODUCTION:
Romania has limited experience and expertise in
the use of Health Technology Assessment (HTA) to support evidence-informed policy decision-making. While the selection of medicines for the public reimbursement formulary is nominally subject to an HTA ‘process’, this is based on the application of a checklist drawing principally on reimbursement decisions in other jurisdictions, and thus does not enable a direct assessment of a product’s value for money in the Romanian setting. Moreover, an effective domestic HTA mechanism would enable more transparent and evidence-based decision making, support anti-corruption objectives and strengthen governance.

METHODS:
As a pivotal component of a larger project supporting the Ministry of Health (MoH) in Romania we undertook a landscape analysis and inventory of current HTA skills and experience, existing processes, available training, and data and resource gaps, in order to identify strategic issues in developing the HTA institutional processes in Romania.

RESULTS:
Based on the landscape analysis and drawing on international experience we developed a series of institutional models intended to enable the development of technical capacity and the application of HTA to support policy decision-making across the healthcare sector. We present the key findings of that analysis and describe the various institutional models we developed, with particular emphasis on the rationale for the selected institutional model, and the proposed program and current progress towards its implementation.

CONCLUSIONS:
An important aspect of implementation, not always recognised in technical assistance projects of this nature, is the need to ensure that appropriate regulatory reforms are enacted. This can present challenges, especially in legal environments that require extensive codification of both process and methods, leaving little room for HTA systems to grow ‘organically’.

VP12 Developing A Value Set For The EQ-5D-Y To Support Its Use In HTA

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ABSTRACT SUMMARY:
There are no value sets available to support the use of the EQ-5D-Y (the child-friendly version of the EQ-5D instrument) in HTA. This presentation will: (i) provide an overview of the challenges in defining and valuing children’s health states; (ii) summarise two studies undertaken in parallel to provide the basis for an EQ-5D-Y value set for the UK.

INTRODUCTION:
There are challenges in measuring self-reported health in children, and in valuing the resulting health states. For example, whose preferences should be used to value the health states defined by a preference-based measure designed to measure children’s health? The EuroQol Group has developed a child-friendly version of the EQ-5D – the EQ-5D-Y – but to date there have been no value sets available to support its use in HTA decision-making. The aims of this presentation are to: (i) provide an overview of the challenges in defining and valuing children’s health states; (ii) report two studies undertaken in parallel to provide the basis for developing an EQ-5D-Y value set for the UK, and a set of methods that can be
recommended for use in other countries requiring an EQ-5D-Y value set.

METHODS:
The first study was a discrete choice experiment (DCE) administered via an internet survey (n=1,000). The second study was administered via computer-assisted personal interviews, and involved comparisons of four techniques: visual analogue scale, DCE, time trade-off and an innovative ‘location-of-dead’ approach (n=300). In both studies adult UK general public respondents were asked to value EQ-5D-Y health states considering the health of a 10-year-old child. Descriptive methods and various discrete choice models were used to analyse the data.

RESULTS:
Preliminary results indicate that preferences for child health states differ from those for equivalent adult health states. Response patterns also vary across the different preference elicitation techniques. Full results will be available by the annual meeting.

CONCLUSIONS:
This research has advanced our understanding of the normative and practical challenges involved in valuing children’s health states. The presentation will conclude by outlining the next steps required to develop an EQ-5D-Y value set.

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VP13 Individualized Data Visualizations In Health State Modeling

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ABSTRACT SUMMARY:
We used chart reviews, a database’s application programming interface (API), and a popular open source data visualization library to allocate individual prostate cancer patient’s time into health states, with tabular and graphic portrayals of each patient’s clinical experience from diagnosis to end of observation or death. These can be used for clinical decision-making and research applications.

INTRODUCTION:
We used chart reviews, a database’s application programming interface (API), and a popular open source data visualization library to allocate individual prostate cancer (PC) patient’s time into health states, with tabular and graphic portrayals of each patient’s clinical experience from diagnosis to end of observation or death. These can be used for clinical decision-making and research applications.

METHODS:
We conducted chart reviews of 200 PC patients attending ambulatory clinics at a cancer centre in Toronto, Canada, who received androgen deprivation therapy in 2000–2010 or developed metastases in 2005–2016. Variables included pathology, treatments, drugs, prostate-specific antigen (PSA) and testosterone values, and imaging tests. Simultaneously, we conducted a literature review and elicited expert opinion to develop a disease progression model with 18 discrete health states from PC diagnosis to death (e.g., initial treatment, post-treatment surveillance, PC recurrence and progression (based on PSA values), and castration-resistance). We then programmed an algorithm that used the chart review database’s application programming interface (API) and a popular open source data visualization library to allocate each patient’s time into health states, based on rules for entering and exiting each health state in the disease model.
RESULTS:
Leveraging a popular open source data visualization library enabled the algorithm to output an interactive, graphical timeline that clearly identified each patient’s health state trajectory, with treatments, drugs, PSA and testosterone data overlaid. Design choices facilitated rapid comprehension of the visualization by both clinical experts and lay people. Throughout the algorithm’s Agile development process, the cross-functional team found that the individualized data visualizations served as an indispensable tool with multiple uses: algorithm validation, edge case detection, and data quality assurance.

CONCLUSIONS:
Our algorithm provided tabular and graphic portrayals of each patient’s clinical experience from diagnosis to end of observation or death. This type of approach to data visualization can be used for clinical decision-making and for other research applications.

VP14 Is EQ-5D Sensitive In Non-Melanoma Skin Cancer?

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ABSTRACT SUMMARY:
The Irish reference case for HTA specifics generic measures of quality of life (QOL) are preferred. However, in some instances generic measures are not sufficiently sensitive to detect changes in QOL. This study examines the sensitivity of EQ-5D-3L, a generic preference based measure, in detecting changes in QOL in patients undergoing surgical removal of non-melanoma skin cancer.

INTRODUCTION:
This study uses three validated quality of life (QOL) instruments to assess and compare QOL before and after the removal of non-melanoma skin cancer (NMSC) by two different surgical techniques. Results will inform a health technology assessment (HTA) comparing the surgical methods.

METHODS:
Patients (n=200) presenting at the Dermatology Department of a university teaching hospital in Ireland for removal of NMSC either by Mohs microscopy or surgical excision are eligible for inclusion. Consent patients complete three QOL questionnaires prior to the removal procedure, and again three months after the procedure. Two condition specific measures (CSMs) are administered, Skindex 16 and Skin Cancer Index (SCI), and one generic measure, EQ-5D-3L. Data analysis is conducted using R, according to the published scoring algorithms.

RESULTS:
Baseline demographics of the recruited patients reflected the broader Irish population. In an interim analysis (n=50) QOL was decreased by NMSC across all domains of the CSMs pre-procedure. QOL using the generic EQ-5D-3L instrument is high (0.91). Three month follow up data (n=15) shows a distinct trend towards improved QOL post-procedure as assessed by the CSMs, and a statistically significant improvement in the ‘Emotion’ domain of the Skindex-16 instrument (p=0.008). There is no change in the EQ-5D-3L values post procedure (0.9, p=0.87).

CONCLUSIONS:
The CSMs in this study detected reduced QOL due to NMSC pre-procedure, and were highly suggestive of improved QOL post-procedure. By contrast, the EQ-5D-3L did not detect impairment in QOL of life pre-procedure, and showed no
change post-procedure. This may suggest that EQ-5D-3L is not sufficiently sensitive to detect changes in QOL in patients with NMSC, and may not be appropriate for use for HTA of treatment approaches for NMSC. Further results from a larger population size will be presented at the conference.

VP15 Impact Of Obesity On Lifetime Costs And Health Outcomes In Canada

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
An economic model was created to estimate life years, QALYs and costs based on current adiposity, gender and age in Canada. Results suggest that there are substantial difference in life years and QALYs based on adiposity but limited differences in lifetime health care costs. Treatments targeting adiposity may significantly improve health but are unlikely to reduce healthcare costs.

INTRODUCTION:
In 2016, the Senate of Canada published “Obesity in Canada” highlighting the effect of obesity in terms of increased health care costs and premature mortality. Given the lack of existing studies, the objective of this study was to develop an economic model to estimate life years, QALYs and costs based on current adiposity, gender and age.

METHODS:
A Markov model simulated the movement over time in terms of adiposity for a cohort of Canadians based on their initial age (18-85), gender and adiposity. Analysis incorporated changes in adiposity by age and gender, mortality by age, gender and adiposity, health care costs by age and adiposity and utility values by age, gender and adiposity. Long-term outcomes were discounted at 1.5%.

RESULTS:
For women aged 25, the discounted lifetime QALYs based on current adiposity status were 31.9, 31.8, 31.0, 30.3, 28.8 and 28.4 for “underweight”, “normal weight”, “overweight”, and obese classes 1, 2 and 3 respectively. Similar trend in results for life expectancy were found. Lifetime health care costs were $25,801, $25,489, $25,459, $25,739, $25,858 and $25,812 respectively. Trends were similar for other age-gender cohorts.

CONCLUSIONS:
Expected QALYs and life years were higher for individuals who are “normal weight” compared to those who are obese. There is however little difference in lifetime healthcare costs. Public health interventions targeted at adiposity may bring substantial health benefits but are unlikely to significantly reduce healthcare costs.

VP16 Cost-effectiveness For Treatment Of Acute Gastroenteritis In Brazil

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ABSTRACT SUMMARY:
The objective was to conduct a cost-effectiveness study of oral rehydration therapy compared to intravenous rehydration for the treatment of acute gastroenteritis, without severe dehydration, in children under 5 years, from the perspective SUS. Initiating the rehydration by the use of intravenous technologies represents a higher cost, without
a corresponding or even significant increase in effectiveness.

INTRODUCTION:
In Brazil, it is estimated that oral rehydration therapy is an underutilized resource in emergency services for the management of children with non-severe dehydration. This is related with the lack of infrastructure and resources dedicated to the performance of oral rehydration therapy in this modality of health service. The objective was to conduct a cost-effectiveness study of oral rehydration therapy compared to intravenous rehydration for the treatment of acute gastroenteritis, without severe dehydration, in children under 5 years, from the perspective of the Unified Health System (SUS).

METHODS:
To estimate the cost-effectiveness of the different therapeutic approaches for acute gastroenteritis in children under 5 years of age without severe dehydration, a model was constructed according to health results expressed in meta-analysis studies, psychometric studies that assessed the related quality of life to the various outcomes of acute gastroenteritis and in accordance with previous economic evaluation studies. TreeAge Pro 2009 simulation software was used to develop the model. After identifying several possible arrangements for the different parameters, these were incorporated into a decision tree, which simulated the disease in individuals with acute gastroenteritis, without dehydration, under a variety of different treatment scenarios. Regarding the treatments, the model contemplated the probabilities of suspension of the treatments and dose. The comparison strategies were those adopted from the current recommendation of the Ministry of Health for the treatment of acute gastroenteritis. Possible uncertainty was assessed by means of a sensitivity analysis.

RESULTS:
The treatment regimen that was initiated by strategy 1 with oral rehydration was the most attractive from the economic point of view, according to the results of the model and sensitivity analysis. The strategy of initiating oral rehydration in children under five shows the most efficient behavior that explores the most diverse combinations of values for the variables of interest. In absolute terms, initiating the rehydration of children under five years of age by the use of intravenous technologies represents a higher cost, without a corresponding or even significant increase in effectiveness.

CONCLUSIONS:
The review of information on epidemiology and the consequences of acute gastroenteritis in its different stages highlighted the existence of a significant knowledge gap in the world and in Brazil. At the moment, the paucity of parameters presents itself as the main barrier for the development of simulation models more compatible with the accumulated knowledge in clinical practice.

VP17 HCV Treatment: A Meta-analysis Of Long-term Efficacy

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ABSTRACT SUMMARY:
Treatment of chronic HCV has undergone a revolution. Several direct acting antivirals (DAAs) have reached the market and many others are in development. However, as long-term efficacy is still
not widely proven, meta-analysis are required.

INTRODUCTION:

Efficacy of second generation direct-acting antiviral agents (DAAs-2) in terms of sustained viral response (SVR) 12 weeks after the end of treatment (EOT) has widely been proven; however, long-term efficacy is still controversial due to the low number of available studies with a small number of patients. The objective of the study is to conduct a systematic review and, if possible, a meta-analysis of existing clinical evidence in terms of long-term efficacy (SVR longer than 12 weeks after EOT) of DAAs-2 for HCV treatment.

METHODS:

A systematic review was performed with the use of CENTRAL, MEDLINE, Embase, Pubmed and SBBL-CILEA/METACRAWLER databases. Trials were initially screened by the title; secondly, full papers and abstracts were analysed. The meta-analysis included randomised controlled trials (RCTs) with adult patients affected by HCV, treated with DAAs-2 and assessed for longer than 12 weeks after EOT. Study quality assessment was undertaken using the Jadad scale. Heterogeneity analysis of the studies was conducted with chi-square and I²; the statistical analysis of the efficacy rate was performed using the meta package with the R software. The effect estimate was expressed in risk ratio (RR) with 95% confidence interval (CI 95%) and pooled using a random effects model.

RESULTS:

Of the 106 identified studies, 11 high quality RCTs were included for meta-analysis (25 were duplicate publications, 70 did not meet the inclusion criteria). Considered genotypes were 1 (9), 2 (1), 3 (1). Meta-analysis included 3720 patients (2698 treated with DAAs-2; 1022 treated with placebo or a first generation DAA ± Ribavirin ± PEG-interferon). Heterogeneity between studies was high (p<0.001; I²=90.2%), however it was absorbed by the model (τ²=0.08). Long-term efficacy was expressed as SVR 24 weeks after EOT, since longer timescales were not available. According to the pooled RR, the incidence of efficacy was 1.5 (CI 95%; 1.24-1.83, p<0.001).

CONCLUSIONS:

The meta-analysis demonstrated that DAAs-2 for HCV treatment have long-term efficacy at SVR 24 weeks after the EOT; however, the number of studies is mostly based on genotype 1. More RCTs are required to confirm long-term efficacy at more than 6 months after EOT for all treated genotypes.

VP18 Antibiotics And Orthopaedic Surgery Without Implant: A Meta-analysis

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ABSTRACT SUMMARY:

Preoperative antibiotic prophylaxis is administered routinely by surgeons in orthopaedic procedures without implant even if such practice is not recommended by guidelines. A systematic review and meta-analysis was conducted to evaluate existing clinical evidence on reduction of the incidence of surgical site infections (SSI).

INTRODUCTION:

According to guidelines, antibiotic prophylaxis in orthopaedic surgery without implant is not recommended for the reduction of the incidence of surgical site infections (SSI), however the evidence level is low. Surveys have shown that preoperative antibiotics for orthopaedic procedures without
implant are administered routinely by surgeons due to medico-legal concerns. Such practice may have an important impact on costs, side effects and emergence of antibiotic resistance. Therefore, the objective of the review is to evaluate existing clinical evidence.

METHODS:
A systematic review was performed with the use of Pubmed, EMBASE/MEDLINE, CENTRAL, SBBL-CILEA/METACRAWLER, ISRCTN Registry, ICTRP and ClinicalTrials.gov databases. Trials were initially screened by the title and abstract; secondly full papers were analysed. The meta-analysis included randomized controlled trials (RCT) with patients undergoing surgery as treatment for any orthopaedic impairment that did not need implantation. Heterogeneity analysis of the studies was conducted with chi-square; the statistical analysis of the infection rate was performed using the meta package with the R software. The effect estimate was expressed in risk ratio (RR) and pooled using a random effects model. Study quality assessment was undertaken using the Jadad scale.

RESULTS:
Of the 184 identified papers, 129 were excluded since they did not meet inclusion criteria and 45 were discarded because considered duplicate publications. After analysing the 10 potentially relevant studies, only 2 were included. The study population consisted of 1152 patients. No heterogeneity was observed, however the studies were outdated and associated with a high risk of bias. According to the pooled RR, the incidence of infection in the intervention group was lower than the control group favouring prophylaxis (RR=0.39; 95% CI 0.16-0.96, p=0.040).

CONCLUSIONS:
The meta-analysis demonstrated, in contrast to the guidelines, that antibiotic prophylaxis can reduce the incidence of SSI in elective orthopaedic surgeries without implant; however, the low number of available studies and the high risk of bias show that the effect estimate is non-statistically significant. Considering that antibiotic prophylaxis usually is administered in clinical practice, RCTs are required to establish whether antibiotic prophylaxis in orthopaedic procedures without implant is recommended or if this practice could cause more harm.

VP20 Strategies To Reduce Government Costs Of Monopolized Drugs

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ABSTRACT SUMMARY:
Access and financing of new drugs pose challenges for governments around the world. We did a narrative review of the international literature to identify strategies of cost containment and guarantee access to new and high priced medicines in countries with universal health systems. The main strategies identified were value-based pricing (VBP), risk sharing agreements (RSA), and external reference price (ERP).

INTRODUCTION:
Access and financing of new drugs pose challenges for governments around the world. Although drug cost issues have a major impact on health systems, specific pricing and reimbursement policies for high-cost new medicines have not yet been widely established by governments.

METHODS:
We conducted an exploratory review of the international literature an governmental documents on the current strategies of cost containment
and guarantee access to new and high priced medicines in countries with national health systems, including Canada, the United Kingdom, Sweden and Australia. Searches were conducted with the terms “Pharmaceutical Pricing Policies” in Pubmed and selected articles in English and Portuguese. The gray literature was searched in the repositories of the World Bank, in the electronic bookstore of the Organisation for Economic Co-operation and Development (OECD) and on the website of the World Health Organization (WHO). Complete publications with information related directly to the topic were included in the review. Publications were excluded where the full text was not available, only with a summary, which did not directly address the subject researched and also not linked to the countries surveyed. The findings were systematized using the taxonomy for Policies and Health System of Lavis et. al, focusing on governance and financing arrangements.

RESULTS:
We found 539 records using the defined search criteria associated with the name of the four countries surveyed. After removed duplicates and analysis of abstracts, 37 publications were included for narrative synthesis. The main strategies identified were value-based pricing (VBP), risk sharing agreements (RSA), and external reference pricing (ERP). The ATS-associated VBP strategy has been the most widespread in the countries surveyed since it is the basis for decision-making on reimbursement / incorporation of new drugs by countries with universal health systems. The ERP has lost space as an access strategy because of the limitations on exchange rate volatility and the difficulty of comparison without considering the context of each country although it is still widely used in European countries for the pricing and negotiation of new drugs. APRs are presented as a newer and more innovative approach with increasing use to finance oncology drugs and rare disease treatment in countries with universal health systems.

CONCLUSIONS:
The main strategies identified were value-based pricing (VBP), risk sharing agreements (RSA), and external reference pricing (ERP). APRs have emerged as a newer and more innovative approach, with increasing use to finance oncology drugs and rare disease treatment in countries with universal health systems. According to the experience of the countries surveyed, many challenges have been reported mainly in relation to the implementation and management of these agreements.

VP21 Factors Associated With Recommendations On Drugs For Rare Diseases

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ABSTRACT SUMMARY:
This study analyzed factors associated with positive recommendations on cancer and non-cancer drugs for rare diseases. While a statistically significant improvement in final endpoints was associated with a positive recommendation for all drugs for rare diseases, there appear to be differences in the other factors that influence the recommendations for cancer drugs compared to other drugs for rare diseases.

INTRODUCTION:
In Canada, reimbursement recommendations on drugs for common and rare indications (for example, orphan drugs) are made through the pan-Canadian Oncology Drug Review (pCODR) and the Common Drug Review (CDR). However, some
stakeholders have called for a separate mechanism for orphan drugs, arguing that existing processes place too much weight on their high price tags. The purpose of this study was to examine factors associated with positive recommendations on drugs for rare diseases.

METHODS:
Information was extracted from CDR and pCODR recommendations on drugs for diseases (prevalence < 1 in 2,000) until October 2017. Univariate and multivariate logistic regression models were applied to explore the influence of the following variables on recommendations: year; prevalence; clinical effectiveness (quality of life, symptoms, use of a surrogate marker, and final endpoints); safety; quality of evidence (availability of comparative data; external validity; bias); unmet need; treatment cost; and incremental cost-effective ratio (ICER). Two-way interactions were also tested.

RESULTS:
Of 128 recommendations, 48 (73%) and 36 (58%) were positive for cancer and non-cancer indications, respectively. Cancer: All submissions reporting statistically significant improvements in quality of life and symptoms received a positive recommendation. A statistically significant improvement in surrogate and final endpoints and the specification of unmet need were predictors for a positive recommendation. Submissions showing a lack of external validity were significantly less likely to receive a positive recommendation. Non-cancer: More recent submissions and those presenting statistically significant improvements in final endpoints were associated with positive recommendations. Submissions reporting safety issues were less likely to receive a positive recommendation. Prevalence, treatment cost and ICER were not determinants of positive or negative recommendations.

CONCLUSIONS:
For both cancer and non-cancer orphan drugs, impact on final endpoints, not cost, appears to be a key factor in the formulation of recommendations.

VP22 Future Trends For Managed Access Agreements In The UK

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ABSTRACT SUMMARY:
NICE are increasingly using Managed Access Agreements (MAAs) to reimburse innovative products with high levels of uncertainty. 13 MAAs have been agreed, predominantly based on either ongoing data collection (e.g. from RCTs) or existing registries. NICE have recently proposed significantly expanding the scope of MAAs, which may encourage manufacturers to invest in more innovative and bespoke MAAs to achieve access.

INTRODUCTION:
In recent years, the National Institute for Health and Care Excellence (NICE) has increasingly agreed to reimburse innovative products with high levels of uncertainty as part of managed access agreements (MAAs) while new data are collected; namely, this has occurred through the new Cancer Drugs Fund (CDF) and highly specialized technology (HST) appraisal pathway. This research aimed to provide a review of ongoing data collection arrangements as part of MAAs agreed with NICE.

METHODS:
We reviewed all current MAAs entered into between NHS England and manufacturers as of 24
RESULTS:
13 MAAs were identified (10 through the CDF; 3 through HST). All MAAs involved an observational data collection agreement. The source of observational data collection was existing NHS databases (11 MAAs: 85%), existing independent registries (1 MMA: 8% [ataluren]); bespoke MAA registry maintained by manufacturer (1 MAA: 8% [asfotase alfa]), and registries developed as a requirement for regulatory approval and maintained by the manufacturer (1 MAA: 8% [elosulfase alfa]). Only 4 MAAs (asfotase alfa, ataluren, elosulfase alfa, and venetoclax) had observational data collection as the sole basis of the data collection agreement. The other 9 MAAs (69%; all from the CDF) also required on-going data collection from clinical trials as a key component of the data collection agreement.

CONCLUSIONS:
This research shows that current MAAs have predominantly utilized either ongoing data collection (e.g. from RCTs) or existing registries to date for which limited additional set-up administration and costs would be required. However, NICE plan to increase the use of MAAs, with ongoing NICE consultation for changes in the appraisal process to expand MAAs to include all indications. In future, manufacturers will have more opportunities to explore and leverage innovative and bespoke MAAs to help achieve access.

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ABSTRACT SUMMARY:
In 2016, the Cancer Drugs Fund (CDF) became a temporary reimbursement fund collecting observational data for subsequent NICE appraisals. In most cases to date, the CDF has enabled temporary access until future trials read-outs are available. However, CDF observational data is being used to address key areas of uncertainty, potentially representing a future model for oncology drug reimbursement.

INTRODUCTION:
The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access oncology therapies that are not routinely publicly funded. In April 2016, the CDF became a temporary reimbursement fund under the remit of NICE with the aim of collecting observational data to inform subsequent technology appraisals. This aims to evaluate how the reformed CDF has been utilized in the 18 months since this reform.

METHODS:
NICE Final Appraisal Determinations for Single Technology Appraisals of oncology drugs from (29 July 2016 to 24 November 2017) were identified and key data extracted.

RESULTS:
74 oncology drug:indication appraisals were identified, 54 (73%) were recommended/optimised, 10 (14%) were not recommended and 10 drug:indication pairings (14%; osimertinib, brentuximab vedotin, pembrolizumab, olaratumab, obinutuzumab, venetoclax, nivolumab [3 indications], and ibrutinib) were referred to the CDF. For most, the greatest uncertainty in their cost-effectiveness analyses related to their survival benefits, intended to primarily be resolved through
subsequent clinical trial readouts. However, for venetoclax, ibrutinib and brentuximab, the main areas of uncertainty (relating to comparative survival benefit, pre-progression mortality, and rate of subsequent stem cell transplants, respectively) are expected to be resolved primarily through observational data collected under the CDF.

CONCLUSIONS:
The newly reformed CDF has been utilised in a minority of cases. Typically, the CDF acts as a temporary access mechanism for treatments that receive market authorization based on early/ single-arm trial data until longer-term and/or Phase III data are available. However, venetoclax, brentuximab, and ibrutinib demonstrate how the CDF may address significant areas of uncertainty through the collection of uncontrolled observational data. For venetoclax, with only single-arm supportive clinical trial data, observational data of this intervention and appropriate comparator are to be collected, providing a potential case study of how to appropriately manage reimbursement in the face of significant clinical uncertainty.

INTRODUCTION:
The Health Technology Assessment (HTA) of esthetic procedures was performed by the French National Authority for Health (HAS), at the request of the French Ministry of Health (MoH), and under a new regulatory framework enabling the government to ban esthetic procedures considered harmful or potentially harmful to patients and consumers by HAS. Objectives: Describe HAS’ 7-year experience with the safety assessment of 4 esthetic procedures.

METHODS:
This is an HAS review of its methods used in 4 HTAs for the following evaluated techniques: lipolysis, cryolipolysis, esthetic mesotherapy, and UV radiation in tanning devices. The review aimed to describe how these assessments have been undertaken and information sources used, from 2010 to 2017, to appreciate the safety profile of these procedures.

RESULTS:
A systematic literature review (SRL) and analysis was performed for all 4 HTAs. Since findings did not allow for thorough appreciation of safety, additional sources of information were consulted to address evidence gaps. Sources may have included any combination of the following: • National and international health care authority data and alerts • Legal and ethical frameworks • Public consultation • Expert opinion • Patient-consumer association opinion • Economic analysis

CONCLUSIONS:
An adaptation of the HTA methodology was necessary to meet the specific requirements of

VP24 HTA To Assess Esthetic Procedures In France: HAS’ 7-Year Experience

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ABSTRACT SUMMARY:
Popularity and demand for esthetic procedures has increased in recent years, driven by the emergence of new technologies and a change in cultural norms concerning both image and appearance. This fast-growing trend has raised a number of important ethical and safety questions in France, prompting the French Ministry of Health to respond and issue a regulatory report on esthetic procedures.
these assessments. Despite sources cumulated and consulted within the 7-year period, quantitative data was found insufficient to fully appreciate the safety profile for any one of the studied esthetic procedures. National regulatory reinforcement on the reporting of adverse events (AE), with implementation of a centralized online tool, is expected to generate and capture reliable data on the frequency and severity of adverse events associated with esthetic procedures. Recent European Union regulatory requirements on the safety and performance of medical devices include equipment used for esthetic procedures, indicating agreement and alignment on national and EU-level monitoring efforts.

**VP25 The Gap Between CPGs And Reimbursement Decisions**

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**ABSTRACT SUMMARY:**
CPGs should be a reference point for the reimbursement decisions. This study aims to determine the gap between the evidence based clinical practice guidelines and reimbursement decisions. When we compared guidelines with the reimbursement decisions, anemia guideline was in line with the reimbursement decisions. However, the recommendations in low back pain guideline about diagnosis and treatment had differences between reimbursement decisions. For example; the guideline used in primary care recommended the patients with low back pain should be x-rayed, but in Turkey we don’t have the opportunity to the X-ray in primary care. Also, the guideline suggested patients with chronic low back pain use gabapentin topiramat, but physicians in primary care were not authorized to write the gabapentin.

**CONCLUSIONS:**
CPGs served as a reference point for clinical decision making should also serve as a reference point for reimbursement decisions. Explicit considerations of how the guideline recommendations link with reimbursement decisions is needed. If a country wants evidence-informed policy, a guideline development process needs to be embedded in the health system at all levels.
VP26 A Critical Appraisal Tool For Systematic Mixed Studies Reviews

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ABSTRACT SUMMARY: 
Systematic mixed studies reviews are a type of systematic reviews that combine qualitative, quantitative and mixed methods studies. A critical appraisal tool was developed to address the challenge of assessing several study designs: the Mixed Method Appraisal Tool (MMAT). A new version of the MMAT will be presented.

INTRODUCTION: 
Systematic mixed studies reviews are a type of systematic reviews that combine qualitative, quantitative and mixed methods studies. They are gaining in popularity due to their potential for providing in-depth answers to complex clinical problems and practical concerns. However, several challenges are encountered in systematic mixed studies reviews because of the heterogeneity of included study designs. One of these challenges is related to the quality appraisal of included studies. To address this challenge, a critical appraisal tool for assessing the quality of quantitative, qualitative and mixed methods studies was developed in 2007: the Mixed Methods Appraisal Tool (MMAT). The aim of this project was to strengthen the content validity of the MMAT.

METHODS: 
A new version of the MMAT was developed using the results from a literature review on critical appraisal tools and a modified e-Delphi study with methodological experts (n=73) to identify the core relevant criteria to include in the MMAT.

RESULTS: 
The results of this project and the new version of the MMAT will be presented. The MMAT has three main characteristics. First, it can be used for different studies designs since it includes criteria for qualitative, quantitative and mixed methods studies. Second, the MMAT focuses on the core relevant methodological criteria and has five criteria per category of study. Third, it includes specific criteria for assessing mixed methods studies.

CONCLUSIONS: 
Currently, there exists over 500 critical appraisal tools; making the task of selecting the proper tools for use in systematic mixed studies reviews more difficult. The MMAT offers an alternative solution by proposing a unique tool that can appraise the quality of different study designs. Also, by limiting to core criteria, the MMAT can provide a more time efficient assessment.

VP27 The Environmental Impact Of A Health Technology: A Scoping Review

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ABSTRACT SUMMARY:
A scoping review was conducted to identify articles that presented frameworks/methods or case studies on the environmental impact assessment of a health technology. Eleven publications were included. Central themes identified were transparency and repeatability, integration of components in a framework or evidence into a single outcome, data availability to ensure the accuracy of findings, and familiarity with the approach used.

INTRODUCTION:
At CADTH, Optimal Use (OU) reports are health technology assessments (HTAs) that include recommendations. The Health Technology Expert Review Panel is an advisory body to CADTH that develops recommendations on non-drug health technologies using a deliberative framework. The framework spans several domains, including the environmental impact of the health technology(ies). Our research objective was to identify articles that presented frameworks/methods or case studies on the environmental impact assessment of a health technology.

METHODS:
A literature search in major databases and a focused grey literature search were conducted. The main search concepts were health technology assessment and environmental impact/sustainability. Eligible articles were those that described a conceptual framework/methods used to conduct an environmental assessment of health technologies. Case studies on the application of an environmental assessment of a health technology were also eligible. Two reviewers independently performed the study selection and data abstraction of included articles.

RESULTS:
From the 1,698 citations identified, 11 publications were included in our review. Most (n=9) were published in 2009 onwards, and two articles presented a framework to incorporate environmental assessment in HTAs. Central themes to the characteristics of these frameworks/methods include transparency and repeatability, integration of components in a framework or evidence into a single outcome, data availability to ensure the accuracy of findings, and familiarity with the methods used. The authors also cautioned that some of these approaches can be labour-intensive and time-consuming to complete.

CONCLUSIONS:
The results of our scoping review indicated that there are different proposed frameworks or methods to conduct an environmental assessment of a technology. The need for transparency, reproducibility, and integration are the main challenges. Our review is an initial step of a larger initiative by CADTH to develop the methods and processes to address the environmental impact question in an HTA.

VP28 Translating Search Syntax In Ovid Medline, Cochrane And PubMed

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ABSTRACT SUMMARY:
This presentation discusses the differences in search syntax used in Ovid Medline, Cochrane and PubMed and introduces a tool for automatically translating search strategies for the different databases. An application has been developed which allows Boolean combinations of line numbers to be easily translated from Ovid Medline to PubMed and Cochrane, as well as translating several other search fields.
**INTRODUCTION:**
Ovid Medline, Cochrane Libraries and PubMed are three medical databases commonly searched for systematic reviews, all of which allow use of MeSH terms and which share many other common fields. However, the search platforms demand very different syntax which means search strategies cannot be used interchangeably. This project seeks to evaluate the fields which are common to all three databases and presents a time-saving application for translating searches.

**METHODS:**
Information was taken from online help guides and searches were tested in the search platforms.

**RESULTS:**
In all three search platforms it is possible to use all of the different ways of using MeSH terms: unexploded, exploded, focused (major focus), exploded major focus, and limited to a MeSH subheading (exploded or not). Floating MeSH subheadings are permitted in all three search platforms. There is an existing web-based translator (Polyglot Search Syntax Translator - https://www.npmjs.com/package/sra-polyglot) but at present it cannot translate either focused MeSH terms or line numbers. The new application is currently under construction. The most useful feature is the ability to translate line numbers grouped by Boolean commands. The application generates a long string of line numbers for use in PubMed or Cochrane from a grouped string in the Ovid format. For example, or/1-4 translates to (#1 or #2 or #3 or #4) and (OR #1-#4).

**CONCLUSIONS:**
It is possible to translate most types of search query between the three search platforms explored here. The application for automating the translation of search syntax is a work in progress but there are some promising features particularly the ability to translate Boolean combinations of line numbers which could save a significant amount of time when translating large, complex searches for different search platforms.

VP29 Rapid Response In Health Technology Assessment: A Delphi Study

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**ABSTRACT SUMMARY:**
We developed a rapid response standard to be carried out in 35 days with eight steps, based on two rounds of a modified Delphi approach. All items reached consensus between 73% and 91%. This is the first consensus to our knowledge on methodological requirements on rapid response for health technology assessment to endorse a decision-making process.

**INTRODUCTION:**
Rapid response in health technology assessment comprises a set of steps used to retrieve reliable information about medical products and services from the perspective of the health manager. We build a consensus among Brazilian specialists in health technology assessment to propose guidelines for the development of rapid response.

**METHODS:**
Based on a systematic review that proposed eight methodological steps to conduct rapid response, we applied a modified Delphi technique (without open questions in the first round) to reach consensus among Brazilian experts in health technology assessment. Twenty participants were invited to judge the feasibility of each
methodological step in a five-point Likert scale. Consensus was reached if the step had 70% positive approval or interquartile range ≤ 1. The achievement of consensus was reached in the second round.

RESULTS:
The Delphi panel reached consensus in eight steps: definition of the structured question of rapid response; definition of the eligibility criteria for study types; search strategy and sources of information; selection of studies; critical appraisal of the included studies and the risk of bias for the outcomes of interest; data extraction from the included articles; summary of evidence; and preparation of the report.

CONCLUSIONS:
The guidelines for rapid response in health technology assessment may help governments to make better decisions in a short period of time (35 days). The adoption of methodological processes should improve both the quality and consistency of health technology assessments of rapid decisions in the Brazilian setting.

INTRODUCTION:
To make itself more relevant in a longer perspective HTA will have to make use of novel ways to improve its services; in particular in terms of rapid response, cost savings and reduction of risk of bias. The use of Artificial Intelligence (AI) offers significant assistance at essentially all stages of any HTA. It can search, retrieve, read and organise relevant literature, not only from traditional databases but from numerous data sources related to specific issues such as for example clinical trials, health outcomes, payment of services, and from databases in other areas such as in social, justice, and educational services, and public health.

METHODS:
This oral presentation will explain the use and feasibility of AI in HTAs based on the findings from a currently ongoing project in the province of Alberta Canada. It will include 1) An overview of AI in healthcare 2) Selected international efforts of using AI in systematic reviews, such as the Robotreviewer 3) Describe the information needed, and the development of the algorithms for using AI in HTAs 4) Report on the findings from a comparative study of human vs AI resources in performing an HTA.

RESULTS:
This project has just started, however preliminary findings from the comparative analysis of AI vs human performance on a specific topic for HTA will be presented.

CONCLUSIONS:
It is expected that the comparative study will demonstrate that artificial intelligence will become a useful tool in HTA in that it will significantly speed up systematic reviews, and decrease the risk of bias in syntheses of findings from research.

VP30 The Use Of Artificial Intelligence (AI) In HTA

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ABSTRACT SUMMARY:
Artificial Intelligence (AI) has been used in many different sectors of the society. It is now beginning to penetrate also healthcare. The structured way of performing HTAs fits very well with the approaches used and capacities available in AI. It will therefore most likely become an important part of the methodological arsenal for researchers in health technology assessment.
Optimizing Treatment For OSA: What Treatment? For Whom?

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ABSTRACT SUMMARY:
CADTH conducted an HTA to provide evidence on the clinical effectiveness, cost-effectiveness, patient perspectives and experiences, ethical issues, implementation issues, and environmental impact of treatments for obstructive sleep apnea (OSA). Study findings led to evidence-informed guidance on how to tailor treatments based on patient characteristics.

INTRODUCTION:
OSA is a prevalent disorder with substantial economic and societal burden. Although many treatments exist (e.g., positive airway pressure, oral appliances, surgery, and lifestyle modification), it remains unclear which intervention is best suited to each patient. To address this question, CADTH undertook an HTA to review the evidence surrounding the direct and indirect consequences of these treatments.

METHODS:
An overview of systematic reviews, meta-analyses, and HTAs, supplemented with a review of primary studies in areas of knowledge gaps, was conducted to understand the comparative clinical efficacy and safety of treatment. Systematic literature reviews of patient preferences and reviews of ethical, environmental, and implementation considerations were also performed. A lifetime Canadian stratified cost-utility analysis from a public payer perspective informed the economic evidence.

RESULTS:
All treatments significantly improved excessive daytime sleepiness and OSA severity, with similar effect sizes for excessive daytime sleepiness among interventions across trials. Continuous positive airway pressure showed the largest effects in improving OSA severity. In patients with moderate-to-severe OSA, treatment appeared to be a cost-effective although which intervention was considered most cost-effective depended on OSA severity and patient characteristics. Adherence in non-surgical therapy was essential to achieving clinical benefits and cost-effectiveness, and this can vary by highly-individualized patient behaviours and attitudes.

CONCLUSIONS:
The evidence was reviewed by a Canadian expert committee that developed a set of recommendations reflecting the need to tailor treatment based on OSA severity and other patient factors. This research has been a catalyst for some Canadian health insurers to review their reimbursement policies for OSA treatment.

Peroral Endoscopic Myotomy For Achalasia Treatment: A Rapid Review

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ABSTRACT SUMMARY:
The statewide HTA Program developed a rapid evidence review to inform a hospital network application to use a novel procedure POEM not evaluated in Australia. The comprehensive systematic report synthesized and methodologically appraised data from 26 published and grey literature, with key local stakeholders inputs in developing statewide evidence-based recommendations on appropriate patients and specific outcomes inform success and complications.

INTRODUCTION:
The best available research and funding policy evidence regarding the regulatory status, patient selection criteria, safety, clinical-effectiveness and financial impact of POEM for the treatment of achalasia were synthesized for statewide decision-making for a South Australian local health network.

METHODS:
A comprehensive systematic search in 23 grey literature sources and 3 published databases for international evidence was conducted, based on a priori inclusion criteria. Methodological quality of included studies were critically appraised. Data extraction and synthesis were conducted in narrative form.

RESULTS:
Short-term safety and clinical data from very low level studies show that POEM appears to be a relatively safe and clinically effective endoscopic treatment for Oesophageal Achalasia, compared to Laparoscopic Heller's Myotomy (LHM). Of primary safety concern consistently highlighted by the literature is gastroesophageal reflux (GER) after POEM, since no antireflux procedure is involved. Operative time and length of hospital stay for POEM are comparable to LHM, and can potentially favour POEM. The long term and comparative POEM procedure outcomes are not known. No studies have investigated the cost-effectiveness of POEM. Conflicting findings were reported on whether POEM is cheaper or more expensive than LHM. POEM is a technically challenging procedure with a substantial learning curve. Patients who undergo POEM may require postoperative surveillance and testing to evaluate procedural success and identify potential complications. Current literature shows limited analysis and systematic elucidation of an optimal patient group that may best benefit from POEM.

CONCLUSIONS:
POEM procedure should be carried out at experimental or trial level only with strict auditing of results. POEM procedures should ideally be performed at institutions where adequate level of surgical and critical care backup is available to provide expert care should complications arise. Monitoring of patient outcomes including symptom improvement is recommended for clinical assessment and reporting to determine future adoption in South Australian public sector.

VP34 Incorporation Of Medical Equipment In Northeastern Brazil

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ABSTRACT SUMMARY:
This study aims to analyze medical diagnostic equipment incorporation in a Brazilian state. Evaluative research was carried out using data from Brazil’s Unified Health System (SUS). An expressive
number of medical devices were incorporated in public and private health services, with higher rates in the latter. Extra coverage reveals an uncritical incorporation that was not based on real needs.

INTRODUCTION:
Improving universal health coverage is a big challenge in many nations. Nevertheless, in countries like Brazil, the Constitution provides for universal access to meet population needs. Medical equipment is indispensable for the diagnosis and treatment of diseases in public and private health services. This study aims to analyze medical diagnostic equipment incorporation in a Brazilian state.

METHODS:
This evaluative research was carried out using data from Brazil’s Unified Health System (SUS) and Private Health Services. The research took place in Ceará, Northeastern Brazil. It is the eighth most populous Brazilian state, with 8.8 million inhabitants. Data on the types and quantity of medical devices in the public and private services were collected from August 2005 to August 2017. The results were analyzed by comparing population and normative parameters with technology incorporation in Brazil.

RESULTS:
A mean of 17,610.6 devices were incorporated each year in SUS versus 31,715.7 in the private services. Over a 12-year period, the incorporation of equipment increased 59.7% in the public system and 152.6% in the private services. The production from these technologies increased 18.1%. Considering both public and private services, tomography equipment coverage exceeds (147.4%) the parameter established by the Ministry of Health while magnetic resonance imaging equipment coverage is 90.5%.

CONCLUSIONS:
An expressive number of medical devices were incorporated in public and private health services, with higher rates in the latter. Both services presented a downward trend, suggesting that the incorporation of equipment is no longer needed. Such an extra coverage reveals an uncritical incorporation of these devices, that was not based on real needs; therefore, it is necessary to develop an action plan aimed at a better distribution of these devices to allow effective universal coverage.

VP35 Comparison On Efficacy And Safety Of 7 Therapies For PHC In China

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ABSTRACT SUMMARY:
This network meta-analysis, using multivariate Meta regression random effect model, based on frequency-framework was used to compare the efficacy and safety of 7 types of therapies (TACE, radiofrequency ablation (RFA), microwave ablation (MWA), high intensity focused ultrasound (HIFU), TACE+RFA, TACE+MWA and TACE+HIFU) in treatment of primary hepatic carcinoma (PHC) in China and to support clinical decisions on appropriate therapies for.

INTRODUCTION:
There has been debates on which kinds of thermal ablations (TAs) is better for treatment of primary hepatic carcinoma (PHC) and whether the combination therapies of TAs with transcatheter arterial chemoembolization (TACE) can improve the efficacy and safety. Our study aim was to compare the efficacy and safety of 7 types of therapies (TACE, radiofrequency ablation (RFA), microwave ablation (MWA), high intensity focused ultrasound (HIFU), TACE+RFA, TACE+MWA and TACE+HIFU)
in treatment of PHC in China and to provide an evidence for clinical decisions.

**METHODS:**
Eligible references, from January of 2010 to December of 2016, were searched and selected from PubMed, Chinese Biomedical Literature database (CBM) and China National Knowledge Infrastructure (CNKI) according to criteria. Network Meta-analyses, using multivariate Meta regression random effect model, were conducted to compare the efficacy and safety of 7 types of therapies for the patients with PHC.

**RESULTS:**
fifty-nine RCTs with 4944 patients were included in the study. The study showed that the combination therapy of TACE and RFA ranked the first in 3-year overall survival (OS) rate (SUCRA 3-year OS rate =87.7%). For the perspective of incidence rate of major postoperative complications, RFA ranked the last among 7 types of therapies (SUCRA RFA =31.7%) and TACE+RFA ranked the last among 3 types of combination therapies (SUCRA TACE+RFA =37.3%).

**CONCLUSIONS:**
It is useful to apply network Meta-analyses to simultaneously compare the efficacy and safety of TAs and their combination therapy with TACE for the patients with PHC. The combination therapy of TACE and RFA may be the better choice in the thermal ablation for the patients with PHC.

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**ABSTRACT SUMMARY:**
To control cost of claims payout and improve the claims processing time under the Ghana National health Insurance scheme, electronic processing of claims (E-claims) was introduced in 2013. This study assessed the efficiency of E-claims compared to manual processing in a benefit cost analysis. E-claims was more efficient, thus provide an economic case for scaling-up to all facilities in Ghana.

**INTRODUCTION:**
Since the inception of the Ghana National Health Insurance Scheme (NHIS), it has been pursuing a number of provider payment mechanisms that could not only control the continuous escalating costs of claims payout, but also facilitate the claims processing time. In lieu of this, electronic processing of claims (E-claims) was introduced in 2013 as part of the World Bank supported Health Insurance project that sought to facilitate the financial and operational management of the NHIS. It was piloted in 29 health facilities up to March 2014. Reported are cost savings made by the NHIS using E-claims, hence calls for its scaling up. However, the comparative effectiveness and cost effectiveness of E-claims compared to manual claims processing to the health system is unknown. Therefore, to provide decision makers with the appropriate information to choose between manual and E-claims processing, this study sought to evaluate the cost benefit of E-claims.

**METHODS:**
Since the inception of the Ghana National Health Insurance Scheme (NHIS), it has been pursuing a number of provider payment mechanisms that could not only control the continuous escalating costs of claims payout, but also facilitate the claims processing time. In lieu of this, electronic processing of claims (E-claims) was introduced
in 2013 as part of the World Bank supported Health Insurance project that sought to facilitate the financial and operational management of the NHIS. It was piloted in 29 health facilities up to March 2014. Reported are cost savings made by the NHIS using E-claims, hence calls for its scaling up. However, the comparative effectiveness and cost effectiveness of E-claims compared to manual claims processing to the health system is unknown. Therefore, to provide decision makers with the appropriate information to choose between manual and E-claims processing, this study sought to evaluate the cost benefit of E-claims.

RESULTS:
Processing claims electronically led to incremental gains by both providers and purchasers. Providers gained additional USD 2008.51 while the purchaser gained USD 2,300.02. The IBCR was estimated at -19.75, 25.56 and 5.10 for all providers, purchaser and both providers and purchaser of the health system respectively.

CONCLUSIONS:
The electronic processing of claims is more efficient compared to manual processing in the Ghana NHIS. This provides decision makers with evidence on scaling it up to all the facilities in Ghana.

VP37 Research On Organizational Justice Of Village Doctors

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ABSTRACT SUMMARY:
The aim of this study was to evaluate the current situation of village doctors’ organizational justice based on the three-dimension model of organizational justice, discuss the main causes of unfairness, and put forward pertinence countermeasures and suggestions under the background of the new medical reform.

INTRODUCTION:
Village doctors who rooted in the vast rural areas play an irreplaceable role in ensuring the health of rural residents in China. But at present, the problem of low work initiatives and the brain drain is very serious, which affects the development of rural health service in China. Previous studies have been discussed in the education and training, salary, system guarantee and other aspects, not involved in the psychological level of organizational justice issues. The positive prediction function of organizational justice on employees’ work attitudes and behaviors has been verified in other research fields. Therefore, this study, combined with the background of the new medical reform, analyzes the current situation of Village doctors’ organizational justice, discusses the main causes of unfairness, and puts forward pertinence countermeasures and suggestions.

METHODS:
The methodology was quantitative combined with qualitative and the study design was cross-sectional. Based on the three-dimension model of organizational justice put forward by Niehoff and Moorman: distributive justice, procedural justice and interactional justice. Combined with the background of the new medical reform to analysis the organizational justice status of village doctors.

RESULTS:
The distributive justice of village doctors showed: the income gap was widening between expectation
and reality, and was widening between village doctors and rural teachers, and village cadres. The procedural justice of village doctors showed: the essential medicine system and the basic public health service policy were all had deficiency that caused village doctors felt unfair. The interactional justice of village doctors through the attitude of managers conveying policy and the construction of information feedback mechanism all affected the village doctors’ sense of interactional justice.

CONCLUSIONS:
First, based on the equity theory, we should design an explicit salary incentive system which is consistent with the job characteristics of village doctor. Secondly, based on psychological contract theory, we should adopt the invisible incentive measures to achieve procedural fairness. Finally, based on the attribution theory, we should implement the communication to meet the respect, affiliation and other social needs for rural physicians village doctors.

INTRODUCTION:
As healthcare delivery systems face heightened pressure to ensure appropriate use of health technologies throughout their lifecycle, HTA organizations have begun to revisit their processes. This has resulted in a shift from HTA to HTM. Traditionally, HTA has mainly relied on published studies to examine the safety, clinical and cost-effectiveness of a technology. However, to support HTM, a broader scope, set of methods and data sources are required to reflect contextual factors that impact appropriateness. This project aimed to take an HTM approach to determine for whom, when and where robot-assisted radical prostatectomy (RARP) should be provided within Alberta’s single provincial health authority, Alberta Health Services (AHS).

METHODS:
AHS’s quadruple aim framework guided the work, which was overseen by an advisory group comprising clinical, operational, and strategic leaders, patients, HTA methodologists, and government representatives. Outcomes corresponding to the 4 aims of the quality improvement framework were identified. They spanned short and long term clinical, procedural/OR, and economic outcomes, resource utilization, broader system implications, and surgeon and patient preferences. They were assessed through systematic reviews and meta-analyses; economic modeling; interviews with the manufacturer, surgeons, patients, and front-line staff; and analyses of real-world evidence from administrative and registry data.

RESULTS:
To date, 5,000 RARPs have been performed across three hospitals in Alberta. Compared with open surgery, RARP had fewer complications but higher case costs. These were attributable to equipment requirements, not OR time, which was similar across procedures. Surgeons expressed a strong preference for RARP, which published studies have found to be less cognitively and physically
demanding than open surgery. Based on broad stakeholder feedback, the final report was seen as “balanced and fair”.

**CONCLUSIONS:**
The adoption of a quality improvement framework provided a useful means of providing a more holistic view of the value of a technology to support HTM.

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**VP40 Robotic Surgery: From HTA To State Health Policy**

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**ABSTRACT SUMMARY:**
Robotic-assisted surgery continues to replace open and laparoscopic procedures (typically in private hospitals) despite a lack of studies comparing safety, clinical and cost effectiveness of robot-assisted surgery with other surgical modalities. Public hospital surgeons are lobbying CEOs to establish this technology in public hospitals at a time when public health service funding is under increasing access and funding pressure.

**INTRODUCTION:**
The ageing population means more men are diagnosed with prostate cancer, resulting in greater demand for treatment. Robot-assisted radical prostatectomy (RARP) claims to offer additional benefits to patients and providers. The independent Victorian Health Technology Program Advisory Committee assessed safety, clinical effectiveness and cost effectiveness evidence and financial impact to inform policy, access and reimbursement decision-making by state government policy makers and public hospital providers.

**METHODS:**
Public and private hospital activity and costs for 2008-09 to 2012-13 from the Victorian Admitted Episodes Database (VAED) and the Victorian Cost Data Collection (VCDC) were identified, extracted and reviewed based on: DRGs M01A and B; primary diagnostic code C61 (ICD-10-AM); and Australian Classification of Health Interventions procedure codes for open (ORP), laparoscopic (LRP) and RARP; supplemented by Victorian Prostate Cancer Clinical Registry data. English language HTAs/systematic reviews published January 2009 to January 2015 were identified and analysed with comparative clinical outcomes data for RARP vs. ORP and RARP vs. LRP analysed. Not all reported the same data and most outcomes data presented were odds ratios and risk ratios.

**RESULTS:**
RARP offers patients a shorter length of stay (LOS) compared with ORP or LRP, but the procedure takes longer to perform. While RARP has similar safety and clinical effectiveness profiles compared with ORP and LRP, published data do not unequivocally demonstrate that RARP is superior to ORP or LRP in terms of clinical outcomes. RARP is more expensive than ORP and LRP. The cost differential increases when capital costs are taken into account. Cost offsets from a reduced LOS are insufficient to justify the higher cost.

**CONCLUSIONS:**
Since RARP produces similar clinical outcomes to ORP and LRP but at a higher cost, the Victorian Health Technology Program Advisory Committee considered the case for public sector support of RARP is weak and recommended: i) State Government resources are not used to procure RARP capital equipment; and ii) public hospitals can refer patients to a RARP provider, provided costs are negotiated prior to patient transfer and fully covered by the referring hospital.