HTA Beyond 2020: Ready For The New Decade?

ABSTRACT BOOK
## Contents

### Oral Presentations

<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP01 Building Control Arms For Cancer Clinical Trials From Real-World Data</td>
<td>14</td>
</tr>
<tr>
<td>OP02 Matching Methods In Precision Oncology: An Introduction And Example</td>
<td>14</td>
</tr>
<tr>
<td>OP03 Patient Survival From Non-Small Cell Lung Cancer (1973-2013)</td>
<td>15</td>
</tr>
<tr>
<td>OP04 Real Biased Evidence? Comparing “Real World” Mortality Data And RCTs</td>
<td>16</td>
</tr>
<tr>
<td>OP05 Systematic Review Of Effectiveness Of Systems Approaches In Healthcare</td>
<td>17</td>
</tr>
<tr>
<td>OP06 Evaluating Public Health Interventions: A Neglected Area In HTA Field</td>
<td>18</td>
</tr>
<tr>
<td>OP07 Developing A Decision Tool For Selecting Approaches For Rapid Reviews</td>
<td>19</td>
</tr>
<tr>
<td>OP08 MCDA For HTA: Which Agenda To Address Methodological Challenges?</td>
<td>20</td>
</tr>
<tr>
<td>OP09 Analysis Of Medical Devices Studies For Market Access In Europe</td>
<td>21</td>
</tr>
<tr>
<td>OP10 Approaches To Gain Reimbursement For Medical Devices In Germany</td>
<td>21</td>
</tr>
<tr>
<td>OP11 Could Early Dialogues In Medical Devices Accelerate Reimbursement?</td>
<td>22</td>
</tr>
<tr>
<td>OP12 PLEG In Europe: From National Practices To Cross-Border Collaboration</td>
<td>23</td>
</tr>
<tr>
<td>OP13 Cost Analysis Of Neonatal Tele-Homecare Compared To In-Hospital Care</td>
<td>24</td>
</tr>
<tr>
<td>OP14 Progress In Use Of Telerehabilitation For Persons With COPD</td>
<td>25</td>
</tr>
<tr>
<td>OP15 Use Of Digital Health Information Among HIV Populations In Uganda</td>
<td>26</td>
</tr>
<tr>
<td>OP16 Assessing The Viability Of Medical Equipment Procurement In Hospital</td>
<td>27</td>
</tr>
<tr>
<td>OP18 A Case Study Of Local Context-Dependent Decision Making In HTA</td>
<td>27</td>
</tr>
<tr>
<td>OP19 Does The HST Represent A Best Practice Model For Ultra-Orphan HTA?</td>
<td>28</td>
</tr>
<tr>
<td>OP20 Has The New HST Process Improved The Recommendation Chance In England?</td>
<td>29</td>
</tr>
<tr>
<td>OP21 Enhancing Capability: Patient Impact In Ultra-Orphan Conditions</td>
<td>30</td>
</tr>
<tr>
<td>OP22 Patient-Based Evidence: Its Role In Decision Making On New Medicines</td>
<td>31</td>
</tr>
<tr>
<td>OP23 Smart Searches For Context-Sensitive Topics: Geographic Search Filters</td>
<td>32</td>
</tr>
<tr>
<td>OP24 Challenges Of Translating Search Filters Between Different Interfaces</td>
<td>33</td>
</tr>
<tr>
<td>OP25 Organisational Learning Principles Applied To Information Retrieval</td>
<td>33</td>
</tr>
<tr>
<td>OP26 Search Approaches In Information Retrieval Presented In HTAi SuRe Info</td>
<td>34</td>
</tr>
<tr>
<td>OP27 Engaging Patients: The EuroCAB Programme</td>
<td>35</td>
</tr>
<tr>
<td>OP28 Patient Involvement At AQuAS: Experiences And Reflections For Future</td>
<td>36</td>
</tr>
<tr>
<td>OP29 Building A Global, Public Repository Of Patient Experience Data</td>
<td>37</td>
</tr>
<tr>
<td>OP30 Impact Of Patient Reported Outcomes Data On HTAs In AML</td>
<td>38</td>
</tr>
<tr>
<td>OP31 HTA And Patients’ Preferences: Starting A Discrete Choice Experiment</td>
<td>39</td>
</tr>
<tr>
<td>OP32 Stakeholder Requirements For Real-World Drug Utilization Evidence</td>
<td>40</td>
</tr>
<tr>
<td>OP33 Treatment Of Mitral Insufficiency And Multicriteria Decision Making</td>
<td>41</td>
</tr>
<tr>
<td>OP34 One-Way Sensitivity Analysis For Cost-Effectiveness Analysis</td>
<td>42</td>
</tr>
<tr>
<td>OP35 A Framework For Economic Evaluations With Interactions Between Groups</td>
<td>42</td>
</tr>
<tr>
<td>OP36 The Probabilistic Incorporation Of Structural Uncertainty In Models</td>
<td>43</td>
</tr>
<tr>
<td>OP37 Impact On Uncertainty Of Disaggregating Cost Data</td>
<td>44</td>
</tr>
<tr>
<td>OP38 Implementing Social Innovations: From Evidence-Based To Theory-Driven</td>
<td>45</td>
</tr>
<tr>
<td>OP39 Adapting HTA To Suit Emerging Needs - An Australian Experience</td>
<td>46</td>
</tr>
<tr>
<td>OP40 Criminal Justice Costs And Benefits Of Mental Health Interventions</td>
<td>47</td>
</tr>
<tr>
<td>OP41 Intercultural Medical Decision Support System Using NLP</td>
<td>48</td>
</tr>
</tbody>
</table>
OP42 Updated Qualitative Syntheses: What Can They Offer To HTA? ................................. 50
OP43 Sourcing Professional Advice: Striving For Consistency ........................................... 51
OP44 Robot-Assisted Surgery: Joint HTA To Inform Australian Policy And Fund .................. 51
OP45 Biological Drugs And Rheumatoid Arthritis In Brazil: An Overview ......................... 52
OP46 Evaluating Statin Utilisation In The NHS Scotland .................................................. 53
OP47 Need For New Thrombectomy Centres? A Practical Decision Framework ................. 55
OP48 Nursing Requirements In Long-Term Care: A Health Technology Assessment .......... 56
OP49 MAIC-ing Use Of Trials? Study Of Matching Adjusted Indirect Comparison ............... 57
OP50 IQWiG And GRADE – An Exemplary Comparison Of Methods ............................. 57
OP51 Comparison Of The Measurement Properties Of The PROBE And EQ5D On Pain ......... 58
OP52 Use Of Intention To Treat And Magnitude Of Treatment Effects .............................. 59
OP53 HTA Acceptability Of Innovative Survival Metrics In Oncology ............................... 60
OP54 Monitoring Evidence On Overall Survival Benefits Of Anti-Cancer Drugs ................. 61
OP55 Effects Of Regulatory Major Objections On Reimbursement Decisions ..................... 62
OP56 Are TPRs Driving Pharmaceutical Reimbursement Outcomes In Spain? ..................... 63
OP57 Threats And Opportunities To Digital Health In Primary Care .................................. 64
OP58 Developing An Evaluation Based Taxonomy For mHealth Apps ............................... 65
OP59 HTA Of A mHealth App For Young People With Diabetes ....................................... 65
OP60 Challenges In Evaluating Smart Medical Devices .................................................... 66
OP61 Data From Smart Devices: The Apple Watch And Atrial Fibrillation ......................... 67
OP62 Let’s Co-Design A Tool To Assess Overweight And Obesity Health Apps .................. 68
OP63 Clinical Videoconferencing - Critical-Realist Review As Evidence? ............................ 69
OP64 Implementation Of Whole Exome Sequencing For Rare Diseases ............................ 70
OP65 Health Technology Assessment Of Orphan Drugs: Impact Of Extra Criteria? ............. 71
OP66 Cost Of Direct Import Unlicenced And Orphan Medicines In Turkey ......................... 72
OP67 A Composite Model For Pricing New Orphan Drugs .............................................. 72
OP68 Value-Engineered Translation: An Example For Bladder Cancer Diagnosis ............... 73
OP69 Initiatives To Improve The Timeliness Of Cancer Diagnosis ..................................... 74
OP70 Aligning Value In Regulatory And Health Technology Assessments ......................... 75
OP71 Understanding Hospitals’ Performance Variability: Conceptual Framework ............... 76
OP72 HTA Beyond 2020 In China: HB-HTA Rising Up In Tertiary Hospitals ...................... 77
OP74 Stoma Cover Use By Fully Laryngectomized Patients .............................................. 78
OP75 Facts And Values In HTA: The Case Of Non-Invasive Prenatal Testing ..................... 79
OP76 HTA And The Right To Health Care: Lessons From South Africa ............................. 80
OP77 Nudging In NIPT: Ethical Guidance ......................................................................... 81
OP78 Picturing ELSI+: Mapping Ethical, Legal, Social And Value Issues ......................... 82
OP79 Improving Public Understanding Of Scottish Medicines Consortium Advice .......... 83
OP80 Impact Of Patient Group Participation At SMC Committee Meetings ....................... 83
OP81 Building Technical Capacity To Promote Patient Involvement In HTA ..................... 84
OP82 An Economic Evaluation Of Mobile Messages Aided Smoking Cessation In [...] ........... 85
OP83 Iterative Formative Research Informing Primary Care Education Design ................... 86
OP84 Collaborative Program To Improve Early Management Rheumatoid Arthritis .......... 87
<table>
<thead>
<tr>
<th>Abstract Number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP85</td>
<td>Persistence Leads To Ongoing Decreases In Primary Care Antibiotic Use</td>
</tr>
<tr>
<td>OP86</td>
<td>Exploring Public Utilisation Data For Primary Care Education Programs</td>
</tr>
<tr>
<td>OP87</td>
<td>A Conceptual Analysis Of QoL Measures: Ethical Implications For HTA</td>
</tr>
<tr>
<td>OP88</td>
<td>Digital Approaches For RCT Recruitment Or Retention: A Systematic Map</td>
</tr>
<tr>
<td>OP89</td>
<td>Conference Abstract Searching In NICE Health Technology Appraisals</td>
</tr>
<tr>
<td>OP90</td>
<td>Robotic Surgery’s Value: When The Evidence ‘Fuels’ The Controversy</td>
</tr>
<tr>
<td>OP91</td>
<td>Developing A Celtic Connections Regional HTA Alliance</td>
</tr>
<tr>
<td>OP92</td>
<td>One Size Fits All? Will EU Cooperation On Assessments Improve HTA?</td>
</tr>
<tr>
<td>OP93</td>
<td>Collaboration Between HTA And Procurement: A Rapid Mixed-Methods Study</td>
</tr>
<tr>
<td>OP94</td>
<td>Surrogate Endpoints In HTA: A Methods Guidelines Review Across Europe</td>
</tr>
<tr>
<td>OP95</td>
<td>Patient Reported Outcome Measures In Health Technology Decision Making</td>
</tr>
<tr>
<td>OP96</td>
<td>Assessing Impact Of UK Health Technology Assessment Programme Trials</td>
</tr>
<tr>
<td>OP97</td>
<td>Cost-Effectiveness Model Appraisal Guidelines For HTAs In Ireland</td>
</tr>
<tr>
<td>OP98</td>
<td>Limitations In Health-Economic Guidance For Medical Devices</td>
</tr>
<tr>
<td>OP99</td>
<td>Musings On Equity, Opportunity Cost And Health Economic Evaluation</td>
</tr>
<tr>
<td>OP100</td>
<td>Cost-Effectiveness Analysis: Based On Real-World Data From China</td>
</tr>
<tr>
<td>OP101</td>
<td>Is Lung Cancer Screening Cost Effective? A Systematic Review</td>
</tr>
<tr>
<td>OP102</td>
<td>How To Invest In Getting Cost-Effectiveness Screening Into Practice?</td>
</tr>
<tr>
<td>OP103</td>
<td>Incorporating HTA In The Development Of A Clinical Care Pathway</td>
</tr>
<tr>
<td>OP104</td>
<td>Hospital-Based Health Technology Assessment In China</td>
</tr>
<tr>
<td>OP105</td>
<td>Factors Affecting Horizon Scanning For Hospital-Based HTA</td>
</tr>
<tr>
<td>OP106</td>
<td>The Xpert™ C. Difficile Kit In The Hospital Health Technology Assessment</td>
</tr>
<tr>
<td>OP107</td>
<td>Transition From Conventional Pathology Lab To Digital Lab: A Mini-HTA</td>
</tr>
<tr>
<td>OP108</td>
<td>Association Of Shared Decision Making With Patient Satisfaction</td>
</tr>
<tr>
<td>OP109</td>
<td>The Need For Building Pharmacists HTA Capacity; The Nigerian Scenario</td>
</tr>
<tr>
<td>OP110</td>
<td>Trends In National Health Insurance Enrolment In Ghana</td>
</tr>
<tr>
<td>OP111</td>
<td>Project Management In EUnetHTA Non-Pharmaceutical Technologies</td>
</tr>
<tr>
<td>OP112</td>
<td>The META Tool: Helping Medtech Developers To Understand HTA</td>
</tr>
<tr>
<td>OP113</td>
<td>Towards Common Understanding Of HTA Education And Training Programs</td>
</tr>
<tr>
<td>OP114</td>
<td>Expanding Perspectives: The Role Of Environmental Scanning In HTA</td>
</tr>
<tr>
<td>OP115</td>
<td>Horizon Scanning Influence In Incorporation Of Biologics For Psoriasis</td>
</tr>
<tr>
<td>OP116</td>
<td>Optimising Horizon Scanning For New Medicines Using Machine Learning</td>
</tr>
<tr>
<td>OP117</td>
<td>Capability Of Opinion Leaders In HTA: Public Involvement In Korea</td>
</tr>
<tr>
<td>OP118</td>
<td>Reimbursement Decisions In The Netherlands – A Citizen Panel</td>
</tr>
<tr>
<td>OP119</td>
<td>Changing Views: Qualitative Results From A Deliberative Citizen Panel</td>
</tr>
<tr>
<td>OP120</td>
<td>High Risk High Complexity and Cost Devices Hospital-Based Management Impact</td>
</tr>
<tr>
<td>OP121</td>
<td>Resource Use Measurement Issues: A Scoping Review</td>
</tr>
<tr>
<td>OP122</td>
<td>A Cost-Effectiveness Registry For Prioritization In Emerging Markets</td>
</tr>
<tr>
<td>OP123</td>
<td>Disinvestment – A Global Challenge Requiring Collaboration?</td>
</tr>
<tr>
<td>OP124</td>
<td>Disinvestment Activities And Candidates In The HTA Community</td>
</tr>
<tr>
<td>OP125</td>
<td>RWD Supplements Evidence To Update UK Commissioning Policy</td>
</tr>
<tr>
<td>OP126</td>
<td>Sugar And Spice And All Things NICE Managed Access Agreements</td>
</tr>
<tr>
<td>OP128</td>
<td>Extracorporeal Membrane Oxygenation: A Six-Year Real-World Evaluation</td>
</tr>
<tr>
<td>OP129</td>
<td>Healthcare Utilization After Bariatric Surgery</td>
</tr>
<tr>
<td>OP130</td>
<td>Evidence-Informed Policy For Biologic Medicines In Brazil</td>
</tr>
<tr>
<td>OP131</td>
<td>Rapid Review For Policy: Interchangeability Of Biological Medicines</td>
</tr>
<tr>
<td>OP132</td>
<td>What Future For Drugs After An Early Dialogue Procedure?</td>
</tr>
<tr>
<td>OP134</td>
<td>Adopting Genomic Testing In Canada: Latest Evidence And Challenges</td>
</tr>
<tr>
<td>OP135</td>
<td>CAR T-Cell Therapy HTA Informs Australian Policy</td>
</tr>
<tr>
<td>OP136</td>
<td>Provision Of A Chimeric Antigen Receptor T-Cell Program: A Rapid Review</td>
</tr>
<tr>
<td>OP137</td>
<td>Translating Results From Clinical Audit Studies To Local Context</td>
</tr>
<tr>
<td>OP138</td>
<td>Stakeholders' Involvement When Developing A mHealth Assessment Tool</td>
</tr>
<tr>
<td>OP139</td>
<td>Mobile DCE App To Facilitate Shared Treatment Decision Making</td>
</tr>
<tr>
<td>OP140</td>
<td>Adult Patient Access To Electronic Health Records</td>
</tr>
<tr>
<td>OP141</td>
<td>Assessment Of An Electronic PROM System For General Practice</td>
</tr>
<tr>
<td>OP142</td>
<td>Reviewing Methods For Early Assessment</td>
</tr>
<tr>
<td>OP143</td>
<td>Assessment Of mHealth Apps: Is Current Regulation Policy Adequate?</td>
</tr>
<tr>
<td>OP144</td>
<td>mHealth App Evaluation Framework For Reimbursement Decision Making</td>
</tr>
<tr>
<td>OP145</td>
<td>Born Fyne-An mHealth Intervention To Increase Access To Maternal Health</td>
</tr>
<tr>
<td>OP146</td>
<td>Impact Of Disability Weights On Disability-Adjusted Life Years</td>
</tr>
<tr>
<td>OP147</td>
<td>Educational Costs And Benefits Of Mental Health Interventions</td>
</tr>
<tr>
<td>OP148</td>
<td>Stepped-Care Treatment For Depression May Have Economic Benefits</td>
</tr>
<tr>
<td>OP149</td>
<td>Economic Evaluation Of Pharmacological Treatments For Type 2 Diabetes In China</td>
</tr>
<tr>
<td>OP150</td>
<td>Impact Of Biologics On Rheumatoid Arthritis: How Have Costs Evolved?</td>
</tr>
<tr>
<td>OP151</td>
<td>Cost-Utility Of Gender-Neutral HPV Vaccination In Ireland</td>
</tr>
<tr>
<td>OP152</td>
<td>Pharmacoeconomic Assessment And Drug Expenditure Reduction In Ireland</td>
</tr>
<tr>
<td>OP153</td>
<td>The Value Of Health Technology Assessment: A Mixed Methods Framework</td>
</tr>
<tr>
<td>OP154</td>
<td>Strengthening Health Technology Assessment Systems In The Global South</td>
</tr>
<tr>
<td>OP155</td>
<td>Assessing Value Of Medical Technologies Early On In Emerging Economies</td>
</tr>
<tr>
<td>OP156</td>
<td>Assessing Resource Allocation At Intersection Of Efficiency And Equity</td>
</tr>
<tr>
<td>OP157</td>
<td>Carbon Ion Radiotherapy: A Systematic Review</td>
</tr>
<tr>
<td>OP158</td>
<td>Antiepileptic Drugs As Prophylaxis For Postcraniotomy Seizures</td>
</tr>
<tr>
<td>OP159</td>
<td>Frequency And Bayesian Network Meta-analysis Of SR Versus TAs For HCC</td>
</tr>
<tr>
<td>OP160</td>
<td>The Real-World Validation Of A Stakeholder Participation Checklist</td>
</tr>
<tr>
<td>OP161</td>
<td>Patient Preferences In HTA: Focus Groups With Stakeholders</td>
</tr>
<tr>
<td>OP162</td>
<td>Stakeholder Involvement In EUnetHTA Relative Effectiveness Assessments</td>
</tr>
<tr>
<td>OP163</td>
<td>HTA Participation And Prioritization In Core Outcome Set Development</td>
</tr>
<tr>
<td>OP164</td>
<td>The Mission Possible: Introducing Technology, Co-Creating Value</td>
</tr>
<tr>
<td>OP165</td>
<td>HTA And Public Health Priority Setting In China</td>
</tr>
<tr>
<td>OP166</td>
<td>Increasing US Patient-Community Capacity To Engage On Value Assessment</td>
</tr>
<tr>
<td>OP167</td>
<td>Bridging Epistemological Gaps: HTA, Value Assessment And PSRA</td>
</tr>
<tr>
<td>OP168</td>
<td>The EUnetHTA Quality Management System: Development And Evaluation</td>
</tr>
<tr>
<td>OP169</td>
<td>Implementation Of Quality Management System In Spanish Network Of HTA</td>
</tr>
<tr>
<td>OP170</td>
<td>How Can HTA Participate In The Healthcare Quality Improvement?</td>
</tr>
</tbody>
</table>
Vignette Presentations

VP01 Methods Of Patient Involvement Now And Beyond 2020: A Case Study

VP02 Involving Patients In HTA Beyond 2020: A Thematic Review

VP04 The Influence Of Sponsorship On The Treatment Effects Of Trials

VP05 Conflicts Of Interests Of Clinical Practice Guideline Panel Members

VP06 HTA And Health Industry: Key Aspect Of Their Relationships

VP07 Cost-Effectiveness Of HTA Fees

VP09 The Value Of Freedom: The Dynamics Between Capability And Wellbeing

VP10 Bulgarian HTA Capacity Compared To International Best Practice

VP11 Use Of Health Technology Assessment Adaptation In Latin America

VP12 HTA And Medicines Security: Need For Capacity Building In Africa

VP13 Transferability Instrument Of Health Economic Evaluations For Chile

VP14 Cost Analysis For HD And Peritoneal Dialysis For ESRD In South Africa

VP15 Consumer Willingness To Pay For A Hypothetical Zika Vaccine In Brazil

VP16 A NICE Way To Manage Managed Access: Case Study In Muscular Dystrophy

VP17 Do Swedish Managed Access Agreements Include Recommended Components?

VP18 Potential Of Real World Evidence For 'IDEAL' Procedures Research

VP19 Cost-Effectiveness Of Combination Inhaled Long-Acting Bronchodilators

VP20 A Cost Analysis Of The Lung Cancer Screen Program In Beijing

VP21 Economic Burden Of Pertussis Treatment In Brazil, 2014

VP22 Applying The IDEAL Framework To NICE Interventional Procedure Guidance

VP23 Assessing The Effectiveness Of A Medical Device With Limited Evidence

VP24 Fast Product Development Of Medical Devices: Implication On Assessment

VP25 HTA Enables Nurses To Discontinue Continuous ECG Monitoring

VP26 HTA In Nursing: Scoping Trends With An ICF Component Analysis

VP27 Countrywide Screening Of Cardiovascular Diseases Through Telemedicine

VP28 Building A Virtual Diagnosis Network Through A Telemedicine Platform

VP29 Designing A Mobile Clinical Decision Support System For Dementias

VP30 Evaluation Of CINAHL In Six Systematic Reviews On Maternal Care

VP31 Searching Non-English Literature For HTA Reports May Be Unnecessary

VP32 Incorporation Of The Only Drug For Primary Biliary Cholangitis Brazil

VP33 Pharmacoeconomic Submission Requirements: Africa Compared With England

VP34 Impact Of Adverse Events On Reimbursement Recommendations

VP35 Effectiveness And Safety Of Cyanoacrylate Ablation For Varicose Veins

VP36 Beyond Traditional Patient Groups: Building Patient Input Capability

VP37 Patient Involvement In EUeHTA Assessments (Non-Pharma Technologies)

VP38 Development Of The Patient Organisation Submission Process In The NCPE

VP39 The Alphabet Lottery? How NICE Outcomes Vary By Appraisal Committee

VP40 Increasing Divergence Of IQWiG And G-BA Benefit Assessments Over Time?

VP41 NICE Interventional Procedures Advisory Committee Recommendations

VP42 One Size Fits All – Experiences With Using Collaborative European HTA
VP43 How EUnetHTA Joint Assessment Can Speed Up National Appraisal Process .................................................. 196
VP44 The Value of Health Technology Assessment: A Realist Synthesis ................................................................. 197
VP45 Post-Surgical Complications In Patients With Vascular Surgeries .............................................................. 198
VP46 German Claims Data In Rare Disease HTA: Diffuse Large B-cell Lymphoma .................................................. 199
VP47 Secondary Prevention For CV Disease: Population And Outcomes Using RWD ............................................... 199
VP48 Cost-Effectiveness Of Transcatheter Aortic Valve Implantation (TAVI) A [...]. ..................................................... 200
VP49 Real-World Evidence For Economic Evaluation Of Medical Devices ............................................................ 201
VP50 Cost-Utility Analysis Of SR And RFA For Early Hepatocellular Carcinoma ...................................................... 203
VP51 Comparison Between HTA, Pharmaceutical Pricing And Reimbursement ....................................................... 204
VP52 Use Of C Reactive Protein Testing To Reduce Antimicrobial Prescribing ...................................................... 204
VP53 Long-Acting Insulin Analogues In Brazil: Clinical And Economic Impact ....................................................... 205
VP54 Digital Tools For More Efficient Conduct Of RCTs: Trials Unit Survey ......................................................... 206
VP55 Trial Recruitment And Retention Using Digital Tools: A Qualitative Study ...................................................... 207
VP56 Using Capital Bids For Hospital-Based Health Technology Assessment .......................................................... 208
VP57 Prioritized Implementation Of Radiotherapy Procedures: A New Approach ..................................................... 209
VP58 The MedicineWise App: Extended Applications Beyond Medicine Management ........................................... 210
VP59 Rapid Review: Screening For Atrial Fibrillation Using A Smartphone .......................................................... 210
VP60 Rapid HTA Of The CarbonCool Full Body Suit For Exertional Heat Injurie ....................................................... 211
VP61 The EUnetHTA Companion Guide: A New Repository To Support European HTA ........................................... 212
VP62 BEUnetHTA Planned And Ongoing Projects Database: Usage And Challenges ............................................. 213
VP63 The Use Of EUnetHTA Joint REAs To Inform Economic Evaluation .............................................................. 214
VP64 Judicialization of Health And Access To High-Priced Drugs In Uruguay .......................................................... 215
VP65 Caring For Children With Neurodevelopmental Disorders ............................................................................. 216
VP66 Recommendations From A Dialogue On Patient-Centered Value Assessment ............................................. 216
VP67 Review Of Patient Input Science In Drug Lifecycle: Europe And The US ...................................................... 217
VP68 Effectiveness Of Behavior Modification Interventions In T2MD Patients .......................................................... 218
VP69 Barriers To Access To Biologic Products: A Rapid Review .............................................................................. 219
VP70 Impact Of Comparator Choice On Oncology Drugs’ Market Access ............................................................... 220
VP71 A Comparison Of In Vitro Diagnostic HTA Practices In Western Europe ...................................................... 221
VP72 Orphan Black Box: Explanatory Principles ...................................................................................................... 222
VP73 Improving Access To Ultra-Orphan Medicines In NHS Scotland ................................................................. 222
VP74 MCDM For Orphan Drugs In Ireland – A Methodology Ready To Deliver? .................................................... 223
VP75 Extrapolating ICERs At Different Discount Rates ............................................................................................. 224
VP76 The Case For A Higher Cost-Effectiveness Threshold For Ultra-Rare Cond[...]. ............................................. 225
VP77 Reimbursement Of NSCLC And MS Drugs With High ICER Values: Key Drivers .............................................. 225
VP78 Opportunity Cost In Cost-Effectiveness Evaluation .......................................................................................... 226
VP79 Adjusting The Commercial Value Of Technologies For Cost-Effectiveness .................................................. 227
VP80 Impact Of Evidence Synthesis Methods On Outcome Of Economic Evaluation ........................................... 228
VP81 Health Economics Distance Learning For Healthcare Workers In Brazil ....................................................... 229
VP82 Tool For Prioritizing Coverage Of Health Technologies After Assessment .................................................. 230
VP83 Value Framework And Evidence For Cancer Drugs In China: A Pilot Survey .............................................. 231
VP84 Disruptive HTA For Disruptive Technologies .................................................................................................. 231
<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>VP87</td>
<td>Scale Expansion Or Efficiency Promotion Of County Public Hospitals?</td>
<td>233</td>
</tr>
<tr>
<td>VP88</td>
<td>Identification Of A Strategy For Disinvestment In The Italian NHS</td>
<td>233</td>
</tr>
<tr>
<td>VP89</td>
<td>A Preliminary Equity Checklist To Support The HTA Process</td>
<td>234</td>
</tr>
<tr>
<td>VP90</td>
<td>Which Matching Adjusted Indirect Comparison Method Is Best?</td>
<td>235</td>
</tr>
<tr>
<td>VP92</td>
<td>Portable Robotic Exoskeleton Stride Management Assist (SMA®)</td>
<td>236</td>
</tr>
<tr>
<td>VP93</td>
<td>Choosing Relevant End-Points: The Capability Approach</td>
<td>237</td>
</tr>
<tr>
<td>VP94</td>
<td>Neonates With Persistent Ductus Arteriosus: Oral Ibuprofen Treatment</td>
<td>238</td>
</tr>
<tr>
<td>VP95</td>
<td>Getting The Best Of Three Ways-Merging EUnetHTA GRADE And Cochrane Guides</td>
<td>238</td>
</tr>
<tr>
<td>VP96</td>
<td>Activities To Optimize Quality And Efficiency Of Medicines In Scotland</td>
<td>239</td>
</tr>
<tr>
<td>VP97</td>
<td>A Rapid Review On Laser Lithotripsy For Bile Duct Stones Via Endoscopy</td>
<td>240</td>
</tr>
<tr>
<td>VP98</td>
<td>Horizon Scanning For New Alternatives To The Treatment Of Leishmaniasis</td>
<td>241</td>
</tr>
<tr>
<td>VP99</td>
<td>Study On The Responsiveness Of Primary Medical Institution In ZJ And GH</td>
<td>242</td>
</tr>
<tr>
<td>VP100</td>
<td>Ultraradical Ovarian Cancer Surgery Comparative Clinical Effectiveness</td>
<td>243</td>
</tr>
<tr>
<td>VP101</td>
<td>Intrauterine Surgical Interventions: A Rapid Review</td>
<td>244</td>
</tr>
<tr>
<td>PP01</td>
<td>Real World Evidence: How To Include It In Health Technology Assessment</td>
<td>245</td>
</tr>
<tr>
<td>PP02</td>
<td>Using Real World Data To Identify The Market For A New Technology</td>
<td>245</td>
</tr>
<tr>
<td>PP03</td>
<td>Development Of A Medical Device Maintenance Management System</td>
<td>246</td>
</tr>
<tr>
<td>PP04</td>
<td>Health Technology Assessment And EU’s Digital Single Market Strategy</td>
<td>247</td>
</tr>
<tr>
<td>PP05</td>
<td>The First Choice Of Health Institutions Of Elderly In ZJ And GH, China</td>
<td>248</td>
</tr>
<tr>
<td>PP06</td>
<td>Health Technology Assessment In India (HTAin): Towards Better Health</td>
<td>249</td>
</tr>
<tr>
<td>PP07</td>
<td>Future Direction Of HTA In Japan; Proposals From The Experts</td>
<td>249</td>
</tr>
<tr>
<td>PP08</td>
<td>Evaluation Of The Brazilian Health Technology Assessment Network</td>
<td>250</td>
</tr>
<tr>
<td>PP09</td>
<td>Cost-Effectiveness Of Chronic Obstructive Pulmonary Disease Management</td>
<td>251</td>
</tr>
<tr>
<td>PP10</td>
<td>Quality Of Reporting Economic Evaluations In Rehabilitation Research</td>
<td>252</td>
</tr>
<tr>
<td>PP11</td>
<td>Cost-Effectiveness Of Aerobika Device For COPD Exacerbation Management</td>
<td>253</td>
</tr>
<tr>
<td>PP12</td>
<td>Cost Utility Analysis Of Dolutegravir For HIV-1 Infection In Thailand</td>
<td>254</td>
</tr>
<tr>
<td>PP13</td>
<td>Cost-Effectiveness Of Varenicline For Smoking Cessation</td>
<td>255</td>
</tr>
<tr>
<td>PP14</td>
<td>Budget Impact Of Sapropterin Dihydrochloride For Phenylketonuria</td>
<td>256</td>
</tr>
<tr>
<td>PP15</td>
<td>Comparative Effectiveness And Safety Of Monoclonal Antibodies For mCRC</td>
<td>257</td>
</tr>
<tr>
<td>PP16</td>
<td>Rapid Products In Health Area: Time To A Standard?</td>
<td>258</td>
</tr>
<tr>
<td>PP17</td>
<td>Rapid Productions: Guidelines International Network Results</td>
<td>258</td>
</tr>
<tr>
<td>PP18</td>
<td>Should Academic Detailing Be Used To Disseminate Guidelines In Brazil?</td>
<td>259</td>
</tr>
<tr>
<td>PP19</td>
<td>Process Quality Of Medical Care In SR And Tas For Inpatients With PHC</td>
<td>260</td>
</tr>
<tr>
<td>PP20</td>
<td>Challenges In The HTA Of New/Emergent Non-Pharmacological Technologies</td>
<td>261</td>
</tr>
<tr>
<td>PP21</td>
<td>High Risk Class Medical Devices Evaluation In Germany: Another AMNOG?</td>
<td>262</td>
</tr>
<tr>
<td>PP22</td>
<td>Methodological Standards For EU Joint Clinical Assessment Beyond 2020</td>
<td>262</td>
</tr>
<tr>
<td>PP23</td>
<td>Plain Language Advice On Medical Devices</td>
<td>263</td>
</tr>
<tr>
<td>PP24</td>
<td>The Impact Of Real-World Evidence On Demonstrating Clinical Value In Health Technology Assessments</td>
<td>264</td>
</tr>
<tr>
<td>PP25</td>
<td>Using Healthcare Analytics Tools To Selecting Medical Equipment</td>
<td>265</td>
</tr>
<tr>
<td>PP26</td>
<td>Shift From Regional To Federal Funding: Methodological Considerations</td>
<td>266</td>
</tr>
</tbody>
</table>
PP27 Additional Capabilities In HTA To Support Decision Making ........................................ 267
PP28 Adoption Of Non-Pharmaceuticals In Galicia: Beyond Conventional HTA ......................... 268
PP29 Early Experiences With CADTH/NICE Parallel Scientific Advice Pilot ............................. 268
PP30 Do Conditional Regulatory Pathways Affect HTA Recommendations? ............................ 269
PP31 Medical Device Regulation: What Is New? ..................................................................... 270
PP32 Joint Early Dialogues Between Medical Device Regulation And HTA ............................... 271
PP34 Costs Of Healthcare-Associated Infections In Latin America .......................................... 272
PP35 Valuing Intersectoral Costs And Benefits Of Interventions .............................................. 272
PP36 Inflammatory Bowel Disease: The Disability Costs Among Italian Workers ..................... 273
PP37 Economic And Epidemiological Impact Of Dengue Illness In Brazil ................................. 274
PP38 Productivity Loss In Patients With Chronic Diseases: A Pooled Analysis ......................... 275
PP39 Budget Projections And Health Impact Of PD-1/PD-L1 Inhibitors .................................. 276
PP40 Brentuximab Vedotin Budget Impact In CD30+ Cutaneous T-Cell Lymphoma .................. 277
PP41 Cost-Effectiveness Modelling Of CAR T-Cell Therapies .................................................. 277
PP42 Wearable Cardioverter/Defibrillator: Body Of Evidence Assessment .............................. 278
PP43 Decision-Making Tool In Case Of B-Lactam Allergy: How To Help Clinicians .................. 279
PP44 Optimal Use Of Warfarin: Self-monitoring From A Quebec Perspective ........................... 280
PP45 Determining The Barriers And Facilitators To Use CPGs In Primary Care ....................... 281
PP46 Lactobacillus Rhamnosus And Dermatitis In Children: A Meta-Analysis .......................... 282
PP47 Systematic Placental Examination In The Value-Based Care Era .................................... 282
PP48 Risk Of Bias Of Systematic Reviews Connected To Journal Impact Factor? ..................... 283
PP50 How Do Target Population Sizes In HTAs Impact Drug Price Changes? .......................... 284
PP51 Automated Solutions To Network Development In Network Meta-Analysis ...................... 285
PP52 Interim Decision Making To Address Uncertainty At Early Assessment ........................... 286
PP53 Impact Of Therapy Lines On The Size Of Target Population In Germany ....................... 286
PP54 A Cohort Case Study On Implantable Cardioverter Defibrillators ..................................... 287
PP55 The Effectiveness Of Viabahn In Peripheral Artery Aneurysms ....................................... 288
PP56 The Growing Role Of Bariatric Surgery In The Management Of Obesity ......................... 289
PP57 Outcomes On Transcatheter Aortic Valve Implantation (TAVI) ....................................... 290
PP58 The Alliance Between HTA And Public In National Screening Policies ........................... 291
PP59 The National Program For HTA Of MDs In Italy Out Of The Starting Block .................... 292
PP60 The Evaluation Study On The Status Of General Practitioner Allocation .......................... 293
PP61 Advanced Therapy Medicinal Products Germany: Drugs Or Methods Review? .................. 294
PP62 Cost-Effectiveness Of Cervical Cancer Screening In Estonia ............................................ 295
PP63 A Novel Chinese Model For Breast Cancer Screening ..................................................... 295
PP64 Economic Evaluation For Esophageal Cancer Screening In China .................................... 296
PP65 Methods Applied For Systematic Reviews Of Economic Evaluations In HTA .................. 297
PP66 Increasing Burden Of Out-Of-Pocket Healthcare Expense On Patients ............................ 298
PP67 Physicians Knowledge Of Cost Of Prescribed Medications In Nigeria ............................. 299
PP68 Indicators From The Real World Data To Improve Opioids Use ..................................... 300
PP69 Potential Gains In HALE From Reducing Four NCDs Among Chinese Elderly ................... 301
PP70 Identification Of Prostheses With Results Worse Than Expected ..................................... 301
<p>| PP71 | Clinical And Economic Evaluations Of Multiple Myeloma Patients | 302 |
| PP72 | Using INTEGRATE-HTA On The Example Of Rasterstereography For Scoliosis | 303 |
| PP73 | Framework Proposal For Early HTA In Translational Phase | 304 |
| PP74 | Training Using Case Report Forms Improves Quality Of Faxed Data | 305 |
| PP75 | Design Of Healthcare Horizon Scanning System In China | 306 |
| PP76 | The Registry Evaluation And Quality Standards Tool (REQueST) For HTA | 307 |
| PP77 | Relation Between Atrial Fibrillation And Cancer Based On Claims-Data | 308 |
| PP78 | Analysis Of Resource Utilization On Psoriasis Care In Brazilian Health | 308 |
| PP79 | Impact Of Hidradenitis Suppurativa On Healthcare Resource Utilization | 309 |
| PP80 | A Systematic Review Of Gugging Swallowing Screen Effect For Dysphagia | 310 |
| PP81 | Real World Data: The Early Access To Medicines Scheme Catches The Worm | 311 |
| PP82 | Instruments For Assessing Health Policymakers Capacity To Use Evidence | 312 |
| PP83 | A Conceptual Decision-Making Framework For Pharmaceutical Innovations | 313 |
| PP84 | Different Interpretation Of Evidence By HTA Body And Decision Maker | 314 |
| PP85 | Market Agreements And Budget Impact: The Antiangiogenic Case | 314 |
| PP86 | To Reimburse Combination Oncology Products: Can Two [Companies] Tango? | 315 |
| PP87 | Inpatient Drug Reimbursement: Approaches For Democratic Processes | 316 |
| PP88 | Economic Impact Of New Diagnostic Tools In Severe Sepsis | 317 |
| PP89 | Cost-Effectiveness Analysis Of Hepatitis A Vaccination In India | 318 |
| PP90 | Pneumococcal Vaccine In Elderly: Review Of Cost-Effectiveness | 319 |
| PP91 | Burden Of Post-Surgical Complications In Patients With GI Surgeries | 319 |
| PP92 | Burden Of Post-Surgical Complications In Patients With Cardiac Surgery | 320 |
| PP93 | Efficacy Of Pharmacological Treatments For Type 2 Diabetes In China | 321 |
| PP94 | Clinical Effectiveness Of Regorafenib In Metastatic Colorectal Cancer | 322 |
| PP95 | Ovarian Tissue Cryopreservation And Transplantation In Cancer Patients | 323 |
| PP96 | The Genomic Signatures In Early Breast Cancer In France | 324 |
| PP97 | Analysis Of International Activities Of INAHTA Member Agencies | 325 |
| PP98 | Educating Medical Students Toward Quality-Targeted Leadership | 326 |
| PP99 | HB-HTA Units In Brazil: Today And Future | 327 |
| PP100 | Unravelling Hospital-Based Health Technology Assessment In Brazil | 328 |
| PP101 | Assessment Of Midwife-Led Model Of Care For The Uncomplicated Pregnancy... | 329 |
| PP102 | The Configuration And Impacts Of A HTA Unit In Primary Care | 329 |
| PP103 | A Comparative Study Of CHE In ZJ and QH Province, China | 330 |
| PP104 | Predictive Validity Of Pressure Injury Assessment Tools for Patients | 331 |
| PP105 | Organizational Analysis In HTA – Experiences From A Danish HTA Agency | 332 |
| PP106 | Concomitant Music Therapy In Adult Cancer Patients | 333 |
| PP107 | Harpoon™: A Novel Device For Transapical Mitral Valve Repair | 334 |
| PP108 | Assessing CHA2DS2-VASc In predicting IS In Non-AF Populations | 335 |
| PP109 | Mapping Of Brazilian Health Technology Assessment Studies: Analysis Of [...] | 336 |
| PP110 | The Impact Of Primary And Secondary COAs On HTA Recommendations | 336 |
| PP111 | PROs In Orphan Drug Review: How Do Regulatory And HTA Reviews Compare? | 337 |
| PP112 | Do Positivist Assumptions Hold True In Complex Interventions? | 338 |</p>
<table>
<thead>
<tr>
<th>Abstract ID</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP113</td>
<td>A Framework To Enhance EAEU Cooperation On HTA: Lessons From EUnetHTA</td>
<td>339</td>
</tr>
<tr>
<td>PP114</td>
<td>Reuse Of The EUnetHTA Outputs: A Bibliographical Analysis</td>
<td>340</td>
</tr>
<tr>
<td>PP115</td>
<td>Comparing Observed Uptake Of Medicines With Estimated Uptake - England</td>
<td>340</td>
</tr>
<tr>
<td>PP116</td>
<td>Measuring Uptake Of A Condition-Wide Group Of Technologies In England</td>
<td>341</td>
</tr>
<tr>
<td>PP117</td>
<td>Determination Of The Number Of Patients Suffering From Lung Cancer</td>
<td>342</td>
</tr>
<tr>
<td>PP118</td>
<td>Cost-Effectiveness Analysis In Stage IIIAN2 Non-Small Cell Lung Cancer</td>
<td>343</td>
</tr>
<tr>
<td>PP119</td>
<td>Cost-Effectiveness Of Early Detection Of Hepatocellular Carcinoma</td>
<td>344</td>
</tr>
<tr>
<td>PP120</td>
<td>Cost-Effectiveness Of Treatments For Extensive Small-Cell Lung Cancer</td>
<td>344</td>
</tr>
<tr>
<td>PP121</td>
<td>How Involve Patient In Antibiotic Prophylaxis Decision After Tick Bite</td>
<td>345</td>
</tr>
<tr>
<td>PP122</td>
<td>Patient Associations Network: Evidences From Italy</td>
<td>346</td>
</tr>
<tr>
<td>PP123</td>
<td>Management of Patients' Conflict Of Interest And Of Commitment In HTA</td>
<td>347</td>
</tr>
<tr>
<td>PP124</td>
<td>Smart Capability Building For Effective Patient Involvement</td>
<td>348</td>
</tr>
<tr>
<td>PP125</td>
<td>Photovoice: Promoting Knowledge Exchange About Patients Experiences</td>
<td>349</td>
</tr>
<tr>
<td>PP126</td>
<td>Analyses Of User Requirements In The Evaluation Of Medical Equipment</td>
<td>350</td>
</tr>
<tr>
<td>PP127</td>
<td>Asthma Patient Value Framework: Lessons From Patient Focus Groups</td>
<td>351</td>
</tr>
<tr>
<td>PP128</td>
<td>Quantifying The Relative Importance Of COPD Symptoms To Patients</td>
<td>351</td>
</tr>
<tr>
<td>PP129</td>
<td>CPAP For Obstructive Sleep Apnea In Patients With Down Syndrome</td>
<td>352</td>
</tr>
<tr>
<td>PP130</td>
<td>Oral Supplements For Protein Energy Wasting In Chronic Kidney Disease</td>
<td>353</td>
</tr>
<tr>
<td>PP131</td>
<td>Omalizumab And Ciclosporin For Chronic Spontaneous Urticaria</td>
<td>354</td>
</tr>
<tr>
<td>PP132</td>
<td>Telemedicine Enhance Community Hospital Response Capacity</td>
<td>355</td>
</tr>
<tr>
<td>PP133</td>
<td>Ensuring Secure Health Data Exchange Across Europe. SHIELD Project</td>
<td>356</td>
</tr>
<tr>
<td>PP134</td>
<td>Changing The Paradigm: Accessing Primary Health Care And Triage Throug</td>
<td>357</td>
</tr>
<tr>
<td>PP135</td>
<td>Setting The Scope For Assessing E-Health Technologies In Hungary</td>
<td>358</td>
</tr>
<tr>
<td>PP136</td>
<td>How To Apply HTA On Large-Scale E-Health Processes</td>
<td>358</td>
</tr>
<tr>
<td>PP137</td>
<td>Toric IOLs And Spectacle Independence: A Systematic Review</td>
<td>359</td>
</tr>
<tr>
<td>PP138</td>
<td>Value-Based Policies To Support Innovations In Precision Medicine</td>
<td>360</td>
</tr>
<tr>
<td>PP139</td>
<td>Adapting HTA And Procurement To Tackle Antimicrobial Resistance</td>
<td>361</td>
</tr>
<tr>
<td>PP140</td>
<td>Gene Therapy For Transfusion-Dependent β-Thalassemia</td>
<td>362</td>
</tr>
<tr>
<td>PP141</td>
<td>Functional Connectivity By Magnetic Resonance Imaging To Detect Autism</td>
<td>363</td>
</tr>
<tr>
<td>PP142</td>
<td>Health Technology Assessment -- A Major Bottleneck In Patient Access?</td>
<td>364</td>
</tr>
<tr>
<td>PP143</td>
<td>Cost Of Ventricular Assist Device Implantation Versus Transplantation</td>
<td>365</td>
</tr>
<tr>
<td>PP144</td>
<td>Bone Marrow Transplant Costs: A Patient Level Analysis Using TDABC</td>
<td>365</td>
</tr>
<tr>
<td>PP145</td>
<td>Cost-Effectiveness Of Cervical Cancer Screening Strategies In India</td>
<td>366</td>
</tr>
<tr>
<td>PP146</td>
<td>Micro Costing Of Denture And Overdenture In Brazil</td>
<td>367</td>
</tr>
<tr>
<td>PP147</td>
<td>Budgetary Impact Of Oral Rehabilitation With Dentures In Brazil</td>
<td>368</td>
</tr>
<tr>
<td>PP148</td>
<td>A Stakeholder-Informed Strategy For Effective Communication</td>
<td>369</td>
</tr>
<tr>
<td>PP149</td>
<td>Evaluation Of Competency Of Rural Doctors Based On BP Neural Network</td>
<td>370</td>
</tr>
<tr>
<td>PP150</td>
<td>Bevan Health Tech Exemplars: Early Dialogue To Systematise HTA</td>
<td>371</td>
</tr>
<tr>
<td>PP151</td>
<td>Establishing HTA Impact Evaluation With Stakeholder Input From Day One</td>
<td>372</td>
</tr>
<tr>
<td>PP152</td>
<td>HTA At Local Level In Lombardy: Perceptions From Professionals</td>
<td>372</td>
</tr>
<tr>
<td>PP153</td>
<td>Direction Of HTA: To Build Evidence-Based Decision-Making Culture</td>
<td>373</td>
</tr>
<tr>
<td>PP154</td>
<td>Clinical And Financial Implications Of Medicine Consumption In Kenya</td>
<td>374</td>
</tr>
<tr>
<td>Abstract ID</td>
<td>Title</td>
<td>Page</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>PP155</td>
<td>Demand Side And Supply Side Of Healthcare Supply Chain</td>
<td>375</td>
</tr>
<tr>
<td>PP156</td>
<td>Reimbursement Of New Treatment Methods In Hospitals: Status In Germany</td>
<td>376</td>
</tr>
<tr>
<td>PP157</td>
<td>Health Technology Assessment Model By Public Hospital, Brazil</td>
<td>377</td>
</tr>
<tr>
<td>PP158</td>
<td>Prospective Trial Cases Of Conditional Approved Technology Of nHTA</td>
<td>378</td>
</tr>
<tr>
<td>PP159</td>
<td>Is Community Paramedicine A Safe/Effective Alternative to Usual Care?</td>
<td>379</td>
</tr>
<tr>
<td>PP160</td>
<td>Management Of Patients Affected By Neuropathic Pain In Italy</td>
<td>380</td>
</tr>
<tr>
<td>PP161</td>
<td>An Update Systematic Review And Meta-Analysis Of Non-Invasive Prenatal</td>
<td>381</td>
</tr>
<tr>
<td>PP162</td>
<td>Safety Of Human Papillomavirus (HPV) Vaccines: An Overview Of Reviews</td>
<td>382</td>
</tr>
<tr>
<td>PP163</td>
<td>Introducing The Notion Of Potential Clinical Value</td>
<td>383</td>
</tr>
<tr>
<td>PP164</td>
<td>Improving Medical Diagnosis Through Advanced Data Analytics Tools</td>
<td>384</td>
</tr>
<tr>
<td>PP165</td>
<td>Content Instead Of Orders: Experiences Of Launching A Knowledge Base</td>
<td>385</td>
</tr>
<tr>
<td>PP166</td>
<td>A Mobile Clinical Decision Support System for Autism Spectrum Disorder</td>
<td>385</td>
</tr>
<tr>
<td>PP167</td>
<td>Appropriate Health Technology Listing In China</td>
<td>385</td>
</tr>
<tr>
<td>PP168</td>
<td>Impact Of Health Technology Assessment In China, India And Thailand</td>
<td>387</td>
</tr>
<tr>
<td>PP169</td>
<td>First Insights Into Health Technology Assessment Of ATMPs In Germany</td>
<td>388</td>
</tr>
<tr>
<td>PP170</td>
<td>Quantifying The Life-Cycle Value Of Innovative Medicines: The Case Of [...]</td>
<td>389</td>
</tr>
<tr>
<td>PP171</td>
<td>Cost And Effectiveness Of Chronic Hepatitis C Treatment In Brazil</td>
<td>390</td>
</tr>
<tr>
<td>PP172</td>
<td>Cost-Effectiveness Evaluation Of Opioid Substitution Therapy</td>
<td>391</td>
</tr>
<tr>
<td>PP173</td>
<td>Is Early Modelling Too Late? Preventing Pitfalls And Optimizing Value</td>
<td>391</td>
</tr>
<tr>
<td>PP174</td>
<td>EUnetHTA Early Dialogues For Medical Devices Created With Stakeholders</td>
<td>392</td>
</tr>
<tr>
<td>PP175</td>
<td>EUnetHTA Early Dialogues – In Light Of Stakeholder Feedback</td>
<td>393</td>
</tr>
<tr>
<td>PP176</td>
<td>How To Build An Expand HTA Capabilities In The Public Life</td>
<td>394</td>
</tr>
<tr>
<td>PP177</td>
<td>Health Preference Research In Europe: A Review Of Its Use</td>
<td>395</td>
</tr>
<tr>
<td>PP178</td>
<td>Health Technology Assessment Of Laboratory Medicine</td>
<td>396</td>
</tr>
<tr>
<td>PP179</td>
<td>Health Technology Assessment Of Pediatric Intensive Care Ventilators</td>
<td>397</td>
</tr>
<tr>
<td>PP180</td>
<td>Safety First: Rapid Reviews To Evaluate Minimally-Invasive Technology</td>
<td>398</td>
</tr>
<tr>
<td>PP181</td>
<td>Systematic Review Of Nutritional Screening Tools For Hospital Settings</td>
<td>399</td>
</tr>
<tr>
<td>PP182</td>
<td>Natalizumab Therapy For Relapsing-Remitting Multiple Sclerosis</td>
<td>400</td>
</tr>
<tr>
<td>PP183</td>
<td>The Improvement Of Pregnancy Outcome With Community Nutrition Program</td>
<td>402</td>
</tr>
<tr>
<td>PP184</td>
<td>Assessment Of Adolescent Scoliosis Screening Intervention Project</td>
<td>402</td>
</tr>
<tr>
<td>PP185</td>
<td>Clinical Papers: Which Are Ongoing Studies To Assess mHealth In 2020?</td>
<td>403</td>
</tr>
<tr>
<td>PP186</td>
<td>Telemonitoring With Pacemakers For Patients With Heart Failure</td>
<td>404</td>
</tr>
<tr>
<td>PP187</td>
<td>Robotic Surgery, Any Updates?</td>
<td>405</td>
</tr>
<tr>
<td>PP188</td>
<td>Robotic Surgery: Comparing Evidence For Cancer Indications</td>
<td>406</td>
</tr>
<tr>
<td>PP189</td>
<td>Filling In The Blanks: Is RWE From MAAs Used In NICE Decision Making?</td>
<td>407</td>
</tr>
<tr>
<td>PP190</td>
<td>Oral Anticoagulants: Impact Of Real World Data For The French HTA Body</td>
<td>408</td>
</tr>
<tr>
<td>PP191</td>
<td>2008-18 HTA Experience Of The UCSC Inst. Of Bioethics And MH - Rome (IT)</td>
<td>409</td>
</tr>
<tr>
<td>PP192</td>
<td>An Institutional Ethical Framework For HTA: Stakeholder Participation</td>
<td>409</td>
</tr>
<tr>
<td>PP193</td>
<td>How Does HTA Address Social Expectations Now? An International Survey</td>
<td>410</td>
</tr>
<tr>
<td>PP194</td>
<td>Intersectoral Costs And Benefits In The Societal Perspective</td>
<td>411</td>
</tr>
<tr>
<td>PP195</td>
<td>Cognition On Clinical Stem Cell Research In Public Hospitals Of China</td>
<td>412</td>
</tr>
<tr>
<td>PP196</td>
<td>How Much Should Be Paid For Nusinersen?</td>
<td>413</td>
</tr>
</tbody>
</table>
PP198 Biological Treatments In RA: A Systematic Review Of Economic Models .......................................................... 414
PP199 Eculizumab For Paroxysmal Nocturnal Hemoglobinuria .................................................................................. 415
PP201 Trends In The Cost Of New Drugs Launched Between 1981 And 2015 ............................................................... 416
PP202 Analysis On Factors Affecting The Effect Of Rural Doctor Training ................................................................. 417
PP203 Influences of Doctors’ Job Embeddedness On Their Turnover Intention ............................................................... 417
PP204 Involving Stakeholder: Application Of The INTEGRATE-HTA Framework ....................................................... 418
PP205 Describing Unmet Needs In Advanced Cutaneous Squamous Cell Carcinoma .................................................. 419
PP206 Search Filter To Identify Reports Of RCTs In CINAHL .................................................................................. 420
PP207 Evaluation On Effects Of Antimicrobial Stewardship In Tertiary Compreh......................................................... 421
PP208 Evaluation Of Program For Prevention And Treatment Of VTE Based On IT ...................................................... 422
PP209 Orphan Drug Benefit Assessments At The Federal Joint Committee ................................................................. 423
PP210 Identification Of Frailty To A Healthy Ageing In European Population .......................................................... 424
PP211 3D Printed Versus Non-3D Printed Standard Implants And Cutting Guides ....................................................... 425
PP212 Heated Humidified High-Flow Nasal Cannula For Preterm Infants ................................................................. 425
PP238 Budget Impact Of Methionine-Free Amino Acid Formula For Homocystinuria .................................................. 426
Oral Presentations

**OP01 Building Control Arms For Cancer Clinical Trials From Real-World Data**

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**ABSTRACT SUMMARY:**
High-quality, real-world data sources combined with rigorous and transparent analytic approaches hold substantial promise to support health technology assessments. This presentation will highlight the specific opportunities, hurdles and lessons learned in using real-world data to replicate the control arms of a range of cancer clinical trials.

**INTRODUCTION:**
Rigorously selected real-world cohorts could support health technology assessments in settings when randomized designs are infeasible or insufficient. We examined whether longitudinal data from a curated electronic health record (EHR) database of cancer patients could replicate the outcomes observed in the control arms of a systematically selected sample of oncology clinical trials that supported recent regulatory approval in the US (n=21).

**METHODS:**
Our stepwise process to identify appropriate real-world cohorts included: (i) selecting patients from Flatiron Health’s EHR database with the relevant disease who received therapy consistent with the trial’s control arm, (ii) aligning the real-world cohort with the trial’s eligibility criteria, and (iii) weighting real-world cohorts to address remaining differences in baseline characteristics with the trial cohorts. We compared overall survival (OS) and/or progression-free survival (PFS) from each trial’s control with those obtained from real-world patients and used a meta-analytic approach to pool hazard ratio (HR) estimates.

**RESULTS:**
The control arms for 6 of 21 trials were infeasible to replicate for reasons that ranged from using biomarkers not yet part of the standard of care (and thus not available in real-world cohorts) to define the cohort to identifying an insufficient number of real-world patients, particularly for rare tumor types and/or when the control arm therapy did not reflect the standard of care observed in the real-world. OS and PFS from real-world cohorts were similar to those observed in the trial’s controls: pooled HR for OS and PFS associated with being in the trial’s control arm versus the weighted real-world cohort was 0.98 (95% CI: 0.89, 1.09) and 0.94 (95% CI: 0.86, 1.04), respectively.

**CONCLUSIONS:**
Data from the EHRs of rigorously selected real-world cancer patients have substantial promise to support health technology assessments by serving as an external control for clinical trials in certain settings.

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**OP02 Matching Methods In Precision Oncology: An Introduction And Example**

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ABSTRACT SUMMARY:
Quasi-experimental matching combined with big data offers a solution to non-randomized enrollment in precision oncology. We provide an introduction and illustrative example of matching, focusing on British Columbia’s Personalized OncoGenomics program. While overall survival does not significantly differ across cases and matched controls, patients whose genomic information leads to treatment change are at a significantly reduced hazard of death.

INTRODUCTION:
Randomized controlled trials (RCT) are uncommon in precision oncology. In the absence of RCTs, quasi-experimental matching methods and big data can be used to estimate the health impacts of omics-guided care. We provide an introduction to matching and illustrate how these methods can be used to analyze precision oncology interventions using real-world big data.

METHODS:
Our case study focuses on British Columbia’s Personalized OncoGenomics (POG) program, which applies whole-genome and transcriptome analysis (WGTA) to guide advanced cancer care. Our cohort comprises patients who participated in POG between July 2014 and December 2015 and matched controls. We generated our matched cohort using population-based administrative data combined with 1:1 propensity score matching (PSM) and genetic matching. After matching, we estimated Kaplan-Meier survival functions and Weibull regression models to explore the survival benefits of POG.

RESULTS:
During our study period, 230 patients participated in POG and 5,224 control patients were eligible for matching. Final weighted matched cohorts each included 230 controls. Genetic matching outperformed PSM when achieving balance on covariates of interest. Survival analyses on unmatched and matched cohorts indicated that overall survival did not significantly differ across POG and control patients (p>0.05). Stratification by WGTA-informed treatment revealed differences in estimated survival. In all cohorts patients whose WGTA information led to treatment change were at a statistically significantly reduced hazard of death compared to controls. Estimated hazard ratios ranged from 0.33 (95% CI: 0.13, 0.81) in propensity score matched patients, to 0.34 (95% CI: 0.14, 0.86) in genetic matched patients, to 0.41 (95% CI: 0.17, 0.98) in unmatched patients.

CONCLUSIONS:
Matching combined with big data offers a solution to the challenges of non-randomized enrollment observed in many applications of precision oncology. Yet validity relies on strong underlying assumptions. Careful study design and balance assessment are critical to ensure reliable effect estimates.

OP03 Patient Survival From Non-Small Cell Lung Cancer (1973-2013)

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ABSTRACT SUMMARY:
Analyses of survival of patients diagnosed with NSCLC between 1973 and 2013 have shown survival improvements over time are limited to the first 3 years following initial diagnosis. This finding should be taken into account when extrapolating short-term trial data to accommodate economic model lifetime time horizons.

INTRODUCTION:
The NICE reference case requires cost-effectiveness models that provide results for health technology assessments of new therapies to cover patients’ lifetimes. However, overall survival (OS) data from clinical trials of new therapies are generally only available for much shorter periods. Analysis of registry survival data can provide information to inform the extrapolation of available clinical trial data.

METHODS:
Data from patients with a first diagnosis of non-small cell lung cancer (NSCLC) during the years 1973-2013 were extracted from the US Surveillance, Epidemiology, and End Results (SEER) registry. Results for OS, relative survival (RS) and expected survival (ES) (excluding NSCLC deaths) were compared across 10-year bands of diagnosis age.

RESULTS:
Results showed that very similar OS and RS trajectories were followed for all age bands for up to 30 years. The highest mortality risk occurred during the first 2-3 years from NSCLC diagnosis, followed by similar low-risk of mortality thereafter. For the first 3 years following NSCLC diagnosis, there was a clear differentiation between the age at diagnosis cohorts showing some evidence that the very high initial risk of death from NSCLC had decreased between 1973 and 2013 by about 9% per annum in year 1, to only 1% in year 3. Thereafter, the mortality rate settles to a steady common value of about 6% per annum. There was no evidence of any substantial and/or consistent differences in ES by date of diagnosis.

CONCLUSIONS:
Improvements in the survival of patients diagnosed with NSCLC between 1973 and 2013 are limited. Detected survival gains only appear to occur during the first 3 years following initial diagnosis. Thereafter, NSCLC continues to present a steady substantial fatal risk to NSCLC survivors. This finding should be taken into account when extrapolating short-term trial data to accommodate economic model lifetime time horizons.

OP04 Real Biased Evidence? Comparing “Real World” Mortality Data And RCTs

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ABSTRACT SUMMARY:
Are “real world” data as valid as those of randomized controlled trials (RCTs)? Telecardiology allows a direct comparison, since both RCTs and large registries are available. Therefore, we compared the mortality results of non-randomised studies in telecardiology with those of a meta-analysis including RCTs only, finding sharply contrasting results. We elucidate possible reasons for this discrepancy.

INTRODUCTION:
Advocates of “real world evidence” argue that when adequately adjusting for bias, “real world” data might be as valid as those of randomized controlled trials (RCTs). In telecardiology, both RCTs and large
registries are available. Therefore, we compared the mortality results of non-randomized studies (NRS) in telecardiology with those of a meta-analysis including RCTs only.

METHODS:
In January 2018, we searched for NRS examining telemonitoring via implantable cardioverter-defibrillators (ICDs) or cardiac resynchronization therapies (CRTs) in patients with heart failure. The ten largest NRS adjusting for confounders and published after 2007 (date of first RCT published) with a parallel control group and a minimal size of 100 patients per study arm were considered. We compared the mortality results of the NRS with those of a meta-analysis consisting of seventeen RCTs including 10,130 patients (last search: August 2017). In addition, we will assess the NRS’ risk of bias (RoB) using ROBINS-I.

RESULTS:
We identified six NRS (number of patients ranging from 312 to 185,778; median: 19,365 patients). All six NRS showed a significant beneficial association with all-cause-mortality for patients followed remotely (Hazard Ratios [HRs] for death ranging from 0.19 to 0.67). These significant results stand in sharp contrast to those of the meta-analysis of RCTs (Odds Ratio [OR]: 0.92; Confidence Interval [95 %-CI]: 0.81–1.05; p: 0.218). We will summarize whether the NRS’ invalid results are reflected in a high RoB.

CONCLUSIONS:
The large discrepancy between NRS and RCT results suggests that residual confounding is a substantial problem of “real world evidence”. In telecardiology, confounding by indication and self-selection are the most likely explanation. Given their limited validity regarding efficacy, registry data should not be contribute to HTA but rather be used for other purposes, especially when RCT evidence is already available.

OP05 Systematic Review Of Effectiveness Of Systems Approaches In Healthcare

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ABSTRACT SUMMARY:
Systems approaches in engineering have led to significant improvements in reliability of large systems. This systematic review evaluates studies using Systems Approaches in healthcare design and delivery. We included 23 studies, most reported benefits from using systems approaches, for example 47% reduction in operating room turnover time, or reduction of wrong intraocular lens implants in cataract surgery.

INTRODUCTION:
Systems approaches in engineering, using Systems thinking, Design thinking, Risk thinking and People thinking, have led to significant improvements in reliability of large systems. In healthcare, though, there is growing interest in its use, evidence for the approach has not yet been systematically assessed. In this systematic review we evaluate studies using Systems Approaches in healthcare design and delivery. Prospero database (CRD42017065920).

METHODS:
Included were quantitative comparative primary research studies in any country or healthcare setting using a systems approach. Database
searches were conducted in August 2017. Reference lists of relevant studies were checked. Results were analysed by types of systems approach and healthcare delivery metric used. Data extraction is ongoing and exploratory meta-analysis will be performed as appropriate (using RevMan 5.3).

RESULTS:
From 11,463 citations, 23 studies were included evaluating a wide range of types of health services, including reduction of wrong intraocular lens implants in cataract surgery, and improving operating room turnover time. Most studies reported benefits from using systems approaches, for example about 47% reduction in operating room turnover time.

CONCLUSIONS:
There were surprisingly few studies demonstrating the impact of systems approaches in healthcare delivery, but these are sufficient to draw conclusions on its effectiveness, though further work is required. Full results will be presented at the conference.

INTRODUCTION:
Public health (PH) interventions are crucial for ensuring sustainable healthcare infrastructures. Nevertheless, they represent a neglected area in the HTA field due to various methodological issues and their complex design that goes beyond clinical setting. Our study provides an environmental scan of HTA initiatives related to the assessment of PH technologies on a global level.

METHODS:
The Initiative for Public Health Outcomes Research And Measurement (INPHORM) interest group has conducted a survey among European and international societies, health bodies and networks during September 2018. The questionnaire evaluates what kind of PH technologies and/or interventions have been evaluated in the last five years, or are planned for the future.

RESULTS:
Our preliminary findings from November 2018 indicate a total of 94 initiated and 44 completed surveys. Among the completed ones, the majority of respondents came from European countries (36 %), followed by North (30 %) and South America (16%) countries. Sixty-eight percent of institutions reported engagement in any aspect of HTA in the area of PH (N=30). Medical aspects of the PH technology are considered by 83% of the institutions, followed by organizational impact (67%), economic evaluation (60%) and societal consequences (60%). An average of 4 PH technologies has been evaluated by the institutions in the last five years. In reference to methodological aspects, 90% of institutions used the classical HTA.
approach for evaluating PH interventions, while 40\% used budget impact analyses. Among the barriers for reaching a decision, conflicting stakeholder priorities, lack of data and clear methodological frameworks were most commonly cited.

CONCLUSIONS:
Data analysis is currently on-going and final results will be presented during the Cologne meeting. This study will allow us to raise awareness about the importance of PH interventions in the HTA field, identify existing gaps and propose future methodological developments.

INTRODUCTION:
Rapid reviews are of increasing importance within evidence synthesis and health technology assessment (HTA) due to the need for timely evidence to underpin the assessment of new technologies. Financial constraints have also contributed to the increase in rapid reviews. There are many rapid review methods available. However, there is little definitive guidance as to which methods are most appropriate. We developed the STARR (SelecTing Approaches for Rapid Reviews) decision tool for adapting review processes through a modified Delphi approach. The STARR tool was initially developed around our work in rapid reviews.

METHODS:
A modified online Delphi survey was conducted in May 2018. The STARR tool covers four themes: interaction with commissioners/policy-makers, scoping and searching the evidence base, data extraction and synthesis methods, and reporting of rapid review methods. The Delphi included 8 questions on theme headers and descriptors plus 11 questions on items in the tool. Following independent pilot testing, a panel of 30 experts who had published rapid reviews or been involved in development of their methods were invited to complete an online questionnaire through an iterative process including suggestions for changes. Importance of each item was rated on a scale of 1 (not important) to 9 (critically important). Consensus was ≥70\% agreement across each item rated ≥7. All responses were collected in Delphi Manager® software.

RESULTS:
Consensus was reached at Round 1 (30 respondents). However, following Round 1, one additional item on quality assessment that was suggested was added, and suggestions to improve clarity and understanding of the decision tool were made. Final consensus of 20 STARR items was reached after Round 2 (24 respondents).
CONCLUSIONS:
Delphi consensus of the final STARR decision tool was reached after two rounds. Roll-out of the STARR decision tool is now planned to assist in helping plan rapid reviews.

OP08 MCDA For HTA: Which Agenda To Address Methodological Challenges?

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ABSTRACT SUMMARY:
This study departs from an overview of MCDA in HTA literature to reflect upon a methodological agenda to advance the area.

INTRODUCTION:
Multi-criteria decision analysis (MCDA) concepts, models and tools have been increasingly used within Health Technology Assessment (HTA), with several studies pointing out practical and theoretical issues related to its use. This study departs from an overview of MCDA in HTA literature to reflect upon a methodological agenda to advance the area.

METHODS:
A systematic review was conducted to identify studies discussing, developing or reviewing the use of MCDA for evaluating health technologies using aggregation approaches, with 129 studies being analysed. The PROACTIVE-S approach was built and used to analyse model applications’ methodological quality. Reported methodological-related limitations and challenges of reviewed studies were digested. Following these analyses, research pathways with the potential to address the identified limitations and challenges were identified and described.

RESULTS:
Key results of the systematic review are: despite MCDA in HTA is a growing field, model applications show poor compliance with good methodological practice regarding behavioural analyses, discussion of model assumptions and uncertainties, modelling of value functions, and dealing with judgmental inconsistencies. Top 5 challenges reported by MCDA in HTA researchers relate to: evidence and data synthesis; value systems’ differences and participants’ selection issues; participants’ difficulties in understanding processes and methods; methodological complexity and resources balance in MCDA modelling; and criteria and attributes modelling.

CONCLUSIONS:
There is a need for developing new model features and good practice guidelines to assist MCDA in HTA modelling, as well as technologies to enable participation and behavioural research. Several research pathways need to be followed, including the following: novel techniques with a potential to collect the views of a large number of stakeholders and experts and to promote consensus in model building; new methods to provide friendly protocols of questioning so as to help participants overcoming their difficulties in answering to assessment exercises; and novel models’ features to deal with evidence and data issues.
OP09 Analysis Of Medical Devices Studies For Market Access In Europe

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ABSTRACT SUMMARY:
With the new European Medical Devices regulation (MDR) on the horizon, there is an increasing demand of a better alignment between market authorisation and Health Technology Assessment (HTA), in particular regarding their requirements on clinical evidence. We analysed confidential study applications to gain an insight into studies with medical devices requiring regulatory approval in Germany.

INTRODUCTION:
With the new European Medical Devices regulation (MDR) on the horizon, there is an increasing demand of a better alignment between market authorisation and Health Technology Assessment (HTA), in particular regarding their clinical evidence requirements. However, due to shortcomings of the current European regulatory framework it is largely unknown what clinical studies on medical devices are being performed. Here, we analysed confidential study applications to gain an insight into studies with medical devices requiring regulatory approval in Germany.

METHODS:
We analysed a consecutive sample of study applications received by the Berlin Ethics Committee between March 2010 and December 2013 that required approval by an ethics committee and the competent federal authority. These included pre-market studies on devices that had not yet received a CE (Conformité Européenne) mark or had previously been CE marked for a different indication. As MD study applications are commercially confidential, confidentiality was maintained.

RESULTS:
122 study applications were analysed: 98 (80%) concerned therapeutic rather than diagnostic devices and 84 (69%) were pre-market studies. The proportion of studies on Class I, Ila, IIB and III devices was 10%, 15%, 28% and 39%, respectively. 10 studies (8%) investigated IVD-MDs. A randomized controlled trial (RCT) was planned in 70 (57%) of the 122 applications; studies with non-randomized controls groups (n= 23; 19%) or without controls (n= 29; 24%) were less common. In the subgroup of pre-market studies on therapeutic devices, the proportion of RCTs was 66% (43/65). 87 studies (71%) considered at least one patient-relevant outcome.

CONCLUSIONS:
A large proportion of MD studies in Germany apply a randomized controlled design. This allows an optimistic view on the development of a common understanding of clinical evaluation principles suitable for both market authorisation and HTA. Further, it contradicts the industry argument that RCTs on MDs are commonly infeasible.

OP10 Approaches To Gain Reimbursement For Medical Devices In Germany

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ABSTRACT SUMMARY:
In Germany, market access processes and the approach of gaining reimbursement differ significantly between medical devices, depending on their risk class, operational area, and intended use. The underlying analysis will illustrate potential pathways and specific hurdles for different types of MDs.

INTRODUCTION:
Medical devices (MDs) differ regarding their risk class (I to III), operational area (in-, outpatient), intended use (diagnostic, monitoring, intervention), and with regard to available clinical evidence. Therefore, the market access processes as well as the approach of gaining reimbursement differ significantly. From a variety of potential approaches the underlying analysis illustrates five MD-specific processes.

METHODS:
Based on a systematic search of publicly available regulations, the main pathways of potential reimbursement for MDs were evaluated.

RESULTS:
MDs to be used in the in-patient setting can be divided into three categories: (a) an innovative MD is exceeding a current reimbursement framework (OPS/DRG), (b) falls within an existing reimbursement rate, or (c) the MD is based on a known mode of action (MoA) for which already adequate reimbursement exists. Due to less empirical data from MDs for a) and b), a health technology assessment (HTA) is required before inclusion in a DRG, whereas a MD with known concept (c) will be grouped into existing price structures. Initiators of these processes are hospitals through so-called NUB application. MDs entering the outpatient sector are covered by another reimbursement catalogue (EBM/GOÄ) and have to pass an assessment by the G-BA (rapid HTA) if based on new MoA (d). Such an assessment can only be initiated by respective umbrella organizations of service providers (e.g. KBV (National Association of Statutory Health Insurance Physicians)). MDs not being positively recommended by the G-BA are not reimbursable. For MDs (e) with known MoA no HTA is required.

CONCLUSIONS:
For a successful market launch including sufficient reimbursement not only the market potential, but also the specific regulatory pathways have to be considered carefully. New and innovative MDs in the outpatient sector may have a longer application process to gain a positive reimbursement decision than MDs used in inpatient setting.

OP11 Could Early Dialogues In Medical Devices Accelerate Reimbursement?

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ABSTRACT SUMMARY:
Medical devices licensed in Europe often lack HTA-relevant evidence at market launch. Promoting early dialogues among stakeholders may improve the HTA evidence base. However, our survey indicated that stakeholders’ knowledge of early dialogues may be limited. Therefore, HTA bodies should actively promote the possibility of early dialogues to manufacturers of HTA relevant medical devices.

INTRODUCTION:
Medical devices (MD) licensed in Europe often lack HTA-relevant evidence at market launch. Manufacturers have to provide evidence on product safety and technical performance to
obtain a CE-marking; not on (cost-) effectiveness. Current medical device regulation (MDR) emphasizes post-market clinical follow-up, wherefore HTA-relevant evidence is generated once the device is used in clinical practice. HTA evidence base may be improved by promoting an early dialogue (ED) between manufacturers, HTA-bodies and regulatory authorities in an early stage of the development process. We want to assess stakeholders’ knowledge, opinion and expectations about EDs in MDs and aim to assess how bi- and tri-partite EDs can lead to timelier HTA-evidence.

METHODS:
We sent paper-based questionnaires to informed persons of HTA-bodies, notified bodies (NBs), and competent authorities (CA) in 8 European countries. Questionnaires were supplemented by telephone-based semi-structured interviews. Manufacturers were surveyed online. Data was transcribed and analyzed using qualitative and quantitative methods. Based on the consolidated information, potential pathways for bi- and tri-partite EDs were derived.

RESULTS:
Manufacturers’ knowledge of EDs appeared to be low. Most of the manufacturers have not been affected by HTA requirements as HTA of MDs is in its infancy. CA were knowledgeable about HTA and ED, whereas NBs knowledge seemed to be limited. HTA-bodies provided insights about drivers and barriers of HTA of MDs and ED. HTA-bodies and manufacturers seemed to favor an alignment of CE and HTA evidence requirements, CA and NBs tended to oppose.

CONCLUSIONS:
In general, stakeholders’ knowledge of HTA might be considered to be low. Therefore, HTA-bodies should actively promote the possibility of EDs to manufacturers of HTA-relevant MDs. Initiatives for tripartite EDs and an alignment of CE and HTA-evidence requirements should be postponed after the end of the transition period of the new MDR.

**OP12 PLEG In Europe: From National Practices To Cross-Border Collaboration**

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**ABSTRACT SUMMARY:**
During the last years several healthcare systems have established frameworks for post-launch evidence generation (PLEG), in order to collect real world data for HTA purposes. This presentation focuses on PLEG frameworks in three different European countries (Italy, Spain and Sweden), as well as on EUnetHTA activities on piloting cross-border collaboration on PLEG.

**INTRODUCTION:**
During the last years several health care systems have decided to establish frameworks for post-launch evidence generation (PLEG), that allow for patients to have a rapid access to innovative health technologies whilst ensuring the collection of additional real world data to resolve the key uncertainties that may persist at market entry. Whilst the underlying frames can differ amongst countries, the body of evidence available and remaining evidence gaps can be similar across systems, suggesting room for cross-border collaboration in the field of PLEG.

**METHODS:**
The presentation of national practices is an experience-based outlook of different HTA-oriented PLEG frameworks.
EUnetHTA WP5 activities on piloting cross-border collaboration on PLEG are carried out as a collaborative project, building on previous EUnetHTA methodological work and national experiences of involved partners.

RESULTS:
The three countries represented illustrate different ways of PLEG implementation, covering pharmaceuticals both at inpatient and at outpatient level, as well as other technologies. These frameworks mostly include patient or product registries and the use of claims databases.

EUnetHTA WP5 results include five completed or ongoing pilots, which consisted in defining the requirements (data set and methodology) for real world data collection for a specific product or a disease. Some of the pilots were performed in collaboration with regulators. Beside common requirements, these pilots also helped identify issues related to cross-border collaboration on real world data collection and exchange.

CONCLUSIONS:
There is an increased interest in the use of real world data to support HTA and decision makers in the price and reimbursement definition process, with different frameworks set up in European countries. Key learning from EUnetHTA pilots on PLEG should set the path for sustainable cross-border collaboration in the field beyond 2020.

OP13 Cost Analysis Of Neonatal Tele-Homecare Compared To In-Hospital Care

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ABSTRACT SUMMARY:
The analysis assessed costs of Neonatal Tele-Homecare (NTH) compared to regular neonatal hospital care. Resource use of in-hospital bed-days were lower in the intervention group, and total costs, including equipment and intervention costs were lower for very preterm infants. NTH may be an appropriate model of care for preterm infants and their families.

INTRODUCTION:
Neonatal homecare (NH) has been developed to give the parents the opportunity of bringing their cardiopulmonary stable preterm infant home for tube feeding and establishment of breastfeeding supported by neonatal nurses visiting the home. Home visits can be challenging for hospitals covering large regions. As an alternative to home visits telehealth has been introduced in NH, and run as Neonatal tele-homecare (NTH). Positive infant outcomes and optimizing of family-centred care have been described, but the costs of telehealth in NH remain unknown. The objective was to assess costs of NTH compared to regular neonatal hospital care.

METHODS:
The cost analysis was based on an observational study of NTH and followed the Consolidated Health Economic Evaluation Reporting Standards. The intervention group constituted of preterm infants receiving NTH (n=96). The control group constituted a historic cohort of preterm infants receiving standard care in the neonatal intensive care unit (NICU) (n=278). NTH infants and the historical group were categorized according to gestational age at birth at/under and over 32 weeks. Outcomes were NTH resource utilisation, in-NICU hospital bed days, re-admissions and total costs on average per infant. The time horizon was from birth to discharge.

RESULTS:
The costs of NTH resource utilisation were on average €695 per infant, and the total costs per infant on average were €12,200 and €4,200 for infants at/under and over 32 weeks, respectively.
The corresponding costs of the control group were €14,300 and €4,400. The difference in total costs showed statistical significance for the group of infants under 32 weeks (p<0.001).

CONCLUSIONS:
The cost analysis identified that preterm infants can receive NTH with positive clinical outcomes and without an increase in costs per infant. The NTH group with GA≤32+0 weeks had lower costs on average. Therefore NTH may be an appropriate model of care for preterm infants and their families.

OP14 Progress In Use Of Telerehabilitation For Persons With COPD

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ABSTRACT SUMMARY:
Review of telerehabilitation for persons with chronic obstructive pulmonary disease (COPD). Telerehabilitation was successful in 11 studies, unsuccessful in nine, success was unclear in six. There were difficulties with availability of skilled mentors, motivational support, and access to reliable technology. Telerehabilitation for COPD must be linked to suitable education of patients and timely support from healthcare professionals.

INTRODUCTION:
Telerehabilitation shows promise in many fields though strong evidence of benefit has been limited. We reviewed progress in the use of telerehabilitation for persons with chronic obstructive pulmonary disease (COPD). A challenge in caring for persons with this condition is the ability to achieve high levels of patient participation and compliance with rehabilitation processes.

METHODS:
Relevant publications were identified through literature searches from November 2009 to May 2018. We selected those that described studies of telerehabilitation in the management of COPD and reported clinical or administrative outcomes. Study quality was assessed using an approach that considers both study performance and study design. Judgments were made on whether the telerehabilitation application had been successful, if reported outcomes were clinically significant, and if further data were needed to establish the application as suitable for routine use.

RESULTS:
Twenty-five publications, on 26 studies, were selected. Twelve were of high or good quality. In 11 studies the telemedicine application was successful. Nine studies had unsuccessful applications, and for six studies success was unclear. Further data before routine use would be required or desirable for all successful applications. In many studies there were difficulties associated with availability of skilled mentors, motivational support for patients and access to reliable remote monitoring and communication technology.

CONCLUSIONS:
Various types of telerehabilitation are potentially helpful in the management of COPD. Availability and access to these technologies should improve. However, in management of this clinically challenging condition their use must be linked to suitable training and education of patients with COPD and timely support for them from healthcare professionals.
OP15 Use Of Digital Health Information Among HIV Populations In Uganda

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ABSTRACT SUMMARY:
The WHO guidelines emphasize the incorporation of cellphones as a tool to support HIV adherence and information dissemination. Call for Life Uganda study is a randomized control trial undertaken to improve outcomes in HIV. Majority (85%) of the participants utilized the information mostly about adherence. We recommend increased incorporation of such platforms to disseminate information in this key population.

INTRODUCTION:
Cellphones can be used to support treatment and disseminate health information. Literature has shown an unmet need for information for people living with HIV (PLHIV) and others affected by the epidemic. The WHO emphasizes the incorporation of cellphones as a tool to support HIV adherence and information dissemination. We sought to assess rates of utilization of health information provided through the Call for Life Uganda (CFLU) platform among HIV-positive individuals.

METHODS:
CFLU uses the MoTeCh-based software Call for Life™ developed by Janssen (J&J) and adapted to the Uganda setting in collaboration with Infectious Diseases Institute (IDI) offering daily pill reminder calls/sms at time scheduled for pills, health info tips; symptom reporting and clinic appointment reminders. CFLU is used in a randomized control trial (RCT) undertaken to improve outcomes in HIV patients providing information categorized into Anti Retro Viral (ARVs) and adherence, positive living, general health, pregnancy, breast-feeding, and sexuality. We used data from the RCT between August 2016 to June 2018 to generate frequency distributions and gender differences regarding utilization of health information.

RESULTS:
From a total of 300 respondents receiving CFL intervention, majority were females (70%), aged 16 to 35 years (62%), married (74.7%), secondary and higher education (57.3%), and employed (67.7%). Overall, 255/300(85%) utilized at least one of the health-tips categories. Participants utilized mostly general health information 211/300(70%); followed ARVs and adherence 173/300 (57.7%); pregnancy and breast-feeding 137/300 (45.7%), sexuality 113/300 (37.7%), and positive living 98/300 (32.7%). Gender differences were noted regarding ARVs and adherence utilization with higher percentage of females to males (61% vs 50%) and for sexuality, a higher percentage of males to females (41.6% vs 33.3%)(p<0.05).

CONCLUSIONS:
The findings indicate that when availed with platforms for health-related information, PLHIV populations will utilize them mostly for adherence. We recommend increased incorporation of such technologies to disseminate information in this key population.
OP16 Assessing The Viability Of Medical Equipment Procurement In Hospital

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ABSTRACT SUMMARY:
Combined ABC and MCDA analysis in the process of assessment the viability of medical equipment procurement can give the opportunity to make comparative assessment of different types of medical equipment (ME) based on standardized criteria; determine the priority for procurement of new ME; avoid the influence of subjective factors on the managerial decision-making process in hospital.

INTRODUCTION:
ABC-VEN analysis is easy method of clinical and economic analysis on the costs of drug coverage; and important tool for monitoring and ensuring the rational use of medicines. However, this methodology is difficult to apply in assessing the viability of medical equipment procurement (MEP) in hospital, and using combining model of ABC analysis and Multiple criteria decision analysis (MCDA) can be useful tool.

METHODS:
We created and approved our own five standardized multiple criteria which present the main results of assessment of the viability of MEP for implementing new health technologies (HTs) and contain the following: 1) Novelty/innovation; 2) Comparative clinical effectiveness and safety; 3) Relevance (demand); 4) Economic effectiveness; 5) Payback period.

Based on these criteria we determine the threshold values of priority for MEP: 1) High priority; 2) Medium priority; 3) Low priority.

RESULTS:
Using ABC model and 5 standardized criteria we analyzed all proposals from the hospital units for implementing new HTs connected with MEP for 2018. In total, proposals contained 11 items of ME, among them 3 items were in group A (27%), 2 items – in group B (18%), and 6 items – in group C (55%).

All units were high priority for procurement with the exception of 1 item from group B with medium priority. Items with low priority were not revealed which can be considered as a direct indicator of the operational effectiveness of Hospital-based HTA Unit. Exclusion from the procurement plan the ME with a medium priority can reduce hospital costs by 13.5%.

CONCLUSIONS:
Combined ABC and MCDA analysis in the process of assessment the viability of MEP can give the opportunity to make comparative assessment of different types of ME based on standardized criteria; determine the priority for procurement of new ME; avoid the influence of subjective factors on the managerial decision-making process in hospital.

OP18 A Case Study Of Local Context-Dependent Decision Making In HTA

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ABSTRACT SUMMARY:
Antibiotics impregnated calcium sulfate (AI-CaSO4) is an innovative practice to ensure local diffusion of antibiotics especially in the treatment of prosthesis or medical implants infections. Local data analysis was used to influence decision making about the use of AI-CaSO4 in surgery.

INTRODUCTION:
Antibiotics impregnated calcium sulfate (AI-CaSO4) is an innovative practice to ensure local diffusion of antibiotics especially in the treatment of prosthesis or medical implants infections. A recent introduction of AI-CaSO4 at CHU de Québec was followed by a rapid increase in use and costs. A hospital-based health technology assessment (HTA) was then requested to assess the clinical relevance of AI-CaSO4 in the surgical site infection (SSI) management.

METHODS:
A systematic review of the effectiveness and adverse effects of AI-CaSO4 was performed in indexed databases and grey literature. The local context analysis included different methodologies: 1) interviews with pharmacists, surgeons and operating room managers, 2) data extraction from electronic patient records (EPR), 3) procurement database on CaSO4, and 4) interdisciplinary working group including orthopedic and vascular surgeons, pharmacists, infectiologists, and hospital managers.

RESULTS:
Available evidence suggest that AI-CaSO4 could contribute in the treatment of osteomyelitis whereas no conclusion can be drawn for other medical indications in both treatment and prevention of SSI. A review of 113 surgical procedures showed that AI-CaSO4 was rapidly adopted after only one year and used for various medical indications in neuromodulation, orthopedic and vascular surgery. Osteomyelitis treatment accounted for less than 3% of cases. Al-CaSO4 was mainly used in prevention of SSI (65%) and surgical revisions (74%). Furthermore, local safety issues were raised by a lack of standardization for the preparation and under recording of antibiotics use with Al-CaSO4.

CONCLUSIONS:
The current state of knowledge does not support the widespread use Al-CaSO4 at CHU de Québec. This study highlights the importance of adapting HTA approach to their local context to influence decision making especially in the context of innovating practice in order to insure the relevance, safety and sustainability of care.

OP19 Does the HST Represent A Best Practice Model For Ultra-Orphan HTA?

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ABSTRACT SUMMARY:
This research compares NICE HST appraisal outcomes with corresponding guidance by other HTA bodies. Although all NICE HST final guidance to date has been positive, few technologies have completed this process after substantial delays from MA. Other cost/QALY HTA bodies (i.e. excluding the G-BA and HAS clinical- assessment HTAs) have shown low appraisal and recommendation rates for these technologies; therefore, ultra-orphan technologies
INTRODUCTION:
Ultra-orphan therapies (prevalence: <1:50,000) can have trouble meeting Health Technology Assessment (HTA) clinical- and cost-effectiveness criteria, set by HTA bodies to inform reimbursement decision-making, due to low patient numbers limiting the supporting clinical evidence generated and high per-patient prices. Since 2013, National Institute of Health and Care Excellence (NICE) appraise Highly Specialised Technologies (HST) (“for use in the provision of services for rare and very rare conditions”) using a distinct appraisal framework. This research compares NICE HST appraisal outcomes with corresponding guidance by other HTA bodies.

METHODS:
All NICE HST technology guidance was screened (01/01/13-06/11/18) alongside corresponding guidance by Gemeinsamer Bundesausschuss (G-BA), Haute Autorité de Santé (HAS), Scottish Medicines Consortium (SMC), and National Centre for Pharmacoeconomics (NCPE).

RESULTS:
NICE have published eight HST guidance all with positive recommendations after a median of 21 months (range: 7–38) after European Marketing Authorization (MA). An additional eight HST have guidance in-development despite having European MA for a median of 12 months (range: 2–46) with 5/8 having draft guidance issued, all being “not recommended”. Of the 18 HSTs with NICE guidance published/in-development, 29% (2/7), and 33% (2/6) have been assessed with positive outcomes (definition: “recommended”/“accepted”/“conditional”/“restricted”) by SMC, and NCPE, respectively vs. 100% (9/9) by G-BA (definition: any additional benefit), and 50% (5/10) by HAS (definition: ASMR I-III). Median delays between European MA and positive appraisal outcomes were 7 (G-BA), 9 (HAS), 12 (NCPE), and 19.5 months (SMC).

CONCLUSIONS:
Although all NICE HST final guidance to date has been positive, few technologies have completed this process after substantial delays from MA. Other cost/QALY HTA bodies (i.e. excluding the G-BA and HAS clinical-assessment HTAs) have shown low appraisal and recommendation rates for these technologies; therefore, ultra-orphan technologies may require a distinct appraisal process/framework but the HST may not (yet) represent best-practice.

OP20 Has The New HST Process Improved The Recommendation Chance In England?

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ABSTRACT SUMMARY:
We investigated the impact of this more quantitative approach on the likelihood of a HST receiving a positive recommendation. It has 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.

INTRODUCTION:
The National Institute for Health and Care Excellence (NICE) in England has a separate appraisal process for drugs for very rare conditions, i.e. Highly Specialised Therapies (HST). In April 2017, the HST process has been changed to incorporate
a quantitative approach: automatically fund treatments with incremental cost-effectiveness ratio (ICERs) up to £100,000 per quality-adjusted life year (QALY). For treatments with an ICER above £100,000 per QALY, NICE will consider treatments that offer a substantial magnitude of improvement, with additional QALY weighting. We investigated the impact of this more quantitative approach on the likelihood of a HST receiving a positive recommendation.

METHODS:
All HST appraisals and draft guidance documents were reviewed (up to November 2018) and data were extracted on ICERs, incremental QALY gain, budget impact, and recommendations. The extracted data from each HST were assessed based on the interim HST guidance.

RESULTS:
All HST appraisals and draft guidance documents were reviewed (up to November 2018) and data were extracted on ICERs, incremental QALY gain, budget impact, and recommendations. The extracted data from each HST were assessed based on the interim HST guidance.

CONCLUSIONS:
It has 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 for many products.

OP21 Enhancing Capability: Patient Impact In Ultra-Orphan Conditions

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ABSTRACT SUMMARY:
To enhance the capability of patient involvement at NICE and to further develop understanding of how patient generated evidence and input in ultra-orphan conditions can support the HTA agencies beyond 2020, the Public Involvement Programme systematically reviews the impact the evidence has on committee decision making. This study captured data from September 2018 to August 2018 for seven ultra-orphan evaluations.

INTRODUCTION:
Written evidence is submitted to NICE by patient organisations for all ultra-orphan evaluations. To enhance the capability of patient involvement at NICE and to further develop understanding of how patient generated evidence and input in ultra-orphan conditions can support the HTA agencies beyond 2020, the Public Involvement Programme systematically reviews the impact the evidence has on committee decision making.

METHODS:
This study captured data from September 2018 to August 2018 for seven ultra-orphan evaluations.

A paper questionnaire was given to each committee member to complete for each evaluation and entered in to an online system for analysis. Findings were used to inform the committee views which were highlighted in feedback letters to the patient groups.

The questions included:
- how much impact and what sort of impact the patients had
- both qualitative and quantitative data
- a specific question on clarification of quality of life data
RESULTS:
We obtained 93 responses showing the submissions:

- had a moderately high or high impact
- gave the committee particular insight into quality of life data not provided elsewhere
- provided new evidence
- interpret the data from other sources
- demonstrated consistency with other sources

CONCLUSIONS:
Patient evidence is particularly useful for ultra-orphan conditions where other forms of evidence are limited; patients can provide a unique insight into the burden of disease, the patient population, any updates of treatments and the impact on patient and carers.

They provide real life data to the committee including information that standard Quality of Life Years measures do not. This varies between conditions; quality of life examples include fear and anxiety. The examples are recorded, updated annually and will be shared with national patient groups and offered internationally through the HTAi Interest Group on Patient and Citizen Involvement.

OP22 Patient-Based Evidence: Its Role In Decision Making On New Medicines

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ABSTRACT SUMMARY:
The Scottish Medicines Consortium (SMC) assessment process for end-of-life and orphan medicines uses input from patients and clinicians (termed Patient and Clinician Engagement (PACE) to support decision making. The aim is to obtain information about the added value of these medicines that may not be captured in the company submission. This study investigates how committee members use this information in decision making.

INTRODUCTION:
The Scottish Medicines Consortium (SMC) advises NHS Scotland on the clinical and cost-effectiveness of new medicines. Since 2014, evidence from patients and carers on end-of-life and orphan medicines has been gathered during Patient and Clinician Engagement (PACE) meetings. The output is a consensus statement which describes the added value of a new medicine from the perspective of the patient/carer and clinician. This study investigates the importance of factors identified through PACE to committee members and how these are used in their decision-making.

METHODS:
Survey methodology was used to gain an understanding of the factors from the PACE statement that are most likely to influence members (n=26) in decision making. The survey instrument was informed by a literature review and observation of PACE and SMC meetings. Likert scale questions were used to determine the relative importance of factors in the PACE statement, including information relating to eight prominent ‘quality of life’ themes (family/carer impact, health benefits, tolerability, psychological benefit, hope, normal life, treatment choice and convenience), that were identified by an earlier thematic analysis of these statements.

RESULTS:
Analysis of survey responses will use mainly descriptive techniques to generate percentages and ranges. Correlation analysis will be considered to investigate relationships between members’
demographics, type of medicine (end-of-life, orphan) and the importance of different factors in the PACE statement. Preliminary results indicate that key quality of life themes highly valued by patients/carers are also important to committee members in their decision making. Challenges in assimilating qualitative patient-based evidence from PACE alongside quantitative clinical and economic data were highlighted.

CONCLUSIONS:
Findings from this survey will provide valuable insight into how PACE evidence is used by SMC decision makers alongside traditional clinical and economic evidence and will help shape future improvements to the PACE methodology.

OP23 Smart Searches For Context-Sensitive Topics: Geographic Search Filters

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ABSTRACT SUMMARY:
Using the National Institute for Health and Care Excellence (NICE) United Kingdom (UK) filters for MEDLINE and Embase (OVID) as examples, this presentation discusses how geographic search filters enable smarter literature searching for context-sensitive systematic review topics. The NICE UK filters reduce systematic review development time-frames by retrieving the majority of evidence for UK topics while lowering search result volumes.

INTRODUCTION:
Some systematic review topics are context-sensitive and informed by evidence about a specific geographic setting. Smart information retrieval methods are required to identify such evidence in an efficient manner. This presentation will discuss how validated geographic search filters enable smart literature searching for context-sensitive reviews using the National Institute for Health and Care Excellence (NICE) United Kingdom (UK) filters for MEDLINE and Embase (OVID) as examples.

The NICE UK filters were developed in 2016. The filters demonstrated high recall and high precision, however, further research was required to confirm these results.

METHODS:
In 2018, the filters’ recall of references from 100 UK-based multidisciplinary reviews was calculated. Reproducible search strategies were identified from twenty-six of the 100 reviews in MEDLINE and from nine reviews in Embase. From this the precision and number-needed-to-read (NRR) were calculated.

RESULTS:
The MEDLINE filter achieved 96 percent recall (1401 out of 1454 UK references), 2.1 percent precision and a NNR of forty-seven. The Embase filter achieved 97 percent recall (1520 out of 1560 UK references), 0.7 percent precision and a NNR of 146. Compared to not using a filter, the MEDLINE and Embase filters reduced the number of search results by an average of 87 percent and 80 percent respectively.

CONCLUSIONS:
The filters retrieve the majority of evidence for UK topics while reducing search result volumes and so enable smart literature searching for context-sensitive topics. Large literature search result volumes can increase development time-frames for systematic reviews. Using the filters can therefore save time for reviews with a UK focus.

There are currently two other validated geographic search filters for Africa and Spain. It is hoped that the NICE UK filters’ successful retrieval
performance will encourage the development of validated search filters for more geographic regions.

OP24 Challenges Of Translating Search Filters Between Different Interfaces

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ABSTRACT SUMMARY:
It is challenging and time consuming to test search performance in different interfaces, in what might be anticipated to be the same database. However, our research has found it is essential to test performance, so that appropriate adjustments can be made. Unexpected problems may be encountered that require adjustments.

INTRODUCTION:
Background: Information specialists frequently translate search filters from one interface to another. It is unlikely that the impact and performance of such translations is investigated in depth because of the time needed to conduct a thorough assessment and information specialists may well assume that databases are the largely the same across different publishers and that therefore interface adjustments are the only issue for successful translation. Objectives: To investigate whether we would find the same set of records after translating the Cochrane Embase search filter from one interface (Ovid) to another (Embase.com).

METHODS:
We compared the records produced by searching with the original Cochrane Embase filter (for Ovid) with the records produced by searching using a carefully translated filter (for Embase.com). Results of the searches were compared line by line to see if each line had found the same records in each interface.

RESULTS:
Even though the majority of the same records were retrieved from the two filters in the different interfaces, a range of unexpected differences were also identified. Some records had differences in publication years and subject headings between the two versions of the database, and some records were in one database but not in the other. We also encountered interface differences relating to truncation, proximity operators, and use of the original title or original abstract field. We contacted both Ovid and Embase.com to highlight unexpected technical issues.

CONCLUSIONS:
It is challenging and time consuming to test search performance in different interfaces, in what might be anticipated to be the same database, but it does seem to be essential to test, so that appropriate adjustments can be made. The translation can be impacted by version differences and also by interface differences in unexpected ways. Translating a filter may not be straightforward and any search filters intended for regular use in new interfaces should be carefully tested.

OP25 Organisational Learning Principles Applied To Information Retrieval

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ABSTRACT SUMMARY:
Organisational learning is the study of how individual knowledge becomes incorporated more widely in an organisation. Knowledge is divided into tacit (abstract, personal, know-how) and explicit (definable, shareable and fixed) types. This abstract describes how organisational learning principles of sharing tacit and explicit knowledge can be applied to information retrieval processes.

INTRODUCTION:
A key discussion point during HTAi’s 2018 Meeting was how HTA practitioners might borrow ideas from other industries or academic areas. Organisational learning (OL) is the study of how individual knowledge is shared within an organisation to become institutional/group knowledge. There are several models of OL, all focusing on how tacit knowledge (abstract, personalised, hard to define, action-based) is converted to explicit knowledge (definable, concrete, fixed, information-based). Effective knowledge sharing is crucial to leveraging individual knowledge to drive innovation, efficiency and effectiveness. Information retrieval is a knowledge-intensive field, with many processes requiring both tacit and explicit knowledge. Ideas from OL demonstrate ways to improve practice by increasing knowledge sharing.

METHODS:
Nonaka & Takeuchi’s (1994) SECI model describes the cyclical process by which knowledge is shared. The model includes 4 stages: socialisation (tacit-to-tacit), externalisation (tacit-to-explicit), combination (explicit-to-explicit) and internalisation (explicit-to-tacit). Each stage describes how knowledge sharing takes place and highlights ways to ameliorate these processes. Information retrieval involves many elements that require or benefit from knowledge sharing and both tacit and explicit knowledge is required.

RESULTS:
In the SECI model the Socialisation stage is characterised by face-to-face learning; peer reviewing of search strategies, open dialogue and team working are ways of facilitating this stage.

The Externalisation stage is crucial to OL. This can be seen as the practice-into-research stage; the results of successful experimentation, for example with search filters.

The Combination stage is the easiest to understand. Communities of practice, inter-organisational networks can widen knowledge sharing and help refine or increase detail of best practice.

The Internalisation stage is the hardest to conceptualise or measure. The extent to which guidelines become adopted in individual practice is one way to gauge Internalisation.

CONCLUSIONS:
Information retrieval practitioners could benefit from thinking about ways to improve knowledge sharing. Models of OL can be instructive in this regard.

OP26 Search Approaches In Information Retrieval Presented In HTAi SuRe Info

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ABSTRACT SUMMARY:
Summarized Research in Information Retrieval for HTA (SuRe Info) is an open-access website with a selection of up-to-date key papers presented in summarized overviews. The structure and work of SuRe Info is presented on the basis of the chapter “Value of using different search approaches”. According to this chapter, the most well-known
approach, offering the most evidence, is citation searching.

INTRODUCTION:

It is a challenge to stay up-to-date with the latest developments in information retrieval for health technology assessment (HTA). Summarized Research in Information Retrieval for HTA (SuRe Info) is a well-established open-access website with a selection of up-to-date key papers presented in summarized overviews. SuRe Info is maintained by the HTAi Interest Sub-Group on Information Resources; its main target group are information specialists. SuRe Info is updated twice a year by experienced information specialists. Publications on information retrieval methods are identified by running topic-specific search strategies in relevant databases. Publications fulfilling the SuRe Info inclusion criteria receive a structured abstract together with a brief critical appraisal prepared by one SuRe Info information specialist and checked by another. The key messages from the appraisals are summarized in topic-specific chapters.

METHODS:
The structure and work of SuRe Info is presented on the basis of the chapter "Value of using different search approaches".

RESULTS:
The chapter "Value of using different search approaches" was last updated in September 2018. It examines various alternative search approaches in bibliographic databases beyond the conventional Boolean search. According to this chapter, the most well-known approach, offering the most evidence, is citation searching (direct or indirect citation relationships). In contrast, little research has so far been conducted on other approaches such as full-text searches, automated retrieval methods or hand searching.

CONCLUSIONS:
SuRe Info is an important resource for information specialists to keep up-to-date with the literature on information retrieval. In particular when information specialists work alone and not within a larger team, it is necessary to rely on collaboration projects such as SuRe Info.

OP27 Engaging Patients: The EuroCAB Programme

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ABSTRACT SUMMARY:
The EuroCAB programme consists in Community Advisory Boards of patients who scan the horizon in their respective disease areas, meet with relevant developers of technologies, and provide guidance on all aspects of the development, and share feedback to regulators and/or HTA. Created in the 90s in AIDS, haemophiila and cancer, they now operate for several rare diseases.

INTRODUCTION:
When developing a health technology that requires clinical studies, developers institute working relations with clinical investigators. In certain diseases areas, patients' representatives creates their own advisory boards, which proved their utility in the early 90s, in particular for the development of products to treat HIV infection. Inspired by this model, where patients with a same disease join and meet with relevant developers and discuss all aspects of the research, the European Organisation for Rare Diseases (EURORDIS) proposes a new programme of such Community Advisory Boards for Rare Diseases (CAB).

METHODS:
For this programme, EURORDIS invites developers
to sign a Charter of principles when engaging with patients, and provides guidelines on CABs, together with a mentoring programme for patients’ networks who are less experienced with the development and the evaluation of health technologies.

CABs are driven by patients who set their agenda, who sign a Memorandum of Understanding with each developer, and who organise the sessions. Sessions typically last for 2 to 4 days during which different meetings with different developers can take place, or trainings.

All meetings can take place under confidentiality arrangements, and minutes are written to keep track and to follow-up with all points discussed. Participants and agendas are made public.

RESULTS:
As of 2018, 4 CABs exist and operate (for tuberous sclerosis complex, for scleroderma, for cystic fibrosis, for Duchenne muscular dystrophy) and 18 other are in discussion and many will start in 2019.

Topics discussed cover the target population, the study feasibility, the endpoints including patient reported outcomes, the comparator choice and/or the acceptance of a placebo controlled trial, the quality of life, the practical aspects of the trials, the identification of previously unknown or unmet patient needs/preferences. For products which are more advanced in their life-cycle, discussions can also cover compassionate use, pricing policy, relative efficacy etc.

CONCLUSIONS:
This represents a well-structured programme for the engagement of patients, where collective thinking and exchange between different patients ensure high quality dialogue with developers and can inform HTA also.

OP28 Patient Involvement At AQuAS: Experiences And Reflections For Future

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ABSTRACT SUMMARY:
AQuAS is incorporating patient involvement in HTA. In 2018 we conducted two experiences using mix-methods techniques. Learnings showed that patient-involvement in HTA is useful to complement HTA reports helping decision making regarding the disinvestment or incorporation of health technologies, improving tools/surveys accuracy and doctor-patient communication. We envision future involvement regarding the social perspective in economic evaluations or in recommendation consensus panels.

INTRODUCTION:
AQuAS is gradually incorporating patient involvement in HTA. We present two experiences conducted during 2018 and the different methods and approaches used. The aim is to reflect on learnings from those experiences to improve ways for increasing patient involvement with HTA at AQuAS.

METHODS:
We conducted two experiences using different quantitative and qualitative techniques (mix-methods approach). The first, a focus group discussion regarding the use of 3D-technologies for maxillofacial reconstruction with a selection of hospital patients that received maxillofacial reconstruction, which included the use of a quality-of-life retrospective self-assessment tool. The second, a sequence of email correspondence regarding cataract surgery technology (FLACS,
in the context of an EUnetHTA) with a patients’ association representative, to learn their opinion regarding the use of laser technology.

RESULTS:
Main learnings were: (1) patients and associations have different levels of knowledge and expertise worth to consider when planning an HTA; (2) sharing experience and knowledge among peers (i.e. focus group) proved to have a positive impact on patients and worked as a resource for some to improve knowledge on their condition; (3) critiques were received regarding a specific Patient Reported Experience template for HTA patient involvement (iv) quality of life retrospective self-assessment tool provided unexpected positive and negative results.

CONCLUSIONS:
Recent patient involvement in HTA at AQuAS proved to be useful to complement HTA reports. We believe that patients’ experiences and opinions can help decision making regarding the use, disinvestment or incorporation of health technologies, contribute improving tools and survey’s accuracy and improve doctor-patient communication. Their involvement might be beneficial for them to gain more knowledge, share experiences, reflect on their health situation and improve communication with the professionals that treat them. Future patient-involvement in HTA is needed, e.g. considering the social perspective in economic evaluations or including patients in recommendation consensus panels.

ABSTRACT SUMMARY:
Patient Experience, Expectations and Knowledge (PEEK) is a systematic patient feedback and real-world data collection program that uses mixed methodologies to understand what it is like to be a patient at a specific point in time and what their expectations of future treatment, care, information and support. It has been implemented in Australia and is now being expanded globally.

INTRODUCTION:
Quality of life studies are often reported in the context of clinical trials or health related quality of life measures. While these are both necessary and valuable, there is limited data available about the real-world experience of people diagnosed with various conditions and illnesses. Where quality of life studies do aim to address quality of life, they are often focused on one specific part of a person’s experience, rather than taking a holistic approach. The PEEK protocol was developed so that a holistic, comprehensive, independent, proactive and systematic approach could be taken in collecting information about what it is like to be a patient at a given point in time and their expectations of future treatment, care, support and information. It is a single protocol that can be implemented across disease areas, allowing for comparisons between diseases, and also in various countries for comparison across health settings. PEEK studies provide insights that can not only feed into health technology assessment processes, but also other parts of the health sector. It is not hypothesis-driven, but rather hypothesis-generating. Each PEEK study is made publicly available which over time will result in a freely accessible repository of patient experience data to help us all drive decisions that are driven by patient experience and need. The program was developed by the International Centre for Community-Driven Research (CCDR), a non-profit organisation bringing much needed change to the way we think about community engagement in health and research. Our vision is to facilitate meaningful connection between service providers, research organisations, the non-profit sector, practitioners,
industry, government and the communities for which they provide a service or aim to benefit. The program began in Australia and CCDR is now working to implement the program in various countries so that there can be a central repository of patient experience data that all stakeholders can benefit from.

METHODS:
PEEK studies include a quantitative and qualitative component. The quantitative component is based on a series of validated tools that provide baseline health and demographic data for the study population. The qualitative component is the result of two years of protocol testing by CCDR to develop a structured interview that solicits comprehensive and holistic patient experience data, and provides patients with the opportunity to provide advice on what they would like to see in relation to future treatment, information and care.

In this presentation, the results of selected PEEK studies completed in Australia will be presented to highlight the value that patient experience data in the context of health technology assessment.

RESULTS:
PEEK studies in breast cancer, bladder cancer, lung cancer, spinal muscular atrophy, atopic dermatitis, chronic kidney disease, chronic heart failure and mitochondrial disease have been completed in the Australian context.

Data is available to comparing the experience of patients across disease areas for use in the context of health technology assessment. Holistic patient experience themes are presented in the studies that are freely accessible, commencing with symptoms and diagnosis experience, through to communication, information, treatments experienced and quality of life. Information is also available in relation to participant’s expectations of future treatment, care, information and communication.

CONCLUSIONS:
The process of providing patient feedback and real-world evidence in the context of health technology assessment is often ad-hoc. The lack of consistency means that it has been difficult to assess the impact of patient engagement and feedback in the context of health technology assessment. The PEEK protocol is an example of a systematic, independent and holistic approach to patient experience and real-world evidence data collection that provides the sector with an opportunity to proactively engage the community in decisions that are made about treatment, care and support.

OP30 Impact Of Patient Reported Outcomes Data On HTAs In AML

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ABSTRACT SUMMARY:
Patient-reported outcomes (PRO) data are not routinely collected/included in HTA submissions. We assessed the impact of PRO data on reimbursement for AML indications by analyzing HTA bodies' appraisals of AML indications. Overall, 35% of products with PRO evidence received positive feedback from ≥1 HTA body. Thus, PRO data are essential to demonstrate the value of AML products to HTA bodies.

INTRODUCTION:
Patient-reported outcomes (PRO) data are not routinely collected/included in HTA submissions.
We assessed the impact of PRO data on reimbursement for AML indications by analyzing HTA bodies’ appraisals of AML indications. Overall, 35% of products with PRO evidence received positive feedback from ≥1 HTA body. Thus, PRO data are essential to demonstrate the value of AML products to HTA bodies.

**METHODS:**
This analysis was conducted using IQVIA’s HTA Accelerator, which contains HTA appraisals from ≥100 HTA agencies in 39 countries. Included in the analysis were single-technology appraisals (original submissions, resubmissions, extensions of original indications, and renewals); relevant regulatory approvals and pivotal trials were also analyzed.

**RESULTS:**
Of the 185 AML appraisals from 16 HTA bodies, 66 (36%) included PRO data. Within these, 13 different PRO instruments were identified, none of which have been validated in patients with AML. For 7 of 20 in-scope products, PRO evidence positively impacted ≥1 of the HTA decisions. Although the same HTA bodies (ie, Scottish Medicines Consortium, pan-Canadian Oncology Drug Review, and the National Institute of Health and Care Excellence) generally accepted the PRO evidence, others were critical of the evidence (ie, Haute Autorité de Santé and the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen). The most common concerns raised by the HTA bodies in regards to the PRO evidence included trial design and low patient response rate.

**CONCLUSIONS:**
Of the products that included PRO evidence in their HTA submissions, 35% received positive feedback from ≥1 HTA body on their submitted PRO evidence. Attention to PRO data collection is key to demonstrate the value of AML products to HTA bodies. Without these data, a clear gap in the understanding of patients’ experience is evident.

**OP31 HTA And Patients’ Preferences: Starting A Discrete Choice Experiment**

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**ABSTRACT SUMMARY:**
Hospital-based health technology assessment (HB-HTA) needs to consider all relevant data to help decision making, including patients’ preferences. In this study, we comprehensively describe the process of identification, refinement and selection of attributes and levels for a discrete choice experiment (DCE).

**INTRODUCTION:**
Hospital-based health technology assessment (HB-HTA) needs to consider all relevant data to help decision making, including patients’ preferences. In this study, we comprehensively describe the process of identification, refinement and selection of attributes and levels for a discrete choice experiment (DCE).

**METHODS:**
A mixed-methods design was used to identify attributes and levels explaining low back pain (LBP) patients’ choice for a non-surgical treatment. This design combined a systematic literature review with a patients’ focus group, one-on-one interactions with experts and patients, and discussions with stakeholder committee members. Following the patient’s focus group, ranking exercises were conducted. A consensus about the attributes and
levels was researched during discussions with committee members.

RESULTS:
The literature review yielded 40 attributes to consider in patients’ treatment choice. During the focus group, one additional attribute emerged. The ranking exercises allowed selecting eight attributes for the DCE. These eight attributes and their levels were discussed and validated by the committee members who helped reframe two levels in one of the attributes and delete one attribute. The final seven attributes were: treatment modality, pain reduction, onset of treatment efficacy, duration of efficacy, difficulty in daily living activities, sleep problem, and knowledge about their body and pain.

CONCLUSIONS:
This study is one of the few to comprehensively describe the selection process of attributes and levels for a DCE. This may help ensure transparency and judge the quality of the decision making process. In the context of a HB-HTA unit, this strengthens the legitimacy to perform a DCE to better inform decision-makers in a patient-centered care approach.

INTRODUCTION:
The pharmacoeconomic evaluations that inform drug reimbursement decisions are often based on clinical trial evidence, which may not reflect real-world utilization. Analysis of pharmacy claims data could provide an important source of real-world drug utilization evidence to better inform health technology management processes. To enable our analysis to be more impactful we sought to engage stakeholders in the drug reimbursement process. We aimed to identify the need for and value of real-world evidence to stakeholders to inform the content and presentation of our analyses.

METHODS:
We selected organisations that represent a range of stakeholders in the drug reimbursement process in Ireland. Stakeholders completed an initial questionnaire which sought to establish their role and information requirements in relation to real-world drug utilization evidence. We asked stakeholders to rate the importance of different types of evidence on a Likert scale and summarized these using means. Results from the initial questionnaire informed the content and reporting format for our analyses. Stakeholders were then asked to provide feedback on draft reports to enable further improvement.

RESULTS:
Stakeholders saw real-world evidence as an important additional source of data to inform decision making. Disadvantages included availability of data, data protection issues and analytical challenges. Expenditure (9.2), health outcomes (9) and patient numbers (8) received the highest mean ratings for importance to organisations, on a scale from 0 ‘not at all important’ to 10 ‘very important’.

OP32 Stakeholder Requirements For Real-World Drug Utilization Evidence

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Analysis of pharmacy claims data could provide an important source of real-world drug utilization evidence to better inform health technology management processes. We aimed to identify the need for and value of real-world drug utilization evidence to stakeholders in the drug reimbursement process in Ireland.
CONCLUSIONS:
Results from the questionnaires informed the content and reporting format for our analyses. Claims data can provide information on expenditure and patents numbers, but not health outcomes. We will seek further feedback from stakeholders to assess how they implement using our real-world drug utilization reporting.

OP33 Treatment Of Mitral Insufficiency And Multicriteria Decision Making

PRESENTING AUTHOR:
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Laurie Lambert, Canada

ABSTRACT SUMMARY:
Significant uncertainty related to transcatheter mitral valve repair with a clip (TMVRc) has led to refusal or conditional acceptance within different jurisdictions worldwide.

We used a systematic multicriteria framework integrating literature review and consultations with expert and scientific advisory committees, clinical teams, industry, and INESSS clinical excellence committee to ensure a fair and reasonable decision regarding TMVRc use in Quebec.

INTRODUCTION:
Controversy regarding the efficacy of transcatheter mitral valve repair with a clip (TMVRc) in reducing the mitral regurgitation is related to the lack of solid scientific evidence. Worldwide, refusal or conditional acceptance for implementation of TMVRc, reflect ongoing uncertainty. We sought to apply a systematic multicriteria framework to ensure a fair and reasonable decision regarding the use of TMVRc in Quebec.

METHODS:
The framework included the following domains: context, quality of evidence concerning safety, efficacy, and effectiveness, unmet patient needs, expected volume of patients, impact on the health system including costs. Each domain within the framework was examined by a review of the literature and through consultations with a scientific advisory committee, a TMVRc clinical expert committee, TMVRc clinical teams, industry representatives and the INESSS clinical excellence committee.

RESULTS:
The literature review indicated that uncertainty about the efficacy and effectiveness of TMVRc, particularly in the real world context persists and this view was supported by scientific experts. The TMVRc clinical teams provided insight into the burden of mitral insufficiency on patients and the health system and their belief in the promise of TMVRc. They also highlighted the challenges of patient selection and organizational issues related to the introduction of TMVRc within their institutions. The advisory committee stressed the need for further evaluation prior to wide diffusion.

CONCLUSIONS:
Using a multicriteria framework facilitated a more standardized and transparent approach to our literature review and consultations as well as to the development of the proposed recommendations. This was especially important in the context of an evaluation of a promising new approach to treat mitral valve disease with many important uncertainties. This multi-criteria approach will facilitate more standardized process for deliberation on how new health technologies should be implemented into the Quebec health system.
OP34 One-Way Sensitivity Analysis For Cost-Effectiveness Analysis

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ABSTRACT SUMMARY:
The uncertainty in model parameters can have a fundamental impact on the conclusions drawn from any model-based cost-effectiveness analysis. Although a well-used method, deterministic one-way sensitivity analysis has a number of fundamental shortcomings, that can lead to erroneous conclusions being drawn. These shortcomings are discussed, and then an alternative, stochastic one-way sensitivity analysis, is proposed which overcomes these issues.

INTRODUCTION:
Although stochastic analysis has become the accepted standard for decision analytic cost effectiveness models, deterministic one-way sensitivity analysis continues to be used to meet the needs of decision makers to understand the impact that changing the value taken by one specific parameter has on the results of the analysis. However, there are a number of problems with this approach.

METHODS:
We review the reasons why deterministic one-way sensitivity analysis will provide decision makers with biased and incomplete information. We then describe a new method, stochastic one-way sensitivity analysis (SOWSA), and apply this to a previously published cost-effectiveness analysis, to produce a stochastic tornado diagram and conditional incremental net benefit curve. We then discuss how these outputs should be interpreted and the potential barriers to the implementation of SOWSA.

RESULTS:
The results illustrate the shortcomings of the current approaches to deterministic one-way sensitivity analysis. For SOWSA, the expected costs and outcomes are captured, along with the sampled value of the parameter and these are linked to the probability that the parameter takes that value, which can be read off the probability distribution for the parameter used in the stochastic analysis. From these results it is possible to gain insights into probability that a parameter will take a value that will change a decision.

CONCLUSIONS:
Although a well-used technique, one-way deterministic sensitivity analysis has a number of shortcomings that may contribute to incorrect conclusions being drawn about the importance of certain parameter values on model results. By providing fuller information on uncertainty in model results, it is hoped that the methods here will lead to more informed decision making. Although, as with all developments in the presentation of analytic results to decision makers, care will be required to ensure that the decision makers understand the information provided to them.

OP35 A Framework For Economic Evaluations With Interactions Between Groups

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Interactions have primarily been considered in the literature for different interventions in the same population. However, interactions between different populations may be generated through the provision of a price reduction, if it is conditional on reimbursement in two subpopulations as opposed to restricted reimbursement in one subpopulation. We propose a novel framework to describe how interventions with such interactions should be assessed.

INTRODUCTION:
Interacting interventions have non-additive effects. This means that the effects of giving interventions simultaneously does not equal the sum of their individual effects. Interactions have primarily been considered in the literature for different interventions in the same population. However, interactions between different populations may be generated through the provision of a price reduction, if it is conditional on reimbursement in two subpopulations as opposed to restricted reimbursement in one subpopulation. We have previously proposed a novel method to quantify cost-effectiveness in these scenarios: the cost-savings that are generated by a price reduction in a reimbursed subpopulation are included in the calculation of the incremental cost-effectiveness ratio (ICER) in the remaining subpopulation which reduces the ICER. However, this method may not always apply if the intervention is not cost-effective in either subpopulation at the original price. We propose a novel framework to describe how interventions with such interactions should be assessed.

METHODS:
The framework is presented as a flow diagram summarised into three parts: 1. Defining the Decision Problem; 2. Considering the cost-effectiveness of restricting reimbursement to subpopulations; 3. Jointly considering the cost-effectiveness of extending reimbursement to both subpopulations.

RESULTS:
The decision problem may be classified as four mutually exclusive options: No Reimbursement; Reimbursement in subpopulation 1 at the original price; Reimbursement in subpopulation 2 at the original price; Reimbursement in both subpopulations at the negotiated price. Branches of the flow diagram describe the form of incremental analysis that should be conducted at each stage and the recommended reimbursement decision for each result.

CONCLUSIONS:
Failure to account for interactions means that biased estimates of cost-effectiveness may be generated. This has an opportunity cost due the failure to adopt cost-effective interventions. Adoption of this framework will allow analysts to more accurately consider the cost-effectiveness of interacting interventions.
uncertainties in decision models. Our case-studies show that by parameterizing each structural assumption probabilistically, more accurate recommendations for future research can be made.

**INTRODUCTION:**
The use of probabilistic sensitivity analysis (PSA) to incorporate parameter uncertainty in decision models is widely recommended. Value of information (VOI) analysis, using PSA results is increasingly used in health technology assessment (HTA) to prioritize future research requirements. However, VOI applications typically ignore uncertainty surrounding structural assumptions in models, and may therefore under-state the value of future research.

**METHODS:**
This paper reviews the literature on methods to incorporate structural uncertainty into single point estimates of the incremental cost-effectiveness ratio (ICER). The advantages and disadvantages of different methods (model averaging, discrepancy approach, and probabilistic sampling) are summarized. Two case studies, with applications in dentistry and incontinence, are used to demonstrate the pros and cons of different approaches. The impact on base-case results, PSA scatter-plots, and VOI analyses are all compared across methods.

**RESULTS:**
Model averaging and the discrepancy approach are useful tools to incorporate structural uncertainty. However, it is possible to consider multiple structural uncertainties simultaneously by parameterizing each assumption probabilistically within the model. This generates a single point estimate of the ICER and scatter-plots reflect a more complete description of uncertainty. Furthermore, the approach allows for a more accurate representation of the value of future research to resolve decision uncertainty. Our case studies show that VOI analysis based on parameter uncertainty alone underestimates expected value of perfect information (EVPI) and fails to capture the value of research to reduce uncertainty when structural assumptions are required. Partial EVPI can then be used to describe the value of future research to reduce structural uncertainty. Full results of both case studies will be presented.

**CONCLUSIONS:**
Most VOI analyses ignore structural uncertainty in decision models. Inclusion of structural uncertainty in decision models is crucial, and these uncertainties should be incorporated probabilistically where possible. By parameterizing structural assumptions probabilistically, more accurate recommendations for future research can be made.

**OP37 Impact On Uncertainty Of Disaggregating Cost Data**

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**ABSTRACT SUMMARY:**
Economic models contain several parameters ordinarily subject to uncertainty. Unlike most other model parameters, costs can constitute numerous distinct components. This study explored how disaggregation of cost data may impact on uncertainty and found that analysing uncertainty by aggregated or disaggregated costs can have implications for presenting uncertainty in costs to decision makers.

**INTRODUCTION:**
Economic models contain several parameters ordinarily subject to uncertainty. Unlike most other model parameters, costs can constitute numerous
distinct components. For example, a surgical intervention can require a variety of disposables and reusable equipment. A micro-costing output may be disaggregated or presented as a total cost. Uncertainty could be applied to individual cost components or to total cost. We aimed to explore how disaggregation of cost data may impact on uncertainty using a case study.

METHODS:
A set of simulations using hypothetical scenarios were developed with uncertainty set at ±20%. The simulations investigated the impact of number of cost components, balance between components, and correlation between them. A cost-utility model from an assessment of robot-assisted radical prostatectomy was analysed; procedure cost was divided into 32 individual cost components or treated as a total cost.

RESULTS:
Based on five equal cost components, uncertainty reduces from ±20% for correlated variables to ±9% for uncorrelated variables. With increasing numbers of uncorrelated cost components, the uncertainty in the total cost decreases markedly. The uncertainty around total robot-assisted surgery procedure equipment costs was ±19.7% when components were correlated and ±9.4% when uncorrelated. The impact on uncertainty in the ICER was negligible but the ranking of parameters in the univariate sensitivity analysis changed.

CONCLUSIONS:
Analysing uncertainty by aggregated or disaggregated costs can have implications for presenting uncertainty in costs to decision makers. Applying uncertainty to aggregated costs essentially implies that variation in the cost of individual components is perfectly correlated. By disaggregating cost components they are being treated as uncorrelated, which can substantially reduce uncertainty in the total cost. In this case study we found that although the reduction in uncertainty could be clearly seen in the cost parameter, it had a negligible impact on uncertainty in the ICER.

OP38 Implementing Social Innovations: From Evidence-Based To Theory-Driven

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ABSTRACT SUMMARY:
When implementing complex interventions, alternatives to simply importing evidence-based practices are needed that take into account contextual factors. A research project tests a theory- and stakeholder-driven approach in an Austrian region. The process has been set up successfully. It remains to be seen whether the developed interventions will be implemented successfully and result in benefits for the target group.

INTRODUCTION:
For the last decades, health technology assessment has been strongly promoted in order to provide evidence-based rather than eminence-based healthcare. However, when it comes to implementing interventions that are based on processes and behaviour rather than products, importing evidence-based interventions is likely to fail because it ignores the strong influence of contextual factors. In a recently started research project, an alternative approach is tested.

METHODS:
The project aims at improving identification and
support of children who have parents with a mental illness in an Austrian region (Tyrol). A theory- and stakeholder-driven approach has been designed in order to co-develop, implement and evaluate practice approaches for improving the situation for children. The former addresses the questions whether, how and why suggested practices may work and the later brings together evidence and practice to develop interventions that are feasible and take the regional context and service settings into account.

RESULTS:
Based on evidence from various sources (literature, international and local stakeholder interviews), theories that describe the key mechanisms of action to influence outcomes for children have been developed. A regional and interdisciplinary group of practitioners and people with lived experience has been established to facilitate the development of the theory of change and practice approaches for the region and local service settings. The final practice model is then monitored in the respective organisations with implementation support from the research team.

CONCLUSIONS:
Theory-driven and co-designed-based approaches are a feasible alternative to ‘off-the-shelf’ evidence-based practices for supporting decision makers in implementing complex interventions. However, they require a broad variety of skills within the research team as well as willingness to accept uncertainties of the final outcomes produced, which can also be of risk to funders. The ongoing project will demonstrate whether the developed practices will be implemented successfully and result in benefits for the affected children.

OP39 Adapting HTA To Suit Emerging Needs - An Australian Experience

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Australia has adapted a well developed HTA process, but recently it has had to adapt to suit emerging health care needs of the Australian community. This presentation will discuss how an experienced HTA system has been adapted to assess novel therapies which haven’t easily lended themselves to standard HTA.

INTRODUCTION:
Australia has a well-developed HTA system for approving, funding and disinvesting in medical services, but how does it cope when it assesses new or existing services when health system frameworks, policy and legislation do not keep pace? This presentation will present a number of case studies where HTA methods have adapted to suit emerging health needs of the Australian community.

METHODS:
Australia’s HTA system has been adapted over recent years to allow it to perform HTA on novel services that do not fit into its standard HTA pathway to public funding. There has also been an increasing number of assessments where HTA has been unusually sponsored by the funder to assess priority health care needs.

RESULTS:
More Medicare funding for addiction and sexual health consultation services are an example of a novel HTA which led to more public funding for these services. Limited evidence for these services was available and there was difficulty in demonstrating that increased public funding would
lead to better outcomes for patients. A range of techniques, such as examining real world data and stakeholder views were partnered with HTA to assess these services.

Currently, HTA is being utilised to assess a novel medical treatment known as the anti-CD19 chimeric antigen receptor T cell (CAR-T) therapeutic process. This is a complex, non-standard HTA which encompasses aspects of the Australian hospital funding system, Medicare and the Pharmaceutical Benefits Scheme and requires an adapted HTA process to assess evidence across a range of funder systems.

CONCLUSIONS:
Australia’s well established HTA system has adapted to become more agile to suit emerging health care needs for a range of interest groups, the government, sponsors and consumers. Consultation with stakeholders and the community have assisted in developing and refining these new processes.

OP40 Criminal Justice Costs And Benefits Of Mental Health Interventions

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ABSTRACT SUMMARY:
Little is known about intersectoral costs and benefits (ICBs): the costs and benefits produced outside the healthcare sector. This study focused on identifying and prioritizing costs and benefits from mental health interventions produced in the criminal justice sector. Results of this study facilitate the use of ICBs in economic evaluations.

INTRODUCTION:
Mental health disorders and its treatments produce costs and benefits in both healthcare and non-healthcare sectors. The latter one is often referred to as inter-sectoral costs and benefits (ICBs). Limited research is available on the inclusion of these inter-sectoral costs and benefits (ICBs) in economic evaluations. In this study, we focus on the identification and classification of ICBs of mental health-related interventions within the criminal justice sector in a broader European context. This study was conducted as part of the PECUNIA-project, which aims to develop new standardised, harmonised and validated methods and tools for the assessment of costs and outcomes in European healthcare systems. The aim of the study is to further conceptualize an internationally applicable list of ICBs of mental health-related interventions in the criminal justice sector. Additionally, we aim to facilitate the inclusion of ICBs in economic evaluations across EU by prioritizing important ICBs.

METHODS:
Data has been collected via a systematic literature search on PubMed and PsychINFO. Additionally, a grey literature search was carried out in six European countries. In order to validate the international applicability of the list and prioritize the ICBs, a survey was conducted with an international group of experts from the criminal justice sector.

RESULTS:
The literature search allowed identifying additional ICBs and creating a comprehensive list of items. A multi-dimensional list is constructed, distinguishing between costs as consequence of crime, and costs in response to crime. Based on the expert survey, the international applicability was of the list was validated and determined most important ICBs from the economic perspective.
CONCLUSIONS:
This study laid further foundations for the inclusion of important societal costs of mental health-related interventions within the criminal justice sector. More research is needed to facilitate the use of ICBs in economic evaluations even more.

OP41 Intercultural Medical Decision Support System Using NLP

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ABSTRACT SUMMARY:
Early diagnosis is a key to reduce costs and improve outcomes for most diseases. Technology engaged life allows us to obtain countless data in healthcare in order to upgrade health services to more practical, smarter, cost efficient and time saving methods. In this study it is aimed to reach patients using different languages.

INTRODUCTION:
Early diagnosis is a key to reduce costs and improve outcomes for most diseases. Technology engaged life allows us to obtain countless data in healthcare in order to upgrade health services to more practical, smarter, cost efficient and time saving methods. Improvements in data science are causing data repositories to expand rapidly. Healthcare is one of the most vital human right, however, there are large number of people around the globe who has no equal access to healthcare services. To reduce the unwilling effects of wrong or late diagnosis we propose a smart disease prediction engine. In this study it is aimed to reach patients using different languages while providing an opportunity to enter symptoms in their everyday language text besides medical expressions of symptoms. The era of digitization has led computers to become the real face of handling commercial processes across a wealth of industries. As institutions today specifically in the medical domain have resorted to these virtual machines for realizing their goals, more and more medical data is being generated on a continuous basis (Davis et al., 2008). This data is being used in many recommendation systems which deliver a personalized individual’s health profile model (Bolón-Canedo et al., 2015). The quality of health care can be precisely defined and measured with a degree of scientific accuracy comparable with that of most measures used in clinical medicine (Schiff, 2009). Every year very large number of population is affected by wrong or late diagnosis (Leape et al., 1991). With an increased significance on providing better quality and reducing costs, new systems are required to improve in public healthcare. Clinical decision support systems (CDSS) are computer systems designed to impact clinical decision making about individual patients at the point in time that these decisions are made (Kaul, Kaul, & Verma, 2015). The potential for information technology in health care is still in the process of being actualized. Large dimensionality of data in medicine together with the common reduced sample size of pathological cases makes indispensable the use of advanced machine learning techniques for clinical interpretation and analysis (Spyns, Nhàn, Baert, Sager, & De Moor, 1998). Information technology (IT) maintains a significant, sustainable knowledge which is vital for organization development. There are a wide range of techniques that can be applied to analyzing these texts, as reflected in the considerable amount of research in the field of natural language processing (Popowich, 2005). The electronic patient records contains a rich source of valuable clinical information, which could be used for a wide range of automated applications aimed at improving the health care process, such as alerting for potential medical errors, generating a patient problem list, and assessing the severity of a condition (Friedman et al., 2004). However,
these applications are not applicable since large amount of information is in textual form (Tange et al., 1998). Techniques for automatically encoding textual documents from the medical record have been evaluated by several groups. Examples are the Linguistic String Project (Xu et al., 2010), and Medical Language Extraction and Encoding system (MedLEE) (Friedman et al., 2004). MedLEE has been recently adapted to extract Unified Medical Language System (UMLS) concepts from medical text documents, achieving 83% recall and 89% precision (Alan R Aronson, 2001). Other systems automatically mapping clinical text concepts to a standardized vocabulary have been reported, like MetaMap (Zou et al., 2003), IndexFinder (Pratt et al., 2003), and KnowledgeMap (A R Aronson & Rindflesch, 1997). MetaMap and its Java version called MetaMap Transfer (MMTx) were developed by the US National Library of Medicine (NLM). They are used to index text or to map concepts in the analyzed text with UMLS concepts.

METHODS:
In this study, process of data collection allows patients to enter their symptoms by typing in everyday language. Therefore, to increase the accuracy firstly it is required to clean and eliminate significant words. During the preprocessing, stop words, vague abbreviations are removed. Each symptom and other data valued words including severity, duration, location, cause, accompanied by any other symptoms, change in intensity are also extracted from written expression (as an individual expression or sentence structure of symptoms) accordingly.

An Intelligent context utilizing recommendation engine for medical diagnosis is developed to convert the clinical data into significant and effective information. Python is used to develop the most efficient and appropriate model. Fuzzy String Matching, also called approximate string matching, is implemented as the process of finding strings which approximately match a given pattern. The closeness of a match is often measured in terms of edit distance which is the number of primitive operations necessary to convert the string into an exact match.

In training process as indicated in Figure3 text-based symptoms, patients’ personal information and past medical history is used as input data. In the next step, data is trained for the possible detected diagnoses and recommend appropriate treatment and as a result of training we expect to get out model output.

After the training process, the system is tested for various diagnoses and patients, then the percentage risk of possible disease is represented as output information. Corresponding to this, treatments and recommendations (any medical examinations, tests) are driven.

RESULTS:
Named entity recognition (NER) techniques, based on natural language processing (NLP), applied to develop language independent predictive model. 4280 different symptoms processed for the corresponding 880 diseases. From highest to lowest, predicted diseases are printed on the user’s screen with matched symptoms made bold. To exclude irrelevant results, a minimum threshold of 20% is set. Extracted terms are implied as an input of the model and analyzed for matching diagnosis where an accuracy of 83% has been accomplished for specific foreign language than English.

CONCLUSIONS:
The goal was to make a system that will give as correct classification as possible regardless of spelling mistakes. Different inputs were tested to assess the abilities supported by the TextBlob library. Output is based on the result obtained using FuzzyWuzzy library regardless of some spelling mistakes that user might have done in giving input. After testing the system, an accuracy of 83% has been accomplished. The impact on outcomes, assessing whether the project reduces time from diagnosis to treatment, reduces cost, and improves
quality the benefits of the study in global health care environment.

**OP42 Updated Qualitative Syntheses: What Can They Offer To HTA?**

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**ABSTRACT SUMMARY:**
The importance of updating quantitative systematic reviews and statistical meta-analyses is now well established. As science evolves with the accumulation of new evidence, health care technologies previously considered to be safe and effective may in the future prove to be harmful or ineffective, or vice-versa. Likewise, ignoring changes in preferences, needs, and values could undermine the applicability of qualitative syntheses.

**INTRODUCTION:**
Updating –typically defined as “a process aiming to identify new evidence to incorporate into a previously completed systematic review”– is now common practice for quantitative systematic reviews and statistical meta-analyses. Yet, the same does not apply for syntheses of qualitative evidence, for which, to date, the process of updating has remained largely unexplored. We sought to update for the first time a systematic review and meta-ethnography, conducted by a different team of reviewers, and offer lessons learned from our experience.

**METHODS:**
The original work explored GPs’ experiences of antibiotic prescribing for acute respiratory tract infections (ARTIs), including their views of interventions aimed at more prudent prescribing. We expanded the initial scope to encompass all primary care professionals (PCPs) who can prescribe or dispense antibiotics for ARTIs. We systematically searched MEDLINE, EMBASE, PsycINFO, CINAHL, ASSIA and Web of Science, and identified 53 articles that met our inclusion criteria. We grouped studies according to their thematic focus (usual care vs. intervention) and performed two separate line-of-argument syntheses.

**RESULTS:**
The original meta-ethnography concluded that, to maximize acceptability, interventions should incorporate five aspects: allow GPs to reflect on their own prescribing; help decrease uncertainty; educate GPs about appropriate prescribing; facilitate more patient-centred care; and be beneficial to implement in practice. Seven years later, our updated synthesis suggests that one-size-fits-all approaches are doomed to result in variable uptake, as different PCPs experience the same elements in a very different way (Compromise; “Supportive aids”; Source of distress; Unnecessary).

**CONCLUSIONS:**
Our work provides empirical evidence for the necessity of regularly updating qualitative syntheses, and shows that, in the same way that updated meta-analyses can inform about whether healthcare technologies continue to be safe and effective, updated qualitative syntheses can provide evidence on whether these remain relevant to individuals’ changing needs, preferences, and experiences.
OP43 Sourcing Professional Advice: Striving For Consistency

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ABSTRACT SUMMARY:
Input from professional experts is crucial for the development and credibility of health technology assessment (HTA) guidance and advice. The National Institute for Health and Care Excellence (NICE) is looking at how professional experts are sourced by its HTA teams. It aims to improve consistency and make the process a more positive experience for internal and external stakeholders.

INTRODUCTION:
Input from professional experts is crucial for the development and credibility of health technology assessment (HTA) guidance and advice. Professionals can provide valuable knowledge and insights. However, it is important that appropriate experts are used and inconsistent processes for sourcing professionals can lead to challenges. The National Institute for Health and Care Excellence (NICE) is undertaking work to improve how professional experts are sourced by its HTA teams.

METHODS:
A symposium of Royal Colleges (RCs) and Specialist Societies (SSs) was held to collect feedback on their experiences of working with NICE, including their involvement in identifying experts. Internal information gathering exercises, using surveys and a workshop, were conducted to map the current methods used for sourcing professional advice for eleven of NICE’s HTA teams and obtain staff feedback. Subsequently, steering and working groups were established to develop and implement recommendations.

RESULTS:
The feedback from RCs and SSs revealed differences between HTA teams, such as terminology used, the amount of information provided on experts’ roles, and communications. The internal information gathering found inconsistencies between HTA teams in how professional experts were selected and validated. It also revealed the challenges in finding an appropriate expert and ensuring timely expert input. Recommendations were made in response to the areas highlighted that aim to increase consistency whilst taking into account necessary differences between teams. Changes will be implemented to improve the experience for both internal and external stakeholders.

CONCLUSIONS:
This work provides an example from the United Kingdom (UK) of how a HTA organisation has sought to enhance its current processes for sourcing professional advice. NICE will implement changes that strive to improve the speed, reliability and consistency of expert input. Collaboration between HTA organisations could be beneficial to share learning and develop standards for the identification and ratification of professional experts.

OP44 Robot-Assisted Surgery: Joint HTA To Inform Australian Policy And Fund

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ABSTRACT SUMMARY:
In response to increasing surgeon, media and community interest in robot-assisted surgery (RAS) in Australia, the New South Wales (NSW) and Victoria state health departments jointly commissioned a health technology assessment (HTA) to explore the safety, clinical effectiveness, risks and economic implications of RAS to inform policy and investment decisions.

INTRODUCTION:
RAS has been available in Australia since 2003. There are 50 da Vinci RAS systems in Australia (18 in NSW and 12 in Victoria) with most in the private hospital sector. In Australia the capital cost of a da Vinci RAS system is up to AUD$3.8 million, which excludes annual maintenance fees of AUD$250,000 and consumable costs of AUD$3,500 for each procedure.

METHODS:
The NSW Ministry of Health and Victorian Department of Health and Human Services commissioned an HTA to explore the benefits, risks and economic implications of surgical robotics, which involved a review of the peer reviewed literature, a cost benefit analysis of public sector patients who received RAS and broad stakeholder consultation to document current perspectives on RAS applications.

RESULTS:
RAS is as safe and effective as other surgical modalities when performed by sufficiently skilled surgeons, although evidence generally comes from small studies with limited follow-up time and few studies report long term mortality, morbidity or patient-reported outcomes. Comparative benefits of RAS are uncertain as most studies conclude little or no difference in procedure related or functional outcomes. While RAS reduces length of stay, which offers patient and health system benefits, this is insufficient to fully offset high capital and consumable costs currently charged to Australian providers. Government and clinical stakeholders identified that establishing an RAS service requires consideration of important factors, including: i) Governance is critical; ii) Higher case volumes may improve financial viability; and iii) a need for state-wide/national standards for surgeon training and credentialing.

CONCLUSIONS:
RAS is as safe and effective as other modalities when performed by skilled surgeons. However, uncertainty remains around long-term outcomes and clinical and cost-effectiveness. An accredited training program and monitoring and evaluation will be critical to ensure outcomes data informs ongoing evidence assessment and government policy and investment.

OP45 Biological Drugs And Rheumatoid Arthritis In Brazil: An Overview

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ABSTRACT SUMMARY:
Biological drugs consume about 40% of the public budget for pharmaceutical provide in public health system in Brazil. Rheumatoid Arthritis (RA) is the largest consumer of these resources. The study present data about the provision, expenditure and profile of users of biological drugs for rheumatoid arthritis in SUS between 2012 and 2017.
INTRODUCTION:
The Brazilian Unified Health System (SUS) is known worldwide for ensuring universal assistance to citizens, which includes the supply of medicines free of charge. Biological drugs consume about 40% of the public budget for pharmaceutical services in the SUS and Rheumatoid Arthritis (RA) is the largest consumer of these resources, serving about 110 thousand patients. Since 2002 there has been a clinical guideline of care for patients with rheumatoid arthritis in Brazil, currently providing 10 biological drugs for treatment of RA. The objective of this study is to present data about the provision, expenditure and profile of users of biological drugs for rheumatoid arthritis in SUS.

METHODS:
Retrospective and exploratory study, using administrative data regarding the purchase and consumption of biological drugs infliximab, etanercept, adalimumab, rituximab, abatacept (intravenous and subcutaneous), tocilizumab, golimumab and certolizumab pegol for the treatment of RA between 2012 and 2017 in SUS.

RESULTS:
There was an expenditure of approximately $421.7 million from the Brazilian Ministry of Health with the supply of about 2 million pharmaceutical units of biological drugs for treatment of rheumatoid arthritis, 79% of them destined for female users and 89.2% for the 40-69 age group. The M05.8 and M.06.0 codes of the International Classification of Diseases (ICD-10) were the most prevalent among the arthritic population served. Adalimumab and Etanercept accounted for 68.3% of total expenditure. A reduction in the use of these medicines was observed after the availability of new drugs for treatment of the disease between 2014 and 2017.

CONCLUSIONS:
Brazil is one of the largest consumers of biological medicines in the world. The use of real-life data allows monitoring trends and costs about the use of these drugs as well as changes in this scenario with the entry of new therapies and biosimilars medicines.

OP46 Evaluating Statin Utilisation In The NHS Scotland

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ABSTRACT SUMMARY:
This retrospective cohort study aims to evaluate discontinuation, persistence, and adherence to high-intensity statin therapy in comparison to low and moderate intensity therapy in Scotland, using data extracted by linking NHS Scottish records, from January 2010 to December 2015. Increasing the intensity of statin therapy does not seem to negatively impact adherence to treatment.

INTRODUCTION:
Evidence from clinical trials and epidemiological studies has consistently shown a strong relationship between high low-density lipoprotein cholesterol (LDL-C) levels and incidence of CVD. Statins, competitively inhibiting 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase, remain central to lipid-lowering therapy for preventing atherosclerotic CVD, and their use is associated with significant reductions in CVD morbidity and mortality. Recent evidence has suggested that the effectiveness of statins in real-world settings can be inferior to that seen in clinical trials, which may be due to issues of dosing and sub-optimal adherence and persistence. Measuring and understanding
persistence and adherence with treatment are not only critical to determining drug safety and effectiveness but also important in assisting the design of programs to improve the quality of medicines use and thereby health outcomes. This study aims to evaluate discontinuation, persistence, and adherence to high-intensity statin therapy in comparison to low and moderate intensity therapy in Scotland.

**METHODS:**

This retrospective cohort study used data from the NHS Scotland, extracted by linking Prescribing Information System (PIS) records to hospitalisation data, out-patient data, lab data and the death registry. The study population comprises adult patients (≥ 18 years old) who initiated statin therapy from January 2010 to December 2015. The date of first statin prescription was the index date. Included patients were required to be new statins users (no statin prescriptions in the year prior to the index date); have at least one year of registration within PIS prior to the index date; received at least one of the statins provided by NHS Scotland: atorvastatin, fluvastatin, pravastatin, rosuvastatin, or simvastatin, identified by the British National Formulary (BNF) code; did not use statins associated with other lipid-lowering drugs; and have at least one year of follow up time after the index date. The individual end date was either date of death or removal from a Scottish general practitioner register for other reasons, or the study end date. Statin users were stratified into three exposure groups (high, moderate, and low intensity), based on the current NICE classifications. The statin utilization study included three variables: adherence, discontinuation and persistence. Discontinuation has been calculated using the refill-gap method with censoring of patients after the first discontinuation event, defined as a gap of more than 60 days without supply following the assumed end of a prescription (grace period). Persistence at pre-specified points in time (6, 12, 18, 24 and 36 months after treatment initiation) has been assessed using the anniversary method to account for intermediary treatment interruptions. Adherence was assessed by calculating the proportion of days covered (PDC), which is the cumulative amount, through successive dispensations, to ensure treatment without interruption. Associations between adherence to statin treatment and patient characteristics were assessed by logistic regression, adopting a significance level of 5.0%. The adjustment quality was verified by Hosmer-Lemeshow test.

**RESULTS:**

A total of 73,716 patients with a minimum follow-up time of one year have been included in the analysis: 7,163 initiating high intensity statin therapy (9.7%), 65,125 moderate intensity (88.3%), and 1,428 low intensity (1.9%). The mean age at time of treatment initiation was 61.4 years (SD 12.6), and 47.7% of patients were female; the mean time of follow up was 1,436 days (SD 650.0).

The majority of patients (72.3%) started treatment with simvastatin 40mg; of all patients initiating high intensity statin therapy, 22.8% received atorvastatin 80mg as drug of first choice, while atorvastatin 20mg and 40mg were prescribed to 43.1% and 32.3% of patients, respectively.

Discontinuation, persistence, and adherence differed significantly between intensity levels. Patients treated with high intensity statins were least likely to discontinue treatment, with a median time to discontinuation of 911 days (IQR 843 – 1007).

The persistence after one year of statins use (admissible gap 60 days) was 69.9%, being highest at high intensity statin use (74.7% at high intensity vs. 53.1% at low intensity and 69.8% at moderate intensity). The percentage of persistent patients decreased over time, from 76.8% after six months of statin use to 59.2% after three years of statin therapy.

Adherence (PDC≥80%) was highest among high-intensity statin users with 63.7%, compared to 51.6% in moderate-intensity and 40.5% in low-intensity statin therapy. Adherence to statin treatment
increased with age, being greatest in the elderly (aged 65 years or more), for all intensity levels. The statin adherence was greater in the high intensity use group than among both moderate and low intensity treatment across all patient characteristics.

CONCLUSIONS:
Discontinuation, persistence, and adherence differed significantly between intensity levels. Increasing the intensity of statin therapy does not seem to negatively impact adherence to treatment. Further analysis is ongoing to adjust for confounders (e.g. primary versus secondary prevention), and to evaluate clinical outcomes associated with high-intensity statin therapy.

METHODS:
Data sources included provincial administrative healthcare databases, population density statistics, field evaluation of Québec’s four existing EVT care networks, and literature review concerning structural and performance criteria for EVT centres. We consulted EVT clinical teams, interdisciplinary stroke experts, patients, professional association representatives, healthcare managers and decision-makers.

RESULTS:
Access to EVT is suboptimal in all 17 regions of Québec, with virtually no access in remote areas. Results of key performance indicators indicated favourable treatment delays after arrival at the EVT centre. However, door-to-needle and door-in-door-out times were long for patients transferred from non-EVT centres. High use of ambulances indicated the potential to transport patients to the most appropriate centre. In light of ‘real world’ results and other sources of information, the need for a new EVT centre should consider the following criteria: sub-optimal EVT access within the region; transport time to an existing EVT centre >1 hour; expected patient volume within 2 hours of transport; impact on volume of existing programmes; availability of long-term financial support; availability of a critical mass of neurointerventionists, vascular neurologists, and neurosurgeons; demonstrated quality of stroke care and presence of a stroke unit.

CONCLUSIONS:
The triangulation of literature, clinician experience and the Québec context enriched the evaluation...
process. Furthermore, this facilitated the development of a framework that was broadly applicable across regions to the real-world setting of decision making in a complex system of care.

**OP48 Nursing Requirements In Long-Term Care: A Health Technology Assessment**

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**ABSTRACT SUMMARY:**
The relationship between nurse staffing and quality of care in long-term care (LTC) continues to receive attention. This study examined published research evidence and real world evidence (RWE) to inform policy makers about the relationship between nursing staff coverage, nursing care hours, and quality of care in LTC facilities. Results illustrate the potential of RWE analysis in health technology assessment.

**INTRODUCTION:**
The objectives of this study were to systematically review published research on the relationship between nursing staff coverage, care hours, and quality of care (QoC) in LTC facilities; and to conduct a real world evidence (RWE) analysis using Alberta real world data (RWD) to inform policy makers on whether any amendments could be made to current regulations.

**METHODS:**
A systematic review (SR) of research evidence published between January 2000 and May 2018 on the relationship between nursing staff coverage, care hours, and QoC in LTC facilities was conducted. Panel data regressions using available RWD from Alberta, Canada, were performed to assess associations between nursing care hours and LTC outcomes. Outcomes of interest included quality indicators related to resident outcomes, hospital admissions, emergency room visits and family satisfaction. Nursing care hours considered in SR and RWE analysis included those provided by registered nurses (RNs) and licensed practical nurses (LPNs).

**RESULTS:**
The SR found inconsistent and poor quality evidence relevant to the questions of interest, indicating a great uncertainty about the association between nursing staff time and type of coverage and QoC. Although some positive indications were suggested, major weaknesses of reviewed studies limited interpretation of SR results. RWE analysis found that impact of care hours on LTC outcomes was heterogeneous, dependent on outcome measurements. There was evidence that total staff, RN, and LPN hours had positive effects on some resident outcomes and magnitude of effect differed for different nursing staff.

**CONCLUSIONS:**
No definitive conclusion could be drawn on whether changing nursing staff time or nursing staff coverage models would affect residents’ outcomes based on the research evidence gathered in the SR. RWE analysis helped to fill a gap in the available published literature and allowed policy makers to better understand the impact of revising current regulations based on actual outcomes.
OP49 MAIC-ing Use Of Trials? Study Of Matching Adjusted Indirect Comparison

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ABSTRACT SUMMARY:
We assess the benefits and drawbacks of using a Matching Adjusted Indirect Comparison (MAIC) in a Network Meta-Analysis (NMA). We find MAIC to be beneficial as a sensitivity analysis. However, we recommend using either a standard NMA or a mixed IPD/AgD NMA for the base case analysis, given the potential bias that can arise in an MAIC.

INTRODUCTION:
When conducting an NMA for a Health Technology Assessment (HTA), the submitting company typically will have access to Individual Patient Data (IPD) from their own trials, but only aggregate data (AgD) for the comparator. In this case, they can re-weight the IPD so that the covariate characteristics in the IPD trials match that of the AgD trials, using the increasingly popular method of MAIC.

METHODS:
We carry out a simulation study to investigate this method in a Bayesian setting. We simulate 3 IPD trials comparing treatments A and B (AB-IPD trials), and one aggregate data trial comparing treatments B and C (BC-AgD trial). We investigate two options of weighting covariates: 1. all three studies are weighted separately to match the BC-AgD trial (MAIC Separate Trials). 2. patients are weighted across all three IPD studies to match the BC-AgD trial, but the NMA still considers each trial separately (MAIC Pooled Trials). We compare the results of the MAIC to a standard NMA and a mixed IPD/AgD NMA. We apply these methods to a network of treatments for multiple myeloma.

RESULTS:
MAIC can provide more accurate estimates of the relative treatment effects than a standard NMA in the BC-AgD trial population. However, MAIC will decrease the accuracy of the relative treatment effects in the overall population. Treatment rankings were unchanged when applying MAIC to the multiple myeloma network.

CONCLUSIONS:
MAIC is beneficial as a sensitivity analysis to demonstrate that results hold across patient populations. If there is a difference in relative treatment effects attributable to population imbalances, then it is useful to be able to quantify this difference. However, we recommend using either a standard NMA or a mixed IPD/AgD NMA for the base case analysis, given the potential bias that can arise in an MAIC.

OP50 IQWiG And GRADE – An Exemplary Comparison Of Methods

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ABSTRACT SUMMARY:
Efforts to harmonize HTA processes and methods across Europe are currently intensified. In this
context, GRADE has been proposed as a “common ground” in joint HTAs. However, GRADE has been primarily developed to support authors of clinical guidelines. We therefore compared GRADE with IQWiG’s methods with respect to three exemplary domains and present notable differences and similarities.

**INTRODUCTION:**
Efforts to harmonize HTA processes and methods across Europe are currently intensified. In this context, GRADE has been proposed as a “common ground” in joint HTAs. However, GRADE has been primarily developed to support authors of clinical guidelines. Therefore, it is unclear whether HTA reports based on GRADE are compatible with the methods currently applied by European HTA organizations.

**METHODS:**
We exemplarily contrasted IQWiG’s methods paper and publications by the GRADE Working Group with regard to the following domains: 1) risk of bias (RoB) assessment 2) prerequisites for “greater benefit” (assuming that IQWiG’s “greater benefit” corresponds to a GRADE assessment of at least low certainty and a small important effect) and 3) consideration of non-randomised studies (NRS). We present exemplary differences and highlight similarities.

**RESULTS:**
Overall, RoB assessments are very similar under both approaches. However, we identified several important differences. In case of very severe publication bias, IQWiG methods preclude drawing a conclusion, whereas GRADE requires only downgrading the certainty of evidence while still allowing for a conclusion on effect sizes. Secondly, IQWiG generally requires a statistically significant effect for a “greater benefit”, while GRADE does not (statistically non-significant effects would only necessitate downgrading the certainty of results for imprecision). Another difference is that in general, NRS are not included in IQWiG assessments when randomized studies (RS) are available and thus possible. In contrast, preliminary GRADE guidance recommends considering NRS in addition to RS when the RS evidence is of low or very low certainty.

**CONCLUSIONS:**
While GRADE and IQWiG’s method share some similarities, our exemplary analysis shows that there are some notable differences. Therefore, GRADE should not be used “out of the box” for European HTAs. To foster further discussion, more research (including a comprehensive comparison of methods and an analysis of resources for adaptation) is needed.

**OP51 Comparison Of The Measurement Properties Of The PROBE And EQ5D On Pain**

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**ABSTRACT SUMMARY:**
This study aims to investigate the measurement properties of the pain assessment of the PROBE questionnaire compared with EQ5D-5L. Main findings reveal that the pain questions on the PROBE questionnaire are well correlated with the pain domain on EQ5D-5L. The strength of
PROBE is that it provides more informative data on pain assessment.

INTRODUCTION:
The Patient Reported Outcomes, Burdens and Experiences (PROBE) questionnaire has been developed for assessing patient reported outcomes in people living with hemophilia (PWH). This study aims to investigate the measurement properties of pain assessment of the PROBE questionnaire compared with the pain and discomfort domain of EQ5D-5L.

METHODS:
The participants of the PROBE study were recruited via national patient organizations. Descriptive data were reported as a proportion and mean (standard deviation) as appropriate. We calculated the correlation coefficient between EQ5D-5L (pain domain) and the occurrence and inference of acute pain and chronic pain from the PROBE questionnaire. We investigated the discriminative property of the pain domain of the PROBE questionnaire and EQ5D-5L.

RESULTS:
A total of 1675 participants were included in the analysis (PWH 68.7%, 31.3% participants without bleeding disorders). Mean age was 37.5 years (SD 17.4). Data from the PROBE revealed that during the past 12 months, 60.5% and 51.1% of participants reported they have acute and chronic pain, respectively. 79.6% of participants reporting the use of pain medications. Acute pain occurred when walking (30.5%) followed by night time and weight bearing. Acute pain interfered with general activities the most (38.3%) followed by walking ability and mood. Chronic pain occurred when walking (38.9%), followed by stairclimbing and weight bearing. Chronic pain interfered with general activities the most (35.7%), followed by walking ability and mood. The correlations were moderate between acute pain (PROBE) and the pain domain on EQ5D-5L, whereas the correlations were strong between chronic pain (PROBE) and the pain domain on EQ5D-5L. When classifying participants to 4 groups by severity, the discriminative property of PROBE and EQ5D-5L-pain was excellent.

CONCLUSIONS:
The pain questions on the PROBE questionnaire are well correlated with the pain domain on EQ5D-5L. The discriminative property of both tools is found to be excellent to separate people with various severities of hemophilia as well as people without bleeding disorders. The strength of the pain domain on the PROBE questionnaire is that it provides more informative data on the use of pain medication, occurrence and interference of acute and chronic pain. Therefore, the PROBE questionnaire is a disease-specific patient reported outcome measure, which will provide more insightful information regarding pain status in PWH.

OP52 Use Of Intention To Treat And Magnitude Of Treatment Effects

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ABSTRACT SUMMARY:
Intention to treat (ITT) is a gold standard strategy to analyze the results of randomized controlled trials (RCTs). However, the extent to which the use of ITT or not is related to the effect size estimates in RCTs has poorly explored. This study determined the association between the use of intention to treat and magnitude of treatment effects in RCTs.
**INTRODUCTION:**
Intention to treat (ITT) is a gold standard strategy to analyze the results of randomized controlled trials (RCTs). ITT analysis has been considered a methodological quality indicator since it has been used to determine trial’s quality. The extent to which the use of ITT or not is related to the treatment effects the in RCTs has poorly explored. Therefore, the main objective of this study was to determine the association between biases related to attrition and missing data and the use of intention to treat principle and changes in effect size estimates in RCTs.

**METHODS:**
This was a meta-epidemiological study. A random sample of RCTs included in meta-analyses was identified. Data extraction including assessments of the use of intention to treat principle, missing data and drop-outs was conducted independently by 2 reviewers. To determine the association between biases related to attrition, missing data, and the use of intention to treat and effect sizes, a 2-level analysis was conducted using a meta-meta-analytic approach.

**RESULTS:**
393 trials included in 43 meta-analyses, analyzing 44,622 patients contributed to this study. From these, 134 trials (34.1%) used ITT and 218 (55.5%) did not use ITT. Trials which did not use the ITT principle, or which were assessed as having an inappropriate control of incomplete outcome data (based on the Cochrane risk f bias tool) tended to underestimate the treatment effect when compared with trials with adequate use of ITT (ES = -0.13; 95%CI -0.26; 0.01) or trials which were assessed as having an appropriate control of incomplete outcome (ES = -0.18; 95%CI -0.29; -0.08).

**CONCLUSIONS:**
Our results suggest that when evaluating risk of bias of primary RCTs, systematic reviewers should pay attention to these biases since they could underestimate treatment effects. Systematic reviewers should perform sensitivity analysis including trials with low risk of bias in these domains.

**OP53 HTA Acceptability Of Innovative Survival Metrics In Oncology**

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**ABSTRACT SUMMARY:**
Oncology therapies are increasingly receiving regulatory approval in the neo-/adjuvant setting with primary trial endpoints typically as surrogate survival metrics. We find that whilst sufficient for regulatory approval, translating this to favorable HTA decisions has been more challenging. We recommend clearly establishing linkages between surrogate survival metrics and OS alongside measuring metrics that clearly portray patient benefits to improve HTA-acceptability.

**INTRODUCTION:**
Most new oncology therapies are studied in the advanced/metastatic setting. However, there is an increasing focus on earlier stage disease. Nevertheless, measuring Overall Survival (OS) in neo-/adjuvant therapy trials can be very challenging due to the increased life expectancy and the confounding effects of subsequent treatments. Thus, their primary endpoints tend to be surrogate survival metrics (e.g. metastases-free survival). This research aims evaluates the HTA-acceptability of such endpoints through recent neo-/adjuvant HTA assessments.

**METHODS:**
The EMA website was screened for any neo-/adjuvant oncology therapies approved (01/01/2013-22/10/2018) and any corresponding
publicly-available assessments by HTA bodies (NICE, SMC, IQWiG, G-BA, CADTH, PBAC, HAS) were identified and key data extracted.

RESULTS:
Six neo-/adjuvant therapies have received marketing authorization by the European Commission (EC). These six have been on the market for an average of 8.9 months (range: 0.9-39.3 months, median: 3.3 months). In 4/6, the pivotal trial primary endpoints were measures of relapse-/disease-free survival, (others: pathological complete response and PFS/OS co-primary). Only 1/6 had mature OS data available at EC-approval. 4/6 therapies had received at least draft guidance by an HTA body, encompassing 11 HTA assessments in total (4: NICE, 2: IQWiG, HAS; 1: SMC, CADTH, G-BA). Only 2/11 (18%) were positive outcomes (both NICE), the remaining nine were negative.

CONCLUSIONS:
Oncology therapies are increasingly receiving regulatory approval in the neo-/adjuvant setting. However, their pivotal trials are frequently powered to show benefits in disease-/metastases-free survival. Whilst sufficient for regulatory approval, translating this to favorable HTA decisions has been more challenging. Clearly establishing linkages between surrogate survival metrics and OS alongside measuring metrics that clearly portray patient benefits (e.g. time to symptomatic progression) could improve HTA-acceptability. Further, some payers allow for temporary reimbursement whilst additional evidence is generated (e.g. Cancer Drugs Fund in England).

ABSTRACT SUMMARY:
The introduction of fast-track licensing strategies increases the approval of anti-cancer drugs with ambiguous benefit-risk profiles. Our objective was to monitor these therapies and identify any post-approval updates on survival. Our findings indicate that there is a lack of knowledge in one-third of oncology drugs after several years of approval. Therefore, systematic post-approval monitoring mechanisms will be of high relevance.

INTRODUCTION:
The introduction of fast-track licensing strategies increases the approval of anti-cancer drugs with ambiguous benefit-risk profiles. Thus, in many instances there is lacking evidence about overall survival (OS) at the time of marketing authorisation. Our objective was to monitor and characterise therapies with ambiguous benefit-risk profiles and identify any post-approval updates on median OS after at least three years of approval by the European Medicines Agency (EMA).

METHODS:
We included all originator anti-cancer drugs with initially ambiguous benefit-risk profiles that received marketing authorisation by the EMA between Jan 1, 2009 and May 31, 2015. Our monitoring timeframe was at least three years after EMA-approval. To identify study updates, the following three sources were included: clinicaltrials.gov, EPARs, and PubMed.

RESULTS:
In total, we identified 102 eligible approval studies. Out of these, a negative difference in median OS or no information was available in 43 (42.2%) instances. During monitoring, 11 updates with accessible information on median OS could be identified. Including monitoring results there are still 32 remaining therapies (31.4%) where no or negative information (n=27 [26.5%] and n=5 [4.9%], respectively) regarding median OS is present at least three years after EMA approval.

OP54 Monitoring Evidence On Overall Survival Benefits Of Anti-Cancer Drugs

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CONCLUSIONS:
One-third of oncology drugs with ambiguous benefit-risk profiles fail to demonstrate a survival benefit even after several years of marketing authorisation. Systematic and transparent post-approval monitoring mechanisms will be of high relevance to assure a clinically relevant patient benefit, since the trend towards faster access to medicine with uncertain benefit is increasing rather than declining.

INTRODUCTION:
To enhance timely access to medicines, the European Medicines Agency (EMA) may accept less conclusive clinical evidence with a higher level of uncertainty at time of marketing authorization (MA). How this affects reimbursement recommendations remains unknown. We aimed to (i) determine whether the existence of major clinical objections (MOs) regarding phase III data during the MA procedure as a measure for uncertainty is associated with negative reimbursement recommendations, and (ii) identify differences in clinical studies used for decision making by EMA and reimbursement agencies.

OP55 Effects Of Regulatory Major Objections On Reimbursement Decisions

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ABSTRACT SUMMARY:
This study assesses the relation between uncertainty in clinical evidence used for regulatory decision making (measured in major objections raised by the EMA) and reimbursement recommendations (measured by proportion of negative recommendations). Results show that acceptance of uncertainties by regulators may be associated with negative reimbursement recommendations, which indicates that different considerations regarding clinical evidence exist between regulators and reimbursement agencies.

METHODS:
For a cohort of innovative medicines that received MA (2009 & 2010, excluding vaccines) we identified all publicly available initial reimbursement recommendations in England, France, the Netherlands and Scotland. Risk ratios (RRs) and 95% confidence intervals (CI) were calculated overall and per jurisdiction for the association between MOs identified in MA dossiers (Putzeist et al, 2012) and negative reimbursement recommendations. Data on clinical studies were extracted from reimbursement dossiers and EMA’s public assessment reports (EPARs), and compared.

RESULTS:
For 35 medicines, 109 reimbursement recommendations were made, of which 43 percent were negative. The presence of clinical MOs was associated with an increased, although non-significant, risk for a negative reimbursement recommendation: 1.4 (95% CI 0.9 to 2.3). For England, France, the Netherlands and Scotland, the RRs were 0.6, 1.5, 2.1 and 1.1, respectively (all non-significant). The proportion of studies in the EPAR also used for reimbursement recommendations varied from 24 (England) to 55 (France) percent. The proportion of studies used for reimbursement decision making that were not included in the EPAR varied from 13 (France) to 55 (England) percent.
CONCLUSIONS:
Acceptance of uncertainties by regulators may be associated with negative reimbursement recommendations. This study suggests different considerations regarding clinical evidence between regulators and reimbursement authorities. Many studies in the EPAR are not used for reimbursement recommendations, and vice versa.

OP56 Are TPRs Driving Pharmaceutical Reimbursement Outcomes In Spain?

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ABSTRACT SUMMARY:
The objective of this study was to assess the impact of therapeutic positioning reports (TPRs) on the speed and outcome of reimbursement recommendations made by Spanish Inter-Ministerial Pricing Commission for Pharmaceuticals (CIPM). Drug-indication pairings with ‘positive’ and ‘alternative’ TPR outcomes were shown to be associated with significantly better and faster CIPM recommendations than those with ‘not recommended’ TPR outcomes.

INTRODUCTION:
Following marketing authorization in Spain, new medicines are assessed by the Inter-Ministerial Pricing Commission for Pharmaceuticals (CIPM), which provides reimbursement recommendations with a maximum ex-factory price. However, there are 17 autonomous regions, which can make distinct reimbursement decisions. To drive consistency, the Spanish Agency for Medicines and Health Products has issued national Therapeutic Positioning Reports (TPRs) for new medicines since 2012. Since November 2017, CIPM recommendations have been published monthly, giving the opportunity to analyse the impact of TPRs on the speed and outcome of CIPM decisions, which this research evaluates.

METHODS:
Publicly-available CIPM and TRP decisions were identified from www.msssi.gob.es and www.aemps.gob.es, respectively. Marketing authorization dates were identified from www.ema.europa.eu or www.aemps.gob.es (10/3/2007-11/02/2018). Pearson’s chi-squared and Mann-Whitney U statistical tests were performed using R.

RESULTS:
193 drug-indication pairings with an associated TPR were identified. The majority (62% [120/193]) were recommended as alternative treatment options with only 19% (36/193) deemed to be superior and 19% (37/193) not recommended. 108 CIPM recommendations were identified across seven monthly reports, issued a mean of 12.2 months after market approval, 59% (64/108) were positive and 41% (44/108) were negative recommendations. There were 34 drug-indication pairings with both CIPM and TPR recommendations available. Of these, 24%, 56% and 21% had TPR outcomes of ‘superior’, ‘alternative’ and ‘not recommended’, respectively and 71% and 29% had positive and negative CIPM outcomes. Drug-indication pairings with ‘negative’ TPRs were significantly more likely to have negative CIPMs than those with either ‘alternative’ or ‘superior’ TPRs (71% vs. 19%, respectively, X_1^2=5.16, p = 0.02) and were more likely to experience significantly longer delays to CIPM recommendation (23.9 vs. 13.5 months, respectively, W = 50, p=0.03).

CONCLUSIONS:
Drug-indication pairings with ‘positive’ and ‘alternative’ TPR outcomes are associated...
with significantly better and faster CIPM recommendations than those with 'not recommended' TPR outcomes.

OP57 Threats And Opportunities To Digital Health In Primary Care

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ABSTRACT SUMMARY:
The integration of digital technologies in primary health care and services has been slow due to several factors. We propose an integrative framework that could inform technology promoters, healthcare managers, clinicians and researchers on the best strategies to improve integration of digital health solutions in primary care.

INTRODUCTION:
The use of digital technologies in healthcare systems (digital health) – such as electronic health records and telehealth – can improve primary care (PC). However, integration of digital health can be constrained/impaired and/or facilitated due to several factors. We propose an integrative framework for classifying the factors that could favour or limit digital health integration in PC in order to guide the identification of strategies that could be helpful for technology promoters, managers, clinicians and researchers.

METHODS:
Based on a systematic review, our framework includes seven categories to classify the main opportunities and threats to digital health integration in PC: technological; individual/interpersonal; professional; organisational/institutional; ethical/legal; sociopolitical; economical. We consulted a panel of researchers, managers, clinicians, and citizens/patients in a scientific meeting regarding the main opportunities and threats to the integration of digital health in PC. We performed a content analysis of the reported factors according to the framework.

RESULTS:
Technological factors such as maturity, interoperability and ease of use were often mentioned as key conditions for digital health integration. Individual and interpersonal factors such as depersonalisation and digital literacy were seen as threats. The impact on workload and shared responsibility were threats at the professional level, whereas silos and change management were noted as organisational threats. Current policies and social trends favoured digital health. Threats regarding privacy and confidentiality were mentioned at the legal/ethical level. The possibility to reduce costs and sharing of benefits were noted as opportunities at the economic level.

CONCLUSIONS:
Knowing these multidimensional conditions, perceived as either threats or opportunities depending on the context of each PC setting, is essential to inform decisions, from strategic planning to evaluation. Our integrative framework allows a simple classification of opportunities and threats that can guide the development and implementation of tailored strategies favouring the integration of digital health in PC.
OP58 Developing An Evaluation Based Taxonomy For mHealth Apps

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ABSTRACT SUMMARY:
The potential impact of mHealth apps to improve outcomes for service users and promote more efficient use of healthcare systems is limited by risks involving lack of categorisation and appropriate evaluation. This work developed a preliminary framework for categorising apps and guiding risk assessment which aims to improve the confidence of care professionals in the recommendation and use of apps.

INTRODUCTION:
MHealth apps offer potential to promote greater public engagement in health, improve efficiency and open up new care pathways and models of care. However, the volume and heterogeneity of apps has led to uncertainty and lack of standardisation around app definitions. Some mobile apps carry minimal risks to consumers, but others can carry significant risks. Work has been carried out to develop a framework for assessment (for example, for the NHS app library [beta version]). We discuss work helping to inform a preliminary framework of categorising mHealth apps for proportionate assessment and validation, and the challenges involved.

METHODS:
A literature review was carried out to identify different types of categorisations used to define health apps and the most important dimensions for their assessment. A taxonomy of apps and a process for routing them towards appropriate methods of evaluation was developed through iterative review, discussion and refinement.

RESULTS:
Fourteen types of mHealth apps were established which were categorised by app function and by the potential risk involved with use. Subsequently, this research suggested a method of routing apps towards the most appropriate and proportionate method of evaluation, by using four example dimensions of impact (population size, disease burden, priority of clinical condition, and innovation), and four levels of risk.

CONCLUSIONS:
The outcome of an evaluation framework should be to enable healthcare professionals and patients to select and use safe and effective mHealth apps with greater confidence. A preliminary taxonomy and method of routing apps towards appropriate assessment are presented. Both need larger scale discussion, iterative testing and refining.

This research faced significant challenges, including a high volume of heterogeneous apps with poorly standardised app definitions and associated nomenclature.

OP59 HTA Of A mHealth App For Young People With Diabetes

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ABSTRACT SUMMARY:
A mHealth application for young patients with type 1 diabetes was developed and tested in a randomized controlled trial for effect on self- management. The health technology assessment report included assessment of technical aspects, clinical effect, patient and organisational experiences and economic consequences.

INTRODUCTION:
In a participatory-design project the mHealth application ‘Young with Diabetes’ (YWD) was developed to support young people in self-managing type 1 diabetes (T1DM). YWD included disease-specific information, enabled contact with healthcare providers and included a chat room. A randomised controlled trial tested the effect of YWD on self-management. Additionally, a HTA-report explored patient experiences, organisational and economic aspects.

METHODS:
151 young patients (14–22 years) with dysregulated T1DM (HbA1c>8%) were randomised to YWD or usual care (UC) for 12 months. Self-management was measured by glycated haemoglobin (HbA1c) and by the questionnaires ‘Perceived Competence in Diabetes’ (PCD), ‘Problem Areas in Diabetes’ (PAID) and ‘Health-Care Climate Questionnaire’ (HCCQ) after 12 months. App-activity was based on log-files. Patient experiences were explored by questionnaires and individual interviews. The organisational aspects were investigated by focus group interviews with healthcare providers. The cost analysis measured investments costs, running costs and costs related to the use of hospital resources.

RESULTS:
YWD had a weekly average of 9 (12%) users. After 12-months HbA1c was significant lower in UC compared to the intervention group, however a subgroup-analysis showed no difference between users of the intervention group (>5 days activity) and UC. No differences were observed in PCD, PAID or HCCQ. More than 80% of the intervention group would recommend YWD to peers. Young people reported reduced feelings of loneliness and increased knowledge and skills for managing T1DM. The healthcare providers were satisfied with the user-friendly design but reported low usage of YWD. The cost analysis showed investment and yearly running costs of 416€ and 215€ per patient, respectively. No differences in the use of hospital resources were observed.

CONCLUSIONS:
YWD did not improve HbA1c, PCD, PAID or HCCQ, but it reduced feelings of loneliness and helped young people gain knowledge and skills for managing T1DM. YWD was associated with increased cost per patient.

OP60 Challenges In Evaluating Smart Medical Devices

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ABSTRACT SUMMARY:
There are several challenges in evaluating smart medical devices because of its complex nature and innovative character. Demands on the evaluation of such technologies have been worked out with literature reviews and scenario technique using the example of intelligent rollators. The research shows the need to adapt common methods used in economic evaluation to the characteristics of such technologies.

INTRODUCTION:
Smart medical devices can empower elderly to live independently in their familiar surroundings. To enhance their dissemination, they have to be shown to be cost-effective. Economic studies evaluating such technologies are missing or are criticized for their low quality. There are several
challenges in their evaluation because of its complex nature and innovative character. The question arises, how they can be evaluated to show their benefits and cost-effectiveness. This research has the aim to outline challenges and demands on the evaluation of smart medical devices.

METHODS:
The embedding of the technology in existing structures can influence the effectiveness of the technology. By comparing such a technology with a regular intervention, learning effects have to be considered. Regular modifications and further developments of these technologies can complicate the traceability of the effects. Complex cause-effect relationships with possible interactions arise that are difficult to quantify and express in standardized endpoints, utilities or monetary values. Demands on the evaluation of smart medical devices have been worked out with literature reviews and scenario technique using the example of intelligent rollators.

RESULTS:
It is important to apply mixed-method approaches not only in the clinical but also practical setting and conduct observational as well as qualitative studies. Potential user, their relatives and care personnel should be involved in the evaluation of intelligent rollators and attention should be payed to subjects with disabilities. Prospective studies should be conducted at different stages along the lifecycle of the technology. A conceptual model should be developed and evaluated as well as adapted on a regular basis.

CONCLUSIONS:
The research shows the need to adapt common methods used in economic evaluation to the characteristics of smart medical devices. As a next step, a framework for the economic evaluation of such technologies within the scope of Health Technology Assessment is developed based on these demands.

OP61 Data From Smart Devices: The Apple Watch And Atrial Fibrillation

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ABSTRACT SUMMARY:
Smart devices can provide valuable data for HTA-decisions. We have looked at data on Artrial Fibrillation provided by the Apple Watch 4. Our findings suggest that the data provided by the device are not yet ready for use in HTA. The findings highlight the importance of critically assessing any smart device delivering data used in an HTA context.

INTRODUCTION:
Smart devices potentially provide valuable data on health conditions/outcomes for use in HTA studies. One such device, the Apple Watch series 4, received FDA clearance for ECG monitoring and irregular heart rhythm notification in September 2018, getting considerable attention because of its other status as a consumer device. We asked whether or not the Apple Watch series 4 provides reliable data on the existence of atrial fibrillation. Such data could be used as a component in a range of research designs to assess the effectiveness of medical and/or life style interventions.

METHODS:
A literature review of popular and scientific sources and research in clinical trial registries.

RESULTS:
To our knowledge no data about any function have yet been published in peer-reviewed journals. Only
the media have reported data. According to these reports the ECG-function identifies individuals affected by atrial fibrillation with an accuracy of 98.3 percent and non-affected individuals with an accuracy of 99.6 percent (n=566). However, the device could not classify about 10 percent of all recordings. Atrial fibrillation indicated by the irregular rhythm notification feature could be confirmed in 78.9 percent of all alarms (n=226). Further studies are registered in clinical trial registries and will probably lead to more scientific data being available in the future, which could improve decision making on the use of this device and comparable ones (for example: Apple Heart Study).

CONCLUSIONS:
The findings highlight the importance of critically assessing a smart device which delivers data. FDA clearance itself does not necessarily guarantee high quality data as the clearance may be restricted. However, one should note that the device looked at is still in the early stages of development and further evidence is currently being generated.

ABSTRACT SUMMARY:
We present a co-creation process considering both the evidence and the expertise of professionals to develop a tool for the assessment of weight control apps. We have identified relevant criteria to evaluate the efficacy and safety of mHealth interventions in the management of overweight and obesity.

INTRODUCTION:
There are more than 320,000 accessible health apps, being the most downloaded those related to physical exercise and weight control. However the initiatives for their validation address only partial aspects of the evaluation. EVALAPPS project aims to develop an assessment tool for overweight and obesity management apps, based on the evaluation of efficacy, effectiveness and safety. In the present phase of the project, the team is co-creating the assessment tool considering both the evidence and the expertise of professionals (co-creation process).

METHODS:
Proposed co-creation methodology includes:
1) a modified Delphi process for selecting the assessment criteria. Criteria were identified through a) an exhaustive review on the criteria used by several mHealth assessment tools and b) a systematic review of efficacy, safety and effectiveness criteria used in mHealth interventions that assess overweight and obesity management.
2) A co-creation session using “Design Thinking” techniques for defining the final content and appearance of the tool (November 2018).

RESULTS:
Ten dimensions and 133 criteria were identified, both in relation to the outputs (Usability, Clinical Effectiveness, Security, Development, etc.) and the outcomes (such as weight loss, number of steps). Of those, 114 were included in the modified Delphi, in which 31 professionals participated. A set of 63 criteria were selected as candidates for being part of the tool. Mainly, criteria belonged to Security (22%) and Usability dimensions (14%), followed by
Quality (11%), and outcomes related to Activity (11%) and Physical status (11%). Once the co-creation session has been performed, the final tool will be developed.

CONCLUSIONS:
Relevant criteria to evaluate the efficacy and safety of mHealth interventions in the management of overweight and obesity have been identified. Once the tool is developed it will be user tested and piloted on users of overweight and obesity management apps.

OP63 Clinical Videoconferencing - Critical-Realist Review As Evidence?

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ABSTRACT SUMMARY:
A critical-realist review and qualitative meta-synthesis was conducted for clinical videoconferencing. The presentation discusses the value of this approach for decision relevant knowledge production. The approach has strengths as complementary to systematic reviews for complex and emerging digital health services.

INTRODUCTION:
Exploring complimentary decision relevant knowledge production in digitalisation. It is not clear yet whether new digital health interventions can and should be assessed by using “conventional” HTA methodology. In response to the question about of how much and which type of evidence is needed for decisions on new digital health interventions, this presentation discusses complimentary evidence as generated through a critical-realist review and a qualitative meta-synthesis. Conventional HTA methodology i.e. controlled trials of dynamic, heterogeneous services are difficult to apply, and results of systematic reviews and meta-analyses might be outdated when published.

METHODS:
The review was conducted for clinical videoconferencing with the purpose of building generative knowledge on what works, for whom and under which circumstances.

Realist review is designed to work with complex social interventions or programmes. Such assessments are undertaken in real life settings [1]. The aim is to enable decision-makers to reach a deeper understanding of the intervention and how it can be made to work most effectively.

A critical review goes beyond mere description of identified articles and includes a degree of analysis and conceptual innovation. An effective critical review presents, analyses and synthesizes material from diverse sources [2]. A critical review provides an opportunity to “take stock” and evaluate what is of value related to a previous body of work.

RESULTS:
User patterns of digital health interventions, for instance videoconferencing for clinical purposes, are depending on contextual factors like clinical condition, motivation, technological skills, professional and organisational arrangements, and the perceived value they add compared with “services as usual” [3]. Services are therefore differently configured and used in different clinical areas. The configuration and impact of clinical videoconferencing is also dynamic as this develops during use, often relative to new technological details or features, which add to the existing ones. The experience of professionals and patients also affect outcome. Hence, the value of interventions are relative to dynamics of ongoing changes in the intervention and patterns of use. The value in itself may also rapidly change.

CONCLUSIONS:
The in depth accounts of different clinical use
resulting from such a review, provide decision makers with highly practical understanding of complex social interventions which is likely to be of use when planning and implementing programmes at a national, regional or local level. A critical-realist review of digital services can complement controlled studies and evidence summaries in HTA.

References


OP64 Implementation Of Whole Exome Sequencing For Rare Diseases

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ABSTRACT SUMMARY:
In our state, rare undiagnosed genetic conditions affect 2,400 people and 30 babies born each year, all requiring complex management. The ‘diagnostic odyssey’ could be replaced with sequencing, leading to early diagnosis, early treatment and cessation of inappropriate interventions. However, it’s unclear when and how this technology should be implemented. We have co-designed policy with stakeholders.

INTRODUCTION:
The Victorian Department of Health and Human Services provided $25 million over four years to determine the place of whole exome sequencing (WES) for patients attending public genetics clinics. Comparative analysis of WES and ‘usual care’ determined that WES increased diagnosis rate (from 14 to 58 percent), changed clinical management in one third of patients and identified relatives and couples at high risk of recurrence in future pregnancies. Translating this into routine care requires co-design with clinical and laboratory stakeholders.

METHODS:
Victoria’s clinical and laboratory genetics service system uses a ‘hub and spoke’ model. Representatives from these were invited to join a ‘Clinical Adoption Group’ (CAG) to oversight implementation of new government funding ($2 million per year) to ensure statewide access to, and funding of, WES for children with rare undiagnosed genetic conditions. The CAG developed terms of reference, ‘traffic light’ evidence-based eligibility criteria, a pricing model and reporting mechanism, and recommended funding for sequencing, curation, curator training and multidisciplinary team (MDT) meetings to support implementation.

RESULTS:
Funding was distributed across hub and spoke sites reflecting clinical and laboratory demand and workforce requirements. All cases demonstrated clinical utility and were reviewed at MDT meetings. To date, 37 percent of patients have received a diagnosis changing management, with equity of access between metropolitan and regional areas demonstrated. Eligibility criteria are reviewed as new evidence is published to ensure new evidence is incorporated, although curation capacity limits turn-around-times.

CONCLUSIONS:
Co-designing a statewide and evidence-based clinical model has resulted in sector (i.e. clinician
and laboratory) buy-in and supported broad access to funded WES. In addition, the sector has developed a better understanding of how evidence informs policy and funding decisions, which has resulted in delivering equitable WES that provides early diagnosis leading to changed clinical management and cessation of unnecessary interventions.

**OP65 Health Technology Assessment Of Orphan Drugs: Impact Of Extra Criteria?**

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**ABSTRACT SUMMARY:**
Orphan medicinal products undergo the same Heath Technology Assessment (HTA) process as conventional medicines. This study aimed to identify supplementary criteria that could be feasibly applied to the HTA process for orphan drugs. It also aimed to assess the impact, if any, that application of these criteria would have on final reimbursement recommendations.

**INTRODUCTION:**
There is ongoing debate as to whether conventional Health Technology Assessment (HTA) methods are appropriate for orphan medicinal products (OMPs). The National Centre for Pharmacoeconomics (NCPE) in Ireland has a well-defined process for conducting HTAs of pharmaceuticals, which is the same for OMPs and non-OMPs. The objective of this study was to identify supplementary criteria that could be adopted by the NCPE in the pharmacoeconomic evaluation of OMPs and to determine the effect of these criteria on final reimbursement recommendations.

**METHODS:**
A literature search was conducted to identify criteria. Orphan drug HTAs assessed by the NCPE between January 2015 and December 2017 were identified and supplementary criteria, where feasible, were applied.

**RESULTS:**
Fourteen HTAs were included in the study. Three criteria that could feasibly be applied to the NCPE evaluation process were identified, all three of which essentially broadened the economic perspective of the HTA.

- **Higher cost-effectiveness threshold:** Despite being arbitrarily raised from EUR45,000/QALY to EUR 100,000/QALY, only one orphan drug demonstrated cost-effectiveness at this higher threshold.

- **Weighted QALY Gain:** Here, a weighted gain of between one and three is applied to drugs demonstrating QALY gains between 10 and 30, respectively. No OMPs included in the study showed a QALY gain of more than 10. Thirteen demonstrated QALY gains less than 10 and one could not be evaluated.

- **Societal Perspective:** Six submissions incorporated societal perspective as a scenario analysis. Despite incremental cost-effectiveness ratios (ICERs) being reduced between 4 percent and 58 percent, only two OMPs demonstrated cost-effectiveness at the higher threshold (EUR 100,000/QALY).

**CONCLUSIONS:**
Broadening the economic perspective of the HTA did not alter the final NCPE reimbursement recommendations for OMPs included in the study. HTA can support decision making for OMPs, but decision makers need an additional tool that can encompass multidimensional factors which are
associated with these highly specialised expensive treatments.

OP66 Cost Of Direct Import Unlicenced And Orphan Medicines In Turkey

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ABSTRACT SUMMARY:
The study will provide a general overview on the Turkish reimbursement process and its associated costs but will in particular address an unique aspect of the Turkish Reimbursement of pharmaceuticals which is called ‘Medicines Bringing From Abroad (MBFA)’. MBFA is used for products that are unlicensed and / or products that are not in the market for various reasons.

INTRODUCTION:
As a result of Turkey’s healthcare reforms initiated in 2003 access to medicines increased rapidly what enlarged the public medicine expenditure. Simultaneously, costs of unlicenced or unmarketed licenced medicines became greater. The goal of this study was to describe the impact of direct imported medicines on the total public medicine expenditure.

METHODS:
The reimbursement system of Turkey was assessed focusing on the mechanism of imported medicines. The MBFA list used published by TMMDA and sales data from Turkish Pharmacist Association (main provider for direct import medicines in Turkey) were used for the study.

RESULTS:
Total budget of product listed in appendix 4/C has reached to 2 Billion TL (USD 548 Million) which takes 8,2% of total public pharmaceutical expenditure as of 2017. Even though number of medicines remain low, especially due to first 10 expensive products in the list, cost of unlicenced or unmarketed licenced medicines reached significant expenditure in Turkish healthcare system. The total cost for MBFA reached to 548 Million USD for 86,855 patients in 2017. In this case, the amount paid to 7,4% of the all patients for the first 10 medicines constitutes 78,05% of the total MBFA budget.

CONCLUSIONS:
As a finding from our study shows that 9 products out of most expensive 10 products were orphan indicate that specific needs orphan product legislation both on marketing authorisation and pricing & reimbursement process.

Further implementations such as establishing an independent Health Technology Assessment body and conduct HTA studies on product basis especially for orphan products, use real world evidence for decision making will be necessary to create sustainable and fair access to orphan and expensive innovative medicines. Joining International initiatives would be effective for future decisions.

OP67 A Composite Model For Pricing New Orphan Drugs

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ABSTRACT SUMMARY:
For the purpose of pricing new, innovative medicines two pricing models form the extremes of the spectrum: cost–plus pricing (CPP) and value–based pricing (VBP). The purpose of this study
was to develop a composite model that strikes a compromise between CPP and VBP depending on the size of the target population and other factors.

**INTRODUCTION:**
For the purpose of pricing new, innovative medicines two pricing models form the extremes of the spectrum: cost-plus pricing (CPP) and value-based pricing (VBP). Whereas VBP nowadays presents the gold standard in many industrialized countries, CPP is still influential in reimbursing orphan drugs. An intense dispute revolves around the question of how to adapt incremental cost-effectiveness thresholds used for VBP to the orphan drug space. The purpose of this study was to develop a composite model that strikes a compromise between CPP and VBP depending on the size of the target population and other factors.

**METHODS:**
This study uses a Bayesian shrinkage estimator to create a composite model combining R&D costs and health benefits for the purpose of determining reimbursement prices. The weight placed on R&D costs is a normalized standard error of the relative health benefit. Therefore, less weight is placed on R&D costs when population health benefits are more reliably estimated. Possible inefficiency of the R&D process can be reflected either in the uncertainty of health benefits or in the numerator of the incremental cost-effectiveness ratio used for VBP.

**RESULTS:**
Applying the Bayesian shrinkage estimator, the cost-effectiveness threshold increases inversely proportional to the square root of the population size. The measure is able to incorporate R&D inefficiencies resulting from CPP.

**CONCLUSIONS:**
A composite model for pricing new orphan drugs is able to account for the small target population of orphan diseases and to adjust incremental cost-effectiveness thresholds accordingly. Further research is needed on how to allocate global R&D costs to each country.

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**OP68 Value-Engineered Translation: An Example For Bladder Cancer Diagnosis**

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**ABSTRACT SUMMARY:**
Economic evaluations for technologies at early stages of development require innovative methods so investors are informed about the risks and rewards of continued investment. These methods are illustrated using a new test for bladder cancer. The results indicate that the test clears the value hurdle in terms of cost-effectiveness, providing the opportunity to make a return on future investment.

**INTRODUCTION:**
The Institute of Health Economics offers a suite of analyses that provide developers an understanding of the expected commercial viability of an early stage health technology. In combination, these analyses form the Value-Engineered Translation (VET) framework. These methods incorporate innovative methods to manage uncertainty in early economic evaluations, in particular, moving beyond current stochastic assessments of headroom to account for inter-market variability in value hurdles, as well as incorporating social value premia...
considerations. An illustration of these methods is demonstrated using the example of a non-invasive diagnostic test (called DCRSHP) at an early stage of development, compared to current practice of cystoscopy in the diagnosis of bladder cancer.

METHODS:
Competing technologies were identified to inform the headroom assessment based on price and effectiveness. Then, a model-based cost-effectiveness analysis was undertaken incorporating headroom analysis, stochastic one-way sensitivity analysis, and value of information analysis using data from secondary sources.

RESULTS:
Currently there are number of non-invasive tests available, but none have sufficient test accuracy to be suitable for bladder cancer diagnosis alone. From the headroom analysis, DCRSHP can be priced at up to $790CDN and still be cost-effective compared to the current practice of cystoscopy. Interestingly this price can be increased for patient groups that have lower levels of bladder cancer prevalence.

CONCLUSIONS:
The requirements of economic evaluations depend on the stage of technology development, and analysis approaches must reflect this. The results here indicate that DCRSHP clears the value hurdle in terms of being cost-effective, and thus provides the opportunity to make a commercial return on future investment. Future analysis of DCRSHP could consider the cost drivers for development of the technology, including the regulatory pathways, costs associated with the intellectual asset management for the technology, and alternative manufacturing costs. All of which contribute to the research-to-practice continuum.

OP69 Initiatives To Improve The Timeliness Of Cancer Diagnosis

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ABSTRACT SUMMARY:
This environmental scan describes the impact of initiatives that aim to accelerate the speed of cancer diagnosis by integrating and coordinating diagnostic services. Wait time reductions spanning several days to weeks were often associated with improved patient experience, but not less advanced cancer stage or increased survival. Costs, enablers, and barriers associated with program implementation and maintenance were also described.

INTRODUCTION:
Conventional wisdom suggests that accelerating the speed of cancer diagnosis should improve health outcomes. However, cancer diagnosis requires complex coordination and effective communication between care providers working across many areas of the healthcare system. Since 2000, several nations and jurisdictions have aimed to improve timeliness of cancer diagnosis by integrating and coordinating cancer diagnostic services for patients. The objective of this study was to describe the impact of these existing initiatives.

METHODS:
We conducted an environmental scan consisting of a literature review (published academic and grey literature) and key informant consultations (online surveys and telephone interviews with experts who have knowledge of existing initiatives). We searched
for initiatives in the United Kingdom, the Nordic countries, Canada, Australia, and New Zealand. For each initiative, we extracted data on their development and implementation, structure and functioning, intended outcomes and effectiveness, costs and cost savings, and enablers and barriers.

RESULTS:
Eight-nine relevant documents and 20 key informants contributed to this study. We identified 21 relevant initiatives, including seven national initiatives targeting multiple types of cancer. The literature review found that most initiatives accelerated the diagnostic phase of cancer care by several days or weeks. These wait time reductions were often associated with improved patient experience, but not less advanced cancer stage or increased long-term survival. Insights from key informants improved our understanding of the costs, enablers, and barriers associated with program implementation and maintenance.

CONCLUSIONS:
These results can be used as a first step to inform the development, evaluation, and improvement of international cancer diagnostic pathways. Stakeholders wishing to accelerate cancer diagnosis should consider the feasibility of achieving their intended program outcomes based on the existing research evidence, desired type of initiative, and jurisdiction’s unique contextual factors.

OP70 Aligning Value In Regulatory And Health Technology Assessments

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ABSTRACT SUMMARY:
The recent proliferation of value assessment frameworks with a range of approaches and methods has confused many potential users. This policy analysis explores their differences and similarities. Four key decision contexts—regulatory benefit-risk analysis, coverage and reimbursement, treatment guidelines and clinical pathways, and clinical shared decision making—can be aligned by using the quality-adjusted life year as the central value element.

INTRODUCTION:
The recent proliferation of value assessment frameworks with a range of approaches and methods has confused many potential users. This policy analysis explores their differences and similarities, and explores the implications for regulatory and related types of health technology assessment. In particular, we explore how they could be aligned to support overall clinical and economic value in a health system.

METHODS:
We review the objectives and methods of seven different value frameworks: (1) American College of Cardiology/American Heart Association; (ACC/AHA); (2) American Society of Clinical Oncology (ASCO); (3) Institute for Clinical and Economic Research (ICER); (4) Memorial Sloan Kettering Cancer Center (MSKCC) Drug Abacus; (5) National Comprehensive Cancer Network (NCCN); (6) European Society of Medical Oncology (ESMO), and (7) Avalere Patient-Perspective Value Framework (APPVF).

One important difference among the approaches is whether they are based on multi-criteria decision analysis (MCDA) or some variant of health-outcomes modeling using the quality-adjusted life year (QALY) (i.e., health gain) as the key value element.

RESULTS:
We find that these frameworks differ substantially in their place in the health care system—what
has been called “decision context.” Some (ASCO, ESMO, NCCN, APPVF) are aimed to support clinical shared decision making. Some (ACC/AHA, NCCN) support the development of treatment guidelines and clinical pathways. Finally, others (ICER, MSKCC) support decisions about inclusion and reimbursement in the health plan benefit package. Clinical value in regulatory benefit-risk balance is a fourth important decision context.

We find that a QALY-based approach has several advantages over an MCDA-based approach when it comes to alignment across these decision contexts.

CONCLUSIONS:

We argue that the four key decision contexts—regulatory benefit-risk analysis, coverage and reimbursement, treatment guidelines and clinical pathways, and clinical shared decision making—can be aligned by using the QALY as the central value element in each of these related decision contexts.

ABSTRACT SUMMARY:

The European Commission has recently funded a research project within the horizon 2020 frameworks aimed at experimenting advanced tools to assess the impact of health technologies in health systems. Within IMPACT HTA, WP8 is dedicated to design and test new methodologies to adapt and use results from full HTAs in specific organizational contexts.

INTRODUCTION:

The understanding of the role of organizational factors in determining the real value of health technologies is one of the major challenges for the use of HTA methodology within hospitals and other healthcare organizations. At the same time the responsibility of assessing and measuring hospital performance constitutes one of the major challenges of healthcare managers and policy makers. Hospital performance is largely dependent on local-organizational factors as well as on the concrete capability of technologies to produce “value”. Although a number of managerial tools are indeed available to appraise systematically clinical and non-clinical outcomes, there is little evidence on the role of contextual organizational variables and how they might contribute to the overall hospital performance.

METHODS:

Based on three extensive literature reviews in the fields of public health, HTA and management, a pragmatic framework has been developed in order to understand how to address the impact of patterns of interactions between organizational factors and health technologies on hospitals’ performance. Such framework leads the analysis through three main causal relationships:

- first, the direct relationship existing between contextual organizational/managerial factors and hospital performance. Although vast attention has been dedicated to organizational and managerial trends in healthcare, it is still unclear how these are connected to performance;
• second, the effect of organizational/managerial factors on the capability of technologies to “produce value” within the organization, affecting, in turn, hospital performance;

• third, the influence of organizational factors on clinical evidence-based decision making, since inappropriate use of health technologies due to a non-evidence-based approach by clinicians can reduce the performance of staff as well as of healthcare organizations.

This pragmatic framework has been designed within the IMPACT HTA UE Horizon 2020 Research Project, aimed at improving new methods and at creating actionable tools for enhancing HTA.

RESULTS:

Results from the literature reviews have fostered the development of the pragmatic framework that will be presented at the HTAi 2019 Annual Meeting. In particular, each literature review has produced evidence on the contents of the dimensions under analyses.

The organizational/managerial dimensions (i.e. the tools hospital management can use in order to affect performance) are ascribable to five main domains: organizational structure and patient-oriented design; managerial accounting tools; information and communication tools; human resource management tools; hospital-based health technology assessment procedures.

The impact of organizational/managerial factors on technologies’ ability to produce value is highly overlooked in literature. Although some effort in this sense has been spent in the analysis of health information technologies, a lot less is known on how such factors affect other medical technologies (i.e. equipment, devices, drugs, procedures). Moreover, among the organizational dimensions potentially able to affect technologies’ value, only human resource management tools have inspired a rather lively debate, being all the other dimensions scarcely studied.

The definition of hospital performance is amenable to multiple domains: accessibility, appropriateness, efficiency, safety, patient-centerdness (continuity of care). Although all relevant in principle, the last domain is broadly overlooked in practice and in many hospital scenarios poor attention, if any, is dedicated to the assessment of continuity of care indicators.

CONCLUSIONS:

Although hospital performance is a pivotal topic in the healthcare sector –characterized more and more by increasing pressures and challenges- a deep understanding of how contextual (organizational and managerial) factors may affect it is still missing. The theoretical framework developed in this study provides a tool to understand and disentangle the multiple dimensions able to affect hospital performance, enhancing a clear understanding of their impact with particular attention to the role of health technologies. On the one hand contextual dimensions may provide a direct effect on hospital performance, affecting numerous aspects of the daily functioning of these complex organizations. On the other, they may affect the extent to which technologies are capable of producing value within the continuum of care they are involved in. In turn, this has relevant implications in terms of health technology assessment procedures, given that a reasoned and structured assessment of the contextual factors that will affect the technology’s value is often absent in real life.

OP72 Hta Beyond 2020 In China: HB-HTA Rising Up In Tertiary Hospitals

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ABSTRACT SUMMARY:
The concept of hospital-based health technology assessment (HB-HTA) has gradually attracted attention in China in recent several years. We interviewed government officials, doctors, nurses and chiefs in 30 hospitals, made the conclusion that HB-HTA is in high demand in China and it will continue to develop rapidly over the next decade along with the development of China’s HTA.

INTRODUCTION:
Health technology assessment (HTA) was introduced into China more than 20 years ago and has developed rapidly recently. While, the concept of hospital-based health technology assessment (HB-HTA) has gradually attracted attention in China only in recent several years. The purpose of this study is to investigate the views of government officials, decision makers and relevant stakeholders in the management and application of medical technologies in hospitals, within the environment of Health system Reform in China. We analysed the current situation and identified obstacles and prospects of HB-HTA in Chinese tertiary hospitals.

METHODS:
We conducted semi-structured interviews in 8 provinces in Eastern, Central and Western China, in 2-4 tertiary public hospitals in each province. We interviewed doctors, nurses, and Chiefs in hospitals, and key informants in National Center for Medical Service Administration.

RESULTS:
A total of 98 people participated in the panel discussions and interviews. We found that: 1. China’s tertiary public hospitals have embraced HB-HTA, and various hospitals have performed different forms of HB-HTA (including ambassador model, Mini-HTA model, and internal committee model). However, the assessment process, standards, and methods are yet to be standardized.

OP74 Stoma Cover Use By Fully Laryngectomized Patients

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ABSTRACT SUMMARY:
The use of stoma covers has been a common clinical practice for laryngectomized patients for several years. Two hospital-based HTA units located in Québec, Canada, joined their expertise to assess the relevance of providing HMEs to more patients, depending on their clinical characteristics. A systematic review and a field appraisal were conducted.
INTRODUCTION:
The use of stoma covers has been a common clinical practice for laryngectomized patients for several years. In the province of Québec, Canada, laryngectomized patients can obtain stoma covers through a dedicated program providing them with medical supplies and voice re-education services. For many years, the program’s supply has included cloth and/or foam covers, but the supply of Heat and Moisture Exchangers (HME) has been limited. Two hospital-based HTA units joined their expertise to assess the opportunity of providing HMEs to more patients, depending on their clinical characteristics.

METHODS:
Their joined assessment rested on a systematic review (SR) and a field assessment. The systematic review aimed at assessing the efficacy, clinical effectiveness and safety of various types of stoma covers. The field inquiries intended to assess the perceptions of clinicians and managers towards stoma covers in clinical practice.

RESULTS:
Twenty-seven studies were included in the SR. Most of them appraised the clinical effectiveness or safety of HME filters. Their methodological quality was very low with potential conflicts of interest whereas many studies were financed by the industry. The heterogeneity of study designs, expected outcomes and paucity of comparative studies prevented the pooling of results. Industry sponsorship appeared to be an important issue, since 17 of the included studies were sponsored. The SR did not provide conclusive evidence concerning the efficacy, clinical effectiveness and safety of the various types of stoma covers.

The field inquiries intended to assess the perceptions of clinicians and managers towards stoma covers in clinical practice. It showed that industry representatives are quite active in clinical settings, promoting their products. Clinicians’ opinions and preferences were coherent with the systematic review main observations: in a context where the quality of the evidence is low, clinicians’ recommendations of stoma protectors for laryngectomized patients are mainly based on their professional experience and academic training.

CONCLUSIONS:
Future research should aim at defining objective criteria adapting the choice of a stoma protector to laryngectomized patients’ condition.

OP75 Facts And Values In HTA: The Case Of Non-Invasive Prenatal Testing

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ABSTRACT SUMMARY:
An analysis of the fact-value relationship in HTA reports on non-invasive prenatal testing showed that the pivotal role of values in defining what counts as relevant evidence, and why, is rarely acknowledged. Recognizing that abstract values always need specification in order to reach concrete cases opens up new opportunities for exploring in what way values are affected by healthcare technologies.

INTRODUCTION:
Health Technology Assessment (HTA) is where facts and values meet: the evidence that is considered relevant to the assessment of a technology depends on the value framework used. In the context of the European project VALIDATE (Values
in doing assessments of healthcare technologies), we assessed to what extent this interplay between facts and values is acknowledged in HTA reports on non-invasive prenatal testing (NIPT). Our aim is to gain a better understanding of this fact-value relationship, and to contribute to the development of capacity for ethical analyses in HTA.

METHODS:
Five reviewers independently analyzed HTA reports on NIPT, obtained from the National Institute for Health Research (NIHR) HTA database, by answering a structured questionnaire on: (i) arguments, values, and conclusions; (ii) relations between values and collected evidence; (iii) operationalizations of the values involved. Ethical argumentation was analyzed using the method of specifying norms. This method holds that for general, abstract ethical principles to reach concrete cases, principles need to be specified in such a way as to achieve maximal coherence between different value commitments and practice. The results of the analysis were discussed in joint meetings to arrive at a consensus on interpretation.

RESULTS:
Our results show that the pivotal role of values in defining what counts as relevant evidence and why, is rarely acknowledged. The same holds for the importance of specifying values as a means to achieve greater coherence between the use of healthcare technologies and a range of values.

CONCLUSIONS:
There is ample room for improvement in clarifying the role of values in HTA: they can serve to explain and justify what evidence is considered relevant to the assessment of a healthcare technology. Recognizing that abstract values need specification in order to reach concrete cases opens up new opportunities for exploring in what way values are affected by healthcare technologies.

OP76 HTA And The Right To Health Care: Lessons From South Africa

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ABSTRACT SUMMARY:
The constitutional right to health care has implications for the development of a value framework to guide HTA decision making. We present findings from a content analysis of landmark South African Constitutional Court cases related to the right to access health care. We discuss the ethical values and trade-offs described in the court opinions.

INTRODUCTION:
HTA should consider context-specific values, especially as it becomes increasingly important for achieving high-quality universal health coverage. As South Africa moves toward National Health Insurance, there is a commitment to implement HTA and work is underway to develop an ethics framework for HTA decision making. Given that South Africa’s Constitution includes a right to access health services, the country’s body of constitutional law can and should inform the identification and interpretation of context-specific ethics principles for consideration in this framework.

METHODS:
We identified landmark cases using the Southern African Legal Information Institute database and search terms related to health care and relevant sections of the South African Constitution. We reviewed all cases to identify ethical principles and trade-offs central to each decision. Findings were
reviewed by an independent expert in South African human rights law who suggested additional cases. Synthesized findings were mapped to the principles comprising the provisional ethics framework.

RESULTS:
The cases suggest that vertical and horizontal equity considerations should sometimes outweigh effectiveness and affordability and should apply to both specific populations and health conditions. While appropriateness and health system capacity are important considerations, insufficient capacity may not justify failing to provide care for those most in need. Effectiveness, efficiency, or affordability considerations may need to meet a higher bar to outweigh negative impacts on respect and social relationships that can follow from failing to provide access to health care. The cases also emphasize the importance of a systematic and evidence-based process for allocating resources toward progressive realization of the right to access health care services, potentially providing additional support for the use of HTA.

CONCLUSIONS:
The right to health care in South Africa has important implications for the development of a value framework to guide HTA decision making. Designing HTA consistent with this right may improve HTA legitimacy.

OP77 Nudging In NIPT: Ethical Guidance

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ABSTRACT SUMMARY:
There are normative challenges with the application of Non-Invasive Prenatal Testing (NIPT) in universal coverage systems. Further challenges, however, also arise with respect to choice design and nudging when putting NIPT into practice. Nudges used in NIPT are analyzed and an ethical guidance along the lines of accountability for reasonableness is suggested.

INTRODUCTION:
Non-Invasive Prenatal Testing (NIPT) has already established itself in many European countries (either via public or private institutions) as an option at hand that pregnant women can choose. Based on mother’s blood, NIPT claims to “quasi-diagnose” among other things the presence of chromosomal abnormalities caused by an aneuploidy of a chromosome (such as Trisomy 13, 18, and 21). Apart from normative issues concerning the question of “whether to fund NIPT by universal coverage”, NIPT gives rise also to normative issues concerning the question of “how to put NIPT into practice” – the analysis of which is the goal of this study.

METHODS:
Complemented by a hand search, we have conducted a systematic literature search in Ovid MEDLINE and PsycINFO for combinations of NIPT and nudging, NIPT and participation, and NIPT and ethics. Screening was based on content analysis of titles, abstracts, and articles. Writing of the study is in progress.

RESULTS:
83 references were identified and 39 were included. The main instance of nudging (or also of unintentional choice design) was the use of default bias (the application or reduction of friction cost/hassle factor) that influenced the turnout to NIPT. In establishing NIPT in universal coverage systems, further potential biases identified were the use of authority bias, bandwagon effect, sunk-cost bias, and framing effect. The core ethical challenges with nudging in NIPT derive from the lack of transparency of the methods applied and the challenge of paternalism.

CONCLUSIONS:
Along the line of accountability for reasonableness,
4 specific recommendations are suggested as the ethical guidance to using the tool of nudging in NIPT: 1) Decision-makers should recognise that some choice design is inevitable. 2) Nudging should be done transparently. 3) Rationales for nudging should be publicly accessible. 4) Revision procedure should be put in place.

OP78 Picturing ELSI+: Mapping Ethical, Legal, Social And Value Issues

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ABSTRACT SUMMARY:
Incorporating ethical, legal, and social issues, and patient values (ELSI+) into HTA is challenged by lack of conceptual clarity. Using concept mapping, we identified 5 key “ELSI+” clusters: patient preferences and experiences, patient quality of life and function, patient burden/harm, fairness, and organizational issues. Conceptual consonance, rather than academic disciplines, provides a more coherent framework for considering ELSI+ in HTA.

INTRODUCTION:
Health technology assessment (HTA) is value-laden. Consideration of ethical, legal, and social issues (ELSI), and patient values (ELSI+), is challenged by lack of conceptual clarity and the multi-disciplinary nature of ELSI+. This study used concept mapping to identify key concepts in the ELSI+ domain and their interrelationships.

METHODS:
We conducted a scoping review using Medline and EMBASE (2000-2016, English-language) with search terms related to ethics, legal/law, social/society/patient, “ELSI”, and HTA/technology/assessment. Items from the review and additional items from an expert brainstorming session were consolidated into 80 ELSI+-related statements which were entered into Concept Systems® Global MAX software. Participants (N=38; 36% researchers, 21% academics; 42% self-identified as HTA experts) sorted the statements into thematic groups that made sense to them, and rated the statements on their importance in decision making about adoption of technologies in Canada: 1 (not at all important), 5 (extremely important), 2, 3, and 4 (unlabeled). We used Concept Systems® Global MAX software to create and analyze concept maps with 4 to 16 clusters, which were reviewed by the study team.

RESULTS:
We selected the map with 5 clusters because its clusters represented different concepts and the statements within each cluster represented the same concept. Based on the concepts, we named these clusters: patient preferences and experiences, patient quality of life and function, patient burden/harm, fairness, and organizational. The highest mean importance ratings were for the statements in the patient burden/harm (3.82) and organizational (3.92) clusters.

CONCLUSIONS:
This study suggests an alternative approach to conceptualize the domains originally described as “ELSI+”. We identified clusters of relevant concepts that focus on patient perspectives (preferences, experiences, quality of life, function), burden and harm, fairness (individual and societal), and organizational issues. Basing ELSI+ on conceptual consonance, rather than academic disciplines.
or traditions, provides a framework for coherent consideration of ELSI+ in HTA.

OP79 Improving Public Understanding Of Scottish Medicines Consortium Advice

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ABSTRACT SUMMARY:
The Scottish Medicines Consortium (SMC) appraises all new medicines and publishes detailed technical advice documents aimed at healthcare professionals. The decisions are not easily understandable from the patient/public perspective. To address this ‘Decision Explained’ plain English summaries have been developed and are published alongside the technical advice.

INTRODUCTION:
Transparency of processes and decision making is important to SMC. An independent review of access to new medicines in Scotland in 2016 recommended that SMC should review its communication of decisions with a view to achieving greater transparency. SMC therefore began to develop plain English summaries of advice on each new medicine.

METHODS:
A multi-stakeholder approach was adopted to develop the summary documents, with patient groups involved. Firstly, a review of communications for the public from other HTA organisations was conducted. The public involvement team then held a workshop to find out what patient groups felt would be important to include when explaining SMC decisions to patients and the public. The process was also informed by reviewing examples of good practice from other parts of NHSScotland, including patient versions of SIGN (Scottish Intercollegiate Guidelines Network) clinical guidelines. Exemplar documents were then developed and feedback sought from the Public Involvement Network (PIN) Advisory Group.

RESULTS:
A format was developed for the SMC ‘Decision Explained’ summaries consisting of a question and answer format for each medicine decision in a two page document. The summaries were piloted internally over a six month period, during which the development process and layout were finalised. Since September 2018 these summaries have been published on the website alongside the technical advice.

CONCLUSIONS:
Partnership working between SMC and patient groups has helped to develop a new way of communicating SMC’s decisions to patients and the public in a clear way, helping to improve transparency and understanding. Evaluation of the summaries will be undertaken from six months of publication.

OP80 Impact Of Patient Group Participation At SMC Committee Meetings

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ABSTRACT SUMMARY:
Since July 2017 the Scottish Medicines Consortium (SMC) has encouraged patient group representatives to participate in the decision-making committee meeting. The process was developed to allow active and valued contributions to discussions that precede decision making. Thematic analysis of these contributions has been undertaken. Patient groups report that discussions may now better reflect the lived experience and enrich committee deliberations.

INTRODUCTION:
The Scottish Medicines Consortium (SMC) encourages patient group (PG) representatives to participate in the decision-making committee meetings, answering questions from committee members and providing points of clarity throughout discussions if required. In a continuous improvement approach the process and the participant experience is continually evaluated to monitor impact and emerging themes.

METHODS:
The interactions between committee members and PG representatives are recorded in writing by the public involvement team to monitor the questions or points of clarity raised. These interactions were analysed using thematic analysis to look for emerging themes. Following the meeting, PG representatives are invited to complete an online survey on their experience of working with SMC.

RESULTS:
From July 2017 to October 2018, 36 PG representatives have attended committee meetings for the discussion of their submission. 17 PG representatives were asked by committee members to contribute. Key themes that have emerged to date include insight into the impact of living with the condition on quality of life and how a new medicine may affect this. Survey feedback has been positive with participants reporting that patient engagement has been strengthened, and that the patient voice is heard, valued and supports committee members in making fully informed decisions. PG representatives expressed a willingness to participate again. Feedback also highlighted that the preparatory support offered to PG representatives by the public involvement team is highly valued.

CONCLUSIONS:
Patient group participation in committee meetings has been received positively by PG representatives. They report that discussions relating to quality of life impact of medicines on patients and carers better reflect the lived experience, enriching committee’s deliberations. This demonstrates SMCs commitment to openness and transparency and has strengthened patient engagement in our processes.

OP81 Building Technical Capacity To Promote Patient Involvement In HTA

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ABSTRACT SUMMARY:
In December 2017, a Patient Involvement Interest Group was created in the RedETS Annual
conference. It started as a voluntary group of HTA methodologists interested in Patient Involvement (PI). The objective of the Group is to support and facilitate PI in the HTA. The main aim of this communication is to present its main lines of work.

**INTRODUCTION:**
In December 2017, a PI Interest Group was created in the RedETS Annual conference. It started as a voluntary group of HTA methodologists interested in PI. The objective of the Group is to promote and facilitate PI in HTA. With the support of the Spanish Ministry of Health and the RedETS Council the Interest Group grew to at least 1 member for each of the 8 RedETS regional agencies and units. It currently has 22 members. The PI Interest Group works in periodic on-line meetings and an annual off-line meeting to establish a space for experiences exchange and reach consensus on main issues regarding PI.

**METHODS:**
The Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS) published a strategy to facilitate effective and efficient patient involvement (PI) in HTA processes in 2017. The long-term objective is to mainstream PI in all RedETS products. This strategy was built on a literature review and a qualitative study with semi-structured interviews. The interviews detected capacity building needs for technicians and methodologist in the network to be able to actively engage patients in HTA reports.

**RESULTS:**
Since the kick-off meeting the PI Interest Group has worked in a number of activities. The main lines of action since its creation were: 1) evaluation of PI process in RedETS HTA reports in 2017 and in current reports. 2) Discussion on main methodological and procedural aspects, and feasibility of different patient participation approaches. 3) Development of technical protocols and templates to facilitate PI 4) the creation/adaptation of educational materials for patients and 5) Translation of the HTAi Glossary for patients to Spanish.

**CONCLUSIONS:**
Peer-to-peer learning processes can foster technical capacity of HTA methodologist in the Spanish HTA Network and may favour the implementation of the PI strategy.

### OP82 An Economic Evaluation Of Mobile Messages Aided Smoking Cessation In [...] 

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**ABSTRACT SUMMARY:**
Mobile health behavior change messages adding to the existing smoking cessation services in Thailand yield better health outcomes and save future healthcare costs from smoking-related diseases. Mobile health behavior change messages were recommended to include as smoking cessation supports in Thailand, due to low cost of implementation and widely targeted population.

**INTRODUCTION:**
Smoking is a leading cause of health problems and economic loss. Smoking interventions have been implemented in Thailand but prevalence of smokers remains high at nineteen percent and economic burden was seventy-five billion Thai baht (THB) (USD two point three billion). Mobile health behavior change messages including
capability (C), opportunity (O), motivation (M) or a combination (CO, CM, OM, and COM) and placebo were developed to support smoking cessation in Thailand. Effectiveness was evaluated under a factorial randomized controlled trial (ISRCTN16022919) of interventions compared with existing smoking cessation services. This economic evaluation aimed to conduct alongside trial to support decision making towards inclusion of mobile health behavior change messages into smoking cessation program in Thailand.

METHODS:
A Markov model was developed to extrapolate the lifetime costs and outcomes in terms of quality-adjusted life years (QALYs) of smoking-related diseases including lung cancer, ischemic heart disease, stroke, and chronic obstructive pulmonary disease. All future costs and QALYs were discounted at three percent annually. Societal perspective was adopted, so direct medical and non-medical costs were included. Effectiveness of intervention was derived from the trial. Uncertainty of parameters retrieved from different sources was also performed by one-way sensitivity analysis and probabilistic sensitivity analysis.

RESULTS:
Mobile health behavior change messages were cost-saving at ceiling threshold at THB 160,000 (USD 4,852) per QALY gained. However, adding more behavior change techniques reduced the value for money, owing to lower effectiveness. Incremental cost-effectiveness ratios (ICERs) were slightly different among sex, moreover, ICERs were higher or more cost-saving as age increasing. Utilities of healthy smokers and quitters were the most influential parameters with a large impact on ICERs.

CONCLUSIONS:
Providing mobile health behavior change messages was shown to be a cost-saving intervention and was recommended to be added to the existing smoking cessation services in Thailand.

**OP83 Iterative Formative Research Informing Primary Care Education Design**

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**ABSTRACT SUMMARY:**
An iterative approach to formative research to inform the design and development of Australian primary care educational programs, including rapid collation and prioritisation of information, is being piloted by NPS MedicineWise. Insights from, and evaluation of, this pilot which is being trialled for a 2019 educational program, will be presented.

**INTRODUCTION:**
NPS MedicineWise delivers nationwide educational programs for Australian general practitioners and community pharmacists. Extensive searching and synthesis of published and grey literature is undertaken to inform program design and development. However, this formative research process is lengthy, labour intensive and attempts to pre-emptively answer questions that could arise during design and development, prompting a process re-evaluation.

**METHODS:**
A more targeted and iterative process is being piloted entailing:

- rapid collation (two weeks maximum) of basic contextual information into a pre-scoping briefing document including high-level statistics on medicines or test usage, key guidelines identification and collation of findings from
relevant government and stakeholder reports
- an internal advisory group reviewing the pre-scoping brief and identifying the highest priority research questions that must be answered to inform the design and development of the educational program
- iterative work to answer the highest priority research questions with findings provided back to the advisory group every fortnight. This involves ad hoc search methods and snowballing techniques to identify the most pertinent literature quickly
- iterative feedback from the advisory group as to whether the resulting work is adequate for program design and development or whether further information is required, and reprioritisation of the work plan if necessary
- completion of the formative research process within 4–5 iterations.

Evaluation of the new approach involves surveys of staff undertaking the formative research, the advisory group and staff involved in design and development. Administrative data on staffing and costs using the new approach will be compared with previous data.

RESULTS:
Insights from, and evaluation of, this pilot which is being trialled for a 2019 educational program, will be presented.

CONCLUSIONS:
Preliminary findings suggest it can rapidly provide appropriate information to inform program design and the iterative approach has allowed greater responsiveness to changing advisory group priorities and process improvements.

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OP84 Collaborative Program To Improve Early Management Rheumatoid Arthritis

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ABSTRACT SUMMARY:
A multidisciplinary co-design approach was used to develop and implement a program to improve early management and quality use of medicines (QUM) for people with rheumatoid arthritis (RA) in Australia. A range of educational interventions were implemented for different audiences with high reach and good uptake and feedback.

INTRODUCTION:
Optimal rheumatoid arthritis (RA) management requires coordinated management and consistent communication by health practitioners with patients. Suboptimal methotrexate use is a factor leading to increased use of biological disease modifying antirheumatic drugs (bDMARDs), which account for significant government drug expenditure.

A multidisciplinary co-design approach was used to develop and implement a program aiming to improve early management and quality use of medicines (QUM) for people with RA in Australia.

METHODS:
Literature review and key informant interviews identified broad potential QUM issues in RA management. An initial exploratory multidisciplinary meeting prioritised QUM issues, identified audiences and perspectives, and scoped focus areas to address with education. Iteratively through
co-design meetings and activities, program objectives were agreed, barriers and enablers for change explored, characteristics of intervention activities considered and rated, and program products developed and reviewed. Program evaluation included participation and distribution data, surveys and interviews, and will include analyses of general practice and Pharmaceutical Benefits Scheme (PBS) data.

RESULTS:
QUM issues addressed include: [1] timely initiation of conventional synthetic (cs) DMARDs; [2] appropriate use and persistence with csDMARD therapy, especially methotrexate; and [3] clarity around professional roles and best practice for prescribing, dispensing, and monitoring DMARDs, and managing lifestyle factors and other risks associated with RA.

The educational program (October 2017 to June 2018) included: an article promoting key messages (email to ~115,000 health practitioners), prescriber feedback report based on PBS data (to all Australian rheumatologists), RA action plan (completed by health practitioners for consumers), interactive case study (553 participants), visits to 1200 pharmacies promoting key messages, multidisciplinary webinar (431 live and 366 on-demand), fact sheets for consumers available through MedicineWise app (medicine management app for consumers), and social media activity.

CONCLUSIONS:
A multidisciplinary co-design process has provided a model for developing a multifaceted QUM program incorporating and addressing multiple perspectives.

OP85 Persistence Leads To Ongoing Decreases In Primary Care Antibiotic Use

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ABSTRACT SUMMARY:
In 2012, NPS MedicineWise implemented a five-year national educational program for consumers, general practitioners (GPs) and pharmacies to reduce antibiotic use in Australian primary care. Surveys have demonstrated improvements in consumer knowledge and analyses of antibiotic prescriptions and use have shown ongoing reductions in antibiotic prescribing at a national level.

INTRODUCTION:
Australia has had high rates of antibiotic use in primary care. Consumer and health professional knowledge and practices in the community vary. In 2012, NPS MedicineWise implemented a five-year national educational program for consumers, general practitioners (GPs) and pharmacies to reduce antibiotic use in Australia.

METHODS:
For consumers, a social marketing approach was used focusing on the winter months. Strategies leveraged collectivism, nudge theory, celebrity endorsement and co-creation and used multiple communication channels. For health professionals, interventions were most intense in 2012 with additional activities implemented each year including face-to-face educational visiting, audits, comparative prescribing feedback, case studies and point-of-care materials.
Surveys were conducted periodically to evaluate changes in knowledge and awareness. Pharmaceutical Benefits Scheme (PBS) claims data were analysed. Organisation for Economic Co-operation and Development data was used to compare Australian antibiotic per capita consumption to other countries. Time series analyses were used to estimate the cumulative program effect comparing observed and expected monthly dispensing volumes of antibiotics commonly prescribed for upper respiratory tract infections (URTIs), had interventions not occurred.

RESULTS:
Between 2012 and 2017, GP antibiotic PBS prescriptions reduced by 18.4 percent. Antibiotic DDDs per 1000 inhabitants reduced from 23.7 in 2012 to 18.4 in 2016, similar to Norway (18.6 in 2016) and UK (18.7). Time series modelling estimated 24.8 percent fewer GP antibiotic URTI prescriptions by 2017 versus no program.

Consumer survey results indicated increased awareness of antibiotic resistance (fifty percent in 2011, seventy-four percent in 2017) and the minority expect/request antibiotics for URTIs (twenty-two percent in 2017).

CONCLUSIONS:
A five-year national educational program with multiple and repeated interventions for health professionals and consumers has resulted in ongoing reductions in antibiotic use in primary care.

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ABSTRACT SUMMARY:
Publicly available utilisation data can be used to inform targets for primary care educational programs addressing inappropriate use of medicines and medical tests. Australian Pharmaceutical Benefits Schedule/Medicare Benefits Scheme data were extracted and trends explored to identify signals of potential inappropriate use. Several medicines and medical tests were detected as possible intervention targets based on high volume or expenditure growth.

INTRODUCTION:
NPS MedicineWise delivers nationwide educational programs to improve quality use of medicines and medical tests in Australia. Targeted horizon scanning approaches are required to detect and address emerging challenges in the healthcare landscape such as overutilisation and unexpectedly high expenditure on medicines and medical tests. Publicly available utilisation and expenditure data from the Australian Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) may provide insights into identifying potential areas for intervention.

METHODS:
Five financial years (2013-18) of publicly available PBS/MBS data was extracted from Australian Government websites and clustered according to medicine class, disease groups or anatomical therapeutic chemical classification (ATC). Usage and expenditure trends were explored with signals of potential inappropriate use identified as unusual spikes or changes.

RESULTS:
PBS data showed two fixed dose combination inhalers for respiratory conditions, three direct oral anticoagulants, four analgesics (including opioids) and two blood glucose lowering agents had high
volume and expenditure growths in the 2016-17 financial year. Cholesterol-reducing medicines and anti-hypertensives also commonly had high utilisation growth. The highest growth classified by ATC level two codes were for urologicals. These signals were collated into themes of stroke prevention, cardiovascular, respiratory, pain management and type two diabetes. MBS data on pathology tests showed viral and bacterial testing had the highest growth, followed by vitamin B12 testing and vitamin D testing. Magnetic resonance imaging had the highest growth in expenditure and volume of services of the various imaging modalities and X-ray of the lower leg had the highest volume of services.

CONCLUSIONS:
Several medicines and medical tests were detected as possible targets for interventions based on high volume or expenditure growth. Themes identified from the data can then be further investigated and contextualised to inform topic areas for primary care education to support quality use of medicines and medical tests.

INTRODUCTION:
The objective of this study is to conduct a systematic analysis of the philosophical presuppositions underlying generic preference-based quality of life (QoL) measures so as to bring out the ethical implications of using a particular measure in HTA.

METHODS:
We conducted a conceptual analysis of QoL measures used in health economic evaluation. First, we looked at the conceptualization of QoL and searched for information about theories of well-being or health justifying the concepts measured. Secondly, we examined how QoL was operationalized and specifically whether the measurement represents objective or subjective QoL. An assessment is more objective (or less subjective) the more independent it is from the desires, preferences, and feelings of the person in question.

RESULTS:
We included the QWB, HUI3, EQ-5D, SF-6D, AQoL-8D, 15D, ICECAP-A, ICECAP-O, and ASCOT for adults and older people, and the EQ-5D-Y, 16D, 17D, CHU-9D, AQoL-6D, QWB and HUI3 for children. Some developers, for example of the QWB, EQ-5D, and SF-6D reference the WHO’s definition of health. More recent measures focus on broader well-being, including elements such as flourishing and autonomy (e.g. ICECAP measures) referencing the capability approach. Measures include a particular mix of objective and subjective QoL indicators in their operationalization. Selecting a measure with a high level of subjectivity (e.g. ASCOT, AQoL-8D, CHU-9D) implies value priority to individuals’ judgements of pleasure, desire and meaning. A potential implication of such measures is, for example, that patients who have adapted
their judgement of their disease or impairment, and report high levels of QoL (e.g. levels of satisfaction) despite living with a severe illness or disability, may be disadvantaged in resource allocation decisions.

CONCLUSIONS:
Through an identification of the salient differences between and commonalities of the QoL measures, the analysis brings out the normative and ethical implications of QoL measurement for HTA. We conclude with a discussion of some of the limitations of existing QoL measurements and discuss possible avenues for improvement.

OP88 Digital Approaches For RCT Recruitment Or Retention: A Systematic Map

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ABSTRACT SUMMARY:
Recruitment and retention of participants in randomised controlled trials is challenging, and is why many RCTs fail or are not completed on time. Digital approaches such as social media, data mining, email or text messaging could improve recruitment and/or retention, but how well they match these purposes is unclear. We used systematic methods to map the digital approaches that have been investigated during the past 10 years.

METHODS:
We searched Medline, Embase, other databases, the Internet, and relevant web sites in July 2018 to identify comparative studies of digital approaches for recruiting and/or retaining participants in clinical or health RCTs. Two reviewers screened references against protocol-specified eligibility criteria. Studies included were coded by one reviewer (with 20% checked by a second reviewer) using pre-defined keywords to describe characteristics of the studies, populations and digital approaches evaluated.

RESULTS:
We identified 9133 potentially relevant references. Screening and mapping are ongoing. Interim results for 37 included studies (of approximately 100 anticipated in the final map) indicate that 97% of studies investigated recruitment but only 16% investigated retention. Study areas included health promotion and public health (32%), cancer (14%), and mental health (8%). Most study designs were observational (81%). The most frequent digital approaches for recruitment were social media (46% of recruitment studies), internet sites (49%), and/or email (35%); and for retention were email (100% of retention studies) or text messaging (60%). Time and costs of recruitment were reported in 33% and 25% of recruitment studies respectively, but time and costs of digital retention approaches were not reported.

CONCLUSIONS:
A wide range of digital approaches have been studied, more for RCT recruitment than for retention, across a range of clinical and public health areas. Full results and the implications of
OP89 Conference Abstract Searching In NICE Health Technology Appraisals

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Searches of conference abstracts reported in 91 NICE technology appraisal company submissions for cancer interventions (2013 until 2018) were extracted. Abstract searching in both database and website sources were compared. Embase has better coverage of cancer conference abstracts than the Web of Science but searching databases alone are inadequate due to restricted access to the latest abstracts and limited indexing.

INTRODUCTION:
The NICE guidelines manual recommend that MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials should be prioritised for searching for reviews of the effectiveness of pharmacological interventions. Additionally, searching trial registries and conference abstracts are recommended to identify ongoing or unpublished research. However, the approaches to searching conference abstracts have not been previously studied. The aim is to analyse searches of conference abstracts reported in NICE Technology Appraisal (TA) company submissions for cancer interventions from 2013 until September 2018.

METHODS:
The company submissions were searched and accessed via the NICE technology appraisal guidance website. The sources used to find conference abstracts were identified from the company clinical effectiveness review search methods and appendices. Conference abstract searching in both database and website sources were compared.

RESULTS:
124 (31%) out of 394 TAs were cancer TAs. 91 TAs were completed or updated between 2013-2018 which covered 18 cancer categories and 52 different named technologies. Technologies to treat lung cancer was the most frequently appraised in the last 5 years. Nivolumab was the most frequently appraised technology. 70 (77%) out of 91 company submissions reported searches for conference abstracts. 58 (83%) reported supplementary searching compared with 11 (17%) searched either/both Embase and the Web of Science Conference Proceeding Index. A total of 54 supplementary sources were search which ranged from 1 and 11 per TA (average 4 sources). ASCO and ESMO were the most frequently searched sources.

CONCLUSIONS:
Whilst Embase has better coverage of cancer conference abstracts than the Web of Science, searching databases alone are inadequate. Supplementary conference websites should be searched for reasons such as access to the most recent abstracts and incomplete indexing of titles within databases. A wide range of cancer specific sites exists although the impact of broad discipline sites (e.g. ASCO) versus topic specific sites is unclear.

OP90 Robotic Surgery’s Value: When The Evidence ‘Fuels’ The Controversy

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ABSTRACT SUMMARY:
One might expect, with the growing body of evidence, that justification for decisions on the acquisition, procurement, and (public) provision of robotic surgery improve. However, our investigation showed that published studies have not eliminated the dispute on whether da Vinci surgery, given the costs incurred, is worth it. Controversy is all-pervading: value varies widely, and the jury is still out.

INTRODUCTION:
We investigated qualitatively the value profile of the da Vinci® surgical robot after fifteen years of dissemination, practice, and research. We aimed to understand whether the swiftly-growing body of published studies on robotic surgery can now, i.e. beyond an early stage, guide decisions on the acquisition, procurement, and (public) provision of this innovation.

METHODS:
Drawing on Science and Technology Studies perspectives, we conducted a constructive technology assessment to outline controversial value issues. We explored both the formal arena (published studies) and the discursive arena (stakeholders’ perspectives in the Netherlands). Scientific literature between 2013-2016 was studied, and 28 in-depth interviews were conducted with a wide range of stakeholders involved in the introduction of robotic surgery in the Dutch health care system.

RESULTS:
This study shows that the literature, including comparative effectiveness research and even randomised trials, has not provided uncontested guidance on the merits of robotic surgery, but served rather as a reservoir of disputes.

Stakeholders in practice also present fairly controversial views on whether robotic surgery’s value – given the costs incurred – justifies its spread/use in clinical care. Beside resonating debates in the literature, many respondents dissent from the current mainstream state of research and surgical practice. Controversy is all-pervading, having taken root in study results, methods, designs, and purposes of studies, down to what the very concept of ‘value’ constitutes. What was unclear a decade ago due to lack of evidence is now unclear because of controversies about evidence.

CONCLUSIONS:
Our analysis indicates the unlikelihood that additional research – amid the mantra ‘more research is needed’ – will resolve the controversy, insofar as the value attributes that matter to stakeholders have not been well-targeted. Striving to settle controversies remains a collective responsibility. The study underscores stakeholder deliberation to resolve, if not solve, controversies in face of the continuing spread of complex, advanced medical innovation.

OP91 Developing A Celtic Connections Regional HTA Alliance

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ABSTRACT SUMMARY:
This presentation describes the development of a ‘celtic connections’ regional HTA alliance between the Irish, Scottish and Welsh HTA bodies charged
with appraisal of non-medicine technologies. It demonstrates that relatively informal collaborations can be very productive and summarises areas where joint working has yielded early successes.

**INTRODUCTION:**
The Irish, Scottish and Welsh national HTA bodies (HIQA, HTAG, SHTG, HTW) have recently (2018) established a ‘celtic connections’ regional HTA alliance on on-medicine technologies. The primary purpose is to add value by realising potential economies of scale and scope in non-medicine HTA efforts.

**METHODS:**
A Memorandum of Understanding (MoU) was agreed to: formalise collaboration and partnership working; improve shared understanding of work programmes and processes; collaborate on and co-produce evidence reviews of mutual interest; increase both the volume and range of technology topics for which advice is developed in each nation; promote knowledge exchange; and enhance professional and personal development for each agency’s staff.

**RESULTS:**
Early benefits include: collaboration on one technology topic resulting in the production of bespoke guidance in 3 countries; an update of a partner’s rapid review; identification of a further potential topic collaboration (sacral nerve stimulation); a 6 month senior staff secondment; and reciprocal observer membership on each country’s national committees. Other general benefits have included: reduced duplication of effort; improved quality assurance through ‘critical friend’ peer review; enhanced access to methodological advice and a broader range of stakeholders; and development of a forum for discussion and peer support.

**CONCLUSIONS:**
The alliance offers real potential to optimise use of the scarce resources for non-medicine technologies across the three countries and increase evidence review and guidance volume through adapting or co-producing outputs. Longer term benefits are anticipated to include: improved knowledge exchange; advancing skills of staff; building and broadening capacity through shared learning and access to a wider professional peer group; improved staff recruitment and retention; production of joint publications and other modes of dissemination; and increased profile for each country’s work.

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**OP92 One Size Fits All? Will EU Cooperation On Assessments Improve HTA?**

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**ABSTRACT SUMMARY:**
In February 2018, the EC put forward detailed plans for greater European HTA harmonization by 2020. This research evaluates the impact of existing EU co-operation under EUnetHTA. We found that involvement in EUnetHTA JAs has not been correlated with either faster reimbursement or higher rates of positive outcomes by participating HTA bodies.

**INTRODUCTION:**
In February 2018, the EC put forward detailed plans for greater European HTA harmonization by 2020. Since 2005, EUnetHTA has supported collaboration between European Health Technology Assessment (HTA) organizations. EUnetHTA activities include piloting Joint Assessments (JAs): HTAs produced together by ≥4 different national HTA bodies. This research evaluates the impact of existing EU co-operation assessing whether drugs evaluated
under EUnetHTA JAs have received better/faster outcomes by participating national European HTA bodies.

METHODS:
Publicly-available information on EUnetHTA JAs for individual drugs were identified alongside the associated appraisals by NICE, SMC, IQWIG, TLV, and HAS (to 16/11/2018).

RESULTS:
Seven EUnetHTA JAs were identified, 5/7 were for oncology indications and 2/7 were orphan drugs. HAS were involved in 7/7, SMC in 4/7, NICE in 2/7, TLV in 2/7, and IQWIG in 1/7 JAs. Amongst completed national appraisals, NICE provided positive outcomes (defined as ”recommended”/”conditional”) for 4/6 JAs assessed, compared with 5/5 by SMC (“accepted”/”restricted”), 0/2 by IQWIG (any level of additional benefit), 3/3 by TLV (“recommended”/”recommended with restrictions”) and 0/7 by HAS (ASMR I-III). For the 14 completed national appraisals where the appraising HTA was also involved in the corresponding EUnetHTA JA, 50% resulted in a positive outcome after a mean delay of 231 days post EC-approval. For the ten completed national appraisals where the appraising HTA was not involved in the corresponding EUnetHTA JA, the recommendation rate was 60% after a mean delay of 235 days post EC-approval.

CONCLUSIONS:
To date, involvement in EUnetHTA JAs has not been correlated with either faster reimbursement or higher rates of positive outcomes by participating HTA bodies. However, the proposed joint European clinical assessments have the potential to significantly reduce duplication of work, accelerating time to reimbursement. Nevertheless, efforts for greater assessment collaboration will likely face significant challenges in aligning divergent national HTA decision-making criteria.

OP93 Collaboration Between HTA And Procurement: A Rapid Mixed-Methods Study

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ABSTRACT SUMMARY:
This study describes the research efforts involved in preparing an evidence-base to inform a Memorandum of Understanding (MOU) between the Irish Health Service HTA Group and procurement. The study involved a document review, a rapid literature review, a survey and a qualitative study. This MOU will underpin collaboration between the two independent national bodies on the procurement/assessment of medical devices.

INTRODUCTION:
The Irish Health Service (HSE) Health Technology Assessment Group (HTAG) aims to maximise the impact of its work by collaborating with HSE Procurement, formalised through an evidence-based Memorandum of Understanding (MOU). This study aims to inform the MOU.

METHODS:
A sequential mixed-methods study design was used. A rapid review of the literature identified no substantive body of evidence on collaboration between independent national HTA and procurement bodies. Personnel involved in HTA or procurement were invited by email to complete a survey, take part in an interview, or both. The quantitative and qualitative data were analysed using descriptive statistics and thematic analysis, respectively. Findings were integrated using a conceptual framework that examined the complementarity of HTA and procurement processes relevant to an MOU.
RESULTS:
Thirteen surveys were completed (response rate 13%). Eleven interviews (5 Ireland, 2 Canada, 3 UK, 1 New Zealand) were conducted between August and November, 2017. No formalised collaboration between independent national HTA and procurement bodies was identified. However in New Zealand, HTA and procurement are an integrated function of the Pharmaceutical Management Agency (PHARMAC). In other jurisdictions, successful ad hoc collaborations occurred where there was a clear need expressed by Procurement for additional evidence required for decision making, and where HTA personnel tailored their research approaches accordingly. Key themes to successful collaboration were relationships, communication, clear roles, rigorous research and ‘system support’. Good individual relationships and ready access/communication promoted successful outcomes. Successful outcomes included improved clinical practice, and major cost savings. Collaboration may be focussed on: innovative or established devices; specific types of HTA/research products; specific categories/specialties; or specific procurement departments.

CONCLUSIONS:
All participants considered collaboration to be beneficial but requiring good relationships and ’system support’. Furthermore, successful collaboration requires clarity regarding the purpose, parties involved, their roles, responsibilities, modes of communication, information to be shared, and the expected outcomes.

OP94 Surrogate Endpoints In HTA: A Methods Guidelines Review Across Europe

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ABSTRACT SUMMARY:
Surrogate outcomes facilitate faster technology adoption by speeding up the clinical trials. However, reliance on such outcomes carries important risks for coverage decisions. We conducted a review of how current European guidelines reflect using surrogate outcomes in cost-effectiveness analyses. Our findings suggest that most guidelines provide some level of recommendation for validating surrogate outcomes, but more harmonisation work is needed.

INTRODUCTION:
The ever increasing demand for early access to innovative therapies puts pressure on the process of evidence collection needed for cost-effectiveness evaluation, leading to increased reliance on surrogate outcomes instead of final, patient-relevant outcomes. Our aim was to explore existing methodological guidance for using surrogate outcomes in across European HTA (health technology assessment) agencies.

METHODS:
We reviewed publicly available guidelines from European HTA bodies in terms of their recommendations on the use of surrogate outcomes.

We screened all identified agencies for methods guidance on HTA and economic evaluations. We...
extracted relevant text and abstracted the data on the consideration of various aspects concerning the use of surrogate outcomes according to a predefined template.

RESULTS:
Of 40 European agencies identified with a published methodological guidance on the technology evaluation process, 27 agencies (67%) mentioned surrogate outcomes. In total, 40 documents from these 27 agencies were identified.

It appeared that guidelines from most jurisdictions have evolved in the recent years, and more agencies are now providing explicit recommendations on handling surrogate outcomes.

19 (47%) of the European documents appear to have based their advice on the use of surrogate outcome on the 2015 EUNetHTA guidelines for relative effectiveness assessment of pharmaceuticals (EUnetHTA. Endpoints used in Relative Effectiveness Assessment: Surrogate Endpoints, 2015). The most detailed methods guidelines for surrogates came from NICE (UK), DIMDI (Germany), IQWiG (Germany). As a comparison, similar Australian and Canadian guidelines contained text with a detail level equivalent or higher than most comprehensive European guidelines.

CONCLUSIONS:
Our review suggests that some two-thirds of European HTA agencies provide some form of methodological recommendations on how to handle surrogate outcomes. However, the wide variety in the level of detail suggests there still is a need for more explicit provisions to support future plans for joint European HTA processes.

OP95 Patient Reported Outcome Measures In Health Technology Decision Making

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ABSTRACT SUMMARY:
ICHOM emphasises the importance of disease-specific outcome measures. Regulators support this to some extent by publishing guidelines for certain indications in which disease-specific outcome measures are suggested. For HTA decision-making purposes the use of generic outcome measures are essential to compare between indications. However, disease-specific outcome measures may be used to assess added value for certain indications.

INTRODUCTION:
Regulatory bodies and Health Technology Assessment (HTA) agencies request clinical outcome measures to support their assessments for marketing authorisation, and pricing and reimbursement decisions. It is of additional value when these outcome measures actually matter to patients. We assessed the extent to which regulators and HTA require outcome measures that matter to patients, as defined by the International Consortium for Health Outcomes Measurement (ICHOM), in pharmaceutical decision making.

METHODS:
ICHOM guidelines for oncological indications were selected. We identified publicly available regulatory and HTA assessment guidelines from the website of the Food and Drug Administration (FDA), European Medicines Agency (EMA), European Network for...
Health Technology Assessment (EUnetHTA), the Dutch National Health Care Institute (ZIN), the National Institute for Health and Care Excellence (NICE), and Institute for Quality and Efficiency in Health Care (IQWiG).

RESULTS:
Of the fifty-one guidelines identified, twenty-four were included in the analysis. The FDA and EMA provided cancer specific guidelines for marketing assessments, as well as guidelines for lung cancer, breast cancer, and prostate cancer. All HTA agencies provided general assessment guidelines. ICHOM guidelines suggest which outcome measures to collect, when to do so and how to report them, while guidelines from regulators and HTA are more general. ICHOM suggests more patient reported outcome measures in disease-specific guidelines as compared to regulators. NICE and ZIN request that quality of life is collected using the EQ-5D, while ICHOM suggests disease-specific quality of life questionnaires.

CONCLUSIONS:
ICHOM stresses the importance of disease-specific outcome measures. This is supported by regulators by publishing disease-specific guidelines in some instances, such as breast cancer and lung cancer. On the other hand, HTA often request generic outcome measures to allow comparisons between indications. Disease-specific outcome measures could, however, be used to identify whether the outcomes of a new treatment actually matter to patients.

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ABSTRACT SUMMARY:
The number of times a clinical trial is cited is often used as a measure of its impact, but where and how these reports are being cited is much more important. This is an analysis to assess the meaningful impact of trials funded and published by the UK HTA programme over a 10-year period (2006-2015).

INTRODUCTION:
Citation analysis is a standard tool for measuring the impact and influence of scientific work. One purpose behind controlled trials is to answer clinical and policy questions and to contribute directly or indirectly (contributing to systematic review and meta-analyses) to the production of practice guidance. The citation of trials within systematic reviews and policy or guidance documents therefore represents an authentic and meaningful measure of impact.

METHODS:
All 136 randomized controlled trials published by the UK HTA programme in a 10-year period (2006-2015) were identified. Web of Science citation index was used to collect citation data relating to each trial. Altmetrics were used to identify additional policy and guidance documents. Citation data were collected and tabulated, and descriptive statistics produced. Additional data were collected for principal ‘spin-off’ publications.

RESULTS:
88% of trials were cited by at least one Cochrane or non-Cochrane systematic review or meta-analysis; 37% by at least one Cochrane review (90 Cochrane reviews in total); 85% by at least one non-Cochrane systematic review or meta-analysis (365 in total). 44% of trials were cited by at least one unique piece of published policy or guidance. Mean number of review citations per published trial: 25.30; mean

OP96 Assessing Impact Of UK Health Technology Assessment Programme Trials

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intrODUCtiOn:
The National Centre for Pharmacoeconomics (NCPE) assesses the cost-effectiveness of new drugs for which reimbursement by the healthcare payer, the Health Service Executive (HSE), is sought in Ireland. This research aims to create a systematic approach for the NCPE review group (RG) to assess each of the cost-effectiveness models submitted by the applicant by creating cost-effectiveness model appraisal guidelines.

MetHODs:
The RG consists of clinical, statistical and health economic expertise. In order to systematically appraise the HTA submission, which includes a cost-effectiveness model, clear guidelines on how each of the members of the RG can work together are required. The current members of the RG in the NCPE were given a draft of the guidelines created by the primary author, and additional feedback and testing was performed using the expert experience of the team. A version of the guidelines was tested for its usefulness.

resUlts:
Three checklists were created. The purpose of the first checklist is to evaluate if the cost-effectiveness model works correctly. The second checklist ensures that each of the assumptions included in the HTA dossier are the same as those included in the cost-effectiveness model. The final checklist validates the assumptions used in the cost-effectiveness model to ensure they are reasonable and appropriate for decision making. The final version of the checklists were validated by choosing cost-effectiveness models with known errors and/or discrepancies and testing that the issues were captured by the checklists.

COnClUsiOns:
These guidelines are not an exhaustive list of checks that should be performed, but are presented as the minimum requirements for consideration to be included with each RG assessment of the corresponding HTA submission. The guidelines will...
be constantly updated as the process evolves over time. The cost-effectiveness models should follow the National HIQA Guidelines for the Economic Evaluation of Health Technologies in Ireland.

OP98 Limitations In Health-Economic Guidance For Medical Devices

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ABSTRACT SUMMARY:
Medical devices are a diverse array of technologies that provide a unique array of challenges to health technology assessment (HTA). Medical device heterogeneity can make standardized guidance difficult, but this should not preclude attempts for improvement. Here a review of current, European health-economic guidance for medical devices is performed and recommendations for improvements collated.

INTRODUCTION:
Health technology assessment (HTA) includes consideration of health and economic factors, playing a key role in optimizing healthcare provision in Europe. Medical devices are an important contributor to both health outcomes and the cost of healthcare provision, yet they are rarely addressed in current guidance for health-economic evaluation. Our aim is to help improve assessment of medical devices via review of European health-economic guidelines and recent research.

METHODS:
Searches for European HTA guidelines were performed and where available were reviewed by two researchers working independently. Additionally, a systematic review of published literature focused on assessment of medical devices was conducted. English, German, or French literature published between 2000 and 2017 was analysed. The status of HTA guidance to date was subsequently reviewed in light of current research findings and suggestions made to help improve standardization.

RESULTS:
Of the 41 investigated European countries, 22 had official HTA guidance. Only 4 of 22 (18%) dedicated documentation to guidance specific to medical devices. Where differences between pharmaceuticals and medical devices were highlighted, specifics for health-economic assessment of medical devices were generally absent. The systematic review yielded 472 unique articles, 28 of which underwent full-text review. Issues surrounding medical device value assessment that commonly emerged were: limited evidence base, learning curve effects, organisational impact, incremental innovation, diversity of devices, dynamic pricing, and transferability. While identification of issues was ubiquitous, actionable suggestions on how to overcome them were less common. The most frequent recommendations were use of Bayesian methods, inclusion of real-world data, and modelling the learning curve. Key to implementation is determination of the medical device type and its impact duration.

CONCLUSIONS:
Current guidelines rarely address the needs of medical devices. Practical recommendations for improvements exist and provide opportunity to start discussion on how best to serve the medical devices field and improve the HTA process.
OP99 Musings On Equity, Opportunity Cost And Health Economic Evaluation

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ABSTRACT SUMMARY:
Health economic evaluation (HEE) has become an increasingly important decision support tool, and the implicit and explicit ways it quantifies the scope of costs and benefits included can impact on the resulting equity and opportunity cost of a decision. Understanding the way HEE guidelines can influence equity and opportunity costs is therefore important.

INTRODUCTION:
Health system decision making requires careful consideration of the tradeoffs between efficiency and equity, along with an understanding of opportunity cost, so that violations of horizontal equity are avoided and a satisfactory level of population health is maintained. Health economic evaluation (HEE) has become an increasingly important decision support tool, and the implicit and explicit ways it quantifies the scope of costs and benefits included can impact on the resulting equity and opportunity cost of a decision. Understanding the way HEE guidelines can influence equity and opportunity costs is therefore important.

METHODS:
This study compared five national HEE guidelines; those produced by: CADTH, IQWiG, NICE, PBAC, and ZIN. The guidelines were systematically compared to identify parameters that have the potential to affect equity and opportunity cost either implicitly (i.e., embedded in the methods or approaches) or explicitly (i.e., stated directly in the guideline).

RESULTS:
Variations in implicit equity and opportunity cost considerations were observed in all five guidelines, e.g., in the choice of method used and the selected perspective taken. Explicit impacts on equity or opportunity cost were observed in all but one of the guidelines (ZIN), e.g., end-of-life or ‘rule of rescue’ or other value judgements.

CONCLUSIONS:
Opportunity cost is not fixed, but rather, it depends on the specific outcomes and costs included in the HEE and any equity weightings that are assigned. For HEE to be fit-for-purpose to support decision makers, a jurisdictionally-appropriate consideration of equity and opportunity costs must be reflected in the HEE guidelines.

OP100 Cost-Effectiveness Analysis: Based On Real-World Data From China

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ABSTRACT SUMMARY:
Based on the real world data from Jiangsu Province, China, decision tree model was used to analyze the cost-effectiveness of malaria rapid diagnostic test (RDT), compared to the microscopy. The result implied that implement of RDT during the elimination phase is more cost-effective than its counterparts.

INTRODUCTION:
RDT is a potential alternative to microscopy since the former is easier to operation, and require
limited training. There are many studies focusing on the effectiveness evaluation of RDT in moderate or high endemic areas, while few researches pay attention to the economic value of RDT, especially under the elimination phase, like China. Our study aims to fill in this gap.

**METHODS:**
A decision tree model was constructed for three malaria diagnostic strategies (microscopy, RDT, series test of RDT and microscopy). The CEA was conducted from health sector and patient perspective. Data collection was conducted in Jiangsu Province from 2016-2018, and the indicators including the necessary cost of patients, the cases that be diagnosed correctly, prevalence, and so on. A cohort of 300,000 febrile patients entered the decision model to simulate the diagnostic trajectory over a year and calculate incremental cost-effectiveness ratio (ICER). Univariate sensitivity analysis was conducted to test the robustness of the results.

**RESULTS:**
There were little differences of effectiveness between microscopy (252 case), RDT (245 case) and series test (233 case). But the cost per confirmed malaria case was lower in RDT (US$7,912) than microscopy (US$12,018) and series test (US$8,294). Compared with RDT, microscopy diagnosed more cases with an ICER of US$155,135 per confirmed malaria case. Even considering 20 percent increase in RDT kit cost, the result of univariate sensitivity analysis show that RDT is still a cost-effective option. The results of CEA were not sensitive to antimalarial drug costs, even taking a 20-percent variation into account. Moreover, transportation expense paid by patients to see a doctor is a significant factor to affect the total cost of diagnosis strategy.

**CONCLUSIONS:**
Implementing RDT in the elimination phase is a cost-effective way contributing to the malaria control.

**OP101 Is Lung Cancer Screening Cost Effective? A Systematic Review**

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**ABSTRACT SUMMARY:**
Cost-effectiveness analyses are important to effectively inform policy makers. Evidence from developed countries demonstrated LDCT screening for lung cancer, implemented among population selected by ages and smoking history, were generally cost-effective, providing direction for less developed regions. Low frequency of LDCT screening for lung cancer could be given priority under limited budget.

**INTRODUCTION:**
Economic evidence for lung cancer screening around the world is still unclear. We aimed to systematically assess the status quo of economic evaluations on lung cancer screening worldwide and to provide reference for further research in China.
METHODS:
PubMed, EMBase, The Cochrane Library were searched to gather economic evaluation studies of lung cancer screening worldwide from inception to 30 June 2018. Quality of included studies were assessed. The ratio of incremental cost effectiveness ratio (ICER) to local gross domestic productivity (GDP) per capita were calculated.

RESULTS:
A total of 23 studies were included, with good quality, of which 22 from developed countries. 55 years old of starting age (11 studies) and 30 pack-years (18) at least of smoking history were common population selection criterion. Low dose computed tomography (LDCT) was only screening technology for evaluation, annual (17) and once-life time (7) screening as common frequencies. 20 studies reported ICERs for LDCT screening compared with no screening, of which 17 studies were below 3 times local GDP per capita, regarded as cost-effectiveness according to WHO’s recommendation. 15 and 7 studies reported ICERs for annual and once-life time screening, of which 12 and 7 studies supported their cost-effectiveness, respectively. Moreover, once-lifetime screening was more cost-effective than annual screening. However, the significant differences of cost-effectiveness among subgroups by starting age or smoking history were not observed.

CONCLUSIONS:
Evidence from developed countries demonstrated LDCT screening for lung cancer, implemented among population selected by ages and smoking history, were generally cost-effective. Such evidence could provide direction for less developed regions, but need to combine with local health resource. Under limited budget, low frequency of LDCT screening for lung cancer could be given priority. However, starting ages, smoking history and other components of screening strategy, need to be precisely evaluated based on local population characteristics.

OP102 How To Invest In Getting Cost-Effectiveness Screening Into Practice?

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ABSTRACT SUMMARY:
Cost-effectiveness gastric cancer screening are implemented slowly and sub-optimally in clinical practices. There is a necessity to inform decisions on how to invest best in public organizational screening under restraint health resources and capacity.

INTRODUCTION:
In 2017, more than 680 000 cases of gastric cancer happened in China, accounting for half of the total cases around the world. More seriously, most of them were detected on advanced stage or above. Despite of the essence of early diagnosis and great advances in endoscopic detection technology, the rate of early endoscopic screening is still very low and no public organizational screening was adopted in China. This study was to help inform decisions on how best to invest in public organizational implementation of gastric cancer screening (GSC).

METHODS:
Based on systemic review, expert consultation and data from statistical reports, we have developed an age-structured calibrated Markov cohort model to assess effectiveness and cost-effectiveness of endoscopic screening in high-risk Chinese population (≥40 years old). Then we used our model to examine GSC screening at ages 40-70 under individual or institutional payment, at
RESULTS:
Comparing to no screening, endoscopic screening under all 3 scenarios to prevent gastric cancer in the high-risk population well highly cost-effectiveness (< ¥183690/QALY gained), while endoscopic screening at ages 40-70 under reimbursement from public health program achieved the lowest cost-effectiveness (<1 ¥61230/QALY gained). For individual or institutional payer with a time horizon of ages 40-70, endoscopic screening was costly, and more clinical benefits achieved at ages >54.

CONCLUSIONS:
Models suggested that endoscopic screenings under any payment level was highly effective and cost-saving. These results can help health services make decisions on investment at different points of the public organizational gastric cancer screening based on the cost and value assessment of different payment levels.

OP103 Incorporating HTA In The Development Of A Clinical Care Pathway

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ABSTRACT SUMMARY:
Clinical care pathways (CPWs) provide a step-wise multidisciplinary care plan for patients with a health condition. They optimise patient outcomes and organisation of care by supporting evidence-based practice. As CPWs become increasingly utilised, there is a need to understand the added value and strategies to integrating HTA as part of CPW development. HTA can be pivotal to good quality CPWs.

INTRODUCTION:
Clinical care pathways (CPWs) provide a step-wise multidisciplinary care plan for patients with a particular health condition. Their aim is to optimise patient outcomes and organisation of care by supporting evidence-based practice. It therefore seems inevitable that health technology assessment should be incorporated within the development process of a CPW. As CPWs become increasingly utilised, there is a need to better understand the added value and strategies to integrating HTA as part of the development of a CPW.

METHODS:
We present a case study in which an HTA on corticosteroid injections and other treatments for low back pain was requested as part of the development of a CPW for chronic musculoskeletal pain. An initial literature search led to three initial key strategies to include HTA in CPWs described by Rehaluk 2016 (i.e., clarity of the organisational positioning of the HTA unit, strengthen partnerships and communication with stakeholders, explore gaps and tools to facilitate the use of HTA findings). A fourth strategy emerged during the project: tailoring the integration of contextual data with evidence from the literature, which was seen as a necessary precursor to Rehaluk’s third strategy.

RESULTS:
Furthermore, we found that the inclusion of HTA through these strategies contributes to the development of a CPW which meets seven of the ten criteria to evaluate the quality of a CPW outlined by the Cochrane Effective Practice of
Care group. Through a strength, weaknesses, opportunities, and threats analysis, we describe how each of the criteria were met and how this led to recommendations influencing our regional organisation of care.

CONCLUSIONS:
The inclusion of HTA in CPW development increases its capacity to directly influence organisation of care. Furthermore, as CPWs are more widely used, HTA can represent a pivotal vehicle to ensure good quality CPWs and thus bridge universal findings of HTAs to contextual realities.

OP104 Hospital-Based Health Technology Assessment In China

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ABSTRACT SUMMARY:
HB-HTA has become an increasingly important decision-making tool in China as it could provide evidence-based information for the decision of new technologies in terms of selection, access, and utilization. We aimed to review the development of HB-HTA and provided references for launching and promoting HB-HTA in China.

INTRODUCTION:
Hospitals need a formalized system to introduce new health technologies. Hospital-based health technology assessment (HB-HTA) has become an increasingly important decision-making tool in China as it could provide evidence-based information for the decision of new technologies in terms of selection, access, and utilization. We aimed to review the development of HB-HTA and provided references for launching and promoting HB-HTA in China.

METHODS:
We searched for and retrieved HB-HTA articles and policies in China from government websites and major Chinese literature databases such as CNKI and Wanfang. The development of HB-HTA was reviewed from the perspectives of government officials, hospital managers and scholars.

RESULTS:
The study found 18 relevant articles and 6 policies. National Health Commission, the former National Health and Family Planning Commission, promulgated a policy that required hospitals to establish a clinical technology assessment system and timely adjust the catalogue of clinical technology according to the policy. Hospitals have been using HB-HTAs in the management of medical consumables and purchasing of medical equipment. Scholars have discussed the organization, guiding principles and application values of HB-HTA in China. In September 2018, experts from government, hospitals, academia and enterprises achieved the Shanghai Consensus on carrying out HB-HTA in the area of medical equipment management in Shanghai.

CONCLUSIONS:
HB-HTA is still in its infancy in China. With basic consensus among experts and the efforts of all relevant parties, HB-HTA will become a bridge for the effective transmission of HTA results into evidence-based decision making at national regional, and hospital levels, bringing a higher level of population health, better patient experience and more reasonable costs of medical services.
OP105 Factors Affecting Horizon Scanning For Hospital-Based HTA

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ABSTRACT SUMMARY:
Horizon scanning is a function used by hospital-based health technology assessment for managing health technology (MedTech) innovations by providing information on the impact on the hospital organisation, the associated benefits, and risks and propose areas for future investments. This work presents the horizon scanning methodology used for informing the strategic MedTech investment for the expansion of a London-based pediatric Hospital.

INTRODUCTION:
The strategic MedTech investment for the expansion of a central London paediatric hospital must sustain its ambitions to remain a state-of-the-art hospital, whilst implementing recent and future MedTech innovations and taking into account spatial and financial limitations. HS is an important HTA tool to achieve these goals. To this end, we developed a methodology to help decide the suitability of investing in the following imaging-based MedTech: a hybrid theatre incorporating a biplane, intra-operative MRI (iMRI), multi-detector CT scanners, and an EOS imaging system and predict the complementary technologies required for the decade to come. These technologies not only require adequate spatial resources but a significant upfront capital investment.

METHODS:
Three sources of information were used: i) a literature search, selected journals and other horizon scanning resources that examined current efficiency, safety, and cost-effectiveness for the proposed technologies, ii) expert elicitation in the form of user-group meetings and one-to-one discussions with clinical and service management teams and iii) hospital data consisting of audit and information from capital equipment bids.

RESULTS:
With the exception of limited comparative data on iMRI (mainly including adults), little evidence exists to support investment in the proposed technologies. However, the decision of whether to adopt these technologies was influenced not only by existing evidence on the proposed technologies and associated cost but other factors such as local disease burdens, hospital staff requirements (training, expertise), space requirements for the new MedTech, and its impact on organizing healthcare services and hospital workflows. Complementary technologies associated with radiation monitoring image visualization and control were identified.

CONCLUSIONS:
Strategic MedTech investment requires a holistic approach that assigns equal weight to information arising by expert elicitation and hospital audit data with existing literature evidence. The decision for adoption is heavily influenced by the clinical expertise and hospital workflows.

OP106 the Xpert™ C. Difficile Kit In The Hospital Health Technology Assesmen

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ABSTRACT SUMMARY:
The Xpert™ Clostridium difficile kit is recommended for discrepant results in enzymatic test and was evaluated for incorporation in a teaching hospital. The performance of the available technology (immunoenzimatic test) was assessed in a clinical study. The total positivity and discrepancy rates were low, as the agreement to the IDSA recommendations for solicitation.

INTRODUCTION:
The Xpert™ Clostridium difficile kit (nucleic acid amplification test) is recommended for discrepant results in enzymatic test and was evaluated for incorporation in the Hospital de Clínicas de Porto Alegre. Besides the evaluation of the evidence, the performance of the available technology was assessed, with a low positivity rate observed in preliminary view. The aim of this study was to assess the agreement to the Infectious Diseases Society of America (IDSA) recommendations for enzyme immunoassay stool test submission and the discrepancy rate.

METHODS:
This is a retrospective cohort study conducted at a tertiary teaching hospital from March 15 to May 8, 2018. We included all consecutive tested patients that were submitted for enzyme immunoassay – glutamate dehydrogenase (GDH) plus toxin detection. Data referent to episodes of unformed stools in 24 hours, use of laxatives and mortality were registered. Statistical significance was tested by Fisher Exact test ($\alpha = 0.05$).

RESULTS:
138 consecutive patients were tested: 4 (2.9 percent) were positive for GDH and toxin (group III); 114 (82.6 percent) were negative for both (group I); 20 (14.5 percent) cases were discrepant, all being positive to GDH and negative for toxin (group II); there weren’t negative GDH and positive toxin cases. In group I, 33 (40.2 percent) of patients followed the IDSA guidelines (>3 unformed stools in 24h without laxatives), while group II and III followed in 3, representing respectively 20.2 percent and 100.0 percent ($p=0.03$).

CONCLUSIONS:
Only a minority of patients contemplated the recommendation of the IDSA for immunoenzymatic test requesting. These data can explain the low positivity rate at the hospital. Considering that discrepancy rate was low, and the uncertainty about the potential of the new test for changing infection control practices, Xpert™ was not recommended for incorporation.

OP107 Transition From Conventional Pathology Lab To Digital Lab: A Mini-HTA

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ABSTRACT SUMMARY:
Digital Pathology (DP), that incorporates the acquisition, management, sharing and interpretation of pathology information in a digital environment, has long been recognized as an important tool in education and research. Here we evaluate the adoption of this innovative solution for
a pathology lab of a large university hospital to help managerial decision making to transform in DP its pathology department.

INTRODUCTION:
Digital Pathology (DP), that incorporates the acquisition, management, sharing and interpretation of pathology information in a digital environment, has long been recognized as an important tool in education and research. The advancement of whole slide imaging (WSI) and the FDA approval have increase interest in DP for diagnoses. The aim of this work was to evaluate the adoption of this innovative solution for a pathology lab of a large university hospital with a workload of 500,000 glass analyses p/a and massive research activity.

METHODS:
Stated the diagnostic accuracy of DP in a preliminary Systematic Review, research question of the assessment was The adoption of a DP at the Fondazione Policlinico Universitario Agostino Gemelli IRCCS will be strategic, sustainable both at economic and organizational point of views? An original adaptation of the AdopHTA mini-HTA template has been applied (Rapid mini-HTA template) to present results of assessment. The adapted Model is based on 8 domains of evaluation: Health Problem and Current Use (CUR), Technical characteristics (TEC), Safety (SAF), Effectiveness (EFF), Economic evaluation (ECO), Ethics (ETH), impact on organization (ORG) and strategy (STG).

RESULTS:
The work is still ongoing, here we summarize the domains already completed. For CUR domain we examined: Organ systems (Colorectal, Urinary bladder, Gynecologic); Research fields (deep learning and next generation tissue microarray); Medical education; Regulatory. For TEC we arranged a comparative table of the WSI systems offered by 11 manufacturers (Slide capacity, Scan speed, magnification) and then we choose 3 alternative to compare for final decision. For SAF and EFF domains our research group performed a preliminary SR in order to retrieve the evidence on accuracy: 11 /127 trials (n=9,253 cases) met eligibility criteria defined in consultation with a trained pathologist. Digital images can be interpreted with comparable accuracy to microscope slides by pathologists. We will assess the sustainability thought a Budget impact and scenario analyses to investigate the changes in the workflow.

CONCLUSIONS:
This report represents the scientific base to inform managerial decision making in the resolution on the transition of its pathology department to DP.

OP108 Association Of Shared Decision Making With Patient Satisfaction

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ABSTRACT SUMMARY:
A cross sectional survey of 3949 inpatients in eighty-nine public hospitals in Shanghai, China in 2018 was conducted to evaluate the association between patient perceived shared decision making (SDM) and their satisfaction with physician service. The overall rate of SDM of inpatients was 95.86% and good SDM can increase inpatient satisfaction with physician services.

INTRODUCTION:
Shared decision making (SDM) in medical care is a process that patients and physicians make decisions together as partners by evaluating all available options and weighing patient values. Our
study aimed to evaluate the association between patient perceived SDM and their satisfaction with physician service.

METHODS:
A cross sectional survey of 3949 inpatients in eighty-nine public hospitals (forty-seven tertiary hospitals, sixteen secondary-level hospitals and twenty-six community health centers) in Shanghai, China in 2018 was conducted. In surveys, each item for evaluating inpatient perceived SDM and satisfaction was scored using a 5-point Likert scale (from 1 for “strongly disagree” to 5 for “strongly agree”). We classified the rating of “strongly agree” and “agree” as positive perception. Chi-square tests and a multi-level linear regression were adopted to test the association between SDM and patient satisfaction.

RESULTS:
95.86 percent of the inpatients in the surveyed hospitals positively rated SDM in medical care and 97.17 percent of them satisfied with physician services. In perceived SDM, the inpatients positively rated inpatient demands for medical information, patient actively participation in SDM, physician encouragement for patients to participate in SDM, informed consents (97.82 percent, 94.60 percent, 96.91 percent, and 96.99 percent). However, the items of “I asked physicians to provide treatment suggestions” and “Physicians informed me different possible therapies” were rated significantly lower in inpatients in tertiary hospitals (89.63 percent and 87.88 percent, respectively) than those in other hospitals (more than ninety-three percent and ninety percent, respectively). Using the multi-level linear regression, the study found that there was a significant association between inpatient perceived SDM and inpatient satisfaction with physician services ($\beta=0.08$, $P<0.001$).

CONCLUSIONS:
In public hospitals of Shanghai, the overall rate of SDM of inpatients was relatively high and good SDM can increase inpatient satisfaction with physician services.

OP109 The Need For Building Pharmacists HTA Capacity; The Nigerian Scenario

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ABSTRACT SUMMARY:
The role of HTA is becoming increasingly important as evidenced by its extensive application in the developed world. However, developing countries seem not to be making significant progress in this area, despite the fact they are needed more here. Hence, there is need to raise awareness and strengthen HTA capacity for healthcare decision-making in developing countries like Nigeria.

INTRODUCTION:
The role of Health technology assessment (HTA) as a systematic approach in the evaluation of health interventions and technologies is becoming increasingly important as the quest for attaining universal health coverage globally continues to increase. Some developed countries in Europe and the Americas now apply HTA extensively in healthcare policy decisions, however, developing regions and countries like sub-Saharan Africa and Nigeria respectively, seem not to be making significant progress in this area. Given that evidence suggests that Nigeria and indeed several countries in sub-Saharan Africa are performing poorly on most healthcare indices as the region continues to be ravaged by predictable and avoidable epidemics and disease outbreaks, the need to build HTA capacity has never been more paramount.

METHODS:
A review of HTA capability in Nigeria was done.
Pharmacists in Nigeria’s Capital were randomly sampled. Semi-structured questionnaires were administered. Descriptive statistics was used in data analysis. P values less than 0.05 were considered to be significant.

RESULTS:
In Nigeria, there is no institution tasked with undertaking HTA and there seems to be limited knowledge, capacity and awareness on the issue. Pharmacists, being the most accessible healthcare professionals according to evidence, are a key group that could play an active role in HTA and its implementation in developing countries like Nigeria. However, out of 322 pharmacists randomly sampled, 93 percent were not aware of HTA and its application in healthcare decision-making.

CONCLUSIONS:
There is no paucity of healthcare programs and plans in Nigeria but they seem to fail due to lack of evidence-based assessment, decision making and implementation. Hence, there is increasing need to raise awareness on the importance of HTA in healthcare decision-making; strengthen HTA capacity by developing and sustaining institutional capacity and adequate human resource for HTA; and creating regional annexes of HTA organizations in Africa.

OP111 Trends in National Health Insurance Enrolment in Ghana

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ABSTRACT SUMMARY:
This study provides trends in enrolment in the national health insurance scheme in Ghana for informed policy decisions towards achieving UHC.

INTRODUCTION:
In 2004, Ghana started experimenting a National Health Insurance Scheme (NHIS) to replace out-of-pocket payment for healthcare. Like many other social health insurance schemes in Africa, the NHIS is striving for universal health coverage (UHC). This paper examines trends and characteristics of enrolment in the scheme to inform policy decisions on attainment of UHC.

METHODS:
We conducted trend analysis of longitudinal enrolment data of the NHIS for the period, 2010-2017. Descriptive statistics were used to examine trends and characteristics of enrolment by geographical region and member groups.

RESULTS:
Over the eight-year period, the population enrolled in the scheme increased from 33 percent (8.2 million) to 41 percent (11.3 million) between 2010 and 2015 and dropped to 35 percent (10.3 million) in 2017. Members who renewed their membership increased from 44 percent to 75.4 percent between 2010 and 2013 and then dropped to 73 percent in 2017. On average, the urban regions had significantly higher number of new enrolments than the rural ones. Similarly, the urban and peri-urban regions recorded significantly higher number of renewals than the other regions. In addition, persons below the age of 18 years and the informal sector workers had significantly higher number of enrolment than any other member group.

CONCLUSIONS:
Enrolment in the NHIS is declining and there are significant differences among geographical regions and member groups. Managers of the NHIS need to enforce the mandatory enrolment provision in
the Act governing the scheme, employ innovative strategies such as mobile phone application for registration and renewals and address delays in healthcare provider claims to improve enrolment.

OP112 Project Management In EUnetHTA Non-Pharmaceutical Technologies

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ABSTRACT SUMMARY:
Centralised and decentralised Project management (PM) within EUnetHTA provides a network of assessment coordination, knowledge management and governance to achieve scale, capacity and capability building through a designated pool of agencies with established roles and growing experience in collaborated HTA production. A qualitative analysis aims to capture the experiences and lessons learned to refine and direct PM models and policy.

INTRODUCTION:
The European Network for Health Technology Assessment (EUnetHTA) facilitates and supports HTA production across Europe. Project Management provides the coordination and strategic overview of assessment production to enable the network flow of scientific knowledge and high-quality methodological assessment publications through collaboration and standardised processes, procedures and documentation.

METHODS:
EUnetHTA established central PM function for non-pharmaceutical technologies at the Ludwig Boltzmann Institute for HTA with centrally coordinated assessment production.

LBI-HTA pursued capacity and capability building through a decentralised hub-and-spoke-PM model. LBI-HTA provides central training, support and supervision to six activity centres (AC). The central oversight consists of two face-to-face training days, four e-meetings, ad hoc email and telephone support as required complemented by standardised operating procedures in the online Companion Guide.

A qualitative data collection is planned via electronic questionnaires to AC-PM, LBI-HTA-PM and authors. Specific questions with free-text responses aim to assess current experiences, communications and task distributions for the centralised and decentralised PM processes from different perspectives.

RESULTS:
The expected thematic results from the PM questionnaires are experiences, challenges and recommendations during centralised and decentralised PM of assessment production.

This will refine and enrich the understanding of the overall capacity and capability building within EUnetHTA PM. It would direct improvements and changes to current and future PM practices and policy to ensure sustainability, resource savings and the overall increase in assessment production.

CONCLUSIONS:
Resultant decentralised coordination of assessments, knowledge management and governance achieve scale, capacity and capability building through a designated pool of agencies with established roles and growing experience in sustainable collaboration of PM and HTA production. Experiences from various perspectives would provide valuable insight into the PM model’s operational efficiency, avoidance of duplication and
improved resource savings with a potential to guide a sustainable post-2020 delivery network policy model of high methodological and scientific quality HTA assessment production.

OP113 The META Tool: Helping Medtech Developers To Understand HTA

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ABSTRACT SUMMARY:
Diffusion and adoption of new health technologies (medtech, diagnostics, apps) is hindered when developers lack knowledge or skills to develop value propositions or evidence relevant to healthcare payers. NICE Scientific Advice has developed the Medtech Early Technical Assessment (META), an affordable, structured online tool disseminated through licensing to develop the competencies of medtech developers.

INTRODUCTION:
Diffusion and adoption of new health technologies (medtech, diagnostics, apps) supports healthcare innovation, leading to improved patient outcomes and health-system efficiencies. These technologies are often developed by individuals or small/medium enterprises, who do not have the knowledge or skills to develop a value proposition or evidence that is relevant to healthcare payers. This lack of understanding about what they do not know (the ‘unknown unknowns’) can affect the quality of submissions from industry resulting in unsuccessful health technology assessments (HTAs). To help address these evidence gaps, NICE Scientific Advice has developed the Medtech Early Technical Assessment (META) tool, for use by NICE and licensed to other ‘facilitating organisations’ to help developers optimise their product’s evidence-generation plans.

METHODS:
The case for development and initial design of META was informed by product developer feedback, literature review, stakeholder interviews and consultation. Prototyping, training needs assessment and piloting were undertaken with potential users and licensees, with further developmental iterations before Department of Health approved the tool’s beta launch.

RESULTS:
The development case included: presence of externalities, information asymmetries, lack of knowledge around value proposition and HTA and coordination failures. This case informed the initial design. Piloting of the META tool and facilitator training package resulted in a revised structure and content, enabling acceptable pricing. Following its 2017 launch, NICE and 8 organisations licensed to use META have completed 17 consultations, and its use has been promoted by Innovate UK as a precondition for funding applications.

CONCLUSIONS:
META has been designed as an affordable, structured online tool, disseminated through licensing to develop the competencies of medtech developers regarding HTA and healthcare payer requirements. The META tool has the potential to improve submissions from medtech developers to NICE and other payers, while facilitating early identification of technology without relevant value propositions for the healthcare system.
OP114 Towards Common Understanding Of HTA Education And Training Programs

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ABSTRACT SUMMARY:
Utilization and generation of HTA products requires specialized skills and competencies. In addition to a graduate program, most countries offer continual professional education, training or post-graduate courses in HTA or in Public Health or other health sciences. This study explores the landscape of education and training options available currently and the similarities and differences in the curriculum offered.

INTRODUCTION:
Governments worldwide faced with constrained resources are under cost pressure to ensure efficiency of healthcare system. Under these circumstances, there is a growing recognition worldwide of the advantage of using and producing HTA. Even though, structure of HTA programs varies within a country and between countries according to the need of decision- and policy-makers, there is no doubt that conducting HTA requires specialized skills. Additionally, there are certain ‘must-have’ and ‘nice-to-have’ competencies and skills needed to practice HTA. The objective of this study is to collect data, through a global survey, to evaluate education programs in HTA.

METHODS:
A survey on a range of educational programs in (I) Universities and (II) HTA organizations and training programs offered at HTA agencies was conducted and the query was sent to HTAi and INAHTA members. Furthermore, websites of Universities worldwide offering courses in HTA or related fields but departments of which had not participated in the survey were hand searched for content of the educational programs offered. Few key educational Institutions, whose staff may not be current members of either HTAi or INAHTA were also individually contacted.

RESULTS:
We collected 30 completed surveys on universities HTA programs: 11 respondents offered Masters level programs. Only 1 responded that the participants of their program do an HTA whereas 9 respondents collaborate in some manner, e.g. joint staff program, with HTA agencies. The second survey to HTA agencies had 14 respondents (response rate 28%). Most offered in-house training in HTA (80%) followed by training in literature searching, systematic literature reviews and Health Economics.

CONCLUSIONS:
There is no standard model in HTA curriculum as this depends upon the need of the decision-making of the country. Our results confirm the assumption that the content of the courses will vary due to the systemic differences of the countries; however, there is a room for harmonization under the concept of core modules and optional modules raising the necessity to map the core modules to “must-haves” or core competencies in HTA.

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OP115 Expanding Perspectives: The Role Of Environmental Scanning In HTA

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ABSTRACT SUMMARY:
Environmental scan reports broadly describe the current local, national, and international landscape surrounding health care practices, programs, or technologies. We first identified existing methods guidance for conducting environmental scans. In this presentation we describe our experience adapting the methods guidance to conduct an environmental scan (literature review, online surveys, and key informant interviews) of initiatives to accelerate cancer diagnosis.

INTRODUCTION:
Environmental scan reports, usually consisting of literature reviews and/or key informant consultations (such as online surveys or personal interviews), broadly describe the current local, national, and international landscape surrounding health care practices, programs, or the use of technologies. Funding agencies and health organizations recognize environmental scans as a valuable way to inform decision-makers about the context, practice variations, and knowledge gaps surrounding a topic. Despite their increasing popularity in HTA, there is limited guidance available for conducting environmental scans, variation in methods used across and within HTA agencies, and lack of consensus on an appropriate definition, purpose, and process.

METHODS:
We conducted an informal literature review and consulted experienced researchers from other HTA agencies to identify existing methods guidance for conducting environmental scans. We then adapted these methods to conduct an environmental scan of initiatives to accelerate cancer diagnosis.

RESULTS:
There was limited and vague guidance on the definition, purpose, and process of conducting environmental scans in the context of HTA. This introduced challenges but provided the flexibility to modify our approach to meet requestor needs. Our environmental scan included: 1) a literature review, to identify and describe relevant initiatives and to locate data on effectiveness (which is often out-of-scope for environmental scans but was of priority to the requestor); 2) stakeholder surveys, which helped “fill in the gaps” of the literature review and helped locate additional initiatives; and 3) targeted key informant interviews, which provided rich follow-up data on the initiatives most important to the requestor.

CONCLUSIONS:
By describing our experiences adapting limited methods guidance to meet requestor needs, we hope to contribute to the evolving discussion about the definition, purpose, and process of environmental scans to inform health policy decision making. We will reflect on challenges encountered, potential solutions, and lessons learned, and will discuss ongoing areas of methodological uncertainty.

OP116 Horizon Scanning Influence In Incorporation Of Biologics For Psoriasis

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ABSTRACT SUMMARY:
Horizon Scanning has been a crucial tool for recommendation-making process in Brazil. There were detected three new biologics for moderate to severe psoriasis with potential superior efficacy profile in comparison to those were being evaluated for incorporation in to Public health care
system. The information has influenced the initial recommendation of National Committee for Health Technology Incorporation (CONITEC).

**INTRODUCTION:**
A Horizon Scanning (HS) study is made for every medicine which is analyzed for incorporation in Brazilian Public Health System (SUS) by the National Committee for Health Technology Incorporation (CONITEC). These studies seek to show for CONITEC’s collegiate what is the short to medium-term scenario of drugs that might impact Brazilian health care system. In early 2018, CONITEC was evaluating the incorporation processes of the biologic drugs adalimumab, etanercept, infliximab, sekukunimab and ustekunimab for moderate to severe psoriasis. This work aims to present how HS influenced the decision-making process of CONITEC.

**METHODS:**
Searches in online databases on ongoing clinical trials, registration sites and scientific databases were performed to find new and emerging drugs for the clinical indication. Information as mechanism of action, administration route, efficacy, regulatory status in Brazil, Europe and United States of America about the new and emerging drugs identified by HS were presented to CONITEC’s collegiate.

**RESULTS:**
There were detected ten emerging drugs for moderate to severe psoriasis, while other three new drugs (apremislat, guselkunumab and ixekizumab) were registered in Brazil for less then 4 months at that time. The available data have shown a potential superior efficacy profile in comparison to those ones that were being evaluated for incorporation onto SUS. The Conitec’s collegiate pondered that HS findings reinforced the idea that it was not suitable to incorporate all the five biologic medicines available in Brazil.

**CONCLUSIONS:**
The HS information have influenced the recommendation that was done by CONITEC. It was shown that HS is a crucial tool for rationalizing and qualifying the incorporation process of drugs in Brazil.

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**OP117 Optimising Horizon Scanning For New Medicines Using Machine Learning**

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**ABSTRACT SUMMARY:**
A novel approach of adopting a machine learning model to support horizon scanning of reputable pharmaceutical news sources.

**INTRODUCTION:**
Horizon scanning (HS) aims to identify new and emerging health technologies to support healthcare decision making. Current methods are very labour intensive and include the routine scanning of reputable pharmaceutical news sources. The aim of this research is to develop a machine learning (ML) model that can screen HS news items and identify important articles.

**METHODS:**
We propose a novel approach of adopting a ML model to automatically assign an importance score for each article (1 to 5, least to most important) obtained for HS data sources. Scores are then used to identify important articles and filter out articles of low importance.
In the approach, we utilise Support Vector Machine as the ML model. We downloaded a sample dataset (1,276 articles) from https://fiercebiotech.com and https://www.biospace.com. The data was then annotated by an HS specialist. There were 807 (63%), 94 (7%), 46 (4%), 30 (3%) and 299 (23%) articles annotated with a score of 1, 2, 3, 4 and 5 respectively. We used 10-fold cross-validation to train and evaluate the ML model on the annotated dataset, 9 folds for training and the remaining fold for evaluation; cross-validation was then repeated 10 times. The performance was the average of 10-run results.

RESULTS:
To evaluate the system, we used the accuracy metric. The preliminary accuracy of the system was as high as 83% and was highest (86.0%) when assigning the least important score (1).

CONCLUSIONS:
Machine learning (ML) holds promise in assigning importance scores to healthcare technology news items. It can help significantly reduce HS workload in screening and identifying important articles. Larger annotated datasets (corpus) will assist in improving the accuracy of the ML model and should be supported. Combined, these data suggest that HS teams should consider developing and applying ML approaches to optimising news driven insights into healthcare innovation.

OP118 Capability Of Opinion Leaders In HTA: Public Involvement In Korea

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ABSTRACT SUMMARY:
We aimed to involve public in the identification HTA topic and evaluation of impact of HTA report. They suggested eighteen topics this year, and developed framework to evaluate impact of HTA. We found that they have capability to be opinion leader who can deliver the patient’s needs to HTA agency and disseminate the research results back to the patient.

INTRODUCTION:
Public involvement becomes increasingly important to Health Technology Assessment (HTA). Public offers invaluable insights to HTA research (INVOLVE, 2012), and HTA agency can help them to improve their health literacy. We thought public could be the key in the new HTA as an opinion leader. In this project, we launched ‘The group on Public Involvement in NECA(PIN)’ and implemented two programs: 1) to identify the HTA topic that the patient needs, and 2) to develop the Korean framework for reporting on impact of HTA reports.

METHODS:
At the recommendation of citizen associations, we organized the PIN of eleven members involving patient, citizen and consumer in July 2018. We tried to involve the PIN in the identification and evaluation of HTA. First, we gave them a month to think about HTA topics with several sentences and discussed their own topics together in the first meeting. Second, we revised ‘The INAHTA framework for reporting on impact of HTA reports’ to Korean version and prepared one scenario for the workshop. This framework was pilot tested to NECA administrative staffs and reviewed by the PIN at the second meeting.

RESULTS:
A total of eighteen topics were proposed by the PIN. An in-depth conference was held with clinical experts on one of the most feasible research topics. All the experts agreed that the topic had necessary
to be discussed, and decided on reimbursement about the transplantation according to the results of the study. In terms of impact evaluation, some members of the PIN had difficulty in using the framework. This was due to differences in understanding of medical terminology and HTA mechanisms. They said it would be better to provide sufficient education in advance to explain the questionnaires. They also suggested that the scenario should be written more concisely, rather than narrative form.

CONCLUSIONS:
This project was an important attempt to engage the public in the planning and evaluation of HTA. The PIN has capability to be an opinion leader who can deliver the patient’s needs to HTA agency and disseminate the research results back to the patient. Through cooperative relationship with them, we expect that the results of HTA will be used for various decisions making. In the long term, patient’s empowerment improved by health literacy will bring positive changes to patient-doctor communication and outcome of treatment.

OP119 Reimbursement Decisions In The Netherlands – A Citizen Panel

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AUTHORS:
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ABSTRACT SUMMARY:
Informed citizens are prepared and, to a certain extent, capable to make reasoned choices about the reimbursement of health services. They realise that choices are both necessary and possible. Broad public support and understanding for making tough choices regarding the benefits package of basic health insurance is not automatic: it requires an investment.

INTRODUCTION:
The government of the Netherlands, like its counterparts in most other countries that have some form of universal health insurance, faces challenges in obtaining public support for its choices regarding the composition of the benefits package. The opinion of informed citizens about services that should be universally accessible and covered under the basic health insurance, and the arguments they use, are largely unknown. A Dutch citizen forum was organized to obtain insight into informed citizens’ preferences and identify the criteria they would propose for decisions pertaining to the benefits package of basic health insurance.

METHODS:
Twenty-four Dutch citizens were selected for participation in a Citizen Forum, which involved three weekends. Deliberations took place in small groups and in plenary, guided by two moderators, on the basis of eight preselected case studies, which were later compared and prioritised. Participants received opportunities to inform themselves through written brochures and live interactions with three experts.

RESULTS:
The Citizen Forum identified 16 criteria for in- or exclusion of treatments in the benefits package; they relate to the condition (2 criteria), the treatment (11), and to individual characteristics of those affected by the condition (3). In most case studies it was a combination of criteria that determined whether or not participants favoured inclusion of the treatment under consideration in the benefits package. Participants differed in their opinion about the relative importance of criteria; and they had difficulty in operationalising and trading off criteria in order to provide a recommendation.
Informed citizens are prepared and, to a certain extent, capable to make reasoned choices about the reimbursement of health services. They realise that choices are both necessary and possible. Broad public support and understanding for making tough choices regarding the benefits package of basic health insurance is not automatic: it requires an investment.

## OP120 Changing Views: Qualitative Results From A Deliberative Citizen Panel

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**Abstract Summary:**
Qualitative results from a Dutch citizen panel show participants became more aware of the complexity of decision making and came to accept that there are limits to the available resources and a role for costs. Furthermore, they came to see the perspective of informed citizens in reimbursement decision making as additional to that of other stakeholders.

**Introduction:**
There is increased interest in the use of deliberative methods as a means to elicit informed perspectives from the public to inform health policy decisions. A Dutch citizen panel was organized to obtain insight into Dutch citizens’ informed preferences and to identify the criteria they would propose for decisions pertaining to the basic benefit package. The aim of this study was to assess whether and how deliberation, which was key to the citizen forum, influenced participants’ views.

**Methods:**
Eight participants of the citizen panel were selected for semi-structured interviews both before and after their participation to explore their views towards decisions pertaining to the basic benefit package. During interviews after the panel participants were additionally asked what they believed caused changes in their views, if any. Interviews were recorded, transcribed, and analyzed using the method of reconstructing interpretive frames. The term ‘interpretive frame’ refers to a quadruple set of elements that determine a respondent’s view: context-specific problem definitions, solutions, empirical and ethical background theories, and normative preferences. Subsequently, participants’ views were compared before versus after to make changes in views explicit over time. Self-reported reasons for changes in views were extracted from interview transcripts and summarized.

**Results:**
Results show participants became more aware of the complexity of decision making and came to accept that there are limits to the available resources and a role for costs. Furthermore, they came to see the perspective of informed citizens in reimbursement decision making as additional to that of other stakeholders. Participants report changes in views are the result of exchanging arguments with other participants on the basis of casuistry and learning about other participants’ personal experiences.

**Conclusions:**
If health authorities want to involve citizens – or their views – in their decision-making processes they are advised to provide them with opportunities to deliberate.
OP121 High Risk High Complexity and Cost Devices Hospital-Based Management Impact

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ABSTRACT SUMMARY:
A skilled healthcare team was developed for High-Risk-High-Complexity & Cost Materials management (HR2HCM). Increased use occurred without incidents and there was no suspension due to management failure in the period. These HR2HCM qualified professionals and internal hospital-based transdisciplinary (materials management and sterilization centers, and operating theatre) network performance improved healthcare, resulted in US$428,723.03/3 years economies, and foster external collaborations for HTA research.

INTRODUCTION:
Less invasive procedures have provided benefits to patient safety, reduced lengthier hospital stays and infections, but required logistics development. A skilled healthcare team was developed for High-Risk-High-Complexity & Cost Materials management (HR2HCM) to ensure standards compliance, safety, traceability, and preserve useful life of laparoscopic and endoscopic devices and surgical equipment, e.g. urologic surgical optics, ureteroscopes, nephroscopes and related accessories. This internal hospital-based network involves materials management and sterilization centers (MM&SC), and operating theatre (OR). A specific workflow for each type of HR2HCM was developed to prevent surgical procedures suspension rate since 2015.

Objective: To report the 3 years economic impact of this HR2HCM management approach.

METHODS:
Methods: Prospective program indicators follow-up and economic assessment.

RESULTS:
Results: HR2HCM urology protocols included specific courses for program team professionals.

This assessment involved surgical optics (4 mm 30 degrees, 2018 market value of US$2,028.00/unit) for prostate resection (with a useful life of 51 reprocesses vs. 20 before); flexible lithotripsy ureteroscopes (60 reprocesses vs. 20 before; US$10,724.32/unit); and microscope for endoscopic surgery (60 reprocesses vs. 20 before; US$13,884.71/unit). During the 3 years follow-up 4,368 patients underwent 3,900 prostate resections, 312 ureteral endoscopic lithotripsy and 156 microscopic surgery using, respectively, 76 surgical optics (versus 195 if same surgery numbers were done before program implementation), 5 flexible lithotripsy ureteroscope (vs. 16 before) and just 3 microscopes (vs. 8 before) at a capital cost of US$154,128.00 (vs. US$395,460.00 before), US$53,621.58 (vs. US$171,589.06 before) and of $41,654.13 (vs. US$111,077.68 before) leading to US$428,723.03 economy. More eligible patients had their treatment, HR2HCM increased use occurred without incidents and there was no suspension due to management failure in the period.

CONCLUSIONS:
These HR2HCM qualified professionals and internal hospital-based transdisciplinary MM&SC-OR network performance resulted in healthcare improvement and economies, and also foster collaborations with Sao Paulo State and Brazilian HTA Networks for current and future HTA research.
OP122 Resource Use Measurement Issues: A Scoping Review

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ABSTRACT SUMMARY:
Resource use measurement methods are often based on practicality rather than on methodological evidence. Measuring true quantities of resources utilized is of major importance for generating valid costing estimates. This study provides an overview of methodological issues and its consequences regarding resource use measurement. This overview could enhance the quality of future economic evaluations.

INTRODUCTION:
Resource use measurement is known to be a challenging and time-consuming, but essential step in economic evaluations of health care interventions. Measuring true quantities of resources utilized is of major importance for generating valid costing estimates. As consequence of the absence of a gold standard and of acknowledged guidelines, the choice of a measurement method is often based on practicality instead of methodological evidence. An overview of resource use measurement issues is currently lacking. Such overview could enhance clarity in the quality of resource use measurement methods in economic evaluations and may facilitate to opt for evidence based measurement methods in the future. This study aims to provide an overview of methodological evidence regarding resource use measurement issues in economic evaluations.

METHODS:
Literature was searched by three different methods. First, a search strategy was used in six different databases. Second, the database ‘DIRUM’ was hand-searched. Third, experts from six different EU countries within the field of health economics were asked to provide relevant studies. Data was analysed according to the Resource Use Measurement Issues (RUMI-) framework, which was developed for this study.

RESULTS:
Of the 3,478 articles provided in the initial search, 77 were fully analysed. An overview with evidence is provided for every resource use measurement issue. Most research focused around the issue ‘how to measure’, in particular the effect of self-reported data versus administrative data. In contrast, little to no research has been done on issues ‘what to measure’ and ‘to which purpose to measure’.

CONCLUSIONS:
Results of this study provide insight in the effect of a chosen measurement method. The results stress the importance of measuring the true quantities of resources utilized for generating valid costing estimates. Furthermore, this article highlights the lack of evidence in appropriate resource use measurement methods.

OP123 A Cost-Effectiveness Registry For Prioritization In Emerging Markets

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ABSTRACT SUMMARY:
The Tufts Global Health Cost-Effectiveness Analysis (GH CEA) Registry is a freely-available, curated dataset that represents a tool for decision-makers in low- and middle-income settings to prioritize the most cost-effective interventions across multiple domains, such as region, disease area, intervention type, quality of analyses performed, and others. An example is provided identifying high-quality studies of cost-saving primary prevention services.

INTRODUCTION:
Decision-makers in low- and middle-income countries (LMICs) often must prioritize health spending without quantitative benchmarks for the value of their purchases. The Tufts Global Health Cost-Effectiveness Analysis (GH CEA) Registry (healtheconomicsevaluation.org/GHCEA Registry/) is a freely-available, curated and standardized dataset designed to address this need.

METHODS:
All indexed English-language articles published between 1995 and 2017 are currently included in the GH CEA Registry. Studies are limited to those reporting cost-effectiveness in terms of cost per disability-adjusted life years (DALYs) averted, a commonly-employed metric in global health. Abstracted data include intervention type, comparator(s), country, funding source, study characteristics (e.g., perspective, time horizon), primary study findings, sensitivity analyses, and disaggregated data on costs and DALYs. Study quality is assessed using a numerical scoring system (from 1-7, higher scores indicating better quality) based on accuracy of findings and comprehensive reporting of methods and results.

RESULTS:
To date, 620 articles have been included in the GH CEA Registry. Among LMICs, studies have been conducted primarily in Sub-Saharan Africa (41%) or South Asia (34%), have focused on communicable diseases (67%), and have involved immunization, educational, or pharmaceutical interventions (67%). As a priority-setting example, 7% of interventions from higher-quality studies (ratings of 5 or higher) were reported to be cost-saving (i.e., lower costs and greater DALYs than standard care), two-thirds of which involved primary disease prevention (e.g., immunization, educational or behavioral interventions).

CONCLUSIONS:
The GH CEA Registry is a new tool for decision-makers in LMICs, particularly those without a formal HTA infrastructure but with a remit for providing access to essential, cost-effective health interventions. New functions are under development, including league tables for priority ranking, a repository for shared models, and tools for enhancing transferability between settings.

OP124 Disinvestment – A Global Challenge Requiring Collaboration?

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ABSTRACT SUMMARY:
Disinvestment and reassessment is a complex area for HTA and presents real global challenges. Australia and South Korea are currently in the process of reassessing all their funded medical services, often using HTA. The two countries are sharing information about how to achieve the best outcomes for their respective health care systems.

INTRODUCTION:
Australia has had some success at utilising HTA to disinvest and reassess medical services. This has been achieved through a range of methods including identifying services through initiatives...
such as ‘Choosing Wisely’, examining real world service data and seeking expert clinical opinion.

This presentation will discuss how better international collaboration in disinvestment and reassessment methods using HTA could lead to more efficient health care systems.

METHODS:
Both the Australian and South Korean governments have a particular interest in disinvestment and reassessment in their health care systems. These countries have been sharing information over the past two years with a common goal of improving their health systems through a rigorous reassessment process.

The Australian Government is in the process of reviewing all publicly funded services utilising expert clinical committee advice, often referring the reassessment of services to a HTA process. A similar process is also being undertaken in South Korea.

RESULTS:
Australia has disinvested in a wide range of services using HTA, including hip arthroscopy, lipectomy and hyperbaric oxygen therapy. It is also undertaking an extensive reassessment of 5700 services. Reassessment may not lead to HTA, but it often includes an examination of whether a service should be subjected to HTA to remain publicly funded.

The presentation will discuss how these two countries have similar approaches in undertaking disinvestment and reassessment. It will also provide an analysis of HTA disinvestment and reassessment strategies that have generated good outcomes for consumers, health care providers and funders.

CONCLUSIONS:
Disinvestment and reassessment of medical services require funders that support the continual improvement of health care systems.

Disinvestment and reassessment HTA can be difficult, mainly due to external interests - an issue experienced by many countries. Further international collaboration in this area may provide a more supportive environment to undertake HTA for disinvestment.

OP125 Disinvestment Activities And Candidates In The HTA Community

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ABSTRACT SUMMARY:
There is a growing interest to establish an information exchange and collaboration on disinvestment initiatives with international organizations. An online survey was conducted to collect information on disinvestment activities in the HTA community. Based on the responses suggested HTA producers are undertaking disinvestment initiatives, and the most common approach used for disinvestment decisions was health technology assessments and reassessments.

INTRODUCTION:
As health care decision-makers continue to face challenges in health services delivery to their patient population with increasing costs and limited resources, disinvestment programs and initiatives are being established for a sustainable health care system. The study objectives were to identify disinvestment candidates and to share the experiences and challenges with disinvestment projects with the intent to establish an information exchange forum.
METHODS:
An online survey was conducted to collect information on disinvestment candidates and activities from members of the Health Technology Assessment International Disinvestment & Early Awareness Interest Group (HTAi DEA IG), the EuroScan International Network and International Network of Agencies for Health Technology Assessment.

RESULTS:
Among the 362 invited members, 24 unique responses were received. Approximately 70% were involved in disinvestment initiatives. The disinvestment candidates identified represented a range of health technologies. Evidence or signaling of clinical ineffectiveness or inappropriate use typically led to the nomination of candidates for disinvestment. Health technology assessments and reassessments were usually conducted to evaluate the technology for proposed disinvestment, and decisions usually led to the limited use of the disinvestment candidate. Main barriers to disinvestment decisions included the strength of interest and advocacy groups and lack of relevant data for assessments, while obstacles to their implementation were clinicians’ reluctance.

CONCLUSIONS:
The survey results suggested that disinvestment activities are occurring in the health technology assessment community. It is very unlikely that the response rate is reflective of the survey sample’s activity level in disinvestment due to confidentiality and privacy concerns with sharing their information, or lack of time to provide details on their disinvestment candidates and activities. Interviews with survey respondents, who are involved in disinvestment initiatives, can help to gain a deeper understanding on the processes and methods used to identify disinvestment candidates, reach a disinvestment decision, and implement it in practice.

OP126 RWD Supplements Evidence To Update UK Commissioning Policy

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ABSTRACT SUMMARY:
Collaborative work between funders, HTA agency, specialist clinicians, national registry linked to routine information and academics can rapidly provide high quality, linked, real world data to evaluate promising technologies with insufficient published evidence to support national routine funding. We will present findings from 4 years’ work.

INTRODUCTION:
Promising technologies or procedures frequently have insufficient published evidence to support national routine funding. To address this gap, the NHS England (NHSE) Commissioning through Evaluation (CtE) programme funds procedures in specialist centres for a limited number of selected patients, with data analysis coordinated by a Health Technology Agency; the National Institute for Health and Care Excellence (NICE) UK. We will present findings from 4 years’ work.

METHODS:
Each project (three cardiac, one paediatric neurosurgery, two specialist oncological) was advised by a national steering group of clinicians, academics, patient representatives, NHSE and NICE. National databases provided a central data collection mechanism for a maximum of two years post-procedure.
Evaluative questions and data analysis plans were agreed at the outset, and answered using efficacy, safety and patient related outcomes from a prospective registry for each project. Data validation and linkage to independent data sources, including national mortality data were done as appropriate.

RESULTS:
Real world data were robust enough to update national commissioning policy for 4/5 evaluations completed to date. Delays in patient recruitment to a new service and information governance restrictions compromised some data collection.

Data linkage to routine data demonstrated validity of the register and provided longer term follow up (e.g. for cardiac procedure designed to reduce stroke: Total neurological events per 100 person years follow up; register 5.0, national statistics 5.3, 95% CI 3.0 to 7.8 and 3.9 to 7.1 respectively).

CONCLUSIONS:
Future CtE projects should include at least 6 months set up period before patients are recruited in order to prepare governance, referral pathways and data collection. Even with this proposed set-up period, meaningful results were available from CtE more quickly than would have been possible with a clinical trial.

ABSTRACT SUMMARY:
This research evaluated the data collection requirements of current MAAs entered into between NHS England and manufacturers. Observational data were collected for all MAAs, mostly through low-cost existing registries, with the majority of MAAs also supplemented with ongoing trial data. The potential expansion of MAAs into other therapy areas could make MAAs an even more attractive proposition in the future.

INTRODUCTION:
NICE has increasingly agreed to reimburse innovative products with high levels of uncertainty as part of managed access agreements (MAAs) while additional data are collected, through the new Cancer Drugs Fund (CDF) or highly specialised technology (HST) pathways. This research aimed to review the data collection stipulations of current MAAs.

METHODS:
We reviewed all current MAAs entered into between NHS England and manufacturers as of 29/10/18 and key data were extracted.

RESULTS:
22 MAAs were identified (19 through the CDF; 3 through HST). All MAAs involved an observational data collection component. The source of observational data collection was existing NHS databases (19/22 MAAs: 86.5%), existing independent registries (1 MAA: 4.5% [ataluren]); bespoke MAA registry maintained by manufacturer (1/22 MAA: 4.5% [asfotase alfa]), and registries developed as a part of regulatory approval and maintained by the manufacturer (1/22 MAA: 4.5% [elosulfase alfa]). Only 8 MAAs (asfotase alfa, ataluren, elosulfase alfa, brentuximab vedotin, venetoclax, ibrutinib, daratumumab, and pembrolizumab) had observational data collection as the primary method of data collection. Additionally, 17/22 MAAs (77%; all from the CDF) also required ongoing data collection from clinical trials as a key component of the data collection arrangement.
CONCLUSIONS:
This research identified observational data collection as a requirement in all MAAs, which is primarily through existing registries (except ataluren, which required development of a bespoke registry), while ongoing trial data collection was limited to the CDF. The relatively low cost of using existing registries to fulfill data requirements, with the ability to achieve reimbursement whilst still collecting data from ongoing RCTs, make MAAs an attractive proposition for manufacturers. NICE reportedly plan to increase use of MAAs, with ongoing NICE consultation for changes in the appraisal process potentially allowing expansion to include all indications, which would mean increased opportunities to explore innovative MAAs to support access in the future.

OP128 Extracorporeal Membrane Oxygenation: A Six-Year Real-World Evaluation

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ABSTRACT SUMMARY:
This province-wide real-world evaluation showed the use of Extracorporeal Membrane Oxygenation (ECMO) increased in Quebec between 2010 and 2016. Outcomes are comparable to other reports but variation in practice support the need for a more structured and coordinated approach to optimize ECMO service. It does also highlight the challenge faced when assessing the value of a high-risk, high-resource use treatment.

INTRODUCTION:
Despite its high cost and limited evidence of its benefit, Extracorporeal Membrane Oxygenation (ECMO) utilization in adults is increasing. This province-wide real-world evaluation examined the use of ECMO in order to inform optimal service organization.

METHODS:
Medical records of all adult ECMO patients between 2010 and 2016 were retrospectively reviewed. Patient characteristics and preferences, processes of care, outcomes and treatment costs were assessed. A systematic literature review was also conducted.

RESULTS:
Eight hospitals offered ECMO. While programs tend to be somewhat organized, important variations in structure, processes, volumes, indications and outcomes were found. Total provincial volume increased from 21 in 2010 to 97 in 2016. Total volume per center varied between 2 to 99 cases. Of 344 patients (median age of 53 years (IQR 39-63), 64% males), 51.7% were supported with VA-ECMO, 19.8% with VV-ECMO and 28.5% with ECPR. The most common primary diagnosis was cardiogenic shock (53.4%) for VA-ECMO, acute respiratory distress syndrome for VV-ECMO (80.9%) and in-hospital cardiac arrest (IHCA) for ECPR (85.7%).

In-hospital survival improved from 14.7% in 2010 to 42.3% in 2016. In 2016, survival was 52.9% for VV-ECMO, 35.4% for VA-ECMO, and 28.6% for ECPR, comparable to rates reported in the literature. Duration of support, ICU and hospital LOS were longer for VV-ECMO than VA-ECMO and ECPR. Complications were reported for 33% of patients, haemorrhage being the most frequent. The mean cost per patient hospital stay was $61,291.78. Cost tended to be higher for VV-ECMO.
CONCLUSIONS:
In Quebec, the use of ECMO increased and survival rates, despite remaining relatively low, improved. Results from this real-world evaluation support the need for a more structured and coordinated approach to optimize ECMO service. It does also highlight the challenge faced when assessing the value of a high-risk, high-resource use treatment when uncertainty about its clinical benefit remains.

METHODS:
This retrospective study included obese patients requiring bariatric surgery from Jan 2004 to Dec 2017 provided by a private healthcare organization in Belo Horizonte, Brazil. Data regarding healthcare utilization were extracted from an administrative database (software Oracle Business Intelligence). Continuous variables were expressed as mean and standard deviation. Log-Rank test was used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This historical cohort resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS:
16,786 patients were included in the study (mean age 37.2 ± 10.2 years; female 79.2 percent; mean BMI 42.4 ± 5.5 kg/m²). Patients were followed for up to 7 years before and after surgery (total of 78,113 patients/year). For this group, the hospitalization rate was 0.099 / patients-year before versus 0.151 / patients-year after the bariatric surgery (p<0.001). 224 deaths (1.33 percent) were identified during the follow-up period, 0.4 percent in the first 30 postoperative days. The average costs for hospitalization were R$ 13,090.30 and R$ 16,875.74 for open and laparoscopic surgery, respectively.

CONCLUSIONS:
Bariatric surgery has been an increasingly popular choice in the management of obesity. In our sample, it did not reduce the overall mid-term healthcare utilization rate.
OP130 Evidence-Informed Policy For Biologic Medicines In Brazil

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ABSTRACT SUMMARY:
The Coordination of Knowledge Management (CGGC) has provided methodological support to the working group responsible for drafting the Brazilian National Policy for Biologic Products, conducting a rapid review and a rapid evidence synthesis to subsidize the decisions and recommendations.

INTRODUCTION:
The Department of Sciences and Technology of the Brazilian Government has played a vital role in drafting the National Policy for Biologic Medicines. The Coordination of Knowledge Management (CGGC) has provided methodological support to the working group, conducting a rapid review and a rapid evidence synthesis to subsidize the decisions and recommendations.

METHODS:
We used the Methodological Guidelines for the Elaboration of Evidence Synthesis for Health Policies, which is a product of our own team, based on the SUPPORT Tools for evidence-informed health Policymaking.

RESULTS:
The CGGC team participated in the key steps to develop an evidence-informed policy. Our product, “Barriers to Access to Biologic Products: a Rapid Review” was used for the prioritization of health problems and the description of the problem. We then proceeded to the evidence synthesis planning and definition of the research question from an acronym. Together with the coordination of the working group, we decided to tackle the problem of interchangeability of biologic products motivated solely by economic factors in a synthesis of policy evidence. Our evidence synthesis went do far as to describe policy options. The working group used this product to inform a Policy Dialog.

CONCLUSIONS:
This was the first time that the CGGC team provided hands-on methodological assistance the development of a health policy. Not all steps recommended in the SUPPORT Tools were feasible due to time restraints. We observed that rapid evidence synthesis products were helpful to inform decision making.

OP131 Rapid Review For Policy: Interchangeability Of Biological Medicines

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ABSTRACT SUMMARY:
Due to the high judicialization rates which pressure the financing of biologic medicines by the Brazilian Unified Health System (Sistema Único de Saúde - SUS), it has been decided to formulate the National Policy for Biologic Medicines. We conducted a rapid evidence synthesis for policy based on an adaptation of the SUPPORT tools and searched in 6 literature databases.

INTRODUCTION:
Due to the high judicialization rates which pressure the financing of biologic medicines by the Brazilian Unified Health System (Sistema Único de Saúde - SUS), it has been decided to formulate the National Policy for Biologic Medicines. After identification of problems and prioritization, interchangeability based only on economic criteria was the main problem to be confronted.

METHODS:
We conducted a rapid evidence synthesis for policy based on an adaptation of the SUPPORT tools and searched in six literature databases. The selection of studies was performed in a systematic, transparent and independent manner. The primary objective was to identify political options to approach the problem of interchangeability in systematic reviews. The INAHTA members were consulted to learn how this practice occurs worldwide.

RESULTS:
We included seven systematic reviews and one policy brief, whose options to approach the problem were: production of robust scientific evidence on interchangeability; implementation of a pharmacovigilance system; appreciation of the clinical efficacy in the practice of interchangeability; and educational strategies for healthcare professionals in Brazil. Nine countries responded to our query.

CONCLUSIONS:
Evidence-informed policy has a central role for the Brazilian Ministry of Health. The present rapid evidence synthesis for policy will subsidize decision making regarding the interchangeability of biologic medicines within the Brazilian Unified Health System.

OP132 What Future For Drugs After An Early Dialogue Procedure?

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ABSTRACT SUMMARY:
By the end of 2018, the French HTA body (HAS) has performed 84 early dialogues. The success rate of clinical development for products that underwent an early dialogue tends to be higher than data from literature: the clinical development was officially withdrawn for only 20 products and drugs appraised by HAS (n=8) all obtained a clinical added value score.

INTRODUCTION:
The French health technology assessment (HTA) body (Haute Autorité de la santé – HAS) started to provide early advice on evidence generation plans to pharmaceutical manufacturers in 2010. It became an official mission in 2016. Requests are eligible when the product has a new mechanism of action, if there is an unmet or partially met medical need in the claimed indication and when the pivotal study has not yet started. This analysis aims to provide a first overview of clinical developments for
which pharmaceutical companies sought an early
dialogue with HAS.

METHODS:
For each product that went through an early
dialogue procedure with HAS, information
regarding the clinical development was collected
on pharmaceutical companies’ pipelines,
clinicaltrials.gov, the website of the European
Medicine Agency (EMA) and HAS’s internal
database.

RESULTS:
By the end of 2018, HAS has performed 84
early dialogues of which 53 were conducted in
collaboration with the EMA and/or others European
HTA bodies. They were mainly focused on phase
III trials. Following early dialogue, the clinical study
for which the Company sought advice was not yet
implemented in 25 cases. When the clinical trial
was effectively launch, results were negative in 10
cases, positive in 11 cases and the study was still
ongoing for 29 products. In nine cases, the clinical
development was officially withdraw or suspended
before the initiation of the trial. Overall, only eight
medicinal products were appraised by HAS, they all
obtained a clinical added value score.

CONCLUSIONS:
The success rate of clinical development for
products that underwent an early dialogue
procedure tends to be higher than data from
literature, although it is likely to decrease in follow-
up analysis. This could be partially explained by
HAS’s eligibility criteria that restrict early dialogues
to promising products and by the scientific
recommendations provided to pharmaceuticals
companies.

OP134 Adopting Genomic Testing In Canada: Latest Evidence And Challenges

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ABSTRACT SUMMARY:
Precision medicine (PM) is challenging Canadian
health technology assessment (HTA) processes. Through a literature review, we examine economic
evidence and evidentiary challenges for adopting
genomic testing in Canada. We find studies are
beginning to produce estimates of the economic
impacts of PM but barriers for HTA remain.
Lifecycle health technology management methods
are necessary to support decision making for PM.

INTRODUCTION:
Precision medicine (PM) poses challenges for
health technology assessment (HTA). Demand
for costly next generation sequencing (NGS)
technologies is increasing and health systems are
pressured to adopt PM interventions in the absence
of sufficient evidence to support decision making.
In Canada, there has been limited reimbursement
of PM. Through a structured literature review, this
study examines whether current uptake of PM in
Canada aligns with available economic evidence
and which evidentiary challenges for HTA remain.

METHODS:
We searched Medline (PubMed) for published
Canadian studies generating economic evidence
for PM informed by NGS. Our search focused on
studies examining the costs and/or value of NGS.
We reviewed included studies and summarized
results according to evaluation type, clinical
context, NGS technology, and test strategy. We then grouped HTA challenges encountered by authors when evaluating NGS.

RESULTS:
Our review included twenty-five studies. To determine the economic impacts of PM in Canada, studies applied cost-effectiveness analysis (52%, n=13), stated preference analysis (20%, n=5), cost-consequence analysis (16%, n=4), and healthcare resource utilization or costing analysis (12%, n=3). NGS panels were the most common technology evaluated (n=13), followed by whole genome and whole exome sequencing (n=6). The included studies highlighted multiple challenges when generating economic evidence, many of which remain unaddressed. Challenges broadly related to: 1) accounting for all NGS outcomes, including non-health outcomes; 2) addressing amplified uncertainty; and 3) improving consistency of economic approaches.

CONCLUSIONS:
Canadian studies are beginning to produce reliable estimates of the economic impacts of NGS-informed PM. Yet challenges for HTA remain. While solutions and real-world evidence are generated, reimbursement and disinvestment policies that share risk between payers and manufacturers can be designed to better support resource allocation decisions for genomic testing in Canada.

ABSTRACT SUMMARY:
Despite its promise to cure cancer, CAR T-cell therapy is associated with serious risks that require admission to intensive care. While New South Wales and Victoria consider CAR T-cell therapy is investigational due to limited evidence of safety, clinical and cost-effectiveness, a review will better inform policy and investment decisions regarding access to manufacturing and clinical providers.

INTRODUCTION:
Chimeric antigen receptor (CAR) T-cell therapy is offered as a once-only treatment for patients with certain cancers that are not responsive to standard treatment. While clinicians, patients and their families increasingly seek access to CAR T-cell therapy, there is no revenue stream to support access through public or private health systems.

METHODS:
The NSW Ministry of Health and Victorian Department of Health and Human Services oversaw an HTA to explore the status and geography of regulatory frameworks supporting delivery of CAR T-cell therapy, evidence for the safety, efficacy and cost, clinical trials conducted or underway and manufacturing aspects.

RESULTS:
CAR T-cell therapies are approved in the EU and USA and being considered in Australia, Canada, China and Japan. Efficacy, safety and cost-effectiveness is limited by the size and single-arm design of early stage trials and variation between them. While overall response ranges from 36–93 percent, early results for some cancers are less favourable. Durability of treatment effect is unknown, adverse events are common and can be life-threatening and risk of delayed onset toxicity remains unknown. Treatment requires access to approved manufacturing facilities (none in Australia) and specialist clinical staff.

OP135 CAR T-Cell Therapy HTA Informs Australian Policy

PRESENTING AUTHOR:
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AUTHORS:
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CONCLUSIONS:
CAR T-cell therapy is promising and demand is increasing, but limited safety profile and evidence base should mitigate policy and investment decisions. Broader consideration should be given to developing, or identifying access to, manufacturing and clinical workforce capability and capacity to meet national demand. Australia is likely to encounter similar issues in other jurisdictions, such as limited evidence base and complex safety issues. Factors to be considered on a local and national basis for assessment and implementation include:

- Regulatory support for industry
- Strategies to manage uncertainties in long-term risks, benefits and costs
- Access to accredited manufacturing facilities
- Developing clinical and manufacturing workforce capability and capacity.

INTRODUCTION:
The recent European Medicines Agency (EMA) approval of chimeric antigen receptor (CAR) T-cell therapies, axicabtagene ciloleucel and tisagenlecleucel, means the imminent arrival of health technology assessment (HTA) submissions to HTA agencies. HTA requires identification of all resources and organisational impacts pertaining to an intervention. Rapid Review is a form of knowledge synthesis that abbreviates certain methodological aspects of systematic reviews to produce information in a more timely manner. Considering the time-sensitive nature of CAR T-cell HTAs, the aim of this research was to conduct a Rapid Review to identify the institutional requirements for the provision of a CAR T-cell program.

METHODS:
A Rapid Review protocol was developed and registered in PROSPERO. Electronic databases, EMBASE and MEDLINE, and grey literature were searched. All study designs published in English after the year 2000 were included. Studies pertained to the use of CAR T-cells in adult and paediatric patients with solid and haematological malignancies. No restrictions were placed on the comparators or study setting. Primary outcomes were organised into two categories; (i) resource use, (ii) processes relating to implementation of CAR T-cell programs. Secondary outcomes included associated costs of implementation and barriers to successful implementation. Screening, review, and extraction of relevant data was conducted by a single reviewer. Extracted data included publication details, population and setting, study characteristics, outcomes and outcome measures, and strengths and limitations of research. Data was synthesised by means of thematic analysis.

RESULTS:
The study specified by this protocol is nearing completion. Preliminary results indicate that the provision of a CAR T-cell program in Ireland will
require the establishment of bespoke infrastructural support. Results will be presented.

**CONCLUSIONS:**
The findings of this Rapid Review will inform the assessment of organisational impacts associated with the introduction of a CAR T-cell program, ensuring a robust HTA assessment.

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**OP137 Translating Results From Clinical Audit Studies To Local Context**

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**ABSTRACT SUMMARY:**
In the absence of other research evidence and local practice data, translating results from clinical audit studies conducted in other jurisdictions, while challenging, can help address appropriateness questions; however, inferences may be suitable only for certain topics or an operating context. This presentation describes the experience and lessons learned from including clinical audit studies in a rapid health technology assessment.

**INTRODUCTION:**
Despite widespread use of oxygen (O2) therapy, there is relatively little available information on routine O2 administration and monitoring; this is an issue particularly when considering the potential risks associated with inappropriate O2 utilization. A rapid health technology assessment (HTA) was conducted to inform the Respiratory Health Strategic Clinical Network Oxygen Summit in Alberta on aspects related to current practice in the use of O2 therapy in acute care, including administration, safety and quality, and inappropriate practice. Clinical audit is a tool used to determine deviations in practice and to identify opportunities for improvement. The objective of this presentation is to describe the experience and lessons learned from including clinical audit studies in the rapid HTA.

**METHODS:**
A standardized rapid review approach was used to identify, select, and synthesize evidence from studies published in English from 2005 to 2016. A supplementary literature search conducted in 2018 provided additional background information on the value, applicability, and limitation of using results from clinical audit studies to inform questions of good practice.

**RESULTS:**
Twenty-four clinical audit studies on O2 therapy were identified; the majority were conducted in the United Kingdom. The studies varied in design, methodology, and data and outcomes reporting. Ten studies investigated the appropriateness of O2 therapy prescription pre- and post-implementation of local initiatives and interventions, which helped pinpoint major gaps in current practice, and identified general recommendations for improvement of practice. A list of reporting criteria is proposed for improving the reporting of clinical audit studies results.

**CONCLUSIONS:**
Conducting clinical audit studies is resource-intensive. In the absence of other research evidence and local practice data, translating results from clinical audit studies conducted in other jurisdictions, while challenging, can help address appropriateness questions. However, inferences from these studies may be suitable only for certain topics or an operating context.
OP138 Stakeholders’ Involvement When Developing A mHealth Assessment Tool

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ABSTRACT SUMMARY:
HTA agencies and evaluation experts need to have a specific evaluation tool for mHealth assessment due to the particularities of this technology. Focus groups and a modification of the Delphi technique are being used to discuss and agree on domains and criteria to be included in the tool with key stakeholders.

INTRODUCTION:
Due to the specific characteristics and challenges of mHealth technologies there is a need to have assessment tools based on their particularities to be used by HTA agencies and evaluation experts. In the development of a comprehensive and practical evaluation tool for the evaluation of mHealth solutions we aim to include the views and opinions of key stakeholders: health professionals, developers, hospital managers, HTA agencies, patients and general public.

METHODS:
Focus groups and an online modification of the Delphi technique are being used to discuss and agree on domains and criteria to be included in the mHealth assessment tool. Domains and criteria used for health apps evaluation were drawn from a literature review on the topic. The initial list includes ninety-five criteria grouped into the following domains: purpose of the app, privacy and security, clinical effectiveness, content of the intervention, user experience and usability, interoperability, expenses, impact on the organization, and legal and ethical aspects. Data coming from focus groups is currently being analyzed from a thematic and content analysis perspective.

RESULTS:
Focus groups with professionals have showed that the most important domains to be considered when evaluating health apps are those related with security, user experience, and clinical effectiveness. Some criteria were considered to be mandatory (mainly regarding safety issues), on which a first step assessment should indicate whether the app ‘pass or fails’ for the subsequent throughout assessment. Focus groups with patients will provide insight on critical aspects related to the choice, use and adherence to a health app.

CONCLUSIONS:
Insights from main stakeholders on the design of the tool for mHealth assessment are relevant and complementary between them. Next steps include a) the agreement of criteria by using an online modification of the Delphi Technique and b) piloting of the tool.

OP139 Mobile DCE App To Facilitate Shared Treatment Decision Making

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ABSTRACT SUMMARY:
The purpose of this study is to test whether
providing personalised feedback about treatment preferences to MM patients using a mobile preference application (based on Discrete Choice Experiments) enhances the shared decision-making process between the patient and the physician, therefore leading to more patient centred outcomes.

INTRODUCTION:

Multiple Myeloma (MM) is a disorder of the plasma cells characterised by the proliferation of malignant plasma cells in the bone marrow. While there is no cure for MM, recent advances in the understanding of the disease have resulted in new treatment options and subsequently, greater survival outcomes for patients. Given these new treatment options, patients’ treatment preferences for treatment are increasingly considered integral to the treatment and care process. The study aims to test whether providing personalised feedback about treatment preferences to MM patients using a mobile preference application (based on Discrete Choice Experiments) is logistically feasible and whether it enhances the shared decision-making process, therefore leading to more patient centred outcomes.

METHODS:

A sample of five Haematologists were recruited to participate in the study. Each physician recruited 4-5 patients into the study who were due to attend a consultation within an eight-week period. Patients were provided information about the mobile App prior to their consultation with their physician and asked to complete the eight to ten minute mobile survey. Once the survey was completed patients were shown a personalised feedback report outlining which treatment features were most important to them. This report was then emailed to their physician for discussion at their next upcoming consultation. After the consultation each patient was interviewed by an experienced qualitative researcher to obtain feedback on the process and gauge the impact on shared decision making. Physicians were also interviewed after each of their recruited patients had visited them.

RESULTS:

The general feedback from the interviews was that the App was beneficial to both patients and physicians. In particular, patients felt more informed, involved and in control of their choices for treatment. Physicians reported that the App enhanced the level of detail discussed in the consultation and helped them the direct conversation to focus on the areas of treatment that were most important to the patient.

CONCLUSIONS:

This study demonstrates that providing real-time feedback to patients about treatment preferences to be used in patient/physician discussions enhanced the discussion to better align with patient values and needs. The findings from this pilot will be used to evaluate the effectiveness of a shared decision-making mobile App and guide the development of larger scales studies which focus on improving patient outcomes through informed decision making.

OP140 Adult Patient Access To Electronic Health Records

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ABSTRACT SUMMARY:

Patient access to electronic health records is supposed to foster patient empowerment and that it may thereby indirectly improve health outcomes, especially in chronic diseases. The results of a Cochrane review do not support this claim.
INTRODUCTION:
In order to facilitate patient information, patient involvement, and to support patient-centered care, healthcare organizations are increasingly offering access to patient data that are stored in the institution-specific electronic health record (EHR). Patients can access these data, read, and print them, or download and integrate them into any type of patient-held record. This EHR access is typically web-based and called “patient portal” allowing the independent access via the Internet from everywhere. A patient portal may also offer additional features such as prescription requests, appointment booking, messaging, personal health-related reminders, individual therapeutic recommendations, personal diaries, and social networking with other patients. In a Cochrane review, we assessed the effects of providing access to EHR for adult patients on patient empowerment and health-related outcomes compared to usual care.

METHODS:
According to the methods of evidence-based medicine, we developed a protocol for a Cochrane review, which is published in the Cochrane database.

RESULTS:
We identified ten randomized controlled trials (RCTs) including 6,668 randomized participants. Seven RCTs took place in the USA, two in Canada, and one in Japan. Additional functionalities of interventions and disease conditions were heterogeneous. Three studies (n=601) reported on patient empowerment. The risk differences reported were neither statistically significant nor clinically relevant. Eight studies (n=2,070) reported on nine different risk factors (blood pressure, blood glucose, poor asthma control, 10-year Framingham risk score, cholesterol, body mass index, composite score of eight variables, intraocular pressure, composite score of three variables). The results were heterogeneous. Mostly there were no statistically significant risk differences between study groups.

CONCLUSIONS:
Overall, there is no evidence for a clear positive effect of patient portals on patient empowerment and health related outcomes (mainly risk factors). However, we identified only a small number of studies. The usage of portals was often low and several studies were older.

OP141 Assessment Of An Electronic PROM System For General Practice

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ABSTRACT SUMMARY:
We evaluated patients', general practitioners’ (GP) and staff’s acceptance of and attitudes towards a new electronic system for patient reported outcome measures (PROM). Preliminary results from questionnaire surveys show that patients, GPs and staff are positive and experience several advantages, and they would recommend the system to peers instead of using paper sheets.

INTRODUCTION:
Patient reported outcome measures (PROM) are highly used in Danish general practices. In 2016 an electronic PROM system, where patients are asked to enter their data electronically instead of using paper sheets, was introduced in order to improve the usage of PROM. The system enables automatic analyses and validation and provides general practitioners (GPs) with valuable information before consultations.

The aim of this organizational assessment was to
assess patients’, GPs’ and staff’s acceptance of and attitudes towards the new electronic PROM system.

METHODS:

Ten GPs, seven staff members and four patients were interviewed in order to design nationwide web-based questionnaire surveys for patients and GPs/staff. The questions concerned topics like user-friendliness, satisfaction, changes in workflow and time spent on different assignments for GPs/staff.

All patients who used the electronic PROM system within a three week period in 2018 were asked to participate in the survey. The questionnaire could be accessed from a link after completing their PROM questionnaire. For GPs/staff the questionnaire could be accessed from a link on the system website and in the national GP newsletter.

RESULTS:

More than 1000 patients and 200 GPs/staff participated in the study. Preliminary results show that according to GPs/staff, more time is spent on introducing patients to PROM. However, there are many indications of benefits, e.g. respondents find that the electronic PROM system is easy to use and they save time on data entry and calculations. Risk of losing data is reduced and GPs feel better prepared for consultations.

For both groups of respondents, the majority is satisfied and would recommend the system to peers.

Of GPs/staff who do not use the system, lack of time for implementation is mentioned as a reason.

CONCLUSIONS:

The electronic PROM system is highly accepted among patients, GPs and staff and is recommended to peers.

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OP142 Reviewing Methods For Early Assessment

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ABSTRACT SUMMARY:
The objective of this study is to reassess the effect of stakeholder insight and scenario drafting by validating the results using empirical data from the first pilot of DigiHelse. The present study presents a first step in evaluating the precision of employing stakeholder insight and scenario drafting as additional information in early assessment of innovation.

INTRODUCTION:
The project DigiHelse aims to support the municipality health in Norway by offering a digital communication platform to users of the home care service nationally. In a concept stage of innovation, an early assessment of the potential socioeconomic value of the project was carried out by means of stakeholder insight and scenario drafting. As the assessment showed favourable potential in providing decision support and reducing risk, the project received funding to move into the pilot phase. The objective of this study is to reassess the effect of stakeholder insight and scenario drafting by validating the results using empirical data from the first pilot of DigiHelse.

METHODS:

Through collecting empirical data on resource consumption and inquiries to the service from four intervention districts and one control district in Oslo, the socioeconomic value of DigiHelse was reassessed. In addition to survey and register data collected before and after the pilot, behavioural data was introduced as a new data source.
RESULTS:
The effect of early assessment by means of stakeholder insight and scenario drafting was successfully studied adding empirical data from the projects first pilot. The real-time data on user behaviour registered in the DigiHelse server contributed to verify the assumptions from the first assessment of the project. Although the results from the analysis were less optimistic than the first assessment consistent cost savings in a national context were detected after the pilot.

CONCLUSIONS:
The usefulness of early assessment is questioned, due to lack of precision of estimates caused by scarce available data. The present study presents a first step in evaluating the precision of employing stakeholder insight and scenario drafting as additional information in early assessment of innovation. The studied approach to early assessment showed potential in enhancing decision support and reducing risk from a concept stage of innovation.

OP143 Assessment of mHealth Apps: Is Current Regulation Policy Adequate?

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Apps presents unique challenges (e.g. rapid lifecycle) to mHealth regulation. Through a policy analysis and case-studies from regulatory agencies, it was determined that compliance with guidance from the International Medical Device Regulator’s Forum(IMDRF) was nominal. Forum member jurisdictions generally did not address the IMDRF safety principles for mHealth apps, namely, the potential dangers of misinformation on patients’ health or cybersecurity.

INTRODUCTION:
Australians are adjusting to mobile health (mHealth) applications (apps) being used in clinical care. The nature of apps presents unique challenges (e.g. rapid lifecycle) to mHealth regulation. The risks they pose are mainly through the information they provide and how it is used in clinical decision making. This study explores the international regulation of mHealth apps. It assesses whether the approach used in Australia to regulate apps is consistent with international standards and suitable to address the unique challenges presented by the technology.

METHODS:
A policy analysis was conducted of all nine member jurisdictions of the International Medical Device Regulator’s Forum (IMDRF), to determine if their regulatory agencies addressed the IMDRF recommendations relevant to the clinical evaluation of mHealth apps. Case studies (submission to regulatory agencies) were also selected on varying types of regulated apps (standalone, active implantable, etc.) and assessed relative to the principles in the IMDRF’s software as a medical device (SaMD): Clinical evaluation (2017) guidance document.

RESULTS:
All included jurisdictions evaluated the effectiveness of mHealth apps, assessing the majority of the key sub-categories recommended by SaMD: Clinical evaluation. The submissions and jurisdictional regulatory bodies did not address the IMDRF safety principles in terms of the apps’ information security (cybersecurity). Furthermore, by failing to use the method recommended by the IMDRF (risk-classification), none of the submissions or
jurisdictions recognised the potential dangers of misinformation on patient safety.

CONCLUSIONS:
None of the approaches used by global regulatory bodies adequately address the unique challenges posed by apps. Australia’s approach is consistent with app regulatory procedures used internationally. We recommend that mHealth apps are evaluated for cybersecurity and are also classified using the IMDRF risk-categories so as to fully protect the public.

OP144 mHealth App Evaluation Framework For Reimbursement Decision Making

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ABSTRACT SUMMARY:
There are currently no policies or frameworks suitable to guide a health technology assessment (HTA) on mHealth apps for reimbursement purposes. To create such a framework, four studies were conducted. This framework uses a standard HTA approach, but incorporates provisions to address, software updates, connectivity, and cybersecurity as well as concerns around practitioner responsibility and the potential for misinformation.

INTRODUCTION:
Mobile health (mHealth) applications (app) are being integrated into healthcare by patients and practitioners in Australia. However, there are currently no policies or frameworks available that can be used to conduct a health technology assessment (HTA) on mHealth apps for reimbursement purposes. The aim of the study was to determine what policy changes and assessment criteria are needed to facilitate the development of a system that evaluates MMAs for regulatory and reimbursement purposes in Australia.

METHODS:
To obtain the information to determine what policy changes are needed and create an evidence-based framework that can evaluate mHealth apps for reimbursement decision making, four studies were conducted. This research included a policy analysis on international mHealth app regulation; a case studies on American and Australian app regulation; a methodological systematic review on the suitability of current mHealth evaluation frameworks for reimbursement purposes; and the identification of HTA pathways and impediments to app reimbursement through stakeholder interviews. An evaluation framework for apps was created by combining and synthesising the results.

RESULTS:
When evaluating mHealth apps for reimbursement purposes, software changes, connectivity, and cybersecurity, need to be considered. Additionally potential dangers of apps providing misinformation, and poor software reliability in current regulation must be considered. Stakeholders indicated that they trust how traditional medical devices are currently appraised for reimbursement in Australian. They expressed caution around the lack of clarity regarding who is responsible for app quality as well as concerns about the digital literacy of medical practitioners and their patients.

CONCLUSIONS:
Since stakeholder trust in the current HTA process for medical devices in Australia is high, the process was adapted to create an evaluation framework for mHealth apps. The adaptations included making provisions for cybersecurity, software updates, and compatibility issues. Provisions to
address concerns around practitioner responsibility and misinformation were incorporated into the framework.

OP145 Born Fyne-An mHealth Intervention To Increase Access To Maternal Health

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ABSTRACT SUMMARY:
Most mhealth applications currently revolutionizing maternal health in developing countries have reported challenges in utilization amongst the non-literate groups. Introducing “BornFyne”- a low cost innovative mobile phone application that uses graphics to help address inequities in literacy by targeting the hard-to-reach communities in using pictographs to communicate health needs to providers especially during emergencies.

INTRODUCTION:
One in every 100 women of reproductive age continues to die from pregnancy-related causes in Cameroon. Most mhealth applications currently revolutionizing maternal health in developing countries have reported challenges in utilization amongst nonliterate groups. In some areas, absence of emergency services, no motor-able roads compel women to trek reasonable distances before reaching a health center.

Objective: To explore community’s perception, acceptability of the use of mobile phone application in delivering maternal health services and, outlined the formative research process used in developing the mhealth platform and its effectiveness compared to standard care.

METHODS:
The formative research involved, stakeholder meetings, key informant interviews and focus group discussions with health care providers, pregnant women and their partners within selected communities in Cameroon. Interviews transcribed and analyse using MaxQda. Directed approach to content analysis used as initial codes are determined based on the three delays model. Followed by a cluster randomized control trial of a target sample of 280 pregnant women into an intervention and control group.

RESULTS:
Key preliminary results of formative study identified demand and supply factors emerging from the three delays themes. Over 90% of the participants owned a mobile phone and all will love to use a mobile phone to communicate with their doctor, however, 83% had never used mobile phone to communicate with a doctor and 83% were able to list more than one benefits of using a mobile phone to communicate health needs. Generally, all participants will love to use graphics to communicate with the doctor. All providers would love to use mhealth to deliver care and listed more than one benefits especially during emergencies. Midterm results of the randomized control trial will be available at the time of the presentation.

CONCLUSIONS:
Based on preliminary findings, cyber health has great potential to increase access and utilization especially in addressing emergency and helps prepare providers during emergencies.
**OP146 Impact Of Disability Weights On Disability-Adjusted Life Years**

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**ABSTRACT SUMMARY:**
Previous DALY estimations for female breast cancer in China may have an underestimation potentially. Population-specific and detailed disability weights need to be produced and applied for more precise disease burden estimation, both in China and worldwide.

**INTRODUCTION:**
The disability weights vary among populations, age groups and cancer-stages, but the current well-known global burden disease studies only considered few values related disability-adjusted life years (DALY) evaluation of cancer, mainly due to the unavailability of data. The study aimed to estimate the impact of disability weights on DALY, taking female breast cancer in China, as an example.

**METHODS:**
Based on our existing utility database (N=2512, from 12 provinces across China, using EQ-5D-3L), we further analyzed age-specific and clinical stage-specific utility scores. Considering the distribution of clinical stages, the disability weights were obtained by calculating the difference of utility scores between breast cancer patients and the general population. With the incidence data from the Global Burden Disease (GBD) 2017 project, years of lived with disability (YLD) was estimated through a model developed by World Health Organization, and YLL was derived from GBD. A series of sensitivity analyses were conducted to reduce the uncertainty related to methodology and values of weights estimation.

**RESULTS:**
The proportion of YLD in DALY was 9.6% if all disability weights were designed to 0.049 (from GBD: controlled phase of cancer), which was similar to the results of GBD (9.4%). In the study, the mean disability weight of breast cancer was 0.172, which contributed to 897.9 thousand YLD person-year (27.9%). When age-specific weights were defined to the upper bound of 95% confidence interval, the YLD was 676.2 thousand person-year (22.6%). When calculated by the method (1- age-specific utility), the mean disability weight was 0.219, and the corresponding proportion of YLD increased to 32.3%. The sensitivity analysis showed the disability weights had a great influence on YLD.

**CONCLUSIONS:**
Previous DALY estimations for female breast cancer in China may have an underestimation potentially. Population-specific and detailed disability weights need to be produced and applied for more precise disease burden estimation, both in China and worldwide.

**OP147 Educational Costs And Benefits Of Mental Health Interventions**

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ABSTRACT SUMMARY:
This study looked at the inter-sectoral costs and benefits (ICBs) of mental health interventions that spread to the educational sector and found that mental health interventions can affect a large number of educational facilities. By identifying these ICBs, this study laid further foundations for the inclusion of important societal costs of mental health interventions within educational sector in economic evaluations.

INTRODUCTION:
The burden of mental health disorders has a wide societal impact affecting primary individuals and their significant others. Mental health interventions produce costs and benefits in the health care sector, but can also lead to costs and benefits in non-healthcare sectors, also known as inter-sectoral costs and benefits (ICBs). The aim of this study was to develop an internationally applicable list of ICBs in the educational sector resulting from mental health interventions and to facilitate the inclusion of ICBs in economic evaluations across EU by prioritizing important ICBs.

METHODS:
Some ICBs of mental health interventions were identified in earlier research, which were used as a basis for this study. Additional data was collected via a systematic literature search of PubMed and a grey literature search carried out in six EU countries. In order to validate the international applicability of the list and prioritize the ICBs, a survey was conducted with the international group of experts from the educational sector. The outcomes of the expert survey were used to create the condensed list containing the most important ICBs.

RESULTS:
The literature search allowed identifying additional ICBs and creating a comprehensive list of items. In order to improve its usability, a multi-dimensional list was constructed distinguishing between tangible (i.e. special education) and intangible items (i.e. cognitive deficits). Based on the expert survey, the international applicability of the list was validated and the most important ICBs from the economic perspective were determined.

CONCLUSIONS:
Mental health interventions can affect a large number of educational facilities. The list of ICBs developed in this study could be used to select relevant educational facilities for economic evaluations of specific mental health disorders. Further research is needed to define, measure, and valuate the identified ICBs in order to facilitate the practical application of the list in economic evaluations.

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OP148 Stepped-Care Treatment For Depression May Have Economic Benefits

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ABSTRACT SUMMARY:
Stepped-care pathway (SCP) has previously been found to be clinically effective for depressive disorder in some, but not all, studies. There is relatively little information regarding which specific SCP may be best. AHS completed a randomized controlled trial of a SCP for depression treatment. Our health economic analysis suggests the SCP model may have potential to improve health system value.

INTRODUCTION:
Literature review found the stepped-care pathway
(SCP) model was clinically effective for depressive disorder in some, but not all, studies. There is relatively little information regarding which specific SCP may be best. Alberta Health Services in Canada completed a randomized controlled trial (RCT) of a SCP for treatment of depression in a primary care setting in efforts to guide reinvestment of mental care capacity and inform evidence-based policy on selecting an appropriate treatment. Here we present the results of the health economics analysis of the multi-arm study. There are no clinically significant differences in health outcome between treatment approaches, however there may be economic benefit from implementing the SCP model.

**METHODS:**

The RCT with 1,400 participants and 12-week follow-up compared impact of SCP, standard care, treatment-as-usual and online cognitive behavioural therapy on quality of life and depression severity. Costs were physician, outpatient and inpatient services collected from health administrative databases. Missing data and uncertainty were handled using an intention-to-treat approach and Monte Carlo simulation respectively. Participants with Patient Health Questionnaire -9 of greater than 10 at baseline were examined in subgroup analysis.

**RESULTS:**

In groups of all participants and depressed subgroup, treatment-as-usual was most expensive while the cheapest was SCP in all participants and online cognitive behavioural therapy in subgroup; Quality-adjusted life years were the highest in SCP while the lowest was treatment-as-usual in both groups. The analysis revealed SCP dominated the other three alternatives in all participants. However, in the subgroup, online cognitive behavioural therapy had the highest probability of being cost-effective (willingness-to-pay cut-off less than CAD50,000), while SCP was highest at cut-off greater than CAD50,000.

**CONCLUSIONS:**

While more work is required to identify the most clinically effective versions of a SCP, our findings suggest that the care pathway may have substantial potential to improve health system value.

**OP149 Economic Evaluation Of Pharmacological Treatments For Type 2 Diabetes In China**

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**ABSTRACT SUMMARY:**

This study developed 20 pharmacological-treatment-strategies for Chinese type-2-diabetes patients based on Chinese guideline and practice, and estimated their cost-effectiveness using Cardiff model. From societal perspective, model-required clinical-data were obtained from systematic-literature-review combined with meta-analysis and indirect-treatment-comparison of 354 studies; costs were collected from claims-database-study of 1164 patients; utilities were obtained from EuroQol-5D survey of 868 patients. Over 40-year simulation, monotherapy strategies averagely increased 0.681QALY at cost-saving of ¥11803 for a patient, while combination strategies increased 1.720QALY with ¥58689 cost-saving. Combination strategies were superior to monotherapy strategies with lower costs and higher QALYs.
**INTRODUCTION:**

There are multiple antidiabetic drugs in China. With the increasing health expenditure related to type 2 diabetes (T2DM), it's important to choose cost-effective drugs to reduce costs and optimize for efficacy. Chinese guideline recommends a stepwise-escalation treatment strategy in T2DM care, which consists of three-therapy-lines to reflect disease nature; and recommends using combination therapy of antidiabetic-drug plus metformin for patients failed on metformin. However, many patients use monotherapy in clinical practice. This study aims to develop several alternative pharmacological treatment strategies and estimate their cost-effectiveness.

**METHODS:**

Based on Chinese guideline and practice, three-lines eight-classes of antidiabetic-drugs were included: 1st-line-drug (metformin), 2nd-line-drug (α-glycosidase-inhibitor, sulfonylurea, glinide, DPP-4-inhibitor, thiazolidinedione), 3rd-line-drug (insulin, GLP-1-receptor-agonist); and 20 pharmacological treatment strategies were developed: using metformin as 1st-therapy-line, one of the five 2nd-line-drugs as 2nd-therapy-line, and one of the two 3rd-line-drugs as 3rd-therapy-line to construct 10(=1*5*2) treatment strategies, which were further subdivided into monotherapy strategies and combination strategies. From a societal perspective, Cardiff diabetes model was used to estimate the cost-effectiveness of 20 treatment strategies vs. non-pharmacological treatment. Clinical data on Chinese T2DM patients were obtained from systematic-literture-review combined with meta-analysis and indirect-treatment-comparison of 354 studies. Costs (2016 Chinese-Yuan[¥]) were collected from claims-database-study of 1164 patients combined with hospital-information-system. Utilities were obtained from EuroQol-5D survey of 868 patients. Discount-rate was 3%. A series of sensitivity analyses were performed.

**RESULTS:**

Over 40-year simulation, compared with non-pharmacological treatment, all the 20 treatment strategies predicted lower incidences of macrovascular and microvascular events as well as mortality events, and combination strategies were better than monotherapy strategies in reducing these events; overall, monotherapy strategies meanly predicted an incremental benefit of 0.681 quality-adjusted-life-year(QALY) (range: 0.879-0.277QALY) and 0.179 life-year(LY) (range: 0.200-0.146LY) at an incremental cost-saving of ¥11803 (range: ¥42577-39852) for an individual patient, while combination strategies meanly increased 1.720QALY (range: 2.329-1.334QALY) and 0.325LY (range: 0.364-0.278LY) at a cost-saving of ¥58689 (range: ¥92294-16915) for a patient. Results of incremental cost-effectiveness ratio(ICER) showed that 70% of the monotherapy strategies were cost-saving (range: ¥-64222/QALY-¥-4360/QALY) with 30% as cost-effective (range: ¥1131/QALY-¥115352/QALY), while 100% of the combination strategies were cost-saving (range: ¥-58332/QALY-¥-9659/QALY) compared with non-pharmacological treatment. Sensitivity analyses confirmed that the results were robust.

**CONCLUSIONS:**

Pharmacological treatments could reduce lifetime-costs and increase QALYs for patients. Combination strategies were superior to monotherapy strategies with lower costs and higher QALYs.

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**OP150 Impact Of Biologics On Rheumatoid Arthritis: How Have Costs Evolved?**

**PRESENTING AUTHOR:**

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**AUTHORS:**

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ABSTRACT SUMMARY:
Over the past two decades, biologic treatment has led to better outcomes in patients with RA and transformed both, the composition and total cost of illness (COI) of RA. This study synthesizes contemporary COI studies to examine this changing landscape. Drug costs have replaced hospitalization costs as the dominant cost driver, but are unlikely to increase in the next decade.

INTRODUCTION:
Over the past two decades, there have been major advances in the management of rheumatoid arthritis (RA). It is now recognized that early diagnosis and intensive treatment can limit disease progression and preserve physical functions in patients with RA. While the introduction of biologics is the landmark of RA management, these expensive drugs have transformed the composition and total cost of illness (COI) of RA. This study aims to characterize the context, design, and findings of COI studies in RA with a particular focus on the changing landscape.

METHODS:
We performed a systematic review of COI studies published after 2000. In the absence of an assessment tool for COI studies we have developed a modified CHEERS checklist to appraise the quality of studies. Narrative synthesis alongside tabulations and conceptual mapping was used to describe the data.

RESULTS:
We identified substantial variations in patient case-mix, healthcare settings, and methodological approaches to estimating COI of RA. Direct cost accounted for approximately 24.8-54.2 percent of total cost. Drug costs were the dominant cost driver accounting for 40.2-60.3 percent of direct costs. The share of hospitalization costs had declined from over 30 percent to 15-20 percent of direct cost. Indirect costs accounted for 20.4-75.2 percent of total cost. Lower hospitalization and outpatient costs were reported for patients on biologic treatment compared to those on DMARDs, however this did not translate into lower direct cost due to higher drug cost. However, some studies already reported that rising drug costs had reached a plateau in 2009 and reported a general reduction in hospitalization costs and productivity loss.

CONCLUSIONS:
The change in treatment strategies has led to better outcomes for patients with RA, which is reflected in the reduction of hospitalizations and productivity loss. Drug costs seem to have plateaued and further decreasing COI is expected with the entry of biosimilars.

OP151 Cost-Utility Of Gender-Neutral HPV Vaccination In Ireland

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ABSTRACT SUMMARY:
We examined the impact of recently observed fluctuating uptake rates on the cost-effectiveness of a gender-neutral HPV vaccination programme in Ireland. A drop in uptake impacts on resilience of the programme and on cost-effectiveness, showing the importance of reflecting real-world experiences into economic evaluation.

INTRODUCTION:
A number of economic evaluations of gender-neutral HPV vaccination have been published,
generally finding that the cost-effectiveness is sensitive to the uptake rate in girls. In Ireland there is a girls-only programme in place, but the initial high uptake rate (>85%) was substantially impacted by high profile negative publicity concerning perceived vaccine safety issues. Efforts to address perceived safety concerns have recently yielded a partial recovery in uptake rates. The aim of this study was to estimate the cost-utility of extending the programme to include boys and explore the impact of fluctuating uptake rates.

METHODS:
A previously published cost-utility model used in the US and Norway was adapted to the Irish setting and populated with Irish epidemiological and cost data. Comparators included no vaccination, and girls-only and gender-neutral vaccination, both with either a 4-valent or 9-valent vaccine. Vaccination is at age 12 years and oropharyngeal and penile cancers were excluded in the base case analysis. Additional analyses were used to incorporate fluctuating uptake rates into the model.

RESULTS:
A 9-valent girls-only programme dominated the existing girls-only 4-valent programme. The incremental cost-effectiveness ratio (ICER) for a gender-neutral 9-valent programme was €50,823/QALY. Gender-neutral vaccination would be cost-effective at a willingness-to-pay threshold of €45,000/QALY when the uptake rate is below 78%. The ICER decreased to between €41,000 and €42,000/QALY when the uptake rate was allowed to fluctuate across 6 to 12 yearly cycles.

CONCLUSIONS:
The cost-effectiveness of gender-neutral HPV vaccination is highly sensitive to the assumed uptake rate in girls. Large fluctuations in HPV vaccine uptake rates have been observed in a number of countries in the last decade. Incorporating fluctuating uptake rates in the model shows that a gender-neutral programme may be more cost-effective than when a stable uptake is assumed.

OP152 Pharmacoeconomic Assessment And Drug Expenditure Reduction In Ireland

PRESENTING AUTHOR:
Cormac Kennedy, Ireland

ABSTRACT SUMMARY:
To determine expenditure reduction due to price agreements during the pharmacoeconomic assessment process, data were recorded for products submitted from 2012-2015. Following application of study criteria, fifteen products were included. National data were obtained to compare expected to actual expenditure. Average expenditure reduction was 8%. Other products may have rebates paid centrally which will be the subject of future research.

INTRODUCTION:
All new products to be reimbursed from the Irish health budget are subject to a rigorous assessment by the National Centre for Pharmacoeconomics (NCPE). Following assessment, a recommendation is made regarding its cost-effectiveness at the submitted price. This may lead a reduction in the drug price. This study aimed to determine the reduction in expenditure due to the pharmacoeconomic assessment process in Ireland.

METHODS:
Product details, submitted price and gross budget impact were recorded for each NCPE submission from 2012 to 2015. The latter was chosen as reimbursement data are currently available until 2016. A product was included if its assessment suggested price reduction was required and the product was reimbursed under the High-Tech Drug Scheme (HTDS), a scheme for high cost drugs in a primary care setting. The utilisation and actual
expenditure of each product was extracted from national reimbursement data for the year after approval. The expected expenditure, calculated using the submitted price, was then compared to the actual expenditure.

RESULTS:
162 products were assessed during the study period. There was a potential price reduction for sixty-five products based on the assessment outcome. Of these, fifteen were reimbursed under the HTDS. A reduction in expenditure was evident for eight of the fifteen products (53 percent). The average reduction was eight percent of the expected expenditure. All products showed an actual expenditure greater the predicted budget impact submitted by the applicant.

CONCLUSIONS:
To the authors’ knowledge, this is the first report of expenditure reduction due to a pharmaco-economic assessment process. With the ever-increasing utilisation of high cost drugs, the study demonstrates the importance of a process to assess and negotiate cost-effective drug prices. However, the study underestimates reductions, as it is yet to include commercial rebates returned to a central budget. Future research will aim to capture these reductions.

OP153 The Value Of Health Technology Assessment: A Mixed Methods Framework

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ABSTRACT SUMMARY:
The benefits concerning the link between health technology assessment (HTA) and outcomes in terms of health improvements have rarely been quantified. A lack of longer-term impact assessment may undermine its importance and value. To address this, we have developed a mixed-methods framework to quantify the value of HTA.

INTRODUCTION:
The benefits concerning the link between health technology assessment (HTA) and outcomes in terms of health improvements have rarely been quantified. The global expansion of HTA, its variable implementation resulting in sub-optimal impact, the lack of quantified evidence on health outcomes, along with an increasing investment in these processes at the systems level in low- and middle-income countries (LMICs) has generated greater interest from policy makers and donors about the value and return on investment (ROI) of HTA.

METHODS:
We use a mixed-methodology aimed at building up a rich picture of process, uptake and impact. The aim is to get over the concepts of potential population net health benefit and realised population net health benefit – and what we can attribute to the HTA process. Central to understanding this is the ‘value of implementation’ (VOImp). Theory-driven approaches will be used to generate and test contextual explanations for a gap between expected and actual gains in population health.

RESULTS:
We present a methodological framework to quantify the ROI in HTA and explanatory programme theory on the mechanisms by which HTA impact can be optimised. In this presentation, we focus only on the application of the quantitative ROI framework. We will test the framework
empirically using country case studies, and will present an example of applying the framework in a middle-income country.

CONCLUSIONS:
We envisage this research, by synthesising economic and more qualitative methods, will provide a framework to quantify the value and impact of HTA on health and economic outcomes, as well as evidence informed theory and recommendations to produce guidance as how to do HTA by context in order to optimise its impact on health.

INTRODUCTION:
Resource allocation in health is universally challenging, but especially so in resource-constrained contexts in the Global South. Pursuing a strategy of evidence-based decision making and using tools such as Health Technology Assessment (HTA), can help address issues relating to both affordability and equity when allocating resources. Three BRICS and Global South countries, China, India and South Africa have committed to strengthening HTA capacity and developing their domestic HTA systems, with the goal of translating evidence into policy. Through assessing and comparing the HTA journey of each country it may be possible to identify common challenges, solutions, and shareable insights. This collaborative research aimed to share knowledge on strengthening HTA systems in the Global South to promote evidence-based decision making.

METHODS:
A descriptive and explorative comparative analysis was conducted comprising a Within-Case analysis to produce a rich narrative of the HTA journey in each country and an Across-Case analysis to explore both knowledge that could be shared across the Global South and any potential knowledge gaps. This study involved experts from each country in order to provide the most pragmatic and appropriate insights.

RESULTS:
Analyses revealed that China, India and South Africa share many barriers to strengthening and developing HTA systems such as: 1) Minimal HTA expertise; 2) Weak health data infrastructure; 3) Rising healthcare costs; 4) Fragmented healthcare systems; and 5) Significant growth in non-communicable diseases. Stakeholder engagement, and the institutionalisation of HTA were identified as two conducive factors for strengthening HTA systems.

CONCLUSIONS:
China, India and South Africa have all committed

OP154 Strengthening Health Technology Assessment Systems In The Global South

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ABSTRACT SUMMARY:
Health Technology Assessment (HTA) and explicit priority setting have gained increased acknowledgement from policymakers in countries of the Global South. A comparative analysis of the HTA journeys in China, India and South Africa revealed that the countries experienced similar challenges. Collaboration across countries could elicit shareable insights for strengthening HTA systems and capacity that are useful and pragmatic.
to establishing robust HTA systems to inform evidence-based priority setting and have experienced similar challenges. Engagement among countries of the Global South can provide a supportive platform to share knowledge on strengthening HTA systems that is more applicable and pragmatic.

OP155 Assessing Value Of Medical Technologies Early On In Emerging Economies

PRESENTING AUTHOR:
Jani Mueller, South Africa

ABSTRACT SUMMARY:
Many of the innovative technologies developed worldwide are appropriate for low resource settings. Ease of adoption in local market may ensure access to markets elsewhere. Early health technology assessment can provide relevant information on the potential value of the technology to the healthcare setting. In addition, when necessary it allows the developer to correct the pathway to further development.

INTRODUCTION:
Access to safe and quality medical device and diagnostics ensures equitable healthcare for the population. In many emerging settings challenging financial resources, poor regulatory controls, ineffective governance and weak management structures and inadequate support result in the use of substandard equipment and devices and lead to challenges and constraints to local innovation.

Use of Health Technology Assessment supports evidence-based decision on safe, effective, patient-relevant and cost-effective healthcare.

HTA also plays an important role early on during the life cycle of a medical technology, already at the innovative concept phase. An early assessment of the technology during basic research till product launch phase can determine its potential value in a healthcare setting and shape the innovation according to market needs.

Universities or entities resulting from private public partnerships are innovation hubs in emerging settings such as in South Africa. Assessments are conducted to inform stakeholders such as biomedical product developers or partners facilitating translation of research outcomes. The objective of this scoping study is to identify and explore current assessment methodologies for medical technologies early on during the development phase.

METHODS:
A current scoping review was updated and conducted to identify different early assessment methods of medical technologies. The review of studies published till 2018 was performed and information on (a) decision context (country of study, technology under development, stage of development) (b) decision problem (c) methods used (d) dimensions considered (e) data needed collected.

RESULTS:
The majority of the studies presented early-stage costing and economic models. Uncertainty was handled using different sensitivity analysis and scenario analysis.

CONCLUSIONS:
This study shows that early health economic evaluations are common in early assessment of technologies. However, due to utilization in hospital or clinic setting a broader set of criteria are needed to assess the potential value of these technologies for the patients and society.
OP156 Assessing Resource Allocation At Intersection Of Efficiency And Equity

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Healthcare leaders are regularly asked to make funding decisions that achieve effective outcomes, value for money, and person-centered care. These decisions are complex, carry significant consequences for people’s health and require balancing competing claims with varying quality of evidence. This presentation shares a novel resource allocation framework currently in use that analyzes financing proposals in a $13 billion/year healthcare provider.

INTRODUCTION:
In the modern context, healthcare leaders are regularly asked to make decisions that achieve effective outcomes, value for money, and person-centered care. These decisions are complex, carry significant consequences for people’s health and require balancing competing claims with varying GRADES of evidence. Recognizing these challenges, Alberta Health Services (AHS) a Canadian public healthcare provider with an annual budget exceeding $13 billion, sought to develop a framework to provide guidance to decision-makers.

METHODS:
Development began in 2017 with a core team of health economists and ethicists. The framework builds on substantive values and existing frameworks from academic and grey literature sources. Development process included two waves of consultation with a wide cross-section of stakeholders internally (clinicians and senior leaders) and externally (patient and family advisory and community advisory groups) that impacted the tool. It is currently in use to assess horizontal and vertical equity of funding proposals that span across technology, drugs, and program changes (e.g. opening new clinics).

RESULTS:
The framework is unique and presents a progression in the field of healthcare resource allocation. The scope of funding possibilities, whose relative merits are compared, is broader than within HTA methodology or most other resource allocation frameworks. It has been piloted with a set of initiatives that were chosen for their specific complexity and relatively different areas of impact surgery, emergency health care, chronic disease, and preventative programming.

CONCLUSIONS:
The framework demonstrates a real world and novel example of resource allocation across a large health organization. It is relevant to finance decision-makers, HTA end-users, and HTA authors. Future work includes a discrete choice experiment testing the internal validity of weightings of efficiency and equity within the framework.

OP157 Carbon Ion Radiotherapy: A Systematic Review

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ABSTRACT SUMMARY:
Carbon ion radiotherapy (CIRT) is a promising cancer treatment. Yet, it is unclear whether the theoretical advantages of CIRT translate into
clinical benefits. This systematic review assessed the evidence of CIRT for 12 oncologic indications. Anno 2018, there is insufficient evidence in seven indications and no evidence in five indications proving superiority/inferiority of CIRT when compared to standard irradiation.

INTRODUCTION:
Due to the promising physical dose distribution of carbon ion radiation therapy (CIRT), CIRT can be regarded as a novel tumour irradiation technique and is sometimes considered as a breakthrough therapy for various tumour types. However, to the best of our knowledge, it is unclear in how far a superiority/inferiority can be claimed when compared to standard irradiation. This study aimed at assessing the scientific evidence regarding the efficacy and safety of CIRT for 12 oncologic indications (and 54 sub-indications).

METHODS:
A systematic literature review was conducted using the EUnetHTA Core Model® for rapid relative effectiveness assessment. The literature search for clinical outcome studies on CIRT was performed in four databases [Cochrane (Central), Centre for Research and Dissemination (CRD), Embase and OVID MEDLINE]. The risk of bias was assessed using the Cochrane Risk of Bias Tool (for randomised controlled trials) and the Institute of Health Economics (IHE) Checklist (for observational studies).

The evidence synthesis was restricted to 12 oncologic indications (and 54 sub-indications) and studies with a low or moderate risk of bias, published between 2005 and 2017.

RESULTS:
Twenty-seven studies were eligible for the qualitative synthesis of the evidence regarding the efficacy and safety of CIRT: one randomized controlled trial that primarily focused on the feasibility of CIRT, three case-control studies, three before-after studies focusing on quality of life, and 20 further case series studies.

Overall, insufficient scientific evidence was found for 13 (out of 54) sub-indications in seven oncologic indications and no scientific evidence was found for 41 (out of 54) sub-indications in 5 oncologic indications.

CONCLUSIONS:
Theoretically, CIRT is undoubtedly a promising cancer treatment. To date, however, it lacks randomised controlled trials, assessing the long-term effectiveness and harms associated with the use of CIRT in the 12 oncologic indications under investigation. CIRT must be considered as an experimental treatment due to the lack of high-quality clinical research.

OP158 Antiepileptic Drugs As Prophylaxis For Postcraniotomy Seizures

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ABSTRACT SUMMARY:
The use of antiepileptic drugs (AEDs) administered pre- or postoperatively to prevent seizures following craniotomy surgery in people with no history of epilepsy has been investigated in a number of randomised controlled trials. We did not find any consistent evidence to suggest that prophylactic treatment with AEDs is effective in reducing the number of post-surgery seizures, deaths or adverse effects.

INTRODUCTION:
Postoperative seizures can precipitate the development of epilepsy. The administration of antiepileptic drugs (AEDs) pre- or postoperatively
to prevent seizures following craniotomy surgery in people with no history of epilepsy has been investigated in several randomised controlled trials (RCTs). In this update to our 2015 Cochrane Review, we investigated the efficacy and safety of administering AEDs to people with no history of epilepsy undergoing craniotomy and examined which AEDs are most effective.

METHODS:
We searched the Cochrane Epilepsy Group Specialized Register, CENTRAL, MEDLINE, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform to identify RCTs of people with no history of epilepsy who were undergoing craniotomy surgery. We did not apply language restrictions, nor stipulate a minimum treatment period, and we included trials using active drugs or placebo as a control group.

RESULTS:
We included 10 RCTs (N=1815), published between 1983 and 2015. Due to the heterogeneous nature of the trials, we did not perform meta-analyses. Five trials compared AEDs with placebo or no treatment; two of these trials reported a statistically significant advantage for AED treatment for early (within 7 days) seizure occurrence; we found no difference between AEDs and controls for late seizures. None of the five trials of head-to-head comparisons of AEDs reported statistically significant results for either early or late seizure occurrence. The incidences of deaths and AEs were poorly reported. We considered the evidence to be of low quality for all reported outcomes.

CONCLUSIONS:
There is limited, low quality evidence to suggest that AED treatment administered prophylactically is either effective or not effective in the prevention of postcraniotomy seizures in people with no history of epilepsy. The current evidence base is limited due to the differences in trial protocols and inconsistencies in the reporting of outcomes. Further evidence from good quality RCTs is needed.

OP159 Frequency And Bayesian Network Meta-analysis Of SR Versus TAs For HCC

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ABSTRACT SUMMARY:
This network meta-analysis (NMA) based on frequency and Bayesian framework was used to compare the efficacy and safety among radiofrequency ablation (RFA), microwave ablation (MWA) and surgical resection (SR) for hepatocellular carcinoma in China, and to support clinical decisions on appropriate therapies for the patients.

INTRODUCTION:
Whether radiofrequency ablation (RFA) and microwave ablation (MWA) can replace surgical resection (SR) as the first-line treatment for hepatocellular carcinoma (HCC), and which thermal ablation (TAs) technique of RFA and MWA is more effective are still controversial. The purpose of this study was to compare the efficacy and safety among RFA, MWA and SR in patients with HCC in China, by constructing frequency and Bayesian network meta-analysis (NMA).

METHODS:
References related to eligible RCTs were searched from CBM, CNKI, PubMed, Embase (Ovid SP) and Cochrane Library, and selected according to criteria. Multivariable meta-regression was used to construct network meta-analysis based on frequency framework by Stata 13.0 software,
and Chaimani random effect model was used to construct network meta-analysis based on Bayesian framework by WinBUGS 1.4.3 software.

RESULTS:
Frequency NMA supported MWA (SUCRA = 66.1%) with the highest 5-year overall survival (OS) rate, while Bayesian NMA supported SR (SUCRA = 64.7%) with the highest 5-year OS rate, when the tumor diameter and liver function were not limited. Both two methods support SR with the highest 5-year survival rate (SUCRA = 89.1% and SUCRA = 88.3%, respectively), when the tumor diameter was less than 5 cm and liver function was Child-Pugh A/B grade. Both two methods showed RFA with the lowest incidence of severe complications, regardless of the limitation of tumor diameter and liver function.

CONCLUSIONS:
When the similarity and consistency are better, the network meta-analysis based on the frequency method also has good applicability as Bayesian method; SR should still be the first choice for early small hepatocellular carcinoma, and the choice of RFA and MWA should have its own emphasis.

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OP160 The Real-World Validation Of A Stakeholder Participation Checklist

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ABSTRACT SUMMARY:
Accountable decision-makers are required to legitimize their priority setting decisions in health to members of society. Health authorities are advised to use the theoretically and real-world validated checklist presented to assist them in the practical organization of stakeholder participation in their priority setting processes and obtaining their moral authority.

INTRODUCTION:
Accountable decision-makers are required to legitimize their priority setting decisions in health to members of society. To assist health authorities in obtaining their moral authority a practical checklist was derived from operationalizing the A4R framework and reflecting on the ethical notions it invokes when addressing the imperative of treating people as moral equals. According to a ‘translational ethics’ perspective, the practical relevance of the checklist ought to be validated (and/or updated) based on qualitative data on what would make the actual adversely affected in practice accept the decision-making process they have experienced as fair.

METHODS:
10-15 semi-structured interviews related to the theoretically derived checklist will be conducted with adversely affected participants in current priority setting processes in the Netherlands to provide insight into their thoughts/reflections on how their participation in decision-making processes have been organized in terms of promoting their status as moral equal to those who actually receive care. We will use systematic text condensation which is a cross-case thematic analysis for qualitative data in medical research. This approach to the material is organized through four systematic steps: 1) total impression - from chaos to themes; 2) identifying and sorting meaning units - from themes to codes; 3) condensation - from code to meaning; 4) synthesizing - from condensation to descriptions and concepts.

RESULTS:
The theoretically justified check-list is already...
published while preliminary results of the real-world validation will become available during the first months of 2019 and will be ready to present during the HTAi conference in June 2019.

CONCLUSIONS:
Health authorities are advised to use the theoretically and real-world validated checklist to assist them in the practical organization of stakeholder participation in their priority setting processes and obtaining their moral authority. Other stakeholders can use the checklist to evaluate current priority setting processes and demand improvements based on their evaluation.

ABSTRACT SUMMARY:
Stakeholder perspectives regarding design, conduct and use of patient preference studies (PPS) was investigated. Eight focus groups were conducted with stakeholders in Europe, United States and Canada. Stakeholders believed that PPS should be designed in collaboration with multiple healthcare stakeholders. They also found that the more a decision is surrounded by uncertainty, the more value PPS have in decision making.

INTRODUCTION:
While patient preference studies (PPS) are gaining attention, the use of their results in assessments and decision making along the medical product lifecycle is limited. The aim of this study was to investigate stakeholder perspectives on how PPS should be designed, conducted and used.

METHODS:
Focus group guides were informed by literature reviews and semi-structured interviews (n=143). Focus groups (n=8) were conducted with the following stakeholders: patients (UK, Sweden, Italy and Romania), industry representatives (EU), regulators (EU and US) and HTA representatives (EU and Canada). Focus groups were analysed thematically using NVivo.

RESULTS:
Patients highlighted factors influencing their participation in preference studies such as encouragement of family and the relationship with the PPS recruiter. Across all focus groups it was found important that PPS sponsors collaborate with other stakeholders including patients, patient organizations, regulators and HTA bodies to limit occurrence of bias, and to ensure comprehensibility of questions and usefulness of results for decision makers. Participants indicated that currently, mostly qualitative input is collected by industry, regulators and HTA bodies and that use of results from quantitative methods is limited but possibly useful for HTA and reimbursement decisions. Regulatory, HTA and industry participants
agreed that the value of PPS in decision making is higher when there is high uncertainty regarding clinical evidence and an uncertain benefit-risk profile. While in this study perspectives of stakeholders were gathered on different decision-making contexts, the focus of the presentation at HTAi will be on the use of patient preferences in HTA.

**CONCLUSIONS:**
Stakeholders believed that PPS should be designed in collaboration with multiple healthcare stakeholders including patients. The value of PPS for decision making might depend on the match of the method (qualitative versus quantitative) to the lifecycle phase and on uncertainties relating to the clinical evidence and profile of the medical product.

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**OP162 Stakeholder Involvement In EUnetHTA Relative Effectiveness Assessments**

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**ABSTRACT SUMMARY:**
The European Network for Health Technology Assessment (EUnetHTA) involves a variety of stakeholders in the elaboration of Rapid Relative Effectiveness Assessments. This participation is reviewed by categorizing stakeholders, describing methods and analyzing trends of collaboration. This study shows that stakeholders’ contribution is increasing, methods having become more standardised over the years, improving involvement.

**INTRODUCTION:**
Appropriate involvement of stakeholders is one of the founding principles of the European Cooperation on Health Technology Assessment. The European Network for Health Technology Assessment (EUnetHTA) produces Rapid Relative Effectiveness Assessments (REAs) to assess Pharmaceutical (PT) or Other Technologies (OT). Stakeholders essentially participate in the scoping, the draft assessment phase, or both.

**METHODS:**
All REAs published since 2013 were reviewed. Stakeholder participation in scoping (project plan) and in draft assessment was evaluated. We aggregated categories of stakeholders in four groups (Health Care Providers and Academia, Patients and Consumers, Manufacturers, and Regulators and Payers). Means of collaboration (meetings, comments to project plan and draft assessment, questionnaires, focus groups) are also analysed. Data is continuously updated with new REAs.

**RESULTS:**
More than twenty REAs have been published at the moment, with a higher number of OT. Health Care Providers and Academia acted as experts in both phases, participating in all REA of OT, and less of PT. Manufacturers participated in all REA in the scoping phase. Payers and Regulators, less involved, participated mainly in the scoping phase. The main methods are providing comments in a standardised form and meetings. Patients’ contribution, similar in OT and PT, has increased over the years. Questionnaires or interviews are the main method of involvement, followed by participation in meetings and focus groups. Visibility and transparency have also improved, with a clearer reporting of the stakeholder contribution in the last assessments.

**CONCLUSIONS:**
The Stakeholder involvement in EUnetHTA REAs is steadily growing, being the different nature of stakeholders’ categories reflected in their
OP163 HTA Participation And Prioritization In Core Outcome Set Development

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ABSTRACT SUMMARY:
This presentation will describe the role of HTA participants in core outcome set development projects, using coreHEM and coreNASH as examples. We will review HTA voting patterns using data from the two projects, and consider how HTA voters can influence the outcomes selected to the final core outcome sets.

INTRODUCTION:
A core outcome set (COS) is a minimum standardized set of agreed-upon outcomes for clinical trials of a specific condition. COS development can improve research by aligning stakeholder priorities for the outcomes most important in decision making across the life-cycle of a product. It is important to include HTA representatives in COS development to ensure that outcomes useful to HTA are consistently included in clinical trials. Here we describe the role of HTA representatives in two COS projects: coreHEM, for gene therapy for hemophilia, a genetic blood clotting disease; and coreNASH, for nonalcoholic steatohepatitis (NASH), a progressive form of fatty liver disease which can lead to cirrhosis. We will describe the voting patterns of HTA representatives and consider aspects of their role in shaping the final COS.

METHODS:
For each multi-stakeholder COS, a modified Delphi process was utilized (3 online surveys plus an in-person consensus meeting). Candidate outcome lists were compiled via a literature review complemented by participant interviews. Voters condensed and prioritized the lists by rating each outcome on a scale of 1-9 (not important-essential). Votes on each outcome were stratified by stakeholder group; HTA votes were compared with those of other stakeholders.

RESULTS:
HTA representatives made up 12.2% and 13.5% of the voters in coreHEM and coreNASH, respectively. They tended to give the highest votes to mortality outcomes, outcomes measuring the severity of disease, and outcomes related to a patient’s quality of life, general well-being and general health perspective. HTA votes helped certain outcomes meet the inclusion criteria in the final voting rounds: without HTA voters, the “mental health status” outcome in coreHEM and the “hepatic-related mortality” and “liver transplantation” outcomes in coreNASH would have been eliminated.

CONCLUSIONS:
HTA participation in COS projects provides HTA representatives an opportunity to help shape COS in clinical research for better decision making.
AUTHORS:
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ABSTRACT SUMMARY:
Three burning issues are discussed with the delegates: what is at stake when introducing a complex medical technology in clinical practice; how we can account for socially responsible introduction of in-hospital innovations, and how multi-stakeholder deliberation can facilitate improved outcomes.

INTRODUCTION:
Many technological innovations — sometimes even big-ticket items — are introduced in clinical practice and put into use in the absence of an established evidence basis and in the face of a considerable uncertainty regarding their societal value. Despite a widespread recognition of multi-stakeholder participation in health care policy-making, it is still uncommon in the decision-making setting involving in-hospital technologies. It is addressed how we can account for a value-driven introduction of in hospital technological innovations when value is prone to — sometimes considerable — uncertainty.

METHODS:
Drawing on the literature from HTA, public policy, and Science and Technology Studies (STS), a conceptual cross-disciplinary analysis is provided. This analysis is constructed by mean of an ‘interpretative knowledge synthesis’ method, i.e., by integrating concepts from different strands of literature and disciplines to address a certain policy problem.

RESULTS:
The contribution of multi-disciplinary, evidence-informed multi-stakeholder deliberation (MSD) to deal with value issues is examined. By sustaining mutual learning about what matters to one another, stakeholders can take their understanding of value upstream, towards value to society at large. MSD, then serves as a platform for ‘value in co creation’: engaging in discursive appraisal of an innovation’s value, comprising the ‘why’ (desirability) and the ‘how’ (appropriation) of an emerging in-hospital technology. Concrete guidance is provided for a multi-stakeholder appraisal of value as part of, for instance, business and implementation planning in order to responsibly introduce new technologies in hospital setting.

CONCLUSIONS:
A collaborative endeavour to co-create value attends to current processes of decentralised, market-oriented introduction of advanced in-hospital innovations. The aim is to legitimise dissemination, realise a socially-desirable impact from limited resources, and act collectively to mitigate uncertainties during the course of implementation. Policy priorities that can be derived from this study will be discussed with the delegates.

OP165 HTA And Public Health Priority Setting In China

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AUTHORS:
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ABSTRACT SUMMARY:
A HTA-informed decision process and value judgment tool for reviewing and optimizing a national essential public health package was explored by the researchers. Multiple criteria decision analysis framework was employed along with HTA tools in developing an evidence matrix and soliciting views of key stakeholders.

INTRODUCTION:
Since 2009, China has initiated a national program
on free provision of essential public health services. The national program has expanded both in terms of service categories and funding, showing China’s great commitment to universal health coverage. However, with slow down of public input in health sector, the government decided to prioritize interventions and optimize the package. Researchers in the Chinese National HTA agency was asked to design the tool and facilitate the decision process.

METHODS:
With multi-criteria decision analysis (MCDA) method, the researchers analyzed value dimensions in public health issues, and built an evidence matrix for the priority-setting decisions. Supported by HTA tools, they appraised interventions and services through literature review and field studies, and projected budget impact of potential adjustment decisions based on cost analysis results. A deliberative process of key stakeholder groups was taken, and their views were counted in making the final recommendations.

RESULTS:
Based on evidence review and scores of stakeholders’ judgment, 2 public health service interventions were recommended for removal, and another 2 for adjustment (one for merger, one for optimizing care pathway). Cost estimation and potential budgetary impact were also analyzed to support financial decisions.

CONCLUSIONS:
HTA and MCDA are key tools for defining value criteria, evidence framework, and deliberative process for the essential public health program. However, lack of cost-effectiveness evidence hinders fine-tuned decisions on resource allocation. Continual health economic evaluation need to be conducted in near future.

OP166 Increasing US Patient-Community Capacity To Engage On Value Assessment

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ABSTRACT SUMMARY:
The National Health Council developed, modified and expanded a patient-friendly training curriculum specific to US patient audiences on value assessment (VA), including basics on health economics. Education throughout the coming year will help expanded patient-group capacity to engage regarding VA so that patients can make more meaningful contributions to VA in 2020 and well beyond.

INTRODUCTION:
Value Assessment (VA) bodies are increasingly willing to engage patients in the development of their value frameworks and assessments. However, VA is new to the patient advocacy community and lack of familiarity, knowledge, and tools can be a barrier to patients’ meaningful contribution. The National Health Council, with its large patient-advocacy-group membership, sought to increase patient capacity to engage by developing, modifying and expanding introductory training on VA and health economics specific to a patient-advocacy group audience.

METHODS:
An Advisory Committee (AC) comprising representatives from patient groups (n=11), VA bodies (n=1), and academic/research organizations (n=4) was formed. Training/resource needs were assessed through needs-assessment interviews.
(patient groups, community organizations, and VAs). Members of the AC reviewed existing resources on involving patients in VA (e.g., HTAi’s PCiG resources) to identify which training/resource gaps could be filled by adopting or adapting existing resources and which required development of new materials. New materials and modules were developed in collaboration with an academic institution.

RESULTS:
The training curriculum will be modified, expanded and delivered in 2019 during an in-person, one-day session in Washington DC followed by online modules. Module topics include an overview of the Current Health Care Environment; the Role of Health Economics; an Introduction to Basic Terms; Cost-effectiveness and why is it used; the Quality-adjusted Life Year; Budget Impact Analysis; an Overview of US Value Frameworks; and the Role of Patients and Patient Advocates in Value Assessment.

CONCLUSIONS:
We modified and expanded a patient-friendly training curriculum on value assessment, including health economics, specific to US patient audiences. Expanded patient group knowledge and skills related to VA can ensure that patients can make more meaningful contributions to VA. VA has the potential to improve health care decision making if the assessments are properly developed with meaningful patient engagement, focused on the outcomes patients and other stakeholders care about.

AUTHORS:
Craig Mitton, Canada

ABSTRACT SUMMARY:
Building capacity to deal with the economic, ethical and political challenges of resource allocation in health care requires clear understanding of the epistemological and operational relationships among HTA, value assessment and priority setting. The present work addresses this discussion and proposes a framework of decision making in priority setting and resource allocation that connects these three elements.

INTRODUCTION:
Growing health care expenditures have led decision-makers and researchers to put enormous emphasis on the development of strategies to ensure that the scarce resources available are spent efficiently. In this scenario, there is an urgent call for value-based practices and adequate processes of priority setting and resource allocation (PSRA). Yet, the diversity of value assessment methodologies makes one inquires about the precise meaning of ‘value’ and its corollaries. Moreover, the boundaries among value assessment, PSRA and health technology assessment (HTA) are not clearly established in the literature.

METHODS:
After conducting a systematic review on existing value assessment frameworks and an international qualitative survey about current PSRA practices in developed countries, the present work relied on the bulk of findings to analyze the epistemological and operational relationships among value assessment, PSRA and HTA. In addition, a framework for decision making in priority setting and resource allocation is proposed linking these three elements.

RESULTS:
Although value is often understood as “health outcomes achieved per dollar spent”, as defined by Michael Porter, many of the published
methodologies described as value assessment frameworks are presented without any explicit statement about their exact underpinning concepts of value. Furthermore, the multiplicity of objectives faced by decision-makers suggests not only that the final measures of value are contextually constrained but also that the proper notion of value is relational. In regard to PSRA practices, our survey findings indicate a lack of understanding on what actually constitutes a PSRA mechanism and on the role of HTA vis-à-vis PSRA.

CONCLUSIONS:
Distinguishing value assessment, PSRA and HTA epistemologically represents a vital step to allow coordinated efforts of capacity building to address problems of technical, cost-effective and allocative efficiency in health care. The PSRA framework presented here connects these three concepts and provides a practical tool for decision-makers to allocate resources in an explicit manner.

OP168 The EUnetHTA Quality Management System: Development And Evaluation

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ABSTRACT SUMMARY:
A quality management system (QMS) is being set up for EUnetHTA and the permanent European collaboration on HTA after 2020. The QMS comprises, among others, Standard Operating Procedures, templates, methodological guidelines and tools as well as related training modules. All its entities are regularly subject to continuous evaluation and improvement. The goal is to assure high quality HTA-reports.

INTRODUCTION:
One objective of EUnetHTA’s (European Network for Health Technology Assessment) Joint Action 3 (JA3) is to set up a quality management system (QMS) for the joint work that serves as a standalone infrastructure for a sustainable European HTA-collaboration. Structures of the QMS (=quality policy, processes and procedures and organizational structures) combined with the measures of QM (=quality planning, assurance, control and improvement) both ensure achieving the objective of producing high-quality HTAs.

METHODS:
Based on a thorough concept with involvement of a spectrum of EUnetHTA partners, re-evaluation, internal workshops and national expertise, the existing inventory consisting of procedures, templates, methodological guidelines and tools is being refined, complemented and revised. Procedures are gradually being transferred into Standard Operating Procedures (SOPs), seamlessly and chronologically covering all assessment phases. Supplemented by quality-control-checklists and templates these SOPs are linked to relevant guidelines and tools. The so-established QMS is subject to continuous improvement by recurrently applying the Plan-Do-Check-Act (PDCA)-cycle. Members of the assessment teams are surveyed after the publication of each EUnetHTA-report (check-phase). Processed results lead to modification, maintenance and improvement of the inventory (act-phase).

RESULTS:
The majority of content has already been developed or revised and was already made available to the assessment teams to put to practical test. The survey results are systematically collected, processed and compiled. Derived from these results, a comprehensive report and
a thorough list of improvement measures have been developed and will serve as a basis for further adaptations.

CONCLUSIONS:
The establishment of structures of QMS and measures of QM both are supposed to assure high-quality HTA-reports for EUnetHTA and the permanent European collaboration on HTA after 2020. The installed systematic data collection, processing and compilation mechanisms are a solid basis for the identification of future needs for developments.

OP169 Implementation Of Quality Management System In Spanish Network Of HTA

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ABSTRACT SUMMARY:
In Spain, HTA agencies coordinate their work through a national network (REDETS). In 2016, a common self-assessment quality tool was developed. Nowdays, in a second step, a group of standards for administration and management of the network have been established in order to complete a quality-assurance system and under the philosophy of continuous improvement processes.

INTRODUCTION:
The Spanish Network of HTA Agencies (REDETS) is a collaboration of 8 agencies, units and services, commissioned by the National and Regional Governments, that coordinate their work within a common methodological and work framework, guided by the principles of mutual recognition and cooperation. In 2016, a common self-assessment quality tool was developed for the implementation of an overall Quality Management System. Currently we are working on the second step that deal with actions about management, joint activities as a network, and organizational aspects of the network.

METHODS:
A structured search strategy in the main electronic databases and a manual search in websites of networks national and international agencies (June 2017) were carried out, in order to gather previous knowledge and developed standards. Through the information included in this review, and with the collaboration of all members, a group of standards for REDETS was developed. Finally, standards proposed were discussed in a face-to face meeting until an agreement was reached.

RESULTS:
A proposal of 31 standards was put forward taking all the collected information. The aim of each standard was defined as well its level of compliance was specified. Those standards were grouped under 9 quality criteria structured in four dimensions: I Responsibility&Resources, II Performance&Membership, III Procedures, and IV Relations.

CONCLUSIONS:
Based on the gathered information and the agreement of the all members, we developed a toolkit embracing group of standards for the joint activities within the Spanish Network, network administration and management, as a complementary instrument of the previous self-evaluating tool, following the establishment of an overall Quality Management System and under the philosophy of continuous improvement processes.
OP170 How Can HTA Participate In The Healthcare Quality Improvement?

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ABSTRACT SUMMARY:
The presentation aims to establish a connection between HTA and healthcare quality. In fact, the domains assessed in each HTA report are matching to the six dimensions of health quality, Known as the "six aims for improvement". They overlap with the HTA objectives because both tend to improve the experience of care. This approach is a great opportunity for LMICs.

INTRODUCTION:
Providing high-quality and affordable care is a big challenge facing the policy makers chiefly in low and middle income countries (LMIC). The purpose of this presentation is to illustrate how Health Technology Assessment (HTA) benefit the improvement of the healthcare quality and to highlight the fact that HTA domains match to the dimensions of health Quality: Safety, effectiveness, efficiency and patient-centeredness.

METHODS:
This presentation will be based on explaining the interest of HTA in opening up the doors of opportunity to improve the healthcare quality. In fact, some countries mainly LMIC, where available resources are limited do not have formal HTA whose goal is to inform the development of safe, effective and patient centred health policies. Then, by submitting theoretical concept related to HTA and presenting the dimensions of healthcare quality, the strong connection between HTA and healthcare quality improvement would prove to be. By way of illustration an example of successful experiences will be given.

RESULTS:
The presentation items are:
• The definition of health technology
• Introduction to health technology assessment as a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology.
• Why is health technology assessment used, the identification of the HTA report domains including Safety, Clinical Effectiveness, Ethical analysis, Social aspects, Legal aspects and the importance of patient experience in HTA.
• The identification of the six dimensions of healthcare quality and the determination of the connection between HTA and healthcare quality improvement.
• A presentation of the international Decision Support Initiative (iDSI) experience in some LMIC.

CONCLUSIONS:
HTA has many meeting points with healthcare quality dimensions. HTA is likely to become an increasingly important influence in health decisions.
Vignette Presentations

VP01 Methods Of Patient Involvement Now And Beyond 2020: A Case Study

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AUTHORS:
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ABSTRACT SUMMARY:
Involving patients and the public in the health technology assessment (HTA) has always been fundamental to NICE. To ensure the appropriate method of patient involvement remains relevant to the evolving types of HTA, NICE uses varying methods of involvement. These methods have been reviewed to ensure they remain current and relevant for HTA now and beyond 2020.

INTRODUCTION:
Involving patients and the public in the health technology assessment (HTA) has always been fundamental to NICE. To ensure the appropriate method of patient involvement remains relevant to the evolving types of HTA, NICE uses varying methods of involvement. These methods have been reviewed to ensure they remain current and relevant for HTA now and beyond 2020, and also to give guidance on the approaches that should form a standard baseline and those that could be optional.

METHODS:
We identified and mapped the different methods of patient involvement used at NICE across five types of HTAs: diagnostics; medical technologies; medicines; ultra-orphan conditions; and surgical procedures. We looked at the varying methods of early engagement identifying similarities and differences, and considered the benefits and challenges of each.

RESULTS:
The different methods of patient and public involvement includes:
• Lay members (generalist and topic expert) involved in decision making
• Individual patient input (written and oral)
• Patient group (organisation) input (written)

The types of involvement fell into the following categories:
• Written group submissions
• Written individual statements
• Surveys of individuals
• Pre-meeting events/workshops
• Oral testimonies at committees
• Written consultation responses

The common methods across all HTA types were generalist lay members and consultations.

CONCLUSIONS:
This review highlighted the varying methods of involvement at NICE and highlighted additional methods that could be standardised across the different types of HTAs as a baseline. These included patient organisation submissions and a method for additionally including individual patients in each type of HTA. We identified that where patient involvement started early and continued at each stage of the process including a pre-meeting event, it was particularly helpful to the stakeholders’ ability to contribute.

VP02 Involving Patients In HTA Beyond 2020: A Thematic Review

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Involving patients and the public in the health technology assessment is crucial and a key part of the NICE patient and public involvement policy. To advance the development of our PPI policy and build capacity for 2020 and beyond, we carried out a thematic review of the existing evidence on the involvement of patients and the public in HTA.

INTRODUCTION:
Involving patients and the public in the health technology assessment (HTA) is crucial and a key part of the NICE patient and public involvement (PPI) policy. To advance the development of our PPI policy in HTA and build capacity for 2020 and beyond, we took stock of knowledge on stakeholders’ views of involving this cohort in HTA.

METHODS:
We carried out a thematic review of the existing evidence on the involvement of patients and the public in HTA, including:
- Technology appraisals consultation 2017: 110 comments.
- Technology appraisals consultation 2018: 205 comments
- PIP review consultation 2017 with a CHTE focus: 162 comments.

We used Thomas and Harden’s (2008) thematic synthesis to code the data ‘line-by-line’, to develop ‘descriptive themes’, and then to generate ‘analytical themes’. This was followed by using Patton’s (1999) triangulation of qualitative data sources to further challenge and refine the emergent themes.

RESULTS:
We identified three themes, namely i) earlier and full engagement, ii) simpler and easier engagement, and iii) patient evidence.

Respondents emphasised the significance of involving patients earlier and throughout the process of developing every appraisal to enable them to gain a greater sense of participation and ownership. Respondents also expressed a strong view of making it simpler and easier for patients to engage in the process through various methods, e.g. standardising the approaches, and support and training. Finally, respondents expressed their positive attitudes toward using patient evidence in HTA, clarifying how patient evidence is captured and used, and offering a clear feedback mechanism to the impact of patient evidence on decision-making.

CONCLUSIONS:
This review highlighted the significance of earlier and full engagement with people, making it simpler and easier for people to work with us, and being clearer about how we use patient evidence with a clearer feedback mechanism as to the impact of their input on the final decisions.

VP04 The Influence Of Sponsorship On The Treatment Effects Of Trials

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ABSTRACT SUMMARY:
Sponsorship bias arises due to potential inappropriate influence of funding on trial findings. The issues of detecting and quantifying the effects
of sponsorship bias in the results of randomized controlled trials (RCTs) is of relevance for different decision makers. This study aimed to evaluate the influence of funding bias on treatment effect of RCTs, using a meta-epidemiological approach.

INTRODUCTION:

Limited public money is available for funding research and the majority of clinical research undertaken is funded by the industry. Mechanisms to regulate conflicts of interest within the research process have been implemented. However, these policies, by themselves, do not protect against potential sponsorship bias that would affect research results to inform decision makers when using the results of these trials. Therefore, the main aim of this study was to evaluate the influence of sponsorship bias on the treatment effects of RCTs.

METHODS:

This was a meta-epidemiological study. A random sample of RCTs included in meta-analyses of physical therapy (PT) area were identified. Data extraction including assessments of appropriate influence of funders was conducted independently by 2 reviewers. To determine the association between biases related to sponsorship biases and effect sizes, a 2-level analysis was conducted using a meta-meta-analytic approach.

RESULTS:

We analyzed 393 trials included in 43 meta-analyses. The most common sources of sponsorship for this sample of PT trials were government (n=205, 52.16%) followed by academic (n=44, 11.2%), and industry (n=39, 10%). The funding was not declared in a high percentage of the trials (n=85, 22%). The influence of the trial sponsor was assessed as being appropriate in 246 trials (63%) and considered inappropriate/unclear in 147 (37%) of them. There was no a significant difference in effects estimates between trials with appropriate or inappropriate influence of funders (ES= -0.15; 95% CI -0.33; 0.03), although trials with appropriate influence of funders tended to have on average a larger effect size.

CONCLUSIONS:

Based on our sample of PT trials, it seems that most of the trials are funded by either government and academia and a small percentage are funded by the industry. These results pointed that perhaps sponsorship bias could be not a big issue in rehabilitation-related trials.

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VP05 Conflicts Of Interests Of Clinical Practice Guideline Panel Members

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ABSTRACT SUMMARY:

Conflicts of interest (COI) might undermine the objectivity of CPG recommendations. If CPG panel members (CPG-PM) have COI, these should be made transparent.

We assessed the COI of CPG-PM using the Open-payment-Database.

CPG-PMs often received a considerable amount of financial support. These were often not or not transparently disclosed. Our findings compromise the objectivity of recommendations in CPG.

INTRODUCTION:

The recommendations in Clinical Practice Guidelines (CPG) should be aimed at maximizing patient benefit. Conflicts of interest (COI) might undermine the objectivity of CPG.
recommendations. If CPG panel members (CPG-PM) have COI, these should be made transparent to enable judgement of the potential influence on the recommendations.

The aim of this study was to analyze the financial relations between GCP-PM and medical device/drug companies and to analyze the completeness of the COI disclosures.

**METHODS:**
We performed a manual search for CPGs on the webpage of the National Guideline Clearinghouse. We included all GCPs published in 2017. The names of all CPG-PM were extracted. For each CPG-PM we checked the Open-Payments-Database for their financial support between 2013 and 2016. Open-Payments is an US-American database that contains all financial relations between companies and governmental licensed physicians. All data extractions were performed by one person and checked by a second.

We calculated descriptive statistical measures for the total sample and according medical discipline.

**RESULTS:**
We included 81 CPGs. We could not found any declaration of COI in the CGP or related documents for 34% of CPG-PMs. We extracted financial support data for 543 CPG from Open-Payments. The total amount of payments in the considered four years was 10.844.938 USD. Sixty-four percent of the CPG-PMs received ≥500 USD. Of these CPG-PMs who received ≥500 USD, 17% reported no COI. The mean and median support was 19.972 USD (standard deviation: 55.2450) and 1.328 USD (inter-quartile-range: 223 to 12.724), respectively. The median support was highest in oncology (4.113 USD) and lowest in physical therapy (745 USD).

**CONCLUSIONS:**
CPG-PMs often received a considerable amount of financial support. These were often not or not transparently disclosed. Our findings compromise the objectivity of recommendations in CPG.

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**VP06 HTA And Health Industry: Key Aspect Of Their Relationships**

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**ABSTRACT SUMMARY:**
We conducted a narrative review of literature searched and a review of websites of international HTA agencies to review key aspects of the relations between HTA agencies and health industries.

**INTRODUCTION:**
Conclusions and recommendations of Health Technology Assessment (HTA) reports have an impact on all relevant actors involved in the health system (health authorities, administrators, health professionals, patients, citizens and industry). The involvement of all those relevant stakeholders in the HTA process facilitates making valid and informed decisions and an efficient allocation of resources. Improving communication, participation and transparency among all agents will lead to more efficient evaluation and decision-making processes.
METHODS:
To review key aspects of the relations between HTA agencies and health industries, two process were carried out: a narrative review of literature searched in Medline, PubMed, Embase, CINAHL and WOS (2007-2017) and a review of websites of international HTA agencies. References and webs with information on the framework, objectives, methodologies, impact or results of the relationships were included.

RESULTS:
A total of 1961 references were located and 45 were selected. From the synthesis of the selected references the following key aspects of the relationships between HTA and industry were identified: 1) the importance of early dialogues with industry to align HTA objectives with the generation of evidence; 2) challenges of the bias in the evidence produced by the industry; 3) difficulties in industry engagement in HTA processes 4) industry interest in HTA.

The review of 6 agency websites provided information on: industry involvement in strategic activities, early dialogues, provision of documentation, management of industry clarifications, review of the report/allegations and other forms of relationship.

CONCLUSIONS:
Both the review of the literature and the contents of the web pages of international agencies with experience in relations with industry, show that the interest is in the creation of collaborative frameworks between regulatory authorities that decide on authorization and price and reimbursement and HTA agencies, while both try to maintain an early, transparent and systematic interaction with the healthcare industry.

VP07 Cost-Effectiveness Of HTA Fees

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AUTHORS:
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ABSTRACT SUMMARY:
HTA bodies charge fees, as part of cost recovery measures, to evaluate the clinical and/or economic impact of new therapies to inform public reimbursement decision making. These fees bear little relation to the drug expenditure and cumulatively exceed €300,000. However, they may be burdensome, especially for SMEs with promising therapies for orphan/rare diseases, and may potentially deter/delay submissions and access.

INTRODUCTION:
Health Technology Assessment (HTA) bodies evaluate the clinical and/or economic impact of new therapies to inform public reimbursement decision making. This research evaluates the value for money of current or proposed fees for HTA in countries with mandatory cost-effectiveness HTA bodies relative to their respective public drug expenditure.

METHODS:
HTA appraisal fees were identified from publicly-available websites: National Institute for Health and Care Excellence (NICE), Canadian Agency for Drugs and Technologies in Health (CADTH), Institut National d’Excellence en Santé et Services Sociaux (INESSS), and Pharmaceutical Benefits Advisory Committee (PBAC), and annual national public drug expenditure (ANPDE) were sourced from the National Health Service England, Canadian Institute for Health Information, and the Pharmaceutical Benefit Scheme.
RESULTS:
NICE is proposing to charge £126,000 (€142,582) for a single technology or highly specialised technology appraisal, CADTH charges CN$72,480 (€48,576) for a Schedule A submission, INESSS charges CN$38,921 (€26,089) for the first evaluation of a new drug or new indication, and PBAC charges AU$136,716 (€87,576) for a Major Lodgment. The ANPDE in England: £16 billion (€18.1 billion), Canada: CN$14.5 billion (€9.7 billion), Quebec: CN$4 billion (€2.7 billion) and Australia: AU$8.7 billion (€5.6 billion). The appraisal cost to drug expenditure ratio for these countries/regions were: 126,984, 200,055, 102,772, and 63,636, respectively.

CONCLUSIONS:
HTA submissions in the UK, Canada and Australia, require financial contributions from manufacturers. These contributions bear little relation to the market size and cumulatively exceed €300,000 (assuming no resubmissions). By adopting charging/cost recovery models, HTA bodies are aiming to reinvest the proceeds to increase the efficiency and capacity of appraisals, expediting patient access. However, these fees may be burdensome, especially for SMEs with promising therapies for orphan/rare diseases, and they may thus have the potential to deter/delay their submissions.

ABSTRACT SUMMARY:
A framework of evaluation which has gained traction in the health economics community is the capability approach of Amartya Sen. Currently, it is unclear how capability freedom and wellbeing are related to each other. This study aims to provide an insight in this dynamic, using a best-fit framework synthesis of qualitative literature. Four factors were identified that influence this dynamic.

INTRODUCTION:
A central aspect of economic evaluation is to measure the value of new health technologies. A framework of evaluation which has gained traction in the health economics community is the capability approach (CA) by Amartya Sen (Sen, 1985). Proponents of the CA argue that the conventional scope of evaluation is too narrow; the scope of evaluation should be the opportunities available to an individual, instead of what the individual has or is. One characteristic of the CA is the importance of freedom and its relation to wellbeing. However, a precise explanation of how freedom and wellbeing are related to each other is currently not available. The aim of this study is to provide an insight in the dynamics between capability freedom and wellbeing.

METHODS:
A systematic literature review using a pearl growing search strategy was used to identify existing papers on the development of a capability instrument. The relationship between capability domains and wellbeing was reviewed using the ‘best-fit’ framework synthesis method for the analysis of qualitative evidence and Robeyns (2017) definition of capability freedom.

RESULTS:
Seven papers were identified. The analysis suggests four central factors influencing the dynamic. (i) Realized options: domains that individuals report to be important for their wellbeing. (ii) Perceived access: the limitations experienced to exercise the
freedom in a particular domain. (iii) Coping: how individuals deal with the respective limitations in access. (iii) Self-realization: the ability to make choices towards aspects that individuals consider to be meaningful in their lives.

CONCLUSIONS:

The identified factors provide an insight in the complex dynamics between freedom and wellbeing. The factors describe how individual wellbeing is influenced by increases and decreases in capability freedom, which could be of interest for researchers using the CA as a framework for economic evaluation. Further qualitative and quantitative research is necessary to improve the understanding in how capability freedom and wellbeing are exactly related.

VP10 Bulgarian HTA Capacity Compared To International Best Practice

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ABSTRACT SUMMARY:
The HTA process was introduced in Bulgaria in 2015. Commission was formed and its activities was regulated by Ministerial Ordinance. The objective was to explore Bulgarian HTA capacity and compare it to the best practices. Additional efforts needed to provide better dynamics of HTA process, map potential issues and overcome possible barriers.

INTRODUCTION:
The exponential growth of medical technology innovation demands an up-to-date decision-making approach. Thus in 2015, the HTA process was introduced in Bulgaria. Commission was formed and its activities was regulated by Ministerial Ordinance #9.

METHODS:
The objective was to explore Bulgarian HTA capacity and compare it to the best practices, established worldwide by applying the Dynamic interactive model for HTA institutionalization, developed in 2015 by us. We performed a critical analysis on Ministerial Order #9 of 1 December 2015 that set the legal framework for HTA. We systematically reviewed the public records of the HTA Commission meetings form January 2016 till October 2018, using INAHTA checklist for HTA reports, thus collecting the additional information on the macro, mezzo and micro environment of the activities and workflow.

RESULTS:
On macro level, the HTA capacity is relatively well developed. All 6 dimensions are ensured, but additional efforts needed to secure technology, economic and socio-cultural ones. The political consensus attracts support from all directions on strengthening HTA capacity; sound regulatory framework is placed; and good communication between institutional settings is achieved. Furthermore, additional efforts needed to provide better dynamics in the mezzo environment. The obvious but expected shortage of experts, as well as a complete lack of international collaboration are paramount obstacles to adoption and implementation of the best HTA practices. The observed weak performance of stakeholder involvement could be altered by an adequate promotion of stakeholder input into assessment. The micro environment – workflow, is well defined by the Ordinance, even though there are unannounced delays and Commission regularly doesn’t meet the legislatively mandated deadline for issuing final recommendation.
CONCLUSIONS:
To facilitate HTA capacity building and to ensure its sustainable development, it is necessary to be aware of all three identified environments – macro, mezzo and micro – as well as their interconnected dimensions. Wider perspective is needed to map potential issues and overcome possible barriers.

VP11 Use Of Health Technology Assessment Adaptation In Latin America

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ABSTRACT SUMMARY:
Development of Health Technology Assessment (HTA) reports is a time consuming process that requires highly trained human resources. The objective of this study is to determine the frequency of use of HTA adaptation process and to describe type of tools used in this process in Latin American Countries.

INTRODUCTION:
Development of Health Technology Assessment (HTA) reports is a time consuming process that requires highly trained human resources. In many Latin American countries, this type of personnel is scarce. Adaptation of HTA could be a saving time process to get inputs for decision. The objective of this study is to determine the frequency of use of HTA adaptation process and to describe type of tools used in this process in Latin American Countries.

METHODS:
The Health Technology Assessment Network of the Americas (REDETSAs) is a nonprofit network formed by ministries of health, regulatory authorities and health technology assessment agencies (PAHO/WHO). During the last meeting of REDETSAs in November 2018, we performed an exploration survey to gather information related to the topic in order to promote the creation of an adaptation working group. The question was whether HTA agencies did adaptation of HTA reports, if so, what methods and tools used and what sections of the report were adapted.

RESULTS:
Thirty-three institutions from 14 Latin American countries answered to the consultation. Seven countries do adaptation of HTA (50%) and one country does adoption. Of those countries that adapt HTA, three do only economic transferibility. Methods and tools are usually developed locally or there is not a systematic approach. In two countries, economic studies transferibility tool developed by Hutter and Antoñaza is used.

CONCLUSIONS:
Adaptation of HTA is not well developed among Latin American agencies, although it seems to be an efficient strategy when assessing efficacy and safety. Adaptation of economic studies is still controversial; nevertheless, it is used in some of the countries of the region. It is necessary to advance in the development of HTA adaptation tools, developed and adapted to local contexts in the region.

VP12 HTA And Medicines Security; Need For Capacity Building In Africa

PRESENTING AUTHOR:
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GLOBALIZATION HAS HELPED AFRICA IN THE AREA OF MEDICINES AVAILABILITY. HOWEVER, THIS HAS RAISED ISSUES IN MEDICINES QUALITY. EVIDENCE SUGGESTS THAT AFRICA BEARS SIGNIFICANT PROPORTION OF THE GLOBAL DISEASE BURDEN YET HAS LEAST NUMBER OF INSTITUTIONS PROVIDING HTA AND HTA CAPACITY BUILDING. HENCE THERE IS NEED FOR BUILDING HTA CAPACITY IN AFRICA TO IMPROVE ACCESS TO AFFORDABLE QUALITY MEDICINES.

INTRODUCTION:
Globalization has helped Africa in the area of medicines availability. Africa has seen an increase in the volume of medicines in national medicine supply chains. However, this has come with its own challenges, one major challenge being the quality of these medical products. The World Health Organization reports that 1 in 10 medical products in developing countries are substandard or falsified and 42% of reported cases are in Africa. Furthermore, an additional 158000 annual deaths from malaria in sub-Saharan Africa is due to counterfeit medicines. These counterfeit medicines have significant implications for treatment failure, avoidable deaths and disabilities, and resource wastage in settings that are already resource-limited. Hence there is a need for Health Technology Assessment (HTA) focus on medicines security in the context of limiting the circulation of poor quality medicines in our supply chains.

METHODS:
A review of the African healthcare system was carried out to ascertain the need for HTA.

RESULTS:
Evidence suggests that Africa bears significant proportion (over 25%) of the global disease burden. Africa has the highest global health threats but the least number of global health institutions providing HTA and HTA capacity building. Africa lacks data availability and applicability, both of which are key requirements in HTA.

CONCLUSIONS:
Thus, beyond 2020, the focus should be on building HTA capacity in Africa, building collaborations for HTA institutionalization and taking advantage of the curricula change occurring in most tertiary institutions in Africa to include HTA so as to meet up with global standards and current global health trends. Building HTA capacity should cut across both individuals and institutions and should be done in a smart way to ensure resource optimization and to successfully contribute to effective and efficient quality healthcare systems as well as improving accessibility and affordability of quality medicines and other health technologies.

VP13 Transferability Instrument Of Health Economic Evaluations For Chile

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Any technology submission for the high-cost treatment fund in Chile require an economic evaluation, however this is time consuming, therefore it is not possible to inform within the established period of time. This article proposes a guide for the transferability of international economic evaluations results to our context, in order to inform decision makers on time
INTRODUCTION:
Any technology submission for the high-cost treatment fund in Chile require an economic evaluation, however this is time consuming and given its high number, it is not possible to inform within the established period of time. This article proposes a guide for the transferability of international economic evaluations results to our national context, with the intention to inform decision makers in a brief period of time.

METHODS:
A literature review on transferability analysis, tools and instruments to perform transferability analysis and on how to assess quality of economic evaluations was conducted. In addition, a workshop was held to discuss the proposal with other relevant researchers, in order to receive feedback.

RESULTS:
The proposed instrument is based on Welte and consists on: (i) a research question is formulated and a systematic review of economic evaluations is conducted, (ii) then the three Welte knock-out criteria are applied to these results, if they meet them, the articles pass to the next stage, (iii) a scored comparison based on twelve criteria is conducted to the articles. Each article is compared against the Chilean (economic) reference case, (iv) the high-scored economic evaluations will be grouped according of their Incremental cost-effectiveness ratio (ICER). If all ICERs do not converge, to the same conclusion, the intervention would not be transferable. If the ICERs of these studies converge, then the results will be compared against the national threshold. If the ICERs are greater than the threshold, the intervention would not be cost-effective. If the ICERs are lower than the threshold, then the intervention would be cost-effective in Chile.

CONCLUSIONS:
Despite a “de novo” analysis is still being a gold standard in order to inform decision makers, the proposed instrument could be used as an alternative, given the short time limit and the scarcity of qualified human resources.

VP14 Cost Analysis For HD And Peritoneal Dialysis For ESRD In South Africa

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ABSTRACT SUMMARY:
HD and PD are commonly in ESRD. However, their costs have grown considerably. Little is known about their costs in the public healthcare system in South Africa. Variable costs (HD; US$172, 359.15, PD; US$20, 488.79) were the highest cost component. Annual cost of HD (US$205,681) was higher than PD (US$25,282 per patient). These cost estimates are useful for future analyses.

INTRODUCTION:
Hemodialysis (HD) and peritoneal dialysis (PD) are commonly used to treat patients with end-stage renal disease (ESRD). However, their costs have grown considerably in recent years as the rates of non-communicable diseases including diabetes and hypertension have grown. This will adversely impact on national health budgets especially in LMICs. Currently, there is limited knowledge about the costs of ESRD and the different components within the public healthcare system in South Africa. Consequently, our objective was to examine the direct medical costs of both approaches from a public provider perspective to provide future guidance.
METHODS:
A prospective observational study undertaken at a leading public hospital in South Africa based principally on patients’ notes and costs from nationally procured lists. A micro-costing approach was used to estimate health care costs among adult patients with ESRD who had received either HD and PD for at least 3 months.

RESULTS:
The majority of patients (35%) were aged 40 to 50 years. Patients aged 29-39 years were mostly on HD (28%) while those between 51-59 years mostly on PD (29%), with HD typically managed in the private sector with limited facilities in the public sector. The average age patients on HD and PD were 41 and 42 years respectively. Variable costs (US$20,488.79) were the highest cost component for PD patients with fixed costs the highest component for HD patients (US$16,231.45). The annual cost of HD (US$31,993.12) was higher than PD (US$25,282 per patient) but not statistically significant (p = 0.816). The overall burden if appreciably more patients with ESRD are managed appropriately within the public system (covering 80% of the population) would be considerable and become unaffordable.

CONCLUSIONS:
HD costs more than PD. These cost estimates are useful for carrying out future health economic analyses and for allocating greater resources to prevent progress to ESRD.

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ABSTRACT SUMMARY:
Zika virus is a newly emerging infection associated with increasingly large outbreaks. However, symptoms are usually self-limiting although some can be severe. A future Zika vaccine can help, but balance against ongoing activities. The maximum willingness to pay for a hypothetical Zika vaccine with a mean effective protection of 80% and some local and systemic side-effects was only US$31.34 (BRL100.00).

INTRODUCTION:
Zika virus is a newly emerging infection associated with increasingly large outbreaks especially in countries such as Brazil where an estimated 326,224 cases were confirmed between 2015 and 2018. Common symptoms associated with Zika include headache, conjunctivitis, fever, erythema, myalgia, vomiting, diarrhea, and abdominal pain. However, the symptoms are usually self-limiting and last on average for 4 to 7 days, with patients typically not accessing the public healthcare system (SUS). In severe cases, symptoms include neurological disorders and neonatal malformations. A future Zika vaccine can contribute to decreasing the number of cases and associated complications. However, this has to be balanced against continuing costs to control this and other vector borne diseases. Consequently, information about consumers’ willingness to pay (WTP) for a hypothetical Zika vaccine can help with price setting discussions in Brazil starting with the private market before being considered within SUS.

METHODS:
A cross-sectional study was conducted among residents in one of the main provinces

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VP15 Consumer Willingness To Pay For A Hypothetical Zika Vaccine In Brazil

PRESENTING AUTHOR:
Brian Godman, United Kingdom
of Brazil (Minas Gerais) regarding their WTP for a hypothetical Zika Vaccine with agreed characteristics. This included a mean effective protection of 80%, with the possibility of some local and systemic side-effects. The discussed price was US$ 56.41 (180.00 BRL) per vaccination as this figure was utilized in a previous WTP study for a dengue vaccine.

RESULTS:
517 people were interviewed. However, 30 would not be vaccinated even if the vaccine was free. Most of the resultant interviewees (489) were female (58.2%), were employed (71.2%), had private health insurance (52.7%), had household incomes above twice the minimum wage (69.8%) and did not have Zika (96.9%). The median individual maximum WTP for this hypothetical Zika vaccine was US$31.34 (BRL100.00).

CONCLUSIONS:
WTP research can contribute to decision making about possible prices alongside other economic criteria once a Zika vaccine becomes available in Brazil alongside other programmes to control the virus.

INTRODUCTION:
Managed Access Arrangements (MAAs) represent a way of enabling patient access to promising treatments while collecting real world data to inform future Health Technology Evaluations (HTE) and commissioning decisions. In July 2016 the National Institute for Health and Care Excellence (NICE) recommended ataluren for treating Duchenne muscular dystrophy within a MAA. NICE is uniquely placed to oversee the implementation and monitoring of this MAA in collaboration with multiple stakeholders to ensure the final outputs meet the needs of a future HTE.

METHODS:
NICE assembled an ataluren Managed Access Oversight Committee (MAOC) consisting of representatives from the manufacturer, patient organisations, commissioning body and treatment centres. This group were to meet 6-monthly under the chairmanship of NICE with the primary function of reviewing the progress of data collection and identifying operational challenges in implementing the terms of the arrangement.

RESULTS:
The ataluren MAOC have convened 4 times since the MAA commenced and these discussions identified a number of important actions. Data completeness was a concern and prompted stakeholders to collaborate on implementing measures to circumvent this, to ensure data quality for future HTE. Lack of awareness and understanding of the MAA in the patient community was highlighted and resulted in the production of lay information. A review of the statistical analysis plan resulted in the need for an agreement amendment. To ensure an audit
trail and appropriate critique, NICE produced an amendment process to define and justify amendments made during the agreement term.

CONCLUSIONS:
MAOC meetings play an important role in monitoring the progress of MAAs and have ensured that implementation issues are identified promptly and resolved with input from key stakeholders. This process allows NICE to coordinate the work of stakeholders to facilitate the success of the MAA, and will be adopted in future NICE MAAs in ultra-rare diseases.

VP17 Do Swedish Managed Access Agreements Include Recommended Components?

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ABSTRACT SUMMARY:
Managed entry agreements (MEA) are used to give access to new technologies. Despite treatment effect being a rationale many MEAs in Sweden, and good availability of digital health data through patient registries, data collection is limited to drug utilization. Investment in an infrastructure for data collection is required if true treatment effects is to become a follow-up measure.

INTRODUCTION:
Managed entry agreements (MEA) are used to give access to new technologies where traditional reimbursement is deemed inappropriate. Three different forms of agreements have been identified by the Health Technology Assessment International Policy Forum; management of budget impact, of uncertainty relating to clinical and/or cost-effectiveness, and utilization to optimize performance. All agreements should clearly identify the rationale for the agreement, aspects to be assessed, methods of data collection, and the criteria for ending the agreement. This study assessed whether Swedish MEAs includes these components.

METHODS:
All MEAs for prescribed drugs were reviewed (up to April 2018) and data were extracted on rationale for agreement, aspects to be assessed, methods of data collection and criteria for ending agreement.

RESULTS:
Thirty-nine agreements including 30 different prescription drugs, a majority being drugs in oncology and infectious diseases, were reviewed and used for reimbursement decisions from the Dental and Pharmaceutical Benefits Agency. The rationale behind the agreements was uncertainty in the number of patients treated (4 percent), treatment effects (4 percent), treatment duration (10 percent), or a combination of the three (49 percent). In 10 agreements the rational was not stated. In all contracts the assessed aspect was drug utilization measured by the number of packages sold based on data retrieved from the National Board of Health and Welfare. All contracts included criteria for ending the agreement.

CONCLUSIONS:
Swedish MEAs all included the recommended components. However, despite treatment effect being the rationale for a significant share of the agreements and the good availability of detailed digital health data through national and regional patient registries, the assessed aspect was drug utilization only, across all contracts. Investment in an infrastructure for data collection, addressing the heterogeneity in patient registries across county councils, is required if true treatment effects is to become a follow-up measure in future MEAs.
VP18 Potential Of Real World Evidence For ‘IDEAL’ Procedures Research

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ABSTRACT SUMMARY:
Cedar researchers propose methods by which Real World Evidence (RWE) can contribute to evaluation and development of safe and effective interventional procedures, guided by the IDEAL Framework. Similarly, IDEAL provides a helpful structure to inform the design of future mechanisms for the collection of relevant RWE. Projects from NICE (National Institute for Health and Care Excellence) illustrate applied examples.

INTRODUCTION:
Randomized trials and similarly robust research methods generate evidence in carefully controlled settings, often with strict inclusion criteria. But patients in the ‘real world’ often have multiple comorbidities, and treatments are delivered within diverse environments. Trials are also difficult to fund, and rarely collect longitudinal data. Because of these, and other limitations, researchers are increasingly recognizing the inherent value of Real World Evidence (RWE). This is not only true for pharmaceutical products, and may have even more relevance in the evaluation of complex interventional procedures and non-medicines healthcare technologies.

The IDEAL Framework guides the developmental ‘pipeline’ of surgical (and other) procedures, as well as medical device research (IDEAL-D). IDEAL informs the production of high-quality evidence of safety and effectiveness, but there is potential to further expand its applications.

METHODS:
Our aim is to investigate the feasibility of using RWE alongside the IDEAL Framework in the assessment of procedures and devices. Methodological experts from the IDEAL Collaboration, HTA agencies and other healthcare research organisations are contributing their unique perspectives and experiences to explore these methods. As part of this work, Cedar healthcare technology research centre has attempted to retrospectively apply the IDEAL criteria to a series of RWE projects conducted on behalf of the NICE Interventional Procedures and Medical Technologies Evaluation Programmes.

RESULTS:
Cedar’s experience indicates that there may be options for using retrospective routinely-collected, linked data, and other existing sources, to address some of the requirements of IDEAL. Likewise, the IDEAL Framework is expected to be a helpful reference when designing new databases and clinical registries for prospective collection of relevant and informative evidence. Examples from several projects will be shared at the HTAi conference.

CONCLUSIONS:
Initial signs are that there are likely to be a number of ways in which IDEAL and RWE could complement one another.

VP19 Cost-Effectiveness Of Combination Inhaled Long-Acting Bronchodilators

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ABSTRACT SUMMARY:
To inform the development of a national clinical guideline for COPD, a systematic review was conducted to examine the cost-effectiveness of long-acting beta2-agonists (LABAs) in combination with long-acting muscarinic antagonists (LAMAs) compared with LAMA or LABA monotherapy. This systematic review found that LAMA/LABA combination therapy is cost-effective compared with LAMA or LABA monotherapy in COPD patients.

INTRODUCTION:
To inform the development of a national clinical guideline for Chronic Obstructive Pulmonary Disease (COPD), prioritised by the National Clinical Effectiveness Committee (NCEC) in Ireland, a systematic review was conducted to examine the cost-effectiveness of long-acting beta2-agonists (LABAs) in combination with long-acting muscarinic antagonists (LAMAs) compared with LAMA or LABA monotherapy.

METHODS:
Medline, Embase, the Cochrane Library and grey literature sources were searched up to 19 June 2018. Studies evaluating cost-effectiveness published post-2008 in English were included. Screening, data extraction, and quality assessment using the Consensus Health Economic Criteria (CHEC-list) and International Society for Pharmacoeconomics (ISPOR) questionnaires were conducted independently by two reviewers. Costs were adjusted to 2017 Irish Euro using consumer price indices and purchasing power parity as per national guidelines.

RESULTS:
From a total of 8,661 articles identified, 9 studies (all cost-utility analyses) were included in the review. Studies ranged from low to high quality and compared LAMA/LABA combination therapy with LAMA monotherapy. The results reported were mixed, ranging from combination therapy being dominated by (that is, more costly and less effective than) LAMA monotherapy to being dominant (that is, less costly and more effective). However, when excluding low quality, less applicable studies, the remaining 6 studies reported incremental cost-effectiveness ratios (ICERs) of between GBP2,088 (EUR2,770) and EUR21,475 (EUR26,462) per quality-adjusted life year (QALY) gained. Only 1 study additionally compared LABA monotherapy as a comparator, reporting combination therapy to be even more cost-effective than in the LAMA monotherapy comparison.

CONCLUSIONS:
Applying a cost-effectiveness willingness-to-pay threshold of EUR45,000 per QALY gained, this systematic review found that LAMA/LABA combination therapy is cost-effective compared with LAMA or LABA monotherapy in COPD patients.

VP20 A Cost Analysis Of The Lung Cancer Screen Program In Beijing

PRESENTING AUTHOR:
A-Yan Mao, China

AUTHORS:
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ABSTRACT SUMMARY:
This is a crude cost analysis of a Low-dose CT exam based lung screen program in Beijing, 2012. There were about 12,953 residents were
involved and the total cost for this program was 898,098 RMB (142,452 US$), cost per funding was about 3,854 RMB (611 US$). We conclude that this program showed its positive potential on medical expenditure saving in Beijing city.

INTRODUCTION:
To conduct with a crude cost analysis of the lung cancer screen program in Beijing, and provide data evidence for further cost-utility analysis.

METHODS:
Based on stratified cluster sampling method, we carried out a 2-stage lung screen program within 6 districts, Dongcheng, Xicheng, Chaoyang, Haidian, Fengtai and Shijingshan, of Beijing city between October, 2012 to May 2013. The first stage of the program was to conducting a packaging cancer risk level evaluation for community residents who were 40-69 years old, and the second stage’s task was to providing low-dose CT scan exam for those high risk people who were selected from the first stage. There were about 12,953 residents were involved in this program. We calculated the main cost of the lung cancer screen program in Beijing, include cost for program management and operation, stage 1 and 2 screening, and other indirected cost.

RESULTS:
2,172 high risk residents were selected by the first stage and 1,739 accepted the Low-dose CT exam, participate rate was 80.06%. A total 233 participates had been found positive nodules and 12 of them were suspected of lung cancer at the second stage. The total cost for this lung cancer screen program, was 898,098 RMB (142,452 US$), and cost per funding was about 3,854 RMB (611 US$). Discussio: Compare with other Low-dose CT scan based lung cancer screening programs, the cost per finding in our study was low. Packaged screening, good social mobilization capacity and low health manpower cost maybe the main reasons. The average medical cost for a lung cancer treatment was 63,931 RMB (9,236 US$) while the GDP per capita for Beijing was 92,210 RMB (14,889) in 2013.

Therefor, although the follow-up cost for further medical care data was not available by now, we could expect a good promising for cost-benefit result in this screening program.

CONCLUSIONS:
The Low-dose CT scan based lung cancer screening program shows its potential on medical expenditure saving in Beijing city.

VP21 Economic Burden Of Pertussis Treatment In Brazil, 2014

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ABSTRACT SUMMARY:
In 2014, the peak of a resurgence in pertussis, Brazil reported almost 9,000 hospitalizations and outpatient cases, with a cost to the national public health system of USD 2.6 million, 1,510 percent more than in a normal endemic year. This burden was largely in children <12 months. Additional prevention strategies are required targeting this population.

INTRODUCTION:
Despite a cheap, widely accessible vaccine, pertussis remains an important cause of morbidity and mortality in children worldwide. A resurgence of pertussis in Brazil peaked at 8,815 cases in 2014. We estimate the economic burden of pertussis hospitalizations and outpatient cases in Brazil in 2014.
METHODS:
Taking the Brazilian public health system (SUS) perspective we obtained numbers of hospitalizations from the National Hospitalization Information System (SIH) for discharge diagnosis ICD10:A37 and numbers of confirmed outpatient cases from the surveillance information system (SINAN). We estimated costs per case for 7 age groups (<1, 1-4, 5-9, 10-19, 20-39, 40-64, and 65+ years). Hospitalization costs were obtained from SIH, which reimburses direct medical (hospital stay, healthcare professional services, and physical therapy) and non-medical costs (parent/caregiver stay accompanying a hospitalized child). Cost of outpatient management was estimated from national guidelines (diagnostic exams, medical visits, and medications) and national pricing lists. Total economic burden was derived by multiplying costs/case by numbers of hospitalized and outpatient cases, respectively, and converted to US Dollars (USD) (December/2014; 1 BRL=0.39).

RESULTS:
A total of 8,815 pertussis cases occurred in Brazil in 2014; 55.9 percent were hospitalized. Total cost to the public health care system was USD 2.6 million, 95 percent for hospitalizations. Cost/case was highest at the extremes of age for both hospitalized and outpatient cases, respectively, and converted to US Dollars (USD) (December/2014; 1 BRL=0.39). Children <1 year accounted for 88.1 percent of hospitalizations, 29.1 percent of outpatient cases, and 89.3 percent of total costs.

CONCLUSIONS:
Pertussis economic burden in an outbreak year was largely due to hospitalizations in children <1y. Additional prevention strategies are required targeting this population.
outcomes measure was the association between stage of evidence on IDEAL framework and the recommendation of published NICE IP guidance.

RESULTS:
There were 21 (20%), 33 (32%), 3 (3%), 40 (39%) and 6 (6%) procedures at IDEAL stages 1, 2, 2a, 3 and 4, respectively. Of those at stage 1 (idea), 48% were given research only arrangements, 43% special arrangements, and 10% standard. Many of the procedures at stages 2 (development) and 2a (exploration) were given standard arrangements (39% and 67% respectively). 43% of stage 3 (assessment) and 67% of stage 4 (learning) guidance were identified standard. At stage 4 none were given a research only recommendation.

CONCLUSIONS:
Procedures given ‘standard’ arrangements guidance are more likely have a mature and robust evidence base as determined by IDEAL. Those with limited evidence are more likely to be given a more cautious ‘research only’ guidance. Routine use of this framework could help inform future guidance production however cannot replace the decision-making function of the NICE committee which also involves patient experiences, population characteristics, risk of serious safety events, and equity issues.

VP23 Assessing The Effectiveness Of A Medical Device With Limited Evidence

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ABSTRACT SUMMARY:
The SecurAcath catheter securement device was evaluated by KiTEC for a NICE Medical Technology Guideline. The poor quality of the available published evidence meant that KiTEC employed novel methods in order to produce a report on which a recommendation for adoption could be made.

INTRODUCTION:
SecurAcath (Interrad Medical), a catheter securement device designed for central venous catheters, was assessed by NICE in 2017 resulting in Medical Technology Guidance 34 (MTG34). Due to the limited number and quality of published evidence, novel methods were used to deliver a report that allowed a recommendation on adoption to be made.

METHODS:
KiTEC, an external assessment centre for NICE, independently evaluated the manufacturer’s submission of clinical and economic evidence. The submission was characterised by a lack of strong clinical evidence, comprising just 1 RCT and a small number of non-comparative observational studies, some of which were available as conference abstracts or poster presentations. KiTEC ran a meta-analysis of these studies along with data on the comparators, securement with sutures and securement with StatLock (Bard Access Systems). Due to the lack of comparative studies, KiTEC pooled data on 5 outcomes (migration, dislodgement, catheter-related infection, CRBSI, unplanned removals/reinsertions) and calculated relative risks for each. KiTEC revised the manufacturer’s cost model, changing a number of parameters and assumptions. The decision to recommend SecurAcath for use in the NHS was also supported by qualitative evidence from expert clinicians who had used the SecurAcath in practice.

RESULTS:
KiTEC’s meta-analysis showed non-inferiority for SecurAcath over the comparators. The limited
VP24 Fast Product Development Of Medical Devices: Implication On Assessment

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ABSTRACT SUMMARY:
The regulatory process of approving medical devices in Europe does not require clinical data on the evidence level of RCTs. In consequence, evidence is often scarce and study data may not be available for the current commercial product(s). We will present an approach how to assess methods, facing the short product lifecycles of medical devices.

INTRODUCTION:
There is a fast development in medical device technology and the regulatory process of approving medical devices in Europe does not require clinical data on the evidence level of RCTs. In consequence, evidence is often scarce and study data may not be available for the current commercial product(s). We developed an approach how to assess methods, facing the short product lifecycles of medical devices.

METHODS:
The approach is embedded in a typical outcome related assessment of benefit and harms. In the following, different models of a medical device are defined as different technical versions of a product of the same manufacturer with the same indication of use.

RESULTS:
Step 1: Search for medical devices with relevance for the method to be assessed.
Step 2: Identification of the CE certificate and/or FDA approval of eligible devices.
Step 3: Systematic literature research for primary trials.
Step 4: Selection of studies that describe the method, using the eligible devices identified in step 2.
Step 5: Constitution of 2 study pools. Pool A comprises the selected studies, using the current available model(s) of the eligible device(s) only; Pool B comprises all selected studies, identified in step 4.
Step 6: Outcome related assessment is primarily based on study pool A. Only if – on the highest evidence level identified – for the current available model(s) no data are available for a relevant outcome, further assessment will rely on study pool B.
Step 7: Summary of results and conclusion.

CONCLUSIONS:
Assessment of methods largely based on medical devices should primarily rely on studies, using the current commercial model(s) of the product. If results are majorly based on studies using precursor
models of the medical device, the question has to be addressed whether the results and conclusions can be transferred to the current available model that is used in clinical practice.

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**VP25 HTA Enables Nurses To Discontinue Continuous ECG Monitoring**

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**ABSTRACT SUMMARY:**
Appropriate use of technology should be considered at the patient level as well as at the hospital or health system level. In this presentation, we give an example of an HTA report focused on finding criteria for the safe discontinuation of telemetry monitoring and empowering nurses to act on this guidance.

**INTRODUCTION:**
Providers frequently issue orders for telemetry (continuous ECG monitoring) of hospital inpatients, but they rarely issue orders to discontinue telemetry. This can cause telemetry beds to be unavailable for patients who need them.

**METHODS:**
Our hospital HTA center conducted a rapid systematic review of evidence on algorithms, guidelines, and other tools for nurses to identify patients who no longer need telemetry. Databases searched included Medline, CINAHL, the Cochrane Library, National Guideline Clearinghouse, and Joanna Briggs Institute.

**RESULTS:**
We found no guidelines or existing systematic reviews of nurse-driven protocols for discontinuing telemetry. There were three published articles describing projects where protocols for discontinuing telemetry were tested. All three of these studies were of low methodologic quality. They all found that use of the protocol reduced the number of hours of telemetry monitoring that were used in the hospital. Two studies published in letter form reported adaptations of computerized order entry systems where nurses assess the patient’s readiness for discontinuing telemetry and either discontinue telemetry or report to the ordering physician when the stated discontinuation criteria are met.

**CONCLUSIONS:**
Our hospitals are now implementing the HTA findings in our electronic ordering system.

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**VP26 HTA In Nursing: Scoping Trends With An ICF Component Analysis**

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**AUTHORS:**
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**ABSTRACT SUMMARY:**
A systematic overview about the a) HTA base and b) outcomes addressed in nursing with an ICF Map, connecting targeted healthcare outcomes with the components of the ICF Classification. Overall, 44 reports did not outline particular outcomes, the remaining 34 reports addressed three ICF components (body functions, activities/participation, environmental factors) with 68 ICF content categories.
INTRODUCTION:
Nursing is a worldwide growing but still underdeveloped HTA field. A systematic overview about the current trends on HTA and nursing would shed some light on the issues of a) the HTA base in this sector and b) outcomes addressed with the interventions and technologies.

METHODS:
We conducted a scoping review using the NHS Centre for Reviews and Dissemination HTA database, including all abstracts of HTA reports related to nursing. To systemize the interventions and technologies assessed in the HTA reports, we designed an ICF Map connecting the targeted healthcare outcomes with the components of the ICF Classification.

RESULTS:
We identified 78 HTA reports related to nursing care, published between the years 1992 and 2018. Overall, 44 reports did not outline any particular outcome and had to be categorized as unclear. The remaining 34 reports addressed three ICF components (body functions, activities/participation, environmental factors) with 68 ICF content categories. Frequent ICF contents were services, systems and policies (code e5, n=15), cardiovascular/respiratory functions (code b4, n=10), mental functions (code b1, n=7), digestive functions (code b5, n=7), domestic life (code d6, n=7), and sensory functions/pain (b2, n=6). Six HTA reports evaluated interventions/technologies with presumed effects on at least four ICF content categories from two ICF components.

CONCLUSIONS:
HTA in the field of nursing is often complex, including multicomponent approaches and a wide range of potential outcomes relevant for the HTA assessment. The ICF model might be useful to support a more streamlined understanding of complex interventions in this sector. Furthermore, reports might benefit from linking the ICF Classification with HTA, especially for the assessment of complex interventions.

VP27 Countrywide Screening Of Cardiovascular Diseases Through Telemedicine

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ABSTRACT SUMMARY:
Through the telemedicine, advantageous telediagnostic systems can be developed to improve the health care of populations that don’t have access to specialists. The usability of telemedicine to improve the countrywide detection of heart diseases according to the national cardiovascular disease prevention program in Paraguay was investigated. The results show that the telemedicine can enhance significantly the EKG screening countrywide.

INTRODUCTION:
Through the telemedicine, advantageous telediagnostic systems can be developed to improve the health care of populations that don’t have access to specialists. However, evidence on how such innovation technology can enhance the countrywide electrocardiographic (EKG) screening to support a prevention program for cardiovascular diseases is limited. The usability of telemedicine to improve the countrywide detection of heart diseases according to the national cardiovascular disease prevention program in Paraguay was investigated.
METHODS:
This cross-sectional survey included adults (≥19 and ≤ 80 years) and children (≥1 and ≤ 18 years) with medical prescription. The 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) to evaluate the utility of a telediagnostic net for detection and prevention program of cardiovascular disease in public health. For this purpose, the results obtained by the EKG telediagnosis net implemented in 60 countrywide public hospitals were analyzed and verified the adherence to the cardiovascular prevention program.

RESULTS:
A total of 246,217 remote ECG diagnoses were performed between January 2014 and August 2018. Of the total, 80.6% (198,494) corresponded to adults and 19.4% (47,723) to children. The adult diagnosis were mainly normal (66.3%), sinus bradycardia (11.2%), right bundle branch block (4.8%), left ventricular hypertrophy (4.7%), ventricles repolarization disorder (4.4%), sinus tachycardia (4.4%), ischemia (1.7%), atrial fibrillation (1.1%), left bundle branch block (0.7%), and unspecified arrhythmias (0.6%). The children diagnosis were mainly normal (79.4%), sinus bradycardia (10.6%), sinus tachycardia (3.2%), unspecified arrhythmias (2.8%), right bundle branch block (1.9%), left ventricular hypertrophy (1.0%), left bundle branch block (0.4%), ventricles repolarization disorder (0.3%), and atrial fibrillation (0.2%). The mean adherence rate to the prevention program was 2.3 between 2014 and 2018 for each thousand diagnosis performed.

CONCLUSIONS:
The results show that the telemedicine can enhance significantly the EKG screening to support a prevention program for cardiovascular diseases and health programs. However, before carrying out its systematic implementation, a contextualization with the regional epidemiological profile must be performed.

VP28 Building A Virtual Diagnosis Network Through A Telemedicine Platform

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ABSTRACT SUMMARY:
Advances in information, communication (ICT) and health technology have enhanced healthcare for many countries around the world. The challenge for low setting countries is to build a telemedicine platform to enhance the community hospital response capacity. In this context the virtual telediagnosis network should be directed towards building better equity in the provision of services in remote locations without specialists.

INTRODUCTION:
Advances in information, communication (ICT) and health technology have enhanced healthcare for many countries around the world. The challenge for low setting countries is to build a telemedicine platform to enhance the community hospital diagnosis response capacity. 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 virtual telediagnosis network should be directed towards developing better equity in the
provision of services in remote locations without access to specialists. The usability of a telemedicine platform to enhance the virtual diagnosis network of community hospitals in rural areas of 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 telemedicine platform to enhance the virtual diagnosis network of community hospitals. For this purpose, the results obtained by the virtual telediagnosis network implemented in 60 public countryside community hospitals were analyzed.

RESULTS:
A total of 427,026 remote diagnoses were performed between January 2014 and October 2018 in 60 community hospitals. Of the total, 35.76% (152,703) corresponded to tomography studies, 62.55% (267,100) to electrocardiography (EKG), 1.68% (7,204) to electroencephalography (EEG) and 0.01% (19) to ultrasound. There were no significant differences between the remote and the "face to face" diagnosis. With the remote diagnosis a reduction of the cost was obtained, that supposes an important benefit for each citizen of the 60 communities.

CONCLUSIONS:
The results show that the virtual diagnosis network based on a telemedicine platform can enhance significantly the community hospital diagnostic services, maximizing professional time and productivity, increasing access and equity, and reducing costs. However, before carrying out its countrywide implementation, a contextualization with the regional epidemiological profile must be performed.

VP29 Designing A Mobile Clinical Decision Support System For Dementias

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ABSTRACT SUMMARY:
PSICODEM Project aims to contribute in eHealth interventions addressed to the management of dementias thought a mobile personalized Clinical Decision Support System (CDSS) based on evidence for choosing the best psychosocial intervention according the symptoms and level of dementia of each patient. Present communication focuses on the first stage if the project.

INTRODUCTION:
eHealth offers the opportunity of supporting the management of several diseases, but most of these tools are far from both being based on scientific evidences and demonstrating their effectiveness and efficacy. PSICODEM Project aims to develop a mobile personalized Clinical Decision Support System (CDSS) based on evidence for contributing in eHealth interventions addressed to the management of dementias that require not only of a pharmacological approach but also psychosocial interventions for improving patients’ quality of life and reducing emotional, cognitive and behavioral symptoms. Present communication focuses on the identification of the evidences on which the CDSS algorithm will be developed.

METHODS:
Three systematic reviews were carried out in order to identify the existing scientific evidence published in relation to the effectiveness of behavioral, emotional and cognitive therapies addressed to
dementia (January 2009-December 2017). Main databases were consulted (PubMed, Cochrane Library, PsychInfo) and only Randomized Control Trials (RCT) were considered. Articles were reviewed for two independent reviewers. The quality of the selected publications was assessed according SIGN criteria.

RESULTS:
Forty-seven RCT were selected for cognitive therapies, thirty-two for emotional ones and fifteen for behavioral interventions. Those therapies with more support of evidence were: skills training for cognitive therapies and reminiscence interventions for emotional interventions; however in behavioral interventions a variety of therapeutically approaches were found. Wide differences were found between studies in terms of types and levels of dementia, forms of intervention (number, length and frequency of sessions) and outcome measures.

CONCLUSIONS:
In-depth analysis of evidences will allow to identify those interventions more adequate for each patient according to their symptoms and level of dementia. According to these evidences, the mobile CDSS algorithm will be developed. Additionally, these findings point out the gaps in psychosocial intervention research.

VP30 Evaluation Of CINAHL In Six Systematic Reviews On Maternal Care

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ABSTRACT SUMMARY:
We retrospectively analyzed the number and relevance of references retrieved from the bibliographic database CINAHL in six systematic reviews on maternal care. In one review on birthing positions, one out of thirteen studies included was indexed only in CINAHL, a small feasibility study that was cited in a subsequent randomized controlled trial and thus could have been identified without CINAHL.

INTRODUCTION:
Information retrieval for systematic reviews (SRs) should include sensitive searches in several bibliographic databases. In addition to standard databases (i.e., MEDLINE, Embase and CENTRAL), researchers might consider subject-specific ones. In the fields of nursing and midwifery, a SR would typically include CINAHL as a subject-specific database. The aim of this study was to analyze the number and relevance of references retrieved from CINAHL in six SRs on maternal care.

METHODS:
We conducted a retrospective analysis of six SRs (e.g., benefit of intrapartum ultrasound or one-to-one care during labor). The study type was limited to randomized controlled trials (RCTs) in all but three SRs. In all cases, MEDLINE, Embase, CENTRAL and CINAHL were searched for primary studies. Further information sources (e.g., study registries and reference lists of SRs) were also considered. The proportion of the additional number of hits and studies included from CINAHL as well as the corresponding number of participants were calculated.

RESULTS:
Overall, the reviewers screened 12,013 references from bibliographic databases and identified forty relevant studies. CINAHL contained 2,643 (22 percent) of the references. In five out of six SRs, no additional studies were identified in CINAHL. In the remaining SR on birthing positions, the reviewers included thirteen RCTs of which one was
a feasibility study with 68 participants indexed only in CINAHL. This corresponds to 0.9 percent of the women participating in all thirteen RCTs (n = 7,861). However, this study was cited in a journal article on a subsequent RCT that was identified and included via MEDLINE and ClinicalTrials.gov.

CONCLUSIONS:
It is not necessary to search CINAHL in SRs on maternal care if standard databases and further information sources are considered. An additional study from CINAHL was included in one out of six SRs, a small feasibility study that could have been identified without CINAHL via a subsequent RCT.

INTRODUCTION:
Currently, IQWiG does not restrict literature searches by language. Given limited resources, it is unclear whether the effort put into screening and translating studies published in non-English and non-German (nEnG) languages yields much new information when compared to including only English and German literature. Therefore, we aimed to analyze the impact of nEnG literature on the conclusion of IQWiG’s health technology assessments (HTAs).

METHODS:
We checked for 72 IQWiG HTAs (all non-drug intervention HTAs published until August 2018 and 3 additional HTAs on drugs) whether they included nEnG studies. For all HTAs including at least one nEnG study, we analyzed whether the statistical significance would have changed for any endpoint without the respective nEnG study(ies). If no endpoint was impacted by a nEnG study, we classified the study as non-relevant to the HTA’s conclusion and specified a reason for this.

RESULTS:
Of 72 HTAs, 29 (40 percent) included a total of 83 nEnG publications. Three HTAs were impacted by the inclusion of altogether seven Chinese publications. For one HTA on systemic therapy, five endpoints’ conclusions were changed; for the other two HTAs, the statistical significance would have changed for one endpoint each. The remaining 76 publications (included in 69 HTAs) were judged as non-relevant to the HTA’s conclusion, the most prominent reason being “meta-analysis would have had the same result without respective study” (44 percent of nEnG publications).

CONCLUSIONS:
Only three of 72 HTAs (4%) were impacted by nEnG publications, the changes being minimal for two of these. When faced with limited time or personnel resources, searching only for English and German publications may be sufficient, especially when generalizability issues are a possible concern.
**VP32 Incorporation Of The Only Drug For Primary Biliary Cholangitis Brazil**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
The CONITEC of the Brazilian Ministry of Health has recently incorporated Ursodeoxycholic Acid after extensive evaluation of the clinical evidence, economic study and budgetary impact for the public health system. The drug is the only registered in the country with indication for primary biliary cholangitis and in use worldwide for two decades, and its availability increases access and good prognosis.

**INTRODUCTION:**
Primary biliary cholangitis (CBP) is a rare autoimmune cholestatic liver disease, inflammation and progressive destruction of small and medium-sized interlobular ducts, progressing to fibrosis, cirrhosis, and death. Currently, the Brazilian public health system (SUS) offers treatment of the symptoms of cirrhosis, and has no medication with indication for CBP.

**METHODS:**
Scientific technical opinion with systematic review (RS) of available evidence in the databases MEDLINE (Pubmed), LILACS and Cochrane Library (accessed July 2017) on Ursodeoxycholic Acid (AUDC). Methodological quality was evaluated with AMSTAR and Newcastle Ottawa tools. Meta-analyses were performed in Review Manager® 5.2 in the random effects model. Analysis of the budget impact calculation deterministic model, from the perspective of 5 years for the SUS.

**RESULTS:**
Ten RS’s and three cohorts were included. There was no statistically significant difference between AUDC and placebo in outcome outcome. Overall survival was significantly (P <0.001) higher in the AUDC group compared to that predicted by the Mayo model or placebo. Treatment with UCD showed an increase in the long-term transplant-free survival time from the fifth year of treatment, with statistically significant results for years 5, 8 and 10 (p <0.01). There were no statistically significant differences for safety outcomes. Based on the assumptions adopted, the incremental budgetary impact with the incorporation of the AUDC into SUS would be R $ 11.77 million in the first year and R $ 98.52 million in the accumulated five years, considering a market share of 10% per year.

**CONCLUSIONS:**
Despite the uncertainties in the evidences of effectiveness and effectiveness of the AUDC and the probably underestimated budgetary impact, AUDC was incorporated into the SUS because it is the only alternative with indication for CBP and in use for more than two decades, allowing everyone access to the medicine.

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**VP33 Pharmacoeconomic Submission Requirements: Africa Compared With England**

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**ABSTRACT SUMMARY:**
The South African Pharmacoeconomic Submissions Guideline (SAPG) was compared against the pharmacoeconomic guideline from Egypt and the
National Institute for Health and Care Excellence Methods Guide, using the European Network for Health Technology Assessment Core Model® (version 3.0). Areas to further develop the SAPG requirements and strengthen evidence for decision making in health technology assessment were identified.

INTRODUCTION:
The South African Pharmacoeconomic Submissions Guideline (SAPG) is currently voluntary for medicines in the private health sector but may become mandatory and more widely used under the proposed National Health Insurance system. To make recommendations on evidence generation and areas where the SAPG could be strengthened, the study compared the SAPG requirements with other African pharmacoeconomic guidelines and the National Institute for Health and Care Excellence Methods Guide (NICE MG).

METHODS:
The World Health Organisation, International Network of Agencies for Health Technology Assessment (HTA), HTA International, and the International Society for Pharmacoeconomics and Outcomes Research websites were consulted, and email requests send to named individuals from retrieved source material. The European Network for HTA Core Model® (version 3.0) (the Model®) provided the evaluation and comparison framework, using three criteria: completely, partly or not completely requiring the same or similar information as the Model®.

RESULTS:
Of forty-five countries identified, only Egypt had a publicly available pharmacoeconomic guideline (Egyptian Pharmacoeconomic Guideline (EPG)). The guidelines varied considerably in their intended audience, size and content. All three guidelines’ primary focus were the cost and economic evaluation, and health problem and current use domains. Safety, organisational, ethical and legal aspects were poorly covered by the SAPG and EPG guidelines (less than thirty percent of issues in each domain completely/partly covered). The SAPG completely or partly required the same or similar information in the Model® for thirty-nine percent of total issues, the EPG thirty-three percent and the NICE MG sixty-six percent.

CONCLUSIONS:
The SAPG was not as comprehensive as the NICE MG and poorly covered some key aspects of HTAs, suggesting that the SAPG could be developed to be more informative for decision-makers. Evidence generation should focus on describing the health problem the technology is targeting and on evidence that can be synthesized into cost-effectiveness analyses.

VP34 Impact Of Adverse Events On Reimbursement Recommendations

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ABSTRACT SUMMARY:
The abstract seeks to evaluate the impact of adverse events (AEs) in asthma medications on their reimbursement recommendations. AEs and reimbursement recommendations were compared by conducting a case study of omalizumab and reslizumab.

INTRODUCTION:
European agencies evaluate the adverse events (AEs) of asthma drugs in studies. The impact of these evaluations on reimbursement decisions remains unclear.
METHODS:
Adult asthma evaluations were accessed from initial regulatory decision by the European Medicines Agency (EMA) through reimbursement evaluations. Omalizumab and reslizumab were chosen for the comparison of an older with a newer asthma drug. A timeline was then constructed to evaluate the effect of AEs on reimbursement recommendations. Evaluations from the United Kingdom (NICE) were not used because their documents are not as complete or in depth. Untranslated evaluations from Sweden (TLV) and Germany (IQWiG) were also not used.

RESULTS:
Omalizumab was first approved as add-on therapy to improve asthma control in October 2005. Of the 6 decisions made between 2006 and 2012, safety information was found in 4 of them, all from 2006 and evaluated by either Scotland (SMC) or France (HAS). They all received either a Do not recommend or a Recommend with restrictions decision. Reslizumab was first approved as add-on therapy for patients with severe eosinophilic asthma in August 2016. Of the 9 decisions made in 2017, safety information was found in 5 decisions evaluated by IQWiG, Germany (G-BA), HAS, or SMC, which gave them a Do not recommend, Recommend with restrictions, or Recommend decision.

Of the Do not recommend decisions, both the omalizumab and reslizumab safety evaluations mentioned common AEs (worsening asthma) and less common AEs (malignant tumors). Of the Recommend with restrictions decisions, the same AEs were seen. Only reslizumab had Recommended decisions. In the safety evaluation, there were no specific AEs named.

CONCLUSIONS:
The impact of AEs on reimbursement decisions could not be detected when comparing omalizumab and reslizumab reviews, as other factors may contribute to the decisions. Further research should be conducted to explore this issue.

VP35 Effectiveness And Safety Of Cyanoacrylate Ablation For Varicose Veins

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ABSTRACT SUMMARY:
This is the first systematic review with meta-analysis comparing endovenous cyanoacrylate adhesive ablation with the most common endothermal treatments, i.e. radiofrequency and endovenous laser ablation. This study will permit endovascular specialists to consider the advantages and disadvantages of cyanoacrylate adhesive ablation compared to endothermal ablation in varicose vein treatment.

INTRODUCTION:
Treatment of varicose veins is currently performed by different interventionist alternatives that include surgical, endothermal and non-thermal ablation therapies. The main guidelines recommended endovenous thermal treatment as the first choice therapy; however present side effects related to thermal energy. Non-tumescent endovenous ablation techniques such as cyanoacrylate ablation (CA) started to develop to avoid these problems. The objective of this study is to assess the effectiveness and safety of CA for saphenous vein incompetence.

METHODS:
A systematic review with meta-analysis was carried out. The search of scientific literature...
was performed in Medline, Embase, Cochrane library, CDR, WoS and Scopus databases. GRADE methodology was used to assess the quality of the evidence and Cochrane risk of bias tool to assess methodological quality of randomized control trials (RCT). Pooled risk ratio was calculated using a random effects model.

RESULTS:
Two RCTs and one non-RCT comprising 1.077 participants were included. Additionally, 10 case series were included for safety assessment. Pooled analysis of closure rates by the two RCTs indicated there were not significant differences between CA and radiofrequency ablation (RFA) or endovenous laser ablation (EVLA). Improvements in venous clinical severity score were reported by all comparative studies without significant differences among groups. The most frequently reported adverse events were ecchymosis, phlebitis, paraesthesia, and thrombosis. The pooled analysis showed significant differences only in ecchymosis rates, with lower probability of ecchymosis in CA groups. CA treatment showed lower pain rates and shorter intervention times and recovery compared to endothermal therapies.

CONCLUSIONS:
The effectiveness of CA devices in the treatment of varicose veins is comparable to EVLA and RFA, while the rates of adverse effects are lower. Despite the limitations of the evidence, CA may be a promising alternative to existing treatments, with the advantages of better patient comfort.

AUTHORS:
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ABSTRACT SUMMARY:
By accepting input from anyone, not just registered patient groups, Australia’s health technology assessments (HTAs) for medicines have the potential to engage a broad section of the population. However, providing appropriate input requires awareness, training and support. Patient Voice Initiative developed and trialled a training program to increase HTA awareness in patient communities and build capability to contribute value-adding input.

INTRODUCTION:
Australia’s patient involvement process for medicine health technology assessments (HTAs) accepts input from anyone not just registered patient groups. Without training to build capability, it can lead to a petition-like response rather than input likely to add value to HTA decision making. However, the Pharmaceutical Benefits Advisory Committee (PBAC) has limited resources and no patient involvement unit. Patient Voice Initiative (PVI) developed and trialled a training program to educate patient communities about HTA and increase their capability to contribute patient insights into PBAC.

METHODS:
The authors developed a four-hour patient workshop to be held in the six state capitals (October 2018 - February 2019). The content was based on information needs identified in previous PVI workshops, feedback from PBAC members and patient groups. Workshops included both educational presentations and an interactive activity. Participants responded to publicity via traditional patient groups, as well online groups and forums. Questionnaires were used to gather data on participants’ needs, experience and knowledge at registration and the workshops’ start and end.
RESULTS:
Interim results show most participants had little knowledge of PBAC. Training participants to identify their unique patient knowledge, as opposed to providing general disease/condition information, was a challenge. After the first workshop content was re-written to increase the likelihood of participants being able to articulate their unique knowledge in the activity and agreeing with final questionnaire statements about being confident sharing information about PBAC.

CONCLUSIONS:
By accepting input from anyone, not just registered patient groups, PBAC has the potential to engage a broad section of the Australian population in HTA. These individuals may contribute rich insights from their own experience or the collated experiences of their online patient communities or other informal groups. They may play a role in increasing public understanding of HTA and encouraging others to participate. Locating and engaging them may require well-resourced, collaborative and evaluated activities and further research into innovative recruitment and training.

VP37 Patient Involvement In EUnetHTA Assessments (Non-Pharma Technologies)

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ABSTRACT SUMMARY:
The European Network for HTA (EUnetHTA) aims to advance and standardise patient involvement processes to add to the quality and applicability of HTAs and to allow capability building. Different methods for patient involvement were tested in eight of sixteen HTAs on non-pharmaceutical technologies. These approaches were useful for complementing HTA processes and need to be further tested and evaluated.

INTRODUCTION:
Patients can provide valuable experience on living with diseases, health-related quality of life, various therapies and relevant outcomes. Their input and perspectives can be helpful in complementing health technology assessment (HTA) processes. The European Network for HTA (EUnetHTA), funded by the European Commission, aims to further advance and standardise patient involvement processes in order to add to the quality and applicability of HTAs and to allow capability building.

METHODS:
Different methods for patient involvement in HTAs on non-pharmaceutical technologies were tested: Patient input templates (open questions sent to relevant patient organisations, or published on EUnetHTA website); scoping meeting with patients/patient representatives; semi-structured interview and focus group. Applied methods depended on the scope of the HTA and other factors like timelines of HTAs and burden of disease for patients.

RESULTS:
Patients were included in eight of sixteen HTAs on non-pharmaceutical technologies. Applied methods were: focus group (n=2), scoping meeting (n=1), patient input templates (n=4), semi-structured interviews (n=2,) and other approach (i.e. written feedback on scope n= 2). In some HTAs more than one method was used. Main reasons for not including patients were inability to identify suitable patients or tight timelines. Patients’ feedback on health-related quality of life and outcome measures proved most useful in the scoping phase.
CONCLUSIONS:
The different approaches were useful for complementing HTA processes, but need to be further tested and evaluated in order to formulate deeper understanding about the impact of patient involvement on HTA. Additionally, feedback from patients that were actively involved in the HTAs should be collected to further improve the involvement methods that should serve as basis for future recommendations post 2020.

METHODS:
(1) POs and participants in a patient HTA educational program were surveyed using both open and closed questions. Themes included communications, difficulties with the current process and suggestions for improvement.

(2) A review and comparison of the POSP in other countries and HTAi tools was undertaken.

(3) The POSP and POSET were revised based on feedback and best-practice from other POSPs.

(4) The revised POSP and POSET were subject to a public consultation period of 1 month to obtain views and comments; advertised via umbrella POs, our website and social media (NCPE Twitter account).

RESULTS:
The survey was sent to 12 POs and 20 course participants and the overall response rate was 40%. The need for guidelines and a dedicated point of contact in the NCPE to assist POs with submissions was identified. The tone and layout of the POSET was refined. The need for a POs database for internal use, a process flow chart and a dedicated patient information section, detailing the POSP on the NCPE website, was identified. Guidelines were developed to assist POs completing the POSET. Feedback from 14 stakeholders obtained via the public consultation led to additional refinements of the final documents and processes; themes included communication, timeliness, clarity, and providing examples of completed templates and surveys. The refined POSP was implemented in August 2018.

CONCLUSIONS:
The NCPE has reviewed their processes for patient involvement in HTA via surveys, direct patient engagement and public consultation to develop the POSP. It is anticipated that the new POSP will
improve the quality and quantity of patient group submissions and improve stakeholder satisfaction in how the NCPE captures and presents the patient voice in HTA. Future considerations include developing online feedback surveys in response to each submission, on-going educational programmes and an annual report outlining patient engagement activities.

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**VP39 The Alphabet Lottery? How NICE Outcomes Vary By Appraisal Committee**

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**ABSTRACT SUMMARY:**
NICE single technology appraisals (STAs) are made by one of four Appraisal Committees (A,B,C,D). We find that STAs undertaken by NICE Appraisal Committee D was associated with a significantly lower rate of ‘recommended’ outcomes but tended to an ‘optimised’ recommendation significantly more than the other committees.

**INTRODUCTION:**
NICE (National Institute for Health and Care Excellence) makes recommendations on the public reimbursement of medicines based on their clinical- and cost-effectiveness. The recommendation is made by an Appraisal Committee (comprising a multi-disciplinary group of independent experts) as part of a technology appraisal. There are four Appraisal Committees (A,B,C,D); this research investigates whether appraisal outcomes vary by committee.

**METHODS:**
All publically-available Final Appraisal Determinations from NICE Single Technology Appraisals (STA) were screened (01/10/2009-14/11/2018) and key data were extracted. Homogeneity in rates of acceptance or rejection across the committees was assessed using Chi-squared tests.

**RESULTS:**
The Appraisal Committee was identified for 298 technologies, 56% (168/298) of which were ‘recommended’. The number of technologies assessed by each committee was similar (A:79, B:62, C:91, D:66). However, STAs conducted by Committee D were significantly less likely to receive ‘recommended’ outcomes (A:68% [54/79], B:65% [40/62], C:53% [48/91], D:39% [26/66]; p<0.01). STAs for oncology indications had higher ‘not recommended’ outcomes than those for non-oncology indications (25% vs. 9%). The lower ‘recommendation’ rates for committee D persisted across oncology (A:60%, B:83%, C: 50%, D: 38%; p=0.01) and non-oncology indications (A:73%, B:53%, C:55%, D:40%; p<0.01). However, STAs conducted by Committee D were significantly more likely to receive ‘optimised’ recommendations (A:16%, B:21%, C:33%, D: 36%; p<0.01) and when considering the rates of ‘recommended’ and ‘optimised’ outcomes compared to ‘only in research’ and ‘not recommended’ outcomes, no significant differences were found (A:85%, B: 85%, C:86%, D:76%; p=0.27).

**CONCLUSIONS:**
STAs undertaken by NICE Appraisal Committee D was associated with a significantly lower rate of ‘recommended’ outcomes but tended to an ‘optimised’ recommendation significantly more than the other committees. Further research is needed to determine if this reflects any deviation in uniform implementation of NICE methodology between Committees.
**VP40 Increasing Divergence Of IQWiG And G-BA Benefit Assessments Over Time?**

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**ABSTRACT SUMMARY:**
Since 2011, new pharmacological therapies in Germany are subject to an early benefit assessment (EBA) upon launch comprising an initial assessment by IQWiG followed by a final resolution by the G-BA. We find that the G-BA has deviated from IQWiG’s initial assessment in around one-third of resolutions, with potential significant rebate consequences and explore how this has varied over time.

**INTRODUCTION:**
Since 2011, new pharmacological therapies in Germany are subject to an early benefit assessment (EBA) upon launch. The Institute for Quality and Efficiency in Health Care (IQWiG) usually conducts an initial assessment, followed by the Federal Joint Committee (G-BA) issuing a final resolution. If the G-BA deem a new therapy offers no additional benefit over relevant comparators, it cannot attain premium-pricing through price negotiations. This research compares G-BA and IQWiG assessment outcomes over time.

**METHODS:**
All EBA resolutions were extracted from the G-BA website alongside corresponding IQWiG assessments (01/01/2011-19/09/2018) and key information compared. For extracted outcome data, the focus was the subgroup of greatest additional benefit.

**RESULTS:**
Of 261 identified EBAs with both G-BA and IQWiG assessment outcomes published, 59% (155/261) did not differ in their additional benefit. The G-BA concluded on an additional benefit where IQWiG deemed none in 13% (34/261) of cases, which was consistent pre-2015: 13% (11/87) and 2015-onwards: 13% (23/174). Conversely, IQWiG deemed an additional benefit where the G-BA concluded on none in 3% (8/261) of cases, none of which were pre-2015 (0/87) vs. 5% (8/261) for 2015-onwards. G-BA and IQWiG both agreed that additional benefit was offered but differed in its extent in 14% (37/261; in 23 cases: G-BA’s rating was lower, 14 cases: G-BA’s was higher) with 19% (17/87) pre-2015 vs. 8% (14/174) 2015-onwards.

**CONCLUSIONS:**
The G-BA has deviated from IQWiG’s initial assessment in around one-third of resolutions, with potential significant rebate negotiation consequences. The divergence in extent of additional benefit (where both agree on additional benefit) appears to be becoming less common over time. However, a slight converse time-trend appears regarding divergence on whether any additional benefit is offered, driven by increased incidence of G-BA deeming no additional benefit contrary to IQWiG. This emphasizes that companies should fully engage with the EBA consultation process post-IQWiG appraisal.

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**VP41 NICE Interventional Procedures Advisory Committee Recommendations**

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ABSTRACT SUMMARY:
This work focuses on the relationship between technical knowledge (the published evidence base) and policy recommendations. Various studies have analysed recommendations from NICE committees that consider cost, but none has explored the role of the evidence-base for a committee where cost is not an element of decision making. This work fills that gap.

INTRODUCTION:
This study explores the factors (principally evidential) that predict guidance recommendations by this NICE committee. There are three main types of recommendations: Standard/normal arrangements (can be done without restriction in the NHS); Special arrangements (can be done under certain conditions); and Research only

METHODS:
The following data were extracted from all published pieces of Interventional Procedure Guidance (IPGs) produced by this committee: year, IPG number, recommendations, evidence base (numbers and types of included studies, numbers of included patients etc.). All data were extracted independently by two researchers, and any disagreements clarified by consensus. Data were tabulated and descriptive statistics produced. Regression analyses will be performed using these data to identify any statistically significant predictors of recommendations.

RESULTS:
IPG recommendations (n=496); year range: 2003-2018. Proportion of IPGs by each recommendation: 50% Standard; 38% Special; 11% Research Only; 2% Do Not Do. Proportion of IPGs with highest level evidence (i.e. systematic review and/or RCT) by recommendation type: Standard=64% (152/239); Special=43% (77/180); Research Only=48% (26/54); Do Not Do=75% (6/8). Mean numbers of patients by recommendation type: Standard=7,838; Special=3,935; Research Only=2,423. There is also a clear trend over time: Standard recommendations decrease for all IPGs from 63% in 2003-2009 to 40% in 2014-2018; and the evidence threshold for Standard recommendations increases over time from 56% based on systematic reviews and/or RCTs in 2003-2009 to 85% in 2014-2018; mean numbers of patients per Standard recommendation also increase from 2,002 to 6,098 over this period.

CONCLUSIONS:
Higher levels evidence and numbers of patients increase the likelihood of the most positive recommendation. However, this evidence might still lack sufficient quality or certainty to answer a policy question. The evidence threshold to achieve a Standard recommendation has also increased markedly over time. As with other NICE committees, factors other than cost and perceived hierarchies of evidence clearly act as drivers of decisions.
international HTA products is dependent on so many different aspects.

INTRODUCTION:
For many years, our main objective of being a part of EUnetHTA was to be inspired by other HTA organisations and to develop our own HTA practice by taking an active part in the development of EUnetHTA models and methods. To establish common ground in the complex processes of international HTA productions has proved to be challenging but also very educational. We have now reached a point in the EUnetHTA development where HTAs are jointly produced and models and methods are used in this production. We would like to share our experiences of this process as a small national HTA organisation being a EUnetHTA partner.

METHODS:
Experience gathering and reflections on international HTA collaboration.

RESULTS:
Experiences with using EUnetHTA products and models:
Over the years we have discussed and partially tested different ways of using EUnetHTA products and models. The increased production in EUnetHTA Joint Action 3, of HTAs on both technologies and pharmaceuticals have, and we are at the moment testing a process where we make a short Danish version of the EUnetHTA assessment (around five pages) and distribute it to relevant persons and milieus. At the moment we are working on aligning our HTA products more with EUnetHTA models to increase the synergy of both participating in the EUnetHTA work and making national HTA work.

CONCLUSIONS:
We find a lot of the joint produced EUnetHTA work useful and relevant in a national context, at least as a supplement to the national HTA work, however we have also experienced that the usefulness is not only related to the content, quality and timeliness of the EUnetHTA products, but also very much related to the national HTA organisation and decision-making processes.

VP43 How EUnetHTA Joint Assessment Can Speed Up National Appraisal Process

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ABSTRACT SUMMARY:
The impact of EUnetHTA pharmaceutical Joint Assessments on the timelines of national assessments is investigated. Recommendations to improve this impact will be made.

INTRODUCTION:
In EUnetHTA Joint Action 3, a number of pharmaceutical Joint Assessments have been produced. EUnetHTA demonstrated that the production process is predictable and of high quality. What is the impact of these Joint Assessments on the production timelines of national assessments?

METHODS:
After publication of each Joint Assessment, the organisations represented in the assessment team are asked to complete a survey on the usage of the respective Joint Assessment. In addition, specific information on national timelines is requested from the authoring agencies. The information requested compares average time on national assessments without a Joint Assessment and time needed on national appraisal when being author or co-author for a pharmaceutical Joint Assessment.
RESULTS:
Until November 2018, 13 agencies completed the survey on the assessment process. One of the HTA bodies that acted as author for a pharmaceutical assessment indicated their national appraisal process was reduced by three weeks. In addition, one of the co-authoring agencies reported reduced national timelines after co-authoring a EUneHTA Joint Assessment. One author reported no usage of the EUneHTA Joint Assessment, because the topic was outside of the agencies scope.

CONCLUSIONS:
Many HTA agencies indicated that EUneHTA Joint Assessments were used on a national level. Authoring or co-authoring agencies reported reduced national assessment timelines. We explore national assessment time for other agencies when they are using EUneHTA reports. In order to enhance impact of Joint Assessments on the timeliness of national assessments, EUneHTA places more focus on the applicability of the scope of the pharmaceutical Joint Assessments. In the future we will evaluate whether EUneHTA Joint Assessments may shorten national assessment timelines of non-authoring agencies.

ABSTRACT SUMMARY:
Efforts to rationalise the use of resources are only valuable if recommendations are implemented in practice. Yet, we know that implementation of HTA findings is variable. Taking a realist approach, we aim to move beyond describing facilitators and barriers to uptake in order to produce tested and data-driven theory on the mechanisms by which HTA impact can be optimised.

INTRODUCTION:
Efforts to rationalise the use of resources are only valuable if recommendations are implemented in practice. Yet, we know that implementation of HTA findings is variable. Whilst much research has established what factors influence improved decision making, it is less understood how such influences interact with local context and health systems, leading to the improved implementation of evidence-based recommendations. We aim to produce tested and data-driven theory on the mechanisms by which HTA impact can be optimised.

METHODS:
Realist synthesis is a relatively new approach to evaluation in health and an innovative way to review the literature pertaining to HTA outcomes. Explanation-building using a realist lens is operationalised through investigating context-mechanism-outcome configurations (CMOs). By drawing on an iterative analysis of the literature and formal theories, we seek to generate, test and refine explanations for the (non-) implementation of HTA recommendations.

RESULTS:
The findings are articulated in the context of the initial programme theory which is used to refine our theory into a working model of how uptake occurs successfully. Preliminary results suggest a layering effect to antecedent factors of uptake: the more of them that are present, the greater the magnitude of effect, such that they all moderate each other. Additionally, readiness for change is
a complex multi-dimensional construct requiring both a willingness and capability to change. Using CMOs, we show using that resources and readiness are both necessary but not necessarily sufficient on their own to facilitate the uptake of HTA decisions.

CONCLUSIONS:
This paradigm of realist methodology can help bring new insight to support learning around HTA in an era of investment and expansion, in particular, into low- and middle-income countries (LMICs), through better understanding of its translation into health outcomes. For LMICs, we want them to have a forward-looking model to support the implementation, and thus optimise the impact, of HTA.

VP45 Post-Surgical Complications In Patients With Vascular Surgeries

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ABSTRACT SUMMARY:
Major post-surgical complications is a serious problem for Thai cardiovascular surgery patients. It increases risk of death, LOS and costs.

INTRODUCTION:
Public tertiary care in Thailand is provided by university hospitals and public hospitals. A recent study found 28-day post-surgical mortality is 13.8% in Thai university surgical ICUs. However, there is still a lack of evidence on the burden of post-surgical complications in cardiovascular surgeries especially in public hospitals.

METHODS:
A retrospective multiregional database analysis of 4 MOPH tertiary hospitals in Thailand was performed. Accounting the maturity of EMR and HIS systems, data from 2013 to 2017 were analyzed. High-risk cardiovascular surgeries are based on Schwarze ML et al (2015). Outcomes of interests included incidence of major post-surgical complications (based on Michard F et al 2015), length of stay (LOS), in-hospital death, and total cost to the health care system. Multivariate regression analyses were performed to test the association between risk factors and post-surgical outcomes and costs.

RESULTS:
A total of 3,737 patients were identified. Of those, 1,442 (38.6%) experienced major post-surgical complications. The top 3 common major complications were respiratory failure (22.8%), myocardial ischemia or infarction (12.0%), and pneumonia (7.6%). In-hospital mortality was 9.5%. Median LOS was 12 days [interquartile range (IQR): 8-12 days]. Median total cost was US$8,669 (IQR: US$4,369-12,775). Multivariate regression analyses suggest that experiencing major complications contributes to significantly higher risk of in-hospital death [odds ratio (OR): 2.61; 95%CI: 2.05-3.33; p<0.001] and higher costs [US$2,784; 95%CI: US$2,215-3,353; p<0.001]. Each level of increase in patient surgical risks per Charlson Comorbidity Index also contributes to significantly higher risk of in-hospital death [OR: 1.21; 95%CI: 1.12 – 1.32; p<0.001] and higher costs [US$450; 95%CI: US$228-672; p<0.001].

CONCLUSIONS:
Major post-surgical complications is a serious problem for Thai cardiovascular surgery patients. It increases risk of death, LOS and costs. Physicians should develop treatment plans to reduce post-surgical complications not only for high-risk cardiovascular surgeries but also for high-risk patients.
**VP46 German Claims Data In Rare Disease HTA: Diffuse Large B-cell Lymphoma**

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**ABSTRACT SUMMARY:**
Routine sick fund claims data provide a meaningful reliable base to analyze rare diseases. German real world data of approximately 5 million insured were used to analyze Diffuse Large B-cell Lymphoma (DLBCL), the most frequent non-Hodgkin lymphoma in adults. Approximately half of the patients did not receive current oncological treatment, while all DLBCL patients frequently required hospitalization, generating significant costs.

**INTRODUCTION:**
In rare disease areas representative data are scarce. Routine sick fund claims data provide a meaningful reliable base for the in- and outpatient treatment landscape. This real world data (RWE) from Germany was used to describe treatment patterns for Diffuse Large B-cell Lymphoma (DLBCL), the most frequent and aggressive non-Hodgkin lymphoma type in adults.

**METHODS:**
Claims data from several sick funds of 4.8 Million insured were analyzed. Diagnosis of non-follicular Lymphoma (C83) was confirmed in 2.178 patients, DLBCL (C83.3) in 819 patients. The analysis was age- and gender-adjusted, observational period was 2014 and 2015. Treatments were analyzed for hospitalization and medication based on ATC-Code, Pharma Central Number and coded diagnoses (per ICD).

**RESULTS:**
Mean age of DLBCL patients was 60.3 years, with two peaks at 50-54 and 70-74 years. Total costs for patients with DLBCL averaged 25,048 EUR versus 1,259 EUR in healthy insured. Charlson comorbidity index (CCI) of 4.58 indicates clinical relevance and severity. Comorbidities included several psychiatric diagnoses such as depression in every fifth patient. Mean 3.2 hospitalizations with average 31.5 hospital days were observed in DLBCL patients. 47 percent of patients during observational time-frame did not receive oncological treatment, including relapsed / refractory patients. Only few patients received stem cell transplantation (2.6 percent) or radiation (3.9 percent). Most pharmacological treatments were Rituximab (RTX) + CHOP (57 percent), followed by RTX mono therapy (25 percent) or RTX in combination with Bendamustine (8 percent).

**CONCLUSIONS:**
Despite limitations in sick fund claims analyses, these provide a reasonable database for rare diseases. They allow standard treatment pathway- and longitudinal analyses. All DLBCL patients frequently required hospitalization and generated significant costs. A high unmet medical need exists for treatments other than palliative care, especially for a tolerable and effective outpatient therapy in elderly relapsed / refractory DLBCL.

**VP47 Secondary Prevention For CV Disease: Population And Outcomes Using RWD**

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ABSTRACT SUMMARY:
The study, based on Italian administrative databases, allowed to estimate the very high risk population in secondary prevention for Atherosclerotic Cardiovascular Disease (SP-ASCVD) in Italy. SP ASCVD population was estimated in 800,000 subjects (prevalence of 4.3 x 1,000 inhabitants). The study highlighted a relevant proportion of no-treated patients and a high proportion of patients that did not achieve recommended LDL-C.

INTRODUCTION:
The study goal was to estimate prevalence of population in secondary prevention for Atherosclerotic Cardiovascular Disease (ASCVD) stratified by the pharmacological treatment and related outcomes using Health Information Systems (HIS).

METHODS:
From HIS of Marche and Umbria Regions (1.8 millions of inhabitants) which collect information related to hospitalizations, drugs prescriptions, outpatient visits and results of laboratory tests, we identified all patients aged ≤ 80 years with one or more hospitalization with DRG related to Acute Coronary Syndrome, Peripheral Artery Disease, Ischemic Stroke and Transient Ischemic Attack and discharge date between 2011 and 2014 (study period).

Pharmacological treatment for each subject was defined selecting all prescriptions of Statins, Ezetimibe and Simvastatin/Ezetimibe, retrieved between the date of the last prescription in the study period and the previous 90 days.

We stratified patient in no-treated, treated with low/medium intensity statins (LMS), high-dose statins (HDS) and other Lipid-Lowering Therapies (LLTs).

Furthermore, for Umbria region, we selected the last blood levels test of LDL-cholesterol occurred in period 2011-2016. Starting from test date, we defined the pharmacological treatment in the previous 90 days. Subject were stratified based on LDL-C levels in target (<70) and not at-target (≥70) patients.

RESULTS:
Population in secondary prevention for ASCVD in period 2011-2014 in Marche and Umbria was estimated in 23,043 (prevalence: 4.3 x 1,000 inhabitants), corresponding to more than 800,000 subjects in Italian population. Within treated patients: 51.3% received LMS, 38.1% HDS and 10.6% other LLTs. No-treated patients were 27.8%.

LDL-C target was achieved by 34.9% of patients treated with LMS and by 46.1% of patients treated with other LLTs.

CONCLUSIONS:
The study, based on Italian administrative databases, allowed to estimate the very high risk population in secondary prevention for ASCVD. It highlighted a relevant proportion of no-treated patients, and an high proportion of patients that did not achieve recommended LDL-C target.

VP48 Cost-Effectiveness Of Transcatheter Aortic Valve Implantation (TAVI) A [...]
Transcatheter Aortic Valve Implantation (TAVI) as Treatment of Patients with Severe Aortic Stenosis and Intermediate Surgical Risk in Norwegian settings.

INTRODUCTION:
TAVI, as a mini-invasive method of aortic valve implantation compared with open surgery, has been recommended for patients with severe aortic stenosis and high or prohibitive operative risk. For patients with intermediate surgical risk, claimed benefits of TAVI compared with open surgery are similar rates of mortality, decreased or similar rates of short term risks and improved or similar functional benefits. Other claimed benefits are related to length of hospital stay and recovery time. Despite shortened hospital stay and recovery, the procedure remains more costly than open surgery in Norway. The aim of this cost-effectiveness analysis is to assess the health economic effectiveness of TAVI for patients with severe aorta valve stenosis and intermediate surgical risk in Norwegian settings.

METHODS:
We constructed a Markov model, with two treatment options available to patients with aortic valve stenosis and intermediate operative risk: aorta valve replacement with conventional surgery or transcatheter aortic valve implantation (TAVI). We used efficacy data from The Placement of Aortic Transcatheter Valves 2A trial to inform the model. Procedure costs data were obtained from the Oslo University Hospital, cost related to rehabilitation and treatment of adverse events were derived from the Norwegian DRG-database.

We calculated cost and effectiveness (in term of QALYs), for both valve replacement options based on simulations of the model. We used 10,000 iterations in the Monte Carlo probabilistic analyses. The results were expressed as mean incremental cost-effectiveness ratio (ICER). The time perspective was 2 years (base case), and lifetime (scenario analysis). The analyses were performed from the health care perspective.

RESULTS:
In the base case analysis, total average 2-year incremental costs of TAVI procedure was 75,347 Norwegian kroner (7,836 Euro), adding 0.068 quality-adjusted life years for patients with severe aortic stenosis and intermediate operative risk. The incremental cost-effectiveness ratio was 1.1 million Norwegian kroner (115,108 Euro) per QALY. When analyses were extended to lifetime time horizon, the incremental cost-effectiveness ratio was 800,275 Norwegian kroner (83,254 Euro) per QALY.

CONCLUSIONS:
Based on the current evidence and procedure cost, TAVI in comparison with surgical aortic valve replacement offers modest improvement in terms of quality-adjusted life-years, but remains a more costly procedure, despite shortened hospital stay. The incremental cost-effectiveness ratios remain above values considered cost-effective in Norwegian settings.

VP49 Real-World Evidence For Economic Evaluation Of Medical Devices

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ABSTRACT SUMMARY:
This work offers a comprehensive assessment of existing sources of real world evidence on medical devices in Europe, at pan-EU level as well as in 13 countries covering different geo-political areas of Europe. The sources of RWD considered are administrative data, registries and observational studies. We use three case-studies, for which we map all existing RWD and illustrate their content.
INTRODUCTION:
Randomized controlled trials (RCTs) are considered the gold standard in the hierarchy of research designs for evaluating the efficacy and safety of a treatment intervention. However, the highly selective populations examined within the setting of RCTs are often not comparable with general populations. The low external validity of RCTs and the general shortage of clinical evidence available to support the use of many medical devices have emphasized the necessity for exploring the use of real-world data (RWD) as a complementary source to RCTs data for establishing a more robust evidence base on the effectiveness of medical devices. The aim of the present project is to assess in a comprehensive way the existing sources of real world data on medical devices in Europe. This work is part of the H2020 EU funded project COMED, which involves six universities and research centres across Europe. The analytic search for consolidated data collection activities will be implemented at the European level, and will be followed by a systematic search in the countries of the project participants and beyond. This way, we are able to cover all different geo-political areas in Europe.

METHODS:
The guidelines to the mapping exercise have been outlined in a research protocol. The research protocol illustrates and explains i) the list of sources of RWD selected for this research; ii) the case studies chosen to implement the mapping exercise; iii) the search strategy.

i) The sources of RWD used in this study are selected according to the general aim of the work, and so we focused on those sources most commonly available and comparable across countries, with large coverage of cases and good representativeness. This corresponds to the following RWD sources: Administrative Data, Registry and Observational Studies.

ii) The mapping of RWD will focus on three case studies, for which less evidence (or no evidence) is available from RCTs. Cases are selected in order to be policy-relevant and cover a spectrum of cases presenting different characteristics in terms of disease incidence, demographic characteristics of patients, type of medical device. Selected case studies are:

1) Orthopaedics focusing on arthrosis of the knee/hip as disease; knee/hip replacement or revision as procedure, and knee/hip endoprosthesis as a device;

2) Robot-assisted surgery, including DaVinci robotic surgery system;

3) Cardiovascular disease focusing on Trans-Catheter Valve Treatment Trans-catheter Aortic Valve Implantation (TAVI) Trans-catheter Mitral Valve Repair (TMVR)

iii) The search strategy consists in three complementary approaches. First, all national relevant sources (e.g. website of Ministry of Health, national institutions, research bodies) are screened, both in local language and English. Second, we perform a systematic search on PubMed using a set of key words for each case study, adapted to each country setting. Finally, we seek advice from key actors in the field of the device and clinical conditions, such as manufacturers or clinicians.

RESULTS:
Information on existing sources of RWD for each case studies are provided in a template including details on the key features of the source (e.g. data producer, data collection period, sample size, study design, geographical coverage) and the main content of the dataset, distinguishing socio-demographic information, clinical and epidemiological data, data on resource use and health outcomes.

The data mapping includes all countries of the project participants, i.e. Italy, UK, Netherlands, Switzerland, Germany, Hungary, and we enlarge the scope of our mapping including other countries: Spain, France, Denmark, Finland, Sweden, Poland and Hungary as well as international databases at pan-EU level.

The number of available sources of RWD and their
quality vary depending on case study and across countries. For example, in the case of orthopaedics, many countries have a national registry and administrative data, such as hospital discharge, contain useful information, although not as detailed. When a registry is not available, it is often the case that more observational studies are available; this occurs for example in France.

CONCLUSIONS:
In this work we shows the importance of RWE and map in an accurate and comprehensive way which source of RWD are currently available and to what extent they are known and used in medical, epidemiological and economic research. The findings of this work will be propaedeutic to a subsequent working package of the COMED project, which aims at developing methodological guidelines to inform data collection on the costs and outcome of medical devices in real world settings, particularly when no experimental and randomised evidence is available.

VP50 Cost-Utility Analysis Of SR And RFA For Early Hepatocellular Carcinoma

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ABSTRACT SUMMARY:
Based on the results of network meta-analysis, we selected the best thermal ablation (radiofrequency ablation, RFA) with relatively good efficacy and safety. Markov decision-making model was established to simulate the clinical process of patients with early hepatocellular carcinoma (HCC) treated by surgical resection (SR) and RFA, in order to explore the economic benefits of this two therapies in China.

INTRODUCTION:
Previous studies have confirmed that the cost of single surgical resection (SR) for hepatocellular carcinoma (HCC) is significantly higher than that of single radiofrequency ablation (RFA), which has led many people, including clinicians, to realize that radiofrequency ablation is more economical than surgical resection. The purpose of this study was to analyze cost-utility between SR and RFA for early HCC patients with Child-Pugh A/B liver function and Milan criteria.

METHODS:
From the perspective of medical and health system, a Markov model was constructed to conduct cost-utility analysis. Relevant data was collected through institutional surveys, systematic reviews and expert consultation. Then the probabilistic sensitivity analysis of the results was carried out.

RESULTS:
When the model runs for only 1 years, RFA had an absolute advantage over SR. When the model runs for 2 or 3 years, the incremental cost-effectiveness ratio (ICER) of SR-RFA were higher than the threshold value (3 times of GDP per capita), which means RFA is still the best choice. But when the model runs for >3 years, the ICER value of SR-RFA were less than threshold value, and SR was more cost-effective than RFA. Probabilistic sensitivity analysis showed that when the willingness to pay threshold is 3 times of GDP per capita, the probability of SR being more cost-effective than RFA is 75.2%, when the model runs for 20 years.

CONCLUSIONS:
In terms of long-term economy, SR is still the first choice for early HCC.
VP51 Comparison Between HTA, Pharmaceutical Pricing And Reimbursement

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ABSTRACT SUMMARY:
This abstract focuses on HTA, pricing and reimbursement of pharmaceuticals in Kazakhstan and Russia. The authors analyzed processes of decision making related to pharmaceutical reimbursement. Both countries have developed complex processes of pharmaceutical pricing and reimbursement, as well as incorporated HTA into decision-making procedures.

INTRODUCTION:
Pricing and reimbursement of pharmaceuticals in Kazakhstan and Russia are regulated at national levels. Therefore they are as different as health care systems of both countries are. In Russia the authorities of selfgoverning regions have a lot of power, so decision making within health care system is shared between federal and region levels. The key policy maker and regulator in the Kazakh health care system is the Ministry of Health, often supported by advisory bodies.

METHODS:
In order to achieve this study objectives, firstly the pharmaceutical reimbursement and HTA processes in Kazakhstan and Russia have been generally described and compared. Secondly, transparency of decision making related to pharmaceutical pricing and reimbursement and HTA processes in both countries has been analysed and assessed. The search for studies published after 2013 was conducted in databases Medline, CyberLeninka and eLIBRARY. In addition to that, content of websites of Russian and Kazakh institutions involved in HTA and national pharmaceutical pricing and reimbursement policies was also reviewed. The language selection criteria in this systematic review included English or Russian.

RESULTS:
Overall involvement of stakeholders is stronger in Kazakhstan than in Russia. In Kazakhstan and Russia that patient preferences were practically not considered within health technology assessments. The analysis techniques used in the Kazakh and Russian process are very complicated, often biased and difficult to assess efficiency frontier approach and to retrace a decision. Not only assurance of appropriate level of understanding of pricing and reimbursement, and HTA processes to the wider audience is important. Apparently the processes in Russia and Kazakhstan are not transparent, where even the final HTA recommendation can be censored and not published in full.

CONCLUSIONS:
It can be concluded that both Kazakhstan and Russia have developed complex processes of pharmaceutical pricing and reimbursement, as well as incorporated HTA into decision-making procedures. The biggest disadvantage of the Kazakh and Russian system is its high complexity. Using the biased data frontier approach makes the HTA reports descent public confidence and fairness.

VP52 Use Of C Reactive Protein Testing To Reduce Antimicrobial Prescribing

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ABSTRACT SUMMARY:
Antimicrobial resistance is a significant and growing threat to public health. It is widely recognized that antimicrobial resistance is driven by excessive and inappropriate antibiotic prescribing. This systematic review assessed the effectiveness of using c reactive protein (CRP) point-of-care testing (POCT) to reduce inappropriate antibiotic prescribing in patients with acute respiratory tract infection (RTI) in primary care.

INTRODUCTION:
Background: Antimicrobial resistance is a significant and growing threat to public health. It is widely recognized that antimicrobial resistance is driven by excessive and inappropriate antibiotic prescribing. This systematic review assessed the effectiveness of using c reactive protein (CRP) point-of-care testing (POCT) to reduce inappropriate antibiotic prescribing in patients with acute respiratory tract infection (RTI) in primary care.

METHODS:
Medline (OVID), EMBASE, CINAHL (EBSCOHost), Cochrane Library and grey literature sources were searched up to 16 April 2018. Two reviewers independently carried out screening, data extraction and quality assessment. The review was reported in accordance with the EUneHTA Core Model® Application for Rapid Relative Effectiveness (REA) Assessments.

RESULTS:
A total of 5,007 citations were retrieved. After removing duplicates and excluding irrelevant studies, 12 studies were included in the systematic review (three cluster randomised controlled trials (RCTs), four RCTs, and five observational studies). The pooled estimate for the RCTs showed a statistically significant reduction in antibiotic prescribing at index consultation (RR 0.76, 95% CI 0.67 – 0.86, I²=70%) and 28 days follow-up (RR 0.81, 95% CI: 0.74 to 0.88, I²=21%) in the CRP test group compared with usual care. Observational studies showed a similar reduction in antibiotic prescribing at the index consultation. There was no significant difference in the number of patients making a substantial improvement or complete recovery beyond seven days between the CRP POCT and usual care groups (RR 1.03, 95% CI: 0.93 to 1.14, I²=0%). None of the included RCTs or observational studies reported the death of a patient.

CONCLUSIONS:
The results suggest that CRP POCT when used to guide management of patients who present with symptoms of acute RTI leads to reduced antibiotic prescribing. This reduction does not appear to negatively affect patient outcomes.

VP53 Long-Acting Insulin Analogues In Brazil: Clinical And Economic Impact

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ABSTRACT SUMMARY:
Long-acting insulin analogues are promising alternatives for glycemic control and prevention of hypoglycemic events in type 1 diabetes mellitus. However, its costs are higher than that of NPH insulin - standard treatment. Because DM1 is a highly prevalent disease, the budget impact may undermine the sustainability of health systems - especially in Brazil, the largest universal system in the world.
INTRODUCTION:
The aim was to evaluate the effectiveness, safety and economic impact of long-acting insulin analogues compared to NPH for type 1 diabetes mellitus (DM1).

METHODS:
A search was performed in five electronic databases to find systematic reviews (SR) comparing at least a long-acting analogue to NPH insulin for DM1. Budget impact analysis was performed from the perspective of Brazilian public health system (SUS), with NPH insulin as the base scenario. The costs were extracted from the Integrated System of Administration of General Services (SIASG). The market share was calculated per month, using a logarithmic function with maximum diffusion of 50% at the end of the time horizon - five years.

RESULTS:
A total of 160 studies were identified and seven SR of low to uncertain risk of bias were selected. Long-acting analogues have shown modest clinical benefit and its effect is more prominent for the control of severe and nocturnal hypoglycaemia. Insulins glargine and detemir compared to NPH were associated with reduction in HbA1c levels between 0.16% and 0.40% and associated with lower risk of episodes of severe hypoglycaemia. Insulin degludec compared to NPH showed no statistically significant difference in the reduction of HbA1c levels and in the episodes of severe hypoglycaemia. The budget impact ranges from USD 290 million (Basaglar glargine) to USD 980 million (degludec) over five years.

CONCLUSIONS:
The use of long-acting insulin analogues as a basal insulin regimen for DM1 may benefit more patients with recurrent episodes of hypoglycemia. However, the fragility of the outcomes considered to evaluate the clinical impact of the insulin analogues and the high budget impact with its use should be considered, and may compromise SUS sustainability.

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VP54 Digital Tools For More Efficient Conduct Of RCTs: Trials Unit Survey

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ABSTRACT SUMMARY:
Recruitment of participants to, and their retention in, RCTs is a key determinant of research efficiency, but is challenging. Digital tools and media are increasingly used to improve the conduct and delivery of research. This abstract presents survey results, of UK CTUs, identifying which digital recruitment and retention tools are being used to support RCTs, their benefits and success characteristics.

INTRODUCTION:
Recruitment of participants to, and their retention in, Randomised Controlled Trials (RCTs) is a key determinant of research efficiency, but is challenging. Digital tools and media are increasingly used to reduce costs, waste and delays in the conduct and delivery of research. The aim of this UK Clinical Trials Unit (CTU) survey was to identify which digital recruitment and retention tools are being used to support RCTs, their benefits and success characteristics.

METHODS:
A survey was sent to all UK Clinical Research Collaboration (UKCRC)-registered CTUs with a webinar to help increase completion. A logic model and definitions of a “digital tool” were developed by
iterative refinement by project team members, the Advisory Board (NIHR Research Design service, NHS Trust, NIHR Clinical Research Networks and patient input) and CTUs.

RESULTS:
A total of 24/52 (46%) CTUs responded, 6 (25%) of which stated no prior use. Database screening tools (e.g. CPRD, EMIS) were the tool most widely used (45%) for recruitment and were considered very effective (67%). The most mentioned success criteria were saving GP time and reaching more patients. Social media was second (27%), but estimated effectiveness varied considerably, with only 17% stating very effective. Fewer retention tools were used, with SMS / email reminders reported most (10/15 67%), but certainty about effectiveness varied. A detailed definition on what constitutes a digital tool with examples and a logic model showing relationships between the resources, activities, outputs and outcomes for digital tools was developed.

CONCLUSIONS:
Database screening tools are the most commonly used digital tool for recruitment, with clear success criteria and certainty about effectiveness. Our detailed definition of what constitutes a digital tool, with examples, will inform the NIHR research community about choices and help them identify potential tools to support recruitment and retention.

ABSTRACT SUMMARY:
Digital tools are increasingly being used to identify, recruit and retain participants. While these tools are being used, there is a lack of quality evidence to determine their value in trial recruitment. The aim of the study was to identify the benefits and characteristics of innovative digital recruitment and retention tools for more efficient conduct of RCTs.

INTRODUCTION:
Recruitment of participants and their retention in randomised controlled trials (RCTs) is key for research efficiency. However, for many trials, recruiting and retaining participants meeting the eligible criteria is extremely challenging. Digital tools are increasingly being used to identify, recruit and retain participants. While these tools are being used, there is a lack of quality evidence to determine their value in trial recruitment.

METHODS:
The aim of the main study was to identify the benefits and characteristics of innovative digital recruitment and retention tools for more efficient conduct of RCTs. Here we report on the qualitative data collected on the characteristics of digital tools required by trialists, research participants, primary care staff, research funders and Clinical Trials Units (CTUs) to judge them useful.

A purposive sampling strategy was used to identify 16 participants from five stakeholder groups. A theoretical framework was informed from results of a survey with UKCRC registered CTUs. Semi-structured interviews were conducted and analysed using an inductive approach. A content and thematic analysis was used to explore the stakeholder’s viewpoint and the value of digital tools.

VP55 Trial Recruitment And Retention Using Digital Tools: A Qualitative Study

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RESULTS:
The content analysis revealed that ‘barriers / challenges’ and ‘awareness of evidence’ were the most commonly discussed areas. Three key emergent themes were present across all groups: ‘security and legitimacy of information’, ‘inclusivity’, and ‘availability of human interaction’. Other themes focused on the engagement of stakeholders in their use and adoption of digital technology to enhance the recruitment/retention process. We also noted some interesting similarities and differences between practitioner and participant groups.

CONCLUSIONS:
The key emergent themes clearly demonstrate the use of digital technology in the recruitment and retention of participants in trials. The challenge, however, is using these existing tools without sufficient evidence to support the usefulness compared to traditional techniques. This raises important questions around the potential value for future research.

VP57 Using Capital Bids For Hospital-Based Health Technology Assessment

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ABSTRACT SUMMARY:
An expansion of a central London Paediatric Hospital required a five-year horizon to be scanned. Capital bids for high-cost medical imaging equipment purchases from the local NHS Trust were assessed from the previous five years. Although some light trends were identified, a longer period may need to be assessed due to the life-span of imaging technology.

INTRODUCTION:
The Evelina London Children’s Hospital (ELCH) is undergoing a period of growth, including a new building planned to be completed within the next five years. Due to limited space and ambitions to be a state-of-the-art hospital, HS was considered important to ‘future-proof’ new facilities. As the aim of HS is to identify signals of coming change, ‘scanning’ the previous five years’ trends may be beneficial to an iterative HS methodology. Thus, it was thought that capital bids could provide a range of useful information required to make procurement decisions.

METHODS:
King’s Technology Evaluation Centre (KITEC) provided hospital-based HTA and HS support for the expansion of a London-based paediatric hospital. KITEC focused on imaging technology due to its large spatial requirements and high-costs and assessed all capital bids made over the previous five years. A capital bidding system is used within GSTT to allocate funding for medical equipment that costs more than £5000 (USD $6540.70). Information was collated for all imaging equipment bid for over the previous five years and assessed for trends in imaging modalities and purchase costs.

RESULTS:
A total of 135 bids were made in the period 2013-2018, eight of which were by ECLH. Bids for ultrasound equipment were most common and rose over the period. Bids for CT scanners also rose, while bids for MRI scanners and x-ray technology were consistent and bids for fluoroscopy fell. The total cost of imaging bids over the interval rose steadily from £5.4 million to £6.9 million.

CONCLUSIONS:
Due to the lifespan of imaging technology, some trends may not emerge within a five year window.
While some interesting findings were made, a ten to fifteen year period may require to be scanned for a robust analysis. This methodology is best applied in an iterative fashion along with standard HS techniques.

VP58 Prioritized Implementation Of Radiotherapy Procedures: A New Approach

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ABSTRACT SUMMARY:
A novel approach has been designed to prioritize the introduction of radiotherapy procedures. The local clinical community will engage in evidence-based decision making at a “HTW Live” workshop. Proponents for each radiotherapy procedure will present supporting evidence, and be challenged by HTA experts. Attendees will rank the technologies according to potential impact. Learnings from this exercise will be shared at HTAi.

INTRODUCTION:
Velindre Cancer Centre (VCC) is a specialist centre providing non-surgical tertiary oncology services to the population of 1.5 million in South-East Wales. A growing incidence of cancer requires transformation of VCC service provision to meet the future needs of its patients. Forecasts predict a 48 percent increase in demand for radiotherapy services by 2025. An initiative is underway to expand existing capacity, including construction of a new VCC building. Health Technology Wales (HTW) has been asked to help prioritize the introduction of new radiotherapy procedures.

METHODS:
The planned evaluation has three consecutive phases:

i) Exploration of available evidence. Literature searches will identify the quantity and quality of evidence supporting each of the 13 proposed technologies. Topic proposers will be engaged in refining the scope.

ii) “HTW Live”. A workshop will be held for local radiotherapy clinicians, to gauge their level of support for each procedure. Topic leads will present their proposals, then HTA experts will ask questions of the presenters. Finally, workshop attendees will use real-time voting to rank their preferred options. Those technologies perceived to have the greatest potential benefit will proceed to the appraisal phase.

iii) Appraisal. Clinical and economic evidence supporting the selected radiotherapy procedures will be critically analysed. The evidence appraisal reports will be shared with the HTW Appraisal Panel and VCC decision-makers.

RESULTS:
The conclusions of the prioritization exercise will inform the introduction of radiotherapy procedures. Results will be presented at the HTAi Conference, including sharing lessons learned about prioritization methods.

CONCLUSIONS:
This novel evaluation approach prioritizes technologies with potential for positive impact for patients and health services. It is anticipated that involving local clinicians in decision making will also facilitate adoption. If these prioritization methods prove successful, HTW will co-ordinate similar exercises for other specialties, and develop methodological resources for widespread use.
**VP59 The MedicineWise App: Extended Applications Beyond Medicine Management**

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**ABSTRACT SUMMARY:**
The MedicineWise app is a free consumer health and medicine management app developed by NPS MedicineWise to encourage better health and medicines information delivery and improve medication adherence and health outcomes. Three use-cases will highlight the MedicineWise app’s utility to provide personalised medicines management offerings. These include curating targeted content, providing triaged adherence support, and heart failure data monitoring.

**INTRODUCTION:**
The MedicineWise app is a free consumer health and medicine management app developed by NPS MedicineWise. With 107,000+ downloads and 78,000+ active sessions per month, the MedicineWise app’s core functions include: keeping track current medicines lists, medicine dose reminders and recording health conditions, allergies, test results and other health information. Recent enhancements also enabled the app to deliver featured health- and medicine-related content to users based on their medicines and/or health conditions. The goal is to maximise the MedicineWise app’s capabilities by personalising to users’ needs and combining with health professional interventions when needed, to encourage better delivery of health and medicines information and improve medication adherence and health outcomes.

**METHODS:**
A number of personalised medicines management service offerings were created by combining a technology solution using the MedicineWise app (including the app’s core functions as well as added targeted content delivery capability) with a humanistic solution (a health professional-mediated phone-based coaching service). MedicineWise app features were developed iteratively using a human-centred design approach. Consumers were involved in the design, prototyping and testing stages before the features moved to technical-build stage.

**RESULTS:**
Three use-cases will be presented to demonstrate how the MedicineWise app was used to provide personalised medicines management service offerings. These include: (1) curating relevant content and delivering push notifications to users for health conditions including asthma, rheumatoid arthritis and osteoporosis; (2) providing a triaged medication adherence support program with escalating levels of intervention for heart failure patients; and (3) collecting user-reported medication usage data and data monitoring by health professionals to provide support for heart failure patients.

**CONCLUSIONS:**
The utility of MedicineWise app can be extended to provide personalised medicines management service offerings in the consumer health care space.

**VP60 Rapid Review: Screening For Atrial Fibrillation Using A Smartphone**

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ABSTRACT SUMMARY:
Atrial fibrillation (AF) is the most common cardiac arrhythmia. As a new screening method for detecting paroxysmal and silent AF, the efficacy of smartphone based fingertip photoplethysmography was evaluated using a Rapid Review approach. Within a ten-week time period a screening of the literature was conducted. Furthermore, evidence synthesis as well as subgroup-analysis of included studies were performed.

INTRODUCTION:
Atrial fibrillation (AF) is the most common cardiac arrhythmia and causes a four-fold higher risk of embolic stroke. Despite good progress in the management of AF, new screening methods need to be established in order to increase detection of paroxysmal and asymptomatic AF. A Rapid Review approach was used to evaluate the efficacy of smartphone-based fingertip photoplethysmography (PPG) for AF screening.

METHODS:
This Rapid Review was executed within a ten-week time period and is based on (a) literature screening and (b) evidence synthesis. Firstly, a search concept was developed using the PICO model, MeSH terms and boolean operators. Literature research was conducted in PubMed. Screening, selection and documentation were completed according to the PRISMA statement. Additionally, the reference lists of included studies were screened. Quality appraisal and risk of bias analysis were then performed and graded using a quality scale. Study results were analyzed regarding diagnostic parameter: sensitivity, specificity, and predictive values. Ultimately, a subgroup analysis was conducted regarding different approaches of PPG waveform analysis: (i) statistical or (ii) machine-learning algorithms.

RESULTS:
The search algorithm retrieved 278 titles. Twelve studies were included in the review, including a total of 1444 participants. No randomized controlled trial (RCT) was included in the review. Eight studies had a cohort, case-cohort or cross-sectional study design. The other four were retrospective studies using PPG files from pre-studies or databases. Risk of bias assessment identified methodological shortcoming of included studies in relation to small sample size and lack of real-world setting. Sensitivity ranged from 89.9 to 100 percent, while specificity ranged from 90.9 to 100 percent.

CONCLUSIONS:
Intermittent screening for AF with smartphone based PPG shows high diagnostic accuracy but further high quality studies are needed to confirm these results. The Rapid Review approach turned out to be a suitable tool for assessing the efficacy of mHealth technologies.

VP61 Rapid HTA Of The CarbonCool Full Body Suit For Exertional Heat Injurie

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ABSTRACT SUMMARY:
The CarbonCool full body suit is a portable, non-invasive core body cooling system for use by first responders and clinicians for targeted temperature management and heat stroke treatment. We reviewed the effectiveness of the suit and whether it might be used in place of a Body Cooling Unit.

INTRODUCTION:
The CarbonCool full body suit is a portable, non-invasive core body cooling system for use by first responders and clinicians for targeted temperature management and heat stroke treatment. It uses pads made of a highly thermal conductive carbon-based cooling medium to absorb heat from the body. Our department was requested to review the
effectiveness of the suit and whether it might be used in place of a Body Cooling Unit (BCU).

**METHODS:**

A rapid review was carried out on the technology. The PICO elements were:

**Population:** Emergency department patients with exertional heat injury

**Intervention:** CarbonCool full body suit

**Comparator:** Body Cooling Unit

**Outcomes:** Adverse effects, clinical outcomes (survival, neurological status), physical measures (rate of cooling)

The NHS Centre for Reviews & Dissemination databases, Cochrane Database of Systematic Reviews, PubMed (MEDLINE) and the US National Guidelines Clearinghouse were searched for systematic reviews, HTA reports and clinical practice guidelines. The importer was contacted to provide supporting studies for their product.

**RESULTS:**

No publications were found on CarbonCool products. The importer provided the unpublished abstract of a retrospective cohort study of 124 post-cardiac arrest patients requiring targeted temperature management. The importer advised that a trial on pre-hospital heat stroke was pending. The full body suit is not intended as a replacement for body cooling units.

Three clinical practice guidelines on management of heat injuries did not mention such cooling systems, but did recommend ice packs as a treatment option.

**CONCLUSIONS:**

The CarbonCool Full Body Suit is not intended as a replacement for a Body Cooling Unit. No published studies were found showing effectiveness for managing exertional heat injuries. A trial on pre-hospital heat stroke was pending. Guidelines on managing heat injuries do not mention the use of the technology. It was recommended to await results of pending trials, or to use it only under research.

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**VP62 The EUnetHTA Companion Guide: A New Repository To Support European HTA**

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**ABSTRACT SUMMARY:**

The web-based EUnetHTA Companion Guide is established in Joint Action 3 as a repository for quality management, scientific guidance and tools. Its purpose is to ensure the production of high-quality HTA reports by providing ultimate support and guidance to the assessment teams of EUnetHTA in all phases of the assessment process.

**INTRODUCTION:**

Good quality management (QM) and the sound application of EUnetHTA’s (European network for Health Technology Assessment) well-established methodology and tools are fundamental prerequisites for reliable and trustworthy joint work. To provide ultimate support and guidance to the assessment teams of EUnetHTA – and further, to ensure a sustainable mode of work for the post-2020 period – a comprehensive web-based so called “EUnetHTA Companion Guide” is established in Joint Action 3.
**METHODS:**
The Companion Guide was created using the open source Wiki software “DokuWiki”. We divided the content into five main parts: 1. EUnetHTA’s QM concept, 2. QM for rapid Relative Effectiveness Assessment (REA) Pharma, 3. QM for rapid REA Other Technologies (OT) 4. Scientific Guidance & Tools and 5. QMS-related training material. The assessment processes for rapid REA Pharma and OT have been subdivided into single process steps for which the Companion Guide provides standard operating procedures (SOPs), checklists, templates, guidelines and tools. The content of the Companion Guide is continuously subject to evaluation by means of a structured survey with regard to the achievement of its purpose to ensure high-quality HTA reports.

**RESULTS:**
In May 2018, the Companion Guide was launched and is now available to all EUnetHTA partners. It provides central access to all components of the newly established quality management system for EUnetHTA. The user has access to training modules that provide information on how to use the Companion Guide. Moreover, the training material enables EUnetHTA partners to build up necessary capabilities for quality management and application of methodologies and tools in the context of EUnetHTA.

**CONCLUSIONS:**
The purpose of the Companion Guide is to ensure the production of high-quality HTA reports by providing ultimate support and guidance to the EUnetHTA assessment teams during their joint work. The continuous evaluation will reveal necessary revisions and the need for further developments and guidance.

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**VP63 EUnetHTA Planned And Ongoing Projects Database: Usage And Challenges**

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**ABSTRACT SUMMARY:**
Systematic data collection and survey were conducted to evaluate the ability of the EUnetHTA POP database to reduce duplication of work among EUnetHTA partners. The POP database helped to identify 169 identical projects in 2016-2017. Delaying the start of a project in order to benefit from others’ results and save resources is a raising trend among EUnetHTA partners.

**INTRODUCTION:**
The European Network for Health Technology Assessment (EUnetHTA) Planned and Ongoing Projects (POP) database allows sharing information on projects of HTA organisations participating in EUnetHTA. It enables users identifying overlaps and therefore has the potential to reduce duplication of work on similar topics. The aim of our research was to examine the usage of the database, how it helps to reduce duplication, and identify challenges to be addressed.

**METHODS:**
We conducted a systematic data collection and analysis on the topic overlaps retrospectively and complemented it with an electronic survey aimed at database users.

The dataset on the overlaps was collected between June 2016 and September 2017. The survey was conducted in 2016.
RESULTS:
During the data collection period, the POP database contained on average 800 projects provided by around fifty percent of the EUnetHTA partner organisations. 169 identical projects could be identified from which ninety-two percent had different starting dates. Twenty-five percent of the identical projects were elaborated on by three organisations, ten percent by four, and six point five percent by five organisations.

Analysis of the survey showed a pattern of “wait and see”: users are informed about what other EUnetHTA partners are working on, wait for a finalised HTA or exchange the project plan, search strategies, search results, extraction tables, etc.

The data collection and survey could not provide a precise number of collaborations initiated based on information gathered from the database.

CONCLUSIONS:
The POP database is suitable for information sharing and has the potential to save time and resources at EUnetHTA partners. The collaboration is hindered by differences in national processes, including the timing and scope of the assessments. The impact of the POP database on the facilitation of collaboration and reduction of duplication of HTAs produced by EUnetHTA partners is yet to be strengthened.

ABSTRACT SUMMARY:
A case study was undertaken to assess how EUnetHTA joint REAs can be used to inform economic evaluation. Nine HTA agencies were interviewed. Consideration should be given to what additional information could be included in joint REAs. Some agencies propose that the remit of joint REAs should be expanded to include certain non-clinical information (e.g. costs and resource use).

INTRODUCTION:
A key objective of the European Network for Health Technology Assessment (EUnetHTA) is to increase the uptake of jointly produced HTA. The purpose of this case study is to explore how joint REAs can be used to inform economic evaluation. The selection of this topic for a case study recognizes that economic evaluation is often thought of as separate from REA but in reality the two concepts are closely linked, and also that health economic expertise and capacity is a challenge for many HTA agencies.

METHODS:
EUnetHTA partners that use health economics as part of their procedures were contacted to see if they wished to participate in the case study. Nine agencies from seven countries agreed to participate and were interviewed using a semi-structured interview pro-forma. The results were analysed thematically to identify key themes.

RESULTS:
The agencies interviewed identified a number of key benefits of using EUnetHTA joint REAs to inform economic evaluation. A good REA was said to give the core information and “engine” for the economic model.

Agencies made a number of proposals on how joint REAs could be improved to make them more useful for economic evaluation, including: giving guidance in the joint REA on key issues for consideration when undertaking economic modelling on the health technology; information on long term
CONCLUSIONS:
Joint REAs can be used to inform economic evaluation at a national level. Consideration should be given to what additional information could be included in joint REAs to make them more useful for economic evaluation. Some agencies propose that the remit of joint REAs should be expanded to include certain non-clinical economic information, such as cost and resource use data.

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VP66 Judicialization of Health And Access To High-Priced Drugs In Uruguay

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ABSTRACT SUMMARY:
In Uruguay, judicialization of health is supported by the Constitution, and has lead to an ever-increasing number of domestic court claims for high-priced medicines. People living in major metropolitan areas and belonging to middle and high socioeconomic classes are overrepresented among the litigants. In Uruguay, judicialization of health contributes to increase health inequity.

INTRODUCTION:
In Uruguay, the Therapeutic Drugs Formulary (FTM by its Spanish initials) defines the pharmaceutical drugs and their indications that must be universally available in the health system to the entire population. Judicialization of the right to health is supported by the Constitution, which requires the state to provide the means for prevention and treatment to those lacking sufficient financial resources. Judicialization has lead to an ever-increasing number of domestic court claims for high-priced medicines not included in the FTM, and the expenditures of the Ministry of Public Health needed to comply with court-ordered medicines increased by 65% between 2010 and 2016. The objective of the present analysis was to examine the distribution of litigations requesting access to high-priced oncologic drugs by selected sociodemographic characteristics.

METHODS:
We reviewed all court claims for oncologic drugs from 2017. Data on main variables, such as sex, region, and private versus public health services provider were extracted to examine the association of these variables with court litigations.

RESULTS:
In 2017, a total of 115 court decisions made mandatory for the Ministry of Public Health to provide for oncologic drugs. The most frequent were cetuximab (27%), for colorectal cancer, and rituximab (22%), for indications not included in the FTM. Women represented 51% of all decisions. The capital city of Montevideo, which represents 45% of the total population of the country, accounted for 69% of all court decisions. The public health system, which provides health care to the less wealthy and serves 33% of the whole population, accounted for only 14% of all court decisions.

CONCLUSIONS:
Our findings show that the majority of litigants live in major metropolitan areas, and that the most vulnerable population has far less access to the court system. These differences support the belief that, in Uruguay, judicialization of health contributes to increase health inequity.
VP67 Caring For Children With Neurodevelopmental Disorders

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ABSTRACT SUMMARY:
This research presents a premature context in the scientific community for the purpose of describing the processes of training of health professionals, education and social assistance in children dealing with children with Neurodevelopmental Disorders.

INTRODUCTION:
Professionals dealing with children with Neurodevelopmental Disorders (NDDs) need to be constantly trained because of the numerous challenges posed by the particularities arising from the multiple conditions that pervade child development. The aim of this study is to describe the training processes of education, health and social care professionals who care for children aged 0 to 12 years with neurodevelopmental disorders.

METHODS:
The revision overview was registered in the PROSPERO platform CRD42018100715 that followed the parameters of the PRISMA protocol and aimed to identify the existing multiprofessional training processes, aimed at health professionals, education and social assistance aimed at promoting skills for care with children and families with TND. The research question was structured according to the acronym PICO. The search was performed in PubMed, Embase, Cochrane Library, CRD, Web of Science, Campbell Collaboration, Health System Evidence, Epistemonikos and Joanna Briggs databases in May 2018.

RESULTS:
We selected 23 articles. Of these, 21 (91 percent) were health professionals, 22 (96 percent) referred to intellectual disability, 16 (71 percent) were in the American continent and 15 (65 percent) used in-service training as educational resource. The outcomes showed that the structuring of teaching-learning in the practice of health, education and social care professionals determines a more inclusive proposal in the treatment of children with NDD.

CONCLUSIONS:
The health professional is the most trained to attend children with NDD, however, training and development policies are lacking for professionals from other areas who act as a gateway to diagnostic services. Establishing in-service training initiatives strengthens the support and structuring of intersectoral programs that would facilitate multiprofessional participation in the prognosis and treatment directed at children with NDD. Therefore, associating the use of assistive technologies allows new opportunities to access tools and electronic devices that allow the formation of professionals.

VP68 Recommendations From A Dialogue On Patient-Centered Value Assessment

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ABSTRACT SUMMARY:
Value assessment (VA) bodies and patient groups identified seventeen recommended actions they could take individually or in collaboration to enhance the patient centricity of VA. Certain recommendations are simple structural changes that can be achieved quickly, while others require greater investment of time and resources. These recommendations can guide VA improvements in the next year, through 2020, and also beyond.

INTRODUCTION:
Challenges associated with patient-engagement activities may discourage both patient groups and value assessors from fully engaging with one another. To address these challenges, we convened representatives from US organizations that have produced value assessments (VA bodies) with representatives from patient groups that have interacted with those organizations. The goal was for participants to collaboratively articulate specific recommendations they could implement to enhance VA patient centricity.

METHODS:
Participants (N=24) were organized into small working groups, pre-assigned to ensure balanced representation of VA bodies (n=6) and patient groups (n=18). Use of Chatham House Rules increased dialogue openness. Three semi-structured discussions were captured by scribes and on storyboards, and included: defining success, improving engagement, and collecting and leveraging patient-provided data. NHC staff drafted recommendations based on notes and storyboards; the draft was circulated to all participants for feedback, and finalized.

RESULTS:
Participants agreed, the goal of patient-centered VA is for patients to have access to treatments they need at prices they can afford. Patient-centered VA exists when patients are engaged, heard, understood, and respected throughout the entire process, their input is incorporated, and it guides decision making. Seventeen recommendations were identified, to be implemented by patient groups, VA bodies, or collaboratively. (e.g., Following an appraisal, the VA body and patient group should debrief on how patient-submitted data were/were not useful, and how it can be improved for the future, with learnings passed on to others.) Additional recommendations include both simple, structural changes to reports that can be achieved quickly, while others require greater investment of time and resources.

CONCLUSIONS:
Patient groups and VA bodies must partner to improve VA patient centricity. Participants affirmed the importance of their collaboration, as well as that with other stakeholders. The recommendations produced will guide VA improvements in the next year, through 2020, and beyond.

VP69 Review Of Patient Input Science In Drug Lifecycle: Europe And The US

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ABSTRACT SUMMARY:
An in-depth review of current use and potentialities of patient input science during lifecycle of drugs from the perspective of multiple stakeholders is presented. Although patient reported outcomes and patient preference information are increasingly being incorporated by regulatory agencies and national agencies to inform their decisions,
efforts should be made to ensure their systematic collection and consistent application.

INTRODUCTION:
In western countries, guidance for regulatory agencies encourages the use of patient input science to optimize the results of both patient engagement in regulatory processes and the collection of quality data on their experience. The aim of this research is to review current use of patient input science during lifecycle of drugs and critically explore its potentialities from the perspective of multiple stakeholders (patients, clinicians, regulatory and appraisal agencies, and industry).

METHODS:
A peer review of FDA and EMA guidance on patient involvement and patient experience information (including patient preference information-PPI- and patient reported outcomes-PROs-) was conducted. Besides the use of PPI and PROs for health technology assessment was examined in published guidelines and specialized working groups.

RESULTS:
Regarding patient engagement, EMA and FDA are increasingly incorporating their voice as group or individual experts in different initiatives. Recently, a patient engagement cluster has been jointly created by both agencies to endorse patient participation by means of their empowerment and by improving research qualitative methods. On patient perspective, PROs are well-established as meaningful inputs of humanistic burden and benefit-risk evaluation, claiming and the facilitation of patient-physician communication. Also, PROs are extensively use for health technology appraisal. Although guidance on PPIs is still at early stages, patient preferences are increasingly considered as relevant inputs to inform regulatory decisions and might contribute to technology appraisal as key indicators of the relative importance of benefit and risk of medicines. Finally, the application of PRO and PPI real-world clinical settings is clearly defined in chronic and oncological diseases with positive results in terms of clinical endpoints, shared decision making and resource consumption.

CONCLUSIONS:
Patient input science is gaining attention to demonstrate unmet needs, evaluate the added value of medicines, inform decisions and improve patient access to medicines. Further efforts to improve methodologies are required.

VP70 Effectiveness Of Behavior Modification Interventions In T2MD Patients

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ABSTRACT SUMMARY:
INDICA study is a RCT that assesses the effectiveness of three different complex interventions for knowledge transfer and behavior modification of patients, families, and healthcare professionals at the primary care level. The interventions include a diabetes-coaching system using a combination of conventional educational workshops with mobile phones, a patient web-based platform, electronic decision aids, and periodic feedback on patients’ outcomes.

INTRODUCTION:
T2DM is a chronic disease whose health outcomes are related to patients and healthcare professionals’ decision making. The aim is to assesses the
effectiveness of multicomponent interventions based on ICTs of knowledge transfer and behavior modification.

METHODS:
INDICA is a RTC with random allocation by primary healthcare centers. Included T2DM patients, 18–65 years of age and uncomplicated.

Patients in group 1 received an educational group program by trained nurses and monitored by means of logs and a web-based platform and automated SMS. Professionals in group 2 received a short educational program to update their knowledge, which includes a decision support tool embedded into the electronic clinical record and a feedback report of patients’ results. Group 3: group 1 + group 2. Group 4 received usual care (UC).

The primary endpoint was the change in HbA1c in 2 years. Others endpoint were cardiovascular risk factors, macro/microvascular complications and PROMs. Mixed models with repeated time measurements will be used.

RESULTS:
A total of 2.334 patients were included. On patients with basal HbA1c levels > 7%, the differences in the HbA1c reduction between the group 1 and the UC was statistically significant, from months 3 to 12. This was also the case for differences between both, group 2 and 3, versus UC, but only until month 6. The differences in AUC at month 24 of HbA1c for groups 1 and 3 remained statistically significant, compared to UC, until the end of follow-up, -0.27% for group 1 (P = .022) and -0.23% (P = 0.041) for group 3. For SBP compared with UC group, PFI and CBI the sample showed significant differences at month 3 and 24 for the first and at month 18 and 24 for the second.

CONCLUSIONS:
INDICA improved the cardiovascular risk in T2DM patients after 24 months of follow up.

VP71 Barriers To Access To Biologic Products: A Rapid Review

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ABSTRACT SUMMARY:
This rapid review identified the main barriers related to the access to biologic products, regarding the following perspectives: user, health professional, health manager and system.

INTRODUCTION:
The elevated costs with biologic products threatens the sustainability of health services, and, therefore, the access to these medicines in the perspectives of user, health professional, health manager and system. The entry of biosimilar products in the market could be an option to subsidize the search for solutions to those problems.

METHODS:
We conducted a rapid review using the databases Medline (via Pubmed), EMBASE, Cochrane Library and CRD. The eligibility criteria were HTAs, systematic reviews and cross sectional studies.

RESULTS:
Literature search retrieved 640 registries and, after duplicate removal, screening of titles and abstracts and full text reading, nine cross sectional studies were selected. From a user’s point of view,
the following barriers were identified: lack of knowledge about the medicine, distance between the place of living and the health service (especially in the rural area), long waiting periods for service, passivity in regards to treatment. From a health professional’s point of view the barriers were: acceptability of the expert in regards to treatment, interchangeability and substitution, the perception of lack of data showing efficacy and safety. Finally, from the payer’s (or health manager) point of view, the barriers were: high cost of medicine, problems with reimbursement and bureaucracy. We did not retrieve any barriers from the health system’s perspective from the selected studies.

CONCLUSIONS:
The entry of biosimilar medicines in the market can induce competition and, therefore, reduce prices of biologic treatments. It is necessary to search for potential solutions to the access barriers identified in this rapid review.

VP72 Impact Of Comparator Choice On Oncology Drugs’ Market Access

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ABSTRACT SUMMARY:
During a drug appraisal process, the Transparency Committee identifies the clinically relevant comparators to recognize the appropriateness of the comparators chosen in the clinical trials. A descriptive study of the comparator choice consequences for oncology drugs has been conducted and suggests that the use of a non-relevant comparator has a negative impact on the TC assessment without consequences on pricing.

INTRODUCTION:
In France, drug assessment is performed by the Transparency Committee (TC) of the French National Authority for Health (HAS). It’s based on two criteria: the clinical benefit (CB) for reimbursement recommendation and the clinical added value (CAV) serving the pricing decision. The CAV is rated on a 5-point scale, from I (major) to V (no CAV). A critical step in the CAV assessment is the identification of the clinically relevant comparators (CRC) serving the TC to recognize the appropriateness of the comparators chosen in the randomised controlled trials (RCT). The objective of this study is to investigate the comparator choice consequences on TC appraisals and pricing.

METHODS:
A retrospective, descriptive study included all oncology indications assessed by the TC between 2015 and 2017. Based on a pre-specified grid, items on the comparators were extracted from final TC’s appraisals.

RESULTS:
Among the 135 indications included, the assessed drugs had no CRC in 20% of cases. A RCT was submitted for 89 indications (66%) whose 67 (76%) were conducted versus a CRC. A CRC was identified by the TC for 70% of the 46 indications without RCT.

An important/moderate CAV (II-III) was granted when there was a RCT versus a CRC in 70% of cases, versus 50% and 43% for minor (IV) and no CAV respectively. The public price was reduced by 13.5% in average compared to the claimed price without impact of the CAV level (n=18).

CONCLUSIONS:
In oncology, comparative data assessed by the TC met its expectations (RCT versus CRC) in a majority
of cases. When there is no RCT or a comparison versus a non-relevant comparator the CAV appraisal is decreased. Surprisingly this study hasn’t shown any impact of this decrease on the public price. A wider analysis in different medical areas would need to be performed to better investigate these results.

VP73 A Comparison Of In Vitro Diagnostic HTA Practices In Western Europe

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ABSTRACT SUMMARY:
As the field of health technology assessments pushes towards increasing harmonization and joint assessments, a crucial first step of reaching said goal is the identification of varying practices. Our research highlights these varying HTA practices in western European countries for in vitro diagnostics.

INTRODUCTION:
The in vitro diagnostic field is rapidly innovating. With it, novel techniques (e.g. such as next generation sequencing) allow for an increased understanding of complex diseases. This information will inevitably influence clinical decision making, and thus affect patient management, health outcomes, financial resources and overall cost-effectiveness of treatment strategies. Careful considerations should thus be made when examining a novel in vitro diagnostic to be included into a statutory health system. In this regard, we look into HTA practices for the adaptation of novel in vitro diagnostics into statutory benefit basket of western European countries.

METHODS:
A comparison of evidence requirements and assessment guidelines was carried out for applications of in vitro diagnostic medical acts for inclusion in the benefit basket. A selection of countries was made based on the frequency of updates to the benefit basket. The following countries were selected: Belgium, The Netherlands, France, Germany, England and Switzerland.

RESULTS:
Preliminary results show a discrepancy in formulated evidence requirements across countries. These were related to the medical context and organizational aspects of the in vitro diagnostic. The guidance on how the evidence should be reported and how the actual assessment is conducted is not only varying in terms of level of detail, but transparency is also lacking when considering public access to this information. Some countries conduct internal assessments at the level of the statutory health insurer (Belgium-RIZIV) whereas others involve national HTA agencies in the procedure for inclusion into the benefit basket (France-HAS). Di novo HTA reports on in vitro diagnostics remain however scarce when compared to other technologies.

CONCLUSIONS:
We identified varying HTA practices in the assessment of in vitro diagnostics across western European countries. As the field pushes towards harmonization and joint assessments, identification of these discrepancies is a crucial first step in reaching that goal.
VP74 Orphan Black Box: Explanatory Principles

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ABSTRACT SUMMARY:
For orphan medicines, translating regulatory approval into reimbursement success has posed some considerable challenges. These very high cost therapies require innovative access and contracting approaches.

INTRODUCTION:
Orphan legislations over the past thirty years have successfully increased the number of drugs receiving marketing authorisation for rare diseases. However, for a therapy to be accessible to most patients, it requires not only marketing authorisation, but market access via public reimbursement. In many major markets, the pricing and reimbursement of new therapies is based on an assessment by a national Health Technology Assessment (HTA) body, for which economic value is typically a key consideration. This research evaluates the outcome of HTAs of orphan drugs in Europe.

METHODS:
HTA decision data (to 31/08/2017) was extracted from Gemeinsame Bundesausschuss (G-BA), Haute Autorité de Santé (HAS), National Institute for Health and Care Excellence (NICE), Pharmaceutical Benefits Advisory Committee (PBAC), and Scottish Medicines Consortium (SMC) websites. EC-approval data was extracted from the European Medicines Agency (to 31/08/2017).

RESULTS:
Only a small minority of drugs for orphan diseases received full recommendations for their licensed indication(s) by NICE (3/35, 9%), SMC (8/66, 12%) and PBAC (1/44, 2%). 37% (26/70) of drugs assessed received positive HTA outcome by HAS (ASMR I-III). In Germany, all approved orphan drugs (100/100) received automatic additional benefit post regulatory approval by G-BA.

CONCLUSIONS:
There have been significant challenges for manufacturers in converting regulatory approval of orphan drugs into commercial success and optimised market access. Attaining positive HTA appraisals for these drugs, which have been approved under expedited regulatory pathways on a less than fully mature dataset, whilst also having high prices, due to small patient populations, limiting commercial returns, may necessitate increased utilisation of alternative reimbursement mechanisms.

VP75 Improving Access To Ultra-Orphan Medicines In NHS Scotland

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ABSTRACT SUMMARY:
The Scottish Medicines Consortium (SMC) advises NHSScotland on the clinical and cost-effectiveness of new medicines. The appraisal process for medicines for rare conditions has evolved over the past four years, in recognition of challenges to
patient access. A new pathway involving coverage with evidence is presented.

INTRODUCTION:
Medicines for very rare conditions present challenges for healthcare globally due to uncertain evidence and often extremely high costs. In 2014, SMC introduced an ultra-orphan framework placing less emphasis on the cost per quality adjusted life year (QALY). Despite this, many medicines continued to be not recommended. A new pathway aimed at improved patient access based on further evidence collection is now being implemented.

METHODS:
The development of the new pathway has involved collaboration with key stakeholders including patient groups, the pharmaceutical industry, and clinicians. Medicines that meet a new definition (based on four criteria including the prevalence of the condition treated) will be appraised by the SMC committee and a data collection plan will then be agreed with the pharmaceutical company.

RESULTS:
From April 2019, medicines validated as ultra-orphans will initially be appraised using the broader decision-making framework and the SMC committee will outline key uncertainties in the clinical effectiveness. The medicine will then be available for a period of at least three years while further data are gathered, potentially comprising ongoing clinical trials, registry data, and patient reported outcome measures. SMC will then re-assess the clinical and economic evidence to inform a final decision on routine use of the medicine in NHSScotland.

CONCLUSIONS:
The new pathway for ultra-orphan medicines will allow further evidence on their longer term clinical benefits to be collected before a final decision on routine use. This approach reflects the current direction of travel in medicines regulation, by making medicines that address an unmet need available to patients at an earlier stage of development.

VP76 MCDA For Orphan Drugs In Ireland – A Methodology Ready To Deliver?

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ABSTRACT SUMMARY:
The HTA approach in Ireland is flexible and may potentially be of greater value to the decision maker, in the case of orphan drugs reimbursement. This project highlighted that the HTA process is capturing many non traditional factors which could potentially be used to support decision making for orphan drugs. guided by MCDA principles.

INTRODUCTION:
The HTA methodological approach in Ireland is flexible and has adapted in recent years to encompass factors such as stakeholder engagement for orphan medicinal products (OMPs). The aim of this study was to highlight the criteria identified in the HTA process for OMPs, which could potentially be used to support decision making guided by MCDA principles.

METHODS:
A retrospective analysis of applicant submissions for OMPs made to the NCPE from January 2016 to July 2018 was conducted. Drugs which had orphan ‘maintenance’ status (as directed by the EMA) were included. A detailed list of all criteria used in the HTA process was documented under the following
domains; disease and its management, intervention under assessment, clinical evidence, decision problem, economic inputs and results, budget impact analysis, patient and clinician engagement.

RESULTS:
Twelve HTAs were identified. The most commonly present criteria were unmet need (availability of other treatments), disease severity (impact on survival), comparative effectiveness, comparative safety, disease burden (patient consensus), expert clinical consensus, size of the affected population, budget impact.

CONCLUSIONS:
The HTA process used in Ireland is already incorporating many non-traditional factors, which could serve as a basis for introducing MCDA into healthcare decision making for OMPs. HTA agencies across Europe may find this approach useful.

VP77 Extrapolating ICERs At Different Discount Rates

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ABSTRACT SUMMARY:
Applicability of incremental cost-effectiveness ratios from another jurisdiction is often affected by a different local discount rate, creating uncertainty about the ICER using the local discount rate. The ICER is sometimes reported at additional discount rates in the sensitivity analysis. We aimed to investigate the extent to which an ICER can be predicted at a given discount rate if estimates are available at least two discount rates.

METHODS:
We used six previously published economic models representing analyses with a range of time horizons and ICERs calculated at discount rates from 1% to 8%. A simulation exercise was applied whereby the ICER at a discount rate selected from the range 2% to 5% was calculated based on ICERs provided at two or three randomly selected discount rates. With two discount rates a linear model was used to predict the ICER at the selected rate. For three discount rates an exponential model was used. Error between the predicted and actual ICER was calculated as the absolute difference divided by the actual ICER.

RESULTS:
For four of the models, ICERs could be well predicted by a linear model (i.e., with two points), with average errors of less than 5%. For the final two models the error was substantial with a linear model but substantially improved to under 15% with an exponential model (i.e., with three data points). The two models with a poor fit to a linear model assessed childhood vaccination programmes over a lifetime horizon.

CONCLUSIONS:
For studies with a relatively short time-horizon, or where the majority of costs and benefits accrue in the short-term, a simple linear extrapolation can facilitate calculation of the ICER at a discount rate other than those reported. With longer time horizons, a third data point facilitates more reliably extrapolation of ICERs at desired discount rates.
VP78 The Case For A Higher Cost-Effectiveness Threshold For Ultra-Rare Cond[...]

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
While one-time gene replacement therapies may offer transformative innovation for management of ultra-rare, health-catastrophic diseases, they also pose challenges to the healthcare systems globally. Historically, many countries have demonstrated a willingness to support higher prices for health gains in rare diseases. This paper provides a health economic rationale for a higher value-based cost-effectiveness threshold (CET).

INTRODUCTION:
While one-time gene replacement therapies may offer transformative innovation for management of ultra-rare, health-catastrophic diseases, they also pose challenges to the healthcare systems globally. Historically, many countries have demonstrated a willingness to support higher prices for health gains in rare diseases. This paper characterizes the challenges for traditional approaches to assessing the value of one-time gene replacement therapies and provides a health economic rationale for a higher value-based cost-effectiveness threshold (CET).

METHODS:
We review the history of and present a list of relevant CET benchmarks. In practice, health technology assessment decision-makers often make comparisons to “benchmarks” to justify both standard and extraordinary CETs. We also sketch out how a broader concept of value could provide the basis for higher CETs for some ultra-rare diseases. This approach builds a broader concept of value outlined by a recent ISPOR Special Task Force on Value Assessment Frameworks.

RESULTS:
There is a general recognition that catastrophic health conditions should be judged against a higher CET. The Institute for Clinical and Economic Review in the US has discussed a range up to $500K per QALY for ultra-rare diseases, and the National Institute for Health and Care Excellence in the UK has described a variable threshold up to £300K per QALY depending on the magnitude of the health gains.

CONCLUSIONS:
In addition to the gains in quality-adjusted life years, other elements of value related to uncertainty are important in this argument. They include: insurance value, severity of disease, real option value, value of hope, and equity. It is imperative that we find a consensus on how to appropriately reward value created by these gene therapies to incentivize appropriate risk-taking and investments by their developers: a higher CET would, by economic logic, support a higher value-based price.

VP79 Reimbursement Of NSCLC And MS Drugs With High ICER Values: Key Drivers

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ABSTRACT SUMMARY:
The objective of this analysis is to compare and evaluate the key drivers behind favorable recommendations from NICE and SMC for non-small-cell lung cancer (NSCLC) and multiple...
sclerosis (MS) drugs associated with high incremental cost-effectiveness ratio (ICER) values.

INTRODUCTION:
The National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) put a significant emphasis on cost-effectiveness in their decision making. Exceptions have been observed; driving factors might differ for different therapy areas.

METHODS:
Eighty-five NSCLC and MS decisions from NICE and SMC between 2009 and 2017 were evaluated for inclusion. Decisions that did not include a manufacturer’s base-case ICER were eliminated from the dataset. ICERs > £30,000 were then isolated and analyzed for key reimbursement trends.

RESULTS:
In total, there were 123 manufacturer’s base-case ICERs; 92 (n = 11, MS and n = 81, NSCLC) were > £30,000. Of these, 66.7% of NSCLC ICERs and 63.6% of MS ICERs were positively reviewed. Of these positive recommendations, 56% of NSCLC ICERs included a patient access scheme (PAS) compared with 29% of MS ICERs. Of ICERs that included a PAS, 50% of MS and none of the NSCLC had a negative HTA decision. The highest and average ICERs, respectively, for an approved MS drug were £17,409,041 (daclizumab) and £309,510, and for an NSCLC drug, they were £205,580 (denosumab) and £65,124. In approximately 70% of the positively reviewed ICERs for both NSCLC and MS, the agency agreed with the economic comparator. Sixty-three percent of positively reviewed, MS, high-value ICERs demonstrated greater clinical efficacy/effectiveness vs comparators as compared with 49% of NSCLC ICERs.

CONCLUSIONS:
PAS inclusion increased the chances of a positive recommendation for NSCLC drugs but not for MS drugs. Incorporating an economic comparator of the agency’s choice in the pharmacoeconomic analysis had a favorable effect on reimbursement decisions for both NSCLC and MS drugs. Clinically superior MS drugs with high ICERs had higher positive reimbursement rates as compared with NSCLC drugs. MS drugs also enjoyed a higher, acceptable, average ICER vs NSCLC drugs.

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**VP80 Opportunity Cost In Cost-Effectiveness Evaluation**

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**ABSTRACT SUMMARY:**
Exploring the opportunity cost approach to explain the result of cost-effectiveness analysis to a larger public.

**INTRODUCTION:**
It may be difficult for healthcare professionals and the general public to understand why the Institut national d’excellence en santé et en services sociaux (INESSS) concludes that some medications are not cost-effective despite generating clinical benefits, quantified as quality adjusted life-year (QALY). Hence, the objective was to propose a framework that incorporates the notion of opportunity cost in order to better explain implications of listing pharmaceuticals with a high incremental cost-effectiveness ratio (ICER) in a context where resources are constrained.

**METHODS:**
A scoping literature review was done and a discussion group was held within INESSS. Throughout this review, relevant opportunity cost models were
identified; all of them included a threshold. It was discussed that the threshold consideration was relevant to add perspective to the ICER result, but not necessarily in order to determine a maximum value per additional QALY. Complementary research was done to consider the threshold meaning, either from the supply-side (i.e. league table, past decisions evaluation or empiric estimation) or the demand-side (i.e. willingness-to-pay).

RESULTS:
It was generally recognized that a supply-side threshold, especially an empiric estimation of the value of a health unit, was the best way to consider the opportunity cost. Unfortunately, no such data was available from a Quebec or Canadian perspective, even though it is becoming available in some countries. Nevertheless, based on three published models, a generic framework, using historic thresholds, was put forward for consideration, but hasn’t been used yet.

CONCLUSIONS:
Even though the proposed framework has limits and more literature is needed on threshold estimation, we believe that an opportunity cost approach could help explain to a larger public why pharmaceuticals with high ICER can result in an overall negative trade-off for the healthcare system. We are looking forward to additional work in this field to be generated by different stakeholders.

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ABSTRACT SUMMARY:
Cost-effectiveness analyses (CEA) of new drugs facilitate reimbursement decisions, thereby influencing the drug’s value. The application of CEA to support investment decisions for early-stage drug candidates has been limited. The study developed a value-based real options pricing (VB-ROP) model that considers patient, payer, and investor perspectives when commercially valuing early stage technologies.

INTRODUCTION:
Cost-effectiveness analyses (CEA) of new drugs facilitate reimbursement decisions, thereby influencing the drug’s value. The application of CEA to support investment decisions for early-stage drug candidates has been limited. The study developed a value-based real options pricing (VB-ROP) model to commercially value a phase 1 somatostatin receptor type-2 antagonist (SSTR2a) that prevents hypoglycemia for insulin-dependent type 1 diabetes patients.

METHODS:
A VB-ROP model was constructed through expert consultation with investors. The model was divided into two stages: the first was a probabilistic Markov model with inputs informed through literature review; the second was a binomial lattice option pricing model to inform go/no-go decisions. The CEA assumed 50% clinical improvements relative to standard of care (insulin detemir). The estimated value-based price using headroom analysis assumed a willingness to pay (WTP) of $50,000 USD per quality-adjusted life year (QALY) and 1.5% discount rate, which was incorporated into the real options model.

RESULTS:
The annualized value-based price was $3,226 [95% CI $1175, $4452] USD with a 50% probability of

VP81 Adjusting The Commercial Value Of Technologies For Cost-Effectiveness

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being cost-effective at $50,000 USD per QALY. The real option value was $2.1 million USD, suggesting to invest in further development. Sensitive model parameters include discount rate, market share, WTP, utilities, and the relative risk of non-severe hypoglycemic events. Real options where the value decreases prior to launching phase 2 and 3 trials should not be exercised.

**CONCLUSIONS:**

The VB-ROP model can be used to evaluate clinical, economic, and industry data along with investor assumptions to commercially value of a drug candidate bounded by cost-effectiveness requirements. The model is intended to enable earlier stakeholder engagement between payers and manufacturers in the drug development process.

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**VP82 Impact Of Evidence Synthesis Methods On Outcome Of Economic Evaluation**

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**ABSTRACT SUMMARY:**

Commonly used methods for evidence synthesis are based on the assumption of proportional hazards in trial data. Alternative methods are increasingly used, where the pattern of hazards in the trial data indicates that the proportional hazards assumption may be violated. The impact of these methodological choices on model outcomes is explored.

**INTRODUCTION:**

Evidence synthesis (ES) is often required for economic evaluation (EE) of pharmaceuticals. Commonly used methods are based on the assumption of proportional hazards in trial data, using the hazard ratio (HR). Alternative methods for ES are increasingly used in EE, in situations where the pattern of hazards in the trial data indicates that the proportional hazards assumption may be violated. The impact of these methodological choices on model outcomes is explored.

**METHODS:**

A network of trials of BRAF-targeted treatments for advanced melanoma, derived using a systematic review of the literature, is chosen for the study. Guyot’s method is used to create individual-patient Kaplan-Meier (K-M) data from published survival curves. Log-cumulative hazard plots and Schoenfeld residuals are derived to examine patterns in hazards within the trial data. All analyses are conducted in R version 3.5.0. Three alternative methods for ES are tested:

1) Network meta-analysis (NMA) based on published HRs and the assumption of proportional hazards.

2) NMA using fractional polynomials (FP) based on digitised K-M data, allowing the relaxation of the proportional hazards assumption.

3) NMA using an accelerated failure time (AFT) model based on digitised K-M data, allowing the relaxation of the proportional hazards assumption.

The derived estimates of relative efficacy from each method are applied in a partitioned survival cost-effectiveness model programmed in Microsoft Excel™.
RESULTS:
The model outcomes predicted by each method (HR, FP and AFT) are presented and compared. Both deterministic and probabilistic results are presented, alongside a discussion around how the uncertainty in these structural assumptions may be captured in EE.

CONCLUSIONS:
Structural assumptions in ES may lead to differences in model outcomes. The impact of these differences may be important in situations where decision uncertainty is high. Methods should be chosen and justified based on patterns of hazard present in the trial data.

INTRODUCTION:
Despite increased healthcare systems costs, limited opportunities for health economics training are available to healthcare professionals. From 2016-2018, with a grant from the Brazilian Ministry of Health, the Federal University of Goias with 7 other universities, implemented the distance learning Postgraduate Certificate in Health Economics for Health Care Professionals (PCHE) aimed at enhancing technical capacity of professionals working in the Brazilian Public Healthcare System (SUS).

METHODS:
This is a descriptive and qualitative assessment of the PCHE implemented in Brazil 88 healthcare professionals working in SUS and involved in decision making in all levels of management were enrolled in a health economics training, through long-distance learning strategy. We present course metrics, describe its workload, content, modalities and structure of training.

RESULTS:
PCHE was structured with 3-day workshops introducing each of the modules, during which students were also evaluated regarding the previous module content. With a total workload of 360 hours, structured in four modules: Public Health and Epidemiology; Introduction to health economics and healthcare funding; Management of healthcare resources; and Healthcare economic evaluation. The module coordinator was responsible for supervision of course materials development, workshop, distance based tutoring activities, and evaluation. Course material included theoretical content and practical tools for economic evaluation and health technology assessment in the workplace, applying problem-based learning strategies. Certificates were granted to students with 75 percent presence and approved in all modules, and final papers approved by an examination board. Each module was completed in 8 weeks (90 hours/module). Within groups of 20 students, tutors performed communication with chats twice weekly and
discussion forums by topic. A total of 88 students were enrolled. Drop-out rate was 35.2 percent (n=31). Additional 10 students did not pass the exams. In total, 47 students completed the training.

CONCLUSIONS:
Health economics training through distance learning is a more efficient use of resources with good results.

VP84 Tool For Prioritizing Coverage Of Health Technologies After Assessment

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ABSTRACT SUMMARY:
This communication describes the development of a tool for prioritization of coverage of high priced drugs in Uruguay. This tool was developed by the government agency and was put in consideration of stakeholders.

INTRODUCTION:
National health system in Uruguay seeks to achieve universal coverage of health technologies (HT) adding clinical benefit to healthcare. However, every year we assess several high priced of these technologies, but budget constrains make impossible to pay for all of them. The description of the development of a tool of prioritization for coverage of high priced drugs is the main objective of this communication.

METHODS:
During 2016 the team of Health Assessment Division performed a review of the literature identifying tools for prioritization of coverage of health technologies and developed a tool adapted to the Uruguayan context. This tool was tested for one year and re-assessed and modified by an extended government team during 2018. This new version of the former tool was put in consideration of stakeholders (academy, users’ and patients’ organizations) and they had the possibility to provide feedback regarding the dimensions of the tool.

RESULTS:
Thirty one professors from the academia and twenty nine users’ and patients’ organizations participated in an in-person consultation meeting. A final version of the document was obtained by collecting the contributions of those consulted. The tool has now six dimensions: pertinence (ethics, legal and human rights); relevance (magnitude of the disease; severity and equity in access of HT); health and economic impact, applicability in health services; alignment with national health policy and demands from the academia, the individual and the society. Pertinence is an exclusion criteria, if a HT does not meet any of pertinence components, the decision is not to cover it. Feasibility of the application of this tool was tested successfully with the list of drug request for coverage.

CONCLUSIONS:
This is the first open consultation of a government-developed prioritization tool performed in Uruguay agreed upon main stakeholders. The next challenge is to validate this tool.
VP85 Value Framework And Evidence For Cancer Drugs In China: A Pilot Survey

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ABSTRACT SUMMARY:
It remains a question of whether health technology such as cancer drugs should be covered and from which dimensions they should be valued, and this study aims to illustrate the dimensions of value measurement and the evidence needed to be presented. It can provide some basis for the establishment of the value framework of health technology assessment in the future.

INTRODUCTION:
In recent years, there has been a surge in the development of frameworks to assess the value of different types of health technologies to inform healthcare resource allocation, especially cancer drugs. Because of limited health resources but high drug price, it remains a question of whether cancer drugs should be covered and from which dimensions they should be valued. From the perspective of different stakeholders, this analysis aims to illustrate the dimensions of value measurement of cancer drugs when they are included in the medical insurance reimbursement list, as well as the evidence needed to be presented.

METHODS:
An online questionnaire including two questions about dimensions and evidence was completed by a sample of 160 subjects, involving the personnel from government, scientific institutions, colleges and universities, hospitals, medical industries, consulting companies, social welfare organization and others. The data obtained are mainly analyzed by multiple responses through STATA software.

RESULTS:
Clinical efficacy (84.82%), economy (82.14%) and safety (76.79%) are the main dimensions chosen by different stakeholders. On the contrary, the people who chose price of drugs (46.43%), unmet demand (24.11%), and drug innovation (21.43%) are the least. In the choice of evidence, HTA/pharmacoeconomics report (88.07%) is the most frequent choice that different stakeholders chose, expect for medical enterprise personnel whose top choice is budget impact analysis report (100%). The people who chose international reference price are the least (49.54%).

CONCLUSIONS:
For the inclusion of cancer drugs into medical insurance reimbursement list, clinical efficacy, safety, economy and HTA/pharmacoeconomics report are considered the most by all stakeholders. This study can provide some basis for the establishment of the value framework of health technology assessment in the future. However, shortage of sample size is the main limitation. More samples are needed to make the results more stable.

VP86 Disruptive HTA For Disruptive Technologies

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ABSTRACT SUMMARY:
Disruptive technologies are technologies that completely change our conceptions and/or practices. Gene editing, BigData, and artificial intelligence (AI) are examples that may radically
alter health and health care. How should we prepare HTA for evaluating disruptive technologies? In particular, do we need disruptive HTA for disruptive technologies? What would a Disruptive Health Technology Assessment (DHTA) look like?

INTRODUCTION:
Disruptive technologies and innovations are those that completely change a field. They may totally change our conceptions, practices and value systems. Gene editing, BigData, and artificial intelligence (AI) are but a few examples that envision altering health and health care. Moreover, such technologies will adjust our value system. Accordingly, disruptive technologies have great implications for HTA, which may need new modes of evaluation. What would a Disruptive Health Technology Assessment (DHTA) look like?

METHODS:
Literature search on (“disruptive technology” OR “disruptive innovation,”) AND (“assessment” OR “evaluation” OR “appraisal”) is combined with content analysis to assess how disruptive technologies and innovations may alter evaluations in general – and HTA in particular.

RESULTS:
Assessing and governing disruptive technologies and innovations is identified as a general challenge. Specific fields, such as personalized medicine call for continuing assessment of disruptive processes.

In order to facilitate assessment of disruptive innovations a scale for the disruptiveness of innovations has been developed. Moreover, the movement from laboratory to application can also identify assessment parameters. An assessment framework that captures the essential characteristics and holistic success factors for disruptive innovation based on the original theory of Christensen has been suggested. However, one challenge is that disruption only can be properly assessed retrospectively.

CONCLUSIONS:
There is a significant hype of disruptive technologies and innovations. Only few technologies are genuinely disruptive, and those who are can oftentimes be properly recognized only after implementation. Early warning and horizon scanning can raise attention to potentially disruptive technologies. Ethics can also point to technologies that can disrupt value-systems. Hence, social sciences and ethics need to be crucial elements of DHTA.

References
**VP87 Scale Expansion Or Efficiency Promotion Of County Public Hospitals?**

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**ABSTRACT SUMMARY:**
County public hospitals serve as the leader of the three-tier healthcare network in China. Previous studies have shown that county hospitals have been excessively enlarging their scale during the healthcare reform since 2009. The purpose of this paper is to assess the technical efficiency and productivity of county hospitals and determine whether, and how scale expansion or efficiency promotion.

**INTRODUCTION:**
County public hospitals serve as the leader of the three-tier healthcare network in China. Previous studies have shown that county hospitals have been excessively enlarging their scale during the healthcare reform since 2009. The purpose of this paper is to assess the technical efficiency and productivity of county hospitals during the reform process from 2012-2016, and determine whether, and how scale expansion or efficiency promotion in Chongqing, of which mountains account for 76%. The results will provide the basis for further deepening reform.

**METHODS:**
We used a purposive sampling design to obtain 360 observations. Data were collected by the Chongqing Regional Health Information centre. Productivity is estimated using the Malmquist Indicator, decomposing the estimated values into efficiency, scale and technological change. A Fixeds-effects Tobit model is explored to investigate the impact of contextual factors on the magnitude of efficiency.

**RESULTS:**
Findings reveal the average Malmquist Productivity Indicator (MPI) score has increased from 2012 to 2016, with a growth rate of 1.2%. Technical efficiency, pure technical efficiency and scale efficiency has increased by 2.1%, 1.9%, 0.2% respectively. Technical progress declined has declined by 0.8%. Tobit regression showed that the main factors contributing to overall productivity gains are increases in daily inpatients per doctor, medical expenses per patient and government subsidy.

**CONCLUSIONS:**
This paper attempts to offer evidence in efficiency and productivity for county public hospitals reform in Chongqing. The results suggest that the improvement of MPI is not mainly due to the promotion of technological progress, nor scale expansion, but the change of technological efficiency. Emphasis perhaps should be placed in diverting hospital patients reasonably to lighten the burden of medical personnel for sustainable development.

**VP88 Identification Of A Strategy For Disinvestment In The Italian NHS**

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**ABSTRACT SUMMARY:**
The disinvestment of ineffective or inappropriate technologies or interventions with an inadequate value for money ratio is a growing priority in order to contribute to the objectives of maintaining high quality and appropriate care and allocation of resources that guarantee the sustainability of the NHS.

**INTRODUCTION:**
The disinvestment of ineffective or inappropriate technologies or interventions with an inadequate value for money ratio is a growing priority in order to contribute to the objectives of maintaining high quality and appropriate care and allocation of resources that guarantee the sustainability of the National Health System (NHS). The possibility of reallocating resources from obsolete and no longer appropriate technologies, allows for recovered resources to be allocated to technological innovation and therefore to the overall sustainability of the system.

**METHODS:**
A systematic review of the scientific literature was carried out with the purpose of analyzing the international disinvestment experiences of health technologies using the Health Technology Assessment method. The systematic review focused on two pathological areas: prosthesis procedure and stenting procedure. The analysis has been developed using the Italian National Health System’s perspective. Through the use of National Dataset, coming from the Italian National Institute of health, real consumption and estimated consumption have been identified. In addition, criteria concerning disinvestment techniques of health technologies and strategies of obsolete technologies, that can be applied within the Italian reference framework, were defined. The study was conducted in two Italian regions: Marche Region and Tuscany Region.

**RESULTS:**
In the development of disinvestment strategies, particular attention will be paid to the identification of an integrated model between the different levels of the NHS (national, regional, hospital). In Italy there are no prior example of a large and complex disinvestment experiences that use HTA methodologies.

**CONCLUSIONS:**
Effective divestment strategies require a systematic approach that are coordinated by a national body and implemented at regional level, must extend to cascade to the organization and provision of services and services by health companies, required to actively involve health professionals and citizens.

**VP89 A Preliminary Equity Checklist To Support The HTA Process**

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**ABSTRACT SUMMARY:**
There is increased recognition of the need to include equity considerations in HTA. Despite this, a recent World Health Organization report has found that this is seldom the case. We developed a preliminary version of an equity checklist in the hopes that tangible guidance will increase such analyses in the future.

**INTRODUCTION:**
There is increased recognition of the need to include equity considerations in HTA. Despite this, a recent World Health Organization report has found that this is seldom the case. We developed
a preliminary version of an equity checklist in the hopes that tangible guidance will increase such analyses in the future and contribute to smart capability building.

**METHODS:**
The checklist is based on the Equity Framework for HTA developed by Culyer & Bombard (2012). The elements presented in the framework were revised to follow the stepwise HTA process. A comprehensive literature search was used to update and complete the elements. The checklist was then piloted in an HTA in 2018 and subsequently further refined through a workshop during a national HTA conference in Canada.

**RESULTS:**
These steps resulted in a 27-item checklist leading to consider different aspects of the three major phases in the HTA process. The scoping phase brings questions relative to defining and contextualizing equity, such as highlighting potential minority groups and including vulnerability factors in the logic model. The development phase leads methodological approaches facilitating the analysis of inequities as well as considering contextual realities leading to inequities. The last phase, drafting of recommendations, aims to be aware of the evidence synthesis approaches as well as the various aspects to ensure recommendations consider existing inequities and avoid contributing to their development.

**CONCLUSIONS:**
Given the essence of HTA to protect health by ensuring optimal technologies and interventions are adopted to the benefit of all system users, the consideration of inequities should constitute an integral part of its process. The use of a pragmatic and simple checklist to aid the planning of an HTA could contribute to greater consideration of inequities in the future. A movement in this direction could also lead to greater methodological developments for health equity analysis in HTA.

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**VP90 Which Matching Adjusted Indirect Comparison Method Is Best?**

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**ABSTRACT SUMMARY:**
In the absence of head-to-head comparative effectiveness data often the next best approach to take, when trying to compare treatments, is an indirect treatment comparison of individual patient data with aggregate level data. Our overall aim was to compare three Matching Adjusted Indirect Comparison (MAIC) methods.

**INTRODUCTION:**
Matching adjusted indirect comparison (MAIC) methods are extremely useful when conducting ITCs, as they reduce baseline imbalances between studies, particularly upon patient characteristics that are confounded with treatment. The standard approach when conducting MAIC is that proposed by Signorovitch et al. (2010). However, there are newer, and potentially better, methods available.

**METHODS:**
Three different MAIC methods (Signorovitch, Entropy Balancing, Polynomial Weighting) were compared using multiple phase 3 RCTs conducted in Diabetic Retinal Edema. The matching ability of each method was assessed, alongside its ability to avoid large weights (i.e. avoiding high leverage), and maximise effective same size (ESS). Each method’s overall ease of use and impact upon estimates of treatment effectiveness were also evaluated.
RESULTS:
All methods were able to precisely match the aggregate level data. However, the Entropy Balancing and Polynomial Weighting both outperformed the Signorovitch method in terms of having the lowest maximum weights. The Polynomial Weighting provided the highest ESS. The Entropy Balancing method was arguably the most challenging to implement, whilst the Signorovitch method the least. The Polynomial Weighting method appears to provide the greatest flexibility to the user.

CONCLUSIONS:
Whilst the Signorovitch method has become almost synonymous with MAIC, the Entropy Balancing and Polynomial Weighting methods offer potentially superior performance. In the absence of head-to-head trial data, these new MAIC approaches should provide less biased and more precise estimates of comparative effectiveness – ultimately leading to better decision making by regulators and payers.

INTRODUCTION:
The Stride Management Assist (SMA®) device consist in a portable robotic exoskeleton designed for gait rehabilitation and training by repetition of walking patterns with automated regular gait cycles. Used for adult population with gait disorders of neurological or musculoskeletal origin that require rehabilitation. The objective of this work is to assess its efficacy and safety.

METHODS:
This technology was identified by the early Awareness and Alert System, “SINTESIS-new technologies” of AETS-ISCI. An early assessment of the technology was conducted. The searched databases were: Pubmed, Embase y WOS, Tripdatabase, ClinicalTrials.org and Cochrane Library. Clinical studies using the device published in any language until 10 October 2018 were reviewed.

RESULTS:
We found 3 abstracts to congresses and 6 clinical trials that evaluated the use of the device. Outcomes measures among studies included spatiotemporal gait parameters, energy expenditure, muscular activity and functional performance. Five studies consisted in proof-of-concept analysis; 3 studies evaluated the effect of gait training with SMA® compared with conventional therapy alone in individuals after stroke (2 studies) and Parkinson disease (1 study); and 1 before-and-after study assessed the effect of gait training with SMA® in elderly adults. During its use, improvements in spatiotemporal gait parameters were described in 4/5 studies, and 2/5 studies showed less energy expenditure versus 2/5 studies that found no differences. After gait training, 3/4 studies described greater improvements in gait parameters when associated its use. Only one clinical trial collected safety data reporting no adverse events.
CONCLUSIONS:
The SMA® device allows to increase the efficiency and parameters of the march during its use. The assistance in the stride might have an impact on health by facilitating the recovery of the gait; however, further research is needed to determine the feasibility in the latter case since comparative studies with conventional therapy are limited.

METHODS:
On the basis of interviews with key informants (various health professionals and parents of deaf children), nine areas of relevant valuable doings and beings were selected, comprising 22 items. 19 children (8 – 12 yrs) with cochlear implants, their parents, and 23 peers were queried, about actual performance and corresponding barriers, using a digital, adaptive questionnaire. Responses were classified on a 5-pt scale, ranging optimal to no capability.

RESULTS:
In spite of impressive results that have been obtained with cochlear implants in terms of hearing and speech, the capability of children with cochlear implants differs from the capability of their hearing peers (54% vs. 72% classified as optimal capability, respectively). In particular, children with cochlear implants appeared disadvantaged in areas such as accessing information, communication, social participation, and participation in school.

CONCLUSIONS:
Children with a cochlear implant who are performing well on linguistic and auditory scores can still experience serious limitations in achieving valued functionings. A capability-based questionnaire may help to identify those limitations and suggest promising actions for remediation. Capability offers a new perspective on how the context-specific value of healthcare technologies may be assessed.

VP93 Choosing Relevant End-Points: The Capability Approach

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ABSTRACT SUMMARY:
The selection of appropriate end-points is a crucially important step in HTA. The value of healthcare technologies may be captured by their impact on patients’ capability, but its measurement is challenging. We present results of the development and use of a questionnaire to determine capability of deaf children with a cochlear implant.

INTRODUCTION:
Capability, as developed by Noble Prize laureate Amartya Sen, reflects the real opportunities that people have to be or do what they have reason to value. Likewise, the impact of healthcare services such as cochlear implants and subsequent rehabilitation can best be inferred from the extent that they protect or restore capability of those affected.
**VP94 Neonates With Persistent Ductus Arteriosus: Oral Ibuprofen Treatment**

**PRESENTING AUTHOR:**
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**ABSTRACT SUMMARY:**
Persistent ductus arteriosus (PCA) is one of the higher morbidities incidence among preterm infants. This study analyze the efficacy and safety of oral ibuprofen compared to the available therapeutic alternatives for the treatment of PCA in neonates. Four systematic reviews showed that oral ibuprofen seems to be a viable therapeutic option for ductus arteriosus closure in neonates.

**INTRODUCTION:**
Persistent ductus arteriosus (PCA) is one of the higher morbidities incidence among preterm infants, leading the mortality causes in this population. In newborns, there is an spontaneous closure of the ductus arteriosus in the first 72 hours of life. In preterm infants, this process may be discontinued or prolonged. The ductus arteriosus can remain open for longer time, being proportionally larger the more immature the infant is. The aim of this study is to analyze the efficacy and safety of oral ibuprofen compared to the available therapeutic alternatives for the treatment of PCA in preterm infants.

**METHODS:**
A broad search was conducted in the databases Embase, Medline, The Cochrane Library, LILACS, Center for Reviews and Dissemination and Brazilian Network of Health Technology Assessment (REBRATS), aiming to find systematic reviews, randomized controlled trials, cohort studies, and health technology assessments on this topic. We used the the following expanded descriptors: (patentductusarteriosus) AND ("ibuprofen") AND ("newborn") AND ("oral administration") AND ("intravenousadministration")

**RESULTS:**
Fourteen studies were found and four systematic reviews of randomized clinical trials were selected. The results showed that oral nasoenteral probe ibuprofen appears to be as effective as injectable ibuprofen and indomethacin for the treatment of PCA in preterm infants. There was a lower risk of failure of the ductus arteriosus closure, as well as a reduced risk of impaired renal function and development of necrotizing enterocolititis, indicating a better safety profile with oral ibuprofen.

**CONCLUSIONS:**
Despite the limitations of the studies, oral ibuprofen seems to be a viable therapeutic option for ductus arteriosus closure in neonates. It is important to emphasize that all the interventions evaluated present risks of adverse reactions.

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**VP95 Getting The Best Of Three Ways-Merging EUnetHTA GRADE And Cochrane Guides**

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We piloted combined use of EUnetHTA, GRADE and Cochrane guidances while carrying out collaborative Relative Effectiveness Assessment of a technology for cataract surgery. The three handbooks, used for the Project Plan and the complete report, contributed to increase transparency of the assessment and stakeholders/external experts involvement, while the addition of the scientific abstract and plain language summary facilitated external dissemination.

**INTRODUCTION:**
European cooperation in Health Technology Assessment (HTA) requires joint assessments to be of high quality, providing findings transferable into national HTA report. To this aim, we piloted the combining of methodological guidances of EUnetHTA for Relative Effectiveness Assessment (REA), GRADE for selection/rating of outcomes and assessing quality of evidence, Cochrane for Systematic Reviews, while carrying out a collaborative REA on Femtosecond Laser Assisted versus Standard Cataract Surgery.

**METHODS:**
While developing the collaborative REA, we used the three organizations’ handbooks, templates and tools for Scope, Project Plan (PP), Summary of Findings, Effectiveness (EFF) and Safety (SAF) domains. We structured the PP according to the EUnetHTA template and added detailed methods on EFF and SAF systematic reviews, as per Cochrane Handbook. For the Scope we convened a multidisciplinary panel for selection and rating of importance of outcomes and clinically significant difference, using the GRADEpro platform. We developed the complete report adopting the EUnetHTA REA Core Model. We used Cochrane’s tool Revman to assess risk of bias of included studies for each outcome, and to carry out metanalyses. We applied the GRADE approach to assess quality of evidence for each outcome and to express level of certainty in the estimates. We used the Cochrane handbook’s guidance for structuring a scientific abstract and a Plain Language Summary to integrate the Summary of Findings.

**RESULTS:**
The PP resulted in a detailed scientific and operational protocol, receiving extensive and constructive internal and external peer review. Reporting of EFF and SAF domains followed EUnetHTA Assessment Elements while keeping the order of stakeholders’ rating of outcomes’ importance. Graphic representation of risk of bias for each outcome contributed to immediacy of the data quality assessment and transparency of the judgement on certainty. The scientific abstract and the Plain Language Summary, facilitated the external dissemination of results.

**CONCLUSIONS:**
Merging of the three most important methodological contributions in the field proved successful without altering the distinctive trait of the REA.

VP96 Activities To Optimize Quality And Efficiency Of Medicines In Scotland

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**ABSTRACT SUMMARY:**
Multiple initiatives are necessary to improve the
quality and efficiency of prescribing with increasing use of medicines with ageing populations and stricter clinical targets, and funding new premium priced medicines, within universal healthcare systems. Scotland provides a good exemplar with high INN prescribing and multiple national and regional initiatives to influence prescribing. These are their impact will be discussed.

INTRODUCTION:
The growing prevalence of non-communicable diseases, combined with greater recognition of the effectiveness of lipid lowering agents (LLAs), has fueled their increasing use in recent years. Similarly, increasing recognition of mental health and, arguably, societal expectations and pressures has driven appreciable growth in antidepressant prescribing in recent years. Concurrent with this, growing resource pressures enhanced by the continual launch of new premium priced medicines necessitates reforms and initiatives within finite budgets. Scotland has introduced multiple measures in recent years to improve both the quality and efficiency of prescribing. There is a need to document these initiatives and outcomes to provide future direction.

METHODS:
Assessment of the utilization (items dispensed) and expenditure of key LLAs (mainly statins) and SSRIs between 2001 and 2017 in Scotland alongside initiatives.

RESULTS:
Multiple interventions have increased international non-proprietary name (INN) prescribing (99% for statins and up to 99.9% for SSRIs). They have also increased preferential prescribing of generic versus patented statins with low costs for generics, reduced inappropriate prescribing of ezetimibe due to effectiveness concerns, and increased the prescribing of higher dose statins (71% in 2015). These measures have resulted in a 50% reduction in LLA expenditure between 2001 and 2015 despite a 412% increase in utilization.

Initiatives to reduce the prescribing of escitalopram as lack of evidence demonstrating cost-benefits over generic citalopram, along with high INN prescribing, achieved a 73.7% reduction in SSRI expenditure between 2001 and 2017 despite a 2.34-fold increase in utilisation. Concerns with paroxetine, and more recently citalopram and escitalopram following safety warnings, resulted in a considerable reduction in their use alongside a significant increase in sertraline.

CONCLUSIONS:
Generic availability coupled with multiple measures has resulted in appreciable shifts in statin and SSRI prescribing behavior and reduced ezetimibe prescribing, resulting in improvements in both the quality and efficiency of prescribing to provide future direction.

VP97 A Rapid Review On Laser Lithotripsy For Bile Duct Stones Via Endoscopy

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ABSTRACT SUMMARY:
Through a rapid quantitative review on the safety, efficacy and cost-effectiveness, we found that compared with traditional open surgery, laser lithotripsy for bile duct stones via endoscopy could remarkably improve the stone removal rate, reduce intraoperative bleeding and incidence of complications, shorten the length of surgery and hospital stay.

INTRODUCTION:
Traditional open surgery is the most common
treatment for Bile Duct Stones (BDS). However, with the application and popularization of electronic endoscope and laser treatment in recent years, the therapies of BDS have gradually become minimally invasive and precise. This study systematically reviewed the safety, efficacy and cost-effectiveness between the laser lithotripsy for BDS via endoscopy and traditional surgery, which aimed to provide reliable evidence for rapid decision making in a provincial insurance agency.

METHODS:
We searched NIHR-HTA Database, Pubmed, Embase, Cochrane Library, and Chinese databases (CNKI, CBM and Wanfang) from inception until July 25, 2018. Studies that reported the prespecified outcomes and compared the two therapies above were included, while those of target patients with cholangiocarcinoma or acute pancreatitis were excluded. Two authors extracted data independently. AMSTAR 2 and 'Risk of bias' tool of Cochrane Collaboration were used to assess the qualities of meta analysis and RCT respectively.

RESULTS:
969 studies were screened, 70 reviewed in full, and 11 enrolled. (1) Safety: the intraoperative blood loss and surgery time of laser lithotripsy group were significantly less than those of traditional surgery group separately (N=165, MD=-27.03ml, 95% CI=[-30.83, -23.23]; N=158, MD=-27.77min, 95% CI=[-33.88, -21.66]); the complication rate of laser lithotripsy group was significantly lower than that of traditional surgery group (N=374, OR=0.22, 95% CI=[0.14, 0.36]). (2) Efficacy: the stone removal rate of laser lithotripsy group was significantly higher than that of traditional surgery group (N=96; OR=9.00, 95% CI=[3.40, 23.88]); the length of stay of laser lithotripsy group was significantly less than that of traditional surgery group (N=173; MD=-3.73d; 95% CI=[-4.53, -2.93]). (3) Cost-effectiveness: no literature reported ICER based on any clinical outcome.

CONCLUSIONS:
Compared with traditional open surgery, laser lithotripsy for BDS via endoscopy could remarkably improve the stone removal rate, reduce intraoperative bleeding and incidence of complications, shorten the length of surgery and hospital stay.

VP98 Horizon Scanning For New Alternatives To The Treatment Of Leishmaniasis

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ABSTRACT SUMMARY:
The present study identified six potential oral drugs for the treatment of cutaneous leishmaniasis, applying Technological Horizon Scanning.

INTRODUCTION:
The usual treatment of American Cutaneous Leishmaniasis is based on intravenous drugs of the 1940s and causes adverse events, having as first choice pentavalent antimonials that require clinical and laboratory follow-up in the hospital setting. The present study aimed to identify potentially more effective and safe oral therapies, applying Technological Horizon Scanning.

METHODS:
The searches were divided into three blocks: clinical trials through the Clinical Trials Registry Platform on the WHO search portal; searches in the PubMed, Embase, Cochrane Library, Lilacs and Center for Reviews and Dissemination databases; and search for patents in the Orbit base. The
searches aimed at identifying drugs, authors, institutions and therapeutic classes in order to proceed with scanning process.

RESULTS:
We found 197 studies and selected 33 in the Americas region. Of these, seventeen (51%) investigated Miltefosine, six (18%) had Azithromycin, four (12%) Fluconazole, two (6%) Pentoxifylline, two (6%) Allopurinol and one (3%) Terbinafine. Of the 26 clinical studies, twelve presented positive results for oral medications, six related to miltefosine, two to fluconazole, one to azithromycin, one to pentoxifylline, one to allopurinol. Through the analysis of patents, 35 documents involving 32 institutions and 134 inventors were identified. Of the 32 institutions that registered patent documents, Novartis is the one with the highest number of inventors.

CONCLUSIONS:
Miltefosine is in the incorporation phase in the Brazilian health system, evaluating its performance and effectiveness in the services. Pentoxifylline was recently incorporated as a coadjuvant to the treatment, and Fluconazole presented positive results, however with a small number of patients and uncertain outcomes. It is recommended to carry out more research directed to the drug association, since the studies indicate the possibility of decreasing occurrence of relapses, dosages and treatment time, increasing adherence to treatment.

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ABSTRACT SUMMARY:
The responsiveness is an important index to measure the service ability of medical institutions. Using multiple linear regression and structural equation analysis, this study found there are differences in responsiveness of primary medical institutions among different groups in Qinghai and Zhejiang. Ethnicity, household registration, occupation, insurance, marriage and education have a significant impact on the responsiveness of primary medical institutions.

INTRODUCTION:
The health system responsiveness, defined as non-medical aspect of treatment relating to the protection of the patients’ legitimate rights, is the intrinsic goal of the WHO strategy for 21st century, and is an important index to measure the service ability of medical institutions.

METHODS:
The data were collected in 2016-2017 and consists of the first visits for patients of grass-roots medical institutions. SPSS21.0 was used to complete statistical description and tests including multiple linear regression model analysis and structural equation analysis.

RESULTS:
1. There are differences in perceived responsiveness of primary medical institutions in Qinghai and Zhejiang. Zhejiang residents believe that the primary medical institutions have better medical environment, medical staff have better attitudes to explain problems, treatment plan explanation is more clear, and the attitude toward listening to patient condition is more serious. However, Qinghai residents think that the waiting time of the basic medical institutions is shorter and the degree of trust in the medical staff is higher. 2. There are differences in health system responsiveness
among different groups. According to the standard of α=0.05, factors such as ethnicity, household registration type, the medical insurance type, the occupational type, the marital status, the educational level have a significant impact on the perceived responsiveness of primary medical institutions.

CONCLUSIONS:
Health system responsiveness exists in the region, which may be related to the differences in the economic development level, the state of health service and the management and investment in health services among different regions. On the other hand, residents living in the same area are more similar in terms of living environment, socio-economic status, ideology and culture, and health beliefs than those from different regions. This may be one of the reasons the results of health system responsiveness assessment are closer than for residents in different regions.

VP100 Ultraradical Ovarian Cancer Surgery Comparative Clinical Effectiveness

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ABSTRACT SUMMARY:
Extensive/ultra-radical surgery aims to improve late stage ovarian cancer outcomes. NICE expressed concerns about efficacy and safety, recommending research comparing extensive and standard surgery complication rates, survival and quality of life. Prospective observational data on complications, quality of life and survival following surgery of different complexity from 258 patients in 3 countries will inform updated Interventional Procedures guidance.

INTRODUCTION:
Ovarian Cancer is usually diagnosed at an advanced stage. Extensive or ultra-radical surgery aims to improve the outcome by removing all visible tumour. National Institute for Health and Care Excellence UK 2013 Guidance expressed concern about its efficacy and safety, recommending research comparing complication rates, survival and quality of life with those following standard surgery. We present prospective observational data on quality of life and survival following surgery for advanced ovarian cancer. Innovative methods were used to collect patient reported outcomes and complex surgical information to compare outcomes of surgery of greater or lesser complexity used in routine practice.

METHODS:
A cohort study collected disease, surgical, complications, survival and quality of life data (validated instruments including EURO-QOL, EORTC-30 and OVA28) across a 2 year period in 12 United Kingdom sites and in parallel studies in Melbourne, Australia and Kolkata, India.

RESULTS:
260 patients undergoing cytoreductive surgery were recruited in 12 months. Centres varied in utilisation of complex surgical procedures. Excluding patients with inoperable disease, 125 patients underwent low, 70 intermediate and 63 high Surgical Complexity Score (SCS) procedures. Complete cytoreduction with < 1cm residual disease was achieved in 100/125 (80 percent) low, 65/70 (92 percent) intermediate, and 57/63 (90 percent) high SCS groups (p=0.023). Compliance with 12 months questionnaires was 89%. All surgical groups had improved EORTC QLC 30 Global at
12 months compared with prior to operation, with overlapping 95% confidence intervals and no between group differences at 12 months. Complications, survival and quality of life adjusted for disease burden and surgical complexity over 2 years’ follow-up will be described.

CONCLUSIONS:
Results will inform the update of NICE Interventional Procedures guidance recommendations on clinical governance arrangements for ovarian cancer surgery and enable clinicians and patients to better understand the outcomes of surgery, informing the consent process.

VP101 Intrauterine Surgical Interventions: A Rapid Review

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ABSTRACT SUMMARY:
Adverse conditions during pregnancy, such as myelomeningocele (MMC), fetal-fetal transfusion syndrome (STFF) and congenital heart disease (CHD) not only significantly increase the risk of fetal death, but also increase the occurrence of severe postnatal sequelae. For STFF, the available scientific evidence indicates that laser ablation is effective and presents better outcomes when compared to other interventions, such as high overall survival. Even though intrauterine interventions in CHD present high rates of live births, high neonatal mortality rates are also reported. Evidence on the efficacy and safety of intrauterine surgical interventions for myelomeningocele and CHD is inconclusive. Regarding myelomeningocele, no significant differences were observed for the outcomes of postnatal mortality, rate of ventriculostomy placement, reversal of posterior brain herniation, motor response and placental rupture.

INTRODUCTION:
Adverse conditions during pregnancy, such as myelomeningocele (MMC), fetal-fetal transfusion syndrome (STFF) and congenital heart disease (CHD) not only significantly increase the risk of fetal death, but also increase the occurrence of severe postnatal sequelae. For STFF, the available scientific evidence indicates that laser ablation is effective and presents better outcomes when compared to other interventions, such as high overall survival.

METHODS:
We conducted a rapid review of the efficacy and safety of intrauterine interventions in MMC, STFF and DCC in comparison to traditional interventions. We searched Pubmed via Medline, Cochrane Library and Center for Reviews and Dissemination databases using the terms indexed and synonyms for each intervention.

RESULTS:
For STFF, the available scientific evidence indicates that laser ablation is effective and presents better outcomes when compared to other interventions, such as high overall survival rate, better perinatal outcomes and less chance of brain injury. Even though intrauterine interventions in CHD present high rates of live births, high neonatal mortality rates are also reported. Evidence on the efficacy and safety of intrauterine surgical interventions for myelomeningocele and CHD is inconclusive. Regarding myelomeningocele, no significant differences were observed for the outcomes of postnatal mortality, rate of ventriculostomy placement, reversal of posterior brain herniation, motor response and placental rupture.

CONCLUSIONS:
There is no consensus regarding the efficacy and safety of intrauterine surgical interventions for myelomeningocele and CHD. Regarding STFF, laser ablation is accepted as an effective intervention. It is necessary to conduct prospective studies in order to evaluate the effect of these interventions, considering the specifications of each condition and the ethical aspects.
**Poster Displays**

**PP01 Real World Evidence: How To Include It In Health Technology Assessment**

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**ABSTRACT SUMMARY:**
Real world evidence use in a context of public drug reimbursement and the development of a standardized method to include RWE in health technology assessment.

**INTRODUCTION:**
Reimbursement decisions are conventionally based on evidence from randomized controlled trials (RCTs). However, they have limited external validity since they have restrictive enrolment criteria and may compare a drug to treatments that are no longer used in practice. Health technology assessment organisations are currently facing an increase in submissions containing real world evidence (RWE). This type of evidence can help support the results obtained in RCTs, thus potentially increasing external validity when assessing health technology. However, incorporating RWE in listing evaluations is deemed challenging for organizations given the lack of standardization.

**METHODS:**
The objective of this presentation is to identify past INESSS submissions that included RWE and analyze how they were integrated in the decision-making process, from clinical and pharmacoeconomic perspectives. A scoping literature review was done and a discussion group was held with INESSS clinical scientific advisors. Complementary research was done to determine how RWE was included in other health technology assessment organizations.

**RESULTS:**
Our research showed that real world data use as supportive evidence to INESSS’s evaluations has been increasing. We also observed that, inclusion of RWE in health technology assessment differs between organizations. INESSS is currently developing a standardized method to include RWE in health technology assessment.

**CONCLUSIONS:**
INESSS is looking forward to applying this method to its decision-making process in order to facilitate the listing evaluations by the scientific professionals.

**PP02 Using Real World Data To Identify The Market For A New Technology**

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**AUTHORS:**
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**ABSTRACT SUMMARY:**
We have devised a methodology that combines the heart failure specific NICOR database and the national Hospital Episode Statistics data for the NHS using real world data to answer specific questions about heart failure patients. Real world data are becoming an important source of information for patient outcomes and combining two complementary registries is a novel way to conduct research.

**INTRODUCTION:**
KiTEC, a UK based HTA consultancy, was tasked with identifying a specific group of heart failure patients who had repeat readmissions in order to accurately identify the potential market for an
innovative device designed to diagnose heart failure as a way to avoid costly and avoidable hospital readmissions. The device enables clinicians to remotely diagnose heart failure and appropriate medication can be administered instead of a hospital visit. Our methodology describes an accurate way to quantify the at risk population without the need for a costly trial.

METHODS:
Using big data from national registries – the heart failure specific NICOR database and the national Hospital Episodes Statistics for the NHS (HES) – KITEC has devised a methodology of linking the two datasets in order to (a) accurately identify patients with repeat readmissions over a 5-year period and (b) calculate the risk factors for readmissions. Data is linked using a common field, meaning information from both databases can be analysed at patient level (it is pseudo-anonymised before KITEC receives it). This allows for unprecedented granularity, as we are able to exploit the heart failure specific detail of NICOR alongside the wealth of admissions data available in HES.

RESULTS:
There are significant challenges surrounding the use of registry data, especially in the enormous size of the datasets and in privacy legislation aimed at protecting personally identifying data. The usual regulatory approvals for health research are also more complex when linked datasets are proposed. These are important considerations, especially when linking two complementary databases.

CONCLUSIONS:
The use of real world data has the potential to paint a true and accurate picture of a patient population, whilst avoiding many of the biases inherent in typically research studies. However, there are other important challenges to overcome, namely difficulties analysing huge datasets and navigating complex legislation to access patient data.

PP03 Development Of A Medical Device Maintenance Management System

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ABSTRACT SUMMARY:
The system to be developed is of low cost and high impact when evaluating the health technologies to be acquired.

INTRODUCTION:
Health technologies are fundamental in an operational health system. Medical devices, in particular, are crucial for the prevention, diagnosis, treatment and rehabilitation of diseases. Recognizing this important role of health technologies, the World Health Assembly adopted, in May 2007, resolution WHA60.29, which addresses issues arising from the inadequate installation and use of health technologies, as well as the need to.

METHODS:
Methods section in English of the Abstract ID # 134

The pilot study of observational and descriptive design will include all the medical-laboratory equipment that the IICS has and that meet the inclusion criteria. The work will be carried out at the Institute of Health Sciences Research (IICS-UNA), which aims to develop a computerized system for the maintenance of equipment; that allows the linking of QR codes to one to an application (WebApp) by means of the cameras of cell phones of the smartphone type, able to relate each QR code (attached to a medical / laboratory equipment) with its corresponding URL and thus be able to access all the technical information of each
IICS team and therefore monitor their maintenance (preventive, corrective, predictive), history, spare parts, budgets, as well as their technical specifications.

RESULTS:
Actually, we have a database of all medical devices installed in the research center, we look forward to develop the program to include the data.

The projection focuses on the effective tool for decision making regarding the evaluation of the installed sanitary technology and those that will be installed.

CONCLUSIONS:
The study proposes an effective solution for maintenance management, data that supports administrative decisions regarding the acquisition of equipment in the future, that is, the system can contribute when it comes to evaluating the installed and acquired sanitary technology.

PP04 Health Technology Assessment And EU’s Digital Single Market Strategy

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ABSTRACT SUMMARY:
The Digital Single Market strategy has enabled the digital transformation of Europe’s health care environment. Once fully implemented, it will revolutionise biomedical research by opening new sources of high quality, diverse and reliable data. As health technology assessments rely on traditional forms of clinical research and data, decision makers should make the most of the opportunities that new technologies provide.

INTRODUCTION:
European Union’s (EU) Digital Single Market (DSM) strategy is important in laying the foundations for advanced technologies to enter health care. These are expected to deliver benefits to the public and influence the way we capture and assess value in health. This work explores the opportunities that DSM opens for decision-makers in the context of health technology assessments (HTAs).

METHODS:
In May 2015 the European Commission (EC) revealed their global strategy on the digital transformation of the European economy. As part of that, in 2018, a policy on the transformation of health and care was published which outlined priorities related to citizens’ access to and sharing of health data; better data to advance biomedical research; digital tools for better patient empowerment and centricity of care. We analysed the opportunities that DSM poses in the context of current methods of HTA and applications of new technologies for data integration and analytics. The analysis considered clinical data collection and quality, definition and valuation of health benefits and decision implementations.

RESULTS:
Achievement of DSM goals through appropriate use of innovative technologies, would allow for large-scale, secure and standardised data collection from a distributed EU-wide IT infrastructure. Process automation and use of technologies (e.g. blockchain) could enhance security and quality of patients’ data, its consolidation from multiple sources and sharing between stakeholders. This will revolutionise biomedical research and improve its reliability and transferability. Digital infrastructure projects will enable machine-learning and advanced predictive analytics for more accurate quantification of uncertainty and risk. Appropriate application of technologies can enable innovative
contracting and flexible reimbursement by improving trust and transparency between parties.

CONCLUSIONS:
Technology will transform biomedical research and open the doors to a more enriched and continuous data collection, analysis and use. HTA bodies need to understand these benefits and prepare the appropriate framework for their utilisation.

INTRODUCTION:
The utilization of medical resources in China is unbalanced and insufficient. In order to find way to maximize their utilization to face challenges in upcoming decade, this study aims to investigate the elderly’s first choice of health institutions when they were ill in Zhejiang and Qinghai provinces, and to explore the potential pathways related to their choices among elderly respectively.

METHODS:
The data used in this study was from cross-sectional surveys in Zhejiang and Qinghai province. According to Anderson Health Service Utilization Model, we applied structural equation modeling to explore the complex pathways from socioeconomic status (SES), accessibility, and health status to elderly’s first choice of health institutions.

RESULTS:
The proportion of elderly selected community health institutions (CHI) as their first choice of medical institutions in Qinghai was higher than in Zhejiang. Zhejiang model revealed a significantly negative direct effect of SES and significantly positive direct effects of accessibility to CHI and health status on the choice of institutions, and a significantly positive indirect effect of SES on choice of institutions, through the mediating factor of health status. SES played an important role in Zhejiang model through direct and indirect way. In Qinghai model, only SES and accessibility to CHI had significantly direct effects on the choice of institutions, which from accessibility to CHI was the biggest. SES had a significant and positive indirect impact on choice of institutions, through the factor of accessibility to CHI.

CONCLUSIONS:
A better understanding of the complex pathways from factors to elderly’s choices of health institutions was essential which may inform priorities for maximizing the utilization of CHI further and prepare to face challenges in the
new decade. Through this research method, policymakers could explore the specific pathways based on their own status of economic and societal.

PP06 Health Technology Assessment In India (HTAI\text{\textregistered}): Towards Better Health

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ABSTRACT SUMMARY:
Institutionalizing HTA in India, bringing states together, capacity building, helping the Government in evidence-based policy decisions in healthcare.

INTRODUCTION:
The year 2017 marked as an important milestone for Indian Healthcare system. To facilitate the process of transparent and evidence-informed decision making in the field of health, Government of India has established an institutional framework called as Health Technology Assessment in India (HTAI\text{\textregistered}) under the Department of Health Research, Ministry of Health & Family Welfare (MoHFW). HTAI\text{\textregistered} is entrusted with the responsibility to analyze evidence related to cost-effectiveness, clinical effectiveness and equity issues regarding the deployment of health technologies by the means of Health Technology Assessment (HTA), and in turn help in evidence-informed decision making for an efficient use of the limited health budget and providing people access to the quality health care reducing out of pocket expenditures (OOPs) on health.

METHODS:
HTAI\text{\textregistered} consists of a Board, a DHR in-house Secretariat, a Technical Appraisal Committee, various Technical Partners (TP) and Regional Resource Hubs across the country. The Secretariat takes up the topic(s) for assessment from the User Department (any Govt. organization directly or indirectly involved in the health sector in India), prioritizes it, identifies the potential TP and allocates the topic(s) to them to undertake the HTA study. TAC appraises the proposal(s) and outcome(s) of the study before passing the recommendations to the Board for final approval. The recommendations are also shared with the stakeholders in the stakeholder consultation meeting.

RESULTS:
HTAI\text{\textregistered} is intended towards a fairer, more inclusive, transparent and evidence-based system of setting priorities for the health system of India in order to best utilize the finite health budget and extend its services to maximum people contributing in taking India towards Universal Health Coverage (UHC).

CONCLUSIONS:
With more than one-sixth of the world’s population residing in India, HTAI\text{\textregistered} is an important step not only for the betterment of the Indian health system but for the global health community.

PP07 Future Direction Of HTA In Japan; Proposals From The Experts

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ABSTRACT SUMMARY:
In March 2018, 12 health economists were convened for the purpose of preparing
recommendations concerning the scientific issues identified in the trial implementation of cost-effectiveness evaluation for price setting in Japan. We discussed issues based on the scientific validity and operational status of HTA overseas. Our proposal has been used as reference for creating rules in full-scale introduction.

INTRODUCTION:
In Japan, trial implementation of cost-effectiveness evaluation for the purpose of setting the reimbursement price was started in April 2016. 13 products including 7 drugs and 6 medical devices were selected. In the trial implementation, several issues to be dealt with were identified.

METHODS:
In March 2018, 12 health economists were convened for the purpose of preparing recommendations concerning the scientific issues on the trial implementation. Members of the Academic Advisory Committee discussed issues based on the scientific validity and operational status of HTA overseas. Major issues included 1) setting method of reference value (threshold), 2) ICER integration method in products with multiple indications, 3) method of considering social and ethical factors, 4) price adjustment method.

RESULTS:
Based on the circumstances of other countries and the results of WTP survey etc., we reached a consensus that 5 million yen / QALY was appropriate for the reference value. For ICER in products with multiple indications it was considered to be reasonable to set prices for each indication and calculate the weighted average price, instead of integrating ICERs. Regarding the method of considering social and ethical factors, it was considered better to change the reference value rather than adjusting ICER value itself. Also, several price adjustment methods based on ICER were proposed.

CONCLUSIONS:
The proposals by the Academic Advisory Committee have been introduced one by one at the special subcommittee of the cost-effectiveness evaluation of the Central Medical Council (Chuikyo) and used as reference for creating rules in full-scale introduction. Continuous cooperation by experts who are familiar with overseas situation is considered necessary for creating scientifically valid rules.

PP08 Evaluation Of The Brazilian Health Technology Assessment Network

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ABSTRACT SUMMARY:
The objective of this study was to evaluate and classify the member institutions of REBRATS. The evaluation of the member institutions of REBRATS mapped the capacity of these institutions to produce health technology assessment activities. The evaluation also provided information on the advances and challenges of health technology assessment in the country.

INTRODUCTION:
The Brazilian Network for Health Technology Assessment (REBRATS) is a network of collaborating
centers and teaching and research institutions, focused on the generation and synthesis of scientific evidence in the field of health technology assessment. Currently, the network is composed of 119 member institutions and mobilizes approximately 1,094 researchers and 4,998 relations. The objective of this study was to evaluate the member institutions of REBRATS.

METHODS:
The evaluation process was developed in seven stages, including the identification of the objectives of the Network; identification of evaluation criteria; selection of performance indicators for each criterion; identification of the measures appropriate to each indicator; data collection and analysis; classification of the institutions and production of the final report.

RESULTS:
The evaluation of the member institutions of REBRATS mapped the capacity of these institutions to produce health technology assessment activities. The evaluation also provided information on the advances and challenges of health technology assessment in the country. In the long term, the initiative will contribute to the strengthening of the evaluation of health technology in Brazil, since the weaknesses of these institutions in the development of activities were mapped.

CONCLUSIONS:
The production of this study will contribute to the dissemination of the evaluation methodology at national and international level. This study is one of the few initiatives that exist in the world on the evaluation of networks and will contribute to the strengthening of the evaluation of health technology in Brazil.

PP09 Cost-Effectiveness Of Chronic Obstructive Pulmonary Disease Management

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ABSTRACT SUMMARY:
To inform the development of a national clinical guideline for COPD, a systematic review was conducted to examine the cost-effectiveness of pulmonary rehabilitation programmes (PRPs), outreach programmes (OPs), and long-term oxygen therapy (LTOT), compared with usual care. There was inconsistent, but generally favourable evidence for PRPs, no clear evidence for the cost-effectiveness of OPs, and evidence that LTOT is cost-effective.

INTRODUCTION:
To inform the development of a national clinical guideline for Chronic Obstructive Pulmonary Disease (COPD), prioritised by the National Clinical Effectiveness Committee in Ireland, a systematic review was conducted to examine the cost-effectiveness of pulmonary rehabilitation programmes (PRPs), outreach programmes (OPs), and long-term oxygen therapy (LTOT), compared with usual care.

METHODS:
Medline, Embase, the Cochrane Library and grey literature sources were searched up to 19 June 2018. Studies evaluating cost-effectiveness published post-2008 in English were included.
Screening, data extraction, and quality assessment using the Consensus Health Economic Criteria and International Society for Pharmacoeconomics questionnaires were conducted independently by two reviewers. Where possible, costs were converted to 2017 Irish Euro using consumer price indices and purchasing power parity.

RESULTS:
From 8,661 articles identified, 7 studies (1 comparing both PRP and LTOT) were included (PRPs: 5; OP: 1; LTOT: 2). PRP cost-utility analyses (n=4) reported conflicting results due to considerable heterogeneity in programme and study design, with incremental cost-effectiveness ratios (ICERs) ranging between CAD17,938 and EUR472,000 (EUR509,122) per quality adjusted life-year (QALY) gained. The remaining study investigated hospitalisations avoided and found outpatient and community-based PRPs to be dominant, whilst home-based PRP produced an ICER of CAD2,989 (EUR1,913). OP was found to be less costly, but also less effective. However, the results were neither statistically nor clinically significant. LTOT was found to be cost-effective, with ICERs of USD16,124 (EUR17,603) and CAD38,993 per QALY gained.

CONCLUSIONS:
Applying a willingness-to-pay threshold of EUR45,000 per QALY gained, this systematic review found that compared with usual care, there is inconsistent, but generally favourable evidence for PRPs, no clear evidence for the cost-effectiveness of OPs, and that LTOT is likely to be cost-effective. However, there was a lack of methodologically robust studies included in the review and most were not directly transferable to the Irish context.

PP10 Quality Of Reporting Economic Evaluations In Rehabilitation Research

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ABSTRACT SUMMARY:
Economic evaluations in healthcare are a growing field of interest in the rehabilitation area. Recent research has questioned the quality of reporting of health economic evaluations. Poor reporting hinders the ability to provide accurate information for health care decision making. This study evaluates the current overall reporting quality of the published literature for rehabilitation economic evaluations.

INTRODUCTION:
Economic evaluations are a growing field of interest in the rehabilitation area. Research has questioned the quality of reporting of health economic evaluations. Poor reporting hinders the ability to provide accurate information for health care decision making. Therefore, the objectives of this study are to document on overall reporting quality of the published literature for rehabilitation economic evaluations; to identify if reporting quality has improved in health economic evaluations within the field of rehabilitation therapy since the publication of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), and to identify factors that could influence the reporting trends.

METHODS:
We searched databases for economical evaluations performed in the rehabilitation area published
between 2013 and 2018. Study selection was performed by two independent reviewers using Covidence software. Data extraction was conducted by one reviewer using Microsoft excel and independently verified by another reviewer. The quality of reporting was evaluated independently by two reviewers using the CHEERS checklist.

RESULTS:
The search of the literature resulted in a total of 2195 published articles. Of these, 117 were considered to be potentially relevant. Independent review of these 117 articles led to the inclusion of 88 articles. This study is ongoing and complete results will be presented at the conference. Fifty papers have been analyzed in full. In general, the quality of reporting of the economical evaluations in the rehabilitation field was poor. The total mean and median for the CHEERS checklist was 17 points (out of 25) (range 8-24). Most of the analyzed studies did not report important methodological features of the economical evaluation as evaluated by the CHEERS checklist.

CONCLUSIONS:
The quality of reporting of economic evaluations in the rehabilitation field is poor and inconsistent. Commonly the methods of the analyzed studies are under reported thereby creating challenges in determining whether the information presented is sound.

PP11 Cost-Effectiveness Of Aerobika Device For COPD Exacerbation Management

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ABSTRACT SUMMARY:
We performed a cost-utility analysis adapting a Markov model from the US to compare both cost and outcome between COPD patients who did and who did not use the Aerobika® device in the Canadian health care system. Results showed that the use of Aerobika® device was dominant (less costly and more effective) in comparison with the no-use of Aerobika® device.

INTRODUCTION:
The Aerobika® Oscillating Positive Expiratory Pressure (OPEP) device is a hand held, drug-free medical device that has been shown to improve lung function and improve quality of life in patients with Chronic Obstructive Pulmonary Disease (COPD). We estimated the cost-effectiveness of this device among post exacerbation COPD patients in the Canadian health care system.

METHODS:
We performed a cost-utility analysis adapting a Markov model from the US to compare both cost and outcome of patients with COPD who had recently experienced an exacerbation between patients who used the Aerobika® device and patients who did not use the Aerobika® device. This cost-effectiveness analysis used costs based on the Alberta health care system perspective as these represent Canadian experience. Probabilities of COPD exacerbation were retrieved from a real-world study in the US. Probabilities of death and utilities for different health states in the model were retrieved from the literature. A one-year horizon with 12 one-month cycles was used.

RESULTS:
For a patient after 1 year, the use of the Aerobika® device would save $694 in health care costs and produce 0.04 more in quality adjusted life year (QALY) outcomes in comparison with no Positive
Expiratory Pressure (PEP)/OPEP therapy. In other words, the economic outcome of the device was dominant (i.e. more effective and less costly). The probability for this device to be the dominant strategy was 73%. With a willingness to pay (WTP) threshold of $50,000 per QALY gained, the probability for the Aerobika® device to be cost-effective was 78%.

CONCLUSIONS:
Given one of the major treatment goals in the GOLD guidelines is to minimize the negative impact of exacerbations and prevent re-exacerbations, the Aerobika® OPEP device should be viewed as a potential component of a treatment strategy to improve symptom control and reduce the risk of re-exacerbations in patients with COPD.

PP12 Cost Utility Analysis Of Dolutegravir For HIV-1 Infection In Thailand

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ABSTRACT SUMMARY:
HIV drug resistance (HIVDR) has significantly increased in Thailand. All alternative treatment regimens comprising a new generation integrase inhibitor for HIV patients in Thailand were found to be not cost-effective at the willingness-to-pay (WTP) of 160,000 baht/QALY. However, the regimen comprising dolutegravir had the lowest lifetime cost.

INTRODUCTION:
HIV drug resistance (HIVDR) has significantly increased in Thailand. In patients who experience treatment failure on the first- and second-line antiretroviral therapies (ART), the following treatment regimen is to use at least two new active antiretroviral agents (ARVs). However, a new generation integrase inhibitor, dolutegravir, have not yet been included in the country’s National List of Essential Medicines (NLEM). Since these drugs are high in costs, an economic evaluation and budget impact analysis are needed to support the decision to introduce them into the NLEM. This study aims to assess the cost-utility analysis of dolutegravir for the treatment of patients resistant to the first- and second-line ARTs.

METHODS:
A Markov model, which monitored a cohort of patients at least 17 years of age with first- and second-line ART resistance in Thailand, was developed to evaluate the cost-utility of alternative treatment regimens from a Thai societal perspective with a lifetime horizon as follows: 1) the current practice of darunavir/ritonavir (DRV/r) + tenofovir (TDF) + lamivudine (3TC); 2) DRV/r + etravirine (ETR) + TDF + 3TC; 3) DRV/r + raltegravir (RAL) + TDF + 3TC; 4). DRV/r + RAL + ETR; and 5) DRV/r + RAL + maraviroc (MVC); 6). DRV/r + dolutegravir (DTG) + MVC; 7). DRV/r + DTG + ETR; 8). DRV/r + DTG + TDF + 3TC. The model incorporated cost data adjusted for 2017 using the consumer price index, and effectiveness data from a review of published studies. Outcomes were measured in life years, quality-adjusted life-years (QALY), and incremental cost-effectiveness ratios (ICER), and future costs and outcomes were discounted at 3% per annum. Finally, a probabilistic sensitivity analysis (PSA) was conducted to deal with uncertainties around the parameters.

RESULTS:
All alternative treatment regimens for HIV patients resistant to first- and second-line ARTs in Thailand were found to be not cost-effective at the willingness-to-pay (WTP) of 160,000 baht/QALY. However, the eighth regimen of DRV/r + DTG + TDF + 3TC had the lowest lifetime cost at 5.3 million baht while increasing QALY by approximately 14 QALYs.
COnclusions:
At a societal willingness to pay of 160,000 THB per QALY gained, dolutegravir for HIV patients resistant to first- and second-line ARTs in Thailand were found to be not cost-effective.

Pp13 Cost-Effectiveness Of Varenicline For Smoking Cessation

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Abstract Summary:
Cost-effectiveness of Varenicline for smoking cessation compared to Bupropion and Nicotine Replacement Therapy were estimated, under the Brazilian public health system perspective. A lifetime microsimulation model was built to comparing all alternatives, using national data sources. Varenicline was a cost-effective alternative in a 1 GDP per capita/QALY threshold.

Introduction:
In Brazil, is estimated 200,000 deaths per year related to smoking. In the world, tobacco is responsible for about 45% of myocardial infarction, 85% of COPD deaths, 25% of deaths due to stroke and 30% of cancer deaths. Keeping this trend will generate 10 million deaths per year until 2020. Varenicline is a smoking cessations drug that has been incorporated in Canada and Australia. The study objective is to build a cost-effectiveness analysis of varenicline for smoking cessation in Brazilian health system perspective.

Methods:
The model was built with a lifetime horizon under Brazilian health system perspective. To evaluate the cost-effectiveness of varenicline, a microsimulation model was developed inspired in BENESCO model. Varenicline was compared to Bupropion, Nicotine Replacement Therapy (NRT) and Bupropion plus NRT. Relative Risks for Stroke, Chronic Heart Disease (CHD), Lung Cancer and Chronic Pulmonary Obstructive Disease (CPOD) and Asthma exacerbation for Brazilian adult smokers and former smoker were used in the model. Utility values for Stroke, CHD and CPOD were also from national sources. Cost studies made with National Health System informed the annual cost of diseases. Systematic reviews with meta-analysis informed the smoking cessation rate of the different interventions.

Results:
The most effective alternative was Varenicline. The incremental QALY gain was 0,26 on Bupropion + NRT and 0,58 on Bupropion alone. The average ICER was U$294,42 versus Bupropion + NRT that was the second most effective alternative. For the willingness to pay threshold of 1 GDP per capita/QALY (U$8,649,95) it was observed a probability of 0,9031 to Varenicline be cost-effective. Baseline morbidity incidence was the most uncertain variable but had limited impact on results when varied in deterministic sensitivity analysis.

Conclusions:
Using Varenicline for smoking cessation has a low ICER and a very high probability of being cost-effective in a conservative willingness to pay threshold. Considering that most patients treat with Bupropion alone or NRT, the use of Varenicline must be even more cost-effective.
PP14 Budget Impact Of Sapropterin Dihydrochloride For Phenylketonuria

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ABSTRACT SUMMARY:
Brazil is a continental size country with a great social inequality and problems of basic sanitation and basic health care for its population. The incorporation of sapropterin dihydrochloride for phenylketonuria represents a significant budgetary impact and covers a small number of patients, bringing discussions about equity in the treatment of rare diseases compared to other public health problems.

INTRODUCTION:
The National Committee for Health Technology Incorporation (CONITEC) has the task of evaluating health technologies and recommending their inclusion or exclusion within the Brazilian Public Health System (SUS) and uses the budget impact assessment to estimate the costs to the system. The guideline of the Ministry of Health (MS) recommends the treatment of phenylketonuria (PKU) with restricted phenylalanine diet and supplementation with phenylalanine-free amino acid formula (PFAAf). CONITEC evaluated the inclusion of sapropterin dihydrochloride for PKU in SUS.

METHODS:
The population eligible for treatment was evaluated by the number of patients receiving PFAAf between 2014 and 2017 registered in the SUS. Patients were stratified by age/weight and a simple linear regression was performed to estimate the future population. The costs of treatment and testing the responsiveness of sapropterin were estimated according to the recommended dosage guideline MS, leaflet and public purchasing prices. A univariate deterministic sensitivity analysis was performed to evaluate different prices, responsiveness test methods and variations in the reduction of formula use.

RESULTS:
The incorporation of sapropterin dihydrochloride would generate an incremental budget impact in SUS of around R$ 79 million (Brazilian Real) in 2019 and R$ 300 million in five years (2019-2023). The univariate sensitivity analysis estimated that the incremental budget impact could be between R$ 66 and R$ 103 million in the first year and between R$ 251 and R$ 388 million in five years of the incorporation in the SUS. Sensitivity analysis showed that the price of sapropterin dihydrochloride was the most sensitive variable in the model.

CONCLUSIONS:
The incorporation of sapropterin dihydrochloride would generate an incremental budget impact in SUS of around R$ 79 million (Brazilian Real) in 2019 and R$ 300 million in five years (2019-2023). The univariate sensitivity analysis estimated that the incremental budget impact could be between R$ 66 and R$ 103 million in the first year and between R$ 251 and R$ 388 million in five years of the incorporation in the SUS. Sensitivity analysis showed that the price of sapropterin dihydrochloride was the most sensitive variable in the model.
PP15 Comparative Effectiveness And Safety Of Monoclonal Antibodies For mCRC

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ABSTRACT SUMMARY:
Assessing the comparative effectiveness of 3 monoclonal antibodies for patients with metastatic colorectal cancer to guide decision making in Brazil with price differences between the 3. There appeared a modest advantage for bevacizumab for a number of outcome measures and costs; however, balanced against the potential for serious adverse events especially hypertension and gastrointestinal perforations.

INTRODUCTION:
Biological medicines are increasingly used in combination with chemotherapy for patients with metastatic colorectal cancer (mCRC), resulting in increased progression-free survival (PFS). However, concerns remain over the extent of their effect on overall survival (OS) given the high costs of these monoclonal antibodies (MoAbs) (bevacizumab, cetuximab and panitumumab) and their safety. Published studies suggest no major differences in effectiveness and safety between the MoAbs; however, differences in costs with cetuximab more expensive than bevacizumab by 127% in Brazil and more expensive than panitumumab by 112%, with panitumumab more expensive than bevacizumab by 6%. Since there is rising litigation in Brazil in order to access these 3 MoAbs as they are not currently reimbursed, we wanted to compare their effectiveness and safety associated with chemotherapy or chemotherapy alone in patients with mCRC to provide future guidance to the judiciary and the healthcare system.

METHODS:
A systematic review and meta-analysis based on cohort studies published in databases up to November 2017. Effectiveness measures include PFS, post-progression survival (PPS), RECIST (Response Evaluation Criteria In Solid Tumors), response rates, metastasectomy rates, OS and safety. We also evaluated the methodological quality of the studies.

RESULTS:
Overall, 21 observational cohort studies were included in the review. There were statistically significant and clinically relevant benefits in patients treated with bevacizumab versus those not treated with bevacizumab (no bevacizumab arm) mainly around PFS, PPS, metastasectomy rates and OS, but not for disease control rates. However, bevacizumab increased toxicities and there were concerns with the heterogeneity of the studies.

CONCLUSIONS:
The results suggested an advantage in favour of bevacizumab for a number of outcome measures and costs in patients with mCRC. However, this advantage may be only clinically modest for bevacizumab. This though has to be weighed against the serious adverse events associated with bevacizumab, especially severe hypertension and gastrointestinal perforations.
**PP16 Rapid Products in Health Area: Time to a Standard?**

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**ABSTRACT SUMMARY:**
There has been an increasing demand from the policy makers to get a rapid access to decision support based on evidence. In response, rapid products have been developed in different health areas (reviews, health technology assessments and clinical guidelines).

**INTRODUCTION:**
There has been an increasing demand from the policy makers to get a rapid access to decision support based on evidence. In response, rapid products have been developed in different health areas (reviews, health technology assessments and clinical guidelines). Our objective is to identify the main elements of a rapid process.

**METHODS:**
A systematic review, including grey literature and hand searching, on rapid process in the health areas was performed.

**RESULTS:**
Few experiments were identified in the different health areas, especially in the one of rapid guidelines (only 5: WHO, CDC, NICE, BMJ Rapid Recommendations and HAS). Rapid products are characterized by high variability in process and deliverables. However, some common elements can be found:
- Methodology remains underdeveloped
- Lack of bias and completeness of evidence could be highly impacted thus requiring developers’ awareness.

**CONCLUSIONS:**
We need to develop innovative and specific processes to provide rapid products in which we can trust, maintaining scientific rigor despite restricted time. This systematic review is the first step to define a minimum set of standards that could be shared for the development of rapid processes. In that context, a GIN Accelerated Guideline Development Working Group has been established to propose a method to develop guidelines in an accelerated way.

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**PP17 Rapid Productions: Guidelines International Network Results**

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**AUTHORS:**
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**ABSTRACT SUMMARY:**
There has been an increasing demand from policy makers to have rapid access to evidence-based decision supports. In this context, a Working Group (WG) was established in the Guideline International Network (GIN) to propose a method to develop recommendations in an accelerated way.
INTRODUCTION:
There has been an increasing demand from policy makers to have rapid access to evidence-based decision supports. In this context, a Working Group (WG) was established in the Guideline International Network (GIN) to propose a method to develop recommendations in an accelerated way.

METHODS:
Accelerated Guideline Development (AGD)-WG performed a systematic review on rapid products, 3 surveys and 4 GIN conference workshops to produce an AGD manual. This manual is currently tested by GIN members.

RESULTS:
The main elements of the AGD process were identified by the review and expertise from GIN members. Based on iterative design the AGD WG selected 18 flexible key elements to be gathered in an AGD core model. The key elements are flexible since they can be used or not according to the context where the core model is adapted: time requirements, type of data available, updating needs, number of questions, controversy in the topic, etc.

The first feed backs showed that some key elements are major to accelerate the process (restricted analysis to high level of evidence, optional working group, no peer review but mandatory consultation of stakeholders) and some others are minor (experienced experts implication, restricted number of experts and meetings, electronic tools used). All documents are available on the GIN website.

CONCLUSIONS:
The current phase involves collecting GIN member experiences in applying the AGD manual in real life with a questionnaire online.

PP18 Should Academic Detailing Be Used To Disseminate Guidelines 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 aims to evaluate the feasibility of an 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:
Academic detailing is a strategy to provide information with the intent of changing health professionals’ prescribing behavior. The Specialized Component of Pharmaceutical Service (CEAF) is a strategy to access high cost medicines in the National Health System of Brazil (SUS), whose lines of care are defined in published Clinical Protocols and Therapeutic Guidelines (PCDT). To access the CEAF, the physician has to follow some requirements and the PCDTs. We delivered an academic detailing program to physicians and present key information regarding the PCDT of Rheumatoid Arthritis (RA) and the CEAF medicines request process. This project aims to evaluate the
feasibility of an academic detailing program about the PCDT of RA and the CEAF medicines request process in SUS.

METHODS:
43 specialists and general practitioners were visited by academic researchers about the PCDT of RA. After the visits, a researcher contacts those to evaluate their satisfaction with the program. A cost analysis was carried out, considering expenses with staff and materials.

RESULTS:
From 43 physicians that were visited, 28 answered to our phone call. 68 percent told that they were very satisfied with the visit. 50 percent told that the content of the visit was relevant to their practice, 64.3 percent told that the duration of the visit did not affect their work, 60.7 percent told that the distributed material were going to be useful for their professional practice. 57.1 percent of those affirmed that the visits added knowledge. A total of BRL14.185,00 (USD 3.373,82) was spent in the program.

CONCLUSIONS:
The prescribers visited represent a large number of deferrals for CEAF drug applications. Therefore, the total amount spent on the implementation of this program and its potential for improving access to these drugs can have a positive impact on the targeting of public expenditures avoiding the judicial process, representing an effective strategy PCDT dissemination.

PP19 Process Quality Of Medical Care In SR And Tas For Inpatients With PHC

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ABSTRACT SUMMARY:
The medical record review forms were designed according to the key steps and requirements of the corresponding clinical pathway and related guidelines. And the process quality of medical care in inpatients with Primary hepatic carcinoma (PHC) undergoing surgical resection (SR) and thermal ablations (TAs) were assessed according to the medical record review forms.

INTRODUCTION:
Implementing clinical pathway management can reduce the variation in the process of disease diagnosis and treatment, control medical cost and improve the quality of diagnosis and treatment. The purpose of this study was to assess the compliance of medical care with corresponding national clinical pathway in the inpatients with primary hepatic carcinoma (PHC) undergoing surgical resection (SR) and thermal ablations (TAs) in tertiary hospitals of Shanghai.

METHODS:
247 medical records of the inpatients with PHC undergoing SR and TAs therapy admitted from 2016 to 2017 were sampled from 3 tertiary hospitals in Shanghai. The compliance of medical care with corresponding national clinical pathway (CP) and the postoperative complications of SR and TAs therapy were assessed.

RESULTS:
The study showed that the average overall compliance rates in inpatients with PHC undergoing SR and TAs therapy in tertiary hospitals of Shanghai were 54.72% and 47.89%, respectively, but there was no significant difference in compliance rates between the two groups. The incidence of complications and serious
complications of SR were 44.78% and 18.66% respectively, which were significantly higher than those of TAs (18.66% and 6.19%, respectively).

**CONCLUSIONS:**
The clinical pathway should be revised to reflect the development of TAs therapy for PHC and to facilitate the standardized practice in the utilization of SR and TAs. In addition, the safety of TAs for PHC is better than SR.

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**PP20 Challenges In The HTA Of New/Emergent Non-Pharmacological Technologies**

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**ABSTRACT SUMMARY:**
Traditional and new/emerging non-pharmacological technologies Spanish guides differ. Both types are compared considering four 2017-2018 real-cases carried out at Catalanian HTA (AQuAS). Main learnings encouraging to improve methods are: lack of protocol and references, difficult identification and data extraction due to scarce quality studies, new type of sources, resource use and economic data evidence gap, or un-definition of comparators and outcomes.

**INTRODUCTION:**
The methodological guides for the assessment of new/emerging non-pharmacological technologies differ from the traditional HTA guidelines developed by the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). The aim of this study is to identify the special features and challenges of carrying out HTA on new/emergent non-pharmacological technologies.

**METHODS:**
The application of traditional and new/emergent HTA guidelines is compared along the consecutive evaluation phases in 4 practical cases carried out at the Agency for Health Quality and Assessment of Catalonia (AQuAS) in 2017-2018.

**RESULTS:**
Main learning and outstanding challenges: (i) Instead of following a defined protocol, the evaluations are carried out from a preliminary short report which generates a lack of justification and delimitation of its scope. (ii) References’ identification and data extraction are often limited due to lack of studies, and sometimes require the use of grey literature or other sources less informative e.g. trial registries. It can be challenging to exclude references related to other indications. (iii) The assessment of resources use and costs of running the technology is complicated due to the lack of public prices information and specific impacts of use. (iv) The evidence considered during the assessment usually does not meet high quality requirements (risk of bias) because of indirect evidence, lack of comparator or no having clearly defined outcomes, among others. (v) It’s difficult to draw conclusions and, consequently, recommendations due to abovementioned aspects and specially for the usual evidence gap that face this type of technologies in early stages of diffusion and/or in a competition situation of manufacturer companies.

**CONCLUSIONS:**
The most recent innovation in non-pharmacological technologies merits a differentiated assessment approach. However, there is need to reconsider the methodology...
applied in order to overcome the challenges and limitations identified.

PP21 High Risk Class Medical Devices Evaluation In Germany: Another AMNOG?

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ABSTRACT SUMMARY:
Requirements and results for assessment of high risk class MDs ($137h) and drugs (AMNOG) are compared. Hospitals and manufacturers jointly submit comparative evidence when applying for additional compensation of MDs. Unlike for drugs evaluated under AMNOG, thus far the majority of new MDs failed to be granted potential benefit as a treatment alternative and might be excluded from reimbursement.

INTRODUCTION:
In 2011 the AMNOG evaluation process for new drugs was implemented in Germany. Since then the evidence requirements follow high standards and results impact reimbursement price negotiations. More recently, in 2016, a legal norm ($137h SGBV) to evaluate new treatment and diagnostic methods (MDs) of high risk classes by the Federal Joint Committee (G-BA) was introduced. The requirements, involved stakeholders, timing and results for both processes are outlined and compared.

METHODS:
Methodological guidelines from G-BA and Institute for Quality and Efficiency in Health Care (IQWiG), consultations and evaluations for MDs according $137h and for drugs according AMNOG were reviewed and compared. Published assessment results were analyzed according the decision criteria and impact on price negotiations with Statutory Health Insurance (SHI).

RESULTS:
Hospitals need to submit jointly with the manufacturer comparative evidence on clinical efficacy, safety and cost when applying for additional compensation (NUB application) for new high risk class MDs being subject to $137h. A fast track assessment by IQWiG/G-BA follows within four months resulting in benefit proven, potential benefit or no benefit compared to alternatives. The latter can lead to exclusion from reimbursement. Until now one MD was granted a benefit, 2 treatments were assigned a potential benefit and 6 MDs no benefit, while 55% of drugs evaluated under AMNOG were granted an additional benefit. Compared to drugs, the required evidence for MDs is similar. Whereas assessment time is shorter, manufacturer can seek advice from G-BA upfront for free and need to collaborate closely with hospitals.

CONCLUSIONS:
Half of MDs examined did not qualify for an assessment under $137h. Unlike for drugs evaluated under AMNOG the majority of new MDs failed to be granted potential benefit as a treatment alternative and might be excluded from reimbursement. Manufacturers are challenged to generate high quality, comparative evidence within their studies.

PP22 Methodological Standards For EU Joint Clinical Assessment Beyond 2020

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
The 2018 European legislative proposal on Joint Clinical Assessments (JCA) raises questions for stakeholders regarding the development of methodological standards and the implications for future EU HTA. The research addresses the current methodological approach to JCA, present challenges faced by manufacturers, and discusses potential solutions.

INTRODUCTION:
In January 2018, the European Commission (EC) presented a HTA regulation proposal aimed at ensuring equal access to innovative health technologies for EU patients and improving business predictability. One key pillar of the EC regulation is focused on Joint Clinical Assessment (JCA), which aims to standardize and centralize HTA procedure for clinical evidence beyond 2020, provided the regulation comes into effect. The JCA methodology approach is supported and underpinned by a series of guidelines, published by the European Network for Health Technology Assessment (EUnetHTA). The objective of this work has been to critically review the current EUnetHTA methodological standards and identify the key challenges faced by pharmaceutical manufacturers in Europe in the development of JCA and implications for future JCA within EU Member States.

METHODS:
Nine of the fifteen methodological guidelines spanning across five core topics have been selected and critically reviewed: clinical endpoints, comparator selection, direct and indirect treatment comparison, health-related quality of life and utility measures, internal validity of studies, and personalized medicine and co-dependent technologies.

RESULTS:
Guidelines must address potential issues that manufacturers may face in meeting the EC’s centralised process including long-term extrapolation from key pivotal studies (e.g. survival analysis for immune-oncologic therapies, statistical methods), variability on surrogate endpoints assessment, and acceptance of real-world evidence. The implications regarding context-specific needs in applying the methods for future JCA are addressed, with an emphasis on the reduction of decision uncertainty.

CONCLUSIONS:
The outcomes from this study are centred on generating a greater understanding of the current consensus in the methodologies to be considered when approaching JCA in Europe. Ensuring that the guidelines include state-of-the-art methods and are suitable for new innovative technologies is key. The findings will contribute to the debate surrounding the development of the guidelines to be implemented under the EC’s proposed regulation on clinical HTA.

PP23 Plain Language Advice On Medical Devices

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
Sharing experiences from Scotland of converting advice aimed at decision-makers into language accessible to the wider healthcare consumer population. Examples of summaries of advice on medical devices and integration of plain language summaries into a national rapid HTA program.

INTRODUCTION:
The Scottish Health Technologies Group (SHTG) produces rapid reviews and advice to inform decision making in NHSScotland. Topics considered by SHTG can be technically complex and involve terms unfamiliar to healthcare consumers.
This poster describes SHTG experiences of producing plain language summaries of advice to a national health service.

**METHODS:**
A template and standard operating procedure for writing plain language summaries were developed. Summaries were created for all SHTG advice since February 2018.

Guidance on presenting systematic review results to healthcare consumers was adapted for SHTG.

Volunteers, known as public partners, were consulted on draft summaries prior to publication.

**RESULTS:**
Eleven plain language summaries were published in 2018. Summaries related to a wide range of topics including: digital breast tomosynthesis, Freestyle Libre® flash glucose monitoring for diabetes, and colon capsule endoscopy for detecting bowel polyps.

Each plain language summary:
- Explains the advice given to NHSScotland
- Describes the condition of interest and the health technology
- Summarizes the evidence used to generate advice
- Highlights any recommended future work on the topic

For one topic, colon capsule endoscopy, a diagnostic test consequence graphic for plain language summaries of Cochrane diagnostic accuracy reviews was used to illustrate the content of the advice summary. This will be included in the poster.

Three public representatives who are members of SHTG, and two patient organisations, have commented on draft summaries. Comments mainly related to choice of wording, clarity of advice, and tone of the summary.

One patient organisation representative stated: “I want to say how good it is to see the summary in plain language – it definitely makes the advice summary much more accessible.”

**CONCLUSIONS:**
Advice on medical devices aimed at healthcare decision-makers can be converted to language accessible to the wider healthcare consumer population. It is hoped future plain language summaries will make SHTG advice more accessible to all stakeholders.

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**PP24 The Impact Of Real-World Evidence On Demonstrating Clinical Value In Health Technology Assessments**

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**ABSTRACT SUMMARY:**
This research investigates the impact Real World Evidence has when submitted to support clinical evidence in Health Technology Assessments.

**INTRODUCTION:**
In 2016, the US Food and Drug Administration (FDA) issued new guidance to facilitate expanded use of Real World Evidence (RWE) in medical device development. Europe’s European Medicines Agency (EMA) initiated a 2-year project, from 2014-2016, which focused on RWE use by drug manufacturers; since then, the EMA has been actively communicating with pharmaceutical
companies to provide guidance on use of RWE for market authorisation purposes. Guidance from health technology assessment (HTA) bodies on the use of RWE is less clear. This delayed conformity of guidance results in a lack of clarity on the impact RWE currently has in HTA decision making. The objective of our research was to investigate the current role of RWE in demonstrating clinical value in HTAs.

METHODS:
All HTAs (original single drug assessments and resubmissions) published by key HTA-bodies in Canada (CADTH), France (HAS), Germany (IQWiG and G-BA), and the United Kingdom (NICE and SMC) between August 2013 and August 2018 were identified. HTA reports were analysed for inclusion of RWE to demonstrate the clinical effectiveness of the drug, and studied on type of RWE submitted, HTA outcome and decision drivers.

RESULTS:
In total, 2,327 published HTAs were identified of which 30% included RWE to support clinical evidence. The use of RWE to support clinical evidence has increased over the years; in 2013, only 21% of submissions included RWE for proving clinical effectiveness, while this increased to 40% in 2018. Extension studies (46%) and observational/ cohort data (36%) were the main sources to collect RWE. We did not see significant differences in HTA outcomes between cases where RWE was, or was not submitted.

CONCLUSIONS:
The use of RWE in HTAs to demonstrate clinical effectiveness is increasing, however to date its impact on HTA decision making has been limited.

PP25 Using Healthcare Analytics Tools To Selecting Medical Equipment

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ABSTRACT SUMMARY:
A medical equipment selection method which takes in account opinions gathered from different end-users, as well as the analysis of tangible and intangible characteristics, enabling managers to rank equipment alternatives in a multi-criteria context. Results showed that the method enabled the assessment of different alternatives of a medical recliner driven by an end-user perspective.

INTRODUCTION:
Medical device acquisition represents a large percentage of hospitals’ annual budgets, which makes cost-efficiency a priority to hospital managers. A key element to achieve cost-efficiency is to identify which manufacturer provides a solution that best fulfils the needs of end-users. However, users may vary in nature and, consequently, they may present different requirements regarding an equipment. Thus, requirements from different types of users should be jointly considered when selecting the best device option. In addition, characteristics valued by end-users in a device may be tangible, such as technological aspects, or non-tangible, such as comfort or maintainability. This paper presents a medical recliner selection method which takes in account opinions gathered from different end-users, as well as the analysis of tangible and intangible characteristics, enabling managers to rank equipment alternatives in a multicriteria context.
METHODS:
The method is divided in two main steps: (1) Definition of importance scores and evaluation coefficients for the equipment characteristics; and (2) Evaluation of equipment alternatives. In each step, different methods were used: decision analysis tools, such as the Analytic Hierarchy Process (AHP), Quality Function Deployment, statistical sample survey techniques and utility functions, such as the desirability function. The proposed method was applied in a case study with the objective of determining the best choice of medical recliner to be used different hospital services.

RESULTS:
Warranty length and Patient safety were the top ranked equipment qualitative characteristics as result of the AHP analysis. Results demonstrated that all hospital services analysed would be able to use the same medical recliner, as no significant difference were found.

CONCLUSIONS:
Results showed that the method enabled the assessment of different alternatives of a medical recliner driven by an end-user perspective, suitable to the requirements of patients and health professionals from different hospital services.

ABSTRACT SUMMARY:
The clinical utility of germline genetic tests depends on how well clinicians understand and convey the results, and subsequent care provided to patients and their families. When there is a shift from regional to federal funding, there are a number of critical issues that must be addressed in the HTA to determine the true value of the test.

INTRODUCTION:
Australia has a two-tier public funding system and many genetic tests are funded by different states and territories prior to being considered for public funding by the Federal government. In this context, HTAs of genetic tests for heritable conditions are problematic. We aimed to discuss the possible impacts on HTA methodology of a shift from regional to Federal funding for genetic testing for heritable conditions.

METHODS:
Several HTA reports and economic models on genetic tests considered by the Medical Services Advisory Committee were reviewed and compared to 'real world' clinical practice.

RESULTS:
Testing for BRCA1/2 for patients with breast cancer currently occurs in Familial Cancer Centres, and testing for germline mutations for familial hypercholesterolaemia currently occurs through specialist lipid clinics. In both settings, both the index patient and family members are given multidisciplinary support, including genetic counselling. In the HTA reports the clinical and cost effectiveness of the tests were evaluated compared to what would be done in the absence of genetic testing (i.e. testing through state/territory-based funding was ignored) and the evidence identified was predominantly sourced from specialised centres. The clinical utility of these tests largely depended on how clinicians understood and conveyed the results. Federal funding means that tests may be ordered by a broader range of specialists or general practitioners.

PP26 Shift From Regional To Federal Funding: Methodological Considerations

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CONCLUSIONS:
The benefit of testing may have been overestimated due to the comparator and setting used (i.e. specialised and centralised care, associated with high clinical utility). Any HTA of genetic testing for heritable conditions, which could result in a shift in the delivery of testing or care for the patient, should consider the applicability of the evidence identified, and the subsequent impact this may have on the effectiveness and cost-effectiveness of the test and the quality of care provided for patients and their family.

PP27 Additional Capabilities In HTA To Support Decision Making

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ABSTRACT SUMMARY:
Additional capabilities in HTA, including systematic review, waste management laws and regulations, local registry of reported incidents/accidents, occupational health and safety database, electronic patient records, field evaluation, costs, and survey were used to assist decision makers on the choice of a fluid waste management system in the planning of thirty operating rooms of a new hospital at the CHU de Québec-Université-Laval

INTRODUCTION:
Decision making regarding an open or a closed fluid waste management system (FWMS) in the planning of thirty operating rooms (OR) of a new hospital at the CHU de Québec-Université-Laval was an opportunity to explore additional capabilities in HTA to support evidence-based planning.

METHODS:
Issues related to FWMS in OR were assessed from multiple data sources including: 1) systematic review (SR) in indexed database and grey literature, 2) waste management laws and regulations, 3) local registry of reported incidents/accidents, 4) occupational health and safety database, 5) electronic patient records (EPR), 6) field evaluation of 2 closed FWMS, 7) costs, and 8) survey on FWMS in OR of other Quebec hospitals.

RESULTS:
Closed FWMS in OR could reduce health care professional exposure to blood and body fluids (BBF) according to two low-quality studies. Cases of occupational and patient exposure to BBF with closed FWMS, some of which had severe issues, were reported to the U.S. FDA. Depending of the volume, discharge of BBF to the sanitary sewer may be authorized upon the approval of the competent municipal authorities. Compared to open system, closed FWMS has the potential to reduce manipulation of canisters during the cases because of large canister capacity (24 L). However, local data showed that BBF and irrigation fluid amounts in OR are < 100 mL in 75% of cases and > 2 L in minority of surgeries whereas closed FWMS is associated with higher costs for BBF volumes < 12 L. Other issues were observed during field evaluation (e.g. occupational noise). Closed FWMS implementation in other hospitals was very limited in the survey.

CONCLUSIONS:
Available evidence do not support the widespread use of a closed FWMS. Use of mixed-methods in this particular HTA allowed to assist decision makers on the choice of a FWMS in the OR planning.
PP28 Adoption Of Non-Pharmaceuticals In Galicia: Beyond Conventional HTA

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ABSTRACT SUMMARY:
The specificities of non-pharmaceuticals can require for adapting classical HTA methodologies and developing additional regional approaches to support decision-making processes.

INTRODUCTION:
The specificities of non-pharmaceuticals can require for adapting classical HTA methodologies and developing additional regional approaches to support decision-making processes. However, little information exists regarding the explicit approaches used in different countries. The aim of this work is to provide an overview of the role and activities of the Galician HTA agency (avalia-t, Spain) regarding assessment, appraisal and continued evaluation across the whole life cycle of non-pharmaceutical technologies.

METHODS:
In depth review and analysis of the activities undertaken by avalia-t during the past 5 years to support the introduction and appropriate use of non-pharma health care technologies at the regional level.

RESULTS:
A multidisciplinary Commission judges the added value of new non-pharmaceuticals and establishes the indications and conditions for use. HTA assessments, which are mandatory for all relevant technologies, rely on the best available evidence on safety and effectiveness but also provide fit for purpose contextualized information based on organizational data and administrative registers. Interaction with multidisciplinary stakeholders is commonly needed to complement the evidence base (ad hoc working groups, face to face discussions), and post-launch studies can be implemented to analyze the utilization and results in real world practice. Performance indicators and other HTA based products can also be required to ensure the quality of health care (appropriate use indications, quality indicators, evidence based patient information, etc.). In additional, technical and scientific advice/support can be provided at different decision levels of the health organization to promote the quality of care and appropriate use of technologies (regional mental health programme, suicide management strategy, bariatric surgery surveillance registry, etc.).

CONCLUSIONS:
Rigorous, comprehensive and systematic processes for supporting non-pharmaceutical technologies adoption and implementation are required. Although it is acknowledged that core information does not differ substantially within countries, contextualized information is recognized essential for establishing the conditions for use at the regional level.

PP29 Early Experiences With CADTH/NICE Parallel Scientific Advice Pilot

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ABSTRACT SUMMARY:
This abstract will detail Takeda’s experiences with the first ever CADTH/NICE parallel scientific advice pilot.

INTRODUCTION:
Randomized controlled trials are considered the gold standard for evidence of clinical efficacy and safety for regulatory and HTA bodies and use in clinical practice. Designing the “right” comparative development programs that maintain clinical relevance in rapidly advancing therapeutic areas is becoming increasingly challenging.

METHODS:
Early scientific advice programs are non-binding services offered by several HTA agencies internationally which have the potential to provide insight into possible areas of concern in the proposed study protocol and RWE collection when modifications are still possible. Takeda is seeking scientific advice from several HTA agencies in order to ensure that multiple HTA perspectives are taken into account in the global oncology development program for a drug that targets a rare patient population in an area of high unmet need. Advice is being sought on both the phase 2 and phase 3 development plans, and on how to optimally generate and use RWE to achieve earlier access for patients.

RESULTS:
Although separate scientific advice was being sought from CADTH and NICE initially to ensure that multiple HTA perspectives were included, Takeda went on to enlist as part of the first ever CADTH/NICE parallel scientific advice that will allow different HTA perspectives to be better aligned.

CONCLUSIONS:
Takeda’s experience with the CADTH/NICE pilot will be highlighted.

PP30 Do Conditional Regulatory Pathways Affect HTA Recommendations?

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ABSTRACT SUMMARY:
In this study, the effects of regulatory conditional approvals were investigated in terms of their HTA recommendations and timing in Europe. Generally, the conditional pathways were associated with a higher proportion of positive recommendations but a longer time between regulatory approval and HTA recommendation as compared to standard pathways.

INTRODUCTION:
In an effort to expedite the approval of drugs treating serious illnesses or addressing unmet medical need, conditional approvals have been used by EMA. In this study, the effects of conditional approvals were investigated in terms on HTA recommendations and timing in Europe.

METHODS:
First HTA recommendations of new active substances (NASs) issued between 2015 and 2017 were collected from NICE (England), HAS (France), IQWiG (Germany), SMC (Scotland) and TLV (Sweden). The HTA recommendations were then classified into the following categories: positive, positive with restrictions, negative and multiple and if the regulatory approval pathway had been standard or conditional.

RESULTS:
Of this cohort of NASs that received a HTA
recommendation, 8/56 in England, 12/83 in France, 11/77 in Germany, 9/58 in Scotland and 4/49 in Sweden were approved via a conditional review. Generally, except England, there were a higher proportion of positive 1st recommendations for conditional approvals when compared to standard approvals, with Germany showing the largest proportional difference (43 percent) between the two pathways and also a faster time to recommendation. This may relate to the proportion of conditional assessments that were orphans medicines. With the exception of Germany, the time taken from regulatory approval to 1st HTA recommendation for products with conditional approvals is higher than those for standard approvals, with the largest difference seen in Sweden (241 days longer).

CONCLUSIONS:
Conditionally approved NASs showed a variable HTA outcome; although there was generally a higher proportion of positive recommendations thus enabling a more likely access in conditional approvals, the timing from regulatory approval to HTA recommendation was longer compared with standard approvals. This warrants a better understanding of the factors and uncertainties underlying these recommendations, supporting timely access of NASs with conditional approval.

INTRODUCTION:
In 2017, the EU commission released the final versions of the Medical Device Regulation (MDR) and In-vitro Diagnostic Device Regulation (IVDR). These regulations will replace the EU directives (MDD, IVDD, and AIMD). EU regulations are effective in all EU countries with date of publication. In contrast, the EU directives must be implemented in national law first.

METHODS:
Guidelines and respective legislation, consultations results and methods/medical devices (MDs) evaluations were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

RESULTS:
Manufacturers have to be aware of the importance of clinical data for demonstrating the compliance of their products. This applies both to the approval of the products and the “post-market activities” and particularly to the “post-market clinical follow-up” (PMCF) for which requirements for Class I and II products need to be further developed. MDR requires manufacturers to collect clinical data before and after approval which could lead to excessive documentation requirements. The term “sufficient clinical data” from the MDR is unclear. A functional Eudamed specification is necessary which enables an automated processing of relevant data.

A stronger involvement in the evaluation process is needed as well as more transparency in the Joint Federal Committee (G-BA) and faster evaluation processes.

PP31 Medical Device Regulation: What Is New?

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ABSTRACT SUMMARY:
In 2017, the EU commission released the final versions of the Medical Device Regulation. MDR requires manufacturers to collect clinical data for the approval of the products and the “post-market activities” and particularly to the “post-market clinical follow-up” for which requirements for Class I and II products need to be further developed. The analysis presents criteria, risks and outcomes.
CONCLUSIONS:
The MDR increases the burden especially for small businesses and it is doubtful that the ultimate goal – improving patient safety – will be achieved. The increased demands and rising costs of the new EU Directive MDR and bottlenecks at Notified Bodies can be a risk for the MD industry. Due to the general reduction in the remuneration for services with a high proportion of technical services it is feared that products will be withdrawn from the market for economic reasons or that they will not be marketed.

PP32 Joint Early Dialogues Between Medical Device Regulation And HTA

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ABSTRACT SUMMARY:
The new Medical Device Regulation (MDR) will have to be applied until 2020. Stricter evidence requirements for high risk medical devices may close the evidence gap as well for reimbursement decisions. Joint early dialogues on evidence generation for manufacturers between regulators and HTA bodies on the European level might be a way forward. Results of a EUenetHTA workshop.

INTRODUCTION:
In Europe, the new MDR and in vitro diagnostics regulation (IVDR) that entered into force 2017, will have to be applied until 2020 and 2022 respectively. Under the old regulation, there was a large gap between evidence requirements for market approval and market access for high risk (class IIb and III) medical devices (MD). The MDR/IVDR will require appropriate clinical investigations for these MD classes. Despite the different purpose of market approval, and surveillance and reimbursement decisions there are possible synergies with regard to evidence generation, e.g. design of pivotal trials and post-launch evidence generation with observational data. In the MDR early scientific advice can be provided by expert panels of the European Commission if requested by MD developers. For medicinal products the European network for Health Technology Assessment (EUenetHTA) has established joint early dialogues (JED) of HTA agencies with the European Medicines Agency and manufacturers. A similar approach might be possible with the MDCG. The objective was to explore possible synergies for JED with the MDCG and EUenetHTA.

METHODS:
In 2018 the European network for Health Technology Assessment (EUenetHTA) has established a task force for HTA and MDR/IVDR. A workshop, which will explore possible synergies, and activities on JED as well as the viewpoints of stakeholders will be held in May 2019. Participants will be Directorate-Generals GROW and SANTE, EUenetHTA members assessing MD, representatives of national competent authorities, Team Notified Bodies, medtech Europe, patient representatives and academia.

RESULTS:
A report on the presentations, the results of the discussion, and next steps in a possible collaboration will be presented.

CONCLUSIONS:
A joint early scientific advice to manufacturers on European level for evidence generation by HTA agencies and the MDCG has the potential to streamline evidence generation in the life cycle of high risk MD.
PP34 Costs Of Healthcare-Associated Infections In Latin America

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ABSTRACT SUMMARY:
We conducted a systematic review of papers reporting on incremental costs, mortality and length of stay of patients with healthcare associated infections in Latin America and the Caribbean, focusing on surgical site infections, catheter associated urinary tract infections, ventilator associated pneumonia, and central line associated bloodstream infection. A total of 87 studies from 17 countries were included.

INTRODUCTION:
Healthcare-associated infections (HAI) are among the most common preventable health adverse event, associated with significant burden globally. Limited data on HAI costs in lower and middle-income countries is available. The aim of this study is assess the cost, additional length-of-stay (LOS) and extra-mortality of HAI in the Latin American and Caribbean (LAC) Region.

METHODS:
We searched Medline/PubMed, Embase, Web of Science, Lilacs, Cochrane, NHS-EED, CRD, Econlit, and gray literature published in any language without restriction of date till July 2017. We included observational studies addressing the outcomes of interest, in which hospitalized patients with HAIs are compared to those without HAI. The following study designs were included: quasi-experimental, controlled before-after, prospective and retrospective comparative cohort, case-control, and cross-sectional studies. We considered the following HAI-sites: surgical site infections (SSI), catheter-associated urinary-tract infections (CA-UTI), ventilator-associated pneumonia (VAP), and central line-associated bloodstream infection (CLA-BSI), as well as cross-infection (CI). Screening of citations, data extraction, and risk of bias assessment were conducted in duplicate by independent reviewers, according to the study protocol registered on PROSPERO. Reported costs were converted to US considering official exchange rates.

RESULTS:
We identified 4,339 citations. After removing duplicates a total of 3,029 citations were screened for eligibility. A total of 87 studies from 17 countries were included. The majority (27.4 percent) reported on VAP, followed by CLA-BSI (21.2 percent), SSI (16.4 percent), and CA-UTI (14.4 percent). Most studies (46.7 percent) reported on incremental LOS, with average of 14.8 days (range 0.9-49 days). Costs were reported by 25 percent of studies, with average incremental costs of USD 3,460 (range 49-12,155). Average extra mortality of 15.6 percent (range -2.8-45.2 percent) was reported by 12.6 percent of studies.

CONCLUSIONS:
Available evidence from LAC Region reports significant economic burden of HAI. This information will be useful for cost-effectiveness analysis of interventions aimed at reducing HAI economic and health burden.

PP35 Valuing Intersectoral Costs And Benefits Of Interventions

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ABSTRACT SUMMARY:
There is a lack of knowledge about methods for valuing health intervention-related costs and monetary benefits in the education and criminal justice sectors, also known as ‘inter-sectoral costs and benefits’ (ICBs). The objective of this study was to develop methods for obtaining unit prices for the valuation of ICBs.

INTRODUCTION:
There is a lack of knowledge about methods for valuing health intervention-related costs and monetary benefits in the education and criminal justice sectors, also known as ‘inter-sectoral costs and benefits’ (ICBs). The objective of this study was to develop methods for obtaining unit prices for the valuation of ICBs.

METHODS:
By conducting an exploratory literature study and expert interviews, several generic methods were developed. The methods’ feasibility was assessed through application in the Netherlands. Results were validated in an expert meeting, which was attended by policy makers, public health experts, health economists and Health Technology Assessment (HTA)-experts, and discussed at several international conferences and symposia.

RESULTS:
The study resulted in four methods, including the opportunity cost method (A) and valuation using available unit prices (B), self-constructed unit prices (C) or hourly labor costs (D).

CONCLUSIONS:
The methods developed can be used internationally and are valuable for the broad international field of HTA.

PP36 Inflammatory Bowel Disease: The Disability Costs Among Italian Workers

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ABSTRACT SUMMARY:
This study estimates the disability insurance costs induced by patients with Inflammatory Bowel Diseases (IBD) and specifically for Crohn’s disease (CD) and Ulcerative Colitis (UC) between 2009 and 2015. In Italy, the Social Security System is financed by public expenditure, and IBD impose a significant burden on it: € 20 million each year, € 143 million in the considered period.

INTRODUCTION:
The aim of the study is to estimate the disability insurance costs (social security system in Italy is financed by public expenditure) induced by patients with Inflammatory Bowel Disease (IBD) and specifically for Crohn’s disease (CD) and Ulcerative Colitis (UC) between 2009 and 2015.

METHODS:
We analyzed the database about the disability insurance awards and the mean cost per benefit of the National Institute of Social Security (INPS) for two types of social security benefits: incapacity pensions (IP - for people without workability) and disability benefits (DB - for people with reduced work ability). From this data, we have estimated the total benefit provided and the total costs for each
disease. A probabilistic model with a Monte Carlo simulation was developed in order to estimate the total benefits provided and costs.

RESULTS:
For CD an average of 820 beneficiaries of social security benefits were detected per year (2009-2015): the total expenditure was € 50 million, € 7 million per year (about € 7,900 per patient); for UC about 1,550 beneficiaries per year were detected and the total expenditure was € 93 million, € 13 million per year (about € 8,600 per patient).

CONCLUSIONS:
The disability insurance costs related with the management of CD and UC showed a significant impact on the expenditure for the Italian system: the most important costs for disability for CD and UC in Italy in the analyzed period were DB (92% for CD and 95% for UC). A rapid access to innovative treatments could reduce the costs incurred by the social security system.

PP37 Economic And Epidemiological Impact Of Dengue Illness In Brazil

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ABSTRACT SUMMARY:
1.68 million notified cases of dengue in Brazil in 2015. Several studies have estimated costs but none from a public health (SUS) perspective. Between 2000-2015, there were 739,177 hospitalizations and SUS spent almost US$159 million and US$10 million on dengue and severe dengue, respectively. Hospitalization the main costs as most self-treated at home. Annual DALYs ranged from 72.35 to 6,824.45.

INTRODUCTION:
Dengue is a serious global health problem in endemic countries such as Brazil where it is the most important vector-borne infection. Overall there were 1.68 million notified cases in 2015. This has resulted in multiple initiatives to try and control the disease burden. Most patients with dengue in Brazil are self-treated at home. However, serious complications can arise including leukopenia, hemorrhage and circulatory collapse leading to deaths. Several studies have estimated the cost and disease burden but none from a public health perspective based on the entire population. Consequently, we sought to address this using Brazilian public health system (SUS) databases.

METHODS:
Descriptive study linking together several SUS databases from 2000 - 2015. All procedures and associated costs were obtained via the Hospital Information System (SIH). Data was broken down into specific age groups and incidences to better calculate associated disability-adjusted life years (DALYs) to improve understanding of the disease burden for future policy decisions.

RESULTS:
739,177 hospitalization procedures were verified as dengue and severe dengue during the study years. Overall, SUS spent almost US$159 million and US$10 million to treat dengue and severe dengue, respectively, between 2000-2015. The principal costs for SUS were hospitalization costs as the majority of patients were self-treated at home as only minor symptoms. On average, 273 per 100,000 inhabitants were notified to the authorities for dengue and 3 per 100,000 for severe dengue.
Annual DALYs estimates ranged from 72.35 to 6,824.45 during the course of the study period.

CONCLUSIONS:
The epidemiological and morbidity burden associated with dengue is substantial in Brazil. However, the costs to SUS costs are affected by most patients self-treating at home. Consequently, the Brazilian government urgently needs to proactively evaluate the real costs and clinical benefits of any potential dengue vaccination program versus current prevention programmes and costs to guide future decision making.

PP38 Productivity Loss In Patients With Chronic Diseases: A Pooled Analysis

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ABSTRACT SUMMARY:
A pooled analysis of patient-level data from 11 Hungarian cross-sectional, retrospective, cost-of-illness studies was performed. Female gender and older age resulted in higher productivity loss. Schizophrenia was the disease with highest indirect costs.

INTRODUCTION:
Due to the unprecedented increase in medicine prices in recent years; the socio-economic perspective started gaining importance in health economic evaluations. Productivity loss (PL) evaluations provide a long term economic impact visualization for a more informed reimbursed medicine decisions.

METHODS:
A pooled analysis of patient-level data from 11 cross-sectional, retrospective, cost-of-illness studies was performed. SPSS software was used for our statistical analysis. ANOVA and correlation analysis were utilized to measure the effect of different variables on lost productivity hours. All costs were recalculated to account for the cumulative inflation till 2018.

RESULTS:
Sample size of included studies ranged between 68 (Multiple Sclerosis) and 480 (Diabetes), and total number of patients enrolled in the analysis was 1,881 of which 956 were females. A total of 6,795 hours were reported as missed working hours per year. Overall, female population reported a mean of 689.5 lost productive hours compared to 324.7 in men (p<0.001). This translated into higher indirect costs at 2,748 EUR and 1,530 EUR for females and males respectively. Patients with a college degree or higher reported lower yearly lost productive hours and indirect costs (358.4 hr and 1,749 EUR) (p<0.001) compared to patients with lower education level (845.6hr and 3,534 respectively) (p<0.001). The average indirect cost as a percentage of GDP per capita was highest in Schizophrenia patients at 97.5 percent and lowest in Benign Prostatic Hyperplasia at 1.9 percent. In patients below 65 years, a weak positive correlation was observed between age and lost productive hours with a Pearson value of 0.1 (p<0.001).

CONCLUSIONS:
Female gender and older age resulted in higher productivity loss and Schizophrenia was the disease with highest indirect costs per patient per year.
POster DisPlaYs

PP39 Budget Projections And Health Impact Of PD-1/PD-L1 Inhibitors

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ABSTRACT SUMMARY:
Budget Projections and Health Impact of the PD-1/PD-L1 inhibitors to inform budget planning – the experience from four European countries

INTRODUCTION:
The introduction of immunotherapy treatments in oncology has transformed cancer care, offering greater survival benefit across a range of indications. However, the rapid expansion of treatment options and potential for use for numerous cancer types has led to concerns around the long-term affordability of these products. Evidence on the potential budget and health impact of these new treatment options is required to inform public health policy and ensure adequate allocation of budget for the future in the participating countries.

METHODS:
The Health Impact Projection (HIP) model was developed to compare the economic impact and health outcomes observed in a world with and without PD-1/PD-L1 inhibitors using a traditional budget impact analysis framework. Partitioned survival models were used to estimate overall survival, progression-free survival, life years gained, and the number of adverse events (AEs) in both scenarios over the model’s five-year time horizon. Seven types of high-incidence cancers were included: melanoma, 1L & 2L non-small cell lung cancer, bladder, head and neck, renal cell carcinoma, and triple negative breast cancer. Inputs were based on publicly available data and the literature, and more than ten key opinion leaders (oncologists, health economists) were involved in the model development. The model draws on budget impact analysis for its structure and methods and can be adapted to estimate the effect of different assumptions and scenarios. Both direct and indirect costs can be included in the analysis.

RESULTS:
Using the experience of Belgium, Slovenia, Switzerland, and Italy, the model estimates budget and health impact of the PD-1/PD-L1 inhibitor class. It shows that over 5 years (2018-2022), the class will provide additional life years and avoids thousands of high-grade AEs instances with a manageable budget impact per year compared to the standard of care (SOC). The model also enables policy-makers to assess the adequacy of their budget for the near future and explore the implications of different policy decisions, such as updating the oncology budget to provide additional investment. Results for Belgium show that over the five-year period the PD-1/PD-L1 inhibitors will save 10,635 additional life years (24% increase), avoid 7,597 AEs (35% reduction) and have a budget impact of approximately €260 mln. Results for Slovenia show 1,468 additional life years gained and 869 AEs avoided with a budget impact of approximately €116 mln. For Switzerland, the figures are – 6,775 life years gained (22% increase), 6,953 AEs avoided (41% decrease), €106 mln budget impact. For Italy – 5,019 LYG; 2,040 AEs avoided; €627 mln budget impact.

CONCLUSIONS:
Although limitations exist, the model informs planning by helping quantify the potential impact of immunooncology treatments on health and budget in different scenarios.
PP40 Brentuximab Vedotin Budget Impact In CD30+ Cutaneous T-Cell Lymphoma

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ABSTRACT SUMMARY:
Cost analyses can be considered part of the Health Technology Assessment. This is even more true when talking about orphan disease often treated with high cost drugs: can the expenditure allocated for an orphan disease be considered negligible in the light of the small number of patients who are affected by the condition and who will receive the treatment?

INTRODUCTION:
Brentuximab vedotin (BV) is an orphan drug approved for the treatment of patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. The objective of this 3-year budget impact analysis was to estimate the economic implication of the adoption of BV in the Italian regions.

METHODS:
Direct healthcare costs were calculated comparing two scenarios: Current Scenario, where only treatments today used in Italy for CTCL were considered; Alternative Scenario, where BV is introduced as an alternative. The perspective of the Italian Regional Healthcare Services was adopted. An incidence model was run and the target population was estimated in 101 patients per year. Due to the small dimension of the eligible population, regional epidemiological data were obtained multiplying the national incidence by regional weights (regional weight=regional resident population/national resident population). Unit costs were based on national drug prices, regional tariffs, and published literature. The model was developed in Microsoft Excel®.

RESULTS:
According to the reimbursement conditions currently in place in Italy for BV, the national budget impact would be about €1.5 million at Year 1, €2.5 at Year 2, €3.8 at Year 3. Due to a longer Progression Free Survival and a better Overall Survival of BV vs the other options, the adoption of BV for CTCL would generate savings in terms of subsequent therapies (-23% at Year 1, -37% at Year 2, -55% at Year 3 vs Current Scenario) and end life cares (-3% at Year 1, -6% at Year 2, -9% at Year 3 vs Current Scenario). Due to the small number of eligible patients expected in each region, the budget impact would be negligible on a local level.

CONCLUSIONS:
The adoption of BV for the treatment of CD30+ CTCL patients is economically sustainable, especially in a context where no real options are available.

PP41 Cost-Effectiveness Modelling Of CAR T-Cell Therapies

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ABSTRACT SUMMARY:
This research gives an overview of the first HTA
assessments and appraisals of CAR-T therapies in the UK and the US and identifies the main challenges of estimating their cost-effectiveness for HTA submission purposes.

INTRODUCTION:
This study has two key aims. The first is to review cost-effectiveness (CE) models for chimeric antigen receptor T-cell (CAR-T) therapies that have been appraised by health technology assessment (HTA) authorities. The second is to identify the key challenges of CE modelling of CAR-T based on the main points raised in the HTA appraisals.

METHODS:
A targeted HTA review of published CE models for CAR-T therapies in the United Kingdom (UK) and United States (US) was undertaken.

RESULTS:
Four relevant CE models were identified – three from the UK and one in the US. Of the three UK models – two were single technology submissions to The National Institute for Health and Care Excellence (NICE) and one was a ‘mock’ appraisal undertaken by NICE with a hypothetical evidence dataset. The one US model was published by the Institute for Clinical and Economic Review (ICER) committee. Two key model structures were adopted across the appraisals: a three-health state partitioned survival analysis model and a short-term decision tree followed by a three-health state partitioned survival model. The key modelling challenges identified can by summarised into five main categories: comparator evidence generation, estimation of long-term survival, curative benefit, health-related quality of life, and infrastructure/training requirements.

CONCLUSIONS:
There are many challenges associated with the CE modelling of CAR-T therapies, with the most critical issues related to how uncertainty for long-term efficacy and safety can be addressed and mitigated. With more mature evidence sets in the future, stakeholders will get a clearer picture for the long-term benefit and risk of CAR-T, but until then it is likely that HTA authorities will take a conservative stand when appraising the comparative value of CAR-T therapies.

PP42 Wearable Cardioverter/Defibrillator: Body Of Evidence Assessment

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ABSTRACT SUMMARY:
While sudden cardiac death is the most frequent cause of death, effective risk stratification is of utmost importance. In 2018, the first randomized trial (VEST) was conducted on the Wearable Cardioverter Defibrillator (WCD). Furthermore, new comprehensive HTAs data are expected beginning 2019. It is essential to evaluate newly published data in the context of existing evidence and clinical practice guidelines.

INTRODUCTION:
While sudden cardiac death (SCD) is the most frequent cause of death, prevention and early intervention - especially defibrillation - is of utmost importance. Patients with previously diagnosed cardiovascular disease have a high risk of suffering from SCD in the early stages of the disease, while not eligible for an implantable cardioverter/defibrillator (ICD). Guidelines recommend a waiting period of 1-3 months for risk stratification prior to ICD implantation, during which this risk can be treated and potentially reduced to normal. Studies show that about 40% of patients improve their heart function by optimized heart failure medication, making an ICD unnecessary.
During these early high risk periods, patients can temporarily be protected by a non-invasive WCD. Several systematic literature researches as well as Health Technology Assessments (HTAs) have been conducted on the WCD, which shall be introduced and discussed in short. In 2018, the first randomized trial (VEST) was conducted on the WCD. Furthermore, new HTAs are expected beginning 2019. It is essential to evaluate the newly published data in the context of all existing evidence and clinical practice guidelines.

**METHODS:**
Assessment of HTAs, RCT as well as prospective and retrospective studies. Alignment of evidence with international guideline recommendations.

**RESULTS:**
HTAs should consider all available evidence in order not to be misleading. Restriction to abstract scanning only can lead to wrong conclusions. While conducting an HTA, involvement of medical experts in the relevant field should be mandatory to prevent misunderstanding of the technology. Consistency between high and low level studies should be considered. The WCD has been proven to be safe and effective when worn and to prevent patients from SCD during times of temporary risk.

**CONCLUSIONS:**
Considering all available evidence, the WCD proves itself as a safe and reliable device that is very effective when worn. The WCD allows for a necessary risk stratification during the evaluation phase. If patients are carefully selected and sufficient compliance is ensured, mortality can be significantly reduced in the early phase of a cardiovascular disease.

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**PP43 Decision-Making Tool In Case Of B-Lactam Allergy: How To Help Clinicia**

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**ABSTRACT SUMMARY:**
Fearing cross-reactivity with a beta-lactam when it is indicated to treat infection of a penicillin-allergic patients is not uncommon. To help clinicians to better manage the risk attributed to penicillin allergies a decision aid including an algorithm has been developed by using an approach based on knowledge mobilization framework evidences and interactions with stakeholders to meet the needs of concerned-actors.

**INTRODUCTION:**
Beta-lactams (BLs), especially penicillins, are the most commonly used antibiotics, particularly in primary care, and one of the most reported drug allergies. Fearing cross-reactivity, clinicians refrain from prescribing another BL (e.g., cephalosporin or carbapenem) to penicillin-allergic patients. This can have significant consequences for the patients and the health-care system (e.g., exposure to broad-spectrum antibiotics, an increased risk adverse effects, and increased health-care costs).

**METHODS:**
To assess the absolute cross-reactivity risk, two systematic reviews with meta-analysis were conducted. Then, an approach based on knowledge mobilization framework considering scientific, contextual and experiential evidences, has been used. Focus groups with stakeholders,
including primary care clinicians, paediatricians, infectious disease specialists and allergists/immunologists have also been held to meet the needs of all actors concerned.

RESULTS:
Following this work it is appeared that true allergies to penicillin are very rare. Indeed, in patients with a history of penicillin-allergy, very few are truly allergic and thus the risk of cross-reaction with another BL is even lower, varying according to structural and physicochemical similarities with alleged-penicillin. Moreover, the risk of having an anaphylactic reaction after penicillin exposure is very low, especially among children. As well, in patient with confirmed penicillin allergy, the observed reactions are usually delayed non-severe skin reactions. However, with a confirmed penicillin allergy, it is important to remain cautious when administering a new BL, especially if the initial reaction was serious or severe. Based on these key messages a decision aid including an algorithm has been developed. Likewise, individualized algorithms for common infections met in primary care were produced.

CONCLUSIONS:
By these work health professionals non-specialized in allergology should be able to better manage the risks attributed to penicillin allergies. Therefore, patient should receive the most effective and safe antibiotics to treat their clinical conditions in primary care.

PP44 Optimal Use Of Warfarin: Self-monitoring From a Quebec Perspective

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ABSTRACT SUMMARY:
Availability of portable coagulometers holds the promise of reducing the burden of International Normalized Ratio monitoring for warfarin-treated patients. Specific recommendations on the use of self-monitoring in Quebec (Canada) and a decision aid to help discussion between patients and health professionals were thus developed, based on knowledge mobilization framework evidences and interactions with stakeholders to meet the needs of concerned-actors.

INTRODUCTION:
Frequent standard International Normalized Ratio (INR) monitoring by health professionals is one of the major inconveniences reported by warfarin users. However, portable coagulometers are now available to reduce this burden by allowing patients to self-monitor their INR in the comfort of their home, thereby reducing their visiting frequency to a medical clinic. The aim of this work was thus to elaborate recommendations on the use of self-monitoring in the management of warfarin-treated patients in the province of Quebec.
**METHODS:**

Systematic literature reviews were conducted to retrieve the most up-to-date scientific data from primary studies and pharmacoeconomic evaluations as well as recommendations from published clinical practice guidelines. This information was then triangulated with the experiential knowledge of Quebec experts and clinicians collaborating to the project.

**RESULTS:**

The scientific, contextual and experiential evidence gathered during this work provided convincing support for the use of self-monitoring for long-term warfarin-treated patients, leading to a more effective treatment than standard monitoring while being safe, cost-effective and potentially improving patients’ quality of life. However, physical and mental limitations can hinder the use of portable coagulometers, outlining the need for caution in the selection and support of self-monitoring patients.

**CONCLUSIONS:**

This work led to the development of specific recommendations on the use of self-monitoring along with a clinical tool to help discussion between patients and health professionals leading to a shared decision making. This work will be part of two optimal usage guides on oral anticoagulant therapy to be published by the Institut national d’excellence en santé et en services sociaux.

**ABSTRACT SUMMARY:**

To ensure a standard quality in health care services, the implementation and use of clinical practice guidelines should be improved, but this is a complex process. To identify the barriers and facilitators to the implementation of CPGs in primary care we conducted an online survey to family physicians.

**INTRODUCTION:**

Clinical practice guidelines (CPGs) are valuable tools to improve quality of care, patient outcomes and cost-effectiveness with the best evidence. To ensure a standard quality in health care services, the implementation and use of clinical practice guidelines should be improved, but this is a complex process. These factors need to be determined in order to increase the use and implementation of CPGs in Turkey. The aim of the study is to identify the barriers and facilitators to the implementation of CPGs in primary care.

**METHODS:**

We conducted an online survey of family physicians to assess resource, system, and attitudinal barriers and facilitators. We also asked a set of questions related to improving the use of clinical practice guidelines in their daily clinical practice.

**RESULTS:**

322 family physicians approved to participate in the study. 266 of them stated that they heard the definition of CPGs. Most respondents (67.4%) used treatment guidelines. The diseases that the guidelines are most used for are diabetes mellitus (59.1%), hypertension (57.6%) and hyperlipidemia (32.1%). 73.9% of the respondents used guidelines to diagnose. Lack of adequate administrative support and resources was the barrier identified by the most physicians (52.9%), followed by lack of time to have information about existing guidelines, not to be expecting to use guidelines (47%). Most of the physicians agreed with the statement that they can treat their patients better with the guidelines (47.6%) and patients can...
benefit from health care services accurately by guidelines(47.2%) .

CONCLUSIONS:
In order to increase the use of the CPGs, decision-makers need to make many arrangements in health services.

PP46 Lactobacillus Rhamnosus And Dermatites In Children: A Meta-Analysis

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ABSTRACT SUMMARY:
Clinical trials included involved 94 randomized children and did not demonstrate benefit of the addition of L. rhamnosus in dermatitis caused by allergy to cow’s milk protein. Studies have shown that the control and experimental groups evolved to improve dermatitis and did not demonstrate significant differences in severity of dermatitis between the experimental and control groups.

INTRODUCTION:
Allergy to cow’s milk protein (CMPA) is a common disease in children, and symptoms are found in 5 to 15% of children. In addition, hypoallergenic infant formulas should be used as well, which sometimes contain probiotics. To evaluate whether supplementation of infant formulas with L. rhamnosus is effective for the improvement of allergy-related dermatitis to cow’s milk protein in infants and children up to three years of age.

METHODS:
The search for evidence was performed in the electronic databases MEDLINE (Pubmed), EMBASE, LILACS, Cochrane Library / Health System Evidence and BIREME. The search strategy was constructed using controlled vocabulary representative of the components “population” and “intervention” of the structured question. In the MEDLINE and EMBASE databases, the descriptors referring to the “outcome” were also used, since they were bases of more robust data. Selection of the best available evidence was prioritized in the selection of randomized clinical trials, systematic reviews and meta-analyses. The sum of the search results in the electronic databases resulted in 172 references and three studies of randomized clinical trials were selected, and a meta-analysis of these clinical trials was performed.

RESULTS:
The outcome of the meta-analysis of the three clinical trials included involved 94 randomized children and did not demonstrate benefit of the addition of L. rhamnosus in dermatitis caused by allergy to cow’s milk protein. Studies have shown that the control and experimental groups evolved to improve dermatitis and did not demonstrate significant differences in severity of dermatitis between the experimental and control groups.

CONCLUSIONS:
The meta-analysis concludes that the addition of Lactobacillus rhamnosus in infant formula for children with CMPA did not show benefits for improvement of atopic dermatitis when compared to conventional treatment.

PP47 Systematic Placental Examination In The Value-Based Care Era

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ABSTRACT SUMMARY:
In an effort to rationalise services, provincial authorities asked for guidelines related to placenta management and indications for full pathological examination. Considering the multitude of clinical conditions related to placenta examination, as well as the scarcity of evidence for several of them, a Delphi-type method was used to establish a list of indications as well as other related recommendations.

INTRODUCTION:
Examination of placental tissues may reveal the aetiology of various fetal-maternal problems. However, most placentas are normal, coming from term deliveries after a normal pregnancy, with no complications for the mother and the newborn. Therefore, examination of all placentas may not optimize the use of diagnostic resources. With wide variation in practices and no provincial policy, the Quebec Ministry requested the development of guidelines concerning examination of placentas.

METHODS:
A literature search identified relevant clinical practice guidelines, health technology assessment reports, written regulations and policies. Professional, regulatory, and government websites were also consulted. A group of medical experts commented on the scientific literature, provided contextual and experiential informations, and participated in a Delphi-type process to develop a list of indications for placenta examination.

RESULTS:
Seventeen (17) documents presenting selective examination of placentas according to predetermined clinical indications were considered. Overall, 72 clinical conditions related to placenta examination were identified. According to our experts, 21 maternal, 13 fetal or neonatal, and 15 placental conditions require a thorough examination of the placental tissues, (total of 49 indications). Additional recommendations related to the triage process and the transitional conservation of placentas without indications were formulated.

CONCLUSIONS:
These recommendations aim to support local institutions to develop and update their policies concerning the optimal use of pathology services and will aid the decision-making process for clinicians who must decide whether to send a placenta to the pathology service for examination or not. In addition, these recommendations will promote standardization of practices concerning the management of placental tissues.

PP48 Risk Of Bias Of Systematic Reviews Connected To Journal Impact Factor?

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ABSTRACT SUMMARY:
This is an analysis of over five hundred systematic reviews and the potential association between their risk of bias assessments and the impact factor of the publishing journal. Findings confirm that a correlation exists.

INTRODUCTION:
Systematic reviews (SRs) are today’s cornerstone of evidence-based medicine. However, their risk of bias (ROB) may critically impact their findings.
Hence, an impartial assessment of their ROB is paramount to their interpretation.

The objective of this study is to evaluate the potential association between the results of the ROB assessment for a series of SRs and their corresponding journal’s impact factor as determined by the citation reports.

METHODS:
A sample of over five hundred SRs and their corresponding ROB will be employed in this study. The source for these data will be the database KSR Evidence. The corresponding impact factor (IF) for the publishing journal as reported by the Science Citation Index will also be retrieved.

The total of ROBIS signalling questions answered as ‘yes’ or ‘probably yes’ will be used to approximate the awarded quality (Quality) for each systematic review.

An analysis of the potential correlation between Quality and the impact factor (IF) will be performed with a simple linear regression.

RESULTS:
Results will be presented in Tables and Figures. Preliminary results confirm that a statistically significant association between the suggested variables exists though this is of low magnitude.

CONCLUSIONS:
Findings confirm that the risk of bias of a systematic review and the impact factor of the publishing journal are correlated.

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PP50 How Do Target Population Sizes In HTAs Impact Drug Price Changes?

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ABSTRACT SUMMARY:
We conduct a regression analysis to consider whether target population sizes estimated as part of positive HTA decisions impact future price changes. We hypothesize that larger target populations may result in larger drug price reductions, as overall budget impact is an important component of price negotiations. Our results supported this hypothesis, though the magnitude of the effect was low.

INTRODUCTION:
The relationship between heath technology assessment (HTA) recommendations and drug prices has received little attention in the published literature. We consider whether target population sizes estimated as part of positive HTA decisions impact future price changes. We hypothesize that larger target populations may result in larger drug price reductions, as overall budget impact is an important component of price negotiations.

METHODS:
HTA and pricing data were obtained from the Context Matters Market Access Platform (MAP) and IHS Markit’s PharmOnline International (POLI) pricing database, respectively. We analyzed 55 HTA decisions from the G-BA (Germany; Gemeinsame Bundesausschuss) and the HAS (France; Haute Autorité de Santé) for oncology products receiving EMA approval between 2011 and the end of 2014. Pricing and HTA histories were tracked from the beginning of 2012 until October 2018. Using multiple regression to control for HTA agency, country-specific scores (Improvement in Actual Benefit and Additional Benefit scores), pack size, and initial price, we examined the relationship between a drug’s price change in the year following an HTA review and the increase in target population resulting from the HTA decision.
RESULTS:
We found that larger increases in target population were related to larger reductions in drug prices (p = .014). The magnitude of the effect size was low.

CONCLUSIONS:
For the sample evaluated, we found a small but statistically significant association between target population size increases (as estimated by HTA bodies) and price reductions, supporting our hypothesis that target population plays a role in price negotiations. Confidential discounts and managed-access agreements likely account, in part, for the low magnitude of the observed association. Future work on this topic will involve larger samples covering a greater number of HTA agencies to improve the power and generalizability of the analysis.

PP51 Automated Solutions To Network Development In Network Meta-Analysis

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ABSTRACT SUMMARY:
Network meta-analyses are visualised as a complex network of interconnected treatments, treatment arms and the studies contributing to each comparison. However, building networks can be time-consuming and labour-intensive. We conducted a multi-criteria decision analysis, taking the form of a feature analysis, to evaluate software tools which facilitate network building and can help automate the process.

INTRODUCTION:
Network meta-analysis (NMA) is a statistical technique used to compare treatments when there is a lack of direct (head-to-head) evidence or to assess multiple treatments simultaneously in a meta-analysis. The approach considered an important addition to a traditional systematic review of interventions. NMAs are visualised as a complex network of interconnected treatments, treatment arms and the studies contributing to each comparison. However, building networks can be time-consuming and labour-intensive. A number of software tools have been developed which facilitate network building and can help automate the process. However, little is known about their usefulness. The objective of this work is to compare and evaluate a selection of specialised tools that support developing networks as part of a NMA.

METHODS:
We conducted a multi-criteria decision analysis, taking the form of a feature analysis, to evaluate the tools. We developed an initial evaluation framework comprising a set of required features, weightings and scoring instruments to assess the tools. We mainly assessed tools based on their level of automation, ease of adding and removing studies/interventions to and from the network, ability to label nodes and edges, and overall usability. We also took into consideration factors concerning the ease of installation and setup of the tools.

RESULTS:
We compared and evaluated four tools using the framework: namely, NodeXL, yED, Gephi and R (the ‘netmeta’ package). Each of the candidates presented some strengths and some weaknesses. NodeXL had the highest overall score and Gephi had the lowest overall score. NodeXL scored well on automated network development features and less well on ease of introduction and setup. The majority of features in Gephi were considered only partially supported leading to a lower score.
CONCLUSIONS:
The results of this study provide new insight into specialised tools that support network development as part of a systematic review and NMA. The findings have informed a refined version of the feature analysis framework, and an expansion of the Systematic Review Toolbox to classify network development tools.

PP52 Interim Decision Making To Address Uncertainty At Early Assessment

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ABSTRACT SUMMARY:
To address the high level of uncertainty about the clinical effectiveness of new medicines at the time of market access, the Scottish Medicines Consortium (SMC) has introduced a new approach which allows some medicines to be accepted on an interim basis. Early experience with this approach is presented.

INTRODUCTION:
Medicines regulation has become increasingly adaptive to support earlier patient access but the immature clinical data is often challenging for HTA decision makers due to high levels of uncertainty on long term risks and benefits. SMC is therefore exploring new, more adaptive approaches to help manage this challenge.

METHODS:
SMC consulted with key stakeholders including clinicians, the pharmaceutical industry and patient groups on a number of options that would allow the committee to make an interim decision that would be revisited based on later evidence. The ability to collect robust patient level data given data capabilities in NHSScotland was an important consideration.

RESULTS:
To ensure that additional evidence would be available to inform a re-assessment, the new approach applies to medicines with a Conditional Marketing Authorisation (MA) from the European Medicines Agency (EMA). This obligates the company to provide specified clinical data to the regulator within a pre-set timeframe. For these medicines, the SMC decision-making committee can accept or not recommend the medicine as at present but can also accept the medicine on an interim basis, if the regulator’s mandated Specific Obligations are likely to address the uncertainties in the clinical evidence. When the regulator converts the MA from conditional to standard, the company is required to make a further SMC submission to allow a reassessment and a final decision. The company can also provide additional supplementary post-licensing patient level evidence at reassessment.

CONCLUSIONS:
This new decision option allows SMC to test an approach to managing uncertainty targeted at a small number of promising new medicines where there is unmet patient need, with the reassurance that a final decision will be supported by additional clinical data.

PP53 Impact Of Therapy Lines On The Size of Target Population In Germany

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ABSTRACT SUMMARY:
Since 2011, an early benefit assessment is required for all new drugs launched in Germany. The exact determination of the appropriate target population (patients eligible for a drug) plays an important role for subsequent price negotiations. We analyzed 22 dossiers with drugs for non-small cell lung cancer and found out astonishing results.

INTRODUCTION:
Since 2011, an early benefit assessment is required for all new drugs launched in Germany. The Institute for Quality and Efficiency in Health Care assesses evidence submitted by pharmaceutical companies in dossiers. The exact determination of the appropriate target population (patients eligible for a drug) plays an important role for subsequent price negotiations. The patient group with non-small cell lung cancer (NSCLC) presents a complex situation. Our aim was to explore and compare the different steps used in dossiers to calculate the size of the target population. One of these steps was to analyze the impact of shares of patients in different therapy lines.

METHODS:
We analyzed 22 dossiers with drugs for NSCLC published between 01.01.2011 and 31.12.2017. 8 dossiers contained information about first- and second-line chemotherapy. Comparison of the details regarding the estimation of the size of the target population followed.

RESULTS:
3 steps regarding therapy lines were usually applied for patients with NSCLC: 1) share of patients with first-line therapy; 2) share of patients with chemotherapy within the first-line therapy; 3) share of patients with second-line therapy. The share differs moderately, between 76.9% and 93.8%, for the first step, dramatically, between 5.4% and 100%, for the second step and substantially, between 34.9% and 64.9%, for the third step. 5 references are often used to obtain information about the shares. These references differ regarding study location, conducting year, study design, recruited patients, etc. In some references, a patient was counted in both, first- and second-line therapy, whereas in other references a patient was counted in either first or second line therapy or a therapy break.

CONCLUSIONS:
The main reason for difference is the use of variant databases in dossiers. To determine target population in NSCLC and to reduce variation, a harmonization of databases and methods would be helpful.

PP54 A Cohort Case Study On Implantable Cardioverter Defibrillators

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ABSTRACT SUMMARY:
This retrospective study evaluated a cohort of patients with arrhythmia requiring the use of implantable cardioverter defibrillators.
implantable cardioverter defibrillators (ICDs) and/or Cardiac Resynchronization Therapy (CRT) devices. Databanks on real live patients are an important source of information in the study of the results provided by these technologies.

INTRODUCTION:
Many patients presenting with arrhythmias, with or without symptoms, are treated with antiarrhythmic drug therapy. However, for some patients, usually survivors of previous serious ventricular arrhythmias, treatment implies in the use of implantable cardioverter defibrillators (ICDs) and/or Cardiac Resynchronization Therapy (CRT) devices.

METHODS:
This retrospective study evaluated a cohort of patients with arrhythmia requiring the use of ICDs, CRT or ICDs + CRT from Jan 2004 to Mar 2018. Data from a private healthcare organization in Belo Horizonte, Brazil (administrative database, software Oracle Business Intelligence) were used to assess all-cause mortality and the need for replacement of the device. Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log-Rank test were used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This historical cohort resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS:
593 patients were included in the study (median age 67.6 years, range 23 to 89 years; male 62 percent). According to the type of device used to treat these patients, the distribution was 338 (57.0 percent), 169 (28.5 percent), 86 (14.5 percent), for ICDs, ICDs + CRT, CRT, respectively. After a mean follow-up time of 3.12 years (range 0 to 13.6 years) 283 devices were replaced (ICDs n=140; ICDs + CRT n=90; CRT n=53) and 284 deaths occurred (median survival of 6.9 years). The median survival was 7.3, 5.8, 4.8, 5.5 years for ICDs single-chamber, ICDs dual-chamber, ICDs + CRT, CRT, respectively.

CONCLUSIONS:
Randomized trials are often criticized for their enrolment of highly selected patients, unlike those encountered in real life. Studies on databanks are a good alternative since it can provide reliable information regarding the use of implantable cardioverter defibrillators (ICDs) and/or Cardiac Resynchronization Therapy (CRT) devices in the treatment of real-life patients with serious ventricular arrhythmias.

PP55 The Effectiveness Of Viabahn In Peripheral Artery Aneurysms

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ABSTRACT SUMMARY:
Open repair was considered for several years the gold standard therapy for the treatment with peripheral artery aneurysms (PAAs). However, with advancements in endovascular technology increasing attention has been directed toward repairing PAAs using an endovascular stent graft. This retrospective study evaluated a cohort of patients after the correction of PAAs with Viabahn.
INTRODUCTION:
Open repair was considered for several years the gold standard therapy for the treatment of peripheral artery aneurysms (PAAs). However, with advancements in endovascular technology increasing attention has been directed toward repairing PAAs using an endovascular stent graft.

METHODS:
This retrospective study evaluated a cohort of patients after the correction of PAAs with Viabahn. Patients treated from Jan 2011 to Jan 2018 were assessed for all-cause mortality, amputation and the need for re-intervention. Data were extracted from an administrative database from a healthcare organization in Belo Horizonte, Brazil (software Oracle Business Intelligence). Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log Rank test were used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This historical cohort resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS:
52 patients were included in the study (median age 69.1 years, range 15 to 90 years; male 63.5 percent), 3 of whom also received Viabahn for contralateral PAAs. In total, 84 devices were used (average 1.5 per PAAs); with the following distribution: popliteal and tibial arteries (n=30; 57%), femoral and iliac arteries (n=19; 37 percent), axillary artery (n=1; 2 percent), splenic artery (n=1; 2 percent), abdominal aorta (n=1; 2 percent). Two patients, aged <30 years were treated with Viabahn® due to trauma. After a mean follow up time of 1.98 ± 1.68 years, we observed death (n=3; 5.8 percent), amputation (n=3; 5.8 percent) and the need for re-intervention (n=17; 32.6 percent) in 23 patients (44.2 percent). The combined overall survival for the first, second and third year of follow up was 70.2 percent (Confidence Interval 95% CI: 58.9 - 83.6); 63 percent (95% CI: 51.0 - 78.0) and 57.3 percent (95% CI 44.6 - 73.6).

CONCLUSIONS:
There are still several unanswered questions regarding the best approach for patients with peripheral artery aneurysms. In the absence of well-designed clinical studies, the assessment of databanks on real-world patients may contribute to improve our understanding of the treatment alternatives and provide guidance to improve current clinical results.

PP56 The Growing Role Of Bariatric Surgery In The Management Of Obesity

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ABSTRACT SUMMARY:
The search for the ideal nonsurgical or surgical solution for obesity is still under debate. In this meanwhile, bariatric surgery is growing in demand becoming one of the preferred treatment options for obesity worldwide.

INTRODUCTION:
The search for the ideal nonsurgical or surgical
solution for obesity is still under debate. In this meanwhile, bariatric surgery is growing in demand becoming one of the preferred treatment options for obesity worldwide.

**METHODS:**
This retrospective study included obese patients requiring bariatric surgery from Jan 2004 to Dec 2017 provided by a private healthcare organization in Belo Horizonte, Brazil. Data regarding healthcare utilization were extracted from an administrative database (software Oracle Business Intelligence). Continuous variables were expressed as mean and standard deviation. Log-Rank test was used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This historical cohort resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

**RESULTS:**
16,786 patients were included in the study (mean age 37.2 ± 10.2 years; female 79.2 percent; mean BMI 42.4 ± 5.5 kg/m²). 55.3% of the patients had one or more comorbidities: 41.0% hypertension, 14.4% diabetes mellitus, 8.6% arthropathy, 6.3% sleep apnea. Laparoscopic surgery (n=6,686; 57.7%) was the preferred access route when compared to open surgery (n=4,894; 42.3%). From 2004 to 2017, the rate of surgeries increased from 104/100,000 individuals to 204/100,000 individuals. In 2013, previous publications have estimated the rate of bariatric surgery at the Brazilian public healthcare sector to be close to 4/100,000 individuals. In our sample, with the introduction of surgery via video-laparoscopy there was linear growth until 2016 when the rate reached its peak (219/100,000 individuals).

**CONCLUSIONS:**
Obesity is a worldwide current well known major public health problem and its management seems to be steadily shifting toward surgical approaches.

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**PP57 Outcomes On Transcatheter Aortic Valve Implantation (TAVI)**

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**ABSTRACT SUMMARY:**
Severe aortic stenosis with symptoms or left ventricular dysfunction has commonly a poor prognosis and therefore, aortic valve replacement is usually performed aiming at improving the functional class and the survival rate. In this scenario, transcatheter aortic valve implantation (TAVI) has become an alternative to surgical aortic valve replacement for patients at high risk for surgery.

**INTRODUCTION:**
Severe aortic stenosis with symptoms or left ventricular dysfunction has commonly a poor prognosis and therefore, aortic valve replacement is usually performed for patients aiming at improving their functional class and survival rate. Transcatheter aortic valve implantation (TAVI) has become an alternative to surgical aortic valve replacement for patients at high risk for surgery.

**METHODS:**
This retrospective study evaluated a convenience sample of patients at high risk for open surgery
for the correction of aortic valve dysfunction treated with TAVI from 2013 to 2018. Data from a private healthcare organization in Belo Horizonte, Brazil (administrative database, software Oracle Business Intelligence) were used to assess all-cause mortality. Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log-Rank test were used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This study resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS:
52 patients were included in the study (mean 83 ± 5.7 years of age, range 67 to 93 years; female 55.8%). Patients were characterized by: left ventricular ejection fraction (n=30; mean 52.9%, range 26% to 81%); aortic valve area (n=36; mean 0.68 cm², range 0.4 to 1.2 cm²); left atrium size (n=14; range 30 ml/m² to 61ml/m²); pulmonary artery pressure (n=20; mean 53 mmHg, range 31 mmHg to 70 mmHg). Death occurred in 19 patients during the follow-up period (mean 8.4 months, range 0 to 60 months). 9 deaths occurred within the first 30 days of follow-up (17.3%) and 14 (26.9%) in the first year. Stroke occurred in 3 patients (5.8%) in the post-implant period. A pacemaker device was required for 9 patients (17.3%).

CONCLUSIONS:
Being aware of the results derived from real-world data on TAVI might help patients, caregivers and stakeholders drive guideline modifications and clinical practice taking into consideration the local team expertise as well as local healthcare available recourses.

PP58 The Alliance Between HTA And Public In National Screening Policies

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ABSTRACT SUMMARY:
Decision making regarding prenatal & newborn screening policies is recognized to be highly challenging. Within Spain, a formalized collaboration has been established between the National Public Health Screening Advisory Commission and the Network of HTA agencies to support the development of evidence and consensus-based recommendations to support this process. This paper will provide real-life examples of how this framework is implemented.

INTRODUCTION:
Decision making regarding national population-based prenatal & newborn screening policies is recognized to be highly challenging and can rarely be based solely on HTAs. This paper aims to describe the formalized collaboration which has been established between the Spanish National Public Health Screening Advisory Committee (PHSAC) and the Spanish Network of HTA agencies to support the development of evidence and consensus-based recommendations to support this process.

METHODS:
In-depth description and analysis of the strategic and methodological processes which have been implemented within the Spanish NHS prenatal & newborn screening frameworks, with special emphasis on the role, actions, and responsibilities of HTA agencies.
RESULTS:
The role of HTA agencies in the updating of the population screening program is threefold: 1) support the PHSAC by providing fit for purpose evidence on safety, effectiveness and cost/effectiveness of the screening tests/strategies, as well as contextualized information regarding costs, organizational, social, legal and ethical issues; 2) collaborate with the PHSAC in the development of formal evidence and consensus-based recommendations for defining population screening programmes, when required; 3) analysis of real-world data that is generated by piloted programmes. This paper will provide real-life examples of how these processes were implemented in practice, with a special focus on the development of the non-invasive prenatal testing policy. Recommendations for NIPT were developed by a multidisciplinary group based on the EUnetHTA rapid assessment report and the predictive models that were built using national statistics and other contextualized data. These recommendations concern not only the screening algorithm but also the information provided to the woman, the informed consent and the implementation and follow up requirements.

CONCLUSIONS:
The current work represents an innovative approach for prenatal & newborn screening policymaking, which are commonly difficult to evaluate due to the low quality of evidence and the confounding public health issues. The paper pretends to raise awareness regarding the importance of joint collaborations in areas where evidence is commonly insufficient for decision making.

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ABSTRACT SUMMARY:
This presentation discusses rationale and participatory process undertaken as part of the set up phase of the National Program for HTA of MDs in Italy. This program is developing as a comprehensive and structured system including monitoring, link with downstream healthcare policies such as procurement and reimbursement, and based on a bottom-up inclusive methodology ready to support European-wide joint assessments.

INTRODUCTION:
Managing the adoption and diffusion of technological innovation is a key challenge for healthcare professionals. In 2015, a Steering Committee was established at the Directorate General for Medical Devices, Pharmaceutical Services and Safety in Healthcare in Italy to launch the National Health Technology Assessment (HTA) Program for Medical Devices (MDs), a network aimed at promoting the use of HTA tools and safety, effectiveness and cost-effectiveness principles in the evaluation of medical technologies.

METHODS:
In order to promote the active participation of institutions and stakeholders throughout the process, in March 2017 the Steering Committee established a workgroup focusing on methods, training and communication for the national program. This presentation will discuss the rationale and participatory process undertaken as part of this working group as well as the consensus agreed on processes and methods for the National Plan for HTA.
RESULTS:
Five different subgroups have been created as expression of the different stakeholders groups in the HTA system (i.e. patients/citizens representatives, scientific organisations, industry, healthcare organisations, academic researchers). In order to support the set up phase of the National HTA Plan for MDs, these five subgroups discussed and agreed on: 1) methods, format and communication; 2) disinvestment and identification of cost-saving technologies; 3) appraisal and coordination among different institutional levels; 4) link between assessment and procurement and clinical pathways; 5) link between assessment and funding and procedures coding. Agreed principles have been tested on a set of technologies selected for a pilot phase.

CONCLUSIONS:
The National HTA Program for MDs in Italy is developing as a comprehensive and structured system including monitoring, link with downstream healthcare policies such as procurement and reimbursement, and based on a bottom-up inclusive methodology ready to support Europe-wide joint assessments.

ABSTRACT SUMMARY:
General practitioners play an important role in ensuring the health of residents. But there are some problems in China, such as huge gap of general practitioners and unbalanced allocation. It is urgent to improve the general practitioner system. Evaluating the current situation of general practitioner allocation and residents’ utilization of services in China to provide reference for rational allocation of general practitioners.

INTRODUCTION:
Evaluating the current situation of general practitioner allocation and residents’ utilization of services in China, to provide reference for rational allocation of general practitioners in our country.

METHODS:
Based on the data of general practitioners, household registration population, regional area, discharged number of general practitioners and emergency patients in general practitioners and family planning statistical yearbook of China in 2016. The methods of HRDI and TOPSIS were used to comprehensive evaluate the general practitioner allocation and residents’ utilization of services in China.

RESULTS:
The total amount of general practitioners in our country is insufficient, the national average of general practitioners per thousand population is 0.137 1, and the regional distribution is unbalanced. The utilization level of residents to general practitioners is low, and the regional level is unbalanced. According to the comprehensive evaluation results, 87.10 present of the total number of areas with problems in the allocation and utilization of services of the general practitioners, and “low resource, low utilization” type is the main type. Tibet, Xinjiang and other places as the representative of the “low resource, high utilization” type, and Shanghai, Jiangsu as the representative of “high resources, low utilization” type should also attract sufficient attention and solve them.
CONCLUSIONS:
It is found that there is a big gap between the allocation of resources and services in the eastern, the central and the western regions, the government should rationally allocate the general practitioners in different regions from the perspectives of population, geography and health service needs so as to narrow the gap between regions.

PP61 Advanced Therapy Medicinal Products Germany: Drugs Or Methods Review?

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ABSTRACT SUMMARY:
ATMPs in Germany are assigned to either method evaluation or to the AMNOG procedure designated for drugs. This causes difficulties in classifying them as method or drug and a consultation requests to the G-BA is strongly recommended. For individualized therapies evidence beyond RCTs, new reimbursement possibilities should be considered. The current study presents the outcomes of assessments by G-BA.

INTRODUCTION:
Advanced Therapy Medicinal Products (ATMPs) comprise medicines for human use based on gene therapy, somatic cell therapy or bioprocessed tissue products. ATMPs are pharmaceutically manufactured drugs and mostly subject to central authorization requirements. In terms of social law it is an ambiguous situation and more heterogeneously dealt with. ATMPs are assigned to method evaluation as well as to the AMNOG procedure designated for drugs.

METHODS:
Guidelines from G-BA, IQWiG and respective legislation, consultations results and methods/medical devices (MDs) evaluations according to §137h and for drugs according to AMNOG were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

RESULTS:
ATMPs are subject to benefit assessment, with a decision at first on whether to be evaluated as a drug (e.g. Alofisel®) or a method/device (e.g. Holoclar®). By definition, an ATMP is classified as a treatment method, if the correct administration has at least the same significance for a successful therapy outcome as its mode of action. Depending on the respective decision, an evaluation as method follows or it must undergo the AMNOG process. According to G-BA’s and IQWiG’s point of view, RCTs are the “gold standard” for a benefit assessment of new therapies, including ATMPs. However, conduction of RCTs is not always possible for ATMPs which creates a disadvantage in the assessment right from the beginning. Otherwise no distinction is made between drugs and ATMPs in terms of reimbursement modalities. Outcomes based agreements could help overcoming inequalities and lead to quality-oriented reimbursement.

CONCLUSIONS:
ATMPs represent a grey zone causing difficulties in classifying them either as method or drug. For individualized therapies evidence beyond RCTs and new reimbursement possibilities should be considered. Until new regulations are in place it is advisable to enter early into respective discussions with authorities.
PP62 Cost-Effectiveness Of Cervical Cancer Screening In Estonia

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ABSTRACT SUMMARY:
Since a number of countries have introduced HPV-test as the primary method of cervical screening, our objective was to evaluate whether HPV-test would be cost-effective in Estonian cervical cancer screening program compared to the current Pap-test based screening.

INTRODUCTION:
In Estonia, organized cervical cancer screening program is targeted at women aged 30–55(59) and Pap-tests are taken every five years. Since cervical cancer is associated with human papillomavirus (HPV) a number of countries have introduced HPV-test as the primary method of screening. The objective of this study was to evaluate the cost-effectiveness of organized cervical cancer screening program in Estonia by comparing HPV- and Pap-test based strategies.

METHODS:
For the cost-effectiveness analysis, a Markov cohort model was developed. The model was used to estimate costs and quality-adjusted life-years (QALYs) of eight screening strategies, varying the primary screening test and triage scenarios, upper age limit of screening, and testing interval. Incremental cost-effectiveness ratios (ICERs) were calculated in comparison to current screening practice as well as to the next best option. Sensitivity analysis was performed by varying one or more similar parameter(s) at a time, while holding others at their base case value. The analysis was performed from the healthcare payer perspective adopting a five percent annual discount rate for both costs and utilities.

RESULTS:
In the base-case scenario, ICER for HPV-test based strategies in comparison to the current screening practice was estimated at €8,596–9,786 per QALY. For alternative Pap-test based strategies ICER was estimated at €2,332–2,425 per QALY. In comparison to the next best option, HPV-test based strategies were dominated by Pap-test based strategies. At the cost-effectiveness threshold of €10,000 per QALY Pap-testing every three years would be the cost-effective strategy for women participating in the screening program from age 30 to 63 (ICER being €3,112 per QALY).

CONCLUSIONS:
Decreasing Pap-test based screening interval or changing to HPV-test based screening can both improve the effectiveness of cervical cancer screening program in Estonia, but based on current cost-effectiveness study Pap-test based screening every three years should be preferred.

PP63 A Novel Chinese Model For Breast Cancer Screening

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**ABSTRACT SUMMARY:**

Modelling studies on the cost-effectiveness of breast cancer screening have been rising in China, whereas few well-validated models. A novel 15-state natural history model of breast cancer for urban Chinese was developed and validated with more age-specific epidemiological outcomes than previous models. The model can be used for the evaluation of the impact of breast cancer screening strategies in China.

**INTRODUCTION:**

Modelling studies on the cost-effectiveness of breast cancer screening have been rising in China, but only few models were well validated. We aimed to develop a novel and precise population-specific model platform through calibration with multi-outcomes.

**METHODS:**

The model structure was incorporated from systematic reviews with Chinese clinical practice of breast cancer. Transition probabilities, breast cancer survival rate and mortality from other causes were obtained from systematic reviews, national cancer registries and other public databases. Life expectancy, breast cancer incidence and mortality by age, and cancer stage distributions were used to perform simultaneous validation for the model.

**RESULTS:**

A 15-state natural history model was applied to simulate a cohort of women in urban China from 20 to 90 years old. The model predicted a life expectancy of 60.4 years (60.7 years reported in the literature) for women at 20 years old. The age-standardized incidence and mortality rate of breast cancer was 32.5/100,000 and 6.7/100,000 (rates from national cancer registries were 33.4/100,000 and 7.0/100,000, respectively), and the peak of incidence was 112.1/100,000 at 55 years (112.1/100,000 reported from national cancer registries). The proportion of early stage (0-I stage) breast cancer from the model was 20.2%, close to 19.2% reported from a nationwide epidemiological survey. More results of uncertainty analysis are expected to further present from our Monte Carlo simulation packages if possible.

**CONCLUSIONS:**

This comprehensive natural history model of breast cancer for the urban Chinese women were developed and calibrated with more epidemiological outcomes by age than previous models, which can be a useful tool for evaluating the long-term effectiveness and economic impact of various screening strategies and treatment interventions in China.

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**PP64 Economic Evaluation For Esophageal Cancer Screening In China**

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**ABSTRACT SUMMARY:**

The aim of the study was to estimate the cost-effectiveness of esophageal cancer screening compared to non-screening in China.

**INTRODUCTION:**

The aim of the study was to estimate the cost-effectiveness of esophageal cancer screening compared to non-screening in China.
METHODS:
Markov model with six states was conducted followed the history of esophageal cancer. Two groups and 12 different screening strategies target different begging age were carried out. Quality-adjusted life years (QALYs) presented the effectiveness. The incremental cost-effectiveness ratio (ICER) was used to compare the cost-effectiveness of screening to non-screening. Cost-effectiveness ratios (CER) were introduced to compare the screening value within group. Cohort simulation with one-year length was carried out, and the termination condition was the cohort age increased up to 80 years old. Model parameters related to the initial screening cohort, age-specific transition probability and effectiveness were identified from published literatures. Initial non-screening cohort probability and age-related costs were collected by hospital-based retrospective study. A discount rate of 5% was used for costs and effectiveness. Sensitivity analysis was introduced to assess the robustness of the model.

RESULTS:
All the screening group target different starting age costs more and gained less QALYs compared to non-screening. The CER within the non-screening groups showed negative association with increased age, with the CER decreased from 8162.36 at 40-44 years group to 4597.01 at 60-64 years group. In the screening group, 65-69 years group showed the highest CER (9911.80), while 60-64 ages showed the lowest CER with 6953.31. The CER in 55-59 ages, 45-49 ages, 50-54 ages and 40-44 ages in the screening group were 7450.73, 8448.46, 8638.31 and 8913.11, respectively. Sensitivity analysis showed similar patterns.

CONCLUSIONS:
Compared to non-screening, no screening strategy could be recommended from the social perspective. But all the screening strategies could be carried out given willingness to pay was 10000 RMB much less than GPD per capital in 2017 in China.

PP65 Methods Applied For Systematic Reviews Of Economic Evaluations In HTA

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ABSTRACT SUMMARY:
We analysed 83 HTA-reports from international HTA organizations for the methods applied for systematic reviews of economic evaluations (SR-EEs). Methodological features were extracted in standardized tables and synthesized in a structured narrative way. We identified inexplicable heterogeneity in single process steps and often a lack of reporting. Standardized guidance may improve quality and informative value of SR-EEs in HTA.

INTRODUCTION:
When making decisions in health care, it is essential to consider economic evidence about an intervention. The objective of this study was to analyze the methods applied for systematic reviews of economic evaluations in Health Technology Assessment and to identify common challenges.

METHODS:
We manually searched the webpages of HTA organizations and included HTA-reports published since 2015. Prerequisites for inclusion were the conduct of a systematic review of economic evaluations in at least one electronic database and the use of the English, German, French, or Spanish language. Methodological features were extracted in standardized tables. We prepared descriptive statistical (e.g., median, range) measures.
to describe the applied methods. Data were synthesized in a structured narrative way.

RESULTS:
Eighty-three reports were included in the analysis. We identified inexplicable heterogeneity, particularly concerning literature search strategy, data extraction, assessment of quality, and applicability. Furthermore, process steps were often missing or reported in a nontransparent way. The use of a standardized data extraction form was indicated in one-third of reports (32%). 54% of authors systematically appraised included studies. In 10% of reports, the applicability of included studies was assessed. Involvement of two reviewers was rarely reported for the study selection (43%), data extraction (28%), and quality assessment (39%).

CONCLUSIONS:
The methods applied for systematic reviews of economic evaluations in Health Technology Assessment and their reporting quality are very heterogeneous. Efforts toward a detailed, standardized guidance for the preparation of systematic reviews of economic evaluations definitely seem necessary. A general harmonization and improvement of the applied methodology would increase their value for decision makers.

PP66 Increasing Burden Of Out-Of-Pocket Healthcare Expense On Patients

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ABSTRACT SUMMARY:
We sought to analyze the impact of financial burden of out-of-pocket (OOP) healthcare expenditure on patients by understanding the key factors triggering the cost sharing mechanisms, trends of OOP in US, Europe and emerging markets and understand its implications on patient’s health management.

INTRODUCTION:
We conducted an analysis of the key factors triggering cost-sharing mechanisms to understand the status of out-of-pocket [OOP] healthcare expense in the US, Europe, and emerging markets and better appreciate the implications of OOP healthcare expense on patients’ health management.

METHODS:
A review of literature and databases including- (The Organisation for Economic Co-operation and Development [OECD], World Bank) was performed to understand different cost-sharing mechanisms, factors triggering the OOP expenditure and the country-wise trends of OOP expenditure. Additionally, impact of the OOP expenditure on healthcare budget and on patients in terms of medication adherence, uptake of newer therapies and generic substitution was explored.

RESULTS:
The findings reveal that patients are concerned about rising healthcare OOP costs and we observed an increase of 134% in the number of articles published on OOP from 2005 to 2017. The percent household spending that goes OOP as healthcare expense is higher in Brazil, Russia, India, and China [BRIC] countries (~11%) compared to France, Germany, Italy, UK, US, Japan, Canada [G7] countries (~2%). In addition, OOP expenditure increased with age (1.9% of take home income in 55-64 age group versus 1.2% in 18-25 age group) and is higher in the low-income population (2.8%
of take home income versus 1% in high-income group). Whereas, increasing OOP expenditure reduces the overall healthcare expenditure due to generic substitution (28% reduction) and reduction in excessive consumption of supplementary medicines, it also reduces patient adherence (~20% decline in dispensed prescriptions) and may foster a reluctance to adopt newer therapies.

**CONCLUSIONS:**
The population groups most impacted by increasing OOP expense are the older population, those in the low-income bracket and in poorer countries. Whilst OOP expense may help in the effective and judicious utilization of healthcare system resources and medicines usage, its implementation requires a cautious and considered approach.

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**PP67 Physicians Knowledge Of Cost Of Prescribed Medications In Nigeria**

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**ABSTRACT SUMMARY:**
One of the core components of rational prescribing is cost consideration. This is especially important in the setting of Nigeria where majority of the populace purchase healthcare “out of pocket”. This study assessed physicians’ attitude and knowledge about the cost of commonly prescribed medicines in Nigeria.

**INTRODUCTION:**
Healthcare costs are escalating worldwide with medications being responsible for a large proportion of this increase. Because of this fact, there is a continuous struggle to contain healthcare costs in many countries. Rational prescribing entails consideration of the costs of medications; choice of the least costly medications without compromising safety and effectiveness. While a lot of emphasis is put on knowledge about safety and efficacy of medicines during undergraduate and postgraduate medical training, little attention is paid to issues relating to costs of medications. The World Health Organization guideline on rational prescribing has cost consideration as one of the steps to be considered. While many drug utilization studies conducted in Nigeria also focused on medication costs, not much has been done in assessing physicians’ knowledge and attitude towards the costs of commonly prescribed medications. The main objective of the study was to assess physicians’ knowledge of costs of commonly prescribed medications.

**METHODS:**
The study was a descriptive cross-sectional survey conducted among medical doctors in three tertiary institutions in Nigeria using a semi-structured questionnaire. Apart from socio-demographic information, questions on the source of drug information, importance of cost consideration in drug prescription, physicians’ preference for branded or generic medication and average estimated cost of a branded and generic version of 11 commonly prescribed medications were also included in the questionnaire.

**RESULTS:**
A total of 187 questionnaires were returned giving a response rate of 86.6% response rate. Majority (154;82.4%) of the respondents were males while registrars (114;61%) formed the bulk according to professional status. One hundred and seventy-nine (179;95.7%) respondents agreed that cost consideration was important when writing prescriptions. Majority (172;92%) would consider the socio-economic status of the patient before prescribing while 161(86.1%) would change their choice of drugs based on the socio-economic status of patients.
When asked about exposure to any formal training in health economics at either undergraduate or postgraduate level, only 7(3.7%) respondents answered in the affirmative. However, a large majority (153;81.8%) among respondents were of the opinion that health economics should be made part of the undergraduate and postgraduate medical education.

Hypertension (143;76.3%), Malaria (136;72.7%) and Diabetes Mellitus (112;59.9%) were the most common medication conditions. The correctly estimated cost of medicines by physicians ranged from 0 – 49.2% for branded medicines and 0 -17.1% for generic ones. Respondents were more knowledgeable about the cost of medicines used for the treatment of infectious diseases (malaria, bacterial infections) than non-communicable diseases (diabetes mellitus, hypertension and dyslipidaemia).

CONCLUSIONS:
The knowledge of Nigerian physicians about cost of commonly prescribed medicines was poor in this study. This is despite the awareness of respondents about importance of cost consciousness especially in a setting where majority of patients pay 'out of pocket'. There is an urgent need to incorporate “cost consciousness” into the undergraduate and postgraduate medical training curricula in Nigeria.

ABSTRACT SUMMARY:
The vast majority of new users with no history of diagnosed cancer used opioids adequately according to the 5 indicators of potentially inappropriate opioid use fed with administrative databases stored at the Régie de l’assurance maladie du Québec (RAMQ).

INTRODUCTION:
Opioids are being used increasingly to treat chronic noncancer pain despite the uncertainty regarding its long-term benefits. This study served to determine if problems are associated with opioid use in Québec for new users from 2006 to 2013 without history of cancer.

METHODS:
A retrospective longitudinal cohort study was conducted using administrative databases stored at the Régie de l’assurance maladie du Québec (RAMQ) to describe the annual proportion of new users to whom at least one of the five indicators of potentially inappropriate opioid use applied was estimated. These indicators are (1) overlapping opioid prescriptions, (2) overlapping opioid and benzodiazepine prescriptions, (3) the use of long-acting opioids at the start of treatment, (4) a high mean daily dose, and (5) a rapid increase in the opioid dose.

RESULTS:
The annual proportion of new users to whom at least 1 of the 5 indicators of potentially inappropriate opioid use applied decreased from 15.4% in 2006 to 12.3% in 2013. It was mainly the following three indicators that contributed the most to these proportions in 2013: (1) overlapping opioid prescriptions (5.8%), (2) overlapping opioid and benzodiazepine prescriptions (8.2%), and (3) the use of long-acting opioids at the start of treatment (1.8%).

CONCLUSIONS:
The vast majority of new users with no history
of diagnosed cancer used opioids adequately according to the 5 indicators of potentially inappropriate opioid use applied. Improvement could still be made to decrease mainly overlapping opioid prescriptions and overlapping opioid and benzodiazepine prescriptions.

PP69 Potential Gains In HALE From Reducing Four NCDs Among Chinese Elderly

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ABSTRACT SUMMARY:
This research calculated potential gains in HALE after hypothetical elimination of specific diseases to evaluate the disease burden from NCDs among Chinese elderly. This study highlights the potential gains in HALE of NCDs among Chinese elderly from 1990 to 2016. HALE of Chinese elderly could further increase from the reduction of NCDs.

INTRODUCTION:
With the fast speed of ageing, burden from non-communicable diseases (NCDs) is increasing in China, and will continue to increase to 2020 and beyond. This study aims to estimate the potential gains in health-adjusted life expectancy (HALE) after hypothetical elimination of four NCDs among Chinese elderly from 1990 to 2016, including cardiovascular diseases (CVD), cancers, chronic respiratory diseases (CRD) and diabetes mellitus (DM).

METHODS:
Based on data from Global Burden of Disease 2016, we generated life table by gender using Sullivan method to calculate HALE. Disease-deleted method was used to calculate cause-elimination HALE, after hypothetical elimination of specific diseases. This method could combine the impact of mortality and morbidity, which are particularly useful for estimating the impact of the disease and setting priorities for health planning to get ready for the new challenges in upcoming decade.

RESULTS:
From 1990 to 2016, HALE increased for all age groups. After hypothetic eliminating the four main NCDs, potential gain in HALE by CVD, DM and cancers increased while by CRD decreased from 1990 to 2016 for both genders. Among four main NCDs, potential gain in HALE after eliminating CVD was largest and increased most for both genders. Although elimination of DM led to the smallest gain in HALE, the increasing speed of gain in HALE by DM was faster than that by CVD and cancers from 1990 to 2016.

CONCLUSIONS:
This study highlights the potential gains in HALE of NCDs among Chinese elderly from 1990 to 2016. HALE of Chinese elderly could further increase from the reduction of NCDs. Control measures and targeted prevention should be carried out to get ready for the new decade.

PP70 Identification Of Prostheses With Results Worse Than Expected

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ABSTRACT SUMMARY:
Monitoring the effectiveness of knee and hip arthroplasty models could be useful at the patient, surgeon, industry and stakeholder levels. Currently, there is no clear standard of how to perform this monitorization. In this study, we propose an approach for the systematic identification of prostheses with worse results, and apply it to the prostheses used in Catalonia.

INTRODUCTION:
Monitoring the effectiveness of knee and hip arthroplasties could be useful at the clinical, economic and patient levels. In Catalonia, there is currently no systematic monitoring of the different prostheses available. The aims of this study were to propose an approach for the systematic identification of knee and hip prosthesis with worst results in terms of revision rates, and to identify those with possible worse results.

METHODS:
Data from 53 out of 61 public hospitals of Catalonia included in the Catalan Arthroplasty Register (RACat) and recorded from January 2005 to December 2016 was considered. The specific prostheses were classified by joint, type, fixation and, in total hip prostheses, the bearing surface. To identify prosthesis with worst results regarding those classified in the same groups, based on previous literature, a 3-step approach was proposed: 1) a screening using Poisson models, 2) a comparison of prostheses using adjusted Cox models, and 3) a consensus of a panel of orthopedic surgeons to detect possible uncontemplated sources of bias. After this process, identified prostheses were provisionally labeled as having worst results. To definitively classify the prostheses, this process will be repeated periodically within the RACat.

RESULTS:
From the two first steps proposed, 10 knee prostheses and 8 hip prostheses were identified. After the panel discussion (third step), 1 knee and 1 hip prosthesis were excluded as those with possible worse results. The knee prosthesis was excluded because it was a unicompartmental implant and the hip prosthesis because it was a monoblock implant. Finally, 9 knee prostheses and 7 hip prostheses were provisionally identified as prostheses with worse results, awaiting confirmation in subsequent analyses.

CONCLUSIONS:
This study contributes to the current need to identify hip and knee prostheses whose results might be worse than expected. This identification could have an impact at the patient, surgeon, industry and stakeholder levels.

PP71 Clinical And Economic Evaluations Of Multiple Myeloma Patients

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ABSTRACT SUMMARY:
Characteristics, treatment pattern and healthcare costs of incident and prevalent multiple myeloma patients in an Italian clinical setting.

INTRODUCTION:
Incidence of multiple myeloma (MM) has increased over the last years, especially in relation to increased life expectancy. The aims of this study were to assess epidemiology of MM and to describe treatment patterns and economic burden among MM patients.

METHODS:
A retrospective analysis of the administrative databases of three Italian Local Health Units was performed. Inclusion criteria were as follows: hospitalization discharge with primary or secondary diagnosis for MM between 1 January 2011 and 30 June 2014, and the presence of pharmacological treatment for MM. Index date (ID) was the date a patient met the inclusion criteria. All included patients were characterized during 24 months before ID and followed up for 24 months after ID. Treatment pattern, transplant procedure, hospitalizations and outpatient services were analyzed over the follow-up period. Costs analysis included drugs, hospitalizations, with and without transplant procedure, and outpatient services.

RESULTS:
Of the 547 included MM patients (mean age 68.0 years, 52.3 percent male), 127 were incident patients (mean age 69.4 years, 56.7 percent male), and 420 were prevalent patients (mean age 67.6 years, 51.0 percent male). Average follow-up period was 17.3±9.4 months. 355 of prevalent MM patients received a specific treatment; first line treatment mainly consisted in bortezomib (17.2 percent) or lenalidomide (5.1 percent). 121 of the included MM patients underwent a transplant procedure during follow-up, 214 died. Hospitalization costs among MM patients accounted for 57.8 percent of total cost; mean cost per patient for hospitalizations with transplant procedure was EUR 12,506.38, EUR 9,415.51 for hospitalizations without transplant procedure, EUR 12,147.82 for drugs, EUR 3,851.65 for outpatient services.

CONCLUSIONS:
Results from this real-world study showed characteristics of incident and prevalent MM patients and the type of treatment received. Furthermore, costs for MM patients were mainly driven by hospitalizations with and without transplant procedure.

PP72 Using INTEGRATE-HTA On The Example Of Rasterstereography For Scoliosis

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ABSTRACT SUMMARY:
INTEGRATE-HTA is a completed EU project for the development of concepts for a patient-centered integrated assessment of complex technologies. We investigated whether using the methodology may improve an understanding of domains and their interactions. The technology turned out to be rather complex due to a high density of interactions. INTEGRATE-HTA significantly expands the perspective on a technology.
INTRODUCTION:
In full HTA reports not only safety and efficacy of a technology are discussed but also economical, ethical, legal, socio-cultural and organizational aspects. INTEGRATE-HTA is a completed EU project for the development of concepts and methods for a patient-centered integrated assessment of complex technologies. Technologies can be considered as complex if they are particularly characterized by an increased number of interacting components, variability of outcomes or degree of flexibility. In contrast to the usual linear approach by covering the individual domains separately, the INTEGRATE methodology is based on the assumption of interactions of different aspects of the domains. From the very beginning, the interactions are captured systematically using various tools. By continuous reflection and compaction of relations, the process may lead to an extended perspective on a technology. As a result, complexity and mechanisms of action open up, and the public discussion and implementation can be channeled.

We investigated whether using the INTEGRATE-HTA methodology may improve an understanding of individual domains and their interactions.

METHODS:
According to the methodology, an initial logic model was developed and successively expanded. A synoptic table showing multiple mapping of aspects to domains and a complexity checklist were used. In addition, harvest plots were created and the socio-cultural impact of the disease was highlighted as semantic complex. The final logic model and an interaction figure were established to initiate the discussion.

RESULTS:
Having been classified as slightly complex in the beginning, the technology turned out to be highly complex after using a variety of tools and a final graphical representation: the multiple mapping of individual aspects to domains resulted in a high density of interactions.

CONCLUSIONS:
Using the INTEGRATE-HTA methodology contributes to identify interactions between domains and to significantly expand the perspective on a technology. It improves patient-centered understanding and facilitates the discussion of single aspects.

PP73 Framework Proposal For Early HTA In Translational Phase

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ABSTRACT SUMMARY:
A framework for early HTA was proposed, based on the experience gathered through the implementation of HTA to support academician and funders in making decision on their project portfolio in translational research. It allows to identify critical points for the proposals (lacking information and potential areas of investigation to be addressed), allowing a more efficient allocation of resources.

INTRODUCTION:
Funders of biomedical research increasingly ask for early evidence of success for projects they aim at financing. The objective of the analysis conducted is to propose a framework for early HTA, based on the experience gathered through the implementation of HTA to support academician and funders in making decisions on their project portfolio in translational research.
METHODS:
Early HTA was performed on two translational proposals financed by the Netherlands Organisation for Health Research and Development (ZonMw), considering the 9 dimensions proposed by the EUNetHTA Core Model® (Version 3.0). Based on the outcome obtained, methods were adjusted and a new analysis was performed on two additional proposals taking into account the dimensions more suitable for early development projects.

RESULTS:
The early HTA performed lead to the identification of strengths and weaknesses of the proposals. The relatively early stage development of the projects manifested in lack of clinical effectiveness, safety data or manufacturing and application costs - among others - did not allow a complete review of all dimensions considered, however such early assessment can be highly valuable to the Principal Investigators. An HTA framework was then defined, starting with the submission of the proposal by the principal investigator with the help of a template. An early HTA is then performed, considering the EUNetHTA Core Model® topics and issues to identify knowledge gaps in the research project to be addressed during the project’s lifespan. The third phase is related to the collection of the lacking information and a full HTA to be performed towards project completion.

CONCLUSIONS:
The early HTA framework proposed allow to identify critical points for the proposals, allowing a more efficient allocation of resources, a better planning and the definition go/no-go decision criteria while the project is under execution. The suggested framework was implemented by ZonMw in its Translationeel Adult Stemcelonderzoek programme.

PP74 Training Using Case Report Forms Improves Quality Of Faxed Data

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ABSTRACT SUMMARY:
Using data from the Call for Life Uganda randomized trial, evaluating the use of a mobile phone based interactive voice response system. We demonstrate the effect of continuous training on data quality using faxed Case Report Forms (CRF) for people living with HIV participating in a research study in Uganda.

INTRODUCTION:
Case report forms (CRFs) provide fast and efficient ways to collect clinical and scientific data. Minimal data on quality assurance (QA) CRFs in sub-Saharan Africa exists. We demonstrate the effect of continuous training on data quality using faxed CRFs in a research study.

METHODS:
This is a retrospective observational study within the Call for Life Uganda (CFLU) randomized trial, conducted between April 2017 and April 2018. CFLU is evaluating the use of Connect for Life (CfL) in Uganda which is a MoTech-based Software
system, developed by Janssen, the Pharmaceutical Companies of Johnson and Johnson.

Four CRFs of 6 pages are completed every 6 months for each of the 150 recruited patients. CRFs undergo completeness and accuracy checks by the quality control officer (QCO) before faxing to the “DataFax” server. Datafax team undertakes final QA checks and feedback errors to the QCO. We conducted three intensive trainings for study staff on CRF completion and quality assurance. Poisson regression was used to assess change in the number of pages with queries during and after all the three intensified trainings. STATA version 13 was used for analysis.

RESULTS:
Ten percent (170/1596) of the CRF pages faxed, were returned with queries one month after the initial training, increasing to 1093/1245 (87.8%) in the second month after new validation checks introduced, then decreased after the second training to 82/1184 (7%). Thereafter, the CRF pages returned with queries steadily declined to <1% at 6 months. This was a 95% reduction in the number of pages with queries after the intensive trainings compared to the period during the trainings. (IRR=0.05, 95%CI: 0.05-0.06, P<0.001).

CONCLUSIONS:
Continuous training is vital to improve data quality as this is essential for clinical trials and patient management. More research is necessary to ascertain whether electronic CRFs would further reduce errors than the paper based CRFs.

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ABSTRACT SUMMARY:
To introduce the challenges faced in China to build a Healthcare Horizon Scanning System. The choice of the methods for China’s horizon scanning program should be based on the goal, scope of work, time frame, and funding for the program. It appears that the design and initiation of a horizon scanning program require a strong political commitment for the least.

INTRODUCTION:
To introduce the challenges faced in China to build a Healthcare Horizon Scanning System and explore the factors required to design a Healthcare Horizon Scanning System in China.

METHODS:
A combination of methods have been applied to identify existing best practices and effective methods for health technology horizon scanning and to provide input to relevant national agencies in China to design its horizon scanning program. We first performed a comprehensive search for both peer-reviewed and gray literature to identify existing horizon scanning methods for emerging health technologies and then interviewed a few selected key informants within the National Health Commissions for insights.

RESULTS:
Our search identified 26 formally established health technology horizon scanning programs, and more informal ones. With the help of literature and information gathered from interviews, we identified three key steps to set up such system: (1) how to identification and monitoring of technologies of interest, (2) how to assess the quality of evidence of the identified technologies and (3) how to evaluation of potential impacts of the identified technologies.

PP75 Design Of Healthcare Horizon Scanning System In China

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CONCLUSIONS:
Existing horizon scanning programs use different methods to identify and assess emerging health technologies. The choice of the methods for China’s horizon scanning program should be based on the goal, scope of work, time frame, and funding for the program. It appears that the design and initiation of a horizon scanning program require a strong political commitment for the least.

PP76 The Registry Evaluation And Quality Standards Tool (REQueST) For HTA

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ABSTRACT SUMMARY:
Development and piloting of a standardised tool for the evaluation of the quality of registries for HTA use.

European network for Health Technology Assessment (EUnetHTA) partners have developed a new tool comprising of three sections; methodological, essential and specific standards. Feedback from tool testing will be provided and the presentation will end with proposals for its long term sustainability.

INTRODUCTION:
The use of registries is becoming increasingly common in health technology assessment (HTA) as interest grows in the use of observational data to complement randomized clinical trial data and to optimize the access to new technologies. The quality of registry data has been criticised, leading to reluctance to embed their use in HTA. One of the objectives of (EunetHTA), Joint Action 3, Work Package 5B is to produce a draft standard tool to assess the quality of registries in HTA. We report on its progress.

METHODS:
To produce the tool, we surveyed partners regarding current use of registries in HTA, asked for examples of registry assessment tools currently in use and reviewed the Parent Guidelines.

Three HTA agencies volunteered to test the use of the tool on specific registries and all partners have collaborated in the development of a plan for long term sustainability and effective implementation.

RESULTS:
Although many HTA agencies use registry data there were no pre-existing tools fit for purpose available.

The REQueST tool includes three sections: 8 ‘methodological’ items relating to suitability of the registry for a specific purpose; 13 ‘essential’ standards relevant to any registry for HTA purposes and 3 additional considerations for specific purposes.

The 3 pilots will provide feedback on the appropriateness of the REQueST for assessing the quality of registries.

The implementation of REQueST could be phased—initially registries may undertake self-assessment using the tool. With investment it will be possible to develop independent third party online review with a visual output from the tool that facilitates rapid appraisal of registries for potential users.

CONCLUSIONS:
REQueST has the potential to contribute to international efforts to accelerate access to
effective new technologies by improving the quality of registries.

PP77 Relation Between Atrial Fibrillation And Cancer Based On Claims-Data

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ABSTRACT SUMMARY:
A new-onset diagnosis of atrial fibrillation (AF) was reported to be associated with a higher cancer incidence in a population-based prospective cohort study. We examined its disease-specificity based on claims-data. Higher cancer diagnosis rate was observed within 90 days after first diagnosis of AF similar to the previous study. However, the tendency was observed for other diseases besides AF.

INTRODUCTION:
A new-onset diagnosis of atrial fibrillation (AF) was reported to be associated with a higher incidence of cancer in a population-based prospective cohort study (Vinter et al., 2018). In the study, relative cancer risk was highest within 90 days after the new-onset AF diagnosis and remained high within 365 days compared to those without AF using proportional hazards models at the same time on the timescale based on age. We examined whether the association could be considered as disease-specific.

METHODS:
We analyzed Medicare 5% data (US, 2012-2016). New diagnosis rate of cancer and its timing from the first diagnosis of AF were analyzed for patients who had a record of first diagnosis of AF. The rate and timing were also analyzed for patients who had first diagnosis of cataract and Parkinson’s disease (PD).

RESULTS:
Number of patients who were diagnosed as AF, cataract, and PD were 179,502, 215,660, and 23,978, respectively. Monthly new diagnosis rate of cancer within 89 days from first diagnosis of AF was 0.56%, which was higher than those diagnosed within 90-179 days (0.34%), 180-269 days (0.31%), and 270-359 days (0.28%). When comparing daily diagnosis rate of cancer within one year before and after the first diagnosis, highest diagnosis rate (0.11%) was seen on the day after the first diagnosis followed by the same day as first diagnosis (0.09%). Highest diagnosis rate of cancer was seen on the same day as first diagnosis of cataract (0.04%) and PD (0.06%).

CONCLUSIONS:
Higher diagnosis rate of cancer was observed within 90 days after first diagnosis of AF. The diagnosis was higher around the day of first diagnosis not only for AF but also cataract and PD. Diagnosis of cancer may be associated with hospital visit for AF diagnosis, and not with disease itself.

PP78 Analysis Of Resource Utilization On Psoriasis Care In Brazilian Health

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ABSTRACT SUMMARY:
Psoriasis (PsO) is associated with metabolic disorders such as metabolic syndrome (MetS),
INTRODUCTION:
Psoriasis (PsO) is associated with metabolic disorders such as metabolic syndrome (MetS), having a significant negative impact on patient’s quality of life. There is little information about treatment patterns and resources used to treat psoriasis and associated comorbidities. The objective aimed to evaluate the frequency of MetS and estimate costs associated with psoriasis care in Public Brazilian Healthcare System (SUS).

METHODS:
A cross-sectional, observational investigation in 293 Brazilian patients with psoriasis attending selected dermatology outpatient centers in Brazil during 1-year period. Patients underwent detailed skin and rheumatologic assessments and a series of laboratorial tests. The annual costs were estimated by multiplying the amount of each resource consumed for it unit costs.

RESULTS:
The MetS prevalence was high in this cohort (50.0%). Other metabolic disorders presented high frequency, such as hypertension (61.8%), diabetes (30.9%), dyslipidemia (74.5%) and obesity (52.5%), compared with general population. The disease duration was on average 17.2 years. 2,713 consultations were reported by 288 patients (9 per patient/year). Beyond dermatologists (92.7%), other common specialties were general practitioner (41.0%), cardiologist (27.1%), rheumatologist (18.1%) and endocrinologist (12.5%). Among non-physician healthcare professionals visits (n=110, average/patient=11), the most frequently reported was nutritionist (25.5%), followed by psychologist (23.6%) and nurse (21.8%). A total of 279 patients (95.2%) performed at least one medical test, with mean of 18 per/patient. Concerning treatment not directly related to psoriasis, medicines for cardiovascular system were responsible for 64.5% (n=149), myocardial revascularization was the costliest procedure (US$2,298.30) and hospitalizations due to diseases of the circulatory system represented 23.8% (n=5/21).

CONCLUSIONS:
MetS is a PsO frequent associated condition, impacting directly on Brazilian healthcare resource utilization, being involved with a higher consultation costs. Further researches are needed to evaluate the impact of multidisciplinary approach on PsO patients with MetS.

PP79 Impact Of Hidradenitis Suppurativa On Healthcare Resource Utilization

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ABSTRACT SUMMARY:
Hidradenitis suppurativa (HS) is a debilitating, chronic and inflammatory skin disease characterized by painful, nodules and abscesses. Disease recurrence is common, impacting directly on costs for health system, data unknown in Brazil. Through a public healthcare claim database (DATASUS), in a 2-year period, HS costs and recurrence could be demonstrated for the first time in a Brazilian National Level Database.
INTRODUCTION:
Hidradenitis suppurativa (HS) is a debilitating, chronic and inflammatory skin disease characterized by painful, nodules and abscesses. HS has a strong impact on the patient's quality of life. In Brazil, the prevalence was estimated in 0.41%. Medical and surgical treatments present low effectiveness, and disease recurrence is common, impacting directly on costs for health system, which are unknown in Brazil. The objectives of this study were to assess how HS patients utilize medical care (emergency and inpatient care) as well as to describe the all-cause costs.

METHODS:
The data were retrieved from public healthcare claim database (DATASUS), which provides access to information regarding health services and involved costs. DATASUS analysis was used to perform a cost-identification for patients with HS during a 2-year period. A retrospective bottom-up approach was applied to estimate direct costs, by multiplying the amount of each medical resource consumed for it unit costs.

RESULTS:
In a 2-year period we found 90 patients (15.6%) with inpatient care, totaling 151 procedures with total cost of R$ 83,520. Surgeries were the most frequent (73% of total) and expensive procedure for inpatient, costing R$ 73,122 (88% of total costs), followed by clinical treatments with R$ 8,354 (10%) and physician consulting with R$ 1,659 (2.0%). Among 500 emergency patients, the most frequent procedure (Total 3,027) was physician consulting (34.2%), followed by nursing care (11.5%) and small surgeries (10.7%). The mean frequency of procedures was 3 per year.

CONCLUSIONS:
HS presented a high-burden impact disease, demonstrated by high frequency utilization of healthcare system. DATASUS is a public database and costs presented reflect a government reference price, without considering local costs, being a limitation of this study. Health managers should be aware of this finding, and further research is needed to investigate the impact of health care utilization on patient outcomes.

PP80 A Systematic Review Of Gugging Swallowing Screen Effect For Dysphagia

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ABSTRACT SUMMARY:
According to our systematic review, Gugging swallowing screen is a reliable and sensitive tool with high sensitivity for dysphagia. GUSS contributes to reducing a risk of aspiration complications like pneumonia as an early and systematic assessment, and may lead to help effective communication between healthcare providers.

INTRODUCTION:
Dysphagia can be a clinical burden leading to serious complications like aspiration and pneumonia. Complications often give rise to an increase of mortality and hospital stay. Gugging Swallowing Screen (GUSS) is suggested as an instrument of assessing swallowing abilities by allowing separate evaluations for non-fluid and fluid textures, and helps to communicate effectively between healthcare providers. The purpose of this study is to analyze the validity and effect of GUSS for dysphagia screening.

METHODS:
We conducted a systematic review searching electronic databases; Ovid-Medline, Ovid-Embase, the Cochrane library, Koreamed, Research Information Sharing Service (RISS), and Korean studies Information Service System (KISS). We included studies related to dysphagia screening.
of GUSS published in English and Korean up to November 2018. We designed strategies that included Medical Subject Headings (MeSH) and keywords such as ‘dysphagia’, ‘swallowing’, ‘assessment’, ‘screening’, ‘GUSS’, either alone or in combination.

RESULTS:
Of 297 studies, after eliminating duplicates, 219 articles were reviewed by 2 independent reviewers. Finally, 8 articles were identified to be relevant for this study. With regard to validity, GUSS had sensitivity between 89.5 percent and 100 percent, specificity between 50 percent and 87.5 percent. In addition, the result of GUSS was in a significant correlation with the result of videofluoroscopic swallowing (VFSS) or fiberoptic endoscopic evaluation of swallowing (FEES). Regarding the effectiveness, early systematic dysphagia screening using GUSS by nurses has an impact of reducing time of screening and pneumonia rate compared with the control group (p=0.004). And the incidence of X-ray verified pneumonia in the GUSS group was significantly lower than in the clinical screening group (p<0.01), while there was no difference in the occurrence of pneumonia compared with the 10ml water swallowing test.

CONCLUSIONS:
Results show that GUSS is a reliable and sensitive tool for screening dysphagia. Such an early and systematic assessment can provide reduction in occurrence of aspiration and pneumonia, and also, further research is needed to establish the effective of this tool.

PP81 Real World Data: The Early Access To Medicines Scheme Catches The Worm

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ABSTRACT SUMMARY:
This research evaluated whether RWE collected on the UK’s Early Access to Medicines Scheme (EAMS) has been used to support NICE HTA decision making. Most products on the EAMS scheme did not subsequently present RWE in their NICE submission, dupilumab presented real-world efficacy data from EAMS that helped minimize uncertainty surrounding effectiveness in clinical practice and supported economic modelling assumptions.

INTRODUCTION:
The Early Access to Medicines Scheme (EAMS) aims to provide patients with severe, life-threatening diseases without adequate treatment options with access to medicines prior to their marketing authorization. EAMS designation enables the potential collection of UK-specific real world evidence (RWE) prior to health technology assessment (HTA) decision making by the National Institute for Health and Care Excellence (NICE). This research evaluates whether RWE is being gathered through EAMS and being utilised to support HTA submissions.

METHODS:
All EAMS designations as of 07/11/2018 were identified from the Medicines and Healthcare products Regulatory Agency (MHRA) website. For products with final NICE guidance, all publicly-available NICE documentation were reviewed.

RESULTS:
16 product:indication pairings with an EAMS designation were identified, with 12 having received final NICE guidance (11: recommended; 3: cancer drugs fund; 2: not recommended). 7/11 included references to the number of patients or sites with
product access through EAMS; however, only 1 (dupilumab in atopic dermatitis), reported detailed data collected during the EAMS period. The manufacturer reported baseline demographics and disease characteristics from a cohort of 35 patients treated under EAMS to inform the generalizability of trial populations to clinical practice. Follow-up data from the cohort demonstrated that real-world dupilumab effectiveness was comparable with clinical trial data, despite a higher proportion of patients in the real-world cohort receiving immunosuppressant therapy, making efficacy improvements harder to achieve. The committee also noted that this RWE presented supported understanding of dupilumab’s long-term clinical effectiveness and informed assumptions in the economic model.

CONCLUSIONS:
To date, the majority of products have not presented RWE collected through EAMS at NICE reappraisal. Dupilumab illustrates how RWE collected through EAMS can be used to reduce uncertainty around how clinical trial data translates into clinical practice. In the future, RWE may increasingly be used to help inform NICE decisions.

PP82 Instruments For Assessing Health Policymakers Capacity To Use Evidence

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ABSTRACT SUMMARY:
There was limited evidence regarding the validity and reliability of the studied instruments. However, based on the SEPT criteria, two instruments (SEER and Rodriguez’s instrument) were determined as high quality instruments to measure the capacity of health policy makers to use evidence.

INTRODUCTION:
Health policies and macro-level decisions improve outcomes if they are made based on best evidence. Investigating policymakers’ capacity to take advantage of evidence at individual and organizational levels is a prerequisite for developing strategies for appropriate use of evidence. This study aimed to identify the best instrument for assessing policymakers’ capacity to use evidence.

METHODS:
A systematic review of PubMed, Scopus, Embase, and ISI Web of Science databases was conducted until June 6, 2018. Internet search engines, key organizations’ website, and the reference lists of selected articles were also reviewed to find relevant articles. The search strategy for each database was written individually. Article quality was assessed using the Standards for Educational and Psychological Testing (SEPT). Findings and interpretations were provided without abstraction and without generating new theory. Contradictory findings were explained in terms of study design, methodological quality, samples, and locations.

RESULTS:
In total, 16 instruments were identified from 18 studies for assessing the capacity to use evidence at individual and organizational levels of health policy making. It was found that 37% of studies had assessed both validity and reliability criteria. Meanwhile, the SEER instrument (a score of 3 out of 4 for validity and 2 out of 3 for reliability) and Rodriguez’s instrument (a score of 3 out of 4 for validity and 3 out of 3 for reliability) were identified as instruments that may serve as a good basis for assessing the capacity to use evidence at individual and organizational levels of health policy making.
CONCLUSIONS:
The there was limited evidence regarding the validity and reliability of the studied instruments. However, based on the SEPT criteria, two instruments were determined as high quality instruments to measure the capacity of health policy makers to use evidence.

PP83 A Conceptual Decision-Making Framework For Pharmaceutical Innovations

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ABSTRACT SUMMARY:
Healthcare systems try to introduce measures or incentivize market forces to improve access for patients as well as to contain budget-impact. Does this always lead to better access and affordability? Are we really solving a problem or just sticking plasters? Here, we will present a conceptual healthcare decision-making framework that informs decisions on various healthcare investments in a balanced way.

INTRODUCTION:
The trend of growing healthcare expenditures is unsustainable in many countries. The increasing pressure on healthcare budgets for reasons of, for example, ageing of populations, increasing numbers of patients with chronic diseases including multimorbidity and introductions of new (pharmaceutical) innovations leads to political and societal debate. In particular, the introduction of expensive pharmaceutical innovations causes a lot of discussion and uncovers various paradoxes and dilemmas. There is a societal demand for innovation focused on the existing medical need (e.g. oncology, immune-inflammation, orphan diseases), but the price of pharmaceutical innovations more and more results to be a hurdle for patient access. As a consequence, systems try to introduce measures or incentivize market forces to improve access for patients as well as to contain budget impact. This does not always lead to better access and affordability. The aim of this study was to develop and test a conceptual decision-making framework for pharmaceutical innovation.

METHODS:
A retrospective study was conducted to identify the successes and challenges of decision-making systems across Europe. A conceptual decision-making framework including proposed procedures, criteria and HTA requirements (incl. tools) was developed and tested based on specific case-examples (e.g. oncology and hepatitis C).

RESULTS:
The conceptual decision-making framework comprises of an algorithm for relevant decision-making criteria (e.g. clinical evidence, medical need, cost-effectiveness, budget-impact). The algorithm developed hierarchically ranks the criteria in order to optimally inform various types of (investment) decisions. An underlying novel approach for conducting budget-impact analysis, resulted in more realistic predictions of the burden of pharmaceutical innovations to healthcare budgets as part of horizon-scanning processes as well as to inform healthcare decision-making processes next to HTAs. Results will be illustrated based on selected case-examples.

CONCLUSIONS:
The conceptual decision-making framework and underlying proposed method for budget-impact predictions allows for more balanced future healthcare investment decisions.
**PP84** Different Interpretation Of Evidence By HTA Body And Decision Maker

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**ABSTRACT SUMMARY:**
With the provision of addenda, both, IQWiG (HTA body) and FJC (decision maker), gain insights into exactly the same evidence for the benefit assessment of pharmaceuticals in Germany. All relevant documents up to 2017 were screened and essential content extracted to assess the agreement between IQWiG recommendations and FJC decisions. The agreement varies, highlighting different methodological approaches and decisive factors.

**INTRODUCTION:**
Within early benefit assessment of pharmaceuticals in Germany, addenda can be commissioned by the Federal Joint Committee (FJC) to the HTA agency (IQWiG) mainly as a result of a hearing. Our aim is to analyze the issues for and the impact of commissioned addenda as well as the agreement between IQWiG recommendations and FJC decisions.

**METHODS:**
All available relevant documents up to end of 2017 were screened and essential content extracted. Next to descriptive statistics, differences between IQWiG and FJC were tested and concordance was analyzed by agreement statistics (Cohen’s kappa and Fleiss’ kappa).

**RESULTS:**
Most of the 90 addenda commissioned up to 2017 concerned oncological products. In all contingent comparisons, positive changes in added benefit or evidence level on a subpopulation basis (n=124) prevailed negative ones. Fleiss’ ordinal kappa for agreement of assessments, addenda, and appraisals reached a moderate strength for added benefit (0.474; 0.408–0.540). Overall agreement between addenda and appraisals on a binary nominal basis is poor for added benefit (Cohen’s k 0.183; 0.010–0.357) and fair for the evidence quality (Cohen’s k 0.353; 0.187–0.520). Cohen’s k ranges for the first from “less than by chance” (respiratory diseases) to “perfect” (neurological diseases), but is only for neurological and other diseases statistically significant. Exemplarily, three addenda were presented in detail.

**CONCLUSIONS:**
Addenda have a high impact on decision-maker’s appraisals offering additional analyses of supplementary evidence submitted by the manufacturers. Nevertheless, the agreement between addenda and appraisals varies, highlighting different methodological approaches and decisive factors between IQWiG and FJC.

**PP85** Market Agreements And Budget Impact: The Antiangiogenic Case

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**ABSTRACT SUMMARY:**
The abstract analyses the influence of market agreements on the budgetary impact of drug incorporation, using the example of second line treatment of diabetic macular edema (DME). Also discuss its viability in the light of State of Minas Gerais – Brazil, Public Health System–’s budget for drug acquisition.
INTRODUCTION:
Budget Impact Analysis (BIA’s) are the latest studies carried before the incorporation of health technologies (HT) in a health system. The health lawsuits profile in Brazil may point to therapeutic lacks and guide studies of HT, including BIA’s. Market agreements between pharmaceutical companies can raise de costs of a treatment incorporation. Antiangiogenic therapy for Diabetic Macular Edema (DME) with ranibizumab is very often demanded in lawsuits against the Minas Gerais State public Health System (SUS-MG) so we carried a BIA of it’s incorporation including the off-label (due to market agreement) drug bevacizumab.

METHODS:
BIA was performed using the Brazil´s ministry of health suggested deterministic worksheet method using a 5-year horizon and the population/perspective of SUS-MG. Bevacizumab, Ranibizumab and Aflibercept were included in BIA, once it have similar evidences of effectiveness and safety.

RESULTS:
The incremental budgetary impact were R$ 69,493,906.95 for Bevacizumab, R$ 349,319,965.60 for Ranibizumab and R$ 543,867,485.47 for Aflibercept, so that Bevacizumabe proved to be the financially more viable.

CONCLUSIONS:
The theoretical off-label Bevacizumab incorporation would generate an increase of approximately 3% in SUS-MG medicines acquisition budget, what is considered feasible for the System. The at least 5-time price discrepancy between products demonstrates the performance of forces and market agreements. The Ranibizumab/Bevacizumab market agreement practice is apparently executed worldwide. There is a European court order, originating in Italy, which imposed fines on Roche and Novartis of EUR 90.6 million and EUR 92 million, respectively. In addition to a commercial agreement involving the non-registration of an effective drug for DME, the observed phenomenon illustrates a more subtle way of capturing public resources by involving the courts as mediators and use Brazilian laws in companies’ profit benefit. The compulsory licensing or special use authorization of bevacizumab can save resources of SUS-MG and obstacularize the market agreement operation.

PP86 To Reimburse Combination Oncology Products: Can Two [Companies] Tango?

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ABSTRACT SUMMARY:
We evaluated whether dual-branded oncology therapies developed by a single manufacturer had faster and/or better outcomes than those developed by two separate manufacturers. HTA bodies were numerically more likely to issue negative recommendations for dual-branded treatments in oncology indications if each constituent monotherapy was marketed by two separate companies vs. a single company. A single company may have more flexibility.

INTRODUCTION:
A range of innovative targeted anti-cancer therapies have been developed over the past 20 years. More recently, companies have been developing combinations of these drugs. Whilst this holds the promise of substantial efficacy benefits, dual branded oncology therapy combinations have potential substantial economic burden. Obtaining
positive HTA approvals and public reimbursement may be a major challenge, which may be amplified if each constituent monotherapy is marketed by a different company. We evaluated whether dual-branded oncology therapies developed by a single manufacturer had faster and/or better outcomes than those developed by two separate manufacturers.

METHODS:
Recent oncology combination products were screened in November 2018 and identified whether one or two manufacturers were involved. The NICE, G-BA, HAS, SMC, NCPE, CADTH and PBAC websites were screened and relevant data extracted.

RESULTS:
A total of 78 recommendations for dual-branded treatments for oncology indications were identified across the HTA bodies screened (same manufacturer: 26 recommendations, two manufacturers: 52 recommendations). Dual-branded therapies developed by a single manufacturer achieved numerically higher rates of full or optimized/conditional recommendations (58% "recommended" and 12% "optimized/conditional") than those marketed by two separate manufacturers (42% "recommended" and 8% "optimized/conditional"). Dual-branded therapies by two manufacturers were more likely to receive negative HTA recommendations, than those marketed by a single manufacturer (50% versus 31%). However, the median time from European Marketing Authorisation until recommendation in European countries was the same regardless of whether each constituent was marked by a single or two manufacturers (both 6.0 months).

CONCLUSIONS:
HTA bodies were numerically more likely to issue negative recommendations for dual-branded treatments in oncology indications if each constituent monotherapy was marketed by two separate companies vs. a single company. A single company may have more flexibility in its price setting which may facilitate higher HTA recommendation rates.

PP87 Inpatient Drug Reimbursement: Approaches For Democratic Processes

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ABSTRACT SUMMARY:
The introduction of new, cost-intensive medicine demand evidence-based, transparent, fair and efficient decision processes, given limited resources. However, these characteristics can be contradictory: the different characteristics need to be balanced against each other and priorities must be set in the decision process.

INTRODUCTION:
Given limited healthcare resources and high healthcare expenditures, especially in the areas of orphan diseases and oncology, the introduction of new, cost-intensive medicines lead to prioritization between two drugs. In democratic societies, health-political decisions need to be evidence-based, transparent, fair and efficient. Therefore, in some countries standardized (transparent) processes exist. In Austria, no decisions had to be made against the broad refund of new medicines for a long time. The aim of the present study was to develop different scenarios for a standardized, centralized reimbursement process on expensive hospital drugs for Austria, in favor of democratic healthcare-decisions.
METHODS:
In a multi-stage approach, firstly the reimbursement processes (only for original preparations) in individual selected countries as well as in Austria were investigated. Secondly, the strengths and weaknesses of the elaborated processes were analysed based on predefined criteria, following the concepts of “Accountability for Reasonableness” (A4R) and “deliberative decision making”. Thirdly, scenarios for an Austria-wide uniform reimbursement process for hospital drugs were developed.

RESULTS:
Three scenarios were identified: The first scenario includes a reimbursement process for hospital drugs following the existing reimbursement process in the outpatient sector in Austria. The second scenario represents a cooperation of decentralized “Pharmaceutical and Therapeutics Committees” for procurement, using-algorithm and reimbursement decisions for hospital drugs. The third scenario illustrates an adaptation of the existing reimbursement process of non-drug, highly specialized technologies for pharmaceutical interventions.

CONCLUSIONS:
According to the concepts of A4R and “deliberative decision making”, a transparent, evidence-based, fair and efficient allocation of limited healthcare resources seems indispensable to justify decisions on priorities in democracies. However, these criteria can be diametrically opposed e.g., methods/processes/decisions can be evidence-based, transparent and/or fair, but also significantly more time-consuming. Thus, a balance between the individual options for action is necessary and priorities must be set.

PP88 Economic Impact Of New Diagnostic Tools In Severe Sepsis

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ABSTRACT SUMMARY:
The need for cost containment and the increasing burden due to antimicrobial resistances require the development of more effective treatment pathways. Based on a cost consequence model that compares the impact of an improved diagnostic approach in the future to the current processes, it can be shown that the economic savings compensate the expenditures paid for an innovative test.

INTRODUCTION:
Constantly rising health care costs and increased incidence of antimicrobial resistance represent a growing burden on public health affecting patients, physicians, payers and health authorities. This analysis assessed the economic impact of improved diagnostic accuracy in the treatment of septic patients.

METHODS:
A cost consequence model was developed to evaluate two different scenarios for the treatment of severe sepsis: Scenario 1 represents the current status of diagnostic performance used for an antimicrobial treatment. Scenario 2 is based on the assumption that a more accelerated diagnostic process is associated with a 15% higher proportion of patients treated with an efficient antimicrobial drug early in their therapy. The information about average patient related cost for diagnostics (1,182 Euro) and overall costs (12,090 Euro), length of
stay (average LOS: 18.7 days), number of annually affected patients (n=771) were derived from the German DRG-code (T60A) in 2017. Further, the impact of optimal vs inadequate therapeutic approaches on LOS (-38%), hospitalization costs (-40%), and mortality (-28%) were derived from published sources.

**RESULTS:**
By using more efficient tests to enable an earlier detection of sepsis for those patients who otherwise would not have an appropriate treatment, the number of appropriately treated patients can be increased by 36 patients. The overall annual LOS can be reduced by 319 days and the number of sepsis related deaths by 3. The overall annual costs in scenario 1 and 2 amounted to 11.4 mio and 11.2 mio Euro, respectively. The main savings were due to reduced expenses for hospital stay, drugs, readmissions and progression to septic shock.

**CONCLUSIONS:**
The increasing cost pressure and the rise in multi-resistant germs are a burden, which will increase over the next decade. The present analysis shows that scientific development, the willingness to intervene in detrimental developments and to invest in technologies can support an affordable health care.

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**PP89 Cost-Effectiveness analysis of Hepatitis A vaccination in India**

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**ABSTRACT SUMMARY:**
To determine the cost-effectiveness of Hepatitis A vaccination (HAV) in Kerala state, India, a Markov model was performed. The incremental cost-effectiveness ratio based on both societal and payer perspectives shows negative value indicating that HAV is dominant with lower cost and higher effectiveness. HAV strategy would be cost-saving compared to no vaccination in the Kerala state, India.

**INTRODUCTION:**
In India, due to epidemiological transition, a rise in hepatitis A outbreaks in adults in Kerala state is noted. This has intensified the need for introducing hepatitis A vaccination (HAV). However, evidence regarding cost-effectiveness for HAV which is essential to guide the policy decision has been lacking. This study was undertaken to evaluate the cost-effectiveness of HAV among adults in Kerala state.

**METHODS:**
To determine the cost-effectiveness of HA vaccination based on both societal and payer perspectives, a Markov model with cycle length of 2 months was performed to compare lifetime costs and outcomes between HAV and no vaccination with a discount rate of 3%. Model input parameters i.e., cost, coverage, and effectiveness data were taken from published literatures. One way and probabilistic sensitivity analyses were applied. The gross domestic product (GDP) based threshold (1 GDP = ₹ 1,26,057 and 1 USD = ₹ 64.199) was used.

**RESULTS:**
The incremental cost-effectiveness ratio (ICER) based on both societal and payer perspectives shows negative value indicating that HAV is dominant with lower cost and higher effectiveness. Discount rate and utility values of adults with HAV are the most sensitive parameters.

**CONCLUSIONS:**
HAV strategy would be cost-saving compared to no vaccination in the Kerala state, India.
PP90 Pneumococcal Vaccine In Elderly: Review Of Cost-Effectiveness

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ABSTRACT SUMMARY:
In the prevention of pneumococcal disease in elderly, pneumococcal conjugate vaccine (PCV13) is an alternative to commonly used polysaccharide vaccine (PPV23). A literature review revealed that both vaccines are cost-effective compared with no vaccination, but compared with each other, results depend on key parameters and sponsors. PCV13 added to PPV23 seems not to be cost-effective compared to PPV23 alone.

INTRODUCTION:
There are two vaccines available for adults to prevent pneumococcal disease: the pneumococcal polysaccharide vaccine with 23 serotypes (PPV23) and the pneumococcal conjugate vaccine with 13 serotypes (PCV13). In most of industrialized countries PPV23 is currently recommended to elderly. The aim was to resume evidence on efficiency of the use of PCV13 in the immunocompetent elderly population in industrialized countries.

METHODS:
We performed a systematic literature review of economic evaluations that compared cost-effectiveness of the use of PCV13 with no-vaccine strategy or with PPV23, searching in several databases until March 2017. Two researchers selected the articles independently, and the studies were assessed according to their methodological quality. Data extraction was undertaken by one researcher and double checked by a second researcher.

RESULTS:
Thirteen economic evaluations fulfilled the inclusion criteria. Most of the studies have shown that both vaccines are cost-effective when compared with the option of no vaccination. However, the conclusion regarding which vaccine is more cost-effective, i.e. PPV23 or PCV13, varied according to the sponsor (vaccine manufacturer) and to the key parameters and assumptions applied in the studies. Two most recent studies, not funded by the industries, did not consider cost-effective the option of adding PCV13 to the current PPV23 vaccination for immunocompetent elderly population.

CONCLUSIONS:
The use of PCV13 compared to no-vaccination is a cost-effective strategy in the immunocompetent elderly population. However, as a complement to PPV23 it seems not to be cost-effective compared to PPV23 vaccine alone.

PP91 Burden Of Post-Surgical Complications In Patients With GI Surgeries

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We performed a systematic literature review of economic evaluations that compared cost-effectiveness of the use of PCV13 with no-vaccine strategy or with PPV23, searching in several databases until March 2017. Two researchers selected the articles independently, and the studies were assessed according to their methodological quality. Data extraction was undertaken by one researcher and double checked by a second researcher.

RESULTS:
Thirteen economic evaluations fulfilled the inclusion criteria. Most of the studies have shown that both vaccines are cost-effective when compared with the option of no vaccination. However, the conclusion regarding which vaccine is more cost-effective, i.e. PPV23 or PCV13, varied according to the sponsor (vaccine manufacturer) and to the key parameters and assumptions applied in the studies. Two most recent studies, not funded by the industries, did not consider cost-effective the option of adding PCV13 to the current PPV23 vaccination for immunocompetent elderly population.

CONCLUSIONS:
The use of PCV13 compared to no-vaccination is a cost-effective strategy in the immunocompetent elderly population. However, as a complement to PPV23 it seems not to be cost-effective compared to PPV23 vaccine alone.
**Abstract Summary:**
Major post-surgical complications in GI surgeries have generated high cost burden to the health care system and are devastating to patients’ families for the dramatic increase in in-hospital death.

**Introduction:**
Gastrointestinal (GI) surgeries is the top 3 most common surgery category. Study in the US showed that patients with any complications after gastrectomy costed 120% more than those without complications. In Thailand, however, there has not been evidence revealing the magnitude of complications after GI surgery.

**Methods:**
A multiregional database analysis of 4 public tertiary hospitals in Thailand was conducted. Accounting the maturity of EMR and HIS systems, data from 2013 to 2017 were analyzed. Selection of high-risk GI surgeries are based on Schwarze ML et al (2015). Outcomes of interests included incidence of major post-surgical complications (based on Michard F et al 2015), length of stay (LOS), in-hospital death, and total cost to the health care system. Multivariate regression analyses were performed to test the association between risk factors and post-surgical outcomes and costs to the health care system. Costs were converted to US dollars (US$) using an exchange rate of 32.76 THB/USD.

**Results:**
A total of 8,198 patients were identified. Of those, 1,806 patients (22.0%) had major post-surgical complications. The most common complications were respiratory failure or acute respiratory distress syndrome (11.0%), sepsis (3.7%), and pneumonia (3.6%). In-hospital mortality was 8.3%. The median LOS was 8 days [interquartile range (IQR): 6-13 days], with median total costs of US$ 1,957 (IQR: US$1,194 - 3,326). Multivariate regression analyses suggest that experiencing major complications contributes to significantly higher risk of in-hospital death [odds ratio (OR): 4.70; 95%CI: 3.97-5.56], longer LOS [OR: 6.9 days; 95%CI: 2.7-11.1 days; p<0.001] and higher costs [US$2,647; 95%CI: US$1,999-3,296; p<0.001].

**Conclusions:**
Major post-surgical complications in GI surgeries have generated high cost burden to the health care system and are devastating to patients’ families for the dramatic increase in in-hospital death. Clinicians and policy makers should be concerned and develop strategies to reduce the occurrence of major complications.
in major cardiac surgeries in Asia-Oceania countries.

**METHODS:**
A systematic literature search was performed in three databases (PubMed, Embase, and CENTRAL) for publications between January 2000 and July 2018. Inclusion criteria was: 1) original observational studies or randomized control trials published in English; 2) patients receiving CABG and/or heart valve procedures; 3) study measured postoperative (within 30 days) clinical outcomes; and 4) study conducted in Asia-Oceania countries. Pooled effects were calculated using a random-effects model.

**RESULTS:**
Of the 6,032 articles screened, 564 studies with a total of 756,091 patients met our inclusion criteria, including 429 articles for CABG, 127 for heart valve procedures, and 8 for combined procedures. The pooled incidence of hospital mortality and 30-day mortality were similar at 2% (95% confidence interval, 2%-2%). LoS was 13.58 days (13.06-14.10 days). The incidence for atrial fibrillation (AF)/arrhythmia and cerebrovascular accident (CVA) was 18% (16%-19%) and 2% (1%-2%), respectively. Patients with high surgical risks appeared to have higher incidence of hospital mortality (6% [4%-7%] vs 2% [2%-3%]), 30-day mortality (3% [3%-4%] vs 2% [1%-2%]), AF/arrhythmia (24% [0.19-0.30] vs 21% [18%-25%]) as well as LoS (average 15.55, [12.83-18.27] vs 12.21 [11.36-13.06] days).

**CONCLUSIONS:**
This is the first large scale literature review on burden of post-surgical complications in cardiac surgeries in the Asia-Oceania region. Patients with high surgical risks undergoing major cardiac surgeries were prone to increased risk of mortality, AF/arrhythmia and prolonged LoS. There should be treatment strategies recommended at national level to minimize postsurgical complications.

**PP93 Efficacy Of Pharmacological Treatments For Type 2 Diabetes In China**

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**ABSTRACT SUMMARY:**
This study estimated the efficacy of antidiabetic-drugs for Chinese type-2-diabetes patients. Systematic review, meta-analyses and indirect-treatment-comparison were conducted. 354 studies were identified. Results showed that compared with placebo/lifestyle-intervention, pharmacological monotherapies achieved an average greater reduction of 0.90% in HbA1c level, 0.98 kg/m2 in BMI level and 0.35 mmol/l in TC level; while combination-therapies achieved a greater reduction of 1.94% in HbA1c level, 2.66 kg/m2 in BMI level and 1.07 mmol/l in TC level. Combination therapies were superior to monotherapies.

**INTRODUCTION:**
There are multiple antidiabetic drugs in China, which vary in efficacy and safety. However, no study exists comparing all the alternative classes of antidiabetic-drugs simultaneously. This study aims to estimate and compare the efficacy of alternative classes of antidiabetic-drugs in the regimen of monotherapy or combined with metformin for Chinese type 2 diabetes(T2DM) patients.
**METHODS:**
Systematic-literature-review was conducted by searching databases including CNKI, WanFang, CQVIP, PubMed, EMBASE, Web-of-Science, ScienceDirect, Cochrane-Library, to identify randomized-controlled-trials(1990-2016) comparing the efficacy of antidiabetic-drug monotherapy vs. placebo/lifestyle-intervention(i.e., diet/exercise), antidiabetic-drug+metformin vs. metformin in Chinese T2DM patients. Referring to Chinese guideline, eight-classes of antidiabetic-drugs were included: metformin, α-glycosidase-inhibitor, sulfonylurea, glinide, DPP-4-inhibitor, thiazolidinedione, insulin, and GLP-1-receptor-agonist. Meta-analyses were used to estimate the efficacy of antidiabetic-drug monotherapy vs. placebo/lifestyle-intervention, antidiabetic-drug+metformin vs. metformin. Using metformin as common-comparator, indirect-treatment-comparison was used to estimate the efficacy of antidiabetic-drug+metformin vs. placebo/lifestyle-intervention.

**RESULTS:**
99072 records were identified through database-search, with 354 studies finally included. Results showed that compared with placebo/lifestyle-intervention, overall, pharmacological monotherapies achieved an average greater reduction of 0.90% in HbA1c level, 0.98 kg/m2 in BMI level and 0.35 mmol/l in TC level; while combination-therapies achieved a greater reduction of 1.94% in HbA1c level, 2.66 kg/m2 in BMI level and 1.07 mmol/l in TC level. In monotherapies, the top three treatments for reducing HbA1c level were insulin (WMD:-2.37;95%CI:-3.79,-0.95), sulfonylurea (WMD:-1.19;95%CI:-1.56,-0.82) and GLP-1-receptor-agonist (WMD:-1.18;95%CI:-1.45,-0.91); for reducing BMI level were metformin (WMD:-1.77;95%CI:-3.14,-0.39), GLP-1-receptor-agonist (WMD:-1.14;95%CI:-1.88,-0.40) and α-glycosidase-inhibitor (WMD:-0.64;95%CI:-1.46,0.17); for reducing TC level were metformin (WMD:-0.64;95%CI:-1.08,-0.19), GLP-1-receptor-agonist (WMD:-0.58;95%CI:-0.91,-0.25) and DPP-4-inhibitor (WMD:-0.18;95%CI:-0.35,-0.01). In combination-therapies, the top three treatments for reducing HbA1c level were GLP-1-receptor-agonist+metformin (WMD:-2.42;95%CI:-3.11,-1.73), insulin+metformin (WMD:-2.04;95%CI:-2.72,-1.36) and glinide+metformin (WMD:-2.03;95%CI:-2.70,-1.36); for reducing BMI level were glinide+metformin (WMD:-4.25;95%CI:-5.70,-2.80), GLP-1-receptor-agonist+metformin (WMD:-3.27;95%CI:-4.70,-1.84) and DPP-4-inhibitor+metformin (WMD:-2.81;95%CI:-4.22,-1.40); for reducing TC level were insulin+metformin (WMD:-1.79;95%CI:-2.32,-1.26), GLP-1-receptor-agonist+metformin (WMD:-1.43;95%CI:-2.01,-0.85) and α-glycosidase-inhibitor+metformin (WMD:-1.41;95%CI:-2.15,-0.68).

**CONCLUSIONS:**
Pharmacological treatments had better efficacy than placebo/lifestyle-intervention. Combination therapies were superior to monotherapies.

**PP94 Clinical Effectiveness Of Regorafenib In Metastatic Colorectal Cancer**

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**ABSTRACT SUMMARY:**
Regorafenib demonstrated antitumor activity in various tumor models, including models of colorectal and gastrointestinal stromal and hepatocellular tumors, mediated by its anti-angiogenic and anti-proliferative effects. In addition, regorafenib reduced the levels of...
macrophages associated with the tumor and shows an antimetastatic effect.

**INTRODUCTION:**

In the structure of the incidence of malignant neoplasms, colorectal cancer ranks third among men and second among women. According to the World Cancer Report the number of people suffering from this disease is growing steadily. In 2012, there were more than 1.36 million new cases of CRC and approximately 694,000 deaths from this disease in the world.

**METHODS:**

23 references were identified due to using a sensitive search strategy, of which 12 full-text publications were included into our report: a CORRECT phase III study assessing the effect of regorafenib on patients with mCRC, which continues to progress after the using of all approved standard treatment methods; a CONCUR Phase III study - evaluating the clinical effect of regorafenib on patients with mCRC in Asian patients; a CONSIGN study conducted after CORRECT and CONCUR phase III studies to further study the safety profile of the drug prior to market entry; and other systematic reviews and meta-analysis concerning mostly the safety of regorafenib.

**RESULTS:**

The efficacy and safety of regorafenib in the treatment of mCRC was evaluated in two major clinical studies: CORRECT and CONCUR. The studies were randomized, double-blind and placebo-controlled, but they were conducted in different patient populations. Depending on the country, patients before treatment with regorafenib received fluoropyrimidines, oxaliplatin, irinotecan, bevacizumab, and patients with wild type KRAS also received cetuximab and panitumumab.

Results of both studies indicate that regorafenib has a clinically significant effect on progression free survival (PFS) and overall survival (OS) in the treatment of resistant metastatic colorectal cancer.

**CONCLUSIONS:**

Taking into consideration the safety profile of regorafenib, further research is needed to explore alternative approaches to the dosage of regorafenib and the study of clinical and molecular biomarkers that can determine patient choice. The use of regorafenib can be recommended as monotherapy for resistant mCRC, if there are no individual contraindications to use.

**PP95 Ovarian Tissue Cryopreservation And Transplantation In Cancer Patients**

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**ABSTRACT SUMMARY:**

Various publications state the successive increase of live-births observed after ovarian tissue cryopreservation and transplantation (OTC-T) for fertility-preservation in cancer patients by summarizing data from international centers/publications, some calling OTC-T established. We performed a benefit-risk-assessment of OTC-T compared to no therapy focusing on live-birth-rates and procedure-related complications. Considering the current best-available evidence we discuss the interpretability of the observed results.

**INTRODUCTION:**

Ovarian tissue cryopreservation and transplantation (OTC-T) belongs to the fertility-preservation-strategies for cancer patients. Various publications state the successive increase of live-births observed
after OTC-T by summarizing data from international centers/publications, some calling the method established. So far OTC-T is not covered by the German statutory-health-insurance. For the purpose of evaluation a benefit-risk-assessment was initiated.

METHODS:
We performed a systematic review including primary trials which compared OTC-T in postpubertal cancer patients with no therapy. Live-birth-rates were regarded as critical outcome. Procedure-related complications in the cancer patients and/or the live-born children represented further outcomes of interest. We primarily looked for controlled trials to determine the interventions’ benefit and risk. Alternatively an overview of lower-grade-evidence (at least single-arm-trials providing at least five evaluable patients) was planned.

RESULTS:
No controlled trials could be identified, best-available evidence consisted of 8 single-arm-trials presenting cases registered/treated over a specific period. Often, trials did not explicitly report in-/ exclusion-criteria for cryopreservation, and the infertility-risk remained indistinct. Trials lacked a pre-specified course for the application of concomitant therapy. Populations exhibited a wide spectrum of cancer-entities. Due to the described heterogeneity we did not sum up data across trials. Outcome-rates can be calculated as range across trials (for example live-birth-rates varied from eighteen to thirty-three percent), but interpretation of the data is limited due to the high imprecision caused by small numbers of cases in the trials. Reporting of complications was scarce in the identified trials, information on the state-of-health of the live-born children not always provided.

CONCLUSIONS:
Evidence on OTC-T lacks controlled trials comparing OTC-T with no therapy. Outcome-rates could not be assigned to specific treatment chains or cancer-entities. Prospective controlled trials are needed that aim at identifying clear indication-criteria for OTC-T. More standardization of the intervention with subsequent evaluation in respective multicenter-trials can support the broad transferability of results.

PP96 The Genomic Signatures In Early Breast Cancer In France

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ABSTRACT SUMMARY:
We assessed, for listing and reimbursement purposes, the clinical utility of 4 GS in women with early breast cancer in intermediate-risk for recurrence based on standard clinical-pathological criteria. We described several specific populations within the French setting likely to receive adjuvant chemotherapy and for which GS added value is expected.

INTRODUCTION:
The genomic signatures (GS) in early breast cancer are used to improve prognostic and predictive information for patient selection of adjuvant chemotherapy (AC), particularly if treatment benefit is expected to be relatively modest and standard clinical-pathological criteria (SCPC) uninformative. We assessed, for listing and reimbursement purposes, the clinical utility of 4 GS in women with intermediate-risk for recurrence based on SCPC who would be candidates for recommending or considering AC.
METHODS:
In this systematic review, HAS analyzed only direct evidence from prospective GS-based strategy studies from January 2002 to August 2018. A multidisciplinary expert panel was consulted to validate the assessment protocol, describe the clinical context and provide their appreciation of the available evidence. Stakeholders’ consultation was also carried out.

RESULTS:
In women with estrogen-receptor-positive (ER+), human epidermal growth factor receptor 2 (HER2-) negative breast cancer, and affected lymph nodes (0 to 3), we described several specific populations likely to receive AC within the French setting, and for which GS benefit was expected. We then assessed GS clinical utility for those distinct population groups. We included 4 comparative studies in our analysis. Clinical impact data were available for first-generation assays (Oncotype Dx/Mammaprint) but not for second-generation assays (Prosigna/Endopredict). Limitations with the selected studies were described and largely discussed in the report with regards to design, patient selection, thresholds, reporting. A proposal, with expert collaboration, was thus elaborated to benefit a specific population group in the research setting.

CONCLUSIONS:
GS show promise with regards to prognostic improvement in patient selection of adjuvant chemotherapy, but has yet to demonstrate predictive benefit. A number of other clinical trials involving GS are currently underway to generate evidence on clinical utility.

PP97 Analysis Of International Activities Of INAHTA Member Agencies

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ABSTRACT SUMMARY:
In order to enhance the understanding of HTA-agencies’ approach to international affairs (IA), the authors implemented a survey on international activities of INAHTA member agencies. The results showed that in many agencies HTA as international topic is not explicitly established. Yet, some agencies with dedicated departments/ positions for IA are actively shaping the international HTA scene.

INTRODUCTION:
Within the International Network for Agencies on HTA (INAHTA), a Community of Practice (CoP) “International Affairs” (IA) has been established with the purpose to provide a platform for international activities of member agencies, first for getting a better understanding and to support the development of relationships. As background the authors undertook a Survey to analyze the international activities of HTA agencies organised in INAHTA.

METHODS:
The questionnaire circulated to INAHTA members asked 1) if an IA unit is formally defined 2) how many staff are involved in topics with relevance to IA, 3) in which three topics the agency is momentarily interested in at international level, 4) if the agency observes international developments in HTA regularly, 5) how this information is used and 6) what an IA CoP should do.
Secondly, based on the questionnaire, interviews have been held with four representatives of HTA agencies which have a dedicated unit or position for IA.

RESULTS:
The share of questionnaires returned to us was low. Therefore, we contacted the agencies directly. It became clear that many agencies only started to see HTA explicitly as an international issue. Within the interviewed agencies two tracks for IA has been established: a position/ department for IA and direct expert involvement. All four agencies are intensively engaged in international organisations such as ISPOR/ HTAi.

CONCLUSIONS:
Agencies recognise the international scene as important field of activity, only a few have dedicated staff for IA or provide centralised organisation for IA activity. The low return of questionnaires shows that further efforts are needed to improve international exchange between HTA agencies and to build up resources for this field.

PP98 Educating Medical Students Toward Quality-Targeted Leadership

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ABSTRACT SUMMARY:
Aggregating evidence for effective HTA including ‘real-world’ experience is a challenge. We initiated a targeted HTA-orientated education program for medical students. They raised four challenges: the need to initiate a culture of HTA-targeted quality perception, understanding the stakeholders and budget allocation, and incorporating patient expectations. Early medical education may build smart capability creating a professional quality-focused leading group in healthcare.

INTRODUCTION:
Classic HTA is based on safety, efficacy and costs. However, in the dynamic world of medicine, ‘real-world’ experience (RWE) is used to improve HTA. Aggregating evidence is a constant challenge. Physicians are traditionally trained on professionalism (knowledge and skills) alongside compassion, concentrating on the patient and disease, not the technology. Currently medical education also emphasizes quality of care by promoting standardization, and reducing mistakes by root-cause-analysis. Aim: To integrate key parameters of safety, effectiveness, quality measures, economic aspects and assessment guidelines for RWE in medical education.

METHODS:
A program of targeted HTA-orientated education was conducted, focusing on the identification of challenges and barriers in the adoption of health technologies, followed by an analysis of a structured survey.

RESULTS:
243 students participated in the program. They raised four major emerging challenges: (i) the need to initiate a culture of quality and HTA-targeted perception for the individual physician, (ii) to better understand the role of different stakeholders in the ecosystem, (iii) to be exposed to considerations of budget allocation, (iv) to incorporate patient preferences expectations, engagement, making ‘patient-centered-care’ a critical part of HTA.

CONCLUSIONS:
Incorporating values of HTA-targeted-quality at an early stage of medical education, while these future physicians are developing their professional
identity, may create a professional quality-focused leading group in healthcare.

The understanding and implementation of these ‘new’ dimensions, may serve as a platform for opportunities, building smart capability to ensure a better decision-making process by caregivers and medical managers.

PP99 HB-HTA Units In Brazil: Today And Future

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ABSTRACT SUMMARY:
Since 2007, 23 Hospital Based Health Technology Assessment (HB-HTA) Units were established in teaching hospitals among all regions of Brazil. After an exploratory investigation, a profile of HB-HTA Units activities showed that they are extremely relevant despite low resources. HB-HTA decision-making process must continue advancing, since it is even more necessary in lower income countries.

INTRODUCTION:
Since 2007, 23 Núcleos de Avaliação de Tecnologias em Saúde (NATS) (Hospital Based Health Technology Assessment – HB-HTA Units) were established in teaching hospitals among all regions of Brazil. These units aim to promote the development of HTA practice in hospitals, assisting the decision-making process about implementation of new technologies, evaluation of widespread technologies and their rational use.

METHODS:
An online questionnaire was sent by e-mail to all NATS registered in the Brazilian Network for Evaluation of Health Technologies. Information was acquired to comprehensively assess the activity of NATS.

RESULTS:
All 23 HB-HTA units answered the questionnaire. 65.2 percent of the institutions answered that there is a prioritization process to evaluate technologies.

Regarding health technologies assessed, 72.7 percent evaluated drug therapy, 63.6 percent equipment, 63.6 percent medical devices, 45.5 percent clinical protocols, 27.3 percent emerging technologies. Dimensions of HTA process that are evaluated in their organization: 76.2 percent efficacy, 66.7 percent effectiveness, 66.7 percent safety, 52.4 percent costs, 52.4 percent cost-effectiveness/cost-utility, 42.9 percent budget impact.

The areas in the hospital that required more HTA studies were: cardiology (50 percent), infectology (45 percent), hospital management (45 percent), oncology (40 percent), surgery (40 percent), endocrinology (20 percent).

HTA studies supported: incorporation of new technologies (81 percent), protocols or guidelines development (57.1 percent), widen of product applicability (38.1 percent), withdrawal of obsolete technologies (28.6 percent).

50 percent of the institutions also conducted educational or training activities.

The main difficulties reported were: lack of trained professionals (78.3 percent), funding (69.6 percent), material resources (47.8 percent).

CONCLUSIONS:
To low- and middle-income countries, the process of implementing HB-HTA units remains a challenge. Even though human resources and funding are scarce, NATS are still under development, and due
to their importance in the decision-making process every effort to ensure its activities is imperative.

PP100 Unravelling Hospital-Based Health Technology Assessment In Brazil

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ABSTRACT SUMMARY:
Hospital-Based Health Technology Assessment (HB-HTA) Units in Brazil are a trending strategy to facilitate decision-making process in reduced resource settings. A multicriteria analysis study assessed HB-HTA units to comprise profile data, and to provide a diagnostic view. The proposed method was effective in reducing subjectivity, stratifying classification aspects, and allowing weak and strong attributes identification.

INTRODUCTION:
In Brazil, Hospital-Based Health Technology Assessment (HB-HTA) Units have been implemented since early 2000 to improve decision-making process countrywide. Multicriteria methodology (MCDA) can provide deep understanding of several aspects of a given subject. The present study used MCDA methods to evaluate capacity building of HB-HTA units in Brazil.

METHODS:
This study analysed preliminary data from a survey developed and sent to all HB-HTA units in Brazil in 2018. The survey was comprised of 116 questions, covering a wide range of aspects of units. Initially, an expert panel was organized, and 46 objective questions (out 116) were selected by four experts. Next, these experts classified the selected questions and attributed importance weights to each of the classifications. A Likert scale was used to identify importance levels, and its results were converted to importance weights from 0 to 1. Following, experts defined a final importance score threshold of 60% to classify units as fully operational. Grades below this threshold would be indicated to undergo a more detailed evaluation. Finally, 23 (out of 80) survey questionnaires were evaluated by the proposed method.

RESULTS:
Importance weights of each classification were defined as (i) personnel 25%, (ii) level of expertise 31.25%, work production 31.25% and infrastructure 12.50%. HB-HTA units final importance scores presented a mean of 67.81%±22.01. Maximum score achieved was 95.31%, while the minimum score was 15.00%. Fully operational status was achieved by 10 HB-HTA units (out of 23). HTA units were stabilised by an average of 6±4 years.

CONCLUSIONS:
The multicriteria method presented by this study simplified HTA unit evaluation, reducing subjectivity of results. Final importance scores of each unit’s categories indicated which areas should be improved. Results from the study indicate that infrastructure and personnel could be greatly enhanced, even though the production profile seems satisfactory.
**PP101 Assessment Of Midwife-Led Model Of Care For The Uncomplicated Pregnancy**

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**ABSTRACT SUMMARY:**
This project aims at evaluating the impact of the implementation of a Midwife-led model of care for the management of low-risk pregnancies in the Province of Trento, Italy, by analyzing the different dimensions of HTA (including safety, clinical efficacy, costs, organizational and social aspects).

**INTRODUCTION:**
Studies have shown that the implementation of a midwife-led continuity of care leads to better outcome for pregnant women and their babies during the perinatal period. This project aims at evaluating the impact of the implementation of a Midwife-led model of care for the management of low-risk pregnancies in the Province of Trento, Italy, by analyzing the different dimensions of HTA (including safety, clinical efficacy, costs, organizational and social aspects).

**METHODS:**
The evaluation of the project will include 4 steps: 1) A description of the care pathway for women who enter the new “midwife-led model of care” in Trento as well as a description of the old care pathway, 2) A systematic literature review of the description of the “midwife-led model of care” 3) A comparison of the descriptions from the literature review with the new pathway implemented in Trento, 4) A comparison of data from the new “midwife-led model of care” in Trento with retrospective data from the old care pathway. The analyses will include comparisons between clinical and organizational outcomes as well as an assessment of the economic impact of the new pathway using Budget Impact Analysis. The EuNetHTA Core Model Assessment will be used to describe organizational and economical aspects of the new pathway.

**RESULTS:**
Currently, the two pathways have been described and the systematic literature review has been performed. The literature review confirms that “midwife-led model of care” improves the care of pregnant women, especially regarding the woman’s satisfaction, reduction of birth complication, and the use of cesarean section. Results regarding the comparison of the two pathways will be presented at the HTAi Annual Meeting in Cologne 2019.

**CONCLUSIONS:**
Will be presented at the HTAi Annual Meeting in Cologne 2019.

**PP102 The Configuration And Impacts Of A HTA Unit In Primary Care**

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**ABSTRACT SUMMARY:**
In Quebec (Canada), local HTA units are present both in university hospitals and in primary care organisations. Although some studies have looked at the configuration of HTA units and their impacts
on hospital resources, very little is known about how a HTA unit works in the specific context of primary care.

INTRODUCTION:

Health Technology Assessment (HTA) units have been recognized as one of the possible approaches to conduct HTA at local level. In Quebec (Canada), local HTA units are present in university hospitals, but also in primary care organisations. Although some studies have looked at the configuration of HTA units and their impacts on hospital resources, very little is known about how a HTA unit works in the specific context of primary care. In order to fill this gap, the aim of this study is to explore the configuration of a HTA unit in primary care and its impacts on decisions.

METHODS:

A single tracer case is adopted as the method for this study. The single case study is relevant when a contemporary phenomenon, located in a real context, has to be analyzed in order to get rich and detailed knowledge. This study describes the functioning of a HTA unit in the particular case of primary care. Semi-structured interviews are conducted in order to provide insights on the configuration of a HTA unit in primary care, and they are complemented with the analysis of additional materials related to the HTA unit. An inductive coding procedure is adopted.

RESULTS:

As this study is ongoing, results will cover the configuration of a HTA unit in the context of primary care, and how it can impact on decisions. The inputs, processes and outputs of this primary care HTA unit will be described, and its perceived impact will be explored.

CONCLUSIONS:

This study will provide a better understanding of how HTA is conducted in primary care settings. However, this is not without limitations. First, since this study is based on a single case, results cannot be generalized. Second, further investigation is needed in order to compare the functioning of the HTA unit in primary care and in hospitals.

PP103 A Comparative Study Of CHE In ZJ and QH Province, China

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ABSTRACT SUMMARY:

This study compared the rated of CHE and the different performance of factors influencing CHE between Zhejiang and Qinghai province, China. It highlights that the Chinese government should pay more attention to the actual conditions in different provinces, further to make policy decisions according to the local knowledge.

INTRODUCTION:

China has made great achievements in health insurance coverage and healthcare financing; however, the rate of catastrophic health expenditure (CHE) was 13.0% in China in 2008, which is higher than that in some other countries. There remain some differences in life-style, national customs, medical conditions, and health consciousness in different provinces in China. This study aimed to compare the rates of households with CHE, further to explore the different
performance of factors influencing CHE between Zhejiang and Qinghai province, China.

METHODS:
Data were derived from the household surveys conducted in Zhejiang and Qinghai. Sampling on multi-stage stratified cluster random method was adopted. Household with CHE occurs when the out-of-pocket payment for health care equals to or exceeds 40% of a household’s income. Univariate and multivariate logistic regression analyses were used to identify the performance of factors of CHE.

RESULTS:
A total of 1598 households were included in this study, including 995 in Zhejiang and 603 in Qinghai. The average rates of CHE in Zhejiang and Qinghai were 9.6 and 30.5%, respectively. We found that economic status of households and households headed by an employed person are the protective factors for CHE; and number of members with chronic diseases and number of inpatients in household are the risk factors for CHE in the two provinces. Besides, poor/low-insured households in Zhejiang; and households having outpatients and households headed by a minority person in Qinghai are more likely to experience the risk of CHE.

CONCLUSIONS:
This study highlights the importance of improving economic development, expanding employment, and adjusting policies to make greater efforts to protect chronic diseases patients, outpatients, and inpatients, further to reduce the risk of CHE. The Chinese government should pay more attention to the actual conditions in different provinces, further to make policy decisions according to the local knowledge.

PP104 Predictive Validity Of Pressure Injury Assessment Tools for Patients

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ABSTRACT SUMMARY:
According to recent studies, pressure injury (PI) has a high incidence and its particularity in the intensive care unit (ICU). The accuracy of PI assessment tools used to help nurses for early prediction in ICU was controversial. We used meta-analysis to compare and analyze the predictive validity of PI assessment tools for ICU patients.

INTRODUCTION:
Pressure injury (PI) has a higher incidence in the intensive care unit (ICU) than other wards. The validity of PI assessment tools remains controversial because of their suitability for various patients in ICU. Thus, we conducted a systematic review to determine the predictive validity of PI assessment tools used in ICU.

METHODS:
We searched multiple databases including MEDLINE, Embase, CINAHL, Web of Science, the Cochrane Library, China Biomedical Literature Service System(SinoMed), VIP Database, CNIK from database inception to December 2017. Two reviewers independently assessed the articles’ eligibility and risk of bias with Quality Assessment of Diagnostic Accuracy Studies-II. Data was pooled according to sensitivity, specificity, diagnostic OR and the AUC. Subgroup analysis and sensitivity analysis were used to identify potential sources of bias.
RESULTS:
We identified 24 studies including 16 PI assessment tools with good methodological quality, involving a total of 15199 patients in the ICU setting. The results of the meta-analysis showed that the top five assessment tools in the predictive validity were Cubbin & Jackson Index (SEN=0.77, SPE=0.82, AUC=0.8690), EVRUCI scale (SEN=0.84, SPE=0.68, AUC=0.82), Braden The scale (SEN=0.71, SPE=0.51, AUC=0.73), the Waterlow scale (SEN=0.65, SPE=0.41, AUC=0.56) and the Norton scale (SEN=0.51, SPE=0.76). Sensitivity analysis shows that the overall accuracy of the five assessment tools was stable. The other 11 assessment tools involved only one study, so the accuracy needs further verification.

CONCLUSIONS:
Braden scale that is the most commonly used in hospital is not suitable for patients in ICU. Cubbin&Jackson Index and EVRUCI scale that have fine predictive value show good capability to predict the risk of PI but they need to be improved in the future. Further development and testing is required to determine the ICU-specific PI assessment tools.

INTRODUCTION:
When assessing complex medical technologies health technology assessments (HTA) often needs to move from a relatively narrow technical focus to inclusion of broader organizational aspects to meet the requirements of decision makers. To support this development organizational analysis has become an increasingly important part of HTA of complex technologies. Organizational analysis is important in order to understand the effects and effectiveness of such technologies, and to support optimal implementation and diffusion of technologies. Though increasing acknowledgement of its importance conduction of systematic organizational analysis continues to be a rare discipline within HTA and the capability of conducting such analysis among HTA agencies remains low. This presentation aims at giving examples of systematic approaches to conduction of organizational analysis, and presenting and discussing its importance and usability in HTA.

METHODS:
This presentation draws on practical experiences with the conduction of organizational analysis in three Danish HTAs; two completed and one currently ongoing.

RESULTS:
The three organizational analyses to be discussed in this presentation stems from the following Danish HTAs:

1) HTA of Robot-assisted Surgery
2) HTA of Home Mechanical Ventilation
3) HTA of Integrated Operation Rooms
The presentation will focus on discussing the
importance and usability of organizational analysis
in HTA and on presenting and discussing systematic
approaches to conduction of organizational
analysis based on practical experiences.

CONCLUSIONS:
Organizational analysis is important in order to
support the relevance of HTA in political decision
making for complex technologies. Development
of systematic approaches to conduction of
organizational analysis is needed in order to
strengthen the usefulness in management of
service delivery including complex technologies.

INTRODUCTION:
Music therapy (MT) is a complimentary treatment
option in the context of psychosocial care
of cancer patients. The aim of this health
technology assessment (HTA) is to review the
evidence for concomitant MT in adult cancer
patients with regard to effectiveness and safety,
cost-effectiveness, ethical, social, legal and
organisational aspects within Germany. MT is
defined as being performed by a trained music
therapist and covering at least two therapeutic
sessions.

METHODS:
The HTA follows the current method manual of
the German Institute for Quality and Efficiency
in Health Care (IQWiG). A systematic literature
search was done in MEDLINE, Embase, Cochrane
Databases und PsycINFO for the effectiveness
domain, a focussed literature search and hand
search for the other domains. Three patients were
involved through personal interviews.

RESULTS:
The evaluation of effectiveness and safety is based
on ten included randomized controlled trials.
The evidence synthesis was operationalized for
17 outcomes and three evaluation time points.
Significant effects favoring MT were found
predominantly in psychological outcome measures
and mostly in short-term measured outcomes.
Evidence synthesis was adversely affected by
great heterogeneity of measuring instruments
and numerous outcomes. Regarding ethical
as well as legal aspects there is a lack of (legal)
standardization in Germany, which may hinder
quality of supply. No studies on cost-effectiveness
were found.

CONCLUSIONS:
We identified evidence that hints on positive
effects of MT against routine care regarding
particular short-time and partly regarding some
long-term effects. A lack of evidence was found
for outcomes measuring disease management,
resilience and coping as well as for group therapy interventions and comparison of MT to alternative complimentary therapies. Two ongoing studies were identified that could render results on long term effects and resilience.

PP107 Harpoon™: A Novel Device For Transapical Mitral Valve Repair

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ABSTRACT SUMMARY:
Harpoon™ is a device designed for degenerative mitral regurgitation repair by means of transapical expanded polytetrafluoroethylene (ePTFE) cords implantation. This study aims to perform an early assessment of the efficacy and safety of Harpoon™ in minimally invasive mitral valve surgery. This technology seems to have a potential interest as an alternative to current open-heart procedures, however, further research is necessary.

INTRODUCTION:
Mitrail regurgitation (MR) is the most prevalent valve disease in western countries. Open-heart reconstructive mitral valve surgery is the conventional procedure for treatment, among which, cords replacement with ePTFE has become a standard. Novel devices have introduced surgical alternatives such as transapical beating-heart minimally invasive valve repair; among them, Harpoon™ appears to have potential advantages (smaller diameter, valve introducer to minimize bleeding, different anchoring mechanism). The aim of this study is to assess the efficacy and safety of Harpoon™ in minimally invasive mitral valve surgery.

METHODS:
An early assessment of the technology was conducted through review on databases: PubMed, EMBASE, Web of Science, Tripdatabase, the International Clinical Trials Registry Platform, ClinicalTrials.gov, Cochrane Library and the Centre for Reviews and Dissemination. Clinical studies using Harpoon™ in degenerative MR repair until 30 January 2018 were included.

RESULTS:
We found only 2 publications by the same research group that evaluated the efficacy and safety of Harpoon™. An initial 11-patients observational study and the TRACER trial, a prospective, nonrandomized clinical study (n=30). During the procedure, the MR was reduced between 73-86% from severe to none and 14-27% to mild. At one month, MR stayed mild or less in 82-89% patients. At 6 months, 16% patients from the TRACER trial had a worsened MR to moderate/severe. There was a favorable early remodeling of cardiac dimensions after surgery. Safety issues within 30 days (18-27% patients) comprised intraoperative conversion to open surgery, reoperation, pleural effusion, hemopericardium and atrial fibrillation. There was no intra or postoperative mortality.

CONCLUSIONS:
Current evidence about Harpoon™ is scarce. Although published studies showed MR improvement in most patients, there are still issues regarding safety and unawareness about long-term results, comparability with other procedures and costs. While promising, further research is required before recommend routine use of this technology.
PP108 Assessing CHA2DS2-VASc In predicting IS In Non-AF Populations

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ABSTRACT SUMMARY:
In order to provide evidence for clinical decisions, we assessed the accuracy of CHA2DS2-VASc score predicting ischemic stroke in adults(≥18 years old) without atrial fibrillation.

INTRODUCTION:
Cerebrovascular disease has become the first cause of death in China, and the incidence of ischemic stroke (240.3/100,000) is obviously higher than that of hemorrhagic stroke (82.1/100,000). More than 80% of stroke can be prevented early by controlling risk factors. Therefore, screening high-risk groups and hierarchical management of high-risk groups are the top priority in the prevention and treatment of stroke. CHA2DS2-VASc is a key prediction tool for stroke-risk stratification in AF, in which patient stratification of three risk categories, 0 score is low risk, 1 is intermediate and 2 is high risk. Recent reports provide further evidence for the clinical utility of CHA2DS2-VASc score in stroke-risk stratification including non-AF. The present study was undertaken to evaluate the accuracy of the CHA2DS2-VASc scoring systems in stratifying the ischemic stroke risk of patients with non-AF.

METHODS:
We carried out searches of the following databases in June 2018: PubMed databases, Embase (Ovid SP), Cochrane Library. Diagnostic studies (from 2008 to 2018) were designed for predicting ischemic stroke in adults without atrial fibrillation by using the CHA2DS2-VASc score which were included. Study selection, data extraction and quality assessment were performed independently by two authors, then proceed heterogeneity test. We performed quality assessment according to the QUADAS-2 criteria. Methodological variation in selected studies precluded quantitative meta-analysis, therefore results from individual studies were presented with a narrative synthesis.

RESULTS:
A total of 7 prospective studies involving 50,652 patients (6,760 ischemic stroke) were included. Seven studies used different threshold from 2 to 4 which might bring heterogeneity. Three of the seven reported diagnostic accuracy at a threshold of 2 with sensitivity >0.8/specificity ranging from 32.39 to 68, seven studies reported DORs >2 and six studies reported AUC >0.6, one reported c-statistics of 0.616 for a range of thresholds from 2 to 4. Two studies used threshold of 4 with sensitivity of 0.59 and 0.76, specificity of 0.43 and 0.69. In one study, the threshold was 3 with sensitivity/ specificity of 0.79 /0.39. In another study, the threshold was 2 for men, 3 for women with sensitivity/ specificity of 0.80 /0.40. In seven studies when the CHA2DS2-VASc scores were used in the patients who had successfully undergone typical AFL catheter ablation and who had COPD, it turned out good DORs ,10.45(95%CI:2.949-37.026) vs. 4.78(95%CI:4.409-5.173) and AUC (0.798 vs. 0.7128) at the threshold of 2.

CONCLUSIONS:
CHA2DS2-VASc score may predict ischemic stroke in non-atrial fibrillation populations. Thresholds more than 2 are likely be more useful for optimal diagnostic accuracy of CHA2DS2-VASc in ischemic stroke, and the predictive performance may be better in COPD patients without atrial fibrillation.
PP109 Mapping Of Brazilian Health Technology Assessment Studies: Analysis Of […]

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ABSTRACT SUMMARY:
Such analysis promotes not only production and dissemination of studies, but also strengthening and consolidation of an HTA culture in Brazil, which, in turn, supports the sustainability of the health system.

The literature search yielded 7766 papers published whose authors or coauthors were Brazilian. The studies were associated with 427 institutions, present in 24 states and distributed in 70 Brazilian cities, according to author affiliation. The most noticeable concentration was in the South and Southeast regions, with greater representation in the states of Sao Paulo and Rio Grande do Sul. Analysis of Social Network evaluated the relationship between institutions and present the following estimates: 427 nodes, 2156 relationships, with medium degree of 10.11, weighted degree of 11.35, density of 0.024, clustering coefficient of 0.86, number of connected components of 3, diameter 8 and modularity of 0.59. These results show a complex, cohesive network with good grouping.

CONCLUSIONS:
Analysis of Social Network allows monitoring and evaluating HTA networks, and, consequently, draw plan for their restructuring. It is possible to identify adequate interactions amongst the most developed states in the country; however, this is not true for less developed regions. To find ways to disseminate the HTA knowledge to those regions is necessary challenge to strengthen the Brazilian Healthcare System.

PP110 The Impact Of Primary and Secondary COAs On HTA Recommendations

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ABSTRACT SUMMARY:
Do additional COAs have an impact on the HTA decision making for autoimmune diseases? Case examples in Germany, France and UK show this is different per country.

INTRODUCTION:
In autoimmune diseases, suppression of symptoms and improvement in quality of life are key clinical outcome measures. Clinical outcome assessments (COAs) include outcomes reported by patients (PROs), clinicians (ClinROs) and observers (ObsROs). This study aimed to understand the impact of different COAs in health technology assessments (HTAs) by investigating five autoimmune diseases (lupus, psoriasis, arthritis, Crohn’s disease and ulcerative colitis).

METHODS:
HTA reports (original assessments, resubmissions and extensions of indications) by four agencies (HAS, G-BA, NICE and SMC) from 2011-2017 for the five autoimmune diseases were included in the analysis. Drugs assessed by all agencies were selected as case studies for an in-depth analysis of the impact of the COA data. All COAs (classified as PROs, ClinROs, or ObsROs and composite measures) included in the submissions were identified. The data was analysed quantitatively to assess the impact of COA data on HTA decision-making by the different agencies.

RESULTS:
135 HTA records were identified and all full submissions included COA data. In 95% of clinical trials submitted, a disease-specific COA was the primary endpoint, often supplemented with other COAs. Seven drugs were reviewed by most agencies. This study showed that each submitted COA was discussed in detail, and whilst most critical of the COA data it was also the country were COA data had the most impact on the overall assessment. Contrary in France, less details are available and supplemental COA data is not discussed extensively.

CONCLUSIONS:
All HTAs for the seven drugs for auto-immune diseases included COA data as the primary endpoint. Additional COAs are not always all submitted to HTA agencies. There is a clear difference between agencies regarding the weight of each COA endpoint in the final recommendation, with the impact being most apparent in Germany.

PP111 PROs In Orphan Drug Review: How Do Regulatory And HTA Reviews Compare?

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ABSTRACT SUMMARY:
PROs can be used to collect additional data for orphan drugs. EMA does not commonly list PROs, and focuses on significance. HTA bodies in EU3 often list PROs, but heavily critique different aspects including missing data.

INTRODUCTION:
Rare diseases affect a small number of people, creating challenges to collect sufficient clinical data. Patient-reported outcomes (PROs) can be used to collect additional data, which can be used in regulatory submissions and subsequently to obtain health technology assessment (HTA) and reimbursement dossiers. This study compared assessment of PROs in rare diseases in regulatory review versus HTA review.

METHODS:
Products with EMA Orphan Drug Designation (ODD)
from January 2016 to October 2018 were identified and analysed in terms of PRO inclusion in two steps of approval: 1) regulatory review by the European Medicines Agency (EMA) in their European Public Assessment Report (EPAR); and 2) HTA review by HTA bodies in the UK (NICE and SMC), France (HAS) and Germany (G-BA) (EU3). If mentioned, the type of critique was qualitatively assessed and compared between EPAR and HTA reports.

RESULTS:
Out of 38 products with ODD, seven mentioned PROs on their EMA EPAR. 31 had been reviewed by either NICE, SMC, G-BA and/or HAS, of which 24 included the review of a PRO. An analysis of five products with PRO data on both EPAR and in EU3 HTA reveals differences between regulatory and HTA review. EMA solely comments on statistical significance. Contrary, HTA agencies critique low response rates (all four agencies), differences at baseline (NICE), lack of submission of a measured PRO (SMC), or missing psychometric validation (G-BA). PRO discussion in HTA, but not in EPAR occurred for half of ODD products, of which the majority was non-oncology (14/19).

CONCLUSIONS:
PROs are an important part of the evidence package of new medicines for rare diseases. HTA bodies list COA data broadly, but at the same time provide a range of critique. EPAR listing of PRO data may be more challenging for non-oncology compared to oncology ODD products.

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ABSTRACT SUMMARY:
Randomized control trials, RCT, are widely considered as the gold standard for evaluating the effectiveness of clinical interventions. However their appropriateness for evaluation of complex interventions has been called into question. We use case study approach to find out if the basic assumptions underpinning the study design of evaluation studies fit the complexity of the interventions.

INTRODUCTION:
Randomized control trials, RCT, are widely considered as the gold standard for evaluating the effectiveness of clinical interventions. However their appropriateness for evaluation of complex interventions has been called into question. Since year 2000, the british Medical Research Council, MRC, has been developing and improving guidelines for adapting RCTs to real-world situations such as complex public health interventions. Such approaches have been criticized for ignoring the fundamental conflicts between positivist assumptions underpinning an experimental study design and the realist paradigms. The goal of this case study is to investigate if the positivist assumptions hold true in real-word cases. Our cases so far include a prospective non-randomized, matched control, before-and-after study (case 1), The effectiveness and cost-effectiveness of the PAtient-Centred Team (PACT) model: study protocol of a prospective matched control before-and-after study, and an RCT (case 2), Long-term integrated telerehabilitation of COPD Patients: A multicentre randomised controlled trial (iTrain). We are planning to add two more cases.

METHODS:
We take an exploratory qualitative case study approach to review complex intervention
evaluation studies in which the study designs are based on positivist assumptions. The criteria for selecting the cases are that the interventions must be complex, study protocol must be published or accessible for review and the researchers available for interviews. Our starting point is the review of study protocol and we follow-up with semi-structured interviews with the principal investigators and research team members and request supplemental information if needed.

RESULTS:
We are currently finishing review of case 1. This is a real-world evaluation case where randomization was not possible due to operational reasons. Therefore the research team chose propensity score matching.

CONCLUSIONS:
The study has started in late October 2018 and is currently underway. The conclusions will be ready for HTAi conference in June 2019.

PP113 A Framework to Enhance EAEU Cooperation On HTA: Lessons From EUnetHTA

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ABSTRACT SUMMARY:
Using the EUnetHTA as an example of transnational cooperation in HTA, EAEU could consider implementing a project to streamline HTA process across its member states. This may require overcoming a number of challenges pertaining to development of common instruments and methodologies, as well as obtaining support to achieve the recognition of the role of HTA among the stakeholders.

INTRODUCTION:
The Eurasian Economic Union (EAEU), currently including Russia, Kazakhstan, Belarus, Kyrgyzstan and Armenia, was established in 2015. Pursing economic integration and modelled in part after the structure of European Union, the EAEU has also launched a common medicines market in 2017. There have been various developments regarding cooperation in health technology assessment (HTA) across the EAEU countries, exemplified by a conference held in Kazakhstan in 2017. Here we discuss some considerations for potential development of cooperation in HTA throughout EAEU in light of experiences of implementation of the European Network for Health Technology Assessment (EUnetHTA).

METHODS:
Legal and review documents regarding the implementation of EUnetHTA were obtained from the European Commission website and research databases to inform this narrative review.

RESULTS:
Achieving recognition of the role of HTA at an intergovernmental level, akin to the actions of European Commission preceding the establishment of EUnetHTA, appears pivotal at the current stage of affairs in the field of HTA across EAEU members. Similarly to the 2006-2008 EUnetHTA project stage, the existing HTA structures and national standards will need to be accurately and systematically assessed by a working-group-type body appointed specifically for that purpose. Besides the importance of accepting a unifying framework similar to the EUnetHTA Core model, specific implementation features that may appear especially relevant in the context of EAEU countries could include development of common adaptation toolkits and glossaries. Capacity building efforts...
may also prove crucial to ensure the sustainability of HTA-related cooperation.

**CONCLUSIONS:**
Optimization of resources by streamlining HTA processes, whether in research, policy or results dissemination, and avoiding duplications of efforts by HTA agencies is relevant in the context of limited available healthcare resources in developing countries. The presented overview is an attempt at facilitating discussion to inform related policy and research efforts.

**PP114 Reuse Of The EUnetHTA Outputs: A Bibliographical Analysis**

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**ABSTRACT SUMMARY:**
A bibliographical analysis has been conducted to evaluate the reuse of EUnetHTA outputs in the scientific literature. The results show that each type of EUnetHTA material has been reused, and not only by EUnetHTA partners.

**INTRODUCTION:**
Since its inception in 2006, the European network for Health Technology Assessment (EUnetHTA) has delivered different kind of outputs: several joint health technology assessments (primary goal); but also the HTA Core Model® (an HTA ontology), scientific methodological guidelines, online tools and scientific publications. The paper aims to track the use of EUnetHTA materials in scientific literature.

**METHODS:**
Bibliographical research has been conducted, searching for EUnetHTA in title, abstract, keywords, and also citations. Cited EUnetHTA material have been identified, sorted and counted. The source of articles citing EUnetHTA material have been analysed.

**RESULTS:**
EUnetHTA material is cited in various kind of journals, each type of EUnetHTA output has been discussed or reused, also by organizations not belonging to EUnetHTA.

**CONCLUSIONS:**
This paper demonstrates that EUnetHTA material reaches the scientific community beyond its own partners; and that EUnetHTA outputs, therefore, have the potential to support joint international assessments.

**PP115 Comparing Observed Uptake Of Medicines With estimated Uptake - England**

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**ABSTRACT SUMMARY:**
The NHS in England can be slow to take up innovative new technologies. We examined the uptake of selected technologies recommended by the National institute for Health and Care Excellence (NICE). We compared the total expected volume of technologies to the observed uptake.
INTRODUCTION:
The NHS in England can be slow to take up innovative new technologies. We examined the uptake of selected technologies recommended by the National institute for Health and Care Excellence (NICE). We compared the total expected volume of technologies to the observed uptake.

METHODS:
NICE Technology Appraisals in the NHS in England (Innovation Scorecard) reports on the use of technologies which have been recommended by NICE. One or more technologies are selected for development as an ‘estimate’ when inclusion criteria are met. The estimates are developed following a review of epidemiological data, published research and routinely available activity data. If data are not available for part of the estimate, the view of topic and clinical experts is considered. A range is developed around the point estimate to reflect the uncertainty in the estimate. The estimates are used to calculate the total expected volume of technologies at a national level. Observed usage volume of the technology is converted where appropriate into units such as defined daily dose, to allow comparison with the estimated volume.

RESULTS:
Fifteen estimates covering 23 technologies have over 2 years of data since publication of the NICE technology appraisal. For 7 of the estimates, observed usage as a proportion (%) of expected use was at 90% or more of the estimated treatment population or within the calculated range where available. The remaining 8 were below this level.

CONCLUSIONS:
At 24 months, uptake of NICE positively appraised technologies is below expected use for 53% of the estimates. However, for all the estimates, uptake was seen to increase over time. Some barriers to uptake have been identified, such as clinician and patient choice. While there are barriers to uptake which are common across technologies, they should also be reviewed individually to understand why uptake falls below expected levels.
technologies which have been recommended by NICE. The observed use of technologies is compared with the estimated volume, calculated following a review of epidemiological data, published research and routinely available activity data.

An estimate was developed to measure the uptake of NICE-recommended technologies used to treat metastatic castration-resistant prostate cancer (abiraterone, cabazitaxel and enzalutamide). To create this group, the condition pathway was reviewed to identify technologies which are options for use at the same treatment point. To allow analysis across the group, a common measure was calculated based on the amount of medicine used per day.

RESULTS:
For the group of technologies, the observed volume prescribed in year 5 (2017/18) increased by 48% from year 1 (2013/14). For the individual technologies, the change in volume prescribed ranged from a decrease of 27% for abiraterone to an increase of 95% for enzalutamide. Observed usage for the group exceeded the estimated uptake early in year 3.

CONCLUSIONS:
When more than one treatment option is available, measuring uptake across the group of technologies produces more representative results. Uptake of individual technologies can be influenced by factors including clinician and patient choice, local formulary decisions and funding decisions. A grouped estimate lessens the influence of these factors and helps the healthcare system understand the uptake of multiple treatment options for a patient group.

PP117 Determination Of The Number Of Patients Suffering From Lung Cancer

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ABSTRACT SUMMARY:
This analysis examines the extent of difference in the basic population of lung cancer patients in early benefit dossiers in Germany. Identifying the basic population of patients with lung cancer is the first step in determining the NSCLC target population in dossiers. We found that the number of patients identified with lung cancer is heterogeneous and examined the underlying reasons.

INTRODUCTION:
Since 2011, an early benefit assessment is required for all new drugs launched in Germany. Evidence submitted by pharmaceutical companies in respective dossiers undergoes assessment by the Institute for Quality and Efficiency in Health Care (IQWiG), followed by an appraisal by the German Federal Joint Committee (G-BA). In dossiers, estimation and details of the target population in the indication of non-small cell lung cancer (NSCLC) is derived in several steps and differs profoundly. The exact determination of the appropriate target population plays an important role for subsequent price negotiations. We focus on the identification of the basic population of patients with lung cancer as the first step of many in determining the NSCLC target population. We also explore to what extent the basic population of lung cancer patients differs in dossiers.
METHODS:
We analyzed twenty-three NSCLC dossiers published between 01 January 2011 and 31 December 2017, including extraction and comparison of the details regarding the estimation of the basic NSCLC patient population.

RESULTS:
In dossiers, the number of patients identified with lung cancer is heterogeneous. Different epidemiological measures provided the basis for further extrapolations: incidence (ten dossiers), five-year-prevalence (sixteen dossiers), or combinations of both (ten dossiers). The use of epidemiological measures differed as to pretreated or non-treated patients (as stipulated in the specific area of indication) and referred to different years of consideration. The Robert Koch Institute (RKI) in Germany supplied the main database for the basic population derived in dossiers. As RKI data was not available for every year, different ways of extrapolation to the year of consideration took place.

CONCLUSIONS:
To reduce the variation and allow for comparison, a harmonization of extrapolation of methods and databases used to determine the predicted morbidity of lung cancer in the basic population would be helpful.

PP118 Cost-Effectiveness Analysis In Stage IIIAN2 Non-Small Cell Lung Cancer

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ABSTRACT SUMMARY:
A novel method for network meta-analysis and an associated economic model to examine the cost-effectiveness of treatment options for stage IIIA-N2 non-small cell lung cancer, a common presentation with a hotly debated standard of care.

INTRODUCTION:
Stage IIIA-N2 Non-Small Cell Lung Cancer is a common presentation but, despite several RCTs investigating treatment options, the optimal management strategy remains controversial. Patients often receive chemoradiotherapy (CR) or chemotherapy and surgery (CS) but may, more rarely, receive tri-modality therapy with chemoradiotherapy and surgery (CRS). These three treatment options are examined in this analysis.

METHODS:
A novel method for network meta-analyses (NMA) of survival data was used, correlating multiple area-under-the-curve outcomes extracted from RCTs to determine the primary measures of clinical effectiveness; progression-free survival (PFS) time, post-progression survival (PPS) time and probability of survival at study endpoint. An economic model in which short term outcomes were determined by these NMAs and long term outcomes were determined by fitting survival curves to a matched cohort from a patient registry was constructed. The model used a UK National Health Service perspective and its structure and input parameters were ratified by a committee of lung cancer experts.

RESULTS:
The NMA results showed that CRS was associated with a significantly greater PFS than CS and CR. CR was associated with a significantly greater PPS than CS and CRS. There were no statistically significant differences in other outcomes but point estimates favoured CRS. CRS had a very high probability of
producing more quality adjusted life years than CR and CS. CS was not cost-effective compared to CR at commonly accepted UK thresholds and was always extendedly dominated by the combination of CRS and CR in sensitivity analyses. CRS was cost-effective compared to CR. No plausible sensitivity analyses altered these conclusions.

CONCLUSIONS:
The results of this analysis suggest that, for patients who are fit enough for tri-modality treatment with CRS, it is highly likely to be the most effective and cost-effective of the three interventions. NMA using continuous correlated PFS and OS area-under-the-curve data may be useful for HTA.

PP119 Cost-Effectiveness Of Early Detection Of Hepatocellular Carcinoma

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ABSTRACT SUMMARY:
Biannual ultrasound as a surveillance program for early detection of hepatocellular carcinoma in patients with cirrhosis is cost-effective in comparison to no surveillance from the perspective of the Spanish NHS.

INTRODUCTION:
Hepatocellular carcinoma (HCC) is one of the cancers with highest incidence and mortality rates. We studied the cost-effectiveness of a surveillance program that used biannual abdominal ultrasound for early detection of HCC in patients with cirrhosis due to hepatitis B (HBV), cirrhosis due to hepatitis C (HCV), or alcoholic cirrhosis.

METHODS:
We conducted a full economic evaluation where we compared surveillance vs no surveillance in terms of years-live saved (YLS), quality-adjusted life years (QALY), and direct health care costs. A Markov model was designed to represent a lifetime horizon. The diagnosis yield of ultrasound was obtained from a meta-analysis. The other parameters were obtained from literature, statistics, and Spanish sources of costs. The incremental cost-effectiveness ratio (ICER) was calculated and sensitivity analysis were conducted. The perspective used was the Spanish National Health System.

RESULTS:
The ICERs for patients with cirrhosis due to HBV or HCV were below 20000 €/QALY. In patients with alcoholic cirrhosis the ICER was around 25000 €/QALY. Both deterministic and probabilistic sensitivity analyses showed that the model and the results are robust.

CONCLUSIONS:
Biannual ultrasound as a surveillance program for early detection of hepatocellular carcinoma in patients with cirrhosis is cost-effective in comparison to no surveillance from the perspective of the Spanish NHS.

PP120 Cost-Effectiveness Of Treatments For Extensive Small-Cell Lung Cancer

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ABSTRACT SUMMARY:
Extensive stage small-cell lung cancer is associated with poor outcomes and limited treatment options. Standard treatment includes chemotherapy, followed by prophylactic cranial irradiation and potentially thoracic radiotherapy. MRI follow-up is not currently standard clinical practice in Europe. This research evaluates the incremental cost-effectiveness of these three strategies compared with each other and best supportive care for the first time.

INTRODUCTION:
Extensive stage small-cell lung cancer (ES-SCLC) is associated with poor outcomes and limited treatment options. Standard treatment includes chemotherapy, followed by prophylactic cranial irradiation (PCI) and potentially thoracic radiotherapy (TRT) in those patients whose disease does not progress. A recent Japanese study suggested that PCI does not increase overall survival (OS) compared with routine magnetic resonance imaging (MRI) follow-up in people with ES-SCLC without brain metastases. MRI follow-up is not currently standard clinical practice in Europe. This research evaluates the incremental cost-effectiveness of these three strategies compared with each other and best supportive care (BSC) for the first time.

METHODS:
Cost-utility analysis was conducted using a partitioned survival model with three health states (progression-free, post-progression and dead) to evaluate the cost-effectiveness of four strategies; BSC, PCI, PCI+TRT and MRI. OS, progression-free survival, adverse event and treatment data were obtained from relevant randomised controlled trials identified through systematic review. MRI, BSC and PCI+TRT data were related to pooled PCI data via relative effects. Costs and healthcare resource use were estimated from a UK National Health Service and Personal Social Services perspective and utilities were estimated indirectly from a patient perspective. The cost-effectiveness of treatments were expressed as incremental costs per quality-adjusted life year (QALY) gained.

RESULTS:
Preliminary results indicate that MRI follow-up could be considered a cost-effective strategy compared with BSC and confirm that the currently available options, PCI and PCI+TRT, are associated with an incremental cost-effectiveness ratio (ICER) within the range of cost-effectiveness applied by the National Institute for Health and Care Excellence. Final results will include ICERs, as well as total life years gained, QALY gain and results of sensitivity analyses.

CONCLUSIONS:
We will discuss recommendations for current UK clinical practice and the generalisability of the results to other health systems, including the role MRI monitoring may have in this population.

PP121 How Involve Patient In Antibiotic Prophylaxis Decision After Tick Bite

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ABSTRACT SUMMARY:
Lyme disease is increasing in Quebec (Canada). To support discussion between clinician and patient by giving scientific information on real risk to develop Lyme disease after tick bite and the efficacy antibiotic prophylaxis, a decision aid has been developed by using an approach based on knowledge mobilization framework evidences and interactions with stakeholders to meet the needs of concerned-actors.

INTRODUCTION:
Antibiotic prophylaxis with single dose of doxycycline to prevent infection after a tick bite is one of the tool to prevent Lyme disease, which is increasing in Quebec. The aim of this work was to revisit this practice in adult and children under 8 years old.

METHODS:
To assess the absolute risk reduction (ARR) of doxycycline in prevention of Lyme disease and safety for contraindicated populations, two systematic reviews have been conducted with a reanalysis of the original data for efficacy. Then, an approach based on knowledge mobilization framework considering scientific, contextual and experiential evidences, has been used to take into account information about patients and clinicians experience.

RESULTS:
Single dose of doxycycline could prevent developing cutaneous manifestation of Lyme disease (ARR -2.8%, IC95%[-11.7 ; 6.1], p = 0.0614) after a l. scapularis tick bite, without serious side effect, when the delay between tick bite and prescription is ≤72 h and bite occurred in a region where at least 25% of nymph and 50% adults tick are infested. However, level of evidence is low and generalizability to other context is doubtful. Decision prescribing antibiotic prophylaxis can be based on fear associated with Lyme disease rather than effectiveness data and the real risk of developing Lyme disease.

CONCLUSIONS:
In a context where the risk of developing Lyme disease is uncertain but the consequence associated to Lyme disease can scare, it could be challenging for clinicians to address these information with the patient or its family. Decision aids developed by Institut national d’excellence en santé et en services sociaux should support discussion between clinician and patient by giving scientific information on real risk to develop Lyme disease after tick bite, particularly in a Quebec context, and taking an informed decision based on patient preferences and values.

PP122 Patient Associations Network: Evidences From Italy

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ABSTRACT SUMMARY:
Big and national-level patient association tend to have a great amount of ties and a central role in the network for which ties are expensive in term of building and maintenances.

The results of a first analysis provided an exclusive picture about the relations between Italian patient associations, never done before.

INTRODUCTION:
Within highly institutionalized environments, such as healthcare sector, legitimacy is one of the main task in which organizations are involved in order to assure their survival. It can be reached
by respecting rules and norms; by providing high quality cares; and by listening the voice provided by patients’ advocacy associations. Literature provides an ample amount of definitions about patient advocacy, ranging from counsellor, watchdog and representative to potential whistle-blower. All these definitions show a common point by defining the advocacy as the activity in which one person represents another. Although the presence of patients’ association characterizes the Italian healthcare context since its foundation in the 1978, nowadays their importance in the regional and national planning strategies is increasing. However, there is a shortage of information about the dynamics patients’ association use to connect each other’s and the type of relations they develop. Moreover, it could be interesting to investigate how some patients’ association characteristics, for instance geographical location or therapeutics area, shape their network of collaborations.

METHODS:
Data were collected using a survey developed and administered by us. 132 questionnaires were gathered through a six-sections questionnaire. For this study, a social network analysis has been used as a powerful tool to investigate and map the ties existing among organizations. It aimed to investigate the disease area of interest and the presence of relationships between associations at regional or national level.

RESULTS:
Our preliminary results show the existence of 4 clusters of organizations, grouped by therapeutic area or geographical localization. Big and national-level patient association tend to have a great amount of ties and a central role in the network for which ties are expensive in term of building and maintenances.

CONCLUSIONS:
The results of a first analysis provided an exclusive picture about the relations between Italian patient associations, never done before.

PP123 Management of Patients’ Conflict Of Interest And Of Commitment In HTA

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ABSTRACT SUMMARY:
Conflicts of interests and of commitments (COI/Cs) regarding patient participation in health technology assessment (HTA) and clinical practice guideline (CPG) development are little discussed in the academic literature. We reviewed COI/C management policies of ten HTA and CPG organizations and the relevant literature. Patients’ COI/Cs must be managed, together with those of other collaborators, to ensure HTAs’ and CPGs’ integrity.

INTRODUCTION:
Health technology assessment (HTA) and the development of clinical practice guidelines (CPGs) support important health policy and clinical decisions. Conflicts of interests and of commitments (COI/Cs) can undermine the credibility and integrity of these processes, that of the actors involved, and more alarmingly, the health of the population. Management of COI/Cs is thus critical. Although COIs of experts participating in HTA and CPG development are increasingly discussed and managed, little is said about their COCs and the possible COI/Cs associated with patient participation. The aim of our study, which is part of the National Institute for the Excellence in Health and Social Services’ (INESSS; Quebec,
continuing improvement process for COI/C management, was to identify the best practices in that matter.

METHODS:
We conducted a review of COI/C management policies of ten HTA and CPG organizations and performed a review of the relevant academic literature.

RESULTS:
Three HTA and CPG organizations had norms regarding the management of patients’ COI/Cs, whether representatives of patients’ associations or not. These norms address situations such as: when a patient represents a patients’ association; when a patients’ association or an individual patient has important (financial) ties with the pharmaceutical industry; when an expert or one of their family members suffers from the disease related to the HTA or CPG. The declaration of a COI/C does not necessarily lead to the individual’s exclusion from the whole HTA or CPG development process but must lead to its evaluation and management. A patient appointed to share her perspective is not considered to have a COI/C if her mandate as such is explicit.

CONCLUSIONS:
All participants’ COI/Cs in HTA and CPG development should be managed fairly and transparently. Therefore, the management of patients’ COI/Cs participating in HTA or CPG development should be based on the same principles than that of experts.

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ABSTRACT SUMMARY:
Health Technology Wales (HTW) is a new Health Technology Assessment agency that considers non-medicines. HTW recognises the importance of effective patient and public involvement (PPI) and is building smart capabilities. HTW is in a prime position to establish true PPI at the outset, before committing to a specific approach, and will report the impact value accordingly.

INTRODUCTION:
A new Health Technology Assessment (HTA) agency, Health Technology Wales (HTW), has been established to consider the identification, appraisal and adoption of non-medicines in NHS Wales. This includes, for example, medical devices, surgical procedures and diagnostics. HTW recognises the importance of effective patient and public involvement (PPI) and is planning to build smart capabilities in this area.

METHODS:
HTW has consulted with external organisations to identify the first steps towards achieving effective PPI. HTW are recruiting Public Partners as a priority, before working together to develop a PPI strategy. Building smart capabilities will be central to the approach, in order to establish effective PPI and allow future-proofing. HTW aims to ensure PPI shapes all of its work, not just in relation to the individual technologies under consideration. HTW plan to form a working group to inform HTW throughout its work, including the development of processes and procedures.

RESULTS:
Since HTW is in the very early stages of setting up PPI, results are not available at the time of abstract submission. However, they will include what steps have been taken towards PPI, including...
the PPI strategy itself. HTW will report on impact evaluation accordingly, considering clearly defined outcomes, as agreed with the Public Partners and an established PPI working group.

CONCLUSIONS:
HTW is in a prime position to establish true PPI at the outset, before committing to a specific approach, thus helping to ensure that the PPI strategy itself is appropriate and fit for purpose. Through the building of smart capabilities and the measurement PPI impact, HTW hopes to conclude that PPI has been valuable in the appraisal of individual non-medicine technologies and the wider work of HTW.

PP125 Photovoice: Promoting Knowledge Exchange About Patients Experiences

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ABSTRACT SUMMARY:
In the past decades the community-based participatory research method known as photovoice has gained relevance, but there are few published experiences related to its application in the field of HTA and Clinical Practice Guidelines (CPG). The aim of this presentation is to describe a photovoice project linked to a CPG on major depression in childhood and adolescence.

METHODS:
The design of the study was adapted to the main objective (i.e. enhanced understanding of major depression and to improve clinical practice) with the contribution of clinicians, methodologists and participants. 7 adolescents and 10 relatives participated in the study through photovoice sessions and focus groups. All sessions were audio-recorded, transcribed verbatim, and coded, and a thematic analysis was used.

RESULTS:
From the thematic analysis, six themes emerged: 1) lack of understanding and information about depression in childhood and adolescence, 2) importance of support groups; 3) need to favor early care and access to services, 4) adaptation of therapeutic strategies tailored to individual needs, 5) sensitivity of professionals, and 6) foster interaction between health and education systems. Photographic exhibitions to share the main results were planned. This exhibitions were promoted to favor public awareness and de-stigmatization and to reach clinicians and policy makers. From a methodological point of view, the adaptation and implementation of the photovoice in this study has allowed the effective incorporation of patients and relatives lived experiences, concerns and preferences into the GPC. Also confirms the value of photographs and participatory methods. Its main limitations and strengths, as well as suggestions for future research, are outlined.

CONCLUSIONS:
Photovoice is a flexible, effective and innovative method of obtaining information about patients perspectives and experiences and offers the added value of reach the main stakeholders, including policymakers and the public.
PP126 Analyses Of User Requirements In The Evaluation Of Medical Equipment

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ABSTRACT SUMMARY:
A systematic investigation to identify user requirements for the selection of medical recliners to satisfy multiple hospital’s services and end-users based on pre-defined technical characteristics. Senior nurses and clinical engineer’s identified 41 technical characteristics. Patients and healthcare professionals identified 95 different requirements. Correspondence analyses identified similarities between user requirements and technical characteristics leading to less complex recommendation of medical recliner.

INTRODUCTION:
Human-centered approaches to requirements elicitation in medical equipment selection are recognized for their benefits to healthcare outcomes, safety, and end-user satisfaction. Nevertheless, there are many challenges to conduct rigorous investigation to identify requirements that satisfy different hospital services and types of end-users (e.g., patients, healthcare professionals, clinical engineers). By establishing a systematic method for the selection of medical recliners, this study provides detailed technical characteristics and user requirements associated with several hospital areas, as well as a comparison between two end-users (health professionals and patients) and their different perceptions of usability.

METHODS:
First, clinical engineers and senior nurses from seven hospital services identified and rated medical recliners technical characteristics. Ratings were then used to stratify all services in well-defined similar groups using hierarchical and non-hierarchical clustering algorithms. Next, users of hospital recliners (60 patients and 56 healthcare providers) from each group were interviewed to identify requirements of an ideal medical recliner. Finally, analyses of variance were performed to identify consensus decisions from users across the different hospital contexts in specifying which technical characteristics attend the demands from the most relevant requirements.

RESULTS:
Senior nurses and clinical engineer’s contributions led to the identification of 41 technical characteristics. The analysis of user interviews identified 95 different requirements, extracted from 1,052 user suggestions in 116 participants’ interviews. Correspondence analyses of the combined most important requirements of each of the three stratified services groups indicated that two thirds of all user requirements (14 out of 20) were fulfilled by the 5 out of 32 quantitative technical characteristics regardless of context.

CONCLUSIONS:
Human-centred methods, as the presented in this study, can identify similarities between health technology characteristics, leading to less complex processes when selecting technologies, which can attend to the requirements of multiple users and hospital departments.
PP127 Asthma Patient Value Framework: Lessons From Patient Focus Groups

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ABSTRACT SUMMARY:
There is a misalignment between what patients value and what clinicians, payers, and regulators consider in their assessments and decisions. Patients see the burden of asthma as continuous, whereas the other stakeholders have a more episodic focus. Patients expect more holistic approaches to their asthma management and more personalized treatments.

INTRODUCTION:
We sought to examine patients’ perceptions of disease burden and treatment impact, and what patients value over the course of the asthma experience.

METHODS:
Three patient focus groups were conducted in USA (n=8), UK (n=7) and Germany (n=7) to examine aspects of disease burden and patient experiences (physical, emotional, clinical, economic, social). Cause and effect were explored. GINA guidelines were used to screen patients to identify severity, based on age, sex, time since diagnosis, number of attacks, OCS use, and number of therapies to control symptoms. Patients classified and ranked aspects of disease burden and timing, and discussed the interventions used to manage their asthma.

RESULTS:
Overall burden of illness is driven by the combined effect of the disease burden and the burden of the treatment. All patients highlighted the negative impact of oral steroids. Patients believe that they are the key actors in their asthma management (not the health care professionals), and reported the physical and emotional burdens as dominant ones. Understanding of the term “attack” (or “exacerbation”) differs significantly between patients and does not necessarily match the clinical definition. Patients consider asthma to be an individualized condition that drives lifestyle changes. Disease management drives burden and vice versa. Patients perceive that burden is continuous over time, with specific phases of variable duration — before, during, and after an attack, whereas the other stakeholders have a more episodic focus. Patients expect more holistic approaches to their asthma management and more personalized treatments.

CONCLUSIONS:
The research indicates a misalignment between what patients value and what clinicians, payers, and regulators consider in their assessments and decisions. Greater alignment of the different stakeholders and an increase of patients’ roles and values in decision making would improve outcomes.

PP128 Quantifying The Relative Importance Of COPD Symptoms To Patients

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ABSTRACT SUMMARY:
A patient preference study based on discrete choice experiment is conducted to investigate health states and understand COPD patients’ perspective on relative importance of symptoms like cough and mucus production versus more commonly measured clinical endpoints (lung function, exacerbations and hospitalizations). The results may inform value-based decision making in HTA and facilitate a more patient-centered treatment approach.

INTRODUCTION:
Previous qualitative research analyzing social media and online community discussions highlighted the symptomatic burden of cough and mucus (sputum) alongside shortness of breath in patients with chronic obstructive pulmonary disease (COPD). The objective of present study is to determine the relative importance of these different symptoms and consequences thereof (for example, disturbed sleep) to COPD patients, compared with conventional COPD endpoints (lung function and exacerbations).

METHODS:
A total of 750 patients (age ≥40 years) with moderate to severe COPD/chronic bronchitis and regular symptoms of cough and excess mucus production will be recruited through patient advocacy groups (PAGs) from five countries (US, UK, France, Australia and Japan; ~150 per country). A discrete choice experiment has been designed with inputs from clinical experts, the PAGs and scientific advice from a health technology assessment (HTA) agency. Patients’ preferences towards the conditional relative importance of symptoms and impacts of COPD will be quantified based on trade-offs they are willing to make among hypothetical COPD disease state profiles described by differing attributes and levels. Hierarchical Bayesian analysis with effects-coding parameterization will be undertaken on the choice data to robustly estimate (using Gibbs sampling) the relative value each respondent places on an attribute level (part-worth utilities).

RESULTS:
The results will generate evidence that will contribute to development of meaningful patient-relevant endpoints for inclusion in clinical trials, going beyond the traditional endpoints, as well as providing a basis for a more informed patient-physician dialogue around unmet needs in this disease.

CONCLUSIONS:
Patient preference studies evaluating the relative importance of symptom burden through assessment of disease state preference are an important new form of patient-based evidence to inform value-based decision making in HTA. The present study should facilitate a more patient-centered approach to development of new treatments as well as management and care of COPD patients.

PP129 CPAP For Obstructive Sleep Apnea In Patients With Down Syndrome

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ABSTRACT SUMMARY:
Individuals with Down Syndrome often show Obstructive Sleep Apnea Syndrome - a complex chronic disorder with significant clinical consequences. Therefore, it is utmost importance to evaluate safety and efficacy of appropriate treatment options for these patients. In this context, Continuous Positive Airway Pressure (CPAP) seems to be a promising noninvasive therapy, already used in typical patients.

INTRODUCTION:
Individuals with Down Syndrome (DS) often show multiple comorbidities that reduces quality of life and life expectancy if not identified and treated adequately. Among these comorbidities is recognized a high prevalence of respiratory sleep disorders, especially Obstructive Sleep Apnea Syndrome (OSAS) - a complex chronic disorder with significant clinical consequences, such as delayed growth in children and adolescents, cardiovascular and metabolic disorders and neurocognitive deficits, such as lack of concentration and learning difficulties. The objective of this study was to search for and evaluate safety, efficacy and adherence studies of Continuous Positive Airway Pressure (CPAP) devices in this population - a promising noninvasive therapy successfully used in typical patients.

METHODS:
Systematic reviews of randomized clinical trials, randomized controlled trials, case-control studies, and cohort studies on the efficacy, safety, and safety of CPAP in the treatment of sleep apnea in Down Syndrome patients were searched. The searches were conducted in the in the main databases. Assessments of health technologies (ATS) and therapeutic guides on websites of agencies of interest were also analyzed. Randomized clinical trials and systematic reviews were evaluated according to the GRADE system and observational studies according to Newcastle-Ottawa parameters. The budgetary impact of the implementation of CPAP and / or BiPAP in the Brazilian Unified Health System was analyzed through the collection of treatment costs.

RESULTS:
Few scientific papers investigating the use of CPAP by DS patients have been found: only 4 studies were included in this review. All studies presented low sample sizes, differences in treatment parameters and diagnostic criterias and presented poor methodological quality. The selected studies have shown positive results for certain sleep quality outcomes such as reduced apnea-hypopnea index and nocturnal gas exchange.

CONCLUSIONS:
Despite poor quality of clinical evidence, the use of CPAP to treat OSAS in patients with DS seems to be a promising alternative.

PP130 Oral Supplements For Protein Energy Wasting In Chronic Kidney Disease

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ABSTRACT SUMMARY:
We conducted a systematic review on the safety and effectiveness of oral nutritional supplementation with special complete formulas in malnourished chronic kidney disease adults, when requirements are not achieved by diet. The studies included presented high heterogeneity and some inconsistency. There exists a trend towards an
improvement in mortality, undernutrition and other outcomes, but new studies must confirm it.

INTRODUCTION:
Malnutrition, and specifically protein energy wasting (PEW), is common in Chronic Kidney Disease (CKD), and its prevalence increases as CKD progresses. Oral nutritional supplementation (ONS) is a strategy aimed at achieving specific energy and protein requirements when it is not possible by dietary recommendations and advice, especially through the use of complete formulas specific to this pathology. The aim of this poster is to systematically review the available scientific literature on the safety and effectiveness of nutritional therapy with complete formulas special for nephropathies in adults with CKD with PEW, not reversible through ordinary food consumption.

METHODS:
We conducted a systematic search for articles in several electronic databases until May 2018. We included comparative studies that evaluated the safety and effectiveness of complete nutritional formulas for kidney disease, in malnourished CKD adults. Relevant outcomes were mortality, hospitalization rate, improvement in malnutrition, anthropometrics, health-related quality of life (HRQoL) and adverse effects.

RESULTS:
Twenty-five articles were identified: three systematic reviews and 22 primary studies: Nine randomized-controlled trials, nine non-randomised comparative studies and, four before/after studies included only in the safety review. The majority of studies were conducted on haemodialysis. The studies included presented a high methodological heterogeneity in terms of the method used to measure malnutrition, interventions and comparators. There was also inconsistency in the results. Adherence to ONS, especially in the long term, can be a by the taste fatigue that repeated taking of the same formula can produce. Some studies recommend supplementation during hemodialysis sessions.

CONCLUSIONS:
If we take ONS for CKD as a whole, the studies with less risk of bias indicate a trend towards an improvement in mortality, hospitalizations, HRQoL and, to a lesser extent, in serum markers such as albumin and some anthropometric variables. We need new high-quality comparative studies to make conclusive statements about the effectiveness of these interventions.

PP131 Omalizumab And Ciclosporin For Chronic Spontaneous Urticaria

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ABSTRACT SUMMARY:
This meta-analysis aims to evaluate the comparative efficacy and safety of omalizumab and ciclosporin for the treatment of chronic spontaneous urticaria to inform local practices in Singapore.

INTRODUCTION:
Omalizumab and ciclosporin are recommended in international clinical guidelines for treating antihistamine-resistant chronic spontaneous urticaria (CSU). This meta-analysis aims to evaluate their comparative efficacy and safety to inform local treatment practices in Singapore.

METHODS:
PubMed and EMBASE.com electronic databases were searched up to October 2018 using defined criteria for RCTs involving omalizumab or ciclosporin as add-on therapy to H1-antihistamines.
for CSU. Key outcomes were change in weekly Urticaria Activity Score (UAS7), adverse events and health-related quality of life. Pairwise meta-analysis was conducted for each outcome. Due to differences in trial designs and patient characteristics across studies, a random effects model was employed. In the absence of head-to-head trials, Bucher’s method of adjusted indirect comparison was used to estimate the comparative effectiveness between omalizumab and ciclosporin, with placebo as the common comparator.

RESULTS:
Eight omalizumab and two ciclosporin placebo-controlled RCTs comprising 1740 patients were selected. Across all efficacy outcomes, the magnitude of treatment effect of omalizumab was dose-dependent; 300mg was superior to 150mg. Omalizumab 300mg dose, though statistically significantly better than placebo for all efficacy outcomes at week 12, did not achieve clinical significance for all measures. Mean change in UAS7 was statistically better for ciclosporin than placebo (from 1 RCT) at week 4. While the indirect comparison between omalizumab and ciclosporin showed no statistically significant differences for mean change in UAS7, results were uncertain. Omalizumab had a more favourable short-term safety profile than ciclosporin; however, long-term safety data was lacking.

CONCLUSIONS:
Both omalizumab and ciclosporin are effective in treating CSU compared to placebo. However, results of the indirect comparison should be interpreted with caution. On the basis of limited available evidence as well as similar clinical need and place in therapy, results may be considered acceptable to confirm the clinical comparability of the drugs and inform local practice.

PP132 Telemedicine Enhance Community Hospital Response Capacity

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ABSTRACT SUMMARY:
Telediagnostic apps based on information and communication technology tools can be developed to enhance the community hospital response capacity. The usability of different telediagnostic methods to enhance the response capacity of community hospitals in rural areas of Paraguay was investigated. For this purpose, the results obtained by the telediagnosis apps implemented in 60 public countryside community hospitals were evaluated.

INTRODUCTION:
Telediagnostic apps based on information and communication technology tools can be developed to enhance the community hospital response capacity. However, evidence on how such innovation technology can improve health services is now limited but will arise in the new decade. The usability of different telediagnostic methods to enhance the response capacity of community hospitals in rural areas of 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 telediagnostic apps for different disciplines in public health. For this purpose, the results obtained by the telediagnosis apps implemented in 60 public countryside community hospitals were analyzed and evaluated its implementation countrywide.

RESULTS:
A total of 410,840 remote diagnoses were performed between January 2014 and August 2018 in 60 community hospitals. Of the total, 35.93% (147,627) corresponded to tomography studies, 62.41% (256,422) to electrocardiography (EKG), 1.65% (6,772) to electroencephalography (EEG) and 0.01% (19) to ultrasound. There were no significant differences between the remote and the “face to face” diagnosis, the diagnosis accuracy was about 92.9% (n=410,840). With the remote diagnosis a reduction of the cost was obtained, that supposes an important benefit for each citizen of the 60 communities.

CONCLUSIONS:
The results show that the telemedicine can enhance significantly the community hospital response capacity of diagnostic services and health programs, maximizing professional time and productivity, increasing access and equity, and reducing costs. However, before carrying out its systematic implementation, a contextualization with the regional epidemiological profile must be performed.

PP133 Ensuring Secure Health Data Exchange Across Europe. SHIELD Project

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ABSTRACT SUMMARY:
Ethical issues and safety are concerns when data is shared on clinical health records within health systems and countries. On the other side, data are crucial in many processes to ensure the correct management of patients and provide high quality services without compromising safety. SHIELD project is aiming to make this feasible by assessing and validating alternatives.

INTRODUCTION:
Data exchange protection is one of the main challenges when applied to eHealth. Nowadays, many people move from one country to another for various reasons: tourism, work, studies, etc; even with chronic or multi-pathological diseases. The main objective of SHIELD project is to create an open and extendable security architecture with supported privacy mechanisms and trust of citizens, to provide systematic protection for the storage and exchange of health data across European borders.

METHODS:
epSOS is a European project funded and finished dealing with security and interoperability of eHealth data is, that result in an OpenNCP (National Contact Point) architecture. In SHIELD project for the initial validation framework two OpenNCP virtual nodes would simulate the real nodes between Italy and Spain. For the secure exchange different prototype tools have been designed: end-to-end user interfaces (profiles: administrative staff, nurses, physicians, etc.), sensitivity and data hiding tools, consent management tools, reports translation tools and mobile devices tampering detection tools.

RESULTS:
Validation scenarios (realistic use cases) have been
developed in three different member states (Italy, United Kingdom and Spain). The first scenario is an Italian citizen traveling to Spain that has an acute emergency episode (e.g. stroke) and loses consciousness. Spanish emergency department suddenly assists that patient and doctor wishes to check patient’s health record. Results of the first round of validation frameworks of SHIELD project have been made successfully and presented to the European Commission.

CONCLUSIONS:
Security challenges need to be addressed when assessing eHealth solutions. Among others, the challenges are: interoperability, confidentiality, availability, integrity, privacy, ethics, regulations and eHealth data. Which data are going to be shared and by which mean? The first validations will be useful as the basis for both the “in depth” requirements analysis as well as setting the main pillars for the SHIELD architecture detailed design.

PP134 Changing The Paradigm: Accessing Primary Health Care And Triage Throug

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ABSTRACT SUMMARY:
‘Mirembe’ is a personalized health advisor that operates on Facebook messenger using Artificial Intelligence. Mirembe replicates interactive human conversation by processing natural language and using predetermined automated text-based responses. It processes the health symptoms provided against age, gender, symptom severity and duration, known medical problems and other clinical findings to provide a triage recommendation and advice. The client is referred to a qualified medical doctor who is available incase the symptoms are very severe basing on ‘Mirembe’ triage recommendation.

INTRODUCTION:
The current doctor to patient ratio is 0.09:1000 in Uganda. This, coupled with high costs of health care, long distances to health facilities and long queues at health facilities, frustrates the traditional health care delivery system. Uganda has approximately 2.6 Million Facebook subscribers. In October 2018, ‘The Medical Concierge Group’ which is a digital health enterprise in Uganda launched an Artificially Intelligent chat bot named ‘Mirembe’ which offers free triage and care advice to health symptoms in Facebook messenger.

METHODS:
‘Mirembe’ is a personalized health advisor that operates on Facebook messenger. Mirembe replicates interactive human conversation by processing natural language and using predetermined automated text-based responses. It processes the health symptoms provided against age, gender, symptom severity and duration, known medical problems and other clinical findings to provide a triage recommendation and advice. The client is referred to a qualified medical doctor who is available incase the symptoms are very severe basing on ‘Mirembe’ triage recommendation.

RESULTS:
Between 1st October – 2nd November 2018, ‘Mirembe’ had registered 852 clients of which 55% were male, 53% were between the age of 22 -32 years, 23% were between the age of 11-21, 17% were between the age of 33 to 43, 2% were between the age of 44-54. Headache and abdominal pain were the most frequently registered symptoms at 46.0% and 42% respectively. ‘Mirembe’ was able to provide a solution to 97% complaints and the rest were transferred to the TMCG call center doctors.

CONCLUSIONS:
Mirembe has provided a great opportunity to extend health care to many people in different parts of Uganda through its consultation platforms. However, sensitization of the public about the use
of social media platforms in solving health related problems still needs to be done.

PP135 Setting The Scope For Assessing E-Health Technologies In Hungary

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ABSTRACT SUMMARY:
E-health and m-health are emerging fields of health technologies, which could possibly give a new scope for health technology assessment. The objective of this study is to explore the foundations for a HTA guidance on e-health/m-health technologies. The findings of this research will be used to create a recommendation to amend the current Hungarian Guideline for the Health Economic Analyses.

INTRODUCTION:
E-health and m-health are emerging fields of health technologies, which could possibly give a new scope for health technology assessment. The Division for Health Technology Assessment (DFHTA) is currently assessing medicines and non-drug technologies (medical aids: medical devices, intended for patient use; other medical devices: medical devices, intended to be used in hospitals). The experience on assessing other medical devices yielded difficulties which could also arise from the critical appraisal of e-health/m-health technologies. The objective of this study is to explore the foundations for a HTA guidance on e-health/m-health technologies.

METHODS:
A targeted literature review was conducted to map the current status of technology assessment practices of e-health/m-health technologies and to observe its consistency with current reimbursement techniques in OECD countries. Experience from past evaluations of other medical devices which could not be evaluated under the current guidance will guide the literature search. The findings of this research will be used to create a recommendation to amend the current Hungarian Guideline for the Health Economic Analyses.

RESULTS:
The resulting articles of the targeted literature review provided an insight to current practices on the technology assessment of e-health/m-health products, focusing on the domains of safety, quality, and impact on health of such technologies. Recommendations suggest to include a list of requirements for companies to submit for critical evaluation of e-health/m-health technologies, supporting a self-assessment approach.

CONCLUSIONS:
Similarly to other HTA bodies, there is an urgent need to scale up the capacities of DFHTA for the digital health technologies candidates for regular use in the healthcare system, focusing on the clinical domains of assessment. The reimbursement mechanisms of these technologies remain a challenge for public bodies.

PP136 How To Apply HTA On Large-Scale E-Health Processes

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ABSTRACT SUMMARY:
The abstract address how to apply HTA assessment on large-scale e-health solutions like Electronic patient records (EPR).

However it is not clear whether traditional quantitative HTA methodology like RCTs is assessable to complex E-health systems like EPRs, developed and implemented over years as an ongoing process. We therefore introduce the need to shift from quantitative methods to action research.

INTRODUCTION:
The expectations for better e-health solutions to support high-quality healthcare services have grown enormously, with accessibility, efficiency and effectiveness as key goals. E-health encompasses a wide range of information and communication technologies (ICTs) applied to the provision of healthcare. E-health is a field focusing on combining clinical activity and technical development, as well as complying political requirements. It is important to evaluate e-health solutions capability in relation to the desired goals, to justify the high costs associated with such solutions.

METHODS:
Health Technology Assessment (HTA) is a method aiming to produce rational decisions for purchasing new technology and evaluate healthcare investments like drugs and medical equipment, by measuring added value in relation to clinical effectiveness, safety and cost-effectiveness. There is a desire to apply HTA assessment on large-scale e-health solutions as well, however it is not clear whether traditional quantitative HTA methodology like RCTs is assessable to complex E-health systems like Electronic Patient Records (EPR), developed and implemented over years as an ongoing process. There is a risk that in such processes results of systematic reviews and meta-analyses might be outdated when published. Therefore, an action research approach designed to work with complex large-scale programs seems like a more suitable approach.

RESULTS:
The empirical example were we want to apply HTA discusses empirical evidence, generated through a longitudinal action research approach of developing and implementing a large-scale open platform-based EPR system. The purpose of the research is to generate knowledge of the socio-technical interdependencies influencing the deployment of large-scale e-health solutions.

CONCLUSIONS:
The aim is to involve stakeholders in the study to design and define evaluation questions at each phase. This will build confidence between researchers and stakeholders, as well as facilitating informed decision making, in which lessons-learned can be translated into the ingoing program, as well as included in policy decisions.

PP137 Toric IOLs And Spectacle Independance: A Systematic Review

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ABSTRACT SUMMARY:
Astigmatism burden is not reduced after surgery with implantation of standard monofocal IOLs. Uncorrected distance visual acuity worsens as residual astigmatism increases – which suggests that if left uncorrected, astigmatism
can significantly affect patients’ visual outcomes limiting their quality of life, while also imposing an economic burden due to lifetime spectacle acquisition costs.

**INTRODUCTION:**

Astigmatism is a common ocular condition that causes reduced visual acuity. The condition is highly prevalent in cataract patients, with preoperative astigmatism ≥0.5 diopters (D) being present in 78% of cataractous eyes. Residual uncorrected astigmatism post-cataract surgery is associated with significant costs, primarily driven by the lifetime cost of spectacles estimated at €1,608 - €3,608 in Europe. Toric intraocular lens (IOL) have shown to be a safe and effective treatment for correcting astigmatism while also reducing the need for spectacles post-cataract surgery. The objective of this review was to assess the published evidence relating to spectacle independence for patients implanted with toric IOLs compared to non-toric IOLs, with or without astigmatism reducing surgical interventions (SI).

**METHODS:**

A systematic literature review was conducted using electronic searches on Embase®, MEDLINE®, MEDLINE®-In Process, and Cochrane. Articles were selected if they included adult patients, undergoing phacoemulsification, with age-related cataracts and pre-operative regular corneal astigmatism (≥0.5D) and assessed spectacle independence as an outcome.

**RESULTS:**

7 studies met the inclusion criteria: 4 RCTs and 1 non-RCT comparing toric IOLs v non-toric IOLs and 2 RCTs comparing toric IOLs v non-toric IOLs plus SI. Spectacle independence was evaluated as the number of patients who reported not requiring spectacles for distance viewing at 3 months or 6 months. Figures for spectacle independence ranged from 60% to 100% for toric IOLs, 31% to 50% for non-toric IOLs and 36% to 65% for non-toric IOLs plus SI. In each study, toric IOLs demonstrated superior spectacle independence compared to the control group.

**CONCLUSIONS:**

The benefits of toric IOL implantation for astigmatic cataract patients include greater spectacle independence compared to non-toric IOLs ± SI. Hence, for this group of patients – the lifetime economic burden owed to spectacle acquisition costs can be reduced via the implantation of a toric IOL during cataract surgery.

**PP138 Value-Based Policies To Support Innovations In Precision Medicine**

**PRESENTING AUTHOR:**

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**ABSTRACT SUMMARY:**

This policy paper proposes principles to support dynamic efficiency in the development, adoption, and use of personalized and precision medicine. These principles define the need for: a broader concept of value; flexible, value-based, indication-specific pricing of complementary diagnostic tests and medicines; ongoing real-world evidence generation; and appropriate methods to divide and reward value among complementary diagnostic tests and medicines.

**INTRODUCTION:**

This paper addresses an important policy question: “What are potentially transformative strategies and methods to define and measure value at all levels of decision making that are aligned with personalized medicine/precision medicine (PM/PrM)?"
METHODS:
We build on our previous work on PM and our recent work as members of ISPOR’s Special Task Force (STF) on Value Assessment Frameworks. We focus on three key challenges: 1) the need for a broader concept of value for PM/PrM; 2) the development of appropriate concepts and methods for measuring and splitting the innovation reward for PM/PrM; and 3) the application of this expanded concept to align value assessment in the hierarchy of related decision contexts, from formulary inclusion and value-based pricing to shared patient-provider decision making.

Our working assumption is that the goal of policy affecting PM/PrM technologies should be to promote “dynamic efficiency”—the optimal development, adoption, and use of these technologies.

RESULTS:
First, to support PM/PrM development and adoption, we need to utilize a broader concept of value that builds on the conventional cost-effectiveness ratio of the cost per quality-adjusted life year (QALY): for example, complementary diagnostics can generate additional value by reducing uncertainty in several ways. Second, we lay out six basic crosscutting policy principles addressing such important issues as: the need for flexible, value-based pricing; the need for real-world evidence generation; the complementary nature of the inputs in PM/PrM; and the challenging implications for assessing and rewarding value.

CONCLUSIONS:
For PM/PrM value assessment, we argue for: including the “value of knowing”; the need for indication-specific pricing; the importance of updating the economic evaluation and pricing over the product life-cycle; addressing the new challenge posed by next-generation sequencing and high-cost combination therapies; and aligning value metrics across different decision contexts based on health benefit and patient-centered utility.

PP139 Adapting HTA and Procurement To Tackle Antimicrobial Resistance

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ABSTRACT SUMMARY:
There is growing recognition that HTA and contracting systems for antimicrobials need to be adapted to help fight the threat of antimicrobial resistance, but there is little agreement on how. This poster reports findings from a literature review, expert interviews and face-to-face discussions at a Forum. Proposed adaptations present many challenges and much work remains to be done.

INTRODUCTION:
The rise of antimicrobial resistance (AMR) as an international public health threat calls urgently for improved stewardship of antibiotics and for the development of new antibiotics to tackle AMR. There is growing agreement that changes are needed to existing systems for HTA and procurement if antibiotics are to be used appropriately, and manufacturers are to receive rewards that incentivise R&D. However, there has been little discussion of what changes might actually be made.

METHODS:
We conducted a literature review of recent proposals to modify HTA and contracting for antibiotics, and interviewed HTA experts from England, France, Germany, Italy, Japan and Sweden to explore the attractiveness of these and other
proposals for their countries’ systems. A Forum [to be held in February 2019] with government and health system representatives from these countries, as well as from the industry, will promote face-to-face discussions on practical ways to modify these countries’ approaches to recognising the full value of antibiotics and promoting stewardship.

RESULTS:
The focus of the main proposals is on defining value attributes that reflect the societal impact of antibiotics, modelling the dynamics of infection transmission and resistance development, and conceptualising payment models that delink volumes sold from final revenues. However, HTA experts perceived a number of issues with these proposals, including lack of data to demonstrate societal value, complex modelling techniques requiring advanced capabilities, uncertain value estimates, and misalignment with current approaches. At present, it appears that only few countries (England and Sweden) have started to actively address HTA and contracting for antibiotics as a priority.

CONCLUSIONS:
Preliminary findings suggest that efforts and progress on modifying HTA and contracting of antibiotics have been heterogeneous so far. The Forum will shed further light on possible ways forward within the two value assessment approaches of Clinical Added Benefit and Quality Adjusted Life Years.

PP140 Gene Therapy For Transfusion-Dependent β-Thalassemia

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ABSTRACT SUMMARY:
The aim of this report is to provide an overview of the current Italian setting and treatment pathway for the management of transfusion-dependent β-thalassemia (TDT) patients identifying the place in therapy in this scenario and assessing the clinical and economic impact of the gene therapy.

INTRODUCTION:
β-thalassaemia is an inherited blood disorder that affects red blood cells. Globally, 80-90 million people (1.5% of the population) are carriers of β-thalassemia. In Italy, approximately 7,000 patients have β-thalassemia and most of them require transfusions.

METHODS:
A systematic literature review was performed by querying 5 search engines namely, PubMed, Scopus, Euroscan, EBSCO and Clinical Trial database. The selected studies where summarized narratively, following a simplified version of the EuNetHTA Core Model® 3.0 in order to develop this Horizon Scanning. Also, in order to understand the use of this technology and its impact on clinical and economic outcomes, a multidisciplinary advisory board with experts was established in order to collect useful evidence to develop the HTA report.

RESULTS:
In preliminary assessments, the gene therapy, which consists of autologous CD34+ hematopoietic stem cells transduced with the betibeglogene darolentivec lentiviral vector, may lead TDT patients with non-β0/β0 genotype to become transfusion independent. The safety profile after infusion was consistent with that associated with myeloablative conditioning for autologous haematopoietic cell transplantation (HCT) with single-agent busulfan.
No product related serious adverse events have been reported. Long-term data will eventually corroborate the efficacy and safety profile of this innovative gene therapy. Management of TDT patients consume significant healthcare resources, with the total annual direct medical care cost for β-thalassemia treatment estimated to be approximately 287 million of euros.

CONCLUSIONS:
The aim of this report is to provide an overview of the current Italian setting and treatment pathway for the management of transfusion-dependent β-thalassemia (TDT) patients identifying the place in therapy in this scenario and assessing the clinical and economic impact of the gene therapy. This report will be followed by a full HTA report to explore the remaining domains according to EuNetHTA Core Model® 3.0.

PP141 Functional Connectivity By Magnetic Resonance Imaging To Detect Autism

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ABSTRACT SUMMARY:
Functional connectivity by magnetic resonance imaging (fcMRI) analysis is a procedure based on prospective neuroimaging that, using a mathematical model, could predict diagnosis of autism. The objective of this study is to know the efficacy and safety of fcMRI to detect autism in high-risk infants at 6-month-old. Results showed that this procedure could help in early detection of autism.

INTRODUCTION:
Autism is a neurodevelopmental disorder characterised by alterations in the intellectual, social, communication and behavioural levels that rarely is detected before 24-months-old. Early diagnosis and interventions may be more effective at a younger age. Functional connectivity by magnetic resonance imaging (fcMRI) analysis tries to identify at 6-months-old brain connection patterns related to at least one of the characteristics of the diagnosis of autism by prospective neuroimaging data analysis using a mathematical model. These characteristics normally appear at 24-months-old.

METHODS:
Early assessment of fcMRI-analysis to detect autism identified through the Early-Awareness and Alert-System, “SINTESIS—new technologies”, of AETS-ISCIII. The searched databases were: PubMed, WOS, Tripdatabase, Dynamed, Cochrane Library, ICTRP and ClinicalTrials.gov. Clinical studies using the fcMRI to detect autism in children published until December 2018 were reviewed.

RESULTS:
Only one prospective study with 59 infants of 6-months-old was retrieved. A fcMRI-analysis to identify 2635 pairs of functional connections from 230 brain regions was performed. At 24-months-age, an evaluation for autism diagnosis using Gold Standard (GS) tests (DSM IV criteria) was made in the 59 infants. An automatic learning algorithm technique was used to compare the fcMRI data with the GS results and develop the diagnostic algorithm. The functional connections correlated with at least one of the behaviours related to autism evaluated at 24-months-age. Results showed that 11/59 infants were diagnosed with autism at 24-month-age. Comparing the predictive model with the GS results at 24-months, the outcomes were: Sensitivity: 0.82 (95%CI:0.52-0.95); Specificity: 1.00 (95%CI: 0.93-1.00); Positive Predictive Value: 1.00 (95%CI: 0.70-1.00); Negative Predictive Value: 0.96 (95%CI: 0.87-0.99); and
Negative Likelihood Ratio: 0.18 (95%CI:0.05-0.64). No presence/absence of adverse effects was described.

CONCLUSIONS:
The fcMRI-analysis could help in early detection of autism and the development of early preventative interventions. However, the evidence is scarce and it would be necessary to continue further well-designed studies.

PP142 Health Technology Assessment – A Major Bottleneck In Patient Access?

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ABSTRACT SUMMARY:
European reforms have expedited the regulatory approval process through CMAs and AAs. However, this has not translated into expedited patient access, with many medicines failing to achieve positive reimbursement, resulting in delayed or no access. Regulatory and HTA alignment across Europe is required to truly expedite access.

INTRODUCTION:
Conditional Marketing Authorisation (CMA) and Accelerated Assessment (AA) have been introduced to expedite the development of and access to therapies in Europe. However, to reach patients, medicines must also be publicly reimbursed. This research evaluates the reimbursement of therapies which have received European CMAs or underwent AAs.

METHODS:
Medicines approved under CMAs or AAs and their appraisals by major European payer bodies (NICE, SMC, G-BA, and HAS) were identified from the relevant website and key data extracted (01/01/2012-31/12/2017).

RESULTS:
Out of the 38 medicines have received CMAs, 83% (19/23) were assessed by NICE and received positive outcomes compared with 57% (16/26) by SMC (defined as recommended/restricted), 74% (14/19) by G-BA (defined as any level of additional benefit) and 29% by HAS (ASMR I-III). The median delay between EC-CMA approvals and positive HTA outcome were 13.0 months (NICE), 11.0 months (SMC), 7.0 months (G-BA), and 5.0 months (HAS). 32 medicines have received AAs. 68% (17/25) of approved medicines with AAs that were appraised by G-BA received positive outcomes, compared with 29% (7/24) by HAS, 90% (19/21) by SMC and 86% (18/21) by NICE. The median delay between EC-AA approvals and positive HTA outcome were 7.4 months (G-BA), 7.9 months (HAS), 11.7 months (SMC), and 11.8 months (NICE).

CONCLUSIONS:
CMAs have enabled expedited regulatory approvals for products that address severe unmet needs with less stringent data requirements. However, many have failed to gain favourable reimbursement outcomes and, for those that have, this has been at a significant delay. AAs provide market authorisations two months earlier than standard centralised assessment. Although high rates of positive payer outcomes have been achieved, these products typically experience substantial additional delays in securing public reimbursement. A parallel and cooperative approach between regulatory and HTA bodies across Europe is required to truly expedite access.
PP143 Cost Of Ventricular Assist Device Implantation Versus Transplantation

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ABSTRACT SUMMARY:
The objective of this study was to compare the cost of heart transplantation and left ventricular assist device implantation with 3-year follow-up from the Lausanne University Hospital (Switzerland) perspective. LVAD presented higher cost for implantation (+48%) and higher follow-up cost (+69%).

INTRODUCTION:
Heart transplantation (HT) is the treatment of choice for end stage heart failure, but it remains limited by the shortage of acceptable organs. For people waiting for an organ, an implanted heart pump, called left ventricular assist device (LVAD) is a reliable alternative. This technique has long been used to sustain the heart until a compatible organ becomes available (bridge to transplantation). More recently, LVAD has also been considered as a definitive solution for patients not eligible for HT (destination therapy). The objective of this study is to compare the cost of implantation and 3-year follow-up of LVAD versus heart transplantation.

METHODS:
Data were retrieved from the administrative database of Lausanne University Hospital (CHUV – Switzerland). Based on diagnostic and medical procedure codes, we selected all patients who underwent LVAD implantation or HT between 2011 and 2017. Costs were calculated adopting the hospital perspective.

RESULTS:
We included 111 patient stays (HT 81 and LVAD 30). Gender balance (HT 79% and LVAD 83% male, p=0.62) and age (HT 48 and LVAD 51, p=0.31) were not statistically significantly different between the two groups. HT induced shorter mean length of stay (53 days versus 71 days, p=0.08) and lower mean global cost (CHF 255'504 versus CHF380’167, p=0.0041). Cost of follow-up amounted to CHF 63'606 for HT versus CHF 125’221 for LVAD in year 1, CHF 65’376 for HT versus CHF 95’204 for LVAD in year 2 and CHF 42’671 for HT versus CHF 69’292 for LVAD in year 3.

CONCLUSIONS:
LVAD is associated with longer length of stay (+34%), higher cost of implantation (+48%) and higher cost of follow-up (+69%).

PP144 Bone Marrow Transplant Costs: A Patient Level Analysis Using TDABC

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ABSTRACT SUMMARY:
This research applied micro-costing method in tandem with Time-driven Activity Based Costing.
(TDABC) approach to measure and compare direct and indirect costs of Bone Marrow Transplant. The median time length spent on an allogeneic-related BMT was 46 days, and the median cost was USD 77,412.18. TDABC was fundamental to identify detailed and precise costs at a patient level.

INTRODUCTION:
The transplant of bone marrow (BMT) for the treatment of oncohematologic, hereditary and immunological diseases is currently the third most common transplant in Brazil. However, BMT patient’s usage of resources and the duration of each step of the treatment lacks accurate measurement in the Brazilian Healthcare System. This research aims to apply micro-costing method in tandem with Time-driven Activity Based Costing (TDABC) approach to measure and compare direct and indirect costs of BMT.

METHODS:
Assessment were collected from 12 patients undergoing allogeneic BMT in 2017 at a public and a private (non-profit) hospital. The TDABC literature was used to guide the application. Patients’ activities and their required treatment resources were identified through interviews with physicians as well as through the analysis of electronic medical records. The resources were classified as infra-structure resources or personnel resources and had their costs per time unit estimated using hospital financial system and management reports. The length of time spent per patient per activity was identified through EMR review, interviews and chronoanalysis. The study compares costs per activity, per resource and per hospital. The Institutional Development Program of the Brazilian National Health System (PROADI-SUS) supported the present study.

RESULTS:
Seven patients’ activities were identified. The median time length spent on an allogeneic-related BMT was 46 days, and the median cost was USD 77,412.18. Conditioning (USD 2,087.15 per day - 23% of total cost) and period of aplasia (1,593.85 per day - 53% of total cost) were the most expensive activities. Hospital comparison analysis indicated hospitalization costs as the single similarity between institutions, suggesting structure costs and capacities of inpatient areas as probable cause. Different costs were observed in medications and medical materials, other professionals, nursing, physician, and pharmacy.

CONCLUSIONS:
TDABC was fundamental to identify detailed and precise costs at a patient level. This information enabled researchers to identify the length of time spent by hospital departments and personnel with each patient, increasing the level of accuracy of the cost analysis.

PP145 Cost-Effectiveness of Cervical Cancer Screening Strategies in India

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ABSTRACT SUMMARY:
The present study was designed to assess the cost-effectiveness of 3 screening strategies for cervical cancer i.e., visual inspect with acetic acid (VIA), Papanicolaou test (Pap smear) and HPV DNA among the age group of 30-65 years old women at a frequency of every 3 years, 5 years and 10 years in the context of India.
INTRODUCTION:
The establishment of a link between high-risk human papillomavirus (HPV) infection and occurrence of cervical cancer has resulted in the recent development of HPV related control strategies for the prevention of the same. The present study was designed to assess the cost-effectiveness of 3 screening strategies i.e., visual inspect with acetic acid (VIA), Papanicolaou test (Pap smear) and HPV DNA among the age group of 30-65 years old women at a frequency of every 3 years, 5 years and 10 years in the context of India.

METHODS:
The present study based on a markov model, societal perspective and discount rate of 3%, estimated the lifetime costs and consequences in a hypothetical cohort of 30 year old women screened with either of the screening strategy at various time intervals. Sensitivity and specificity of the screening strategies was based on the recently published meta-analysis of Indian studies. Similarly, data on transition probabilities was derived from a published international meta-analysis. Further, primary data collection was undertaken using bottom up micro-costing method for estimating per person cost of screening and cost of treatment for cervical cancer in a public sector facility. In addition, 237 and 223 cervical cancer patients were interviewed from a tertiary care public sector hospital for assessing OOP expenditure and quality of life respectively.

RESULTS:
Introduction of screening led to reduction in occurrence of cervical cancer cases from 19% to 58% along with a decrease in cancer deaths from 28% to 70% as compared to no screening in a lifetime cohort of 1 lakh women. This reduction in cancer cases and associated mortality translated into gain of 3,141 to 6,848 life years and 3,630 to 8,198 QALYs with implementing various screening strategies. Further, VIA every 5 years is the most cost-effective option with an incremental cost of INR 21,196 (USD 320) per QALY gained in the context of India.

CONCLUSIONS:
Our findings may be useful to the government and policy-makers in planning screening programs for cervical cancer in the country.

PP146 Micro Costing Of Denture And Overdenture In Brazil

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ABSTRACT SUMMARY:
Edentulism is highly prevalent in Brazil. About 40% of the elderly over 65 years of age needing at least one denture. The objective of this study was to estimate the costs of two technologies for the treatment of mandibular edentulous, the Inferior Conventional Total Prosthesis (PTCI) and Implant Supported Prosthesis- 2 implants technique (PIS).

INTRODUCTION:
Edentulism is highly prevalent in Brazil. About 40% of the elderly over 65 years of age needing at least one denture. The objective of this study was to estimate the costs of two technologies for the treatment of mandibular edentulous, the Inferior Conventional Total Prosthesis (PTCI) and Implant Supported Prosthesis- 2 implants technique (PIS).

METHODS:
This study deals with a partial economic evaluation in oral health with a bottom-up approach for the calculation of direct costs. The estimates took into account the execution phases of the
techniques, proportion of materials, equipment and instrumental time life, in addition to the time spent with Human Resources. Doubts regarding the clinical and laboratory phases, as well as definition of the appropriate techniques from the perspective of the SUS were solved by a Panel of Experts. To determine the values related to each item, the sources of information available to represent a real and unique national value for each item were consulted and two sites were used: the health price bank, and the price panel website of the Ministry of Planning, Development and Management of Brazil.

RESULTS:
The value for produce a PTCI was R$ 189.89 (1 US$ = R$ 3.70) in the base scenario (ranging from R$ 151.91 more optimistic scenario to R$ 227.89 more pessimistic scenario). The value of a PIS (2 implants) was R$ 632.14, ranging from R$ 501.83 to R$ 753.20. Considering two clinical situations, that is, A) PIS reusing abandoned or disused PTCI and B) PIS as the primary choice, and comparing the costs with the Ministry of Health transfer of funds in the three scenarios, it was verified that there was only spending above in the most pessimistic scenario of clinical situation A.

CONCLUSIONS:
PTCI and PIS are two viable economic technologies and should be induced through public policies due to their positive impacts in several functional domains of health.

ABSTRACT SUMMARY:
There is a high demand for complete dentures, in both dental arches in Brazil, especially in older people. The aim of this study was to develop a Budgetary Impact Analysis (BIA) regarding the possibility of offering complete upper and lower dentures (UD and LD) to an eligible population of elderly people (above 65 years) in the São Paulo state, Brazil.

INTRODUCTION:
There is a high demand for complete dentures, in both dental arches in Brazil, especially in older people. The aim of this study was to develop a Budgetary Impact Analysis (BIA) regarding the possibility of offering complete upper and lower dentures (UD and LD) to an eligible population of elderly people (above 65 years) in the São Paulo state, Brazil.

METHODS:
The methodology consisted in calculating the proportion of eligible, the prevalence of edentulous (upper and lower arch) and defining the eligible population (public health system users) and exclusion criteria (clinical and management difficulties to offer to all individuals of this age group). Afterwards, the BIA was designed and, for this purpose, some criteria were defined: 5-year time horizon (2018-2022), prospect of municipal expenses with prostheses, additional progressive incorporation of technology (UD and LD) at annual rate of 10%, 15%, 20%, 25% and 30%. Sensibility analysis was perform in three different situations (reference, more pessimistic and more optimistic), based on the calculation of spending through measured demand and epidemiological demand.

RESULTS:
The municipal cost for each dentures (UD and LD),
already discounted the value of the transfer of the union for this procedure, was on average R$ 50.97 (1US$ = R$ 3.70). The incremental impact on the budget measured by the epidemiological demand in relation to that assessed was approximately R$ 59,141,510 million over 5 years, meaning an impact of 0.08% (0.01% more optimistic - 0.13% more pessimistic) of the “Medium and High Complexity Care” budget for Unified Brazilian Health System (SUS); and 0.09% (0.03-0.14%) of the Primary Care budget.

CONCLUSIONS:
Budgetary Impact of the increasing the oral rehabilitation with complete dentures for the elderly population in the State of São Paulo is low, relative to the expenses with primary or specialized care budget. Additionally, incorporation of denture rehabilitation would be feasible, according to the financial availability and priorities of each municipality.

PP148 A Stakeholder-Informed Strategy For Effective Communication

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ABSTRACT SUMMARY:
There is increasing recognition of the importance of strategic communication and stakeholder engagement in health technology assessment. As a new organisation, Health Technology Wales has an ideal opportunity to incorporate a strategic approach from the outset. We describe the development and implementation of a communication strategy and delivery framework, to increase the value of our work through awareness and dissemination.

INTRODUCTION:
Effective communication is vital for engaging stakeholders in health technology assessment (HTA), as well as the successful dissemination and adoption of HTA research and guidance. As a relatively new organisation, Health Technology Wales (HTW) has an ideal opportunity to take an effective, strategic approach to communication and stakeholder engagement from the outset.

METHODS:
HTW commissioned Pagoda Public Relations Ltd to develop an informed communications strategy and delivery framework. The strategy used OASIS methodology for public relations planning: Objectives, Audience insight, Strategy, Implementation, and Scoring (evaluation). Initial objectives were developed with input from the HTW team and members of the HTW Assessment Group and Appraisal Panel. Stakeholder insights were collected through an online survey and telephone interviews. These insights were used to inform the communications strategy and framework, outlining key audiences, key messages, communication objectives, methods, tactics and evaluations.

RESULTS:
Seven key objectives were identified, each of which are supported by recommended actions. These are underpinned by the key aims and messages reflecting how we will achieve these objectives. NHS boards, government, clinicians, the technology and research sector, patients and the general public have been identified as key priority audiences. Various different communication channels and activities were identified, aimed at various different audiences. These include the website, social media, traditional media, exhibitions/workshops, as well
as the targeted email dissemination of guidance. Evaluation of HTW communications will be aligned with the wider HTW evaluation strategy and evidence will be recorded through OutNav software (Matters of Focus).

CONCLUSIONS:
HTW is committed to a strategic, effective approach to communication and engagement. We now have an audience-informed communications strategy and plan that outlines our key objectives, how to achieve and evaluate these objectives. Successful implementation will raise awareness and value of HTW’s profile and outputs, both in Wales and internationally.

INTRODUCTION:
Rural doctors are the main undertakers of rural health work in China, they play an important role in improving the quality of rural medical services. To explore an intuitive and efficient way of competency evaluation according to the professional characteristics of rural doctors, evaluates the competency of rural doctors by using BP neural network, and analyses the current situation and main problems of rural doctors’ competency.

METHODS:
In this study, a multi-stage stratified random sampling method was used in 6 sample cities were selected according to the economic level in Shandong Province, a questionnaire survey was conducted among 406 rural doctors. This study combined with the previous research on the competence theory of rural doctors and rural doctor post evaluation system. The dimension of evaluation index system were divided by factor analysis, then confirmatory factor analysis was used for verification. A three-layer BP neural network model was established by Matlab to evaluate the ability of rural doctors, and chi-square test, variance analysis and other analytical methods were used to identify key crowd.

RESULTS:
Exploratory factor analysis established the index system of 24 factors, then using confirmatory factor analysis. The confirmatory factor shows that the main fitting index CMIN/DF=1.86, RMR=0.038, GFI=0.924, and so on, all above meet the fitting requirements, which indicates that the overall fitting effect of the evaluation index system is ideal. BP neural network evaluation results showed that, good level accounted for 43.84 percent at most, followed by general level 28.08 percent, excellent level 23.89 percent and poor level 4.19 percent at least. Through social demographic characteristics under the rural doctor competency level difference inspection found that the poor economic development, under 30 years of age,
education level is above undergraduate level, and practicing physicians, should be listed as a focus on the crowd.

CONCLUSIONS:
This study established 24 indicators of rural doctors competency evaluation index system, the artificial neural network evaluation results show that the level of competency of current rural doctors in Shandong province of China is generally good, but there are still a large room to improve, by identifying key doctors to establishing a sustainable development paths. In future research, we intend to further study the influencing factors of competency.

PP150 Bevan Health Tech Exemplars: Early Dialogue To Systematise HTA

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ABSTRACT SUMMARY:
This presentation will describe a collaboration between an HTA and national innovation body, applying HTA methods to support evidence-informed allocation of scarce innovation funds. It will also outline the HTA support offered to encourage prospective evidence collection to assess the success of the innovations.

INTRODUCTION:
Wales has ambitious health, wealth and innovation policies and a clear ambition to use the economic muscle of the Welsh NHS to support its strong lifescience sector. Health Technology Wales (HTW) has a clear remit to appraise technologies from innovation to obsolescence. HTW is collaborating with the Bevan Commission through their national Health Technology Exemplars (HTEs) that partner NHS and industry stakeholders to strengthen innovation within the Welsh NHS.

METHODS:
HTA methods were used for the first time to produce topic exploration reports to assess the evidence underpinning the applicant innovations. A ‘Dragon’s Den’ expert panel was convened to select the successful HTEs.

RESULTS:
14 Bevan HTEs were awarded funds, matched by industry partners. Application of HTA methods resulted in more critical consideration of the technology value propositions, including: developing pull models of innovation focused on delivering health technology solutions for current NHS Wales problems; supported by early dialogue between the NHS and industry partners aligned around evidencing improvement; with a focus on transformative as opposed to incremental innovation. The most promising innovations will progress to rapid HTA assessment utilising the evidence generated to develop guidance for NHS Wales.

CONCLUSIONS:
HTA methods were productively deployed at the innovation phase of the technology lifecycle to support evidence-informed allocation of scarce innovation resources. In this way HTW is working with key stakeholders to identify and offer early support to the most promising innovations aiming to expedite their adoption and realise the health benefits they offer for the people of Wales as quickly as possible. The Bevan Commission has invited HTW to routinely build in HTA and evidence considerations in its future innovation calls and competitions. Finally, HTW has established a
‘feeder’ pipeline to enable it to consider bottom-up service led innovations and encourage evidence consideration throughout the lifecycle of innovative technologies.

PP151 Establishing HTA Impact Evaluation With Stakeholder Input From Day One

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ABSTRACT SUMMARY:
The evaluation of impact is important in demonstrating the value of Health Technology Assessment (HTA) activities, but long-term consequences of policy decisions are not always easy to measure. We describe the development and implementation of an impact evaluation plan at a new HTA organisation, based on a Contribution Analysis approach. The involvement of relevant stakeholders throughout the process is key.

INTRODUCTION:
Health Technology Wales (HTW) is a relatively new Health Technology Assessment (HTA) agency which focuses on non-medicines. In common with other HTA organisations, it identifies and appraises a range of technologies. However HTW is also looking beyond the publication of guidance, to assess the adoption of advice and its eventual impact.

METHODS:
HTW commissioned development of an Evaluation Plan from independent experts (Matter of Focus). A literature review was carried out to inform an options appraisal of methods for assessing impact. The selected approach was Contribution Analysis, which estimates the counterfactual through engagement of stakeholders.

RESULTS:
Whilst it is too early to report the full impact of HTW’s guidance, a number of activities have taken place to prepare for evaluation. The core HTW team developed a series of logic models to describe the anticipated impact, the mechanisms by which it would be achieved, and key assumptions. Stakeholders were consulted for insight from a range of perspectives, and to manage expectations. This was achieved through individual interviews, presentation and discussion at committee meetings, and the sharing of written materials for feedback. This information was collated to populate bespoke software (OutNav). The collection of data relating to processes, outputs and outcomes is already an ongoing routine task of researchers and support staff.

CONCLUSIONS:
HTW has an opportunity to build impact evaluation into its culture from the beginning. This will facilitate the future reporting of HTW’s influence using a well-designed, evidence-based approach. Furthermore, this pioneering work will clearly demonstrate the value of HTA to funders, commissioners, governments, and other decision-making bodies.

PP152 HTA At Local Level In Lombardy: Perceptions From Professionals

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:  
Despite HTA is widely recognized as a tool utilized for efficient dissemination of technology, there is an urge need to foster the translation of HTA into decisions at the different levels of healthcare systems. The aim of this article is to investigate the factors that can affect the involvement of healthcare professionals in HB-HTA processes in Lombardy (Italy).

INTRODUCTION:  
Despite health technology assessment (HTA) is widely recognized as a tool utilized for efficient dissemination of technology, there is an urge need to foster the translation of HTA into decisions at the different levels of healthcare systems. In particular, previous studies underlined the necessity to adopt strategies aimed at increasing the uptake of research findings. At this purpose, hospital based HTA (HB-HTA) emerged as a way to customize the assessment to local needs and to actively involve healthcare professionals. In order to encourage the use of this tool, the identification of obstacles in the preparation, utilization and implementation of HTA reports is needed. The aim of this article is to investigate the factors that can affect the involvement of healthcare professionals in HB-HTA processes in Lombardy (Italy).

METHODS:  
A web-based survey, composed of 34 questions, comprising four different sections, was delivered to healthcare professionals in the all the hospitals (publicly and privately-funded hospitals, and teaching hospitals) of Lombardy Region to identify the individual and organizational factors affecting HB-HTA process. Additional hand-collected data have been gathered in order to complement information derived from the survey. An online research has been conducted for obtaining information related to individual and organizational determinants that cannot be assessed by self-reported data.

RESULTS:  
Answers from 304 healthcare professionals and 41 hospitals have been collected. Results provided that the majority of respondents is not part of any HTA network and the 20% of respondents is not aware of the functioning of the HTA process. Only 27% of respondents have previously participated in HTA processes.

CONCLUSIONS:  
Despite there is the necessity to widespread the practice of HB-HTA, interventions are needed. In particular, a more adequate access to the bibliographic sources is needed, such the establishment of an HTA culture at organizational level.

PP153 Direction Of HTA: To Build Evidence-Based Decision-Making Culture

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ABSTRACT SUMMARY:  
The HTA is important to identify how the derived information affected the decision makers. In the future of HTA, it should not be limited to a one-size-fits-all approach that creates and spreads good quality evidence through a complete system. It is necessary to make efforts to change their perception by considering external influences, and to build evidence-based decision-making culture.

INTRODUCTION:  
The primary purpose of the HTA is to support decision making in the healthcare sector, and it is
important to identify how the derived information affected the decision makers in some way. In this study, we interviewed health professionals and policy makers who have been involved in the NECA’s HTA research for the last 10 years and tried to understand the utilizing mechanism of HTA results and to search for improvement direction.

METHODS:
The target group was divided into two groups, broadly divided into clinical and policy parts. Using a semi-structured questionnaire, focus group discussion (FGD) and in-depth interviews (IDI) were conducted for 4 to 6 key informants of each group, and interview participants included clinicians and government officials. We also interviewed researchers who participated in the study, and interviews were analyzed using qualitative content analysis.

RESULTS:
A total of 12 participants participated in the interview, and three topics appeared in the data. First, both policymakers and clinicians stated that they accepted NECA’s HTA results, which are perceived as scientific and fair. Nevertheless, there are obvious limits to decision making. Regardless of the usefulness of medical technology, high-quality research results, and robust system construction, it depends on decision makers’ basic beliefs and willingness to use them, and is strongly influenced by policy and administrative environment. Second, an effective implementation strategy is needed along with planning considering the timeliness and topic of research. It is necessary to improve the reliability and involvement of the research by directly participating in the planning and progress of the research. Third, the concept of HTA has not been widely spread yet, and it is necessary to expand education opportunities on the necessity and effect of evidence-based decision making.

CONCLUSIONS:
In order to maximize and sustain the influence of HTA in the future, it should not be limited to a one-size-fits-all approach that creates and spreads good quality evidence through a complete system. It is necessary to make practical efforts to change their perception by considering external influences such as environmental change and various contexts, and to build evidence-based decision-making / practice as a culture.

PP154 Clinical And Financial Implications Of Medicine Consumption In Kenya

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ABSTRACT SUMMARY:
In Kenya over 30% of expenditures in hospitals are for medicines, which needs optimal management. Class A medicines (always) constituted 13.2% to 14.2% of medicines and 80% of total expenditure, whilst Class C medicines (control) constituted 70% of medicines and 5% of expenditure. Vital and essential items accounted for the highest expenditure and need carefully management. This is being undertaken.

INTRODUCTION:
Medicines can constitute up to 70% of total health care budgets in developing countries and considerable expenditure in hospitals. Inventory management techniques can assist with managing resources efficiently. In Kenyatta National Hospital (KNH) over 30% of expenditures are for medicines and this needs optimal management. Consequently, we investigated drug consumption...
patterns, their costs and morbidity patterns at KNH.

METHODS:
Cross-sectional retrospective record review. Inventory control techniques, ABC (Always, Better, Control), VEN (Vital, Essential and Non-essential) and ABC-VEN matrix analyses were used to study drug expenditure patterns. Morbidity data extracted from Medical Records.

RESULTS:
An average of 811 medicine types are procured annually (ATC 5), 80% were formulary drugs and 20% were non-formulary. Class A medicines constituted 13.2% to 14.2% of different medicines procured each year but accounted for an average of 80% of total annual drug expenditure. Class B medicines constituted 15.9%-17% of all medicines procured but accounted for 15% of annual expenditure, whilst Class C medicines constituted 70% of total medicines procured but only 5% of total expenditure. Vital and Essential medicines consumed the highest proportion of drug expenditure. ABC-VEN categorization showed 31% medicine types consumed an average of 85% of total expenditure. Therapeutic category and morbidity patterns analysis showed a mismatch between expenditure and morbidity which needs investigation.

CONCLUSIONS:
Class A medicines are few but consume the largest proportion of hospital drug expenditure. Vital and essential items account for the highest drug expenditure, and also need to be carefully managed. ABC-VEN categorization identified medicines where major savings could potentially be made helped by Therapeutic category and Morbidity pattern analysis. There was a high percentage of non-formulary items, which needs to be addressed. Inventory control techniques should be applied routinely to optimize medicine use within hospitals within available budgets especially in low and middle income countries. This is now being implemented.

PP155 Demand Side And Supply Side Of Healthcare Supply Chain

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ABSTRACT SUMMARY:
In the field of the hospital supply chain, this study provides an overview of the supply chain distribution of drugs and medical devices across Italy. This is a fundamental starting point for identifying the critical issues of each model and for aligning the demand of the hospitals to the providers offers.

INTRODUCTION:
The re-organization of the supply chain (SC) of medicines and medical devices may improve the efficacy and efficiency of the healthcare system. The aims of the study were to 1) identify the offers provided by private operators to NHS 2) analyse the organizational model of the public healthcare SC system and its criticalities.

METHODS:
Two online surveys have been designed.

Regarding the first survey, managers of private providers associated to the National Association of commercial and Logistic Operators (ASSORAM) have been interviewed to identify the offers provided to NHS.
The second one has been submitted to managers of local health authorities and university hospitals associated to the Italian Association of Hospitals (FIASO) in order to gather both organizational/managerial information (warehouse capacity, purchasing, registry, security) and qualitative aspects of the SC. Data collected refers to year 2015.

RESULTS:
On the supply side, 41 providers have been interviewed. More than 70% of associates managed mainly hospital products. 67% of interviewees delivered less than 30% of products to hospitals and only 8% delivered about 70% of the products to hospitals. The providers’ infrastructures (warehouses, transport, IT, cold chain, GDP) are adequately regulated and they adopted a wide list of indicators for monitoring performance. Private providers showed high interest in investing in the hospital sector.

Regarding the first survey, both qualitative data from 56 hospitals (21 University Hospitals UH, 33 Local Health Authorities LHA, 2 Broad Intraregional Areas BIA) and quantitative from 39 hospitals (15 UH, 22 LHA, 2 BIA) have been collected in 15 and 13 regions, respectively. As shown preliminary results [1], the main weaknesses of SC are related to infrastructures, ITs, human resources as well as lack of financial resources and inadequate process control.

CONCLUSIONS:
The study highlighted extremely limited outsourcing in the hospital field to date, weaknesses in the public system and a high interest of private providers in investing in public hospital SC.

PP156 Reimbursement Of New Treatment Methods In Hospitals: Status In Germany

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ABSTRACT SUMMARY:
For innovative technologies not yet listed in the existing German healthcare system the NUB process enables hospitals to receive a supplemental payment. For an optimal process a consultation requests to the G-BA in due time is strongly recommended. Results of 705 NUB assessments are analyzed.

INTRODUCTION:
Since 2005, new treatment and diagnostic methods (NUBs) were reimbursed by individual supplementary fees. The assessment procedure for NUBs is induced by hospitals submitting a request for additional compensation of healthcare treatment to the Institute for the Fee System in the Hospital (InEK). In 2016 the legal norm §137h SGB V was introduced to evaluate medical devices (MD) of high risk classes by the Federal Joint Committee (G-BA). InEK grants a status that is valid for twelve months and impacts additional compensation as well as assessment required by G-BA. The effects of this rating seem to differ between hospitals and Statutory Health Insurance (SHI).

METHODS:
The published InEK decisions on NUBs were analyzed according the decision criteria and possible impact on price negotiations with SHI.

RESULTS:
In 2018, 705 NUB requests were assessed by InEK.
NUB Status 1, granting negotiation of additional coverage, was assigned to 171 procedures. Status 2 – no additional reimbursement possible - was given in 472 cases, the remaining had not sufficient information. Most NUBs (368) requests were not falling under §137h, however those with sub-Status “B” (allocated to 12) lead to controversies: no participant had requested an evaluation according to §137h for the NUB. 2 consultation requests receiving Status 1 B were regarded as not eligible acc. § 137h by the G-BA. To avoid price negotiation delays, early consultations acc. § 137h are recommended by G-BA during the NUB application.

CONCLUSIONS:
The NUB process enables hospitals to receive a supplemental payment when using innovative technologies not listed in the existing German healthcare system. The question which requirements have to be fulfilled to guarantee the reimbursement should be asked at an early stage. Consultation requests to the G-BA in due time are strongly recommended. Contact between manufacturers and hospitals are advisable to support the NUB application.

PP157 Health Technology Assessment Model By Public Hospital, Brazil

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ABSTRACT SUMMARY:
The objective of the present study was to present an experience report of the HTA model used at a public hospital in Brazil. This is a descriptive study of the processes used for HTA by Center of Health Technology Assessment (CHTA) of Clinical Hospital, Botucatu Medical School (CHBMS).

INTRODUCTION:
The increasing emergence of new technologies, reduction of financial resources, the need to choose the best treatment and care to be offered to the population, with lower costs, make it necessary to use methods based on scientific evidence and the creation of Health Technology Assessment (HTA) models for decision making by managers and health professionals. The objective of the present study was to present an experience report of the HTA model used at a public hospital in Brazil.

METHODS:
This is a descriptive study of the processes used for HTA by Clinical Hospital, Botucatu Medical School (CHBMS), as an experience report. It is a general, public hospital, has high technology for care and research, and a high impact on clinical practice. Since 2010, the Center of Health Technology Assessment (CHTA) has been implemented.

RESULTS:
CHTA consists of HTA expert members, who meet monthly, and carry out training, dissemination and preparation of documents for institutional decision making or in external partnerships. The demands are: a) internal (institutional), based on requests from health professionals sent by the Committees of Pharmacy and Health Products Standardization, and Directorate; and b) external, through partnerships with State, Ministry of Health, Judicial System and participation in public calls. Technical-scientific reports are produced (structured document summarizing evidence-based literature, which meets quality criteria and critical analysis) and a rapid review technical note (synthesis document that prioritizes in the following order: systematic reviews, HTA of international
agencies and clinical trials). The deadline for preparing these reports is around 30 to 60 days. In cases of urgency, rapid responses are provided in 7 to 10 days.

CONCLUSIONS:
The model described has presented positive results for the institution in question and can serve as a reference for other hospitals that wish to implement the HTA for decision making.

P158 Prospective Trial Cases Of Conditional Approved Technology Of nHTA

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ABSTRACT SUMMARY:
We conducted a prospective trial in the name of ‘Conditional Approved Health Technology (CAHT)’ to measured safety and efficacy. CAHT is one of the technologies categorized as a health technology that requires clinical evidence accumulation in nHTA. It is a system that accumulates evidence by providing medical services to patients who need this technology for a specific period.

INTRODUCTION:
1) Pancreatic adenocarcinoma is one of the most aggressive malignancies, with a 1-year survival rate less than 20%. Irreversible Electroporation (IRE) is a novel technique that uses a non-thermal ablation to avoid vessel or duct injury.

2) Fluorine-18 (18F) – fluorodeoxyglucose (FDG) positron emission tomography/computed tomography (PET/CT) has been used to predict stages and prognosis of the clear cell renal cell carcinoma (ccRCC). However, unlike glucose, FDG is excreted through the urinary tract, making it hard to identify the malignant lesions in the genitourinary tract. Therefore, its use has been limited. To overcome the limitations of FDG, we confirmed that need to evaluate C-11 methionine (C-11 MET) uptake of ccRCC according to different stages. IRE and C-11 MET were assessed through the New Health Technology Assessment (nHTA) at National evidence-based healthcare collaborating agency (NECA) in each 2014, 2012 as a technology at the stage of needing further researches since there is inadequate research results that can prove its safety and effectiveness in treatment of various cancer patients. Therefore, we conducted a prospective clinical trial with both technology (1 Surgical treatment, 1 Diagnosis test) in the name of ‘Conditional Approved Health Technology’ to measured safety and efficacy. It is a system that accumulates and re-evaluates evidence by providing medical services to patients who need this medical technology for a specific period of time.

METHODS:
In order to reassess the technology through the results of prospective clinical trials, The purpose, method, target patients of using and efficacy/safety indicators were constructed on the basis of the nHTA. This is very important in terms of reproducing results in the real world.

The effectiveness and safety of the IRE procedure of the Pancreatic cancer at the nHTA was analyzed by technical success, overall survival (OS), progression-free survival (PFS) and all complications. Thus, IRE prospective clinical trials was designed to analysis by technical success,
Overall survival (OS), progression-free survival (PFS) and all complications.

C-11 MET diagnosis test of the ccRCC at the nHTA was assessed by comparing with CT and all complications. This also, The effectiveness and safety of the C-11 MET prospective clinical trials was designed comparing with 18F PET/CT and all complications.

In the case of the selection and exclusion criteria, the responsible researcher set up the protocol as the IIT study type, and selected the method of reviewing the number of sites and study period. To ensure patient safety, the responsible researcher received an IRB approval in advance. Also, in the event of a change in the essential documents including protocol, case report form, informed consent form, and etc., nHTA committee of NECA and the IRB of the implementing hospital should be authorized.

For the management of prospective clinical studies, monitoring and data management were conducted through the contract research organization (CRO). Also, we conducted independent Audits once a year to guarantee the quality of the data.

To evaluate the safety and effectiveness of IRE for Locally Advanced Pancreatic Cancer, two hospitals in Korea were approved through a suitability evaluation for the study. And approved the one hospital for implementation of C-11 MET study.

RESULTS:
In the case of IRE, Patients are recruited at one hospital, except for one hospital where no patient recruitment is available.

Eighteen patients (median age, 63.50 years; range, 46–78 years) treated between December 2015 and September 2018 underwent intraoperative IRE for LAPC. This study has resulted in 19 Serious Adverse Event (SAE) to date due to the poor survival of the patients. Therefore, unlike other studies, monitoring and checking of patient safety was emphasized in terms of research management.

But met’s study was different. The c-11 met belonging to the radio-pharmaceuticals had a short half-life, this was confirmed in the results of the study. We could not find the SAE to date, which occurred in the patient. Therefore, the diagnostic accuracy and prognosis prediction of the patients were concentrated.

Thirty ccRCC patients (median age, 60 years; range, 34–86 years) had a C-11 MET PET/CT test between December 2016 and September 2018.

CONCLUSIONS:
We conducted a prospective clinical trial in the name of ‘Conditional Approved of Health Technology (CAHT)’ to measured safety and efficacy. An important aspect of prospective clinical trials is the needs for research management that is tailored to each technology’s characteristics. For in-depth implementation and review of prospective clinical studies for new health technology, overall management of the clinical research process is important. In particular, it should be recognized that Risk Based Monitoring (RBM) of Clinical data is emphasized.

P159 Is Community Paramedicine A Safe/Effective Alternative to Usual Care?

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ABSTRACT SUMMARY:
There has been a recent trend for paramedics to apply their training and skills outside the usual emergency response and transportation model and into community environments. This
presentation describes some of the key findings from a health technology assessment on the safety and effectiveness of community paramedicine in assessing and managing conditions/diseases with low acuity.

## INTRODUCTION:

Due to an aging population, shortage of healthcare staff, and escalating healthcare costs, there has been a recent shift in the professional roles and responsibilities in acute care settings to help bridge the care gap. Paramedics, whose primary responsibilities have been in emergency/transportation services, are increasingly involved in the management of chronic diseases in the community setting. However, even with additional training, there are concerns about the safety and effectiveness of this expanded role.

The objective of this presentation is to highlight some of the key findings from a health technology assessment report on the safety and effectiveness of community paramedicine in assessing and managing conditions/diseases with low acuity.

## METHODS:

A systematic review was conducted to identify studies that evaluated the safety and effectiveness of different community paramedicine programs.

## RESULTS:

Four systematic reviews and 20 primary studies (with one randomized controlled trial, RCT and 19 observational studies) were identified; of these, two systematic reviews and 14 primary studies focused on the safety and effectiveness of Emergency Care Practitioner (ECP) programs, a widely implemented program within which a healthcare practitioner with a paramedic or nursing background undertakes activities traditionally performed by physicians, such as the initial assessment of patients, provision of simple treatment, or referral of patients to other clinical care. Limited evidence showed that ECP program are promising in reducing repeated emergency calls, emergency department visits, hospital admissions/readmissions, and emergency transport charges. While the majority of included studies did not report any safety outcomes, no significant safety issues were identified from the cluster RCT. Evidence for other types of community paramedicine is limited.

## CONCLUSIONS:

Evaluation of the impact of community paramedicine programs remains methodologically challenging. Additional cluster RCTs may help determine the effectiveness of community paramedicine programs; safety outcomes should be a key element of future observational studies.

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### PP160 Management Of Patients Affected By Neuropathic Pain In Italy

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#### ABSTRACT SUMMARY:

The analysis assesses the therapeutical alternatives currently in use in Italy for the management of patients affected by peripheral neuropathic pain focusing on the appropriateness of the setting in which such alternatives are provided and the economic impact of an early recourse to capsaicin as compared to more invasive treatments.

#### INTRODUCTION:

Neuropathic pain is a chronic painful sensation resulting from a deterioration of nerves of the peripheral or central nervous system. Treatments for the management of the disease includes pharmacological and psychological strategies,
although these paths solve the problem only in few cases. Doctors recur to antidepressants, able to alleviate, with moderate success, the symptoms. There are a number of non-pharmacological treatments such as: physiotherapy, PENS (percutaneous electrical nerve stimulation) and TENS (transcutaneous nervous electrical stimulation. Capsaicin has recently been added to the panorama of pharmacological treatments available for the management of peripheral neuropathic pain.

**METHODS:**
We performed a literature review aimed to gather evidences about capsaicin and other pharmacological and invasive alternatives, their efficacy, organizational implications and level of resources’ absorption. Organizational evidence was used to populate a cost-minimization model aimed at determining the differential of expenditure given by the implementation of a therapeutic strategy, after pharmacological treatments’ failure, based on the early use of capsaicin in the most appropriate setting when compared to immediate use of surgical alternatives.

**RESULTS:**
The present analysis is an ongoing study: a decrease in the amount of resources associated to the scenario where an early recourse to capsaicin has been considered as compared to the one that takes into account data based on the Italian real practice would represent an opportunity for the Health Service of funding strategies to address further health needs.

**CONCLUSIONS:**
Considering a comparable level of efficacy and safety of ponatinib as compared to the alternatives in use in the Italian setting for the management of patients affected by peripheral neuropathic pain, it would be desirable an increase in the rate of utilization of the strategy based on an early recourse to the therapy associated to the lowest amount of resources’ consumption in order to achieve significant savings in the Italian Healthcare Setting.

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**PP161 An Update Systematic Review And Meta-Analysis Of Non-Invasive Prenatal**

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**ABSTRACT SUMMARY:**
To inform making-decision on supervision and implementation of the non-invasive prenatal screening test, we updated a systematic review assessing the performance of the massive parallel sequencing (MPS) technology in prenatal screening for trisomy-21.

**INTRODUCTION:**
To inform making-decision on supervision and implementation of the non-invasive prenatal screening test, we updated a systematic review assessing the performance of the massive parallel sequencing (MPS) technology in prenatal screening for trisomy-21.

**METHODS:**
Conducted was exhaustive literature searches of eight databases (the Cochrane Library, Medline, EMBASE, Web of Science, Biosis Previews, CBM, CNKI and WanFang) to identify all relative articles published between October 2016 and August 2018. We included primary screening studies including randomized controlled trials, nonrandomized controlled trials, prospective cohort studies, large sample retrospective cohort studies (sample
size ≥10000), case–control studies. The quality of included studies were rated using a modified QUADAS-II. Summary measures of diagnostic accuracy were calculated using a bivariate mixed-effects model in Stata.

**RESULTS:**

Eight studies were added in this update. The summary sensitivity from bivariate meta-analysis of all fifty-five included studies, combined total of 2302 cases of Down syndrome and 216614 non-Down syndrome pregnancies, was 99.6% (95% CI: 99.1%–99.8%) and the summary specificity was 100% (95% CI: 99.9%–100%). A meta-analysis which only included studies in China to explore the performance and effectiveness of MPS technology at domestic institutions in the policy and business environment which extensively covered this technology also were performed. A summary sensitivity and specificity of twenty-nine included studies in China was 99.5% (95% CI: 98.8% – 99.8%) and 100% (95% CI: 99.9% – 100%), respectively.

**CONCLUSIONS:**

Our updated review, again, confirms the effective performance of MPS technology in non-invasive prenatal screening for trisomy-21. Due to NIPT is still a screening rather than a diagnostic test, meaning that the results should be made a risk indicator rather than a diagnosis decision. In addition to the ethics and business aspects, the training of care providers and patient preferences for information should be considered in order to efficiently and timely manage and utilize this technology.

**PP162 Safety Of Human Papillomavirus (HPV) Vaccines: An Overview Of Reviews**

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**ABSTRACT SUMMARY:**

Substantial evidence in the form of reviews and systematic reviews has accumulated relating to the safety of HPV vaccines. This overview of reviews, encompassing 74,628 RCT participants and over 20 million individuals from cohort studies, demonstrates that HPV vaccination is not associated with an increased risk of serious adverse events or death compared to placebo or control vaccines.

**INTRODUCTION:**

Substantial evidence in the form of reviews and systematic reviews has accumulated relating to the safety of HPV vaccines. The objective of this study was to perform an overview of reviews, also known as a ‘systematic review of systematic reviews’, to document the best available evidence on their safety.

**METHODS:**

A de novo search for systematic reviews evaluating the safety of HPV vaccines (1-, 2-, 4- or 9-valent) was conducted in PubMed, Embase and the Cochrane Library. The methodological quality of the included systematic reviews was assessed using the AMSTAR 2 appraisal tool. Data extraction and quality appraisal was performed independently by two people.

**RESULTS:**

Ten systematic reviews were identified that met our inclusion criteria. Eight included only RCTs and two included both RCTs and observational studies. The number of included studies in reviews ranged from three to 37. Maximum follow-up was 10 years. One review investigated the 9-valent vaccine; only three reviews included males. Total number of trial
participants was 74,628 individuals. Cohort studies covered many million participants (maximum: 20 million people). All systematic reviews were of critically low quality by AMSTAR-2 quality appraisal tool, with the exception of a 2018 Cochrane Review by Arbyn et al. and a 2017 Health Technology Assessment by Parsons et al.

No safety issues were identified for a range of serious adverse events (SAEs) in any review. Five reviews provided a pooled estimate for serious adverse events with none finding a statistically significant association. Minor adverse events that are transient in nature commonly occur following vaccination. An anaphylaxis rate of 1.7 cases per million doses was noted. No deaths causally linked to HPV vaccination were found.

**CONCLUSIONS:**
HPV vaccination is not associated with an increased risk of SAEs or death compared to placebo or control vaccines. Minor adverse events (e.g., transient local or systemic symptoms) following vaccination are very common.

**PP163 Introducing The Notion Of Potential Clinical Value**

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**ABSTRACT SUMMARY:**
This abstract discusses an important paradigm shift in the assessment of new drugs for (ultra) rare disease with unmet medical need and clinical benefit uncertainty by the Institut national d’excellence en santé et en services sociaux (INESSS), HTA agency in Quebec (Canada).

**INTRODUCTION:**
Major changes in the social and scientific context (for example, willingness for faster access to innovative treatments, notably by reducing time to reimbursement; drug commercialization of innovative therapies with lower levels of evidence than in the past on the basis of surrogate endpoints), has prompted the need to adapt the approach for evaluating drugs, particularly those with immature clinical data, high uncertainty and unmet medical need.

**METHODS:**
Without a change in its drug evaluation processes, it would be difficult, if not impossible for INESSS to recommend listing of certain therapies, compromising access to promising drugs that are often the only option for vulnerable populations. As an example, in case of a drug for a very rare disease, it is unlikely that a conventional clinical trial would be available to generate data on the impact of the drug on the progress of the disease. Therefore, INESSS has found it necessary, when assessing specific medications only, to introduce the notion of potential clinical value (also referred to as potential benefit or promise of therapeutic value).

**RESULTS:**
A drug for which a potential clinical value has been recognized would need clinical follow-up, because of uncertainties in the magnitude of the benefit on endpoints such as survival and quality of life. Assessment of real-world evidence, for example, may be used to confirm the value of the drug in time. This approach requires awareness on the part of all stakeholders (manufacturers, clinicians, patient, government) that the drug may ultimately be unable to provide the anticipated benefits. This could lead to disinvestment decisions, in the interest of providing fair and reasonable reimbursement.

**CONCLUSIONS:**
This presentation will describe when it may be
reasonable to apply the concept of potential clinical value during assessment. Case examples could be provided.

PP164 Improving Medical Diagnosis Through Advanced Data Analytics Tools

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ABSTRACT SUMMARY:
New technologies such as data analytic tools and intelligent clinical history are gaining space as possible solutions to aid systems to reduce variability in practice. EXCON project is aiming to assess and validate in real world practice the feasibility of developing and implementing those tools and their capacity to reduce variability.

INTRODUCTION:
Currently the clinical practice is based on clinical guidelines or local protocols built on the basis of Clinical Evidence. This means that clinical variability is reduced, which in many cases involves clinical decisions inefficient, with the possibility in some cases of increased medical errors, decreasing patient’s safety. The aim of EXCON project is to investigate the innovative concept of Intelligent Clinical History (ICH), and to develop functional prototypes of high added value in healthcare services.

METHODS:
EXCON is an innovative project that takes advantage of recent advances in technologies for coding, structuring and semantizing medical information. Thanks to this new structuring, EXCON platform will be developed. Final users will be health professionals and other decision-makers. During development and subsequent validation of the platforms, a group of doctors, nurses, epidemiologist and information specialists have been involved.

RESULTS:
For the development of the ICH, clinical data from different electronic medical record databases have been collected, in a high prevalent symptom, with high variability in clinical practice, such as non-traumatic chest pain in emergency services. The extraction of clinical data to implement new techniques of artificial intelligence, requires a work that must be automated, which today is difficult and tedious (data is often not computerized). Through techniques applied in EXCON, such as natural language processing, relevant clinical data have been extracted and a Decision Support System has been developed and validated. This tool optimizes resources and improves clinical management, reducing errors and increasing patient’s safety.

CONCLUSIONS:
In coming decades a change is expected in the management of patients in health systems, with the application of new advanced data analytics tools, that will allow a more efficient and safe clinical management, decreasing variability in clinical practice and with it, the inequity. That is why the development and assessment of those technologies is necessary.
PP165 Content Instead Of Orders: Experiences Of Launching A Knowledge Base

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ABSTRACT SUMMARY:
A knowledge base was implemented in the Department of Health Technology Assessment in Hungary to facilitate smart capacity building in a resource-constrained environment. The uptake by assessors is fairly good, continuous content development is used to facilitate user engagement and the generation of community knowledge. The overarching aim is to increase the quality of the assessment outputs.

INTRODUCTION:
The local procedure for innovative pharmaceutical products in Hungary allows 43 calendar days for 13 assessors working on the evaluation of reimbursement submissions by using the tools of health technology assessment, creating a robust need for smart capacity building, namely, streamlining the scientific evaluation process, while making sure that the quality of the critical appraisals remain high. The objective of this study was to present and evaluate the implementation of an online knowledge base to distill community knowledge and also for management purposes.

METHODS:
The scope and the content-, functional-, and technical specification was developed, and also IT security requirements were identified during the pre-implementation phase. An already existing platform was chosen for adaptation, ensuring that descriptive follow-up data is available on uptake for monitoring purposes. Both the adaptation and the maintenance was carried out internally by the Department of Health Technology Assessment at the National Institute of Pharmacy and Nutrition.

RESULTS:
The key requirements identified when developing the specification were searchability, low maintenance need, low operating costs and attractiveness for users. An already existing open-source, flat file content management system was chosen for adaptation. In terms of content, a health technology assessment handbook, process documentation, a news bulletin section was created, and corporate identity elements were added. Since the start of the service in September 2018, the number of total daily page downloads to the knowledge base varied between 4 and 1193 (average 205 per day), with the assessment handbook topping the overall page visit statistics.

CONCLUSIONS:
The implementation of this knowledge base enables the Department of Technology Assessment to rely more on the formalized community knowledge when carrying out critical appraisal, while enabling better knowledge and quality management. Uptake remains an issue on the long run, indicating a need for continuous content development.

PP166 A Mobile Clinical Decision Support System for Autism Spectrum Disorder

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**ABSTRACT SUMMARY:**

AUTAPP Project aims to develop an evidence based personalized Clinical Decision Support System (CDSS) using mobile technology for improving the decision process on psychosocial therapies for Autism Spectrum Disorders. Present study focused on the systematic review for identifying those recommendations on which the algorithm of the CDSS will be developed and the next steps of the mobile application design.

**INTRODUCTION:**

eHealth is a new approach for managing several health conditions, but up to now not so many interventions have shown their efficacy/effectiveness. AUTAPP Project tries to add knowledge in eHealth interventions targeted to Mental Health disorders, specifically Autism Spectrum Disorder (ASD) management that requires complex interventions that integrate different psychosocial interventions. AUTAPP aims to develop an evidence based Clinical Decision Support System (CDSS) using mobile technology for improving the decision process on psychosocial therapies in ASD. Present study focused on the systematic review for identifying those recommendations on which the algorithm of the CDSS will be developed.

**METHODS:**

A systematic review was carried out to identify the existing scientific evidence published (November 2009-November 2018) in relation to the effectiveness of: (i) early detection protocols; (ii) assessment tools; (iii) existing non-pharmacological therapies. Main databases were consulted (PubMed, Cochrane Library, PsycholInfo). Articles were reviewed for two independent reviewers. Quality of selected publications and recommendations were assessed according SIGN criteria.

**RESULTS:**

A total number of 147 publications were revised (477 identified): ninety-six for non-pharmacological therapies, thirty-three for assessment tools and eighteen for early detection. Regarding early detection and assessment, twelve recommendations were identified and six obtained the highest level (A), such as the convenience of multidisciplinary diagnose teams and the usefulness of M-CHAT for ASD confirmation.

For non-pharmacological therapies, sixteen recommendations were collected. Those with higher levels of recommendations were the family, environmental and educational interventions (three As and one B). On the other hand, those with the lower levels of recommendation (C) were interventions which included exercise, computers and neurological approaches.

**CONCLUSIONS:**

This systematic review allows both to identify gaps and opportunities in psychosocial interventions research and be the base for the CDSS algorithm. In the future professionals, careers and people diagnosed with ASD will validate the mobile CDSS.

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**PP167**

**Appropriate Health Technology Listing In China**

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**ABSTRACT SUMMARY:**

An evidence-based and stepwise decision-making framework was developed and it contained six steps including problem structuring, definition of criteria, identification of candidates & evidence
collection, screening, priority-setting and appraisal. Finally, Four new and innovative technologies out 58 candidates was selected and recommended to National Appropriate Health Technology List in China.

**INTRODUCTION:**

In 2017, China National Health Commission (CNHC) initiated a national program to promote new, innovative and appropriate health technologies among all county hospitals to strengthen local capacity and improve accessibility to health care. Commissioned by CNHC, our center aim to explore an explicit, stepwise and evidence-based framework to select AHTs for the program.

**METHODS:**

Based on a systemic literature review and expert consultation, a priority-setting framework based on multi-criteria decision analysis (MCDA) was developed for the listing. The framework contained six steps including problem structuring, definition of criteria, identification of candidates & evidence collection, screening, priority-setting and appraisal. Six criteria were identified to score and rank alternatives, which were health needs, maturity, safety, effectiveness, economic, operability and social and ethical impact. A expert committee with 13 shareholders was set up to conduct appraisals and recommend the final list to NHC, which contains decision makers, representatives of county-level hospitals, experts in clinical medicine, public health experts, health economics, medical ethics as well as appropriate technology promotion.

**RESULTS:**

First, 58 candidate technologies were collected along with evidence under 6 criteria form 33 national clinical centers across the country; Then, a primary screening was conducted by 24 clinical experts in 11 disciplines, in order to review and score all candidates against 4 criteria (safety, effectiveness, operability and acceptability), resulting into a screening list with 13 candidates; Further, the performance of these 13 candidates were scored and ranked against all 6 criteria by representatives form 4 country hospitals, the user of AHT, then a short list of 10 technologies was produced. Last, the expert committee conducted an appraisal meeting on the short list and recommended 4 technologies meeting all criteria to CNHC.

**CONCLUSIONS:**

This multi-stages decision-making framework was robust in this study, which made the process more transparent, evidence based and resulted into a jointly decision making against different criteria. The framework has potential to apply in other

PP168 Impact Of Health Technology Assessment In China, India And Thailand

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ABSTRACT SUMMARY:

Strong political wills yet limited resources to achieve UHC were enablers fueling the impact of HTA on policy decision making in China, India, and Thailand. In addition to the common lack of HTA human resources among all three countries, China and India still need to standardize HTA practices and improve mechanisms of HTA coordination.

**INTRODUCTION:**

Despite the fact that health technology assessment (HTA) has been introduced into many Asian developing countries, the impact of HTA on policy decision making varied across countries. This review aimed to compare the progression of integrating HTA into policy decision making in China, India and Thailand, identify barriers and
enablers for achieving HTA impact, and share lessons of strengthening HTA systems towards achieving Universal Health Coverage (UHC).

METHODS:
A systematic search of literature relevant to HTA and policy decision making in China, Indian and Thailand was conducted on databases including PubMed, Embase, and Web of Science from database inception until November 2018. 59 studies were included for literature review after deleting duplicate or irrelevant studies.

RESULTS:
As China, India and Thailand had strong political wills yet limited resources to achieve UHC, HTA has been gradually regarded as a potential tool to assist policy decision making. Thailand has developed national pharmacoeconomic guidelines and considered cost-effectiveness evidence for the inclusion or exclusion of drugs from the reimbursement list with a specified cost-effectiveness threshold. China and India are still exploring the integration of HTA into policy decision-making processes. Shortage of qualified HTA human resources was a common barrier of conducting and using HTA in all three settings. China and India also lacked formal HTA guidelines to standardize HTA practices and clear mechanisms of coordinating HTA among stakeholders.

CONCLUSIONS:
Strong political wills yet limited resources to achieve UHC were enablers fueling the impact of HTA on policy decision making in China, India, and Thailand. In addition to the common lack of HTA human resources among all three countries, China and India still need to standardize HTA practices and improve mechanisms of HTA coordination.

PP169 First Insights Into Health Technology Assessment Of ATMPs In Germany

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ABSTRACT SUMMARY:
The assessment of added medical benefit of ATMPs in Germany is challenging. The data base for ATMPs at time of first EU approval does not necessarily meet the requirements for benefit assessment in Germany. This study deduces challenges and strategies for AMNOG assessments of ATMPs.

INTRODUCTION:
Like all newly approved pharmaceuticals in Germany, ATMPs undergo an assessment of the additional medical benefit, if they are based on a gene therapy or a somatic cell therapy. There are several reasons why the “standard” assessment conducted by the German HTA bodies (G-BA and IQWiG) is not fully adequate for the assessment of the added medical benefit of ATMPs: the evidence base of pivotal studies for ATMP approval often is not comparative and therefore insufficient to quantify the added medical benefit. Low patient numbers, highly individualized therapies and often exclusive hospital-based usage also impede the assessment.

The aim of this study is to analyze the evidence base and the outcome of ATMP assessments and to deduce challenges and strategies for future benefit assessment of ATMPs in Germany.

METHODS:
Information on the assessment of ATMPs were retrieved from a databank containing information
on all AMNOG procedures. Relevant documents were analyzed on indication, evidence base and outcome. Additionally, assessments of non-ATMP pharmaceuticals with low evidence base (single arm trials, registry data) were analyzed for supplemental information.

RESULTS:
At present 12 ATMPs have been approved in the EU. Five ATMPs are obligated to undergo a benefit assessment. Three ATMPs have been fully assessed, three others are currently under evaluation. The pivotal trials of two ATMPs are RCT, all other approvals are based on single arm trials and historical data. All evaluations completed so far resulted in either non-quantifiable added medical benefit only due to the Orphan drug status or in no added medical benefit.

CONCLUSIONS:
The data base for ATMPs at time of first EU approval does not necessarily meet the requirements for benefit assessment in Germany. A support of single arm interventional trials by carefully collected historical data might fill the data gap.

PP170 Quantifying The Life-Cycle Value Of Innovative Medicines: The Case Of [...]
other indications approved during the life-cycle is qualitatively shown. Analyses for Sweden are ongoing but preliminary results indicates the same general patterns. Reported UK results are under review and therefore subject to potential change.

CONCLUSIONS:
The value added by risperidone (SGA) increased during the life-cycle due to the launch of RLAI and the generic competition. Results suggest that price and reimbursement decisions based on cost per QALY at launch should consider the dynamic nature of pharmaceutical markets and value added by innovative medicines over the long-run.

PP171 Cost And Effectiveness Of Chronic Hepatitis C Treatment In Brazil

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ABSTRACT SUMMARY:
In Brazil, treatment for hepatitis C is available in the public health system since the 1990s and in 2015 were incorporated the antivirals sofosbuvir, daclatasvir and simeprevir. The study contextualizes a real-life scenario in Brazil of cost and effectiveness in a specialized center in hepatitis C treatment. The evaluated treatments presented good effectiveness, but high costs.

INTRODUCTION:
With the discovery of new direct-acting antivirals, the cure for hepatitis C appears to be a reality, but its high price and the availability of new antivirals are a major obstacle to curing hepatitis C. In Brazil, treatment for hepatitis C is available in the public health system since the 1990s and in 2015 were incorporated the antivirals sofosbuvir, daclatasvir and simeprevir. The calculation of the budgetary impact of this merger estimated expenditures between 467 and 666 million Reais (USD 121 and 172 million) per year. This study aims to present and discuss the cost and effectiveness of hepatitis C treatment with direct-acting antivirals, in combination or not with alfapeginterferon and ribavirin, based on real-life data, and compare it with the world scenario.

METHODS:
We analyzed the treatment data and outcomes of 253 patients from a retrospective cohort performed in a Specialized Care Service, in the city of Porto Alegre (RS). In relation to costs, the direct costs of antiviral drugs, per unit (tablet), were considered according to financial receipts from public purchases. The total cost of the medications used by each individual in each treatment and the cost per cure obtained, expressed in Sustained Viral Response (SVR), were calculated.

RESULTS:
Most patients (66.8 percent) had genotype 1 of the hepatitis virus and 92.9 percent achieved SVR. The mean total cost of treatment of patients with genotype 1 was USD 5,862.31 and USD 6,310.34 / cure; while in patients with genotype 3 the cost was USD 5,144.27 and USD 5,974.76 / cure. The cost with the most commonly used treatment regimen, sofosbuvir, daclatasvir and ribavirin was USD 5,961.25 and USD 6,536.46/cure. These values were 30 percent lower than the values estimated at the time of drug incorporation.

CONCLUSIONS:
Cost and effectiveness data contextualize a real-life scenario in Brazil. The evaluated treatments presented good effectiveness, but high costs.
PP172 Cost-Effectiveness Evaluation Of Opioid Substitution Therapy

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ABSTRACT SUMMARY:
Cost-effectiveness evaluation of methadone maintenance treatment versus no opioid substitution therapy for treatment of opioid use disorder. We have developed a dynamic model in order to simulate the probability of Human Immune-deficiency Virus (HIV) transmission and the dynamics of HIV development among IDU’s in Kazakhstan for 5 years. We estimated new HIV cases, prevalence rates, mortality rates and costs.

INTRODUCTION:
Opioid dependence is a serious social and economic problem in the world. It is estimated that 69 000 injecting drug users (IDUs) die every year due to overdose of opioids. The number of people suffering from opioid dependence in the world is approximately 15 million people. The aim of the study is to evaluate the cost-effectiveness of methadone maintenance treatment versus no opioid substitution therapy for treatment of opioid use disorder.

METHODS:
This study used the results of systematic reviews, meta-analyses and clinical reviews, as well as clinical guidelines, data from the national reports.

We have developed a dynamic model in order to simulate the probability of Human Immune-deficiency Virus (HIV) transmission and the dynamics of HIV development among IDU’s in Kazakhstan for 5 years. We estimated new HIV cases, prevalence rates, mortality rates and costs.

RESULTS:
Due to 100 percent coverage of Opioid Substitution Therapy (OST), the number of new cases of infection is 1370 times less than without intervention. The number of prevented HIV cases in 5 years will be 115 763. In addition, OST would have prevented 4450 deaths.

The total cost of antiretroviral therapy (ART) for 5 years in the group not receiving OST was 4.5 times higher than the same indicator for the group receiving OST. ART for 20 years of therapy for 115763 prevented cases of HIV infection would be 150.3 million USD, under condition of 100 percent adherence to treatment.

CONCLUSIONS:
OST significantly reduces the number of new HIV infections, thus reducing the cost of ART. Our study showed that performing OST saves 150.3 million USD thankth to HIV infection averted. OST also reduces the mortality rate among IDUs by 2.7 times, compared with the absence of any intervention.

PP173 Is Early Modelling Too Late? Preventing Pitfalls And Optimizing Value

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ABSTRACT SUMMARY:
We demonstrate an increasing trend by NICE towards maximization of value through approval of drugs in select groups of patients. Early modelling has the potential of preventing investment mistakes in trial design, particularly in population selection. We argue early economic analyses should be
performed to identify potential pitfalls, optimize investments and identify evidence gaps requiring additional primary or secondary research.

INTRODUCTION:
Drug development is a risky business. Manufacturers are faced with the dilemma of whether or not to invest at any stage in the development process. Even once marketing authorization has been attained, payers are becoming increasingly expecting evidence to justify price premiums in the face of increasing budgetary pressures. For many, e.g. NICE, SMC, TLV, PBAC, CADTH, cost-effectiveness is a critical decision-making criterion and restrictions to sub-populations is common. Early economic modelling has the potential to be used at very early phases of the development pathway inform optimal investment decision making, including go/no-go decisions and clinical trial design, particularly in population selection. To test the hypothesis of changing payer requirements, we carried out a study on the trends in reimbursement submissions where payers approved but ultimately restricted the population compared to the marketing license or company’s target population.

METHODS:
A systematic literature review of all NICE single technology appraisals was carried (01/01/2006-16/11/2018). We used a linear regression model to examine the relationship of frequency of optimizations and time.

RESULTS:
357 STA outcomes were identified, 55% were recommended and 26% were optimized. The proportion of optimized recommendations increased over time vs all other outcomes (p = 0.01), with more technologies being optimized over time (p < 0.01).

CONCLUSIONS:
The results indicate an increasing trend by NICE towards maximization of value through approval of drugs in select groups of patients. From a manufacturer’s perspective, prediction of such outcomes at an early stage is fundamental for investment purposes and to maximize financial returns. An early stage model provides a framework to examine these issues as well as identifying data gaps, where RWE can be planned to support the value argument for products, and to inform clinical trial design through value of information analysis.

PP174 EUenetHTA Early Dialogues For Medical Devices Created With Stakeholders

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ABSTRACT SUMMARY:
After drafting the initial version of the ED for MD procedure and draft briefing book and in order to receive feedback from as many stakeholders as possible, the ED Secretariat launched a public consultation on the documents. A pilot ED is currently underway. Both experiences will help to finalize the procedure for launch end of 2018.

INTRODUCTION:
Based on SEED and EUenetHTA JA2 where five pilot Early Dialogues (ED) were completed for medical devices (MD) and coupled with the EUenetHTA JA3 experience with pharmaceutical EDs, the DM procedure has been created with the help of all participating HTAB (AQUAS, AVALIA-T, G-BA, HAS, INFARMED, ISCIII, NICE, RER, SNHTA, TLV, ZIN) and input from stakeholders.
METHODS:
After drafting the initial version of the ED for MD procedure and draft briefing book and in order to receive feedback from as many stakeholders as possible, the ED Secretariat launched a public consultation on the documents. The consultation was open from June 22 through July 20th.

All responses were compiled into a master document and were examined by the ED Secretariat and the HTA Bodies involved in ED for MD. Each comment then resulted in a change to the corresponding document and/or a commented explanation.

RESULTS:
Comments from ten organizations were received on the procedure (eight from stakeholder organizations (3 patient groups), two from EUnetHTA members) and seven commented on the briefing book template (four coming from stakeholder organizations, four from EUnetHTA members). Key topics addressed by the stakeholders for both documents included the importance of involving external experts throughout the process (e.g. obligation for manufacturers to share Briefing Book with patients, process for recruiting external experts), more specificity regarding the scope of the EDs (e.g. multi-indication, types of EDs eligible, timing of request), and inquiries regarding conflict of interest (e.g. confidentiality duration, independence of future assessment). A pilot ED is currently underway with 7 HTA Bodies participating to test the procedure prior to its official launch at the end of 2018.

CONCLUSIONS:
The added benefit of the public consultation on EUnetHTA’s ED procedure for Medical Devices and the external stakeholder feedback received will help ensure optimal exchange with MD manufacturers.

PP175 EUnetHTA Early Dialogues – In Light Of Stakeholder Feedback

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ABSTRACT SUMMARY:
The main objective of EUnetHTA EDs is to provide common recommendations on how a product should be developed in order to fulfill HTA requirements across EU Member States. The research aim is to provide a descriptive analysis of stakeholder feedback collected for the EDs completed at the time of the conference.

INTRODUCTION:
Since the beginning of Joint Action 3 (JA3), 14 Early Dialogues (ED) for pharmaceuticals have been completed. The main objective of EUnetHTA EDs is to provide common recommendations on how a product should be developed in order to fulfill HTA requirements across EU Member States. The research aim is to provide a descriptive analysis of stakeholder feedback collected during EDs.

METHODS:
EUnetHTA ED procedures involve many external stakeholders, notably patients/patient representatives and regulators. Feedback is continuously collected and used to update the
procedure. This is done via written feedback questionnaires, interviews, monthly discussions with EMA, and regular meetings with all stakeholders. The documents and activities were subject to quantitative and qualitative targeted review to describe stakeholder feedback in a standardized and structured manner.

RESULTS:
Of the 14 completed EDs, 11 have been performed in parallel with EMA and 10 included patients. Feedback was obtained from the applicant in 6 instances and was systematically collected for patients via an interview conducted by the ED Secretariat.

Overall the positive feedback from industry is reflected in the high demand, high re-demand (24 of 44 requests are return requests), a better understanding of the procedure, and a majority intending to implement EUnetHTA’s recommendations.

The willingness of patients to be involved and the high level of recruitment is also a positive signal.

Feedback received has also underscored that further adaptations are necessary including more transparency and clarification regarding the selection criteria for EUnetHTA EDs, SME participation (5 of 14 EDs) should be increased, patients seek further implication and the need to integrate other stakeholders.

CONCLUSIONS:
Past the midpoint of the JA3, there is increasing need to work on the compilation of overall feedback to create a sustainable ED model post 2020. The engagement of stakeholders should be further facilitated to provide feedback on EDs.

PP176 How To Build An Expand HTA Capabilities In The Public Life

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ABSTRACT SUMMARY:
Health Technology Assessment has focused on professionals, but the public also wants to use health information as the basis for better decision making in their lives. The provision of HTA study results, which is readily accessible anytime, when everyone needs it, is the way forward future HTA.

INTRODUCTION:
Health Technology Assessment has been regarded as a field that is difficult for the public to access because it has focused on providing evidence for policy and clinical decision makers. In order to extend the capabilities of HTA, the result of HTA research should be provided in an easy-to-understand way to the public. This study is aimed at focusing on HTA impact on the public in order to develop new field of HTA research beyond 2020.

METHODS:
We conducted a survey of 467 people who had experiences to see the result of HTA study released by the National Evidence-based Healthcare Collaborating Agency, which is the HTA agency in Korea, in order to understand the users’ satisfaction of HTA result and to know the effective way of providing health information to the public. Respondents were asked about their satisfaction with the result of HTA research, interest information, access path and improvement plan. We also used the Google Analytics tool to identify
behavioral patterns of online users visiting the NECA web-site, where the results of HTA study are always available.

RESULTS:
More than half of the respondents were satisfied with the HTA study results. Their main objectives were to acquire healthcare information (69%), and look for work and educational materials (33.8%). This shows that people need health information that is closely related to their lives. The 36,759 users who visited the NECA web-site stayed for about 187 seconds per session and visited the ‘Research Report’ page the most. Most of the people who visit this web-site frequently access portal sites via desktop during work hours.

CONCLUSIONS:
The result of HTA research should be provided not only as a policy and clinical evidence to the decision makers, but also as easily accessible and understandable information to the public.

We should make continuous endeavor to help people easily get a basis for better decision making in their lives. This is the extended capabilities of HTA research beyond 2020.

PP177 Health Preference Research In Europe: A Review Of Its Use

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ABSTRACT SUMMARY:
HTA and regulatory decisions involve value judgements. As patient groups, industry, and regulatory agencies conduct more preference studies to quantify these judgements, a better understanding of methods is needed. This study used a mixed method approach to identify the use of quantitative preference data by all relevant HTA bodies and regulatory authorities of the EU member states.

INTRODUCTION:
HTA and regulatory decisions involve value judgements. As patient groups, industry, and regulatory agencies conduct more preference studies to quantify these judgements, a better understanding of the methods and practices is needed. Currently, there is no systematic mapping of the use of preference data in Europe.

METHODS:
This study used a mixed method approach based on a systematic literature review, survey and subsequent interviews with decision makers and experts, to identify the use of quantitative preference data by all relevant HTA bodies and regulatory authorities of the EU member states, and to identify key standards and guidelines.

RESULTS:
A total of 62 survey responses were received. Many respondents reported that their agencies were responsible for supporting more than one type of decision, with 69.0% supporting approval decisions,
64.3% supporting reimbursement decisions, 61.9% supporting pricing decisions, and 64.2% supporting guideline development. Respondents reported that their agencies supported these decisions in multiple ways: 78.6% by assessing health technologies; 54.8% by appraising health technologies; 45.2% by compiling an HTA report; 7.1% by conducting primary research; 9.5% by conducting secondary research. More than 40% (42.9%) of agencies had the final say on one of the decisions of interest – approval, reimbursement, or pricing. Of the 31 countries studied, 71% (n=22) used quantitative preference data in their reimbursement and pricing decisions. Of those, 86% (n=19) used general population preferences to inform the estimation of QALY as part of CUA.

CONCLUSIONS:
Much of this use of preference data can be understood within the standard framework of economic analysis adopted by many HTA agencies; either in in the form of: standard ways to estimate QALYs; ways to broaden the impacts of technologies captured in the QALY; or ways to weigh health gain with other decision-making criteria, such as disease severity or innovativeness.

PP178 Health Technology Assessment Of Laboratory Medicine

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ABSTRACT SUMMARY:
The purpose of this study was to conduct an HTA process about the possibility to re-organize and automate the Laboratory medicine of Bambino Gesù Children’s Hospital.

This project examined technological and organizational solutions proposed by two manufacturers, supporting the decision makers to choose between the two technical solutions compared.

INTRODUCTION:
Recent studies have been sustaining the re-organization and automation of a Laboratory medicine as a challenge for the hospital in terms of reduction of costs, turnaround time and workload, optimization of human and technological resources and improvement of safety. The purpose of this study was to conduct an HTA evaluation process about the possibility to re-organize and automate the Laboratory medicine of Bambino Gesù Children’s Hospital.

METHODS:
Decision-oriented HTA (Do-HTA) method was applied to assess the best technology solution involving the integration of the EUnetHTA CoreModel and the Analytic Hierarchy Process. It is an analytical instrument for the identification of the main evaluation criteria leading to the attribution of their performances.

Twenty-one professionals have been involved to define tender specifications related to the adaptation works of the new dedicated rooms and to the automatic technologies and organizational solutions for the new Laboratory Medicine. Finally, two manufactures ‘companies were took into consideration.

RESULTS:
The study was focused, through DoHTA method, only on the laboratory technologies while the infrastructure evaluation was conducted by the Engineer and Logistic Units of the hospital. Results showed that the total performance score of the first proposal was slightly higher (2,5%) than
the second one, proving the comparable high qualitative level of both manufactures technologies. After an accurate analysis, evaluating all aspects (safety, clinical efficacy, cost, organization & technical criteria) and integrating the infrastructure evaluation, the decision has fallen upon the first company offer.

CONCLUSIONS:
This HTA project allowed to examine in depth all technological and organizational solutions proposed. Thanks to DoHTA method, producing and developing data and all needed information, it was possible to guide and assist the decision makers on the choice between the two technical solutions compared.

INTRODUCTION:
A Health Technology Assessment (HTA) process, involving different pediatric intensive care units (ICUs) of Bambino Gesù Children’s Hospital (OPBG) about the evaluation of the best intensive care ventilators manufacturers, has been carried out. The purpose of this study is to show the most relevant features of a ventilator to be considered between different manufacturers and the methodology to conduct the assessment for supporting the decision-making process about the choice to adopt the suitable technology for OPBG.

METHODS:
Decision-oriented HTA method, developed by HTA unit of OPBG, was applied to conduct the assessment. It, involving the integration of the EUnetHTA CoreModel and the Analytic Hierarchy Process with the support of an informatics tool, provided the definition and numerical evaluation of assessment parameters through which it is possible to evaluate the performances of technologies compared. A literature review, with the ICU professional contribution, has led to the definition and weighing of the assessment elements on clinical, technical, organizational, economic, and safety domains. In particular, a subgroup of these indicators has been included in a checklist for the performances evaluation of different ventilator models, each of which was tested in three independent runs performed in three different ICUs.

RESULTS:
Results show that the aspects with the highest impacts within the evaluation are safety and clinical effectiveness followed by organizational, technical and economic aspects. A percentage value per each ventilator has been assigned, representing the global performances regarding the assessment elements.

CONCLUSIONS:
This study presents and discusses the benefits and drawbacks of innovative features of ventilators, all
characteristics to be taken into account during the evaluation process and a methodology to conduct it.

The project identified, through a collective decision, the most performant ventilator model giving a reliable recommendation to the Hospital Decision Makers.

PP180 Safety First: Rapid Reviews To Evaluate Minimally-Invasive Technology

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ABSTRACT SUMMARY:
Health systems are responsible for ensuring patient safety and weigh decisions to provide innovative new therapies against persistent uncertainties regarding effectiveness and safety. An analysis of rapid evidence reviews on minimally-invasive technologies was conducted to ascertain the extent to which the reviews included safety data. Rapid reviews guide decisions especially when they include detail on safety outcomes to monitor.

INTRODUCTION:
Health care systems are responsible for ensuring patient safety and must routinely weigh decisions to provide innovative therapies against persistent uncertainties regarding the effectiveness and safety of new health technologies. The need for systems to evaluate new technologies in an efficient and time-sensitive manner has led to increasing use of "rapid evidence reviews" that employ abbreviated evidence synthesis methods that some believe prioritize the results of effectiveness studies and place less emphasis on studies addressing safety issues.

METHODS:
A retrospective review of rapid evidence reviews conducted between 2015 and 2018 on minimally-invasive procedural technologies produced for a large U.S.-based health system’s new health technology committees was undertaken to ascertain the extent to which the evidence reviews included studies or data on important safety issues that could be weighed against data on effectiveness.

RESULTS:
Forty-two rapid evidence reviews were identified (26 de novo reviews, 16 updates of previous reviews) and nearly all (98%) assessed published evidence on both effectiveness and safety. For the evidence reviews including safety, over 95% included “real-world” published evidence which was graded as low or very low in quality. Despite low-quality evidence about safety, 60% of the technologies reviewed were associated with recommendations to implement the technology in the organization’s delivery system, most often as research protocols or as monitored pilot studies. Factors such as effectiveness data, a high burden of suffering, lack of therapeutic alternatives, and potential for operational efficiencies often drove these recommendations. Many evidence reviews (31%) used to support decision making recommended specific safety outcomes or information to monitor after implementation.

CONCLUSIONS:
Concerns about safety were consistently reported in reviews on minimally-invasive therapeutic technologies, allowing committees to weigh safety against purported benefits. Rapid evidence reviews can guide ongoing management decisions especially if they include detail on safety outcomes and recommend strategies to monitor patient safety.
PP181 Systematic Review Of Nutritional Screening Tools For Hospital Settings

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ABSTRACT SUMMARY:
Nearly a third of hospital in-patients in Ireland experience undernutrition. This systematic review, prioritised by NCEC Ireland, identified validated screening tools used to identify patients at-risk.

All major databases were searched (up to 20 June 2018). 6 languages included.

14 studies validating 12 tools. 18 studies assessing 5 tools for predicting adverse outcomes. No cost-effectiveness studies.

Many NSTs appear as good as each.

INTRODUCTION:
Nearly a third of hospital in-patients in Ireland experience undernutrition, which is associated with adverse events, longer lengths of hospital stay, higher treatment costs and increased mortality. This systemic review was conducted to support the development of the national clinical guideline Nutrition screening and use of oral nutrition support for adults in the acute care setting prioritised by the National Clinical Effectiveness Committee, Ireland. It included three review questions: 1) accuracy of nutritional screening tools (NSTs) for assessing nutritional status, 2) accuracy of NSTs in predicting adverse outcomes, and 3) cost-effectiveness of NSTs for the identification of adults at-risk of undernutrition, in acute hospital settings.

METHODS:
This review updated an earlier systematic review by van Bokhorst-de van der Schueren et al (2014), with additional restrictions applied to the inclusion criteria. Rating method adopted. OVID Medline, Embase, Web of Science, CINAHL and the Cochrane Library were searched on 20 June 2018. Studies published in English, French, German, Spanish, Portuguese and Dutch were eligible. Screening, data extraction, and quality assessment were conducted independently by two reviewers. The strength of the evidence was assessed using the Cochrane GRADE approach. A narrative summary was conducted. Registration number: CRD42018102358

RESULTS:
From 2,594 citations screened, 30 studies were included. Sensitivity ranged from 8% to 100% and specificity 53% to 97% for the 12 NSTs identified in question 1 (from 14 studies). Question two included 18 studies evaluating 5 NSTs in predicting adverse outcomes and demonstrated fair to good validity. The strength of the evidence for both questions was deemed very low. No cost-effectiveness studies were identified for question three.

CONCLUSIONS:
Many NSTs appear as good as each other. Further research is required comparing a range of NSTs in the same population, and cost-effectiveness and related resource implications need to be considered.
PP182 Natalizumab Therapy For Relapsing-Remitting Multiple Sclerosis

PRESENTING AUTHOR:
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ABSTRACT SUMMARY:
A systematic review focusing on the longterm (>24 months) effectiveness and safety of natalizumab therapy for relapsing-remitting multiple sclerosis patients. The primary objective was to compare the intervention with alternative pharmacological treatments with respect to annualized relapse rate, disability progression, quality of life and number of serious adverse effects.

INTRODUCTION:
Worldwide, more than 2.5 million people suffer from Multiple Sclerosis (MS), which is a progressive, degenerating disease of the Central nervous system (CNS). MS is one of the most frequent neurological conditions among young adults, although younger as well as older people can be affected. The typical sclerotic plaques (lesions) within the CNS originate from multiple inflammation processes which ultimately destroy the neuronal tissue. The clinical manifestations are heterogeneous and depend on the location of the lesions. They include motor deficits, sensory problems, speech and vision impairments and malfunctions of the urogenital system and cognitive impairments. Furthermore, the majority of the patients suffer from chronic neuropathic pain caused by the dysfunction of the nervous system. Currently, there is no definitive cure. Therefore, available pharmacological therapies aim to reduce the disease activity either by suppressing or by modulating the immune system. The humanized monoclonal antibody Natalizumab (Tysabri) was approved for the treatment of relapsing-remitting multiple sclerosis by the Food and Drug Administration (FDA) and the European Medical Agency (EMA) in 2006. By binding to the integrin receptor molecule VLA-4 (very late antigen-4), it efficiently blocks the transmigration of immune cells into the CNS. In pivotal placebo-controlled randomised clinical trials, Natalizumab has been shown to be highly effective. However, the therapy has been associated with an increased risk of developing progressive multifocal encephalopathy (PML) which is a severe opportunistic infection of the brain. The rationale of this review is to compare the efficacy and safety of Natalizumab with alternative MS immunomodulating therapies. Furthermore, a more precise estimate of the treatment effect of Natalizumab therapy will be calculated by including randomised trials that have been undertaken since the publication of the first systematic review. Potential long-term effects will be evaluated by including observational studies.

METHODS:
The aim of the systematic review was to investigate whether natalizumab is more effective and safer than alternative pharmacological therapies or placebo over a longterm treatment period (> 24 months) with respect to annualized relapse rate (ARR), disability progression as measured by the Expanded Disability Status Scale (EDSS), quality of life (QoL) and number of serious adverse events (SAEs).

Included in the analysis were adult patients (18-65 years) with a diagnosis of RRMS (according to the accepted McDonald criteria) regardless of age, sex, severity of disease or treatment duration. I compared the effect of standard natalizumab treatment (300mg, IV, every 28 days) versus other immunomodulating therapies irrespective of their dosing regimen. If no other therapy was used, I considered a placebo control.

For evaluating effectiveness, RCTs regardless of the length of the follow-up period were considered. Furthermore, prospective, non-randomized controlled trials with a treatment period of more than 24 months were included in order to evaluate the efficacy and effectiveness, respectively. In contrast, I excluded retrospective studies and those with a follow-up of 24 months or less. In terms
of safety, prospective single-arm studies with a minimum treatment period of 36 months were additionally included in order to be able to assess long-term adverse events. Retrospective studies as well as case series or case reports were excluded.

A systematic literature search was conducted in the following four databases (Medline via Ovid, Embase via Ovid, Toxline and Cochrane Central). The search was limited to prospective studies, articles published since 2011 and in English language. After deduplication, 303 citations were included. Furthermore, the clinical trial registry ClinicalTrials.gov was assessed for ongoing clinical trials and observational studies. In total, the search yielded 35 results, which were assessed in full-text, of which 7 were considered relevant.

RESULTS:

Included studies

For the assessment of clinical effectiveness, three studies met the inclusion criteria. One randomised controlled trial (RCT) and two non-randomised controlled studies. In total, 1,603 patients were included of which 610 were treated with natalizumab for a period between 6 and 51 months. Patients of the corresponding control group received either fingolimod (n=789), placebo (n=47) or did interrupt natalizumab treatment (n=81). The RCT was sponsored by the manufacturer Biogen Idec.

For the assessment of safety, seven studies met the inclusion criteria. The three controlled trials above, and four single-arm studies with a total of 6335 patients. The follow-up periods lasted between 42 to 60 months. Three studies were funded by Biogen Idec.

Clinical effectiveness

No significant differences regarding the annualized relapse rate were found, if natalizumab was compared to fingolimod therapy (rate ratio of 0.93 (95% CI: 0.74-1.17); p=0.53). However, compared to either a placebo control or a group of patients interrupting natalizumab therapy, natalizumab showed an approx. 70% reduction in the annualized relapse rate (rate ratio of 0.33 and 0.31, respectively).

Concerning disease progression, no significant differences among natalizumab and fingolimod treated patients were observed. Yet, in comparison with placebo or a group of patients interrupting natalizumab therapy, the condition of patients of the corresponding intervention groups either improved or remained unchanged.

Concerning QoL, only one trial (RCT) investigated this patient-reported outcome. Yet, no significant difference was observed between the intervention and the control group.

Safety

Four studies reported adverse events. The proportion of patients suffering from serious adverse events ranged from 2.4% to 16%. The most frequent were infections and infestations (up to 4%), neoplasms (up to 2%) and hypersensitivity reactions (0.5% to 2%). In total, 35 cases of PML were reported. 14 deaths occurred, one of which was attributed unambiguously to PML.

CONCLUSIONS:

The current evidence indicates, that in comparison to fingolimod, no significant differences are observed in terms of ARR and disability progression. However, the quality of the body of evidence suggesting this is low to very low. In terms of safety, no evidence was found that natalizumab is safer than alternative treatments. Yet, the reporting of serious adverse events was a point of major concern as partial reporting was assumed in several trials.

In general, challenges with interpreting the data arose due to differences in outcome reporting and the heterogeneity of the study populations. Furthermore, imprecision due to small sample sizes prevented a quantitative analysis of the data.

Thus, future research should provide more head-
to-head RCTs comparing natalizumab with other disease modulating drugs. Moreover, like for all chronic diseases, patients as well as treating physicians would benefit from studies with longer follow-up periods (>24 months) and an additional focus on health-related quality-of-life outcomes.

**PP183 The Improvement Of Pregnancy Outcome With Community Nutrition Program**

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**ABSTRACT SUMMARY:**
This RCT was categorized into the intervention group with nutrition education and counseling (n=98) and control group (n=44) within twenty-two weeks of gestation. Neonatal body weight of the intervention group was greater than control group (3251.5±402.2 vs 2974.5±294.8, p< 0.005). The proportion of neonatal body weight under 3,000gm was significantly lower in the intervention group (23% vs 50%. p< 0.05).

**INTRODUCTION:**
Due to the increasing average age of pregnant women, the risk of preterm birth and health risk for the mother is increasing and therefore nutrition and health care during pregnancy are becoming more important. Maternal care including nutrition intervention through education and counseling is known for the method of improving perinatal outcome. This study was conducted to provide and assess nutrition intervention program developed by medical staff and dietitian for pregnant community members and evaluated the efficacy.

**METHODS:**
One hundred forty-two pregnant women within twenty-two weeks of gestation participated from March to December 2016. At least four times visits by four week interval until childbirth for education and evaluation into three public health care center in Suwon, was categorized as the intervention group. The contents of nutrition education and counseling program included balanced diet, low-salt/low-sugar diet and cooking class for pregnant women, and they were followed by face-to-face, online, and telephone about fulfillment.

**RESULTS:**
The mean neonatal body weight of the intervention group was greater than control group (3251.5±402.2 vs 2974.5±294.8, p< 0.005), and the proportion of neonatal body weight under 3,000gm was significantly lower in the intervention group than control group (23% vs 50%. p< 0.05) Maternal weight gain was within the normal range in both groups. Maternal eating behavior was significantly improved (p<0.001) in the intervention group compared with the control group. More than 90% of participations were reported ‘satisfied’ or ‘very satisfied’ with the contents of the intervention program.

**CONCLUSIONS:**
Through this study, the maternal nutrition intervention during pregnancy helped promoting the birth of healthy babies with normal weight and to achieve ideal gestational weight gain with practicing healthy eating behavior.

**PP184 Assessment Of Adolescent Scoliosis Screening Intervention Project**

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**ABSTRACT SUMMARY:**
From a social perspective, this study evaluated the program, implementation process, and results of CAISS project, which is the first adolescent idiopathic scoliosis screening project in China that has continued for four years. The conclusion is that it would be beneficial to continue such screening program in the long run.

**INTRODUCTION:**
From a social perspective, this study evaluated the program, implementation process, and results of the project to provide policy recommendations on whether the screening should continue. CAISS project is the first adolescent idiopathic scoliosis screening project in China that has continued for four years.

**METHODS:**
This study evaluated the screening population, methods and criteria of the program through qualitative system review and expert consultation. We investigated impact on all three levels: macro (government), meso (institution) and micro (individual or family) levels. The implementation process was evaluated by the focus group discussion, key informant interview and observation. Questionnaire survey, scene investigation and cost effect analysis were used to evaluate the effect.

**RESULTS:**
With appropriate screening population and methods and reasonable criteria, the intervention program was highly targeted and operational. The screening participation rate of the target population has been 100% every year. The hospital that undertook screening interventions was screened according to established time point (March-June, September-November) and frequency (once a year). The government issued a policy and provided a reasonable amount of financial allocation to the hospital. Among a questionnaire survey of 5,324 parents at the screened school, 60 children of the respondents were diagnosed with mild scoliosis (cobb10°~20°). 40 out of the 60 children were diagnosed because of the screening project. The average prevalence rate during 2016 and 2017 was 0.26%, which was lower than the reported prevalence in other parts of China during the same period. 242,612 person-times were screened in four years, and 203 children were diagnosed. Results show that the program seems cost-effectiveness.

**CONCLUSIONS:**
The screening project is beneficial for finding children with mild scoliosis for early treatment, which helps reduce disability and reduce the economic burden of disease. It would be beneficial to continue such screening program in the long run.

**PP185 Clinical Papers: Which Are Ongoing Studies To Assess mHealth In 2020?**

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**ABSTRACT SUMMARY:**
In 2018, HAS consulted Clinicaltrials.gov database for registered studies associated to mobile health and performed a review of registered clinical study designs. In upcoming years, evidence to be used for connected medical device assessment will unlikely be based on new study design.
INTRODUCTION:
Mobile health systems (MHS) are one of the more spreading technologies in the field of medicine. However, identification of useful MHS is rather challenging. Few of them are, or could be, connected medical devices (cMD). Like other medical devices, cMD must be assessed to validate claimed benefits for reimbursement purposes. Clinical added value demonstration is a major criteria used to satisfy administrative requirements. With the increase of clinical studies that are including MHS, study registries can be used for insight into the type of evidence expected to become available in the near future.

METHODS:
In 2018, HAS performed a review of registered MHS clinical study designs. Clinicaltrials.gov database was consulted for all studies indexed with the terms “mHealth” and “mobile health” for the search fields “study title”, “conditions” and “interventions”.

RESULTS:
415 clinical studies were registered. 380 studies were interventional with most comprised of a randomized study design (75 percent). 15 had a crossover design. Only few observational studies (n=35) were registered. These mainly concerned (59 percent) patient use of an app on a smartphone without any other device.

CONCLUSIONS:
Patterns of clinical studies were not found to significantly differ between MHS and other medical devices. Most of the clinical studies were randomized and specific criteria to assess MHS could easily be identified. However, specific methodologies for clinical development are not used in practice for cMD HTA assessment. In the absence of validated and specific methodology for clinical development, current methods that are being used in theses ongoing studies will nonetheless be generating evidence for the upcoming years.

PP186 Telemonitoring With Pacemakers For Patients With Heart Failure

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ABSTRACT SUMMARY:
This presentation describes a national adoption event to understand the value and optimise the use of telemonitoring with pacemakers to manage the disease and improve patient outcomes in heart failure. It exemplifies an effort by a new national HTA body to broaden its focus and move from technology assessment to technology management.

INTRODUCTION:
Evidence supporting the use of pacemakers is well established. However, evidence about the optimal use of pacemaker telemonitoring for disease management in heart failure is not. Health Technology Wales (HTW) held a national adoption event to encourage implementation and best practice in use of pacemaker telemonitoring in NHS Wales to improve patient outcomes in heart failure.

METHODS:
Multi-stakeholder national adoption workshop using a mixture of expert presentations, case studies and interdisciplinary group and panel discussions to agree key actions to understand the value and promote optimal use of pacemakers for remote disease monitoring in patients with heart failure in Wales.
RESULTS:
The workshop was attended by 45 senior professionals with an interest in improving care of patients with heart failure. Actions to progress included: providing a centralised Welsh system to support technical issues that arise with telemonitoring; considering interoperability with other NHS Wales systems; encouraging value-based procurement with collection of a core outcome set; agreeing implementation issues with both professionals and patients; audit to understand experience, resource use and outcomes; and sharing manufacturer evidence on the accuracy of telemanagement algorithms. It was suggested that these actions be progressed via an All-Wales multi-stakeholder approach, led by the Welsh Cardiac Network.

CONCLUSIONS:
Developing a more agile, lifecycle approach to technology appraisal is currently advocated; recalibrating the focus from technology assessment to technology management across the complete technology lifecycle. HTW will endeavour through regular adoption events to facilitate such a paradigm shift that aims to understand value and optimise use of evidence-based technologies.

PP187 Robotic Surgery, Any Updates?

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ABSTRACT SUMMARY:
This work aims to update a previous robotic surgery HTA study, and focuses on the evaluation of the newest evidences that have been emerging for three years. It purposes to identify if there are new perspectives of its introduction in our hospital. Even if, robotic surgery performances slightly improved, laparoscopic system is still considered as the best performance technique.

INTRODUCTION:
This work aims to update the previous robotic surgery HTA study conducted in 2013 in Bambino Gesù Children’s Hospital. The study, focused on the evaluation of the newest evidences that have been emerged for the last three years, aims to identify if there are new perspectives and advantages of introducing this technology in our hospital.

METHODS:
Decision-oriented HTA (DoHTA) method was applied to conduct the assessment. It involved the integration of the EUnetHTA CoreModel and the Analytic Hierarchy Process providing the definition and the numerical evaluation of assessment parameters through which it is possible to evaluate the performances of technologies compared.

After three years the first technology’s evaluation, an update of literature review was conducted, using the same 2013 key words, to identify changes in indicators’ performances score. The performance values have been updated through a quantitative and qualitative evaluation of data gathered from literature review, expert opinion and context analysis.

The global weights’ system, developed in 2013, has not been updated because the relative importance of each domain remained unchanged. The performance values of safety, efficacy, costs, and social aspects have been estimated, identifying the differences in terms of percentage values in comparison with the previous study.

RESULTS:
Results showed a slight improvement on safety and organizational aspects in robotic surgery; however,
clinical effectiveness and economic, social and legal aspects remained unvaried. More specifically, it has been registered a 3% reduction of the difference on the distance between Robotic and Laparoscopic performance values (2013:14,15%; 2017:11,29%).

CONCLUSIONS:
Results highlighted a slight improvement in robotic surgery performances even if it confirmed the previous results for which the laparoscopic system outperformed the others and nowadays is keeping the best performance techniques. Finally, sensitivity analysis and montecarlo simulation were carried out proving the stability and reliability of the solution.

PP188 Robotic Surgery: Comparing Evidence For Cancer Indications

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ABSTRACT SUMMARY:
A comparison of evidence and advice from the Scottish Health Technologies Group on robot-assisted surgery for four cancer indications. Advice to decision-makers on robot-assisted surgery is based on varying quality, quantity and types of evidence. Advice must also consider additional aspects of HTA, such as contextual and patient factors.

INTRODUCTION:
Robot-assisted surgery is a novel approach to treating selected cancers. The Scottish Health Technologies Group (SHTG) conducted rapid reviews and provided advice to NHSScotland on robot-assisted surgery. This abstract compares the evidence and strength of advice on robot-assisted surgery for treatment of four cancers.

METHODS:
Quantity, quality and type of evidence for clinical effectiveness in SHTG advice was extracted from rapid reviews and advice on transoral robotic surgery (TORS) for oropharyngeal and laryngeal cancers (2018), robot-assisted partial nephrectomy for renal cancer (2018) and robotic rectal cancer surgery (2018).

RESULTS:
The quantity, quality and type of evidence varies between indications:

- Partial nephrectomy: two meta-analyses of mostly retrospective observational studies at high risk of bias.
- TORS oropharyngeal: systematic review of two observational studies and two retrospective cohort studies (comparator chemoradiotherapy); three observational studies and one case-control study (comparator conventional surgery); qualitative studies on patient’s treatment experiences.
- TORS laryngeal: narrative systematic review of case-series and one additional case-series; qualitative studies on patient’s treatment experiences.
- Rectal cancer: meta-analysis of randomized controlled trials (RCT), two meta-analyses of observational studies, two RCTs; patient organisation submission; volume-outcome and learning curve studies; clinical expert opinion.
- Subsequently SHTG advised NHSScotland:
  - Partial nephrectomy: evidence is of insufficient quality to advise on effectiveness.
  - TORS oropharyngeal: consider TORS when open surgery is the only option for patients; no conclusions for TORS compared with (chemo) radiotherapy; impact on patient quality of life.
  - TORS laryngeal: no advice due to lack of comparative studies.
• Rectal cancer: consider robot-assisted surgery for selected patients; centralize services to maintain competences.

CONCLUSIONS:
The quantity and quality of evidence guiding decision making on robot-assisted surgery varies significantly between cancer indications. It is likely that comparative and randomize evidence support stronger advice. Advice must also consider other components of health technology assessment frameworks, such as contextual and patient factors.

PP189 Filling In The Blanks: Is RWE From MAAs Used In NICE Decision Making?

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ABSTRACT SUMMARY:
This research evaluated how RWE collected during UK managed access agreements (MAAs) has been used to inform subsequent NICE appraisals. Only 2 drug:indication pairings have been funded through an MAA and subsequently re-appraised. Only one re-appraisal (brentuximab vedotin [BV] in classical Hodgkin’s lymphoma, used observational data, which successfully addressed key clinical uncertainties regarding subsequent real-world treatment patterns for BV.

INTRODUCTION:
NICE may recommend temporary funding through managed access agreements (MAAs) for oncology drugs (via Cancer Drugs Fund [CDF]) and highly specialised therapies for rare diseases. MAAs allow collection of evidence to address key areas of clinical uncertainty, while providing access of medicines to patients, prior to re-appraisal by NICE. Observational data and other real-world evidence (RWE) are crucial requirements for all MAAs and herein we examine the extent these data are being used to inform HTA decisions at re-appraisal.

METHODS:
Existing MAAs entered into between NHS England and manufacturers as of 30/10/18 were identified; for drug:indication pairings with NICE re-appraisals, all information was reviewed and the key data extracted.

RESULTS:
Of the 22 MAAs identified, only two drug:indication pairings have been subsequently re-appraised by NICE: BV(brentuximab vedotin):non-Hodgkin lymphoma (recommended) and pembrolizumab:relapsed or refractory classical Hodgkin lymphoma (recommended). Data from a retrospective questionnaire regarding the proportion of patients that received curative stem cell transplant (SCT) post-BV (from patients who received BV in the old CDF) were accepted to provide sufficient evidence on the post-BV SCT rate by NICE. Meanwhile, for pembrolizumab, long-term survival benefit was the key clinical uncertainty; the primary data collection source was updated phase III RCT data. At re-appraisal no reference was made to the observational data component; more mature survival data reduced uncertainty over survival benefits and were sufficient to support a positive NICE recommendation.

CONCLUSIONS:
Of the 22 MAAs to date, only two drugs have been re-appraised thus far, with both receiving positive NICE recommendations. Observational data were successfully used to address key clinical uncertainties regarding subsequent real-world treatment patterns for BV, but observational data were not referred to in the NICE recommendation for pembrolizumab. The re-appraisal of more
drugs in the future will clarify the importance being placed on observational data collection requested by NICE for existing MAAs.

PP190 Oral Anticoagulants: Impact Of Real World Data For The French HTA Body

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ABSTRACT SUMMARY:
In 2014, persistent uncertainties leaded the French HTA body to recommend the direct oral anticoagulants as second line therapies after vitamin K antagonists. A real world data collection served a reassessment of all anticoagulants in 2017. These new data provide valuable and complementary information to define their position in the therapeutic strategy, detect misuse and promote the appropriate use.

INTRODUCTION:
Since their marketing authorization, the French National Authority for Health (HAS), responsible for health technology assessments, questioned the place of the direct oral anticoagulants (DOAs) in the therapeutic strategy of non-valvular atrial fibrillation and their bleeding risk as compared to vitamin K antagonists (VKAs). In 2014, persistent uncertainties (i.e. absence of antidote, impact of the degree of anticoagulation on efficacy and safety) leaded HAS to recommend DOAs as second line therapies after VKAs. A large real world data (RWD) collection served a reassessment of all anticoagulants in 2017.

METHODS:
All new available clinical data between 2014 and 2017 were considered based on their level of evidence. It includes RWD documenting the use of DOAs in France and comparative trials between all oral anticoagulants, DOAs and VKAs, on morbimortality criteria.

RESULTS:
Mainly 8 observational studies, mostly carried out from national healthcare databases, and pharmacovigilance data have not identified new safety concerns or additional bleeding risk with DOAs as compared to VKAs, confirming what was initially observed in the pivotal trials. DOAs were more prescribed than VKAs as first-line treatment since 2015. Taken together, these new data allowed the recommendation as 1st line treatment for all oral anticoagulants but dabigatran and fluindione. Misuse of anticoagulants, both with DOAs and VKAs, has been identified (e.g. under-dosages and use in low risk embolic risk population). Unfortunately there was no data allowing the quantification of their impact on the bleeding or thromboembolism risks.

CONCLUSIONS:
Observational studies are providing valuable and complementary information to define the position of DOAs in the therapeutic strategy, detect misuse and promote the appropriate use of anticoagulants to health care professionals. The monitoring of the degree of anticoagulation on DOAs (feasibility and populations that may benefit) is still under discussion.
**PP191 2008-18 HTA Experience Of The UCSC Inst. Of Bioethics And MH - Rome (IT)**

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**ABSTRACT SUMMARY:**
Integration of ethics analysis into HTA remains challenging for HTA practitioners. The presentation will show the decennial experience gained from the Institute of Bioethics and Medical Humanities (IBioMedH) of the Università Cattolica del Sacro Cuore (UCSC) of Rome (Italy) intrODUCtiOn:
From the conception of HTA in the 1970s, it has been argued that ethics is a constitutive part of HTA. Anyway, integration of ethics (ETH) domain into HTA processes sometimes remains challenging for HTA practitioners. The goal of this presentation is to show the decennial experience (2008-18) around ETH analyses carried out by the Institute of Bioethics and Medical Humanities (IBioMedH) of the “A. Gemelli” Teaching Hospital Foundation (FPUG) IRCCS, Università Cattolica del Sacro Cuore (UCSC) of Rome. More specifically, objectives will be to: categorize the main experiences; identify the most reported ethically relevant concepts; explicit strengths and weaknesses of this activity.

**METHODS:**
The search was done in an internal HTA reports database. Data extracted were grouped into categories and analyzed using a general inductive method.

**RESULTS:**
21 health technologies (HT) (17 pharmaceuticals, 3 medical devices, and 1 diagnostic procedure) were assessed in HTA processes during the period 2008-2018. 15 were full HTA, while 6 rapid ones. The number of evaluations slowly increased each year, while time for the execution gradually lowered. The EUnetHTA Core Model ETH domain greed was the most used method (13 evaluations) - even though only a small number of greed questions was used – while “Triangular model” (one of the HTA methods quoted in the EUnetHTA ETH chapter) for the remaining 8 HTAs. The most reported ethically relevant concepts were harm-benefit ratio, and fairness. One of the main difficulties encountered was the scarcity of specific HTA ethical literature on HTs examined. External review boards were used only in few cases.

**CONCLUSIONS:**
Ethical evaluation activities are increasing at the FPUG-UCSC IBioMedH. Some obstacles to integration still exist. The method used should be refined to better support decision makers.

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**PP192 An Institutional Ethical Framework For HTA: Stakeholder Participation**

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**ABSTRACT SUMMARY:**
The National Institute of Excellence in Health and Social Services (INESSS) is developing an institutional ethical framework for the evaluation of technologies and interventions in health care and social services for public coverage.
The development of principles for stakeholder participation and the agile deployment of innovative processes like patient partnership are key components of this framework.

INTRODUCTION:
In a context of rapidly evolving technologies and growing evaluative challenges, the National Institute of Excellence in Health and Social Services (INESSS) is developing an institutional ethical framework making explicit and transparent the guiding principles and new modalities of process for health technology assessment for public coverage.

METHODS:
This framework is co-built by the INESSS experts - drugs, social services, technology and health services and cross-cutting methodologies - through literature and practice reviews as well as a consultative process on key topics with external collaborators.

RESULTS:
The development process aims to: 1- identify the principles applicable to all the objects evaluated, 2- define the evaluation strategies used to appropriately address evaluation challenges in the clinical, organizational, economic and societal dimensions, 3- equip the scientific teams to successfully integrate diversified knowledge from the literature, stakeholders participation and medico-administrative data banks, and 4- facilitate deliberation leading to evidence-informed recommendations. It is envisioned as a fully integrated process rooted in a reflexive multi-criteria approach supporting fair and reasonable decision. The presentation will focus on one of the key aspects of this framework, i.e., the development of principles for stakeholder participation based on a recent INESSS methodological forum on the topic, and the agile deployment of innovative processes and tools in various projects, including the patient partnership developed with a pioneering academic centre.

CONCLUSIONS:
This framework provides explicit, transparent and cross-cutting processes and a framework for continuous improvement. The goal is to promote stakeholder engagement and enable increasingly complex arbitration aimed at equity and social justice, in a context of rising costs and uncertainty, and focused on the creation of value for our fellow citizens.

PP193 How Does HTA Address Social Expectations Now? An International Survey

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ABSTRACT SUMMARY:
An international survey was sent to 328 HTA agencies/professionals on the social expectations of HTA. Twenty-seven percent participation showed convergence on its social role and the need to make value judgements explicit in HTA reports, but divergence on the status of ethical analysis required. Expectations from HTA professionals highlight the importance of context dependency at the dawn of the 2020’s.

INTRODUCTION:
After surveying its members on ethical issues
(2003), INAHTA mandated its Ethics Working Group (2005) to reflect on the role of HTA organizations in meeting social expectations. Some aspects of these have since been clarified by two studies addressing either the official position of INHATA’s members or IJTAHC’s authors. An international survey was carried out on the perception of HTA professionals’ expectations when producing HTA reports: how to fulfill HTA’s social role, which value judgments should be made explicit and what should the status of ethical analysis be.

METHODS:
A twenty-two questions, web-based anonymous survey was devised from our recent systematic review on the integration of ethics into HTA and carried from April to July 2018. The information on 328 HTA agencies/contact persons from 75 countries were collected from the website of INAHTA, HTAi, EUnetHTA, EuroScan, RedETSA and HTAsia, 2015 WHO survey, HTAi members, and our local HTA network (Québec, Canada).

RESULTS:
Eighty-nine participants completed and submitted a finalized survey for a 27 percent participation rate representing 33 countries. Regarding how the HTA reports should fulfill its social role, our results showed that over 84 percent of the respondents agreed upon the necessity to address it for decision makers, patients and citizens. At a lower and more variable level, the same result was found about the necessity to make value judgements explicit in different sections of the report, including ethical analysis. This contrasts with the variability of responses obtained on the status of ethical analysis although an agreement on the expertise required was observed. Variability in the usefulness of patient-, public- or stakeholder-participation was observed.

CONCLUSIONS:
At the dawn of this decade, this study reveals high expectations on context-dependency decisions in HTA: the necessity to integrate ‘explicitation’ of value judgements and systematic ethical analysis to fulfill HTA’s social role.

PP194 Intersectoral Costs And Benefits In The Societal Perspective

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ABSTRACT SUMMARY:
Many health care interventions have costs and benefits that spill over to sectors outside the healthcare sector. Little is known about these “intersectoral costs and benefits” (ICBs). From a societal perspective, to achieve an efficient allocation of scarce resources, insights on ICBs are indispensable. The main objective of this study was to identify the ICBs related to interventions.

INTRODUCTION:
Many health care interventions have costs and benefits that spill over to sectors outside the healthcare sector. Little is known about these “inter-sectoral costs and benefits” (ICBs). However, to achieve an efficient allocation of scarce resources, insights on ICBs are indispensable. The main objective of this study was to identify the ICBs related to the health care and provide a sector-specific classification scheme for these ICBs. For this sector-specific classification scheme mental disorders were taken as an example, as we expect that this is the sector with the most ICBs.
METHODS:
Using PubMed, a literature search was conducted for ICBs of mental disorders and related (psycho) social effects. A policy perspective was used to build the scheme’s structure, which was adapted to the outcomes of the literature search. In order to validate the scheme’s international applicability inside and outside the mental health domain, semi-structured interviews were conducted with (inter) national experts in the broad fields of health care.

RESULTS:
The searched-for items appeared in a total of 52 studies. The ICBs found were classified in one of four sectors: “Education”, “Labor and Social Security”, “Household and Leisure” or “Criminal Justice System”. Psycho(social) effects were placed in a separate section under “Individual and Family”. Based on interviews, the scheme remained unadjusted, apart from adding a population-based dimension.

CONCLUSIONS:
This is the first study which offers a sector-specific classification of ICBs. Given the explorative nature of the study, no guidelines on sector-specific classification of ICBs were available. Nevertheless, the classification scheme was acknowledged by an international audience and could therefore provide added value to researchers and policymakers in the field of Health Technology Assessment. The identification and classification of ICBs offers decision makers supporting information on how to optimally allocate scarce resources. By exploring a new area of research, which has remained largely unexplored until now, the current study has an added value as it may form the basis for the development of a tool which can be used to calculate the ICBs of health care interventions.

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**PP195 Cognition On Clinical Stem Cell Research In Public Hospitals Of China**

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**ABSTRACT SUMMARY:**
Clinical stem-cell research provides great hope for patients with refractory diseases, but it faces plenty of challenges, including research ethics. We analyzed the ethical cognition of relevant medical professionals and publics on clinical stem-cell research in public hospitals of China to provide information for policy making.

**INTRODUCTION:**
Clinical stem-cell research provides great hope for patients with refractory diseases, but it faces plenty of challenges, including research ethics.

**METHODS:**
Questionnaire surveys of relevant medical professionals (stem-cell researchers, physicians, IRB members, and managers) and public representatives in and around 10 hospitals from Shanghai, Tianjin, and Guizhou Province of China was conducted to collect the data related to their cognition. Chi-square tests, t-tests, analysis of variance and multivariate linear regressions were used in the study.

**RESULTS:**
882 relevant medical professionals surveyed in the study believed that the main ethical issues in clinical stem-cell research were the inclusion and exclusion criteria without considering possible risks (33.56 percent), exaggeration of possible benefits for study subjects (34.86 percent), and difficulties
in quality assurance in stem-cell preparation (3.03 percent). In addition, the main important contents in the informed consent in clinical stem-cell research were: quality assurance in stem-cell preparation (4.66), quality control measures in the research (4.66), main risks (such as oncogenicity/carcinogenicity) (4.60), management of possible adverse events (4.60) and risk control measure (4.59).

Among 50 surveyed representatives of the publics, 82 percent of them knew stem-cell therapy and 92.0 percent of them supported patients with refractory diseases to participate in clinical stem-cell research. But public representatives believed that patients with refractory diseases did not had high willingness to participate in clinical stem-cell research.

CONCLUSIONS:
China should have a specific ethical regulation on clinical stem-cell research and have more training for medical professionals to promote clinical stem-cell research conducted in an ethical way. We should publicize the possible benefits and risks of clinical stem-cell research to guide the relevant patients to participate in the research.

PP196 How Much Should Be Paid For Nusinersen?

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ABSTRACT SUMMARY:
Spinal Muscular Atrophy (SMA) is a group of hereditary neuromuscular diseases considered the most common genetic cause of infant mortality. Nusinersen emerged as a recently approved therapeutic alternative for the treatment of SMA. In this way, assessing nusinersen efficacy and cost-effectiveness is important in an incorporation scenario.

INTRODUCTION:
Spinal Muscular Atrophy (SMA) is a group of hereditary neuromuscular diseases considered the most common genetic cause of infant mortality. They’re divided into four types and the type I is the most common and of greater severity. Nusinersen emerged as a recently approved therapeutic alternative in several countries for the treatment of SMA. This study aims to evaluate Nursinesen cost-effectiveness.

METHODS:
A systematic review and Markov-model economic evaluation was carried out, with a two years time horizon, from the Brazilian National Health System (SUS) perspective. The effectiveness outcome was Months of Life Gained (MLG). The estimation of expenditures with CCM was done using data from DATASUS, for the identification of patients with the CID-10 G12.0 between 2000 and 2015. The cost with nusinersen was the price SUS has paid through litigation and, also, an estimation based on a precedent threshold of one of the most expensive medicine in the SUS. Brazilian real was converted to dollar ppp 2017.

RESULTS:
The incremental cost-effectiveness ratio was US$128,310.81 per MLG, over a 24-month time horizon, provided that the maximum cost of the nusinersen ampoule does not exceed the amount
of US$26,735.18, based on the precedent threshold adopted by SUS. Industry claims for a higher price, about US$115,1 thousand per bottle, where the cost-effectiveness ratio with nusinersen increases about 3.5 times to US$3,321,009.28 per MVG.

CONCLUSIONS:
In an incorporation scenario, nusinersen has modest results, with a high degree of uncertainty and exorbitant costs. Therefore, it is necessary to use more precise and uniform methods of evaluating the performance of nusinersen, in order to confirm the results of the Clinical Trials. In addition, there is the prospect of new treatments, such as gene therapy.

PP198 Biological Treatments In RA: A Systematic Review Of Economic Models

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ABSTRACT SUMMARY:
To improve future economic assessments of drug treatments for Rheumatoid Arthritis (RA), a systematic review of cost-effectiveness models on biological drugs was performed. We focused on treatments sequences, long term RA activity and disability, costs and utilities. Joint guidance in current HTA guidelines for economic models on how the costs and consequences of AEs is needed.

INTRODUCTION:
Rheumatoid Arthritis (RA), an autoimmune condition, is a common inflammatory joint disease in adults with a prevalence from 0.3% to 1%, affecting more women than men. Our objective was to systematically review the literature of cost-effectiveness analyses (CEAs) of biological disease-modifying anti-rheumatic drugs (bDMARDs) and their biosimilars in the treatment of RA after failure of conventional anti-rheumatic drugs (cDMARDs).

METHODS:
We searched PubMed, Cochrane library as well as websites of national health technology agencies for papers reporting CEAs of RA treatments published from 2000 to 2015. Study selection and data extraction were performed by two reviewers independently using the Consolidated Health Economic Evaluation Reporting Standards Statement (CHEERS). In this presentation, we focus on the reporting of the main components of the economic model: treatments sequences, long term RA activity and disability, costs and utilities.

RESULTS:
Of 808 citations identified in the initial search, 52 publications were retained. Of these, 32 (61%) included bDMARDs and biosimilars sequences. Structural assumptions on treatment effects on long-term disease activity and disability were not thoroughly explained in 9 (82%) of the selected publications. The majority of the studies included costs of bDMARDs. However 13 (25%) included costs of adverse events (AEs) (i.e. serious infections such as pneumonia). Similarly, among the (46, 88%) cost utility analyses, few (5, 11%) considered loss of quality of life related to AE. There was a lack of clear description reporting on how AE were included in the CEA models.

CONCLUSIONS:
Our findings showed that bDMARDs costs were clearly reported but identified concerns in the reporting of structural assumptions on treatment effects on long-term disease activity, disability as well as costs and disutilities of AE.

Clearer and joint guidance in current Heath Technology Assessment guidelines for economic
models on how the costs and consequences of AEs is needed.

PP199 Eculizumab For Paroxysmal Nocturnal Hemoglobinuria

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ABSTRACT SUMMARY:
Paroxysmal nocturnal hemoglobinuria is a chronic hemolytic anemia caused by a defect in the red blood cells. Eculizumab is available, appearing to have clinical benefits in patients with hemolysis, regardless of the history of transfusion. In this way, assessing eculizumab efficacy, safety and cost-effectiveness is important in an incorporation scenario.

INTRODUCTION:
Paroxysmal nocturnal hemoglobinuria (PNH) is a rare chronic hemolytic anemia caused by a defect in the red blood cells. Its treatment is empirical and symptomatic, with the use of blood transfusions, anticoagulation and supplementation with folic acid and iron. Alternatively, eculizumab is available, appearing to have clinical benefits in patients with hemolysis, regardless of the history of transfusion. This study seeks to analyze the scientific evidence of efficacy, safety and cost-effectiveness of eculizumab.

METHODS:
A systematic review and a Markov-model economic evaluation were carried out, with a time horizon of 26 weeks, from the perspective of the Brazilian National Health System (SUS), being evaluated the free fortnight of transfusion (FFT). The purchase price assumed for each bottle of eculizumab was US$26,108.08, based in a historical precedent of one of the most expensive medicine already incorporated in SUS. The estimation of expenditures with the conventional clinical treatment of PNH was performed based on data obtained from DATASUS, identifying patients diagnosed with CID-10 D59.5 between 2000 and 2015.

RESULTS:
At a 26-week time horizon, the cost-effectiveness analysis projects an average cost of conventional care in SUS of US$1,657.66, while the treatment cost with eculizumab would be US$373,569.68, provided that the price of per bottle is a maximum of US$109,522.69. The efficacy was 2 FFT in conventional care and 10 FFT with eculizumab. The incremental cost-effectiveness ratio was US$45,475.23 per FFT.

CONCLUSIONS:
The quality of evidence available in the literature is poor to moderate. Not all patients can benefit from the use of eculizumab, besides studies have shown that 15% of patients, regardless of treatment, may evolve to spontaneous remission, demonstrating a lack of understanding of the natural course of the disease. In addition, the drug has an extremely high price for the results that provides.
PP201 Trends In The Cost Of New Drugs Launched Between 1981 And 2015

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ABSTRACT SUMMARY:
Our study investigates trends in the price of pharmaceuticals, we sought to describe long-term, 35-year trends in the launch price for all new medicines marketed in the UK to treat one of five common conditions that were chosen to represent a range of physical and mental health disorders for which significant pharmaceutical innovation had occurred.

INTRODUCTION:
While prices for new drugs continue to increase overall, this masks significant disparities between therapeutic areas. It is unclear to what extent these patterns represent developers passing on real differences in development and manufacturing costs, or different pricing strategies based on an assessment of the current market and payers willingness to pay more for some conditions. Increased prices could be justified where new drugs meet an unmet clinical need and could encourage developers to focus efforts in priority fields. Our study investigates the trend in launch price of new drugs launched in the UK between 1981 and 2015 for five common health conditions.

METHODS:
Cross-sectional study using data on new drugs launched in the UK between 1981 and 2015 for hypertension, asthma, rheumatoid arthritis, schizophrenia and colorectal cancer. All drugs marketed in the UK between 1981 and 2015 (inclusive), and licensed specifically for the treatment of one of the five chosen conditions were included in the study. Newly launched medicines and their launch prices were identified by hand-searching all editions of the British National Formulary (BNF) in addition to searching the websites of relevant regulatory agencies (European Medicines Agency and Medicines and Healthcare products Regulatory Agency). The launch price in UK pounds for a 28-day supply of each medicine at a typical or usual maintenance dose was adjusted for the effects of general inflation using the Gross Domestic Product (GDP) deflator series.

RESULTS:
105 drugs were included in our study with a mean inflation adjusted 28-day launch price of £261 (SD £584). The launch price of new drugs varied significantly across the five conditions, with drugs for hypertension having the lowest mean price (£27) and drugs for colorectal cancer having the highest mean price (£1,245) (p<0.000). There were large increases in launch prices across the study period, but the magnitude and pattern was markedly different between therapeutic areas. Biologic drugs represented 13.3% of all included drugs and had a significantly higher launch price than non-biologic drugs (£1233 vs £111, p<0.000). 22.9% of included drugs were first of kind and had a significantly higher launch price than follow-on drugs (£630 vs £151) (p<0.0001).

CONCLUSIONS:
Drugs prices continue to increase across different therapeutic areas. This has some association with novelty, but, it is not clear if this increase in price is associated with medical benefits.
**PP202 Analysis On Factors Affecting The Effect Of Rural Doctor Training**

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**ABSTRACT SUMMARY:**
Analysing factors which affecting the training effect of rural doctors by basing on the theory of pre-intervention, then to provide reference for decision making.

**INTRODUCTION:**
The service capacity of rural doctors is far from the current needs of rural Chinese residents. The training for rural doctors has also emerged in an endless stream, but with little success. To this end, this study intends to provide countermeasures and suggestions for improving the training of rural doctors by identifying the influencing factors of rural doctor training.

**METHODS:**
We designed rural doctors’ training questionnaire based on the pre-intervention theory. Then, used stratified random sampling method to randomly select 6 local cities in Shandong Province according to the economic level, and totally selected 432 village doctors for investigating, then 407 questionnaires were finally included in the analysis. Finally, explored the current situation of rural doctor training and the differences in training effects of different characteristics. Finally, used logistic regression analysis to explore the influencing factors of rural doctor training.

**RESULTS:**
Among the rural doctors surveyed, males accounted for 62.9%, and the secondary education was mainly secondary school (63.8%). 73.2% members in better group, result of single factor analysis showed statistically significant among different age, sex, working years and pre-interventions, logistic regression analysis showed “High Positivention” in Meta-Cognitive Strategies, “Clear Purpose” in Goal Orientation, “Hierarchical and Classification training” in Advance Organizers, “Practical Learning” in Preparatory Information, age and other variables affect rural doctors’ training effect significantly.

**CONCLUSIONS:**
Enhancing trainers’ positivention, establishing correct training objects and paying attention to the practicability of the training contents and the pertinence of the training objects point out important direction on rural doctors’ training.

**PP203 Influences of Doctors’ Job Embeddedness On Their Turnover Intention**

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ABSTRACT SUMMARY:
Understanding the level of job embeddedness and turnover intention of rural doctors, exploring the impact of rural doctors’ job embedding on their turnover intention, and to provide feasible suggestions to improve the stability of rural doctors.

INTRODUCTION:
Rural doctors are one of the gatekeepers of the rural three-level health care network. The current instability of rural doctors is gradually increasing, and rural doctors have higher intentions to leave. Previous studies have been involved in many factors affecting the intention of rural doctors to leave their jobs, but their research is still lacking from the perspective of work embedding. Research on job embedding has shown that higher levels of embedding can make employees more motivated and job-satisfied.

METHODS:
Designing the rural doctors’ turnover intention and job embeddedness questionnaires, according to the stratified random sampling method, six cities were randomly selected according to the economic level in Shandong Province. According to the same principle, a total of 18 districts and counties were selected. 1080 samples were taken, of which 1018 were analysed. Then obtaining the status information of rural doctors’ job embeddedness and turnover intention, analyzing the effect of job embeddedness on their turnover intention by multiple stepwise regression analysis.

RESULTS:
Among all the surveyed rural doctors, males were the main (67.29%). The average age of rural doctors was 44.93±10.80 years old, and the average medical time was 23.96±11.83 years. The overall embedded score of the rural doctor was 3.19 points, of which the interpersonal contact score was 4.12 points, the job matching score was 3.04 points, and the work sacrifice score was 2.40 points. The score of the rural doctor’s overall intention to leave the job was 2.76 points, and the intention to leave the job was higher and 16.9%. Regression analysis shows that work contact, job matching, and interpersonal contact have a negative impact on the impact of turnover intention, of which work sacrifice has the greatest impact.

CONCLUSIONS:
In order to stabilize the mentality of rural doctors, on the one hand, we can take the identity of rural doctors to redefine the service content optimization and other measures to meet their various needs, on the other hand we can improve the cognition of managers, society and residents on rural doctor’s identity, relieve rural doctors work pressure, enhance their psychological sense of belonging and sense to work.

PP204 Involving Stakeholder: Application Of The INTEGRATE-HTA Framework

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ABSTRACT SUMMARY:
Illustration of the experiences gained by including stakeholders (e.g. patients, patient representatives, relatives, health care provider) in the consideration of ethical, legal, social and organizational aspects in
an HTA report on “How do non-drug interventions influence coping with suicidal crises in unipolar depression?”.

INTRODUCTION:
The Department of Health Care Management at the Berlin University of Technology was commissioned by the Institute for Quality and Efficiency in Health Care to conduct a Health Technology Assessment (HTA) within the new HTA programme “Topic Check Medicine” which gives members of the public the possibility to propose topics for full HTA reports. The commissioned topic “How do non-drug interventions influence coping with suicidal crises in unipolar depression?” includes a benefit assessment regarding patient-relevant outcomes and a cost and cost-effectiveness assessment of psychosocial (crisis-)interventions in outpatient care as well as an evaluation of the ethical, legal, social, and organizational (ELSO) aspects. The objective of this presentation is to illustrate the methods used for the involvement of stakeholders, mainly for the consideration of ELSO aspects, and its strengths and limitations.

METHODS:
The INTEGRATE (Integrated health technology assessment for evaluating complex technologies)-HTA framework, which was especially developed for analysing complex interventions, was used for approaching the ELSO aspects. In doing so, the framework strongly supports the involvement of stakeholder during the different stages and steps of the HTA compilation and mainly in assessing, analysing and also validating ELSO aspects. For the purpose of the present HTA, interviews with patient representatives were conducted in the process of determining the research question. Furthermore, stakeholder were included by either using moderated focus groups with patients, patient representatives and relatives on addressing ethical and social aspects as well as during the validation phase of results on organisational and legal aspects for example by including health care providers or people from the regulatory side.

RESULTS:
The presentation will include the detailed theoretical approach and experiences gained during the work with the INTEGRATE-HTA framework, focusing on the involvement of different stakeholders.

CONCLUSIONS:
Strengths and limitations in using the INTEGRATE-framework will be identified which could be taken further to have a general discussion about the best way of addressing ELSO aspects as well as including stakeholders in different stages of HTA reports.

PP205 Describing Unmet Needs In Advanced Cutaneous Squamous Cell Carcinoma

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ABSTRACT SUMMARY:
This study aimed to identify the relevance and importance of unmet needs to inform decision-making in advanced Cutaneous Squamous Cell Carcinoma by using Multicriteria Decision Analysis (MCDA). Results showed that the most important criteria to clinicians in defining unmet needs, included disease impact on morbidity and on QOL, and the limited efficacy of current therapies.
INTRODUCTION:
Cutaneous Squamous Cell Carcinoma is a common and usually curable skin cancer. Rarely, the disease progresses to advanced CSCC (aCSCC), which is associated with poor prognosis and until the recent approval of cemiplimab in the USA had no approved systemic treatment options. Knowledge on patient burden and needs in aCSCC is scant. We applied a multi-criteria decision analysis (MCDA) framework to evaluate the relevance and importance of unmet needs to inform decision-making.

METHODS:
A literature review categorized information in an evidence matrix based on decision criteria from the EVIDEM and ADVANCE frameworks. Eight criteria characterized unmet needs: (i) population size; disease impact on (ii) on life expectancy, (iii) morbidity, (iv) quality of life (QOL), and (v) the healthcare system; and, limitations of current treatment on (vi) efficacy, (vii) safety, and (viii) QOL benefit. In a workshop, seven aCSCC clinician experts scored each criteria based on perceived unmet need (0-5, higher score conveying greater need) and weighted their importance for value assessment. Quantitative results were presented using correspondence analysis and visualised on a two-dimensional map. Qualitative analysis of transcripts contextualized findings.

RESULTS:
The highest mean scores were attributed to disease impact on morbidity (5.00 ± 0.0) and QOL (4.86 ± 0.38). Expert ratings also underscored shortcomings of current options in terms of efficacy (4.71 ± 0.49), safety (3.86 ± 0.69) and QOL benefit (3.86 ± 0.90). Weighting revealed that clinicians would value an improvement in morbidity and QOL more than survival. Population size and health system impact were relatively less important for demonstrating value in aCSCC.

CONCLUSIONS:
This is the first reported effort in aCSCC to quantify specific elements of unmet need and their importance for decision-makers. This study identified the criteria that were most important to clinicians in defining unmet needs, including disease impact on morbidity and on QOL, and the limited efficacy of current therapies.

PP206 Search Filter To Identify Reports Of RCTs In CINAHL

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ABSTRACT SUMMARY:
Reports of RCTs in CINAHL may not be being identified efficiently and therefore searchers may be missing studies. This study developed, tested and validated a search filter to identify reports of RCTs, quasi-RCTs and controlled clinical trials from CINAHL Plus.

INTRODUCTION:
The Cochrane CENTRAL database seeks to gather together reports of randomised controlled trials, to inform Cochrane reviews. The Cochrane Editorial Unit is developing methods to identify reviews from a range of databases to include in CENTRAL. Published search filters to identify reports of randomized controlled trials (RCTs) on CINAHL Plus are not recent. Reports of RCTs in CINAHL may not be being identified efficiently and therefore searchers may be missing studies. Objectives: This project was undertaken to develop, test and validate a search filter to identify reports of RCTs, quasi-RCTs and controlled clinical trials from CINAHL Plus.
METHODS:
Eleven sets of relevant and irrelevant records were identified. Nine sets were used to develop and test search filters iteratively. Two sets were used to validate the filter performance in terms of sensitivity and precision. The performance of two previously published filters and the filter built into EBSCOhost were also evaluated.

RESULTS:
Following a sequence of iterative development we have developed a filter which offers sensitivity of 0.88 (95% CI: 0.77 – 0.95) and precision of 0.36 (95% CI: 0.31 – 0.41). This is comparable to the sensitivity of the published filters, but represents a great improvement in terms of precision.

CONCLUSIONS:
A sensitive and precise filter is available for use in identifying reports of RCTs, controlled clinical trials and quasi RCTs from the CINAHL Plus database via EBSCOhost. The precision of the filter is such that it is likely to cut the number of results that need to be scanned by researchers to a third of those retrieved by a subject search alone.

PP207 Evaluation On Effects Of Antimicrobial Stewardship In Tertiary Compreh[...]

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ABSTRACT SUMMARY:
National Health Commission issued special task force on antimicrobial stewardship (AMS). The improvements of the effects of AMS from 2012-2016 in tertiary comprehensive hospitals in Hainan Province, China had been analyzed by the indicators of AMS, to explore the achievement of the task force, to facilitate rational use, to control Antimicrobial Resistance, to ensure safety and quality of care.

INTRODUCTION:
The programs of rational use of antibiotics are designed to optimize antimicrobial therapy and minimize the emergence of bacterial resistance. National Health Commission issued special task force on antimicrobial stewardship (AMS). We assess the effects of AMS from 2012-2016 in tertiary comprehensive hospitals in Hainan Province, China, by the checklist criteria of AMS, to explore the achievement of the task force, to facilitate rational use, to control Antimicrobial Resistance, to ensure safety and quality of care.

METHODS:
Data from HIS of 4 tertiary comprehensive hospitals 2012-2016 in Hainan Province, China according to the checklist criteria of AMS were analyzed. The indicators includes: The proportion of prescriptions of antibiotics use in outpatient, the proportion of prescriptions of antibiotics use in emergency department; antibiotics use rate of inpatient; antibiotics prophylactic use in type I surgical site; antibiotics use density of inpatient; the proportion of drug cost; the proportion of total cost of antibiotics. EXCEL was data entry and SAS version 9.3 was used for analysis.

RESULTS:
The indicators were generally compliance to the national criteria 2012-2016. The proportion of prescriptions of antibiotics use in outpatient in 4 hospitals were gradually reduced (3.25%-11.09%); that in emergency department in 4 hospitals were gradually reduced (1.53%-8.46%); antibiotics use rate of inpatient in 3 hospitals were gradually reduced (3.12%-9.13%); antibiotics prophylactic use in type I surgical site was gradually reduced (3.38%-24.19%); antibiotics use density of inpatient in one hospital was decreased 11.01% , and that in other 3 hospitals in 2016 was higher than that in 2012; the proportion of drug cost was reduced in 4 hospitals (0.12%-5.54%); the proportion of total cost
of antibiotics was reduced in 4 hospitals (0.45%-3.27%); the proportion of total cost of antibiotics in outpatient and emergency department in 4 hospitals was gradually reduced, which were basically below 10%. Pathogenic detection rate of antimicrobial 2013-2016 in 3 hospitals was increased from 38.75% to 59.6%; Pathogenic detection rate of therapeutic cases with limit level and that of special level of antimicrobials 2012-2016 in the other hospital were increased from 64.1%-70.7% and 87.3%-94.4% respectively. Hainan Provincial Antibiotics Resistance Monitoring Network conscientiously performs duties, several important and special detections rates of AMR basically close to the average national level, which have been effectively controlled.

**CONCLUSIONS:**

Significant improvements in rational antimicrobial use have been observed in 4 hospitals 2012-2016. It is needed to continue AMS and enhances the capacity of rational use of antimicrobial of medical professionals. Information systems needs to be developed, coordinated and correlated to monitor the consumption of antibiotic use, surveillance of antibiotic resistance and control of hospital infection rates. AMS needs to be reinforced in medical institutions at grass roots levels.

**PP208 Evaluation Of Program For Prevention And Treatment Of VTE Based On IT**

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**ABSTRACT SUMMARY:**
Evaluation of the application of the hospital management system for prevention and treatment of venous thrombosis based on information technology.

**INTRODUCTION:**
To evaluate the clinical effect, cost and cost-effectiveness of the hospital management system for prevention and treatment of venous thrombosis based on information technology.

**METHODS:**
Inpatients with deep venous thrombosis were included in the study. Data were collected from experimental departments of vascular surgery, respiratory department, orthopedic and department of geriatrics so on. Relevant data from January to May 2016 were selected as the control group and those from June to December 2016 as the trial group. The data were compared between the two groups. T test was used for comparison among groups, and C2 test was used for inter-group comparison of count data. This study uses incremental cost-effectiveness ratio to analyze the effectiveness of the management program.

**RESULTS:**
A total of 75 VTE patients were diagnosed in the control group and 117 patients with VTE were diagnosed in the trial group. There was no significant difference in age and sex between the two groups. After the implementation of hospital VTE prevention management program, the rate of treatment increased (81.9% vs 63.2%, p=0.017), VTE caused deaths decreased (0 case vs 2 cases). The average length of Stay (14.7d vs 17.9d, p>0.05) in the trial group was reduced by 3.2 days compared with the control group, and the difference was not statistically significant (P>0.05). The average hospitalization cost of the patients during the trial group was 45330.5 RMB, and the control group was 47037.2 RMB. The average hospitalization cost during the trial group decreased but the difference was not statistically
significant (P>0.05). This management program is to combine Caprini and Padua risk assessment tools with hospitalization assessment and embed their information into HIS system. HIS system can realize automatic calculation of risk level and early warning management for high-risk patients who need intervention, thus achieving comprehensive and effective evaluation and supervision. Therefore, the improvement of this management program has no cost increase and has increased clinical implementation effect, so this management program is cost-effective.

CONCLUSIONS:
Establishing an information-based hospital management system for prevention and treatment of venous thromboembolism can effectively improve the early diagnosis and intervention rate of VTE patients in our hospital, effectively reduce the risk of VTE without increasing the cost of medical treatment.

PP209 Orphan Drug Benefit Assessments At The Federal Joint Committee

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ABSTRACT SUMMARY:
The Federal Joint Committee (G-BA) is the highest decision-making body of the self-governing health care system in Germany. Aside numerous responsibilities the G-BA performs an (additional) benefit assessment (see § 35a SGB V) for all newly approved drugs including drugs treating rare diseases (so-called orphan drugs [OD]). We conducted an update of our analysis of all OD assessments.

INTRODUCTION:
The Federal Joint Committee (G-BA) is the highest decision-making body of the self-governing health care system in Germany [1]. Aside numerous responsibilities the G-BA performs an (additional) benefit assessment (see § 35a SGB V) for all newly approved drugs including drugs treating rare diseases (so-called orphan drugs [OD]). The experience with the evaluation of OD in G-BA may inform other health systems or countries introducing similar assessments.

METHODS:
We conducted an update of our analysis of all OD assessments since 2011 [2] and added the data from June 2016 to August 2018. We collected data from publicly available documents as well as Summary of Product Characteristics documents. Data extracted included study type of the pivotal studies, the primary endpoint and an assessment of its relevance to patients, the extent of added benefit as given by the benefit assessment category (non-quantifiable, minor, considerable, major) and the assessment of patient quality of life.

RESULTS:
In total, 55 assessments between 2011 and 2018 were considered. Almost half of the assessed ODs were for treatment of oncological diseases and about one-third for metabolic diseases. In 43 of the assessments the evidence was based on least one randomized controlled trial. In 38 assessments, the G-BA assessed the primary endpoint of the pivotal trial as being not relevant for patients. For 35 OD assessments, the extent of the added benefit as determined by the appraisal of the G-BA was non-quantifiable, 13 resulted in a minor added benefit and three in a considerable added benefit. In four other cases separate subgroups were distinguished.
CONCLUSIONS:
The implementation of a systematic process for assessing OD at market entry in Germany provides support for price negotiations and allows transparent insights into the evidence and the additional benefit of ODs for patients, as well as clinicians and policy makers.

METHODS:
Systematic review of literature on gait speed as predictor of frailty was performed.

RESULTS:
A total of 992 articles were retrieved from de literature search and only 11 studies met the inclusion criteria. Frailty is a common geriatric syndrome, characterized by decreased reserve an increased vulnerability to adverse outcomes, including falls, hospitalization, institutionalization and death. Despite frailty is being increasingly recognized in the literature, there is a paucity of direct evidence to guide interventions to reduce frailty. Many single and composite tools to detect the frailty have been proposed but none is consensual, most are time-consuming while evaluating different domains of impairments, and many are not validated. Gait speed seems to be a single, reliable, valid, sensitive, cheap, quick and simple tool that identifies frailty people. However, the way to perform the test parameters vary widely, influencing interpretations of physical performance.

CONCLUSIONS:
• The evidence recommends to detect frailty people in order to achieve an active and healthy ageing.
• Gait speed could be a suitable predictor to identify frailty although this systematic review found many differences between the gait speed protocols used in clinical practice.
• It is necessary to establish a standard protocol of gait speed agreed by experts in the area on frailty to be implemented with success in clinical practice.

PP210 Identification Of Frailty To A Healthy Ageing In European Population

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ABSTRACT SUMMARY:
Active and healthy ageing is a societal challenge shared by all European countries, but also an opportunity.

INTRODUCTION:
The European population is ageing rapidly. The number of Europeans aged over 65 will double in the next 50 years. Active and healthy ageing is a societal challenge shared by all European countries, but also an opportunity. The World Health Organization indicated that frailty has become an indicator of lack of successful aging. Therefore, identification of frail elderly is becoming important. However, there are many different screening tools that are currently used to identify frailty. The optimal test should have the capacity to easily identify from the community-dwelling population, those older people at risk of adverse outcomes. During the past years, gait speed has been repeatedly reported as an appealing instrument as a screening tool to detect frailty.
PP211 3D Printed Versus Non-3D Printed Standard Implants And Cutting Guides

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ABSTRACT SUMMARY:
Recently, 3D-printing in the medical field has increased in growth and is used to print patient-specific anatomic models for implants, prosthesis, splints, and surgical guides. A structured (rapid) core HTA information was produced to examine whether 3D printed implants and cutting guides used in knee, maxillofacial, or cranial surgery were more effective and/or safer than standard medical devices.

INTRODUCTION:
Recently, three-dimensional (3D) printing in the medical field has increased in growth and is used to print patient-specific anatomic models for implants, splints, and surgical guides. We produced structured (rapid) core HTA information to examine whether custom-made or customisable 3D printed implants and cutting guides in knee, maxillofacial, or cranial surgery were more effective and safe than standard instrumentation.

METHODS:
For Effectiveness domain, a systematic literature search was conducted in Cochrane Library, PubMed, and EMBASE within five years for systematic reviews and ten years for controlled clinical trials, randomised controlled trials (RCT’s) and prospective studies. The review was conducted using PRISMA statement. Two reviewers performed study selection using PICO, quality assessment using Cochrane Risk of bias tool, ROBIS, SIGN and quality of body of evidence using GRADE. For Technical, Current use and Safety domains, information were identified through systematic literature search, clinical and technical experts and manufactures’ submission files.

RESULTS:
We identified six RCT’s and two systematic reviews on total knee arthroplasty (TKA), three RCT’s and one prospective study on mandibular reconstruction and one prospective study on cranioplasty. Frequent diseases in these clinical areas were knee osteoarthritis, oral cancer and traumatic brain injury. The studies had short-term outcomes and low to moderate quality. 3D printing in TKA compared with standard instrumentation showed improved accuracy of component positioning and alignment and shorter operating time. In mandibular reconstruction and cranioplasty, no consistent differences between technologies were found. There were no differences in safety outcomes between technologies in the clinical areas.

CONCLUSIONS:
Clinical implications of these findings are unknown. Further research should assess long-term outcomes such as implant survival and patient-related outcomes such as quality of Life. Custom-made and customisable 3D printed technology is under development and evaluation of the best assessment methods is necessary.

PP212 Heated Humidified High-Flow Nasal Cannula For Preterm Infants

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ABSTRACT SUMMARY:
Heated humidified high flow nasal cannula (HHHFNC) is gaining popularity as a mode of respiratory support and may offer an efficacious alternative to nasal cannula positive airway pressure (NCPAP) for some infants, but evidence is lacking for preterm infants with GA ≤28 weeks.

INTRODUCTION:
Heated humidified high flow nasal cannula (HHHFNC) offers an alternative mode of respiratory support and is gaining popularity. In this review, we updated the evidence for HHHFNC versus standard treatments based on a Health Technology Assessment (HTA) published in 2016. The primary outcome was the need for reintubation for preterm infants following mechanical ventilation (post-extubation analysis) or need for intubation for preterm infants not previously intubated (analysis of primary respiratory support).

METHODS:
We searched MEDLINE, Embase and the Cochrane Library (2000-2018) to identify relevant randomised controlled trials (RCTs) of HHHFNC versus standard treatments. We extracted data on a range of clinical outcomes from the included studies. Meta-analysis was conducted using Review Manager 5.3.

RESULTS:
The post-extubation analysis included ten RCTs (n=1201) and the analysis of primary respiratory support included ten RCTs (n=1676). There were no statistically significant differences for outcomes measuring efficacy, including the primary outcome. There were, however, statistically significant differences (moderate quality evidence) favouring HHHFNC versus nasal cannula positive airway pressure (NCPAP) for air leak (Post-extubation, risk ratio [RR] 0.29, 95% confidence interval [CI] 0.11 to 0.76, I² = 0) and nasal trauma (Post-extubation: 0.35, 95% CI: 0.27 to 0.46, I² = 5%; Primary respiratory support: RR 0.52, 95% CI 0.37 to 0.74; I² = 27%). Studies, particularly those of primary respiratory support, included very few preterm infants with gestational age (GA) <28 weeks.

CONCLUSIONS:
HHHFNC may offer an efficacious and safe alternative to NCPAP for some infants but evidence is lacking for preterm infants with GA ≤28 weeks and versus non-invasive positive pressure mechanical endotracheal ventilation.

PP238 Budget Impact Of Methionine-Free Amino Acid Formula For Homocystinuria

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ABSTRACT SUMMARY:
Brazil is a continental size country with a great social inequality and problems in health care. The incorporation of the methionine-free amino acid formula for patients with homocystinuria represents a significant impact on the budget and covers a small number of patients, bringing discussions about equity in the treatment of rare diseases compared to other public health problems.

INTRODUCTION:
The National Committee for Health Technology Incorporation (CONITEC) has the task of evaluating health technologies and recommending their inclusion or exclusion within the Brazilian Public Health System (SUS) and uses the budget impact assessment to estimate the costs to the system.
This study estimated the budget impact of the supply of methionine-free amino acid formula (MFAAf) for patients with classical homocystinuria (HCU) in SUS.

METHODS:
The incidence of one case per 250,000 live births in Brazil and the registration of a Brazilian association of patients with HCU was assumed to calculate the population. Mortality and responsiveness to pyridoxine rates were applied. The costs of treatment were estimated according to the recommended dosage in literature and public purchasing prices. It was assumed for calculating the dose of MFAAf patients with a median age of 19 years and 60 kg, according to Brazilian study data.

RESULTS:
The annual cost of treatment was estimated at R$ 77 thousand (Brazilian Real) per patient. The incorporation of MFAAf for HCU would generate a budget impact in SUS of around R$ 37 million in 2019 and R$ 188 million after five years which considers the epidemiological data, and, a budget impact of around R$ 6.4 million in 2019 and R$ 33 million after five years which considers the information of a Brazilian association of patients with HCU. The wide range of values in the incremental budgetary impact is due to the lack of information on the epidemiology of the disease in Brazil, which makes the budgetary impact very imprecise.

CONCLUSIONS:
Brazil is a continental size country with a great social inequality and problems of basic sanitation and basic health care for its population. The incorporation of the MFAAf in the SUS, represents an important budgetary impact and covers a small number of patients.