OP244 Tools And Experiences To Facilitate Effective Patient Participation In Health Technology Assessment

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Introduction. In 2017, a Patient Involvement Interest Group (PIIG) was created in the Spanish Network for Health Technology Assessment of the National Health System (RedETS) to facilitate and promote Patient Involvement (PI) in Health Technology Assessment (HTA). The PIIG proposed a decisional flowchart to guide researchers' in decisions regarding PI methods in HTA. The flowchart proposed a combination of direct involvement and incorporation of patient-based evidence depending on the scope and the aims of the assessment.

This work aims to present the flowchart and the results of the evaluation of the latest experiences in PI in HTA in RedETS (2018–2020), including direct-involvement and patient-based evidence.

Methods. A survey was sent to the HTA researchers who implemented PI initiatives in RedETS assessments. The survey asked to describe their experiences, lessons learned, challenges and added value regarding the use of direct-involvement, systematic reviews (SR) and primary studies. A descriptive analysis was performed and the results were discussed in an online PIIG workshop.

Results. Thirty-two assessments included direct PI, twenty-one SR synthesized qualitative and quantitative studies about patient experiences, values and preferences and eight included primary studies, mainly of qualitative design. Recruitment and the lack of methodological resources were the main barriers both for direct PI and primary studies. Relevance of the included studies was the main barrier for SR. Added value was found in all PI methods. Direct-involvement had an impact on the project plan and PICO definition, outcomes relevance, information about the health condition and treatments. SR contributed with relevant patient-based evidence, deeper assessment of patient experiences, values and preferences and implementation factors. Primary studies developed new or contextualized knowledge directly applicable to decision-making.

Conclusions. The PI flowchart has served to facilitate the incorporation of patient input in HTA reports. The different approaches implemented have allowed to provide relevant and well-grounded data in each report to inform decision-making in patient-centered healthcare provision, but it is necessary that specific training and resources are provided to enable adequate and timely implementation.

OP248 A Minimum Data-Set For Left Ventricular Assist Device On Destination Therapy: Cross-Border Collaboration Pilot On Real World Data

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Introduction. The European Health Technology Assessment Network (EUnetHTA) Work Package 5B1, is focused on testing the levels of cross-border collaboration on real world data for supporting reimbursement/pricing decision-making. Within this Work Package, we are conducting a pilot on Left Ventricular Assist Device on destination therapy in collaboration with the National Institute for Health and Care Excellence (NICE, UK), the Belgian Health Care Knowledge Centre (KCE, Belgium) and the Italian National Agency for Regional Health Services (AGENAS, Italy). This pilot aims to define the minimum data set for gathering and sharing high quality registry data on key uncertainties found at the time of the health technology assessment (HTA). Furthermore, the pilot will assess the feasibility of carrying out a common analysis or reusing this data for National or Joint Reassessments.

Methods. Evidence gaps were based on the four national assessments. Collaborating partners were responsible for agreeing on the key outcomes and proposing the minimum dataset to be registered. European clinical experts and patients rated and prioritized the dataset using a two round Delphi technique (not relevant, important but not critical; critical). The dataset will confirm the basis for the Spanish LVAD registry, implemented at the national health service level to inform inclusion into the healthcare portfolio.

Results. The key outcomes agreed upon by agencies relate to safety, effectiveness, satisfaction and acceptability of the patient and cost-effectiveness, budget impact and organizational impact. Expert cardiologists and cardiac surgeons representing the European and Spanish Society, among others, participated in the prioritization of basic data. The final dataset is expected by December 2020.

Conclusions. The variation in the quality and definition of outcome measures for measuring key evidence gaps reduces the utility of registries for HTA, making it difficult to compare, link, and aggregate data across countries. The EUnetHTA pilot is intended to offer a model for cross-border collaboration on real world data for supporting the decision-making process for pricing and reimbursement.

OP256 Recognising The Broader Value Of Vaccines In Health Technology Assessment: Worth A Shot?

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Introduction. The COVID-19 pandemic shows that the impact of effective vaccines extends well beyond vaccinated individuals and healthcare systems. Yet, these externalities are not typically considered in health technology assessments (HTA) which may underestimate vaccines' broader value. We explored to what extent future vaccines relevant to England might exhibit such broader value.

Methods. We compared the ten value elements of an existing vaccine evaluation framework to the value elements considered in England according to the Joint Committee on Vaccine and Immunisation (JCVI) and the National Institute for Health and Care Excellence's (NICE) guidelines. Using literature and expert opinion we then explored, for a selection of ten vaccines with an expected UK-launch within five years, on which value elements each vaccine might potentially show added value.

https://doi.org/10.1017/S0266462321000878 Published online by Cambridge University Press

Results. Up to five of ten value elements are unlikely to be considered by JCVI or NICE, including patient and carer productivity, enablement value, impact on antimicrobial resistance and transmission value. Of vaccines studied, 100 percent will potentially generate value on at least one broader value element that is currently ignored; 60 percent to 80 percent may increase vaccinee/patient or carer productivity respectively.

Conclusions. There is a substantial gap between value generation and value recognition of vaccines in HTA in England. This might lead to undervaluation and underutilization of vaccines, leaving societies more vulnerable than needed when faced with infectious diseases.

OP267 Evidence for Health Technology Assessment: The Capability Approach

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Introduction. Healthcare services, such as cochlear implants and subsequent rehabilitation, aim to increase valuable activities and opportunities of those affected. Their impact may be inferred from the extent that they protect or restore capability, which reflects the real freedoms that people have to be or do things they have reason to value. Capability emerges from the dynamic interaction between available resources, individual, social, and environmental conversion factors, and functionings. This model sets the informational requirements of the capability approach.

Methods. On the basis of interviews with thirty-three hearing impaired children and thirty hearing peers, information on capability elements (values, resources, conversion factors, and functionings) was collected. Qualitative results were triangulated with standardized clinical audiological and psycholinguistic quantitative measures.

Results. Hearing impaired children and their hearing peers concurred in terms of the doings and beings they valued, but differed in terms of conversion factors to realize capability. Parents of hearing impaired children played a more upfront role, hearing impairment predominated many areas of life, and communicating through hearing aids required more energy than was usually acknowledged by the people around them.

Conclusions. The capability approach offers opportunities not only to assess impact of technology on dimensions that are important to patients, but also to better understand the mechanisms that are involved in value generation.

OP277 Rapid Development Of An Evaluation Framework: Capturing The Impact Of COVID-19 Activities By A Health Technology Assessment Body

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Introduction. Health Technology Wales (HTW) is committed to evaluating the impact of our work. In March 2020, HTW directed efforts to support Welsh Government and health and social care providers in response to the COVID-19 pandemic. We adapted the HTW evaluation framework to specifically capture the impact of our additional COVID-19 work. Here we analyze data collected since the framework was implemented.

Methods. Both formal and informal feedback was analyzed. Formal feedback was obtained through the HTW Impact Questionnaire, which was developed to support more formalized data capture for all HTW workstreams and to facilitate feedback from all stakeholder groups. It was piloted with a targeted list of individuals and responses were received for COVID-19 work. Informal feedback included feedback received via email or through word of mouth.

Results. HTW COVID-19 products to date include Topic Exploration Reports, rapid evidence summaries and an Evidence Appraisal Report (EAR) on COVID-19 diagnostic tests (molecular and antibody tests). Stakeholders were positive about these outputs, describing them as valuable and informative. Reported impacts included informing policy and decision making, reducing duplication of efforts and helping to target development. The EAR received national and international focus, leading to HTW involvement in the European Network for Health Technology Assessment (EUnetHTA) COVID-19 reviews. Survey participants who gave feedback on COVID-19 activities included two members of Health Technology Assessment organizations, a health board representative and an industry representative; all agreed that HTW's COVID-19 work was useful, that the methods were reliable and robust and that HTW is responsive. All participants also felt that HTW's COVID-19 work had a positive impact in the wider health and social care context.

Conclusions. HTW was able to respond rapidly to the COVID-19 pandemic and adapt current evaluation practices to capture the impact of COVID-19 work. We will continue to evaluate our COVID-19 activities. Future work will involve following up on the developing impact of our COVID-19 work and expanding our methods for data capture, for example conducting stakeholder interviews.

OP279 Data Protection In The European Union Post-General Data Protection Regulation (GDPR): A Barrier Or An Enabler Of Pharmaceutical Innovation?

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Introduction. The expansion of health data offers exciting opportunities to support better and more efficient drug discovery, development and implementation. Data protection and governance provide the legal framework to balance safeguarding patients' privacy with the benefits to society of medical research. Our aim is to highlight current legal barriers to the better use of health data and propose ways to address them.

Methods. Analysis of the relevant legislative texts was supplemented by interviews with external experts in data protection, health research, informatics and cyber security and a workshop with pharmaceutical industry members. We investigated the

https://doi.org/10.1017/S0266462321000878 Published online by Cambridge University Press