(MEP) in hospital. Using a combined model of ABC analysis and Multiple criteria decision analysis (MCDA) may be more appropriate to apply to MEP.

Methods. We created five standardized criteria, which present the main results of assessment of the viability of MEP for implementing new health technologies (HTs). These criteria address the following: 1) Novelty/innovation; 2) Comparative clinical effectiveness and safety; 3) Relevance (demand); 4) Economic effectiveness; and 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 the ABC model and five 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 three items were in group A (27%), two items were in group B (18%), and six items were in group C (55%). All items were high priority for procurement with the exception of one 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. Excluding ME with a medium priority from the procurement plan would reduce Hospital costs by 13.5 percent.

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; and avoid the influence of subjective factors of the managerial decision-making process in hospital.

OP18 A Case Study Of Local Context-Dependent Decision-Making In Health Technology Assessment

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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-Université Laval (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 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. AI-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 AI-CaSO4.

Conclusions. The current state of knowledge does not support the widespread use AI-CaSO4 at CHU de Québec. This study highlights the importance of adapting HTA approach to the 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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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 (1 January 2013–6 November 2018) 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 guidances 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 percent (2/7), and 33 percent (2/6) have been assessed with positive outcomes (definition: "recommended"/"accepted"/"conditional"/"restricted") by SMC, and NCPE, respectively vs. 100 percent (9/9) by G-BA (definition: any additional benefit), and 50 percent (5/10) by HAS (definition: ASMR I-III). Median delays between European MA and positive appraisal outcomes were seven (G-BA), nine (HAS), 12 (NCPE), and 19.5 months (SMC).

Conclusions. Although all NICE HST final guidances to date have 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

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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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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 GBP 100,000 (EUR 113,008 based on the 2018 average GBP / EUR exchange rate) per quality-adjusted life year (QALY). For treatments with an ICER above GBP 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. Eighteen products have been or are currently going through the NICE HST process. Of these, 8/18 (44%) have received a positive recommendation, while 5/18 (28%) have received a draft negative guidance, and for 5/18 (28%) products, no recommendations have been published. For the products with a positive outcome, 5/8 (63%) had incremental QALY gain of at least 10, qualifying these products for additional QALY weighting. For the products that received a draft negative recommendation, the negative decision was related to the cost-effectiveness estimates being higher than GBP 100,000 per QALY (5/5 reported) in all cases, while none of these products were eligible to receive a 'QALY modifier'.

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 GBP 100,000 per QALY for many products.

OP21 Enhancing Capability: Patient Impact In Ultra-Orphan Conditions

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Introduction. Written evidence is submitted to the National Institute for Heath and Care Excellence (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 Health Technology Assessment (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 2017 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; and, a specific question on clarification of quality of life data

Results. We obtained 83 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; and, 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 Adjusted Life Years measures do not. Evidence varied by condition with impact themes highlighting the effects on patient and carers including fear, stress 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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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,

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