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 Health Information and Quality Authority (HIQA) Guidelines for the Economic Evaluation of Health Technologies in Ireland.

## OP98 Limitations In Health-Economic Guidance For Medical Devices

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**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 analyzed. 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 four of 22 (18 percent) 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, organizational 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.

## OP103 Incorporating Health Technology Assessment In The Development Of A Clinical Care Pathway

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

**Methods.** Through a case study of an HTA on treatments for chronic low back pain requested as part of the development of a CPW for chronic musculoskeletal pain, we demonstrated the three key strategies to include HTA in CPWs described by Rehaluk 2016 and added a fourth one. We then showed how these strategies contribute to the development of a CPW which answers the quality criteria outlined by the Cochrane Effective Practice of Care group through a strength, weaknesses, opportunities, and threats analysis.

**Results.** We confirmed four key strategies to including HTA in CPWs (organizational positioning of the HTA unit, partnership and communication with stakeholders, tailoring the integration of contextual data with evidence from the literature, explore tools to facilitate the use of HTA findings). The inclusion of HTA through these strategies contributes to the development of a CPW which meets 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 organization of care.

**Conclusions.** The inclusion of HTA in CPW development increases its capacity to directly influence organization of care. HTA can represent a pivotal vehicle to ensure good quality CPWs.

## OP105 Factors Affecting Horizon Scanning For Hospital-Based Health Technology Assessment

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**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. Horizon scanning (HS) is an important health technology assessment (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

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MedTech: a hybrid theatre incorporating a biplane, intra-operative MRI (iMRI), multi-detector computed tomography (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™ Clostridium difficile Kit Incorporation: Conducting a Local Clinical Study as Part of Hospital Health Technology Assessment

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**Introduction.** The Xpert™ Clostridium difficile kit is a nucleic acid amplification test indicated after discrepant results from an enzymatic test; was submitted for incorporation in a teaching hospital in Brazil. In order to evaluate the potential for improvement with Xpert™ incorporation, the performance of the available technology (enzymatic test) was assessed using a real word evidence approach. Additionally, the association between enzymatic test results and the agreement to the Infectious Diseases Society of America (IDSA) recommendations for stool test submission ($\geq$ 3 unformed stools in 24 hours without laxatives) for Clostridium difficile were evaluated.

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

**Results.** One hundred and thirty-eight 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). Twenty (14.5 percent) cases were discrepant, all being positive to GDH and negative for toxin (group II). There were not negative GDH and positive toxin cases. The IDSA guidelines were followed in 33 (28.9%), 3 (15%) and 3(75%) test orders in groups I, II and III, respectively ($p = 0.03$).

**Conclusions.** Only a minority of patients had discrepant results in enzymatic tests and would be candidates for the Xpert™ test. The low adherence to IDSA guidelines could explain the low positivity rate of enzymatic tests at the hospital. Considering the uncertainty about the potential of the new test for changing infection control practices, Xpert™ was not recommended for incorporation. Using real world evidence data is important for contextualized health technology studies in hospitals.

## OP109 The Need For Building Pharmacists' Health Technology Assessment Capacity; The Nigerian Scenario

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**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 were 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 an 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.

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