

to research the expectations and experiences of the participants of this initiative, in order to reflect on the possibilities and challenges of governing innovative medical technologies.

**Methods.** A questionnaire was sent out to 10 purposively selected representatives of the IHSI MDWG participating countries: Austria, Belgium, Canada, Denmark, Italy, Luxembourg, Netherlands, Norway, Portugal, and Sweden. The survey covered individual countries' respective purposes for an international horizon scanning system as well as questions related to the desired scope and perceived challenges of such a system. The questionnaire was supplemented with online, semi-structured, in-depth interviews with the same representatives from each participating country. These interviews provided for diving deeper into the survey topics as well as discussing the relation between horizon scanning and health technology assessment, the relation to other international horizon scanning collaborations, and the relation between an international versus a national horizon scanning system. In addition, participant observations were conducted at the Dutch National Health Care Institute and during IHSI MDWG working group meetings.

**Results.** Preliminary results are discussed first with participants after which we will draw our final conclusions and recommendations for practice. Our analysis focuses on exploring participants' expectations and experiences with international horizon scanning through triangulating the three sources of data in our analysis.

**Conclusions.** The study will report on the expectations, needs and challenges of setting up an international collaboration for horizon scanning of medical devices and reflect on the regulation and governance of innovative medical technologies across several countries in Europe and Canada.

## OP34 Horizon Scanning A Matter Of Collaboration. A Description Of The Processes Of I-HTS Member Organizations

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**Introduction.** Horizon Scanning (HS) has been part of the health technology assessment (HTA) world since the end of 20th century. In accordance with the life cycle concept of health technologies, there have been different organizations that have devoted part of their portfolio to HS's so called Early Awareness and Alert Systems. In 2017, a legal entity international Health Tech Scan (iHTS) was created on the basis of the previous existing network EuroScan. Our aim is to describe the current achievements of the network, the methods used by its members, and their achievements.

**Methods.** In 2010, EuroScan decided to analyze its members' methods and processes to perform HS. We used a previously defined questionnaire to revisit the analysis of methods, processes, and

impact of the founded legal entity i-HTS. We analyzed the clients, stakeholders involved, impact on health systems and alliances, as well as the current achievements as a group.

**Results.** i-HTS is currently rooted mainly in Europe and Asia-Pacific with members in the Americas and with ambassador programmes in Africa. The individual members have continued their achievements with special focus on three main aspects: proactive approach to innovators, stakeholder involvement, and client orientation. In most cases, the members of i-HTS produce information that is used for decision-making purposes, some of which influences the national or regional benefit package. Methods did not differ but the level of involvement of stakeholders in the different phases of the process. Some members also include in their portfolio early advice to innovators.

**Conclusions.** Early Awareness and Alert Systems are key to inform health care systems around technologies that could impact the management of patients in different contexts. There is a need to better understand the needs of the clients and the importance of HS in order to improve their efficiency. iHTS is in the process of redesigning its methods toolkit with the participation of all its members.

## OP35 Suitability Of Preference Methods Across The Medical Product Lifecycle: A Multicriteria Decision Analysis

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**Introduction.** To understand the importance of the preference methods criteria to stakeholders at each decision point in the Medical Product Lifecycle (MPLC) and to determine the suitability of commonly applied preference methods (Discrete Choice Experiment [DCE], swing weighting [SW], probabilistic threshold technique [PTT], Best-Worst Scaling case 1 [BWS1], Best-Worst Scaling case 2 [BWS2]) for a given decision-point.

**Methods.** Nineteen preference methods criteria of an existing performance matrix were incorporated in an online survey of industry, regulatory, and health technology assessment (HTA) stakeholders. All methods criteria were given a relative weight based on the SW ranking and point allocation task in the survey. Based on this relative weight and the performance matrix values, an overall suitability score was calculated for each method per critical decision point along the MPLC. Several sensitivity analyses were conducted for which the performance matrix was adapted.

**Results.** In total 59 industry, 29 regulatory, and 5 HTA representatives completed the survey. In general, 'estimating trade-offs between characteristics', and 'estimating weights for treatment characteristics' were important preference method criteria throughout all MPLC decision points, while other preference method criteria were most

important only for specific MPLC stages. Both BWS1 and BWS2 seem equally suitable across decision points, DCEs seem most suitable during clinical development and regulatory launch, and SW and PTT seem most suitable throughout industry decision points. Sensitivity analysis showed substantial impact of slight changes in the performance matrix.

**Conclusions.** With rapid changes in preference research, performance matrices of preference methods should continue to be re-evaluated as more and more evidence accumulates. While DCE is the most applied preference elicitation method, other methods should also be considered to address the needs of MPLC stakeholders. Development of evidence-based guidance documents for designing, conducting, and analyzing such methods could enhance their use.

## OP36 A Lifecycle Approach In Evaluating Medical Technologies: Insights From The National Institute For Health And Care Excellence Guidance Review Process

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**Introduction.** Health Technology Reassessment (HTR) is emerging, as the focus of health technology assessment agencies shifts from traditional methods of technology adoption to managing technologies throughout their lifecycle. The National Institute for Health and Care Excellence (NICE) evaluates devices, digital and diagnostic technologies by producing medical technologies guidance, which could recommend for adoption, no adoption, or further research. The desire to move to a lifecycle approach in the evaluation of medical technologies is reflected in the guidance review process, which involves review of the technology every three years or upon notification of significant new evidence. The outcomes of the guidance review can be to amend, update, withdraw, or leave the guidance unchanged.

**Methods.** Information on all technologies which have undergone guidance review since the commencement of the process was collected, including the recommendation before and after review and the basis for this recommendation. The proportion of guidances which were not changed, amended, updated, and withdrawn was calculated and the trends, including the bases for recommendation change were analyzed.

**Results.** In total, 34 medical technology guidance reviews have been performed. During the process, 15 (44%) were amended to reflect minor changes in the economic or clinical evidence, which did not change the recommendation. Ten (29%) were not changed, while three (9%) were updated respectively. Three (9%) were withdrawn. Another three (9%) represent special cases, which entered guidance

review, but were paused due to external reasons. Among the guidances that progressed to update, two out of three had a cost increase, whereas one was broadened to reflect evidence for a larger population.

**Conclusions.** HTR is an important mechanism to improve patient care and system efficiency. In NICE's evaluation of medical technologies, changes in the recommendation stemmed from changes in the technology's (or standard care's) cost, the evidence for clinical effectiveness, or the safety profile.

## OP37 Lifecycle Evaluation Models And Frameworks Used To Assess Medical Devices: A Qualitative Evidence Synthesis

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**Introduction.** Due to the iterative nature of medical device innovation and development, a single once-off assessment does not provide all the answers that decision-makers need over the device's lifetime. Consequently, a lifecycle approach is frequently recommended. However, there is no lifecycle model recognized internationally for conducting such evaluations, nor is there explicit agreement regarding what is meant by, or evaluated over, the lifecycle. The purpose of this review was to identify and explore the range of models/frameworks used for evaluating medical devices across their lifetime – to determine what people mean by 'the lifecycle', what is evaluated, how, and why.

**Methods.** A qualitative evidence synthesis of lifecycle models described in the literature from a wide variety of disciplines was performed. Literature searching and selection of models iterated with analysis. Similarities, differences, and patterns were identified, from which themes became apparent, and explanatory theories were developed.

**Results.** Fifty-three models are included in the synthesis. The dimensions of difference include, amongst others, the lifecycle scope, level of application, evaluation timepoints and methods, factors included in the models, and the focus of interest. These are each influenced by the purpose of the lifecycle evaluation, which depends on the perspective and the decision or activity the evaluation is intended to inform. Few models provide a lifecycle approach to evaluating safety or efficacy. Theories explaining the differences are postulated.

**Conclusions.** Lifecycle evaluation means different things to different actors, with varied reasons for evaluation and different variables included in the models. Thus, discussions between different actors on lifecycle evaluation may be inadvertently at cross-purposes. Without first defining what is meant by the lifecycle (including the stages or phases of activity it covers) and the variables included in an evaluation, care must be exercised when discussing a lifecycle evaluation approach – to ensure that the meaning (and intended objective) is not lost in translation. Indeed, promoting lifecycle evaluation may result in necessary evidence not being generated early enough, being deferred instead until later.