

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 The proportion of guidances which were not changed, amended, updated, and withdrawn was calculated and the trends, including the bases for recommendation change were analyzed.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.