

OP25 Evidence Gathering Across Key Stakeholders Involved In Early Health Technology Assessment

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INTRODUCTION:

The adoption and reimbursement of a new or novel medical device frequently occurs after an economic evaluation of the innovation. One important factor for reimbursement rejections by the English National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme (MTEP) appears to be the little or no attention to early assessment (1). The aim of this study is to achieve a more in-depth and comprehensive understanding of the value of early Health Technology Assessment (HTA) for new medical devices.

METHODS:

This study employs a mixed methods research strategy. Our informant interviews involved two types of key stakeholders: health economists in academia and professionals in medical devices firms with a professional role in research and development or market access departments. Our qualitative analysis focused on two samples from six universities (five in the United Kingdom, UK, and one in Italy) and six small to medium-sized enterprises (five in the UK, and one in Italy). Insights from field work interviews helped to design our complementary quantitative analysis.

RESULTS:

During thematic analysis, barriers to adoption of early HTA emerged across three domains. First, educational barriers (that is, what HTA/early HTA is and how to conduct it) influenced the foundation for the reimbursement strategy. Second, interviewees highlighted the presence of intrinsic barriers (for example, resources for translational and early preclinical research, reliability and reproducibility, evidence, and

dissemination of sensitive information) within existing practices and knowledge. Third, several research gaps (that is, medical device classification, standardization of methods, guidelines for developers, and alignment of stakeholders perspectives) were identified. Finally, academics adopted early HTA to assess different aspects of a medical device early in development; however, developers were focused on the assessment of investment and safety/usability factors, especially for in-house evaluations.

CONCLUSIONS:

If decision makers expect developers to produce better quality evidence and society aims to optimize resources that is, not investing in non-cost-effective technologies, then the incorporation of a more robust analytical framework including a societal perspective is necessary to understand how early HTA can be embedded into all aspects of the development process.

REFERENCE:

1. Alshreef A, Jenks M, Green W, Dixon S. Review of Economic Submissions to NICE Medical Technologies Evaluation Programme. *Appl Health Econ Health Policy*. 2016;14(6):623-634.

OP27 Patient-Reported Outcome Measures In Carotid Artery Revascularization

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INTRODUCTION:

Patient-reported outcome measures (PROMs) provide a way to measure the impact of a disease and its associated treatments on the quality of life from the patients' perspective. The aim of this review was to identify PROMs that have been developed and/or validated in patients with carotid artery disease (CAD)

undergoing revascularization, and to assess their psychometric properties and examine suitability for research and clinical use.

METHODS:

Eight electronic databases including MEDLINE and CINAHL were searched from inception to May 2015 and updated in the MEDLINE database to February 2017. A two-stage search approach was used to identify studies reporting the development and/or validation of relevant PROMs in patients with CAD undergoing revascularization. Supplementary citation searching and hand-searching reference lists of included studies were also undertaken. The Consensus-based standards for the selection of health measurement instruments (COSMIN) and Oxford criteria were used to assess the methodological quality of the included studies, and the psychometric properties of the PROMs were evaluated using established assessment criteria.

RESULTS:

Six PROMs, reported in five studies, were identified: 36-Item Short Form Health Survey (SF-36), Euro-QoL-5-Dimension Scale (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Dizziness Handicap Inventory (DHI), Quality of life for CAD scale by Ivanova 2015 and a disease-specific PROM designed by Stolker 2010. The rigour of the psychometric assessment of the PROMs were variable with most only attempting to assess a single psychometric criterion. No study reported evidence on criterion validity and test-retest reliability. The overall psychometric evaluation of all included PROMs was rated as poor.

CONCLUSIONS:

This review highlighted a lack of evidence in validated PROMs used for patients undergoing carotid artery revascularization. As a result, the development and validation of a new PROM for this patient population is warranted in order to provide data which can supplement traditional clinical outcomes (stroke >30 days post-procedural, myocardial infarction and death), and capture changes in health status and quality of life in patients to help inform treatment decisions.

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OP28 Health Apps: A Proposed Framework To Guide Clinical Risk Assessment

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INTRODUCTION:

Globally, health systems are struggling with reliably appraising the safety and efficacy of rapidly changing digital health interventions whilst allowing useful innovations to be rapidly adopted. Assessment and regulation of the large number of health apps should be proportional to their clinical risk, but there is large uncertainty about suitable criteria to assess risk (1). We aimed to identify criteria for assessing clinical risks associated with different types of health apps.

METHODS:

Our work builds on previous studies that identified some of the risks that health apps can pose and contextual factors that can moderate these risks (2,3). This work is grounded in a review of existing literature; wide consultation of stakeholders; participation in multi-agency policy discussion; and sense-checking successive versions of the framework that evolved over time. We combined different risk domains for apps (technical safety, usability, intervention quality, and engagement) with their functions (learning, behaviour and cognition change, communication, record keeping, and clinical decision support).

RESULTS:

We developed a comprehensive generic risk framework that app users, developers, commissioners, regulators and other stakeholders worldwide can use to guide assessment of the likely risks posed by a specified health app in a specific context. We also propose questions that should help determine whether these risks have been addressed.