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

AUTHORS:
Stefania Manetti (stefania.manetti@santannapisa.it), Richéal Burns, Giuseppe Turchetti

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:

OP27 Patient-Reported Outcome Measures In Carotid Artery Revascularization

AUTHORS:
Munira Essat (m.essat@sheffield.ac.uk), Ahmed Aber, Patrick Phillips, Edith Poku, Helen Buckley Wood, Aoife Howard, Simon Palfreyman, Eva Kaltenthaler, Georgina Jones, Jonathan Michaels

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

AUTHORS:
Michelle Helena van Velthoven (michelle.vanvelthoven@phc.ox.ac.uk), John Powell, Jeremy Wyatt

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.