Methods. Twenty-eight (28) members of the public from across England took part in four iterative two-hour online workshops, held fortnightly in late 2021. They consisted of both plenary and breakout sessions and incorporated a range of stimuli including trade-off exercises and interview clips with HI experts.
Results. The findings show clear public support for HI being a high priority for NICE, albeit with limits on how and when HI should be addressed. Actions towards reducing HI should focus on supporting a preventative and systemic response. Importantly, there is a need for a transparent process for incorporating HI within NICE guidance as well as rigorous staff training in understanding and addressing HI. Recommending technologies that benefit the majority even when not accessible for all is acceptable if there are clear plans to manage access gaps.
Conclusions. Reducing health inequalities should be a high priority for NICE and other HTA organizations. Organizations should seek to have clear processes for embedding HI in decision-making. Priority should be given to actions that focus on prevention of ill health and those that have wider system impacts.

OP65 An Overview Of Participatory Approaches, Stakeholders, Methods, Topics and Challenges In Medical Device Development: A Scoping Review

Kas Woudstra (kas.woudstra@radboudumc.nl), Rob Reuzel, Maroeska Rovers and Marcia Tummers

Introduction. Stakeholder involvement in medical device development draws much attention. To make well-considered methodological choices while involving stakeholders, it is essential to know what approaches are available and what challenges they bring in practice. Therefore, the aim of this review was to study which participatory approaches are used in the early stages of the lifecycle of medical device development, and to describe the most important characteristics of these approaches.
Methods. We conducted a scoping review and searched PubMed, Embase and Web of Science for articles published between July 2014 – July 2019. Papers were included if they presented original research featuring any form of stakeholder participation in the development of medical devices. We used The Spectrum of Public Participation to categorise the approach of each paper. We describe four characteristics of each approach: the stakeholders involved, data-collection methods, topics addressed, and the challenges associated with the approaches as perceived by the researchers.
Results. From the 14,838 papers from the initial search, 278 were included. All papers could be categorized into three levels of participation: collaboration, involvement, and consultation. The results show that patients and healthcare professionals are most frequently engaged in all approaches, besides stakeholders like citizens, relatives, and experts. The most often used data-collection methods are workshops in the collaboration approach, and interviews in the involvement and consultation approach. Topics addressed in all approaches are: the initial problem, requirements of devices, design choices, testing of devices, and procedural aspects of the involvement. Challenges in the approaches are related to sampling, analysis, social dynamics, feasibility, and closure.
Conclusions. This review shows that despite the abundance of methods mentioned in literature, there are three main approaches to involving stakeholders in device development: collaboration, involvement, and consultation. These mainly differ in the degree of power that is granted to stakeholders, but are comparable in terms of data-collection methods, stakeholders, topics, and challenges.

OP67 Considerations Of Treatment Novelty In Health Technology Assessment

Patricia Synnott (psynnott@tuftsmedicalcenter.org), Daniel Enright, Dominic Voehler, Stacey Kowal and Daniel Ollendorf

Introduction. A recent proliferation of value frameworks, as well as the emergence of innovative approaches to treating disease (e.g., cell/gene therapies) have been accompanied by an increased focus on nontraditional elements of value. We sought to understand whether and how health technology assessment (HTA) agencies consider novel aspects of treatment in value assessments.
Methods. We defined treatment novelty as follows: (i) a new mechanism of action or administration; (ii) addresses an unmet need; or (iii) confers a distinct benefit that transforms clinical practice or that is difficult to quantify. We reviewed technical guidance and peer-reviewed literature to investigate how organizations in eight countries (Australia, Canada, England, France, Norway, the Netherlands, Sweden, and the United States) consider aspects of this definition.
Results. All (n = 8) organizations give special consideration to interventions that address an unmet need, particularly in cancer, rare diseases, and other severe conditions. Nearly all (n = 5) organizations consider whether an intervention produces benefits that may not be adequately quantified. Organizations in England, Norway, and France sometimes recommend drugs with less favorable cost-effectiveness estimates than traditionally considered if the drug addresses rare or severe conditions, or if its quality-of-life benefit is thought to be inadequately quantified. The Institute for Clinical and Economic Review in the United States models cost-effectiveness in rare diseases using both a modified societal and health care system perspective. Importantly, the benefits of novel treatments are frequently considered uncertain, particularly treatments with a new mechanism of action. When uncertainty is high, organizations in Canada, England, France, the Netherlands, and Sweden sometimes issue conditional recommendations until additional evidence is submitted. England and Australia have used risk sharing agreements for drugs determined to be novel but uncertain.
Conclusions. The most widely considered aspects of treatment novelty in HTA are unmet needs and potential benefits that are not easily measured. The willingness to pay for novel treatments is often greater, despite inherent uncertainties about benefit and cost-effectiveness.

https://doi.org/10.1017/S0266462322001167 Published online by Cambridge University Press