PD34 Ethics In Health Technology Assessment – A Case Study Of Prosthetic Care And Proposal For An Empirical Approach

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Introduction: Medical devices cause significant spending in healthcare systems and provide methodological challenges for health technology assessment (HTA). This poster presents the results of a dissertation on the HTA of prosthetic limb technology and care, with a focus on the ethical implications of this aspect of health care. It is also a case study for ethics in HTA more generally, which will contribute to methodological discussions in this field.
Methods: The methodology was based on Hofmann´s Socratic approach and empirical ethics. Literature reviews of HTA reports and ethics and social science literature on limb prosthetics and care were supplemented by semi-structured interviews with 16 prosthesis wearers and 18 stakeholders (e.g., insurance payers and orthopedic technicians) from Germany. This material served to identify and prioritize ethical issues and dive deeper into the causes of unequal access to prosthetic limbs. Beauchamp and Childress´ principlism and Norman Daniels' theory of just health were used to describe ethical requirements and conflicts and to discuss the limits of normative recommendations that HTA can provide for decision-makers.
Results: There were 42 ethical aspects related to limb prosthetic technology and care identified, reflecting also general challenges for HTA like artificial intelligence in health and resource scarcity in times of multiple crises. The perspectives of patients and stakeholders provided evidence for unequal access to limb prosthetics that was dependent on socioeconomic status, age, and living region. This is due to a combination of legal framework conditions (not supporting evidence-based reimbursement), socioeconomic success factors in interaction with gatekeepers, non-optimal quality of care (due to lack of data use and scarcity of professionals), and political non-willingness to address rationing–as well as the lack of HTAs.
Conclusions: Access issues in prosthetic care and their implications for patient wellbeing, efficiency, and sustainability may be generalizable to a certain extent to other medical device types and healthcare systems. Governments should provide resources, and synergies with health services research could be leveraged to enable HTA to address the challenges of medical device and ethical assessment.

PD35 A Decade In Review: Assessing The Quality Of Clinical Evidence For Oncology Drugs Submitted To A National Health Technology Assessment Agency

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Introduction: To ensure accurate and objective comparisons between interventions, the best available clinical evidence must be used. This updated analysis sought to review the quality of clinical evidence submitted by applicant companies to a national health technology assessment (HTA) agency in Ireland. This analysis aimed to assess the association between the quality of clinical evidence and the reimbursement recommendation.
Methods: A retrospective analysis of the clinical evidence supporting all oncology HTAs submitted to the National Centre for Pharmacoeconomics (NCPE) from May 2012 to December 2023 was conducted. NCPE recommendations were classed as "conditional-positive/positive" or "conditional-negative/negative" for the purposes of this analysis. Data extraction of key clinical evidence characteristics relating to the main clinical trial and indirect treatment comparison (ITC), if applicable, was informed by EUnetHTA guidance. Trends in clinical evidence characteristics were assessed over time. Potential associations between the quality of clinical evidence and reimbursement recommendations were investigated using a hierarchy of chi-squared tests and multivariate regression analysis.
Results: This analysis included 101 completed HTAs, 84 of which were supported by traditional randomized controlled trials (RCTs). The proportion of HTAs supported by single-arm trials (SATs) increased to 55.6 percent in 2023. HTAs supported by RCTs were more likely to receive a "conditional-positive/positive" recommendation, compared with those supported by SATs (42.8% versus 17.6%). Most of the RCTs were open-label studies (n=49), however recommendations were similar among HTAs supported by blinded and open-label studies. The overall survival data maturity was variable. ITCs were required in 76 HTAs, mostly supported by anchored ITCs. SATs supported by unanchored ITCs were more likely to receive a "conditional-positive/positive" recommendation than naïve comparisons.
Conclusions: Reliance on SATs and open-label studies has increased over the past decade. This analysis proposes that HTAs supported by RCTs remain the gold standard for HTA. A key limitation of this study is that the quality of evidence submitted is only one domain of the HTA evaluation process. No tests were statistically significant, which was partly explained by the small sample sizes.

https://doi.org/10.1017/S0266462324002976