OD05 Frameworks For Synthesizing Qualitative Evidence In Health Technology Assessment: A Scoping Review

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Introduction: Health technology assessment (HTA) agencies and researchers recognize the necessity of evidence-based methodologies beyond quantitative data to assess feasibility, appropriateness, meaningfulness, patient values, preferences, acceptability, and equity. Despite existing guidelines for synthesizing qualitative data, the HTA framework requires clarification. This review aims to describe the frameworks, tools, and processes used to synthesize qualitative evidence and assess the quality of HTA.
Methods: Using the JBI methodology, the authors accessed databases such as MEDLINE, LILACS, CINAHL, Embase, Web of Science, Scopus, PsycINFO, Cochrane Library, JBI Database, and ScienceDirect. Grey literature searches included ProQuest, OpenGrey, CADTH's Grey Matters, Google Scholar, and HTA agencies' websites. Inclusion criteria focused on synthesizing qualitative evidence frameworks, methods for evidence synthesis, and quality rating. The review had a global scope, without specific population and time restrictions. Data, encompassing fundamental concepts, frameworks, methods, subjects, and objectives, were presented in tables and figures.
Results: Out of 2,054 articles, 31 were included, mainly from Europe, with a predominant "guide" authored by an HTA agency and university. The majority of documents did not originate from agencies. Only three agencies developed specific documents. A surge in publications occurred in 2018/2019. Qualitative data in HTA were justified for opinions, acceptability, feasibility, and equity. SPICE was the most cited acronym; RETREAT was the preferred framework. Thematic synthesis was the most cited method, CASP for quality assessment. GRADE-CERQual graded evidence quality, and ENTREQ was cited for reporting qualitative research. The GRADE EtD framework was the sole tool mentioned for recommendations.
Conclusions: This review highlights a growing trend in including qualitative evidence in HTA. While various proposals suggest instruments and methods, few documents cover all necessary steps, resulting in diverse recommendations. Standardizing processes can improve decision-making by guiding the integration of qualitative evidence, potentially enhancing recommendation quality. This ensures evidence on feasibility, appropriateness, significance, patient values, preferences, acceptability, and equity are considered.

OD07 Disaggregation Of The Costs Of Pharmaceutical Research And Development

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Introduction: Costs for pharmaceutical products are increasing. Pharmaceutical companies claim that high research and development (R&D) costs are the reason for the steep price increase of new products. However, there exists little data to support such claims; there is a lack of transparency in R&D cost reporting. This research intends to analyze and to disaggregate the costs of pharmaceutical R&D.
Methods: Studies on the costs of introducing new medications to the market can differ substantially in their methodology, their origin of data, and their results. A scoping review was conducted on costs of R&D for pharmaceutical products using Embase, PubMed, and EconLit, using a combination of the terms "drug research and development" and "costs" or "drug research and development" and "expenditure." Additionally, semi structured interviews with 16 experts from non-governmental organizations (NGOs), pharmaceutical companies, academic researchers, and not-for-profit pharmaceutical companies were conducted to identify the main driving factors for rising costs of new drugs.
Results: Out of 24 studies that analyzed mixed therapeutic fields, the five highest cost estimates had affiliations with industry or received funding from pharmaceutical companies. Non-affiliated researchers are unable to reproduce studies that use confidential data and therefore cannot check the validity of the results. Additionally, different definitions for R&D make analyzing costs challenging. The interviewees emphasized that driving factors influencing costs for pharmaceutical R&D are therapeutic indication, drug complexity, number of patients in clinical trials, length of the development process, and attrition rates.
Conclusions: Due to the diverse nature of drug development and the confidential information held by pharmaceutical companies, it is a challenge to provide an exact assessment of the average costs of pharmaceutical R&D. Transparency policies with well-defined definitions for R&D are necessary to level the information asymmetries between the private and the public at price negotiations.

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