OP62 Economic Evaluations Submitted For Reimbursement To The Brazilian Unified Health System: A Meta-Epidemiological Study

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Introduction: Allocating financial resources efficiently poses a significant challenge for health systems worldwide. In this context, economic evaluations (EE) are pivotal for the health technology assessment (HTA) process, particularly in standardizing approaches to enhance decision-making accuracy. This study focuses on delineating methodological nuances of EE submissions within Brazil's Unified Health System (SUS).

Methods: This meta-epidemiological study analyzed dossiers submitted to the National Committee for Health Technology Incorporation (Conitec) for drug reimbursement from January 2022 to May 2023. We selected dossiers that included complete EE studies such as cost–utility or cost-effectiveness analyses. Our evaluation involved extracting data on the characteristics of the studies, reimbursement decisions, elements of the base case scenario, and parameters used in utility and sensitivity analyses. [Protocol: DOI 10.17605/OSF.IO/JVYEC]

Results: We included 56 dossiers, leading to 11 favorable reimbursement decisions. EE study methods were cost-effectiveness (17) and cost–utility analyses (17), with some employing both (16). Markov chain models were used in 27 dossiers, primarily utilizing quality-adjusted life years as the health outcome measure. Additional outcomes included life years gained and frequency of avoided events. While utility assessment was reported in 33 dossiers, only six adjusted for age and seven accounted for disutility from adverse events. Thirty-two conducted deterministic or probabilistic sensitivity analyses, but only four presented parameters like credibility intervals, and 17 presented acceptability curves.

Conclusions: This study highlights the need for more standardized and refined methods in the EE submitted to Conitec. The existing EE methodological guidelines, dating from 2014, are currently under revision. This update is crucial to integrate recent advancements in health technology assessment and to better address contemporary requirements, particularly in light of the newly defined willingness-to-pay threshold.

OP63 A European Value Assessment Framework For Next-Generation Sequencing And Comprehensive Genomic Profiling Oncology Diagnostics

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Introduction: Advances in next-generation sequencing/comprehensive genomic profiling (NGS/CGP) diagnostics require a value framework (VF) for accurate assessment within cancer care in Europe. Building on a previously established VF for diagnostic technologies in Latin America by the Institute for Clinical Effectiveness and Health Policy (IECS), this study synthesizes insights from a systematic literature review and stakeholder perspectives to inform the co-creation of an NGS/CGP diagnostic framework for healthcare decision-making.

Methods: The study utilized a mixed methods approach including a systematic literature review (SLR) and web-Delphi panel. The SLR identified and mapped existing VFs against the IECS VF, extracting non-overlapping criteria relevant to NGS/CGP in Europe. A Delphi panel further adapted and validated the framework, ensuring comprehensive stakeholder contribution and engagement. The Delphi´s first round was qualitative and involved open-ended feedback from participants to adapt the indicators and domains. Rounds two through four involved Likert-scale judgments of importance of each indicator. In rounds three and four, participants were shown the distribution of responses across stakeholders and could reconsider their answers.

Results: The SLR revealed 42 VFs with an 83 percent criterion overlap with the IECS VF, resulting in 46 indicators forming the literature-adapted framework. Thirty-four participants completed the Delphi. In round one, 14 indicators and 22 descriptions were adapted, 11 indicators were merged, 14 were deleted, and one was kept the same resulting in 29 indicators for scoring in round two. The final VF has 27 indicators: 23 essential and four complementary; two indicators did not reach consensus. The domains included clinical impact, test performance, scientific evidence quality, non-clinical impact, health system integration, economic aspects, ethical/governance concerns, and health system priorities.

Conclusions: This approach has yielded a robust, stakeholder co-created VF for NGS/CGP diagnostics in oncology, tailored to the European setting. It offers a comprehensive set of criteria that extends beyond traditional health technology assessments, incorporating novel aspects like post-test data governance. This framework sets the stage for improving patient access to high-value technologies by aligning European stakeholder values across health systems.