OP74 A Comprehensive Health Technology Assessment Framework For Omics Technologies In The Spanish Setting

Patricia Julia Garcia-Sanz (patricia.garcia.sanz@juntadeandalucia.es), Lorena Aguilera-Cobos, María Piedad Rosario Lozano and Juan Antonio Blasco-Amaro

Introduction: Personalized precision medicine (PPM) is an innovative approach to disease diagnosis, prognosis, and treatment of individual or group characteristics using diverse data sources. While omics technologies are integral to PPM, they pose challenges. Therefore, developing an appropriate methodology to assess these technologies is crucial for patient safety, resource efficiency, and clinical decision-making within the Spanish National Health System.
Methods: This health technology assessment (HTA) methodology procedure was developed by combining three different approaches: a systematic review (SR); a survey targeting experts in omics technology, ranging from basic science researchers to clinicians, and patient associations; and, finally, a consensus method (RAND Appropriateness Method [RAM]).
Results: Through data extraction and evidence synthesis of the 38 studies included in SR, 30 existing frameworks for evaluating omics technologies were identified, as well as the elements needed to assess these technologies, leading to the first version of the framework. Two surveys were performed to integrate the perspectives of omics technology experts and patients. Subsequently, this framework version was further developed by a RAM consensus panel of experts from HTA agencies to ensure a rigorous evaluation of gathered data. The final framework was categorized into 94 elements divided into sections, categories, domains, and subdomains.
Conclusions: A methodological guide, including the assessment framework, was developed for the Spanish HTA network. The framework is divided into several sections addressing evidence-gathering, provision models, organizational elements, economic evaluation, and ethical and social implications. Compared to other available frameworks, our proposal included aspects such as bioinformatics, technological maturity level, and the patient perspective with the personal utility domain.

OP75 Pharmaceutical Innovativeness Index: Evaluation Of Pharmaceutical Innovation In Lung Cancer Treatment Drugs Approved Between 2011 And 2021

Isabela Freitas, Ludmila Gargano (ludgargano@gmail.com), Ariane André, Francisco de Assis Acurcio, Juliana Alvares-Teodoro and Augusto Guerra Jr

Introduction: Lung cancer (LC) ranks second globally in neoplasia diagnoses and exhibits the highest oncological mortality rate. Oncology has seen a marked increase in U.S. Food and Drug Administration (FDA) approvals for novel drugs, notably in the case of LC. This study aims to assess the innovativeness of recently FDA-approved LC treatments compared to existing options, spanning the 2011 to 2021 period.
Methods: The innovativeness of drugs was assessed through the Pharmaceutical Innovativeness Index (PII). The methodology considers population health needs and aggregated clinical benefits, while weighing methodological quality and the adequacy of available evidence. New drugs are analyzed considering available therapeutic alternatives. The assessment assigns an innovativeness score to the drugs, with 1.0 representing the highest degree of innovation. PII was applied to all drugs with their first FDA indication for LC treatment. The evaluation considered specific clinical indications (e.g., treatment of ALK-positive LC), and data from FDA clinical review reports and pivotal clinical trials were considered.
Results: Eighteen new drugs were identified during the period. The drugs were evaluated with a mean PII of 0.615, ranging from 0.474 to 0.811. No discernible trends in innovativeness were observed within specific indications. Overall, the evaluations indicated that these medications were approved to address significant therapeutic needs. However, the added therapeutic value ranged from absent to moderate. Most supporting evidence for these approvals was derived from clinical studies with low risk of bias. Nevertheless, these studies often featured inadequate designs due to the absence of a comparator arm, limiting the assessment of added therapeutic value.
Conclusions: Pharmaceutical innovations in recent years for LC treatment have demonstrated limited clinical benefits when compared to existing alternatives, highlighting a substantial therapeutic need. The application of the PII can assist in healthcare decision-making, guide investments and research efforts, as well as inform pricing and reimbursement of new technologies, thereby contributing to the sustainability of healthcare systems.

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