PP50 Facilitating Academic Life Science Innovation With Early Health Technology Assessment: A Survey Of Potential User Needs And Perceptions

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Introduction: Academic life scientists often struggle to develop and commercialize concrete medical products based on their discoveries. Early health technology assessment (eHTA) can help innovators to define target product profiles (TPPs) with strong value propositions. To understand how eHTA can best help facilitate the clinical translation of university-based inventions, we conducted a survey of stakeholders in the life science innovation ecosystem.
Methods: Our 10-minute online survey includes questions on respondents' location, organizational affiliations, experiences in health technology development, and awareness and perceptions of eHTA. eHTA is broadly defined as the use of tools from health economics, epidemiology, management, and related disciplines to assess the potential value of a medical product candidate for patients, payers, providers, manufacturers, and other stakeholders. The survey is being advertised using social media and email, and it will be followed up with semistructured interviews. Data on 51 complete responses were summarized using frequency tables and cross-tabulations, and the statistical significance of subgroup differences was evaluated using Fisher's exact test.
Results: Of 51 respondents, a majority lived in Canada (38/51; 75%) and had an academic affiliation (39/51; 76%). A "lack of commercialization skills among academic life science teams" was identified as a barrier to clinical translation by 41 percent (21/51), though this varied by academic affiliation (33% vs 67%; p=0.051) and industry experience (65% vs 29%; p=0.033). While 31 percent (16/51) reported familiarity with eHTA, this also varied by academic affiliation (23% vs 58%; p=0.033). Only 20 percent (10/51) had previously used eHTA, but a majority expressed an interest in learning more (39/51; 76%) and in using eHTA in the future (31/51; 61%).
Conclusions: Making eHTA more accessible for academic life scientists who lack commercialization experience may mitigate an important barrier to clinical translation of university-developed health technologies. While awareness of eHTA is relatively low in this group, they are interested in learning more about and using eHTA, and efforts should be made to integrate eHTA with existing product development tools like the TPP.

PP51 Pharmaceutical Innovativeness Index (PII): A New Framework For Assessing Health Technology Innovation Based On Therapeutic And Social Relevance

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Introduction: The value of a new pharmaceutical product should rely on its therapeutic benefits while also considering social health needs. Adapting health technology assessment (HTA) tools, we propose a transparent framework, with well-defined criteria and script, to determine the value of innovation (i.e., innovativeness) with clinical and methodological parameters, based on the social relevance and therapeutic value of new medicines.
Methods: The study was developed by adapting HTA-based methods identified in the literature: the Italian Medicines Agency (AIFA) and the EValuation of pharmaceutical Innovations with regard to Therapeutic Advantage (EVITA) tool. A sample of oncology drugs approved by the U.S. Food and Drug Administration (FDA) between 2011 and 2021 were assessed by researchers trained in HTA tools using those methods. After assessing the sample, researchers discussed the results, difficulties, and issues experienced. Those issues were addressed, resulting in the creation of the new framework, which included the redefinition of domains, definition of classification criteria for each domain, and scores according to relevance.
Results: The Pharmaceutical Innovativeness Index (PII) was proposed, with a script, domains, criteria, and an algorithm. The evaluation begins defining indication, outcomes, therapeutic alternatives, time perspective, and data sources. Four domains were considered: Therapeutic Need, which evaluates the existence and benefits of alternatives; Added Therapeutic Value, which talks about the incremental clinical benefit when compared to those alternatives (these first two domains were graded into five levels ranging from absent to maximum); Study Design and Methodological Quality, both classified into three levels. Classification criteria for each domain can be adapted according to the indication and relevant outcomes.
Conclusions: The PII framework considers clinical and social value weighted by methodological limitation of available evidence to determine the value of innovation of pharmaceutical products. It stands out as a transparent, adaptable, and reproducible tool that aims to reduce the subjectivity of analyses and assist with decision-making. PII has the potential to inform decision-making processes involving value-based pricing, reimbursement, and research and development investment.

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