

PD197 Improving The Impact Of Health Technology Assessment Reports: Experience Of The Synthesis In Catalonia

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Introduction: To enhance the impact of health technology assessment (HTA) on Catalonia's health system, a summary product called "synthesis" was developed. It presents the key information from HTA reports. After initial development and pilot testing, we developed a final version. Our aim was to evaluate its impact on decision-making at different levels.

Methods: We prepared an eight-question survey to assess the impact of the 15 syntheses that were published on the Agency for Health Quality and Assessment of Catalonia (AQuAS) website in 2023. We asked about the role of the healthcare professionals answering the questions, why they used the information of the syntheses, and whether they read the associated HTA report later and recommend it. We invited the professionals of the Catalan health system, providers, and payers to answer the survey by email. The survey also was published on the AQuAS website.

Results: We obtained 31 responses. The roles of the professionals who answered the questions were mainly directors and managers of the institutions of the Catalan health system (45.2%), healthcare professionals (32.3%), and care managers (12.9%). Most of them consulted the synthesis to update their knowledge about a specific topic (71.0%), obtain reliable data (35.5%), or support a strategic or professional decision (29.0%). The HTA report related to each synthesis was only consulted in some cases (38.7%) but was recommended in almost all cases (93.5%).

Conclusions: Summarizing the most important information of an HTA report in a new product can be a useful tool for improving the impact of the HTA on the Catalan health system. Professionals who answered the survey agreed that the syntheses helped them in making decisions related to the health technologies.

PD198 A Review Of Regulatory Theory To Inform Discussion On Aligning Regulation And Health Technology Assessment Of Medical Devices

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Introduction: If regulation and health technology assessment (HTA) are to be aligned, we must understand regulation and regulatory policy goals. Furthermore, regulatory policy is most likely to achieve its goals if it is informed by theory and underpinned by evidence. However, regulatory theories are rarely explored by HTA bodies. Therefore, this study explored regulatory theories as they relate to medical device regulation.

Methods: Literature describing regulatory theories was reviewed and synthesized narratively to explain what is meant by regulation and why governments regulate. Competing theories were discussed, reflecting on their relevance to the regulation of medical devices.

Results: The theory of perfect competition suggests that, when key assumptions hold true, market forces will result in the most efficient allocation of resources. However, when they don't, market failure results. Governments frequently regulate such markets. Stigler suggests that they do so to serve either public or private interests. Market failure is the norm in health care, so it requires regulation. If medical device regulation is intended to serve the public interest, it should be patient-centered, balance market power amongst many producers, reduce information asymmetry, and ensure that only safe and effective devices enter the market. HTA assumes a public interest perspective.

Conclusions: Regulations that maintain the confidentiality of clinical evidence underpinning medical devices and allow them to enter healthcare markets with insufficient evidence of efficacy do not serve the public interest. This raises the questions of whose interests does medical device regulation serve, and can HTA align with this?

PD199 Global Collaboration Post-Brexit: Do Project Orbis And The Access Consortium Improve Access In The UK Compared With Europe?

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Introduction: As the newly independent regulator for medicines in the UK post-Brexit, the Medicines and Healthcare products Regulatory Agency (MHRA) has entered international regulatory collaborations, notably Project Orbis (PO) and the Access Consortium (AC), to help expedite marketing authorizations. This research compared regulatory and reimbursement outcomes for medicines approved in Great Britain through PO and the AC with corresponding outcomes from the EU4Health Programme.

Methods: Products approved by the MHRA through PO and the AC were identified from the PO and New Active Substance Work Sharing Initiative websites, respectively. Marketing authorization dates and reimbursement outcomes were obtained from the respective regulatory and health technology assessment body websites on 20 November 2023.

Results: A total of 21 products have been authorized by the MHRA through either PO (17/21) or the AC (4/21); 17 of 21 have been