scenario analyses were conducted, and province- and state-level estimates were also generated.
Results: Based on an estimated current annual GWS utilization rate of 77 per million in the US, 237 RD SFs would be identified annually (0.9% of 25,663 patients tested), out of which 107 (45%) would be variants linked to hereditary transthyretin amyloidosis (hATTR). In Canada (GWS utilization rate of 169 per million), 45 patients would be identified per year, of which 11 (24%) would be hATTR. Treating 50 percent of hATTR SF patients with patisiran would cost approximately USD26.0 million in the USA and USD2.8 million in Canada annually. In contrast, no cases of RPE65-related retinopathy would be detected at current utilization rates.
Conclusions: The addition of hATTR (with an estimated genetic prevalence of one in 240 in the US) to the ACMG SF list may result in a significant number of additional cases diagnosed per year. While there is an ongoing debate about initiating presymptomatic treatment, reimbursement requests for high-cost drugs like patisiran are likely to increase if GWS utilization continues to grow.

PP31 Logical Model Articulating Pharmacy Commissions And Hospital-Based Health Technology Assessment Nuclei: Collaborative Strategies For The Drug Selection

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Introduction: Collaborative strategies between the Pharmacy and Therapeutics Committee (Group 1) and hospital-based health technology assessment (HTA) nuclei (Group 2) using HTA tools can promote rational use and medicines access. The aim was to develop a logical model for the drug selection process in Brazilian university hospitals, considering the articulation between the Pharmacy and Therapeutics Committee and hospital-based HTA nuclei (NATS).
Methods: A qualitative study created and validated a logical model. The data collection considered documental analysis and semistructured interviews with key informants from both groups about the processes adopted by eight federal university hospitals. The European Project on Hospital-Based Health Technology Assessment (AdHopHTA) was selected as a theoretical reference. The model was discussed in a focal group with the participation of five experts in medicine selection tasks and HTA. The final version of the model was submitted for consistency and vulnerability analysis by the authors. The ethical approval number is 4.784.861.
Results: The logical model was conceived with dimensions of resources, actions, products, results, and impacts. It has allowed a structured and organized view of the 15 actions in the medicine selection. From these 15 actions, seven can be articulated between both groups. The high management support, training, and dissemination of the procedures and flows that organize HTA processes were solutions to minimizing collaborative barriers. The selection of medicines was considered a dynamic process. Some actions, such as the use of pharmacovigilance data, post-selection monitoring, and horizon technology scanning can bring results in terms of treatment innovations and compliance with clinical guidelines.
Conclusions: Collaborative strategies were presented in a logical model with seven joint actions to guide the medicine selection process in hospitals involving tools, flow audits, governance, and human resources. The consistency and vulnerability model analysis defined indicators for HTA collaborative actions.

PP32 Health Technology Assessment Regulation In Europe: Implications For A National Authority

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Introduction: The Regulation (EU) 2021/2282 on health technology assessment (HTAR) for medicines will come into effect in January 2025; initially, new oncology medicines and advanced therapy medicinal products will be assessed at EU level. How will this work in practice? What does this mean for national HTA bodies, such as the National Centre for Pharmacoeconomics (NCPE) Ireland that uses a cost-effectiveness framework to inform decision-making for medicines?
Methods: Joint work to be conducted under the Regulation includes joint clinical assessments (JCA), joint scientific consultations (JSC), and production of procedures and methodological guidance. A review was undertaken of key areas that will be impacted by the HTAR in the Irish HTA process for medicines, including timing, evidence synthesis structure, capacity building, and resource implications.
Results: The HTAR will alter the current process for medicines assessment in Ireland, from early scientific advice to cost-effectiveness assessment post-authorization. JSCs will represent an additional step. Significant training and capacity implications are associated with the JCA, which will require earlier engagement with stakeholders. The NCPE's pragmatic HTA early triaging process, the "Rapid Review," may be delayed due to the non-duplication clause in the HTAR. The availability of high-quality comparative effectiveness evidence may help avoid full HTAs in some cases. The benefit of the JCA will be realized if the results can directly inform treatment-effectiveness estimates in cost-effectiveness modeling.
Conclusions: The HTAR will significantly impact on medicines reimbursement procedures in Ireland. For the HTAR to be effective in achieving its aims, sufficient resources will need to be built into the EU HTA system. The balance between the extra resources needed and the resources spared will depend on the quality of the comparative effectiveness evidence available for the JCA.

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