make sound decisions under conditions of deep uncertainty (i.e., when stakeholders do not know, or cannot agree on, the system model, the probability distributions to place over the inputs to these models, which consequences to consider, and their relative importance). The aim of this research was to evaluate the potential of EM for the early evaluation of health technologies.
Methods. EM and early health economic modelling (EHEM) were applied to an early evaluation of minimally invasive surgery (MIS) for acute intracerebral hemorrhage, and were compared to derive differences, merits, and drawbacks of EM.
Results. The approaches fundamentally differ in the way uncertainty is handled. Where in EHEM the focus is on the value of the technology, while accounting for the uncertainty, EM focuses on the uncertainty. EHEM aims to assess whether the innovative strategy is potentially cost-effective, often using assumptions. EM on the other hand focuses on finding robust strategies (i.e., strategies that give relatively good outcomes over a wide range of plausible futures). This was also reflected in our case study. For example, EHEM provided cost-effectiveness thresholds for MIS effectiveness, assuming fixed MIS costs. EM showed that a strategy with a population in which most patients had severe intracerebral hemorrhage was most robust, regardless of MIS effectiveness, complications, and costs.
Conclusions. EM seems most suited in the very early phases of innovation (i.e., when a problem is signaled). Here, it can explore the robustness of many potential strategies under uncertainty. When potential strategies are selected, EHEM seems useful to optimize these strategies. Yet, EM methods are complex and might only be fully effective when a policy window exists that facilitates flexible research and adoption strategies.

OP08 Early Access To New Direct-Acting Antiviral: A Journey On Introduction Of Ravidasvir For Hepatitis C Treatment In Malaysia

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Introduction. Access to affordable direct-acting antiviral (DAA) remains limited in developing countries, often due to high treatment cost. This study aimed to elaborate the initiatives taken by the Ministry of Health Malaysia (MoHM) to provide early access to ravidasvir, a new DAA for hepatitis C treatment, in Malaysia.
Methods. MoHM collaborated with Drugs for Neglected Diseases initiative (DNDi) to develop ravidasvir, a new chemical entity of oral non-structural protein 5A (NS5A) inhibitor. MoHM co-sponsored and participated the DNDi-led Phase II/III study (STORM-C-1 trial) to assess the efficacy and safety of ravidasvir-sofosbuvir combination therapy. Agreement was signed between Pharmaniaga, Pharco Pharmaceuticals and DNDi to register and supply affordable hepatitis C treatment in Malaysia and South-East Asia. MoHM and Pharmaniaga mutually worked on the registration of ravidasvir in Malaysia. Series of pre-submission meetings took place, rolling submission was allowed and conditional registration pathway was used. As a separate initiative, MoHM partnered with the Foundation for Innovative New Diagnostics (FIND) to implement decentralization and test-and-treat strategies for screening of hepatitis C virus (HCV).
Results. First stage of the STORM-C-1 trial reported that the combination of ravidasvir-sofosbuvir was highly effective across all genotypes and safe. The Drug Control Authority (DCA) Malaysia has granted a conditional registration for ravidasvir hydrochloride 200mg tablet (Ravida®) in June 2021, making Malaysia as the first country in the world to approve ravidasvir. Registration process expedited and took place within 15 months. The supply of Ravida® in Malaysia is expected in near future. Meanwhile, MoHM also implemented nationwide HCV screening using rapid diagnostic test kit in private hospitals, community clinics, prisons and rehabilitation centers which previously was done only in hospitals for outreach to the targeted group.
Conclusions. Ravidasvir-sofosbuvir has potential as a tool to eliminate hepatitis C in Malaysia by 2030, the WHO's global elimination targets. This alternative new drug development model was successful due to strong leadership, public-private partnership and collaborative strategies. This could also be exercised in other disease area.

OP10 Outcomes Of Expanded Access To Transcatheter Aortic Valve Implantation In Ontario: A Model-Based Analysis

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Introduction. Transcatheter aortic valve implantation (TAVI) is a minimally invasive therapy for patients with severe aortic stenosis. In Ontario, increases in capacity have not matched the rapidly growing demand for TAVI. As a result, wait-times for TAVI in Ontario exceed guideline targets, and waitlist morbidity is consequently considerable. The objective of this study was to evaluate the clinical implications of expanded TAVI capacity.
Methods. We performed a decision analysis using an open, parallel, resource-constrained microsimulation from the Ontario Ministry of Health perspective. Simulated patients entered the model during a five-year period, and stayed in the model until death or end of time horizon. Referral numbers increased annually according to historical trends. The additional capacity required to meet wait-time benchmarks in five years was identified by a sensitivity analysis. Clinical outcomes were estimated for three strategies: (i) current practice with annual capacity increases; (ii) accelerated capacity increases achieving benchmarks after five years; and (iii) no increase in capacity. Outcomes included pre-procedural mortality and hospitalization, and the proportion of TAVIs performed urgently.
Results. Over the five years, we estimated that TAVI referrals would increase from 1,980/year to 3,268/year. To achieve wait-time benchmarks during this period, TAVI rates must be increased by approximately 6.3 percent annually, for a total of 12,220 procedures performed over the 5 years. Compared to current TAVI capacity increase, an accelerated increase in capacity achieving wait-time

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benchmarks led to a reduction of 29.36 percent in pre-procedural deaths, as well as 26.38 percent in pre-procedural hospitalizations and 30.31 percent in nonelective TAVIs.
Conclusions. Increases in TAVI capacity in Ontario must be accelerated to meet wait-time benchmarks in five years. Expansion of TAVI care in Ontario would be associated with considerable reductions in mortality and hospitalizations. Without intervention, both wait-times and adverse outcomes on the waitlist are expected to continue increasing. Prioritization strategies to mitigate the adverse effects of long wait-times must be used until wait-time targets are achieved.

OP11 Differences And Similarities In Past Health Technology Assessments In Beneluxa Initiative Countries

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Introduction. Conducting joint health technology assessments (HTA) is one of the main goals of the Beneluxa Initiative. To strengthen this collaboration, this study aimed to assess similarities and differences between past assessments of Beneluxa Initiative member countries (Austria, Belgium, Ireland and the Netherlands).
Methods. A retrospective comparative analysis was performed that investigated the similarities and differences in drug assessments in the period 2016 to 2020 in (i) the number and type of assessed indications; (ii) the conclusions within assessments performed by at least two member countries; and (iii) the main arguments leading to the conclusions through a qualitative analysis of selected cases, looking into the patient population, the intervention, comparator, outcome, timing, and included evidence.
Results. The scope of HTA differs between the countries, with Belgium and Ireland assessing most, the Netherlands focusing on drugs above a budget impact threshold and Austria on outpatient drugs. Furthermore, indications might slightly differ between countries. Therefore, only 44 (10%) of the 444 included drug-indication combinations were assessed through a full HTA by all four countries. Between any pair of countries, the overlap was higher, from 63 (Austria-the Netherlands) to 188 (Belgium-Ireland). Added benefit conclusions matched exactly in 62 to 76 percent of the indications, depending on the compared countries. In the remaining cases, often a difference of one added benefit level was observed (e.g., higher versus equal relative effect). Contradictory outcomes were very rare. Differences were observed with regards to whether a cost-effectiveness analysis was performed. When assessing the underlying arguments within the reports for nine cases with different outcomes, it became clear that organizations agree on almost all aspects, and that differences are mostly attributable to slight differences in weighing of some aspects and uncertainties.
Conclusions. Overall, which indications are assessed differs, but for those indications that are assessed by multiple member countries, considerations and assessment outcomes are similar.

OP12 Post-Launch Evidence Generation Among Health Technology Assessment Bodies In Europe

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Introduction. The need for timely access to innovative technologies has placed a special focus on the development of policies and practices that can guarantee the availability whilst ensuring the safety of these technologies after launch or licensure. The aim of this paper is to present and discuss Post-Launch Evidence Generation (PLEG) practices among health technology assessment (HTA) bodies at the European level to explore cross-border collaboration opportunities.
Methods. In December 2019, a survey composed of nine closed-ended questions with multiple choice answers about the PLEG practices in each country was sent to 25 partners of the European Network of Health Technology Assessment (EUnetHTA) Joint Action 3. In addition to the survey, the national practices were discussed during a face-to-face meeting with all partners of the dedicated work package. A quantitative analysis and a qualitative synthesis of the results was carried out.
Results. Twelve HTA bodies completed the survey. Of these, 11 reported procedures in place for official PLEG requests. In nine of the agencies, the requests are made at the time of the assessment/appraisal. Data collection and analysis mainly lies with companies for pharmaceuticals (60%) while it is more the responsibility of the HTA body for medical devices (75%). Only one agency reported owning the data and being able to exchange the data without asking permission. During the face-to face discussions, it was acknowledged that PLEG practices differ between countries depending on the topic concerned, but most rely on the usage of registries (mainly disease registries) for data collection. Most agencies estimated that a European collaboration could take place.
Conclusions. PLEG practices are in the remit of many European HTA bodies. Data sharing should be anticipated as only some own the data and can exchange them without asking permission. European collaboration on PLEG could commence once the evidence gaps have been defined or during the production of the HTA reports in the case of joint assessments.

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