

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 (EHM) 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 EHM the focus is on the value of the technology, while accounting for the uncertainty, EM focuses on the uncertainty. EHM 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, EHM 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, EHM 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

Nazatul Syima Idrus (nazatul.syima@moh.gov.my),  
Faridah Aryani Md Yusof and Rosliza Lajis

**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

Rafael N Miranda (rafanm@gmail.com), John Peel,  
David Naimark and Harindra Wijeyesundera

**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