OP05 The Role Of Conditional Reimbursement In The Lifecycle Approach

Hedi Schelleman (hschelleman@zinl.nl), Simone van Montfort, Lenneke Sicking and Daniëlle Haasnoot-Volker

Introduction. In 2012, the Netherlands introduced a conditional reimbursement (CR) program to give patients earlier access to promising treatments (i.e., drugs and medical devices). After completion of the CR-study the results are used to (re)assess whether the treatment fulfills the criteria for reimbursement.
Methods. Promising treatments were identified via a bottom-up (physicians/researchers initiated) or top-down process (after the Dutch National Health Care Institute (Zorginstituut Netherland; ZIN) concluded that the intervention did not fulfill the criteria for reimbursement but the initial results seemed promising). A CR-grant was only approved if a committee determined the treatment had an added (health, social, ethical or organizational) benefit compared to Standard of Care (SoC) and the grant proposal was of good quality and fit for purpose. After approval from the Dutch Ministry of Health, all Dutch insurance companies were obliged to reimburse the treatment for patients participating in the CR-study. Researchers could also apply for a research grant (maximum EUR 400,000) from the Netherlands Organization for Health Research and Development (ZonMw), if there was no 'wealthy' manufacturer.
Results. Currently, there are 23 (ongoing and completed) CR-studies. All of them are closely monitored by ZIN, ZonMw, and stakeholders. The results of all completed CR-studies (n = 11) have been used in a (re)assessment. ZIN concluded that five treatments were not effective compared to SoC. Six interventions were effective and cost-effective compared to SoC and are now reimbursed. In most cases (>80%) the physician and patient groups agreed with the conclusion about reimbursement. In some cases there were additional requirements to maintain the clinical effectiveness and cost-effectiveness in clinical practice (such as training of new physicians).
Conclusions. Data from CR-studies are important for reassessments. Factors with a positive influence are: a maximum duration for a CR-study, close monitoring, possibility to adapt the study design (only with approval from ZIN and ZonMw), and active involvement of stakeholders (physician and patient groups). A negative influence was: the legal requirements to ensure only reimbursement for patients participating in a CR-study.

OP06 Percutaneous Transforaminal Endoscopic Discectomy: From Insufficient Evidence To Reimbursement

Hedi Schelleman (hschelleman@zinl.nl), Ingrid de Groot, Daniëlle Haasnoot-Volker and Petra Jellema

Introduction. The standard surgical technique for lumbosacral radicular syndrome in the Netherlands is open microdiscectomy (OM). An alternative technique, preferred by some Dutch physicians, is percutaneous transforaminal endoscopic discectomy (PTED). However, in 2006 the Dutch National Health Care Institute (Zorginstituut Netherland [ZIN]) concluded that the available evidence was insufficient, and a high quality randomized controlled trial (RCT) was needed to assess the cost-effectiveness of PTED compared to OM. The relevant physician group agreed with this conclusion, but they were unable to perform this RCT due to lack of funding and high treatment costs.
Methods. In 2012, the Netherlands introduced a conditional reimbursement (CR) program to give patients earlier access to promising treatments. Researchers, in collaboration with physicians and patients, submitted a grant proposal and in 2016 the Dutch Ministry of Health approved the CR of PTED. Due to this decision, insurance companies were obliged to reimburse PTED for patients participating in the PTED-study (NCT02602093). The Netherlands Organization for Health Research and Development (ZonMw) also provided a research grant to fund the PTED-study. In total, 682 adult patients with greater than 10 weeks of radiating pain, or greater than 6 weeks of excessive radiating pain and an indication for surgery were included. After 4 years and 5 months the PTED-study was completed.
Results. Outcomes of published studies and the unpublished PTED-study were used in the HTA reassessment. Results showed that PTED was noninferior to OM with regards to leg pain (Visual Analogue Scale: mean difference (MD) -0.73; 95% confidence interval [CI] -5.04, 3.59), functional status (Oswestry Disability Index: MD -2.07; 95% CI -3.61, -0.53), and rate of complications (relative risk 0.45; 95% CI 0.18, 1.12) after 6 months (GRADE level 'moderate'). Furthermore PTED was, after the surgeons' learning-curve, cost-effective.
Conclusions. This CR project was successful and PTED is now reimbursed as part of the Dutch healthcare package. However, in order to maintain high quality care in clinical practice, safeguards should be developed (including the appropriate training of surgeons). This example shows that CR programs are essential for promising treatments without 'wealthy' manufacturers. Additionally, all stakeholders are needed to make a CR-study successful.

OP07 Dealing With Uncertainty In Early Health Technology Assessment: An Exploration Of Methods For Decision-Making Under Deep Uncertainty

Mirre Scholte (mirre.scholte@radboudumc.nl), Vincent Marchau, Jan Kwakkel, Maroeska Rovers and Janneke Grutters

Introduction. In early stages, the consequences of innovations are often unknown or deeply uncertain. This complicates health economic modelling. The field of decision-making under deep uncertainty (DMDU) uses exploratory modelling (EM) to help decision-makers

https://doi.org/10.1017/S0266462322000678 Published online by Cambridge University Press

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

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 Wijeysundera

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

https://doi.org/10.1017/S0266462322000678 Published online by Cambridge University Press