OP05 The Role Of Conditional Reimbursement In The Lifecycle Approach

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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

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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

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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

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