have out-of-pocket payment rates of 50 percent and 80 percent, respectively.
Conclusions: The reassessment system through RWD accumulation enabled the evidence-based evaluation for the TAVI. Based on the transition to CED for essential benefits, a systematic framework such as RWD collection from treatment commencement should be introduced to broaden RWD use for benefit management of medical technologies with uncertain levels of evidence. Therefore, this ensures overall quality of care and effective coverage in health.

PP48 Cardiac Implantable Electronic Device (CIED) Infections In New South Wales, Australia: A Non-Interventional Study Utilizing Linked Secondary data

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Introduction: Cardiac Implantable Electronic Device (CIED) infection is a serious complication associated with morbidity, mortality and high healthcare costs. Internationally, the published rate of CIED infection ranges from 1.0 percent to 1.6 percent. There is a lack of data on CIED infection rates in Australia; the reported range is from less than 1 percent at 30 days to 7 percent over 5 years. Due to the variability within the limited number of studies there is a need for further analyses of CIED infection rates in Australia.
Methods: This was a retrospective cohort study using secondary linked hospital (the NSW Admitted Patient Data Collection) and mortality data for patients who underwent CIED procedures between July 2017 and June 2020 in NSW. Overall and procedure-and patient-specific incidence of infection was calculated.
Results: A total of 23,786 CIED procedures were performed among 22,404 patients and 422 CIED infections were identified, giving an overall infection rate of 1.77 percent. When infections were limited to those following a CIED procedure in the period July 2017-June 2020 (n=309), the procedure-specific CIED infection rate was 1.30 percent, ranging from 1.01 percent for permanent pacemaker (PPM) to 2.71 percent for cardiac resynchronization therapy-defibrillator (CRT-D). The proportion of patients undergoing CIED procedures in this period who had a subsequent CIED infection was 1.29 percent, ranging from 0.97 percent for permanent pacemaker (PPM) to 3.05 percent for cardiac resynchronization therapy defibrillator (CRT-D). Procedure-based infection rate in high-risk patients (generator replacement; system upgrade; revision; or CRT-D procedure) was 1.47 percent and patient-based infection rate was 1.68 percent. Infection rate was highest within the first month following the CIED procedure that dropped significantly over time.
Conclusions: Rates of infection were highest among patients with cardiac resynchronization therapy (CRT) devices, and those who underwent revision or upgrade procedures. Ongoing monitoring of CIED infection rates and preventative measures are necessary, especially for high-risk patients. This study highlights the important role linked secondary data has in reducing uncertainty and removing the reliance on international estimates by providing targeted, local data for health technology assessment.

PP49 Cost Of Cardiac Implantable Electronic Device (CIED) Infections In Australia: A Private And Public Sector Payer Perspective

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Introduction: In Australia, approximately 200,000 patients have a cardiac implantable electronic device (CIED), and in an aging population that number is rising. CIED-related infections are also increasing, causing considerable morbidity and mortality, and substantial healthcare costs. Internationally, the rate of CIED infection ranges from 1.0 percent to 1.6 percent, while in Australia, the reported range is from less than 1 percent to 7.0 percent. The average hospital cost to treat an infection in the US ranges between USD48,000–USD83,000. To date, few publications have estimated the cost of CIED infections in Australia. Critical appraisal of these studies has highlighted issues in their methodology, making them unreliable sources for use in economic evaluations. The purpose of this study was to utilize Australian routinely collected health data to robustly model costs of CIED infections to reduce uncertainty for future health technology assessment (HTA).
Methods: The cost of treating a CIED infection was modeled for the public and private sector including cost of system removal and re-implantation procedures, hospital and intensive care unit (ICU) stay, and outpatient follow-up. Cost inputs were obtained from the Australian Prostheses List, Medicare Benefits Schedule, Australian Institute of Health and Welfare, and Private Hospital Data Bureau. Other inputs were obtained by surveying Australian clinicians, which were validated with published data. Phone interviews and online surveys were conducted with clinicians to elicit specific Australian practice pathways for patients with a CIED infection.
Results: The majority of patients with a CIED have their device system removed (95-100%) and re-implanted (83%) once the infection has cleared. In the private sector, cost of infection ranged from AUD80,869 (USD54,384) for a single chamber pacemaker (PM), to AUD140,103 (USD94,248) for a dual chamber Implantable Cardioverter-defibrillator (ICD). Modeled costs of CIED infection were slightly lower in the public sector (AUD73,643-AUD88,446 (USD49,555 – USD59,516) for the same devices).
Conclusions: The cost of a CIED infections to the healthcare system is high and differs by device type. Utilizing local real-world data to

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estimate costs will improve accuracy of economic evaluations and reduce uncertainty for decision makers.

PP50 Early Diagnosis Effect Of Newborns With Critical Congenital Heart Disease Using National Health Insurance Data In South Korea

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Introduction: Critical congenital heart disease (CCHD) refers to a group of heart defects that cause serious, life-threatening symptoms in the neonatal period and requires timely surgical or catheter interventions. We tried to explore current status of CCHD burden and the effect of early diagnosis of CCHD to mortality using the Korean national health insurance (NHI) data.
Methods: We analyzed the national health insurance (NHI) data from 2014 to 2018. We identified CCHD patients using the diagnosis codes and intervention codes from the claim data and the prevalence, mortality and medical expenditure of CCHD were analyzed. We linked neonatal data with their mother's medical claim data and developed retrospective cohort data set for analyzing the effect of early diagnosis to mortality and related outcomes of CCHD treatment.
Results: The annual prevalence of neonatal CCHD in Korea was 0.144% percent. A total of 2,241 CCHD neonates, 1,546 (69.0%) underwent cardiac ultrasound within three days after birth, and mothers of 419 neonates had a record of prenatal fetal ultrasound (18.7%). In our comparison of neonates diagnosed with CCHD within three days of birth with those diagnosed with CCHD on or after day 4 of birth, the probability of early diagnosis increased for preterm infants and infants with low birth rate. Regarding mortality rate, most types of CCHD showed a significantly higher mortality rate in the early diagnosis group.
Conclusions: The reason for the high mortality rate despite a high early diagnosis rate pertains to the high percentage of patients with severe conditions that induce a serious heart rate within three days of birth. More than half of the neonates with CCHD were found to have not undergone a prenatal fetal ultrasound, rendering this an important policy target.

PP52 Will Joint European Health Technology Assessment Provide Additional Benefits Over Individual Country-wise Assessments?

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Introduction: In December 2021 the European Union (EU) Health Technology Assessment (HTA) Regulation, a key pillar of the EU Pharmaceutical Strategy, was adopted by the Council and the European Parliament. The focus areas of Joint HTA Cooperation include Joint Clinical Assessments (JCA), Joint Scientific Consultations (JSC), and joint early-stage horizon scanning. The European HTA regulation will be adopted in a stepwise approach and from 2030 onwards, all products (drugs, high-risk medical devices, and in vitro diagnostics) approved in all indications will be subjected to JCA in EU.
Methods: A targeted literature research was performed for policies and the European Network for HTA (EUnetHTA) methodological guidelines describing the HTA methods including scoping process, comparators, endpoints, the applicability of evidence, and validity of clinical studies. Additionally, the anticipated opportunities and challenges were also summarized with respect to these methods.
Results: EUnetHTA put forward a timeline for different activities over the next three years as part of the new EU HTA Regulation, including key deadlines for ongoing EUnetHTA consultations on the processes and methods. EUnetHTA will set up a new ecosystem across the EU as it aims to reduce duplication and time to access by supplementing multiple national clinical assessments with a joint central assessment. In any case, assessment of added value and pricing and reimbursement decisions will still occur at the national level.
Additionally, EU HTA may promote harmonization of processes, standards, and evidence requirements, which will increase predictability and simplify evidence requirements. However, differences in clinical practice, standard of care, and national priorities may lead to assessments that are not generalizable to all Member States.
Conclusions: The joint EU HTA cooperation will benefit countries which have less developed or do not have established HTA expertise or infrastructure. However, the JCA process could result in increased requirements for clinical evidence generation as relative effectiveness and relevance of outcomes to patients gain further importance for products to successfully gain access across countries.

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