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.

https://doi.org/10.1017/S0266462323001964 Published online by Cambridge University Press