Conclusions. At a societal WTP of THB 160,000 per QALY gained (USD 5,197 per QALY gained), dolutegravir for HIV patients resistant to first- and second-line ARTs in Thailand was found to be not cost-effective.

PP14 Budget Impact Of Sapropterin Dihydrochloride For Phenylketonuria

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Introduction. The National Committee for Health Technology Incorporation (CONITEC) evaluates health technologies to recommend their inclusion or exclusion within the Brazilian Public Health System (SUS), and uses the budget impact assessment to estimate costs to the system. The Ministry of Health (MS) guideline recommends treatment of phenylketonuria (PKU) with restricted phenylalanine diet and phenylalanine-free amino acid formula (PFAAf) supplementation. CONITEC evaluated the inclusion of sapropterin dihydrochloride for PKU in the SUS.

Methods. The population eligible for treatment was evaluated by the number of patients receiving PFAAf between 2014 and 2017 registered in the SUS. Patients were stratified by age/weight and a simple linear regression was performed to estimate the future population. The costs of treatment and testing the responsiveness of sapropterin dihydrochloride were estimated according to the recommended dosage guideline of the MS, leaflet and public purchasing prices. A univariate deterministic sensitivity analysis was performed to evaluate different prices, responsiveness test methods and variations in the reduction of formula use.

Results. The incorporation of sapropterin dihydrochloride would generate an incremental budget impact in the SUS of around BRL 79 million (USD 21.7 million) in 2019 and BRL 300 million (USD 82.1 million) in five years (2019-2023). The univariate sensitivity analysis estimated that the incremental budget impact could be between BRL 66 and BRL 103 million (USD 18 and USD 28 million) in the first year and between BRL 251 and BRL 388 million (USD 69 and USD 106 million) in five years. Sensitivity analysis showed that the price of sapropterin dihydrochloride was the most sensitive variable in the model.

Conclusions. The incorporation of sapropterin dihydrochloride in the SUS represents a significant budgetary impact and covers a small number of patients. Sapropterin dihydrochloride was recommended by CONITEC for the treatment of women with PKU, with a positive drug responsiveness test, and who are in the preconception period or in the gestational period.

PP20 Challenges In The Health Technology Assessment Of New/Emergent Non-Pharmacological Technologies

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Introduction. The methodological guides for the assessment of new/emerging non-pharmacological technologies differ from the traditional health technology assessment (HTA) guidelines developed by the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). The aim of this study is to identify the special features and challenges of carrying out HTA on new/emergent non-pharmacological technologies.

Methods. The application of traditional and new/emergent HTA guidelines is compared along the consecutive evaluation phases in four practical cases carried out at the Agency for Health Quality and Assessment of Catalonia (AQuAS) in 2017-2018.

Results. Main learning and outstanding challenges: (i) Instead of following a defined protocol, the evaluations are carried out from a preliminary short report which generates a lack of justification and delimitation of its scope. (ii) References' identification and data extraction are often limited due to lack of studies, and sometimes require the use of grey literature or other sources less informative, for example, trial registries. It can be challenging to exclude references related to other indications. (iii) The assessment of resource use and costs of running the technology is complicated due to the lack of public prices information and specific impacts of use. (iv) The evidence considered during the assessment usually does not meet high quality requirements (risk of bias) because of indirect evidence, lack of comparator or no having clearly defined outcomes, among others. (v) It's difficult to draw conclusions and, consequently, recommendations due to abovementioned aspects and especially for the usual evidence gap that faces this type of technology in early stages of diffusion and/or in a competition situation of manufacturer companies.

Conclusions. The most recent innovation in non-pharmacological technologies merits a differentiated assessment approach. However, there is need to reconsider the methodology applied in order to overcome the challenges and limitations identified.

PP21 High Risk Class Medical Devices Evaluation In Germany: Another Arzneimittelmarkt-Neuordnungsgesetz?

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Introduction. In 2011 the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) evaluation process for new drugs was implemented in Germany. Since then, the evidence requirements follow high standards and results impact reimbursement price negotiations. More recently, in 2016, a legal norm (§137h SGBV) to evaluate new treatment and diagnostic methods (MDs) of high risk classes by the Federal Joint Committee (G-BA) was introduced. The requirements, involved stakeholders, timing and results for both processes are outlined and compared.

Methods. Methodological guidelines from G-BA and Institute for Quality and Efficiency in Health Care (IQWiG), consultations and evaluations for MDs according to §137h and for drugs according to AMNOG were reviewed and compared. Published assessment results were analyzed according the decision criteria and impact on price negotiations with Statutory Health Insurance.

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Results. Hospitals need to submit jointly with the manufacturer comparative evidence on clinical efficacy, safety and cost when applying for additional compensation (Neue Untersuchungs- und Behandlungsmethoden [NUB] application) for new high risk class MDs being subject to §137h. A fast track assessment by IQWiG/G-BA follows within four months resulting in benefit proven, potential benefit or no benefit compared to alternatives. The latter can lead to exclusion from reimbursement. Until now one MD was granted a benefit, two treatments were assigned a potential benefit and six MDs no benefit, while 55 percent of drugs evaluated under AMNOG were granted an additional benefit. Compared to drugs, the required evidence for MDs is similar. Whereas assessment time is shorter, manufacturers can seek advice from G-BA upfront for free and need to collaborate closely with hospitals.

Conclusions. Half of MDs examined did not qualify for an assessment under §137h. Unlike for drugs evaluated under AMNOG, the majority of new MDs failed to be granted potential benefit as a treatment alternative and might be excluded from reimbursement. Manufacturers are challenged to generate high quality, comparative evidence within their studies.

PP26 Shift From Regional To Federal Funding: Methodological Considerations

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Introduction. Australia has a two-tier public funding system, and many genetic tests are funded by different states and territories prior to being considered for public funding by the Federal government. In this context, health technology assessments (HTAs) of genetic tests for heritable conditions are problematic. We aimed to discuss the possible impacts on HTA methodology of a shift from regional to federal funding for genetic testing for heritable conditions.

Methods. Several HTA reports and economic models on genetic tests considered by the Medical Services Advisory Committee (MSAC) were reviewed and compared to 'real world' clinical practice.

Results. Every HTA of germline testing performed for the MSAC have so far compared genetic testing versus no genetic testing. However, testing for BRCA1/2 for patients with breast cancer currently occurs in Familial Cancer Centres, and testing for germline mutations for familial hypercholesterolaemia currently occurs through specialist lipid clinics. In both settings, the index patient and family members are given multidisciplinary support, including genetic counselling. The HTA comparison therefore did not reflect what the true clinical and cost-effectiveness impact of federal funding would be. Federal funding means that tests may be ordered by a broader range of specialists or general practitioners. The evidence identified was predominantly sourced from specialised centres, where knowledge regarding how to interpret the tests is high. The clinical utility of these tests largely depended on how clinicians understood and conveyed the results.

Conclusions. The benefit of testing may have been overestimated due to the comparator and setting used (i.e. specialised and centralized care, associated with high clinical utility). Any HTA of genetic testing for heritable conditions, which could result in a shift in the delivery of testing or care for the patient, should consider the applicability of the evidence identified. Further, it should assess the subsequent impact this may have on the effectiveness and cost-effectiveness of the test and the quality of care provided for patients and their family.

PP27 Additional Capabilities In Health Technology Assessment To Support Decision Making

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Introduction. Decision-making regarding an open or a closed fluid waste management system (FWMS) in the planning of thirty operating rooms (ORs) of a new hospital at the CHU de Québec-Université-Laval was an opportunity to explore additional capabilities in health technology assessment (HTA) to support evidence-based planning.

Methods. Issues related to FWMSs in ORs were assessed from multiple data sources including: (i) systematic review in indexed database and grey literature, (ii) waste management laws and regulations, (iii) local registry of reported incidents/accidents, (iv) occupational health and safety database, (v) electronic patient records (EPRs), (vi) field evaluation of two closed FWMSs, (vii) costs, and (viii) survey on FWMSs in ORs of other Quebec hospitals.

Results. Closed FWMSs in ORs could reduce health care professional exposure to blood and body fluids (BBF) according to two low-quality studies. Cases of occupational and patient exposure to BBF with closed FWMSs, some of which had severe issues, were reported to the U.S. Food and Drug Administration. Depending on the volume, discharge of BBF to the sanitary sewer may be authorized upon the approval of the competent municipal authorities. Compared to an open system, a closed FWMS has the potential to reduce manipulation of canisters during the cases because of large canister capacity (24 L). However, local data showed that BBF and irrigation fluid amounts in ORs are <2 L in 84 percent of cases and >2 L in a minority of surgeries, whereas a closed FWMS is associated with higher costs for BBF volumes <12 L. Other issues were observed during field evaluation (e.g., occupational noise). Closed FWMS implementation in other hospitals was very limited in the survey.

Conclusions. Available evidence does not support the widespread use of a closed FWMS. Use of mixed-methods in this particular HTA allowed to assist decision makers on the choice of an FWMS in the OR planning.

PP28 Adoption Of Non-Pharmaceuticals In Galicia: Beyond Conventional Health Technology Assessment

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