Introduction. To inform the development of a national clinical guideline for Chronic Obstructive Pulmonary Disease (COPD), prioritized by the National Clinical Effectiveness Committee in Ireland, a systematic review was conducted to examine the cost-effectiveness of pulmonary rehabilitation programs (PRPs), outreach programs (OPs), and long-term oxygen therapy (LTOT), compared with usual care.

Methods. Medline, Embase, the Cochrane Library and grey literature sources were searched up to 19 June 2018. Studies evaluating cost-effectiveness published post-2008 in English were included. Screening, data extraction, and quality assessment using the Consensus Health Economic Criteria and International Society for Pharmacoeconomics questionnaires were conducted independently by two reviewers. Costs were converted to 2017 Irish Euro using consumer price indices for health and purchasing power parity.

Results. From 8,661 articles identified, seven studies (one comparing both PRPs and LTOT) were included (PRPs: five; OPs: one; LTOT: two). PRP cost-utility analyses (n = 4) reported conflicting results due to considerable heterogeneity in program and study design, with incremental cost-effectiveness ratios (ICERs) ranging between EUR 12,391 and EUR 509,122 per quality adjusted life-year (QALY) gained. The remaining study investigated hospitalizations avoided and found outpatient and community-based PRPs to be dominant, while home-based PRP produced an ICER of EUR 1,913. OPs were found to be less costly, but also less effective. However, the results of the underpinning trial were neither statistically nor clinically significant. LTOT was found to be cost-effective, with ICERs of EUR 17,603 and EUR 26,936 per QALY gained.

Conclusions. Applying a willingness-to-pay threshold of EUR 45,000 per QALY gained, this systematic review found that, compared with usual care, there is inconsistent but generally favorable evidence for PRPs, no clear evidence for the cost-effectiveness of OPs, and that LTOT is likely to be cost-effective. However, there was a lack of methodologically robust studies included in the review and most were not directly transferable to the Irish context.

PP10 Quality Of Reporting Economic Evaluations In Rehabilitation Research

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Introduction. Economic evaluations are a growing field of interest in the rehabilitation area. Research has questioned the quality of reporting of health economic evaluations. Poor reporting hinders the ability to provide accurate information for health care decision making. Therefore, the objectives of this study are to document on overall reporting quality of the published literature for rehabilitation economic evaluations; to identify if reporting quality has improved in health economic evaluations within the field of rehabilitation therapy since the publication of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS); and to identify factors that could influence the reporting trends.

Methods. We searched databases for economical evaluations performed in the rehabilitation area published between 2013 and 2018. Study selection was performed by two independent reviewers using Covidence software. Data extraction was conducted by one reviewer using Microsoft Excel and independently verified by another reviewer. The quality of reporting was evaluated independently by two reviewers using the CHEERS checklist.

Results. The search of the literature resulted in a total of 2195 published articles. Of these, 117 were considered to be potentially relevant. Independent review of these 117 articles led to the inclusion of 88 articles. This study is ongoing and complete results will be presented at the conference. Fifty papers have been analyzed in full. In general, the quality of reporting of the economical evaluations in the rehabilitation field was poor. The total mean and median for the CHEERS checklist was 17 points (out of 25) (range 8-24). Most of the analyzed studies did not report important methodological features of the economical evaluation as evaluated by the CHEERS checklist.

Conclusions. The quality of reporting of economic evaluations in the rehabilitation field is poor and inconsistent. Commonly the methods of the analyzed studies are under reported, thereby creating challenges in determining whether the information presented is sound.

PP12 Cost-Utility Analysis Of Dolutegravir For HIV-1 Infection In Thailand

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Introduction. HIV drug resistance (HIVDR) has significantly increased in Thailand. However, a new generation integrase inhibitor, dolutegravir, has not yet been included in the country's National List of Essential Medicines (NLEM). Since these drugs are high in costs, an economic evaluation is needed to support the decision. This study aims to assess the cost-utility analysis of dolutegravir for HIV-1 infection in Thailand.

Methods. A Markov model was developed to evaluate the cost-utility as follows: (i) the current practice of darunavir/ritonavir (DRV/r) + tenofovir (TDF) + lamivudine (3TC); (ii) DRV/r + etravirine (ETR) + TDF + 3TC; (iii) DRV/r + raltegravir (RAL) + TDF + 3TC; (iv) DRV/r + RAL + ETR; and (v) DRV/r + RAL + maraviroc (MVC); (vi) DRV/r + dolutegravir (DTG) + MVC; (vii) DRV/r + DTG + ETR; (viii) DRV/r + DTG + TDF + 3TC. The model incorporated cost data adjusted for 2017 using the consumer price index, and effectiveness data from a review of published studies. Outcomes were measured in life years, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratios (ICERs), and future costs and outcomes were discounted at 3 percent per annum. Finally, a probabilistic sensitivity analysis was conducted to deal with uncertainties around the parameters.

Results. All alternative treatment regimens for HIV patients resistant to first- and second-line antiretroviral therapies (ARTs) in Thailand were found to be not cost-effective at the willingness-to-pay (WTP) of THB 160,000/QALY (USD 5,197/QALY). However, the eighth regimen of DRV/r + DTG + TDF + 3TC had the lowest lifetime cost at THB 5.3 million (USD 172,145) while increasing QALY by approximately 14 QALYs.

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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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