Introduction. A health technology assessment (HTA) process to evaluate the best intensive care ventilator manufacturers has been carried out in different pediatric intensive care units (ICUs) of Bambino Gesù Children's Hospital (OPBG). The purpose of this study is to determine: (i) the most relevant features of a ventilator to be considered between different manufacturers, and (ii) the methodology to conduct the assessment to support the decision-making process about the choice to adopt the suitable technology for OPBG.

Methods. The decision-oriented HTA method (Do-HTA), developed by the HTA unit of OPBG, was applied to conduct the assessment. Do-HTA involves the integration of the European Network for HTA (EUnetHTA) CoreModel and the Analytic Hierarchy Process with the support of an informatics tool. It provides the definition and numerical evaluation of assessment parameters to evaluate the performance of technologies. A literature review involving ICU professionals was used to define and weight the assessment elements on clinical, technical, organizational, economic, and safety domains. In particular, a subgroup of these domains has been included in a checklist for the comparative evaluation of different ventilator models, each of which was tested in three independent runs performed in three different ICUs.

Results. Results show that safety and clinical effectiveness had highest the impact within the evaluation, followed by organizational, technical and economic aspects. A percentage value per each ventilator has been assigned, representing the global performances regarding the assessment elements.

Conclusions. This study presents and discusses the benefits and drawbacks of innovative features of ventilators, all characteristics to be taken into account during the evaluation process and a methodology to conduct it. The project identified the best performing ventilator model through a collective decision, giving a reliable recommendation to the Hospital Decision Makers.

PP182 Natalizumab Therapy For Relapsing-Remitting Multiple Sclerosis

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Introduction. Multiple Sclerosis is a progressive, degenerating disease of the central nervous system (CNS), which affects more than 2.5 million people worldwide. The monoclonal antibody natalizumab (TysabriTM) has been approved by the European Medicines Agency in 2006. Yet, the treatment is associated with an increased risk of developing progressive multifocal encephalopathy (PML). The aim of the systematic review was to investigate whether natalizumab is more effective and safer than alternative pharmacological therapies or placebo over a prolonged period (≥ 36 months) with respect to annualised relapse rate (ARR), disability progression, quality of life and number of serious adverse events (SAEs).

Methods. A systematic literature search was conducted considering randomized controlled trials (no restriction in length) and prospective, non-randomized controlled trials. In terms of safety, prospective single arm studies were additionally included. The risk of bias (RoB) was assessed using the Cochrane RoB tool (RCT), the ROBINS-I tool (NRCT) and the Institute of Health Economics quality appraisal checklist (IHE-20) for case series (single-arm studies). The quality of evidence was determined using the GRADE-method (Grading of Recommendations, Assessment, Development and Evaluation).

Results. For the assessment of clinical effectiveness, three studies (one RCT and two NRCTs) met the inclusion criteria. No significant differences regarding the ARR and disability progression were detected, if natalizumab was compared to an alternative treatment with fingolimod. Yet, if compared to placebo or a group of natalizumab interrupters, a 70 percent reduction in the ARR was observed. For the assessment of safety, seven studies met the inclusion criteria. The proportion of patients suffering from SAEs ranged from 2.4 percent to 16.0 percent. In total, 35 cases of PML occurred. The results were supported by a very low quality of evidence.

Conclusions. Future research should provide more head-to-head RCTs comparing natalizumab with other disease modulating drugs along with a comprehensive documentation of adverse events.

PP185 Clinical Papers: Which Are Ongoing Studies To Assess MHealth In 2020?

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Introduction. Mobile health systems (MHS) are one of the more spreading technologies in the field of medicine. However, identification of useful MHS is rather challenging. Few of them are, or could be, connected medical devices (cMD). Like other medical devices, cMD must be assessed to validate claimed benefits for reimbursement purposes. Clinical added value demonstration is a major criterion used to satisfy administrative requirements. With the increase of clinical studies that are including MHS, study registries can be used for insight into the type of evidence expected to become available in the near future.

Methods. In 2018, the French National Authority for Health (HAS) performed a review of registered MHS clinical study designs. The Clinicaltrials.gov database was consulted for all studies indexed with the terms "mHealth" and "mobile health" for the search fields "study title", "conditions" and "interventions".

Results. Four hundred and fifteen clinical studies were registered. Three hundred and eighty studies were interventional with most comprised of a randomized study design (75 percent). Fifteen had a crossover design. Only few observational studies (n = 35) were registered. These mainly concerned (59 percent) patient use of an app on a smartphone without any other device.

Conclusions. Patterns of clinical studies were not found to significantly differ between MHS and other medical devices. Most of the clinical studies were randomized and specific criteria to assess MHS could easily be identified. However, specific methodologies for clinical development are not used in practice for cMD health technology assessment. In the absence of validated and specific methodology for clinical development, current methods that are

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