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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being used in these ongoing studies will nonetheless be generating evidence for the upcoming years.

PP186 Telemonitoring With Pacemakers For Patients With Heart Failure

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Introduction. Evidence supporting the use of pacemakers is well established. However, evidence about the optimal use of pacemaker telemonitoring for disease management in heart failure is not. Health Technology Wales (HTW) held a national adoption event to encourage implementation and best practice in use of pacemaker telemonitoring in the National Health Service (NHS) Wales to improve patient outcomes in heart failure.

Methods. Multi-stakeholder national adoption workshop using a mixture of expert presentations, case studies and interdisciplinary group and panel discussions to agree key actions to understand the value and promote optimal use of pacemakers for remote disease monitoring in patients with heart failure in Wales.

Results. The workshop was attended by forty-five senior professionals with an interest in improving care of patients with heart failure. Actions to progress included: providing a centralized Welsh system to support technical issues that arise with telemonitoring; considering interoperability with other NHS Wales systems; encouraging value-based procurement with collection of a core outcome set; agreeing implementation issues with both professionals and patients; audit to understand experience, resource use and outcomes; and sharing manufacturer evidence on the accuracy of telemanagement algorithms. It was suggested that these actions be progressed via an All-Wales multi-stakeholder approach, led by the Welsh Cardiac Network.

Conclusions. Developing a more agile, lifecycle approach to technology appraisal is currently advocated; recalibrating the focus from technology assessment to technology management across the complete technology lifecycle. HTW will endeavour through regular adoption events to facilitate such a paradigm shift that aims to understand value and optimise use of evidence-based technologies.

PP187 Robotic Surgery, Any Updates?

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Introduction. This work aims to update the previous robotic surgery health technology assessment (HTA) study conducted in 2013 in Bambino Gesù Children's Hospital. The study, focused on the evaluation of the newest evidence that have emerged over the last three years, aims to identify if there are new perspectives and advantages of introducing this technology in the hospital.

Methods. Decision-oriented HTA (DoHTA) method was applied to conduct the assessment. It involved the integration of the European Network for HTA Core Model® (version 3.0) and the analytic hierarchy process providing the definition and the numerical evaluation of assessment parameters through which it is possible to evaluate the performance of the technologies compared. Three years after the first technology's evaluation, an updated literature review was conducted, using the same 2013 key words, to identify changes in the indicators' performance score. The performance values have been updated through a quantitative and qualitative evaluation of data gathered from the literature review, expert opinion and context analysis. The global weights' system, developed in 2013, has not been updated because the relative importance of each domain remained unchanged. The performance values of safety, efficacy, costs, and social aspects have been estimated, identifying the differences in terms of percentage values in comparison with the previous study.

Results. Results showed a slight improvement on safety and organizational aspects in robotic surgery; however, clinical effectiveness and economic, social and legal aspects remained unvaried. More specifically, it has been registered a 3 percent reduction of the difference of the distance between robotic and laparoscopic performance values (2013: 14, 15 percent; 2017: 11, 29 percent).

Conclusions. Results highlighted a slight improvement in robotic surgery performances even if it confirmed the previous results for which the laparoscopic system outperformed the others and currently is keeping the best performance techniques. Finally, sensitivity analysis and a Monte Carlo simulation were carried out proving the stability and reliability of the solution.

PP189 Filling In The Blanks: Is RWE From MAAs Used In NICE Decision Making?

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Introduction. The National Institute for Health and Care Excellence (NICE) may recommend temporary funding through managed access agreements (MAAs) for oncology drugs (via the Cancer Drugs Fund [CDF]) and highly specialized therapies for rare diseases. MAAs allow for the collection of evidence to address key areas of clinical uncertainty, while providing access of medicines to patients, prior to re-appraisal by NICE. Observational data and other real-world evidence (RWE) are crucial requirements for all MAAs and herein we examine the extent these data are being used to inform HTA decisions at re-appraisal.

Methods. Existing MAAs entered into between the National Health Service (NHS) England and manufacturers as of 30 October 2018 were identified; for drug:indication pairings with NICE re-appraisals, all information was reviewed and the key data extracted.

Results. Of the twenty-two MAAs identified, only two drug: indication pairings have been subsequently re-appraised by NICE: BV(brentuximab vedotin):non-Hodgkin lymphoma ('recommended') and pembrolizumab:relapsed or refractory classical Hodgkin lymphoma ('recommended'). Data from a retrospective questionnaire regarding the proportion of patients that received

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