

2018). We used a linear regression model to examine the relationship between frequency of optimizations and time.

**Results.** In total, 357 STAs outcomes were identified, 55 percent were recommended and 26 percent were optimized. The proportion of optimized recommendations increased over time vs all other outcomes ( $p = 0.01$ ), with more technologies being optimized over time ( $p < 0.01$ ).

**Conclusions.** The results indicate an increasing trend by NICE towards maximization of value through approval of drugs in select groups of patients. From a manufacturer's perspective, prediction of such outcomes at an early stage is fundamental for investment purposes and to maximize financial returns. An early stage model provides a framework to examine these issues as well as identifying data gaps, where real world evidence can be planned to support the value argument for products, and to inform clinical trial design through value of information analysis.

## PP177 Health Preference Research In Europe: A Review Of Its Use

Kevin Marsh, Axel Mühlbacher ([igm@hs-nb.de](mailto:igm@hs-nb.de)), Janine van Til, Christin Juhnke, Yookyung Christy Choi, Alejandra Duenas, Wolfgang Greiner, Kara Haas, Natalia Hawken, Mickael Hiligsmann, Kimberley Hockley, Ilya Ivlev, Frank Liu, Elizabeth Molsen-David, Elisabeth Oehrlein, Jan Ostermann and Thomas Poder

**Introduction.** Health Technology Assessment (HTA) and regulatory decisions involve value judgements. As patient groups, industry, and regulatory agencies conduct more preference studies to quantify these judgements, a better understanding of the methods and practices is needed. Currently, there is no systematic mapping of the use of preference data in Europe. This study aimed to identify (i) the use of quantitative preference data by all relevant HTA bodies and regulatory authorities of the European Union (EU) member states, and (ii) key standards and guidelines.

**Methods.** This study used a mixed method approach based on a systematic literature review, survey and subsequent interviews with decision makers and experts.

**Results.** A total of 62 survey responses were received. Many respondents reported that their agencies were responsible for supporting more than one type of decision, with 69.0 percent supporting approval decisions, 64.3 percent supporting reimbursement decisions, 61.9 percent supporting pricing decisions, and 64.2 percent supporting guideline development. Respondents reported that their agencies supported these decisions in multiple ways: 78.6 percent by assessing health technologies; 54.8 percent by appraising health technologies; 45.2 percent by compiling an HTA report; 7.1 percent by conducting primary research; 9.5 percent by conducting secondary research. More than 40 percent (42.9 percent) of agencies had the final say on one of the decisions of interest – approval, reimbursement, or pricing. Of the 31 countries studied, 71 percent ( $n = 22$ ) used quantitative preference data in their reimbursement and pricing decisions. Of those, 86 percent ( $n = 19$ ) used general population

preferences to inform the estimation of quality-adjusted life years (QALY) as part of cost utility analysis.

**Conclusions.** Much of this use of preference data can be understood within the standard framework of economic analysis adopted by many HTA agencies; either in the form of: standard ways to estimate QALYs; ways to broaden the impacts of technologies captured in the QALY; or ways to weigh health gain with other decision-making criteria, such as disease severity or innovativeness.

## PP178 Health Technology Assessment Of Laboratory Medicine

Roxana Di Mauro ([roxana.dimauro@opbg.net](mailto:roxana.dimauro@opbg.net)), Francesco Faggiano, Martina Andellini, Pietro Derrico and Matteo Ritrovato

**Introduction.** Recent studies have investigated the re-organization and automation of laboratory medicine as a challenge for the hospital in terms of reduction of costs, turnaround time, workload, optimization of human and technological resources and improvement of safety. The purpose of this study was to conduct a health technology assessment (HTA) evaluation process about the possibility to re-organize and automate laboratory medicine at Bambino Gesù Children's Hospital.

**Methods.** The decision-oriented HTA (Do-HTA) method, involving the integration of the European Network for HTA (EUnetHTA) CoreModel and the Analytic Hierarchy Process, was applied to assess the best technology solution. Twenty-one professionals were involved to define tender specifications related to the adaptation works of the new dedicated rooms, and the automatic technologies and organizational solutions for the new laboratory department. Finally, two manufacturer companies were consulted.

**Results.** Using Do-HTA, the study was focused on laboratory technologies while the infrastructure evaluation was conducted by the Engineering and Logistic Units of the hospital. Results showed that the total performance score of the first proposal was slightly higher (2.5 percent) than the second one, proving the comparable high qualitative level of both manufactures technologies. After an accurate analysis, evaluating all aspects (safety, clinical efficacy, cost, organization & technical criteria) and integrating the infrastructure evaluation, the decision has fallen upon the first company offer.

**Conclusions.** This HTA project provided an in-depth examination of two proposed technological and organizational solutions. Thanks to the Do-HTA method, which produced and developed data and all needed information, it was possible to guide and assist the decision makers on the choice between the two technical solutions.

## PP179 Health Technology Assessment Of Pediatric Intensive Care Ventilators

Roxana Di Mauro ([roxana.dimauro@opbg.net](mailto:roxana.dimauro@opbg.net)), Francesco Faggiano, Martina Andellini, Pietro Derrico and Matteo Ritrovato

**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

Eva Fuchs ([eva.fuchs@hta.lbg.ac.at](mailto:eva.fuchs@hta.lbg.ac.at))

**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 (Tysabri™) 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 ( $\geq 36$  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?

Cyril Olivier ([c.olivier@has-sante.fr](mailto:c.olivier@has-sante.fr)), Estelle Piotto, Corinne Collignon, Hubert Galmiche and Chantal Bélorgey

**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