aimed to evaluate the cost utility of TAVI, compared with clinical treatment, in patients with inoperable severe aortic stenosis from the perspective of the Brazilian public health system.

Methods. A Markov model with monthly cycles and a five percent annual discount rate was constructed. A five-year time horizon was chosen, to minimize the uncertainties inherent with data extrapolations, based on the only randomized head-to-head trial, Placement of AoRTic TraNscathetER Valve Trial (PARTNER B). All costs were obtained from Brazil's official healthcare data. Utilities for clinical treatment 0.6 (range 0.56–0.63) and TAVI 0.71 (range 0.69–0.72) were based on studies that used the EuroQol-5D instrument. TAVI's utility measures were penalized by 25 percent in the first month, based on the estimate of the procedure's impact on quality of life provided by the National Institute of Health and Care Excellence in the United Kingdom. Lastly, deterministic and probabilistic sensitivity analyses were used to evaluate the robustness of the results.

Results. The incremental cost-effectiveness ratio was USD35,880 per quality-adjusted life-year (QALY), a result that was mainly sensitive to TAVI's cost in the univariate analysis. In the probabilistic analysis, all values were above the reference willingness-to-pay threshold of three times the Brazilian per capita gross domestic product (USD18,042 per QALY).

Conclusions. In conclusion, even though there is no established willingness-to-pay threshold in Brazil, the cost of TAVI may represent an obstacle for its incorporation into the Brazilian public health system.

PP205 The Use Of Real-World Evidence To Support National Institute For Health And Care Excellence Medical Technology Submissions

Scott Gibson (scott@coreva-scientific.com), Sita Saunders, Maximilian Blüher, Amanda Hansson Hedblom, Rafael Torrejon Torres and Rhodri Saunders

Introduction. Although randomized controlled trials (RCTs) are recognized as providing the highest level of clinical evidence, few medical device RCTs are available due to underfunding or inherent challenges associated with trial design. This study examines the extent to which real-world evidence (RWE) supports the recommendations made by the National Institute for Health and Care Excellence Medical Technologies Evaluation Programme (MTEP).

Methods. All MTEP guidance documents published online prior to October 2020 were reviewed. The "case for adoption" recommendation, type of clinical data, and clinical critiques for each MTEP submission were extracted and categorized. RWE was defined as studies with neither blinding nor prospective selection or control of patient characteristics.

Results. Of the MTEP submissions reviewed, 34 of 45 (76%) received a positive recommendation. Independent of outcome, all submissions included RWE, but only 19 (42%) utilized RCT evidence (15 were recommended and four were not). Meta-analyses of RWE were used whenever possible. The most common clinical critiques in unsuccessful submissions were the following: (i) not generalizable to the United Kingdom National Health Service (NHS); (ii) low quality; (iii) likelihood of bias; (iv) trial design faults; (v) uncertain benefit; and (vi) evidence unrelated to scope.

Conclusions. This study suggests that while the use of RCTs has not always led to a positive recommendation, RWE can be valuable in decision-making. Evidence that is generalizable to the NHS, is related to the scope, and shows clear indication of benefit is more likely to positively influence MTEP decision-making.

PP206 Health Technology Assessment Guidance In The United Kingdom: Addressing Issues Specific To Medical Devices

Scott Gibson (scott@coreva-scientific.com), Sita Saunders, Amanda Hansson Hedblom, Maximilian Blüher, Rafael Torrejon Torres and Rhodri Saunders

Introduction. The United Kingdom spends approximately GBP4.2 billion (USD5.6 billion; EUR4.7 billion) each year on medical devices, but healthcare providers receive little health technology assessment (HTA) guidance on cost-effective device procurement. Our objective was to assess the availability of HTA guidance for medical technologies and to identify key challenges related to the economic assessment of these technologies.

Methods. National Institute for Health and Care Excellence technology appraisal (TA) and Medical Technologies Evaluation Programme (MTEP) appraisals published online between November 2009 and October 2020 were identified. The "case for adoption" recommendation, type of devices, and critiques of economic analyses for each MTEP appraisal were extracted and categorized.

Results. In comparison to 415 publicly available TAs for pharmaceuticals, only 45 medical technologies have been appraised through the MTEP. MTEP-submitted technologies can be categorized into diagnostic (7), monitoring (3), prophylaxis (5), therapeutic (28), and other (2). Furthermore, 11 were implants, seven were used by patients, and 27 had provider interaction. Major points of MTEP criticism were a failure to model cost consequences, training costs, and organizational impact. There was also the barrier of transferring costs across budgeting divisions.

Conclusions. In comparison to HTA guidance for pharmaceuticals, there is a dearth of medical device guidance. Therapeutic and implantable devices appear to be disproportionately overrepresented in the MTEP process. This may be because their appraisal is most akin to pharmaceuticals, for which HTA processes are well established. To encourage more HTAs of medical devices, HTA guidance should elaborate on issues specifically related to medical devices.

https://doi.org/10.1017/S0266462321001306 Published online by Cambridge University Press