

the most affected dimension of the CarerQoL-7D was physical functioning.

Conclusions. Caring for people with drug-resistant FOS has a negative impact on the QoL of caregivers, particularly in the domains of self-care and physical functioning.

PP180 Optimal Treatment Sequence For Targeted Immune Modulators For The Treatment Of Moderate To Severe Ulcerative Colitis

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Introduction. Several targeted immune modulators (TIMs) have demonstrated effectiveness in moderate-to-severe ulcerative colitis, including adalimumab, golimumab, infliximab, infliximab biosimilars, tofacitinib, ustekinumab, and vedolizumab. In addition to assessing individual TIMs, evaluating TIM sequences can inform clinical care as well as coverage and reimbursement policies. Our objective was to identify optimal treatment sequences based on maximum net health benefit (NHB), lowest total cost (cost minimizing), quality-adjusted life-year (QALY) maximization, or convenience (avoidance of intravenous treatments), and to evaluate their cost effectiveness compared with conventional treatment from the health sector perspective.

Methods. We developed a Markov model with eight-week cycles and a lifetime time horizon. The health states were active, clinical response without remission, remission, and death. TIM efficacy was informed by a network meta-analysis conducted by the Institute for Clinical and Economic Review. Sequences were generated by ranking TIMs and then conventional treatment according to NHB, cost minimization, QALY maximization, or convenience and combining top ranked TIMs in the biologic naïve and biologic experienced populations. NHB was calculated at USD 150,000 per QALY. Probabilistic sensitivity analysis (PSA) was undertaken to estimate the probability of each sequence having the highest NHB rank, QALY maximizing rank, and cost-minimizing rank.

Results. Twenty-one sequences were evaluated. The sequence with the highest NHB was infliximab followed by tofacitinib (-0.12 QALYs), which also had the lowest incremental costs (USD37,266). For orally and subcutaneously administered TIMs, the sequence of golimumab-tofacitinib had the highest NHB (-0.34 QALYs). Ustekinumab-vedolizumab was not only the top ranked sequence as measured by QALY maximization (0.172 incremental QALYs), but it also had the highest total incremental cost (USD166,094). Results of the PSA were consistent with deterministic rankings for the top-ranking sequences and showed that the top two or three regimens were close in magnitude.

Conclusions. The optimal sequence with regard to NHB and cost minimization was infliximab or biosimilars, followed by tofacitinib, adalimumab, or vedolizumab. Sequences that generated the most QALYs began with ustekinumab, followed by vedolizumab, tofacitinib, and adalimumab.

PP184 Twenty Years of Health Technology Assessments on Robotic Assisted Surgery: A Summary

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Introduction. Da Vinci robotic-assisted surgery (RAS) has been evaluated by health technology assessment (HTA) organizations across the world. This study aimed to analyze the existing HTA reports over years, countries, and procedures.

Methods. Publicly available health technology appraisal reports on RAS published from January 2000 to November 2020 were identified via a targeted literature search. The literature search was conducted in PubMed, the Centre for Reviews and Dissemination database, the International Network of Agencies for Health Technology Assessment database, and Google scholar. Reports related to the da Vinci RAS were included. Full texts of reports were used for the analysis.

For the HTAs that recommended RAS, the directional conclusion was considered as positive. For HTA reports that discouraged the use of RAS, the directional conclusion was considered as negative. The rest were considered as neutral. The reports were analyzed by year, country, and procedure.

Results. We identified 65 HTA reports comprising 128 procedure-level assessments of RAS by 42 HTA organizations in 21 countries over 20 years. The annual number of assessments increased over time. The countries that completed the most assessments were Sweden (14 reports, including 15 procedure-level assessments: 13% positive and 80% neutral) and Canada (11 reports, including 20 procedure-level assessments: 65% positive).

The topics of the assessments covered 27 surgical indications in urology, gynecology, thoracic, general, and ear, nose, and throat. The conclusions of the HTAs varied by surgical indication. Prostatectomy (33 reports: 85% neutral or positive) was the most widely assessed surgical indication, followed by hysterectomy (16 reports: 81% neutral or positive), nephrectomy (15 reports: 73% neutral or positive), and rectal resection (10 reports: 100% neutral or positive).

Conclusions. The number and breadth of HTAs on RAS have grown at an increasing rate over the last 20 years. The directional conclusion of assessments varied by procedure and country. Further analysis is warranted to understand the factors contributing to HTA conclusions on RAS.

PP195 Cost Utility Of Transcatheter Aortic Valve Implantation For Patients With Inoperable Severe Aortic Stenosis In Brazil

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Introduction. Transcatheter aortic valve implantation (TAVI) represents a new treatment option for aortic stenosis. This study

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

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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

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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.