OP153 Access To Real-World Data For Use In Health Technology Assessment – Still Work To Be Done

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Introduction: Real-world data (RWD) is an important source of evidence for health technology assessment (HTA). It is widely used to fill clinical trial data gaps and to inform risk-sharing agreements. HTA is mandatory in many jurisdictions as it is used for price negotiation between a manufacturer and a payer. HTA practitioners have so far had limited involvement in the debate surrounding access to RWD as regulators have primarily focused on scientific research and market authorization. This study examined the challenges of obtaining RWD for HTA decision-making that is beneficial at the population level when data sources are restricted to maintain the data integrity and rights of the public.
Methods: Types of RWD and processes for obtaining data were assessed for two jurisdictions (Australia and Denmark). Types of data considered were national registries, ongoing or completed cohorts, surveys at various universities, archived historical data, and medical claims data. The assessment was performed by analyzing a series of cases.
Results: There were similarities and differences between the two jurisdictions. In both jurisdictions the process for obtaining data included an ethics application as well as data handling fees. Patients and clinicians had little to no say in what their data are used for. It can take up to six months to obtain data. Person identification numbers enable linking of different datasets. Population wide data are accessible in Denmark only through secure servers, whereas full data sets, such as prescription data, can be released for research in Australia. Public hospital data, such as electronic health records, are not easily obtained in Denmark. In Australia, public hospitals are run by individual states and, therefore, additional effort is required to access nationwide data.
Conclusions: Access to RWD for HTA is challenging in both Australia and Denmark. Improvements in the process of applying for data and linking different data sources for HTA purposes are still needed.

OP154 Horses For Courses: Developing A Proportionate Approach To Health Technology Assessment In England

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Introduction: The number and range of technologies that the National Institute for Health and Care Excellence (NICE) evaluates has never been greater, and with that comes an increasing requirement for capacity. However, not all technologies need the full intensity of the current standard evaluation process. This presents an opportunity to differentiate evaluation processes, and in doing so release capacity for more evaluations. NICE has embarked on a project to develop proportionate appraisal processes, allowing promising medicines to move through refined processes that better match the specific needs of individual evaluations.
Methods: The proportionate approach to technology appraisals (PATT) project was initiated in June 2022. Multiple work strands were established to develop and test potential proportionate approaches, focusing mainly on streamlined approaches for appraisals in which a lighter-touch approach is sufficient. By creating an accountability framework which empowered staff across NICE, new processes were developed using test-and-learn principles: piloting key concepts using retrospective reviews and live appraisals and adjusting the approach based on their findings. The impacts of each approach on NICE, on stakeholders and on the individual appraisals were monitored and assessed.
Results: The project has identified a range of procedural, methodological and operational improvements across the NICE technology appraisal process. Substantial efficiencies have been found, including consolidation of activities, reducing duplication of effort and minimizing disproportionate steps. The test-and-learn approach has proved successful, both in rapidly identifying unsuccessful ideas and in refining and adjusting processes in light of new information and challenges.
Conclusions: The proportionate approach to technology appraisals project represents an important part of improving and streamlining NICE's approach to health technology assessment, reflecting the increasing demands on the program. Developing proportionate approaches allows efficient use of limited evaluation resources to continue supporting rapid, evidence-based access to innovative technologies. The project also provides a valuable demonstration of an agile, flexible approach to process improvement, paving the way to rapid, dynamic updates in the future.

OP156 Systematic Review And Meta-Analysis Of The Perioperative Association Of Gabapentinoids With Sedation And Respiratory Depression After Abdominal Surgery

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Introduction: With the increasing popularity of enhanced recovery protocols and the growing opioid epidemic, recent pain management pathways have emphasized opioid-sparing measures. As a result, gabapentinoids are being used following surgery and have become one of the most common opioid-sparing analgesics prescribed. However, they are not without risk, with several cases of respiratory depression and oversedation being reported.
Methods: This systematic review and meta-analysis aimed to evaluate the impact of gabapentinoids on sedative complications following abdominal surgery in order to guide future clinical decisions. The Pubmed and Embase databases were searched according to PRISMA guidelines to identify randomized controlled trials comparing gabapentinoids with placebo following abdominal surgery with respect to sedation complications. The Cochrane Risk of Bias Tool was used to assess study quality. A comparative meta-analysis was performed on the data.
Results: Of the 3,988 studies retrieved, 19 were eligible for meta-analysis. Eleven of the 19 studies assessed pregabalin (100 to 1,200 mg) and eight assessed gabapentin (300 to 1,200 mg). Postoperative sedation scores were higher in the gabapentinoid group ($p<0.01$) relative to placebo. Subgroup analyses demonstrated higher scores two hours after surgery for gabapentinoids ($p=0.03$), but no statistical difference at 24 hours ($p=0.19$). Different doses did not yield any differences on forest plot analyses.
Respiratory depression rates were higher in the gabapentinoid group, compared with placebo ($p=0.02$).
Conclusions: The preoperative use of gabapentinoids is associated with sedative complications, including respiratory depression. These results may help guide future perioperative pain protocols.

OP157 Evaluating The Clinical And Economic Impact Of Adopting A Closed Peripheral Intravenous Catheter System In A Japanese Hospital

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Introduction: Up to 90 percent of inpatients require an intravenous catheter during their hospitalization. A closed, integrated peripheral intravenous catheter (PIVC) system has been shown to protect veins for longer and reduce the risk of complications and unnecessary restarts when compared with an open system. This study evaluated the annual clinical and economic outcomes of adopting a closed, integrated PIVC system, instead of an open system, for inpatients in a Japanese hospital.
Methods: A budget impact analysis was developed to estimate the clinical and economic impact for a 500-bed hospital with an 85 percent occupancy rate and a 96-hour catheter replacement protocol. For the analysis, the average length of stay for patients was 12 days and 90 percent of inpatients required a PIVC. Inputs such as catheter failure rate, complication rate, consumables costs, and complication management costs were informed by global and local data sources. The outcomes evaluated included consumables utilization, complication events, nurse time, and overall cost impact.
Results: The analysis estimated that 12,604 patients required PIVCs. Moving from an open to a closed, integrated PIVC system resulted in a 68 percent reduction in consumables (3,786 fewer catheters and 36,315 fewer connecting accessories). Complications (occlusion, extravasation, phlebitis, and bending) were reduced by 62 percent (3,682 fewer episodes). Blood exposure was reduced by 98 percent (3,565 fewer episodes), and nurse time decreased by 17 percent (786 fewer hours). This resulted in a potential overall cost saving of JPY3,955,140 (USD28,756) annually, after offsetting the acquisition cost of JPY888,247 (USD6,458) associated with the closed system.
Conclusions: PIVC is the most common vascular access device used in hospitals, and insertion and maintenance are often performed by nurses. Fewer complications can be expected with a closed system, leading to better patient outcomes. In addition, nurses spend less time managing complications and replacing PIVCs, and consumables utilization is reduced. This results in improved operational efficiency and potential cost savings for hospitals.

OP159 Quality Of Evidence For Clinical Benefit Of Cancer Medicines Assessed For Funding In Australia

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Introduction: This study aimed to describe the type of evidence available for and the clinical benefit of cancer medicines assessed for funding in Australia by the Pharmaceutical Benefits Advisory Committee (PBAC). The evidence was assessed with the European Society of Medical Oncology Magnitude of Clinical Benefit Scale version 1.1 (ESMO-MCBS).
Methods: All data on applications submitted to PBAC between 2010 and 2020 were independently extracted in duplicate from PBAC Public Summary Documents available online. Any disagreements were resolved through discussion. ESMO-MCBS ratings were retrieved from the ESMO-MCBS website. Substantial benefit for the ESMO-MCBS was defined as a grade A or B for (neo)adjuvant intent and four or five for palliative intent.
Results: In the study period, 182 cancer indications for 100 cancer medicines were examined by PBAC, including 124 (68%) for solid tumors (116 in the palliative setting) and 58 (32%) for hematological cancers. A total of 138 (76%) indications were recommended for public funding, 40 (22%) were rejected, and four (2%) were deferred. Randomized controlled trials (RCTs) were the main source of evidence in 154 indications (85%) and single-arm studies in 27 (15%) indications. RCTs were available in 113 (91%) and 41 (71%) of the solid tumor and hematological cancer indications, respectively. In submissions with RCTs, mature overall survival (OS) was reported in 81 (53%) indications. For indications with a statistically significant improvement in OS, the median gain was 3.0 months (range 0.9 to 17.0) for solid tumors and 8.2 months (range 1 to 9.1) for hematological cancers. The ESMO-MCBS score was available for

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