transferring patients to the radiology suite, leading to time savings and allowing prompt start to IV therapy. This study aims to estimate the cost and time impact of placing PICCs at the bedside using tip-confirmation technology led by nurses versus in the radiology suite using fluoroscopy by radiologists.

Methods: A budget impact analysis was developed using Microsoft Excel to estimate the annual impact of inserting PICCs at the bedside versus in the radiology suite. The base case scenario was modelled for 1,000 PICCs placed in a private Australian hospital. Impact on bed days, labor time and overall cost was estimated by using global and local data sources for inputs. It was assumed that 100 percent PICC are placed in a radiology suite in current practice, while 95 percent are placed at the bedside and 5 percent in the radiology suite in future practice.

Results: By shifting PICC insertion to the bedside using tip-confirmation technology, the model estimated a reduction of labor time by 221 hours and bed days by 113 days. Despite an increase in the cost of consumables by AUD34,041 (USD22,760) and reduction of Medicare Benefits Schedule rebate by AUD260,730 (USD174,328), overall cost savings of AUD1.01million (USD675,660) was observed due to significant savings due to the t reduced utilization of the radiology suite.

Conclusions: PICC insertion at the patient bedside using tip-confirmation technology by nurses may lead to time and cost savings as compared to placing them in the radiology suite. This can help alleviate the burden on radiology suites and reduce their wait times, potentially leading to timely treatment initiation and discharge. Since PICCs at the bedside are typically placed by specialized vascular access nurses, these cost savings can be redirected to employ and train them.

PP103 Budget Impact Analysis Of Utilization Of WavelinQ Endo-arteriovenous Fistula System For Hemodialysis Patients: An Australian Hospital Perspective

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Introduction: A high proportion of patients with end-stage kidney disease (ESKD) are treated with hemodialysis (HD). To lower morbidity and maintain overall cost control in patients with ESKD, it is crucial for health systems to establish and maintain durable hemodialysis (HD) access. Our objective was to assess the budget impact of utilizing the 'WavelinQ Endo Arteriovenous Fistula (AVF) system' (WavelinQ) for HD patients.

Methods: A one-year economic model from the Hospital (Flinders Medical Centre, FMC) perspective was developed with Australian epidemiological and costing data. Clinical data were collected from real-world sources. The incident (n=50) and prevalent (n=250) cohorts were based on FMC utilization patterns. The current standard of care was surgical AVF (sAVF) and/or central venous catheters (CVC). With introduction of WavelinQ into practice, the substitution rate was set at 50 percent in new patients and ten percent amongst existing patients. Index procedure and reinterventions costs for the patient were based on the weighted average cost using National Efficient Price Determination 2020 to 21. Total costs pre-WavelinQ introduction were compared to post WavelinQ substitution to determine the budget impact.

Results: Based on FMC expected patient cohort and WavelinQ substitution rates, the mean annual cost savings per incident and prevalent patient were AUD26,873 and AUD3,549, respectively, which lead to overall mean annual cost savings per patient of AUD7,437. The calculated per patient additional upfront cost of AUD7,010 with the WavelinQ index procedure versus sAVF was more than offset by the savings due to less post-procedure reinterventions. Overall, at the assumed substitution rates with WavelinQ, the model predicted a cost saving of approximately AUD2.2 million dollars for FMC.

Conclusions: The use of WavelinQ is expected to lead to cost savings of AUD2.2 million dollars from the FMC perspective. Hospitals should consider not just the increase in upfront costs but also potential savings from less reintervention procedures. There is a need for continued research on the budget impact of different HD modalities across multiple settings.

PP104 Impact Of New Permbrolizumab Indications After Initial Registration By Brazilian Health Regulatory Agency (ANVISA)

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Introduction: Most new drugs have only clinical studies focused on a single population at the time of first registration, hence their indications for use are restricted to this population. For clinical conditions when there are no other treatments available, new drugs have higher costs in Brazil. There is no review of prices when these medications broaden their therapeutic areas, and this can have a significant financial impact. This study's objective is to assess the financial implications of pembrolizumab's incremental indication after its initial registration.

Methods: We calculated the annual cost to treat all Brazilian patients with indications for use in the first registration and all incremental indications of pembrolizumb. Populations were estimated by epidemiological data from the pembrolizumab clinical trials called, KEYNOTE studies, and the INCA 2023 cancer estimate for the Brazilian population. Costs were calculated by CMED-ANVISA price value and considering the dosing of 200mg every 3 weeks.

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Results: In 2016, pembrolizumab was granted registration in Brazil was restricted to patients with advanced melanoma. In 2022 the indication was expanded to more than 20 new indications, with several studies in progress that potentially will lead to further inclusions. The estimate of patients eligible for indications increase of 1,796 to 99,544 patients with an increased total cost from BRL625,802,837 to BRL34,685,366,192 (USD121,185,677.4 to USD6,716,763,399.04).
Conclusions: The financial burden of pembrolizumab's expanded uses after it was first approved could significantly rise, endangering the long-term viability of healthcare systems. In Brazil, where medicine costs are not regularly monitored, the annual inflation adjustment is the only factor that causes prices to change. In order to lower medicine prices in response to the addition of new indications, the expansion of therapeutic options for the same condition, or even obsolescence, regulations are required.

PP105 Efficacy, Effectiveness And Safety Of Letermovir For Prophylaxis Of Cytomegalovirus Infection And Disease Post-Allogeneic Hematopoietic Stem Cell Transplantation

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Introduction: Clinically significant cytomegalovirus infection (CSI-CMV) is an important factor associated with mortality in patients undergoing hematopoietic stem cell transplantation (HSCT). It is estimated that the incidence of CSI-CMV in the post-HSCT period is 30 percent to 70 percent in transplanted individuals. Therefore, CSI-CMV is considered a complication in allogeneic HSCT, which can trigger Cytomegalovirus disease (CMVD). Letermovir is an antiviral agent indicated especially for the prophylaxis of CMVD post-HSCT. The objective of this work was to evaluate the efficacy, effectiveness and safety of letermovir, comparing it with placebo or other existing prophylactic treatments.
Methods: A systematic review was carried out according to PRISMA 2020. A strategy was developed for searching electronic bibliographic databases. Retrieved publications were selected by a pair of reviewers. The same pair performed the data extraction. A qualitative assessment of the efficacy, effectiveness and safety of letermovir was performed.
Results: Eighteen studies were included, being experimental and observational. Overall, the pivotal RCT demonstrates the efficacy of letermovir in reducing the incidence of CSI-CMV. However, there was no statistically significant difference in all-cause mortality and letermovir-related overall survival, events of graft versus host disease, neutropenia, acute kidney disease and 48-week mortality. Observational studies, in general, present results similar to those found in the pivotal RCT. The main adverse events associated with letermovir were peripheral edema (14.5%), vomiting (18.5%), headache (13.9%), cough (14.2%), abdominal pain (11.8%) and fatigue (13.4%).
Conclusions: The prophylactic use of letermovir in CMV-R+ patients after allogeneic HSCT demonstrates beneficial results in the prevention of CSI-CMV. However, there were no identified improvements for other outcomes. As for safety, it was observed that there is still little information about adverse events related to the drug, and studies assessing this aspect are needed for better comprehension.

PP106 Integrating Organizational Impacts Into Health Technology Assessment: How To Take Them Into Account For Medical Devices?

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Introduction: The organizational impact (OI) of new technologies is becoming a major driver for our healthcare systems and for modernizing the care pathway for the benefit of users and professionals. Some technologies give rise to a reorganization of the healthcare system, particularly in the case of connected medical devices.
The Medical Device Committee at Haute Autorité de Santé (HAS) appraises medical devices (MD) in view of their reimbursement by the French health insurance scheme. The Committee's evaluation criteria take account of the therapeutic benefit of the MD and its public health benefit. OI-related aspects are frequently claimed by health technology developers (HTD) in their MD submission dossiers. However, this aspect is rarely documented. Therefore, guidance explaining how HTD should support and structure any claim of an OI was needed.
Methods: This work was based on the HAS OI Map for Health Technology Assessment published in 2020, the analyses of specific HAS opinions, hearings with concerned stakeholders (HTD, service providers and patients), and a committee meeting focused on OI.
Results: The HTD guide for MD submission was updated with guidance to support OI claims. For each claimed OI, the HTD should identify the criterion corresponding to the most relevant OI, the indicator to describe each selected criterion, the stakeholders concerned, and the data to be provided. The choice of method is according to the OI: if the indicator is measurable, data from validated measurement tools are expected. If not, especially in cases where the use of the MD requires a specific organization before its deployment, the absence of data must be justified and a detailed impact

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