ensuring patient access to device-based technologies. The nascent medical device reimbursement process offers a promising opportunity for interventions driven by a diverse group of stakeholders. We conducted policy research to capture these diverse perspectives and highlight key elements to develop a structured framework for reimbursement.

**Methods:** This research was a two-part process, including secondary research with expert interviews followed by policy research using focus group discussions (FGDs) through an online workshop with key stakeholders. We developed a white paper proposing changes to the reimbursement pathway, based on a benchmarking study of global markets and interviews with experts in the field. As a next step, key changes proposed in the white paper were deliberated upon by three focus groups (six to eight participants). Group participants were selected by quota sampling and represented key stakeholders in the reimbursement process. A discussion guide was used to capture participants' opinions and an addendum to the white paper was released highlighting small, actionable, and impactful changes to the reimbursement process.

**Results:** FGDs with key stakeholders highlighted the need to establish a more structured, inclusive, and transparent process. Accordingly, we proposed key recommendations to the medical device reimbursement process in India. A first change is the creation of an online submission portal allowing different healthcare stakeholders to submit new technologies for consideration through a streamlined pathway. Secondly, we proposed enhancing evaluation transparency by improving availability of publicly shared information on the evaluation process, metrics, and assessment timelines. We also suggested adoption of adaptive health technology assessments to leverage existing evidence for faster, efficient decision-making.

**Conclusions:** Through this process, we created a pragmatic and concrete call for a stronger voice from care-providers and patient groups in the evaluation process. Consecutively, the proposed innovative framework introducing value-based incentives for implantable medical devices will be instrumental in enabling access to quality health care for poor patients. These strategies follow the principles of value-based care and will go a long way in achieving better health outcomes for the population. The scientific initiative has been made possible with the support of St. Jude Medical India Pvt Ltd (now Abbott).

## PP41 Using Medicare Claims Data To Support Reimbursement Of A Novel Leadless Pacing System For The Management Of Bradycardia

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**Introduction:** The Micra Transcatheter Pacing System (Micra TPS) is a single-chamber transcatheter leadless pacemaker (LPM). LPMs do not require leads or a subcutaneous pocket, which represent the primary sources of device-related complications with conventional transvenous pacemakers (TVPMs). Complications such as infections and lead dislodgements cause significant patient burden, which have significant economic consequences. Running a randomized controlled trial (RCT) to estimate risk differences of infrequent events requires large sample sizes and long follow-up periods. Real-world observational data, while informative, requires an appropriate study design and statistical adjustments to control for potential biases.

**Methods:** The Micra Coverage with Evidence Development (CED) study was a cohort study of LPM versus TVPM based on US Medicare claims data of 16,431 patients with 2-year follow up (LPM: n=6,219; TVPM: n=10,212). Propensity score matching (PSM) was applied to account for differences in baseline characteristics. As no RCT was identified in the literature, this study was presented to the Australian payer as the primary source of clinical evidence, upon which a cost-utility analysis was conducted.

**Results:** After PSM, the CED study demonstrated significantly more complications with TVPM versus LPM with adjusted rates of 6.5 percent and 4.6 percent ($p<0.001$). Significant differences favoring LPM ($p<0.01$) were observed in device breakdown (1.4% vs 2.0%), dislodgment (0.4% vs 1.2%) and infection (<0.1% vs 0.6%). Based on these findings, a claim of superior safety was accepted by Medical Services Advisory Committee (MSAC) to support reimbursement. In making this decision, MSAC considered that the large sample size and propensity weighting overcame some of the potential biases and the magnitude of the benefit supported cost-effectiveness relative to TVPM.

**Conclusions:** The lack of a sufficiently powered RCT with an extended follow-up period can mean the impact and benefits of new technologies that reduce clinically important adverse events of relative infrequency are not formally incorporated into payer decision making, particularly where RCTs are a requirement. A well-designed observational study can provide valuable, real-world evidence to support a HTA for reimbursement decisions.

## PP42 Insights Of Health Technology Assessment In Brazilian Health Unified System: Areas Of Interests In Health

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**Introduction:** The National Committee for Health Technology Incorporation of the Brazilian Public Health System' s (Conitec) principle is to advise the Ministry of Health (MS) in the tasks related to incorporation, exclusion or modification of any health technologies into the Unified Health System (SUS). Moreover, this also involves alteration of clinical protocols or therapeutic guidelines.

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All of the recommendations consider the international classification of diseases (CID) as a common language that allows health professionals and managers to understand standardized information, to identify trends and benefits of recommendations in each therapeutic area.
**Methods:** This exploratory, descriptive and retrospective study aims to provide qualitative and quantitative data from the technologies evaluated by the Conitec in the period June 2012 to November 2022. Data were extracted in Conitec's website.
**Results:** The searches resulted in 763 recommendations in total. Among them, the most evaluated therapeutic area was Infectology with 126 technologies (16.5%). In this field the highlighted diseases and conditions were Hepatitis 42 (33.3%); HIV 23 (18.3%) and COVID-19 11 (8.7%). In Oncology, 113 recommended technologies (14.8%) were identified, in order of prominence for the diseases: Breast Cancer 21 (18.6%); Colorectal Cancer 11 (9.7%); Leukemias 17 (15.0%). In the Respiratory Diseases area, 89 technologies (11.7%) were recommended, among them: Chronic obstructive pulmonary disease (COPD) 17 (19.1%); Asthma 15 (16.9%) and COVID-19 11 (12.4%). These results clarify which diseases are most needing new technologies to be treated.
**Conclusions:** The results show what conditions and fields in health needs to be prioritized for public policies and prevention measures. This study demonstrates how important is to make accessible the public health information, improving public knowledge and social actions in SUS.

## PP44 Time Is Now: Advancing Value Assessment Of Cancer Therapies To Help Eliminate Cancer As The Cause Of Death

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**Introduction:** Earlier cancer diagnosis and advances in science are resulting in improved patient and societal outcomes. However, payer frameworks and methods can find it difficult to keep pace with scientific progress, evolution of endpoints, and assess the wider value of these advances.
**Methods:** A multidisciplinary, international group of experts working in the cancer field was brought together to reach consensus on key principles of defining and assessing of cancer treatment value. A Delphi-based approach including surveys, virtual panels, interviews and structured online discussions was used to reach consensus. This work was initiated and funded by AstraZeneca.
**Results:** Twenty-four experts from across the world (including patient advocates, oncologists, health economists, regulators, members of payer and health technology assessment (HTA) bodies) reached consensus on seven key principles across two themes, oncology relevant endpoints and dimensions of value. Three of the seven principles were found to be of particular relevance to HTA bodies and payers: assessing broad economic impact of new medicines (including socio-economic and caregiver impact), where early-stage cancer treatments can enhance patients' ability to lead productive lives and contribute to economic activity; consider other value aspects of relevance to patients and society; use of Managed Entry Agreements (MEAs) supported by ongoing evidence collection to help address decision-maker evidence needs and address clinical uncertainty.
**Conclusions:** Incentivizing access to early-stage treatments can promote cancer control, improved outcomes and generate long-term societal benefit. Furthermore, early diagnosis and treatment at earlier stages of cancer can be cost-effective, and sometimes cost-saving, as well as provide opportunities for cure. Expanding value components in therapy assessments to include, for example, insurance value, the value of choice, scientific spillovers, and wider societal perspectives, along with structured MEAs to manage clinical uncertainty and balance budgets will help realize the potential to eliminate cancer as the cause of death.

## PP47 Experience And Its Implication For Reassessment Of The Transcatheter Aortic Valve Implantation Using Real World Data

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**Introduction:** South Korea has introduced conditionality to coverage decisions for certain difficult or high-risk procedures. The transcatheter aortic valve implantation (TAVI) was included in the coverage with evidence development (CED) in 2014. This study reviewed the results of reassessment for the TAVI using real world data (RWD) and suggested its implications.
**Methods:** Healthcare providers authorized to use the promising technologies are required to collect the RWD for suitability evaluation, safety monitoring, and cost-effectiveness, differing from the general reassessment process. In 2021, 45 healthcare providers collected clinical information for TAVI patients. Their registries were linked with the national health insurance claims, which provided data on 19 items to assess safety and effectiveness such as overall mortality, reoperation rates, hospital readmission rates, and degree of functional improvement.
**Results:** According to the Society of Thoracic Surgeons' predicted risk of mortality (STS), 988 TAVI patients were classified into three groups; high (STS >8 percent, n=347), intermediate (STS 4-8 percent, n=272), and low (STS <4 percent, n=369); We compared main outcomes and estimated survival probabilities between subgroups. Within 30 days, the overall mortality rates were 4.9 percent (high), 2.6 percent (intermediate), and 1.4 percent (low); major bleeding rates were 7.6 percent (high), 6.2 percent (intermediate),and 1.4 percent (low); incidence of new atrial fibrillation were 6.8 percent (high), 4.2 percent (intermediate), and 3.2 percent (low). Based on the quantitative results using RWD and systematic review for the safety and effectiveness, TAVI is reported to have essential benefits for high-risk group and elderly patients (>80 years). Whereas, intermediate and low-risk groups

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