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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