

PD09 Hospital-Based Health Technology Assessment: Evaluating Skirted Aortic Valves For Transcatheter Aortic Valve Implantation

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Introduction: Aortic valves for transcatheter aortic valve implantation (TAVI) vary in design. Traditional models without a skirt, used at the Amosov National Institute of Cardiovascular Surgery, have notable disadvantages. This study conducted a hospital-based health technology assessment (HB-HTA) to evaluate the feasibility of implementing skirted aortic valves to optimize resource utilization within the facility.

Methods: The Amosov National Institute of Cardiovascular Surgery of the National Academy of Medical Sciences of Ukraine (the Institute) conducted this project as part of a national pilot to introduce health technology assessment (HTA) in hospitals. The institute formed a multidisciplinary team of specialists with clearly defined roles and responsibilities. The team relied on Ukrainian methodological guidelines for implementing HTA in hospitals that were approved in 2023 and were derived from recommendations from Adopting Hospital-Based Health Technology Assessment (AdHopHTA) and the Danish Centre for Evaluation and Health Technology Assessment.

Results: The analysis of clinical effectiveness and safety showed that aortic valves with a skirt have advantages over those without a skirt for aortic valve replacement in patients with aortic stenosis. A systematic review of literature from PubMed and the Cochrane Library found reduced rates of paravalvular leakage (10 to 20%) and complications with skirted valves, minimizing the need for corrective interventions and further monitoring. Budget impact analysis revealed that using skirted valves reduced cost overruns and optimized resource use. Transitioning to this model required no structural changes and offered significant strategic and economic benefits.

Conclusions: Considering the clinical efficacy, safety, and economic feasibility of aortic valves with a skirt, their introduction into the Institute's practice is highly justified. These valves offer the potential to enhance long-term treatment outcomes, reduce the incidence of complications such as paravalvular leakage, and optimize resource utilization. This implementation represents a strategic step toward improving patient care and healthcare efficiency.

PD11 First Comprehensive Assessment Of Artificial Intelligence At Canada's Drug Agency: Evidence Review Methods, Lessons Learned, And Next Steps

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Introduction: Canada's Drug Agency (CDA-AMC) conducted a health technology assessment of RapidAI for detecting ischemic stroke and hemorrhagic stroke to test and learn from its first comprehensive assessment of an artificial intelligence (AI)-enabled health technology.

Methods: The assessment included a review evaluating the effectiveness, accuracy, and cost-effectiveness of RapidAI for detecting ischemic and hemorrhagic stroke, alongside an implementation review capturing digital infrastructure considerations. Ethics and equity considerations were integrated throughout, informed by literature, patient engagement, and expert input. Checklists and other AI or digital health tools were applied. The Health Technology Expert Review Panel (HTERP), an advisory body to CDA-AMC, reviewed the evidence and developed recommendations on the appropriate use of RapidAI for stroke detection, considering the following domains: unmet clinical need, clinical value, economic considerations, impacts on health systems, and distinct social and ethical considerations.

Results: Patient input highlighted speed and accuracy in stroke diagnosis. Low certainty clinical evidence suggested that using the AI functionalities of RapidAI to assist diagnoses may result in clinically important time reductions. Its effects on other clinical outcomes were very uncertain. Ethical and equity considerations have implications across the technology life cycle when using RapidAI for detecting stroke; however, little relevant information was identified from the literature. We found no relevant economic evaluations. The implementation review identified key considerations for AI-enabled health technologies for decision-makers. Given the evidence gaps and uncertainty, HTERP could not recommend for or against the use of RapidAI for stroke detection.

Conclusions: Our appraisal and deliberative processes identified evidence limitations that may be common across many AI-enabled health technologies, identifying challenges that need to be addressed in their evaluation. Based on this experience, for AI evaluations CDA-AMC plans to add AI-specific implementation and other considerations to its evidence reviews and to consider a broader range of information sources.