*Title* **Transcatheter Aortic Valve Implantation: Evaluation of the evidence and synthesis of organizational issues**

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**Aim**

The Ministère de la Santè et des Services Sociaux (MSSS) gave the Institut national d'excellence en santé et en services sociaux (INESSS) the mandate to perform an evaluation of transcatheter aortic valve implantation (TAVI).
The objectives of this evaluation are to:

1. synthesize, via a systematic review, the recent evidence on effectiveness, safety and economic issues related to TAVI using the Cribier-Edwards / Edwards SAPIEN or CoreValve bioprostheses for adult patients with severe, symptomatic aortic stenosis, with an emphasis on clinical results at 1 year; and to
2. synthesize, via a narrative review, the principal organizational aspects of delivering this procedure, including the selection of patients before implantation and key considerations concerning ethics and the patient's perspective.

**Conclusions and results**

In the systematic review of clinical results, 17 studies met our selection criteria: 13 were research studies (1 randomized controlled trial, 4 controlled cohort studies, 8 case series), and 4 were analyses of registries (2 national, 2 from industry), which can be considered as case series. Most studies were from outside North America. In the clinical trial (PARTNER B cohort), 179 patients were randomized to transfemoral TAVI, and 179 were randomized to medical treatment (most of the patients in this group also underwent balloon aortic valvuloplasty (BAV) for aggravation of their aortic stenosis). We also retained 3 HTA reports and 2 systematic reviews.

In each of the 17 studies, the patients eligible for TAVI were considered either inoperable, not suitable for surgery or at high surgical risk. In almost every study, it was indicated that patient selection was based on the consensus decision of a multidisciplinary team. In general, TAVI patients were elderly (with a mean age of at least 81 years) and the majority were in New York Heart Association (NYHA) class 3 or 4, but the extent of surgical risk varied greatly across studies.

**Recommendations**

Considering the results of our evaluation and discussion of these with a scientific committee of Quebec clinical experts, INESSS made recommendations on:

- Patient selection criteria
- Patient selection process
- Organizational issues related to the practice of TAVI
- Requirements for performing centres
- Provincial registry

**Methods**

A systematic search of the scientific literature published between January 2008 and January 2011 was carried out using bibliographic databases (2008 being the year when clinical results on mortality at 1 year began to become available). In order to summarize issues pertaining to organizational aspects and patient eligibility, we retrieved relevant information from the following sources: 1) the most recent expert consensus documents from North America and Europe; 2) health technology assessment (HTA) reports published between 2008 and 2010, and the 2011 update of a report by the National Institute for Health and Clinical Excellence (NICE); 3) relevant articles retrieved from our literature search; and 4) a key research article and accompanying editorial, published in June 2011, concerning cohort A of the PARTNER randomized controlled trial.

**Written by**

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