Assessment of transcatheter aortic valve implantation (TAVI)

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BACKGROUND
In 2007, TAVI showed signs of potential benefit for inoperable patients with severe symptomatic aortic stenosis. HAS supported innovation and recommended TAVI for reimbursement under several conditions:
- Agreement for an interim period for limited indications;
- Restriction of activity to selected centres;
- Setting up of a national registry to confirm clinical benefit;
- Anticipated reassessment.

OBJECTIVES
To assess effectiveness and safety of TAVI (Edwards Sapien and Corevalve devices) to support reimbursement decision by the French National Insurance Funds (FNIF).

METHODS
Systematic search
- Medline, National Guidelines, Cochrane Library, Embase, Pascal, HTA database, learned societies web sites.
- Manufacturers’ data.

Critical assessment of clinical and economical data
- Pre-specified criteria for selection of studies.
- Study design quality.

Multidisciplinary experts’ panel
- 16 experts proposed by learned societies.

Appraisal and validation by HAS Committees

RESULTS
Evidence about clinical effectiveness and safety
- Fourteen selected clinical studies including 2 RCT.
- At 1 year, TAVI significantly reduced death rate compared to standard therapy in inoperable patients (30.7% vs 49.7%, HR 0.55 IC95% [0.40 – 0.74]). For high-surgical risk patients, TAVI was noninferior to open-heart surgery in terms of death (24.2% vs 26.8%, HR 0.83 IC95% [0.60 – 1.15]). However, these 2 techniques had their own complications: bleeding for surgery, strokes and vascular complications for TAVI.
- Pacemaker implantation: Corevalve > Sapien.
- Results of French practice (FRANCE 2 registry):
  - In accordance with literature in terms of effectiveness and safety;
  - Some misuses (contraindications in CE mark) and “off-labelled” implantations (moderate surgical risk).

Economic evaluation
- No study investigating efficiency were available.
- Cost study on French registry data ➔ ratio of the refund paid to the hospital by the FNIF + average cost of the hospital stay were appropriate.

CONCLUSIONS AND RECOMMENDATIONS FOR FURTHER RESEARCH

Comparisons of different HTA guidelines

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<thead>
<tr>
<th>Type of devices</th>
<th>Accepted indications</th>
<th>Recommended access routes</th>
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<tbody>
<tr>
<td>HAS France Oct 2011</td>
<td>Edwards Sapien XT*</td>
<td>Patients with contraindication of surgical valve replacement following assessment by multidisciplinary team. The multidisciplinary approach enables to: • confirm the necessity of aortic valve replacement with the evaluation of severity of aortic stenosis and symptoms; • select patients with the evaluation of risk scores (log Euroscore ≥ 20%, STS ≥ 10%), comorbidities not included in these scores, anatomical contraindications, life expectancy, frailty and assessment of feasibility of TAVI.</td>
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<td>Corevalve Accutrak*</td>
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<tr>
<th>KCE Belgium Sept 2011</th>
<th>Edwards Sapien</th>
<th>Patients considered to be inoperable due to anatomical factors.</th>
<th>Transfemoral</th>
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<tr>
<th>USA Oct 2011</th>
<th>Edwards Sapien</th>
<th>Patients determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis.</th>
<th>Transfemoral</th>
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| NHS UK Mar 2012 | All devices available | Patients who are considered to be unsuitable for surgical aortic valve replacement by a multidisciplinary team. | Transluminal and transapical |

* Previous generations (Edwards Sapien and Corevalve) not available in France

Further research:
- FRANCE 2 registry: long-term results expected (up to 5 years).
- Current valves: any extension of indication to patients for whom surgery is not contraindicated must be subject to a demonstration of efficacy, safety and efficiency vs surgical aortic valve replacement.
- New valves: Data comparing the efficacy and safety of the various types of valves in the validated indications.