HTA of medical devices in the Netherlands: what parts of reimbursement decisions are relevant for other HTA agencies and industry?

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Thanks: Saskia de Groot, Rian Rijnsburger, Juanita Heymans

Netherlands: Health Care Insurance Board (CVZ)

- CVZ coordinates the implementation and funding of various types of health care services.
- CVZ is the gatekeeper of the basic coverage/insurance package
  - advises Minister of Health on:
    • reimbursement of new interventions
    • removal and rearrangement of reimbursed interventions
- Minister of Health makes the final decision about reimbursement

Assessment for reimbursement in the Netherlands

1. Necessity: does the illness or required care justify a claim for solidarity (given the context in society)?
2. Effectiveness: does the technology deliver what is expected of it (broadly speaking)?
3. Cost-effectiveness: are the extra effects worth the extra costs (from a societal perspective)?
4. Feasibility: is inclusion in the basic package feasible now and in the future?

How much cooperation is there between countries?

- Sharing of preliminary versions of HTA reports with other organisations (e.g., Netherlands, Belgium)
- Collaboration via EUnetHTA
- Co-authorship of report written by Belgian Health Care Knowledge Center (KCE) on pre-market evaluation of innovative high-risk medical devices
- What information about reimbursement decisions is relevant for other countries?
What is generalisable in reimbursement decisions?

- Should the technology be reimbursed?
  - Yes
  - No
  - Sometimes?

**THE BIG QUESTION**

**THE BIG ANSWER**

<table>
<thead>
<tr>
<th>Necessary?</th>
<th>Effective?</th>
<th>Cost-effective?</th>
<th>Feasible?</th>
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<tbody>
<tr>
<td>specific questions</td>
<td>specific answers</td>
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**Evidence of effectiveness**

- Systematic literature reviews look at the evidence of effectiveness
- BUT: How do we decide how much evidence of effectiveness we want (for reimbursement)?
- Is an RCT always needed as part of the evidence base?

\[ \text{PICO} \rightarrow \text{Population, Intervention, Comparator, Outcome, (Time)} \]

**Evidence of effectiveness: questions to determine if RCT evidence is desired**

<table>
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<tr>
<th>Are blinded randomised controlled trials</th>
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<tr>
<td>Necessary?</td>
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<tr>
<td>Intervention is generally accepted</td>
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<tr>
<td>Small change in current practice</td>
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<tr>
<td>Extension of current indication</td>
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<td>Dramatic effect</td>
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<td>Immediate effect</td>
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The answers will not always be generalisable to other countries, but the questions may be!

**Deep brain stimulation for depression**

- P: Therapy-resistant depression
- I: Deep brain stimulation
- C: Conservative treatment
- O: Primary: depression (e.g., Hamilton Depression Rating Scale)
- T: 1 year

**Conclusion regarding effectiveness**

- Randomised controlled trials are desired and possible
- However, number of clinical studies is limited
- Effectiveness has not been demonstrated

\[ \text{PICO} \rightarrow \text{Population, Intervention, Comparator, Outcome (T=time)} \]
Transcatheter aortic valve implantation (TAVI)

- **P**: Patients with severe aortic stenosis (AS) who are deemed inoperable
- **I**: TAVI
- **C**: Conservative treatment
- **O**: Overall mortality
- **T**: At least 1 year

**TAVI in 2009: proof of effectiveness and its use**

- No controlled studies had yet been completed by 2009
- CVZ: “RCTs were desired and possible”, “need long-term data”
  (the PARTNER RCT was ongoing in 2009)
- Conclusion by CVZ: not yet sufficient proof of effectiveness
- In the meantime, many TAVIs were conducted in Germany

**Flowchart to determine desired level of evidence**

1. **Is** (blinded) randomised controlled research necessary, appropriate, and ethical?
   - Yes: Blinded randomised controlled research is desirable
   - No: Next question
2. **Is** non-randomised controlled research necessary, appropriate, and ethical?
   - Yes: Non-randomised controlled research is desirable
   - No: Non-controlled research in combination with opinions of clinical experts is desirable

**PICO** – Population, Intervention, Comparator, Outcome (T=time)