EUnetHTA: Common European HTAs of Medical Devices

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WP 5 Associated Partner

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Outline

- Background and use of the HTA Core Model®
- Work distribution, teams, organization and process
- Example of production of a common core HTA
- Output and collaborative issues
EUnetHTA works in Work Packages

JA2 WP1 - Coordination
JA2 WP2 - Dissemination
JA2 WP3 - Evaluation

**JA2 WP4 - Testing collaborative production of HTA information for national adaptation and reporting**

**JA2 WP5 - Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting**

JA2 WP6 - Information Management Infrastructure and Services (IMIS)

**JA2 WP7 - Methodology development and evidence generation: Guidelines and pilots production**

JA2 WP8 - Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information
## WP5 partners

### Associated Partners:

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<thead>
<tr>
<th>WP5 partners</th>
<th>Collaborating Partners:</th>
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<td>CVZ</td>
<td>Donau Universität Krems</td>
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<td>LBI-HTA</td>
<td>RIZIV</td>
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<td>HVB</td>
<td>Medical University of Sofia</td>
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<td>BIQG/GÖG</td>
<td>University of Erlangen-Nuremberg</td>
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<td>KCE</td>
<td>Swiss Federal Office for Public Health</td>
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<td>MoH (Cyprus)</td>
<td>University Hospital 'A. Gemelli</td>
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<td>MoH (Czech Republic)</td>
<td>DGCF MSSSI</td>
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<td>Basque Office for HTA</td>
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# The Domains of the HTA Core Model®

<table>
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<tr>
<th>DOMAIN</th>
<th>Description</th>
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| **Rapid** | 1. **Health problem and current use of technology**  
2. **Description and technical characteristics**  
3. **Safety**  
4. **Clinical effectiveness**  
5. **Costs and economic evaluation** |
| **Full** | 6. **Ethical analysis**  
7. **Organisational aspects**  
8. **Social aspects**  
9. **Legal aspects** |
The Domains of the HTA Core Model®

**DOMAINS**

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

**TOPICS**

A. Mortality
B. Morbidity
C. Function
D. Quality of life
E. (...)

**ISSUES**

Research questions (assessment elements)

a. What is the expected beneficial effect of the intervention on overall mortality?

b. What is the expected beneficial effect on the disease-specific mortality?

c. (...)

European network for Health Technology Assessment | JA2 2012-2015 | www.eunethta.eu
For Medical Devices in WP5

- **Output:** at least 4 joint assessments with >2 national/local reports per assessment

- **Topic selection:**
  1. Call for collaboration: authoring agency selects relevant topic out of its own work program
  2. POP database: overlaps in topics listed at POP

- **Assessment process:**
  1. Scoping phase
  2. Research phase (assessment phase)
  3. Consultation phase with stakeholders

- **Editing and publishing**
Scoping Phase

Project Plan
- Defines the PICO(S) = population, intervention, comparator, outcomes (study design)
- Describes project approach and method (literature search strategy, use of quality assessment tools and evidence tables)
- Includes selection of assessment elements = research questions
- Includes checklist for potential ethical, organisational, social and legal aspects
- Timetable
Assessment/consultation phase

- Manufacturer, external expert(s), other stakeholders
- WP5 members
- Dedicated reviewers
- Co-authors
- Authors
- Coordination team

Timeline (days): 0, 45, 55, 65, 75, 80

Process coordination:
- Writing of 1st version of pilot rapid assessment
- Review of 1st version of pilot rapid assessment
- Writing of 2nd version of pilot rapid assessment
- Review and consultation of the 2nd version of pilot rapid assessment
- Writing final version of pilot rapid assessment
- Translation of pilot rapid assessment to national/local reports
Current status in WP5

Of the 4 rapid reviews on medical devices: 1 finished + 1 ongoing

1. Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes mellitus (LBI-HTA): PUBLISHED

2. Renal denervation systems for the treatment of drug-resistant hypertension (RDN):
Rapid assessment of renal denervation (renal nerve ablation) for drug-resistant hypertension: **RDN**

**Pilot team**

- **Authors (and project leader):**
  Norwegian Knowledge Centre for the Health Services (NOKC), Norway

**CLINICAL EFFECTIVENESS DOMAIN**
*Katrine Frønsdal, Tove Ringerike*

- **Co-authors:**
  Galician Health Technology Assessment Agency (Avalia-t), Spain

**SAFETY**
*Leonor Varela Lema, Gerardo Atienza Merino*

  Public Health and Quality Improvement, Central Denmark Region (CR.DK), Denmark

**HEALTH PROBLEM AND CURRENT USE + CHARACTERISTICS OF THE TECHNOLOGY**
*Karla Douw and Claus Løvschall*

- **Dedicated reviewers:**
  HIS (Scotland), FinOHTA (Finland), AHTAPol (Poland), GYEMSZI (Hungary), IQWIG (Germany)
### Scope of assessment of RDN: defining the «PICO»

| **Population** | Patients with treatment-resistant arterial hypertension (defined as persisting hypertension despite administration of at least three antihypertensive drugs in adequate doses including a diuretic) with blood pressure ≥ 140/90 mm Hg (Calhoun 2008; Mancia 2013) and without secondary cause of hypertension.  

ICD-10 code: Hypertensive diseases I10 - I15  
MeSH terms: Hypertension; Blood Pressure  
Intended use of the technology: treatment |
| **Intervention** | Renal nerve ablation/denervation systems.  
The intervention involves destruction of sympathetic nerve endings within the wall of the renal arteries to reduce sympathetic nerve traffic, thereby causing a reduction in blood pressure.  
MeSH terms: Denervation; Kidney Catheter Ablation |
| **Comparator(s)** | Standard of care (which includes here: pharmacological treatment, device-based therapy of hypertension and sham treatment) |
| **Outcome(s)** | **Primary outcomes:**  
Overall mortality  
Cardiovascular mortality  
Cardiovascular morbidity (stroke, myocardial infarction, heart failure)  
Blood pressure (changes of systolic and diastolic blood pressure)  
Complications during or after the treatment  
**Secondary outcomes:**  
Left ventricular hypertrophy/Systolic and diastolic cardiac function  
Kidney function |
| **Study design** | Efficacy/effectiveness: Systematic reviews/HTAs, randomized controlled trials (RCTs) and, if data from randomized controlled trials are lacking or insufficient, prospective, controlled studies  
Safety: As for efficacy but also all prospective studies |
| **Languages** | English, Spanish, French, German, Swedish, Danish, Norwegian |
Output: the report (rapid assessment)

1. Production of result cards = answers to each research question (assessment elements)
2. Writing of domain specific summaries
3. Writing of a executive summary
4. Compilation of the final rapid assessment with appendices, tables etc.
Output: learnings from the assessment

- Ensure standardized terminology
- Scoping phase is critical: must be detailed enough
- Agree on the interpretation of a research question
- Early contact with clinical experts
- Agree initially on stages of and degree of involvement with manufacturers
- Plan exact review periods and what the review should focus on at the different stages of the assessment
- Define sequential work flow as some domains depend on results from others
Output: learnings from collaborating

- Working across differences: various professional backgrounds, language barriers, different methodological approaches, …

- Not underestimate good communication practice: mailing lists, have one person assigned for issuing reminders etc.

- Keeping timelines is crucial

- Have clear roles on who is doing what –and WHEN

- International collaboration is something you learn and grow on !!!
Thank you for your attention

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme