

# Advance HTA

Rethinking the future of Health Technology Assessment

## Creating a database on medical devices from an HTA perspective

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# Agenda

- 1. Background and Objective**
- 2. Methods**
- 3. Results**
- 4. Conclusions**
- 5. Future steps**

# 1. Background and Objective

## ADVANCE\_HTA Project

### Overall objective

- Complement and address areas of intense methodological debate in the application, use and implementation of HTA
- Make recommendations for improvements in HTA methods, which can be taken further by competent authorities

### Objective WP 5 (TU Berlin leading partner)

- Map different assessment approaches towards medical devices (MDs)
- Identify areas where knowledge and tools are lacking
- Offer insight into how current HTA assessment tools can be modified or adapted

# 1. Background and Objective

## Background

- MDs encompass a broad and heterogeneous range of technologies
  - device-specific elements influence evaluation process
- Widely established assessment tools for pharmaceuticals
- Limited availability of tools that provide detailed guidance for researchers and policy-makers interested in MD evaluation

## Objective

- Conception of a database development containing **structured** and **systematically recorded** information about the assessment of MDs

## 2. Methods

### First step: Development of the database concept

Taxonomy about existing classifications and nomenclatures of MDs

Systematic review of current HTA methodologies, processes & practices across EU Member States

Validation of taxonomy

Concept of database

### Second step: Piloting and refinement

Pilot-test for applicability of the variables using SPSS Statistics based on data from 50 reports

## 3. Results

### First step: Concept extraction tool

- Captured 19 variables that include:

#### 1) Technology elements

- **EU classification** (90/385/EEC, 93/42/EEC, 98/79/EC)
- **Type of technology** (Assistive devices for medical professional or patient or artificial body parts/ implants)
- **Purpose of technology** (therapeutic or diagnostic)

## 3. Results

### 2) Report specific elements

- **Indication** according to MedDRA-Terminology (System Organ Class, SOC)
- **Country**
- **Publication year**
- **Language of HTA report** (e.g. official language, English)
- **Publication type** (abstract, summary, full text)
- **Single or Multiple Technology Assessment** (STA or MTA)
- **Type of report** (e.g. update of report, adaptation)

## 3. Results

### 3) Assessment elements

- **EUnetHTA Core Model elements** (e.g. effectiveness, safety)
- **Level of evidence** according to Cochrane classification (Ia-IV)
- **Evidence base** (submission, independent research)
- **Comparator** (active, placebo)
- **Endpoints** (e.g. mortality, morbidity, QoL, safety)
- **Evidence appraisal** (yes/no, appraisal tool used)
- **Stakeholder involvement** (yes/no)
- **Cost and economic evaluation** (e.g. only costs, full economic evaluation)



## 3. Results

### Second step: Piloting and refinement

- Pilot-testing shows that the defined variables seem to be applicable
- Pilot-testing did not lead to changes to content
- Pilot-testing led to an adjustment of some variables regarding their coding, examples:
  - level of evidence
  - technical difficulties
- Further adjustments might be necessary (e.g. EUnetHTA core model elements)

## 4. Conclusions

- **An HTA database with recorded information regarding current methods used for MD evaluation could be helpful for:**
  - researchers: in planning and conducting HTA on MDs
  - policy makers: in swiftly identifying information
- **Balance between quantity and quality**
  - database needs to be effective and efficient, but also flexible enough to deal with the heterogeneity of the reports and technologies

## 5. Future steps

- Further discussion on the usefulness of the database
- Implementation of the database
- Development of appropriate IT-applications to create a repository that is dynamic and stays up-to-date
- Collaboration with existing databases and networks for ongoing database development/optimization

**Thank you for your attention!**