AdvanceHTA
Rethinking the future of Health Technology Assessment

A taxonomy of medical devices in the logic of HTA

Cornelia Henschke[1]
Dimitra Panteli[1]
Matthias Perleth[2]
Reinhard Busse[1]

[1]Berlin University of Technology, Department of Health Care Management
[2]Federal Joint Committee (G-BA)

Background

- Many countries have introduced regulatory instruments to identify technologies that minimize risk and offer value/ value for money
- Most formal decision structures incorporating evidence-based approaches were established for pharmaceuticals
- Suitability of general HTA methodology for medical devices increasingly a topic of scientific discourse
- Several classifications/ nomenclatures for medical devices
  - Based on varying rationales
  - Used for different regulatory purposes and decisions on value and coverage

Objectives

- To compare and analyse existing classifications/nomenclatures for medical devices used for different regulatory purposes and decisions on value and coverage in and across EU Member States
- To develop a taxonomic model that would:
  - (1) Classify medical devices in categories based on relevant characteristics derived from existing classifications
  - (2) Highlight the suitability of different device categories for HTA
  - (3) Indicate if and how assessment tools can and should be modified to achieve best results depending on taxonomic position

Methods

- Classification schemes selected to account for different characteristics of medical devices
  - EU licensing process for medical devices (Directives 90/385/EEC, 93/42/EEC, 98/79/EC)
  - International classification for medical devices used by the Global Medical Device Nomenclature (GMDN)
  - Categorization employed in the OECD Classification of Health Care Functions

→ Analysed in combination to develop a comprehensive taxonomic model

Results

- A matrix in table format was created
- Basis: relevant aspects from the existing classification schemes

(1) Elements of risk and role/functionality of device types

- *Licensing process of medical devices:*
  - Council Directive 93/42/EE … n medical devices
  - Council Directive 90/385/E… ctive implantable medic…
  - Coun… ostic medi…

Implication for HTA:

While risk is not the main dimension for HTA, it is important for patient safety; it may also guide the selection process of which medical devices should be assessed

Results

(2) GMDN - Global Medical Device Nomenclature

- *International classification for medical devices*

Code	Classification
01	Active implantable devices (e.g. cardiac [illegible]makers)
02	Anaesthetic and respiratory devices (e.g. [illegible]mask)
03	Dental devices (e.g. dentistry tools)
04	Electro mechanical medical devices (e.g. X[illegible])
05	Hospital hardware (e.g. hospital bed)
06	In vi[illegible]
07	Non[illegible]
08	Oph[illegible]
09	Reus[illegible]
10	Sing[illegible]
11	Assi[illegible]
12	Diag[illegible]
13	Complementary therapy devices (e.g. acupuncture needles)
14	Biologically derived devices (e.g. tissue heart valves)
15	Healthcare facility products and adaptations (e.g. special toilets)
16	Laboratory equipment (e.g. pipettes)
17	Medical software (e.g. operating system software)

Implication for HTA:

Not very useful; potential for creating a more complete list in order not to forget certain medical device categories

Results

(3) OECD Classification of Health Care Functions

→ Procure[illegible]imbursement activities

•

Implication for HTA: high

Assistive technology devices:
for HTA, "device" = "technology" → closest to pharmaceuticals
(at least for devices with a therapeutic objective)

Artificial body parts (implanted by medical procedures):
for HTA, "medical procedure" (in which device is a decisive component) = "technology"

Medical devices for the assistance of medical professionals: for HTA, potentially very different usages of device (by indication, by part of body etc.) = "technology"

Results

(4) distinction between the diagnostic or therapeutic nature of devices

Implication for HTA:

An important distinction for HTA (cf. Core Model™), which is missing from the classifications

→ relevance of different device categories in regard to HTA varies considerably

→ color-coded matrix: high suitability to non-applicability

Results

Classification criteria of EU-Directives according to risk aspects		Classification according to the relevance of product and service/ and reimbursement characteristics (includes OECD Classification of Health Care Functions) + HTA logic					
		Diagnostic			Therapeutic		
		Assistive technology devices (directly used by patients)	Artificial body parts (implanted by medical procedure)	Medical devices for the assistance of medical professional	Assistive technology devices (directly used by patients)	Artificial body parts (implanted by medical procedure)	Medical devices for the assistance of medical professional
93/42/EEC and 90/385/EEC	I			Stethoscope	Walking frame		
	IIa			Ultrasound	Hearing aid		
	IIb			X-ray, PET-CT	Insuline pen, corrective lenses		
	III						
	IV						
98/79/EC	V-VIII						

Discussion – Advantages of classification

1. Separates diagnostic and therapeutic activities, accounting for particularities, e.g. the problem of separating the value of improved diagnosis from the value of improved outcomes from subsequent treatment
    - Evaluation methods have to account for this (→ cf. Core Model™)
    - Devices with both a diagnostic and therapeutic part should undergo two assesments

Discussion – Advantages of classification

2. Separates (A) Assistive technology devices/ (B) Artificial body parts/ (C) Medical devices for the assistance of medical professionals

   - Assistive technology devices are products directly used by patients → in most cases products could be assessed “alone”
   - Artificial body parts and medical devices for the assistance of medical professionals are used within procedures → assessment has to account for dimensions such as device-operator interaction

Conclusions

- Existing medical device classifications are not suitable for the purposes of HTA or economic evaluation as they are based on different underlying logics

- General HTA methodology does not consistently account for device-specific elements

- The taxonomy

  (1) combines these two worlds and

  (2) adds further considerations such as device use within a procedure

Conclusions

- Important step towards advancing the debate on HTA/ economic evaluation by grouping medical devices according to their relevance for HTA activities
  - ranging from high suitability to non-applicability

- Next step: establish basic methodologies in HTA that explicitly consider peculiarities of different categories of medical devices

Thank you for
your time and attention!

cornelia.henschke1@tu-berlin.de
dimitra.panteli@tu-berlin.de