Towards a taxonomy of medical devices in the logic of HTA and economic evaluations rather than marketing authorization

Cornelia Henschke[1]
Sabine Fuchs[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
- BUT: Most formal decision structures incorporating evidence-based approaches were established for pharmaceuticals
- Suitability of general HTA/ economic evaluation 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
  - *But useful for HTA/ economic evaluation?*

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 and economic evaluation
  - (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 → procurement/ reimbursement

→ 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/EEC on medical devices
    → differentiates risk categories I, IIa, IIb & III based on non-invasive vs. invasive, length of stay in body, contact with vessels or CNS, active vs. non-active
  - Council Directive 90/385/EEC on active implantable medical devices (IV)
  - Council Directive 98/79/EC on in vitro diagnostic medical devices (V)

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  - Co[illegible] plantable
    me[illegible]
  - Co[illegible] gnostic
    me[illegible]

Implication for HTA/ economic evaluation:

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 pacemakers)
02	Anaesthetic and respiratory devices (e.g. oxygen mask)
03	Dental devices (e.g. dentistry tools)
04	Electro mechanical medical devices (e.g. X-ray machine)
05	Hospital hardware (e.g. hospital bed)
06	In vitro diagnostic devices (e.g. pregnancy test)
07	Non-active implantable devices (e.g. hip replacement)
08	Ophthalmic and optical devices(e.g. contact lenses)
09	Reusable devices (surgical instruments)
10	Single use devices (e.g. needles)
11	Assistive products for persons with disability (e.g. wheelchairs)
12	Diagnostic and therapeutic radiation devices (e.g. radiotherapy units)
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)

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03	Dental devices (e.g. dentistry tools)
04	Electro mechanical medical devices (e.g. X-
05	Hospital hardware (e.g. hospital bed)
06	In vi
07	Non
08	Oph
09	Reu
10	Sing
11	Assi
12	Diag
13	Complementary therapy devices (e.g. acupuncture needles)
14	Biologically derived devices (e.g. tissue heart valves)
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Implication for HTA/ economic evaluation:

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

→ Procurement/ reimbursement activities

- HC.5.2 Therapeutic appliances and other medical goods
  - HC.5.2.1 Glasses and other vision products, HC.5.2.2 Hearing aids , HC.5.2.3 Other orthopaedic appliances and prosthetics, HC.5.2.9 All other medical durables including medical technical devices

  → Assistive technology devices (dispensed and used by patients)

  (includes devices used to increase, maintain, or improve functional capabilities of individuals)

- HC.1 Curative care

  → Artificial body parts (implanted by medical procedures)

- HC.4.1 Laboratory services, HC.4.2 Imaging services

  → Medical devices for the assistance of medical professionals

Results

(3) OECD Classification of Health Care Functions

→ Procuren imbursement activities

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Implication for HTA/ economic evaluation: *high*

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

Artificial body parts (implanted by medical procedures):
"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"

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of

Results

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

Implication for HTA/ economic evaluation:

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

Results: Some Examples

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			
	III					Cardiac stents Artificial joints	
	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 assessments

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 (based on methodological guidelines and actual assessments)