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Advance HTA

Rethinking the future of Health Technology Assessment

Medical devices: a taxonomy suitable for HTA

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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

- 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

(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	Reus
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

(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

(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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(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

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	Thermometer		Stethoscope	Walking frame		Spatula
	IIa	Pulse oxymeter*		Ultrasound	Hearing aid	Dental crown	Tracheal tube
	IIb			X-ray, PET-CT	Insuline pen, corrective lenses	Dental implant Bone prosthesis	Laser RT- Unit
	III			Neuro-endoscope	Condoms with spermicide	Cardiac stents Artificial joints	Angioplasty balloon catheter
	IV		ICD: heart monitor unit			ICD: defibrillator unit	
98/79/ EC	V-VIII	Glucose strip, pregnancy test		ABO/Rh (D) blood analyzer			

695 technologies
from 650 reports classified

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 216			**Therapeutic** 479		
		Assistive technology devices (directly used by patients) A1	Artificial body parts (implanted by medical procedure) B1	Medical devices for the assistance of medical professional C1	Assistive technology devices (directly used by patients) A2	Artificial body parts (implanted by medical procedure) B2	Medical devices for the assistance of medical professional C2
93/42/EEC and 90/385/EEC	I	Thermometer		Stethoscope 3	Walking fra 13		Spatula 5
	IIa	Pulse oxymeter* 3		Ultrasour 48	Hearing aid 19	Dental crown 3	Tracheal t 55
	IIb			X-ray, PET 82	Insuline pen, corrective le 5	Dental impl 22 Bone prosth	Laser 134 RT- Uni
	III			Neuro-endoscop 10	Condoms wit spermicide 2	Cardiac ste 94 Artificial joi	Angioplast 96 balloon ca
	IV		ICD: heart mo r unit 2			ICD: defibr 31 unit	
98/79/ EC	V-VIII	Glucose strip, pregnancy tes 8		ABO/Rh (d analyzer 60			

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)