Testing the plausibility of a taxonomy for medical devices in the logic of HTA

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Introduction

Despite the general debate on the extent to which medical devices (MDs) require tailored assessment methods, no categorisation exists that considers devices from the viewpoint of HTA. With the aim of providing policy-makers and researchers with an orientation guide on how to approach the assessment of MDs, the presented work includes the following steps:

(1)Developing a taxonomic model that (i) groups MDs for HTA purposes by building upon existing classification schemes to (ii) provide a tool for evaluating and how assessment methods can be modified to achieve best results depending on the taxonomic position.

(2)Plausibility testing of the taxonomy based on identified HTA reports, which sets the focus of the poster.

Methods

(1)Development of a taxonomic model

We analysed exiting classification schemes in combination to inform a comprehensive taxonomic model.

(2)Plausibility testing

(a) Identification of reports

We systematically identified European HTA institutions (based on [1]) and searched for publicly available reports. These were screened and matching documents were downloaded and inventoried in Microsoft Excel.

(b) Selection of reports

Reports were eligible if they focused on a MD (alone or within a procedure) and were evidence-based and systematically developed between the years 2004 and 2014.

Excluded were:

- other types of evidence-based documents (clinical guidelines etc.),
- reports that focus on the treatment of a disease exploring several different technologies,
- reports on telemedicine and screening applications only focusing on the intervention as a whole,
- reports on a procedure requiring MD where the MD was not among the main assessment components,
- reports on screening not addressing the diagnostic tests involved.

(c) Assignment of taxonomic position

The technologies evaluated in included reports were assigned a taxonomic position in the model developed in step 1. At this point in the work no distinction was made between tests with a purely diagnostic compared to a prognostic nature.

Results (1)

A matrix in table format was created based on relevant aspects from the existing classification schemes, incorporating elements of risk (as described in EU-Directives 90/385/EEC, 93/42/EEC, 98/79/EC) and role/functionality (as described in OECD Classification of Health Care Functions [2]) of device types (A, B, C).

Active implantable devices (IV) as well as in-vitro diagnostics (V) were assigned separate rows. The matrix further incorporates a distinction between the diagnostic (A1-C1) or therapeutic (A2-C2) nature of devices, which can be crucial for HTA purposes.

The relevance of different device categories in regard to HTA was considered quite variable and was color-coded in the matrix, including high ('green'), intermediate ('yellow') and low ('red'). 'Grey' fields were those where no MDs and assessments would be expected.

Classification criteria of EU-Directives according to risk aspects:		Classification according to the relevance of product & service and reimbursement characteristics (includes OECD Classification of Health Care Functions) + HTA logic					
		Diagnostic Technologies			Therapeutic Technologies		
		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	I	Thermometer		Stethoscope	Walking frame		Spatula
	IIa	Pulse oximeter		Ultrasound	Hearing aids	Dental crown	Tracheal tube
	IIb			X-ray	Insulin pen; Corrective lenses	Dental implant; Bone prosthesis	Laser RT- Unit
	III			Neuro-endoscope	Condoms with spermicide	Cardiac stents; Artificial joints	Angioplasty balloon catheter
90/385/EEC	IV		ICD: heart monitor unit	⟷		ICD: defibrillator unit	
98/79/EC	V	Glucose strip; pregnancy test		ABO/Rh (D) blood analyser			

Figure 1: Taxonomy for medical devices and indicative examples

Results (2)

We included 1006 reports of different types and length addressing 1,234 technologies produced by 32 European institutions (e.g. Agenas, HAS, IQWiG, KCE, LBI-HTA, NICE) from 17 countries.

General Characteristics of identified reports/technologies:

- 72% of all technologies assessed were devices with therapeutic purpose
- individual brand name products were less frequently assessed
- broad range of indications was captured, most frequently oncological, cardiovascular and musculoskeletal

Insights related to the plausibility of the taxonomic model:

- Reports sometimes assessed more than one technology (n=78) and sometimes these technologies belonged to different categories (n=27).
- Some reports assessed a technology which fall in more than one field (n=19) such as implantable cardioverter defibrillator (ICD), these were counted twice in figure 2.
- For one originally grey fields (B1/III) we identified a technology.
- For one originally green field (A2/III) and one red field (A1/I) no report could be identified.

Classification criteria of EU-Directives according to risk aspects:		Classification according to the relevance of product & service and reimbursement characteristics (includes OECD Classification of Health Care Functions) + HTA logic									
		Diagnostic Technologies 355						Therapeutic Technologies 898			
		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	
		Example	*No.*	*Example*	*No.*	*Example*	*No.*	*Example*	*No.*	*Example*	*No.*	*Example*	*No.*
93/42/EEC	I		0			Ophtalmo-scope	7	Wrist splint; Insoles	23			Wound dressing	7
	IIa	Home blood pressure monitor	8			MRI; Ultrasound	142	Hearing aids	23	Grommets; Dentures	13	TENS device	99
	IIb					X-ray imager	88	Insulin pumps	7	Intraocular lenses; BAHAs	71	Endovenous laser therapy	275
	III			Pulmonary Artery Press. Monitor	1	OCT using catheter	1		0	Stents; TAVI	138	Intracoronar Brachyther.	177
90/385/EEC	IV			ICD: heart monitor unit	6	⟷				ICD: defibrill. unit	65		
98/79/EC	V	Glucose strip; Pregnancy test	15			HPV test; Genetic tests	87						

Figure 2: Taxonomy for medical devices and number of technologies identified during the plausibility testing including actual examples from the report pool

Conclusions

Main findings:

Overall, the distribution of identified reports on the matrix generally confirm that the taxonomy is plausible. Only one report was identified for one grey field where no HTAs were expected. The majority of reports in the sample addressed technologies from the green fields, considered of high relevance. Relatively few reports were available for the red fields considered of low relevance. Some correlation to risk level and type of device is apparent, at least for devices that are implanted or serve to assist medical professionals.

Further steps:

In-depth analysis of reports corresponding to specific taxonomic positions regarding methodological approaches adopted so far and if/how these vary by taxonomic position is ongoing. As assessing MDs can be inefficient in some cases or particularly complex in others, we are exploring for example the purpose and methodology of those reports carried out for devices theoretically considered of low relevance for HTA (red fields).

Furthermore, interviews with HTA institutions about the usefulness of the taxonomy and suggestions for refinement are being conducted.

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References

[1] Panteli D, Busse R, Kreis J. A systematic approach for identifying current practices of doing HTAs across international HTA agencies (Poster). Berlin; 2012. Available at: http://www.mig.tu-berlin.de/fileadmin/a38331600/2012.publication/Panteli__Kreis___Busse_2012.pdf

[2] OECD, Eurostat, WHO. A system of Health Accounts. OECD Publishing. 2011. Available at: http://www.who.int/nha/sha_revision/sha_2011_final1.pdf