Advance HTA

MiG Health Care Management

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Advance HTA

Rethinking the future of Health Technology Assessment

HTA of medical devices: how to group them, how to evaluate them – current status and perspectives

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ADVANCE_HTA (WP5) – Aims & Methods

- **Task 5.1 -** Taxonomy of medical devices (MDs) for HTA (taking existing classifications and nomenclatures into account) and plausibility testing
- **Task 5.2 -** Systematic review to identify and compare current HTA methodologies, processes and practices for MDs across EU Member States and analysis of report samples across taxonomic positions
- **Task 5.3 -** Survey (interviews) with HTA bodies to clarify and supplement earlier findings, and to trace methodological and procedural challenges and trends
- **Task 5.4 -** Recommendations for future consideration in the assessment of MDs, derived from tasks 5.1-3

TAXONOMY OF MDs AND TESTING (PLAUSIBILITY & USEFULNESS)

Taxonomy of MDs in the logic of HTA

Development of a taxonomic model that

(i) groups MDs for HTA purposes by building upon existing classification schemes

(ii) provides a tool for evaluating if and how assessment methods can be modified to achieve best results depending on the taxonomic position

Testing of the taxonomy:

(i) Plausibility: based on identified HTA reports (Task 5.2)

(ii) Usefulness: based on interviews with 16 European institutions (5.3)

Classification according to the relevance of product & service and reimbursement characteristics
(includes OECD Classification of Health Care Functions) **+ HTA logic**

Classification criteria of EU-Directives according to risk aspects:		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			

Testing: Plausibility

- Based on **1006 reports** of different types and length addressing **1,234 technologies** produced by 32 European institutions (e.g. HAS, IQWiG, KCE, NICE)

- General Characteristics of identified reports/technologies:
  - 72% of all technologies = devices with therapeutic purpose
  - individual brand name products: less frequently assessed
  - broad range of indications was captured, most frequently oncological, cardiovascular and musculoskeletal

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			

Testing: Plausibility

Main findings:

- Distribution of identified reports on the matrix generally confirm that the taxonomy is plausible
- The majority of reports (67%) in the sample addressed technologies from the green fields, considered of high relevance
- Relatively few reports (3%) were available for the red fields, considered of low relevance
- Only one report was identified for one grey field where no HTAs were expected

Based on Interviews with HTA agencies (n=16)

CHALLENGES FROM A EUROPEAN AGENCIES' PERSPECTIVE

Challenges from a regulatory perspective

- **Weak EU regulation regarding licensing of MDs:** existing regulation on licensing of MDs is not as strict and structured as for drugs and does not require (well-established) effectiveness of the device
- **Decentralisation:** notified bodies use different processes and additionally these vary by countries

Most*

Example: *"EU is a testing ground for the Americans. There are MDs in an experimental stadium on the market with this miserable CE mark, which will never be approved by the FDA, because there are of high risk. It's a dilemma, an ethical dilemma …"*

*Categorisation of major themes in some (10-30%), many (31-65%) and most (66-100%), % of main themes made by interviewees

Challenges from a structural perspective

National legal framework:

- existence of different scopes for assessment defined by national law or predefined specific reimbursement criteria

Many

Example: *"We have regulatory criteria for reimbursement. This criteria are mandatory – we have to assess medical devices with this criteria."*

Transparency:

- lack of information about which MDs are entering the market or are currently on it and there are no available registers

Many

Example*: "They (from the drug department) know in advance for the next year which drugs they are looking at, they're usually able to plan a year in advance, and fill up all their slots. With the diagnostics and the medical devices, we rely on company notifying the programme."*

Challenges from a procedural perspective

Coordination of assessment:

- incorporation of stakeholder input at different points during the assessment process
- stage of *'Information retrieval'*, particularly requests to manufacturers for additional data/information
- Flexibility in terms of timeline

Many

Example: *"Sometimes we can resolve ourselves and sometimes this can lead to a working group where we involve different parties … It's like a fit-for-purpose approach."*

Example: *"For MDs the assessments tend to be at the request of the health system, it's not automatically produced by the manufacturers."*

Challenges from a methodological perspective

Evidence base

- Weak evidence and limited knowledge
- Lack of publicly available information
- Weak reporting quality of available studies

Most

Example: *"We have to work with case studies, case series, with 5 patients, it's really a low, low level of evidence."*

Rapid pace of MDs:

- Short-life-cycle, variations of MDs make assessment difficult (e.g. framing the research question, findings are transferable)

Many

Example: *"There are a whole class of products or even one product but multiple generations of devices and that also brings with it some specific aspects in terms of knowing what to focus on and which literature to focus."*

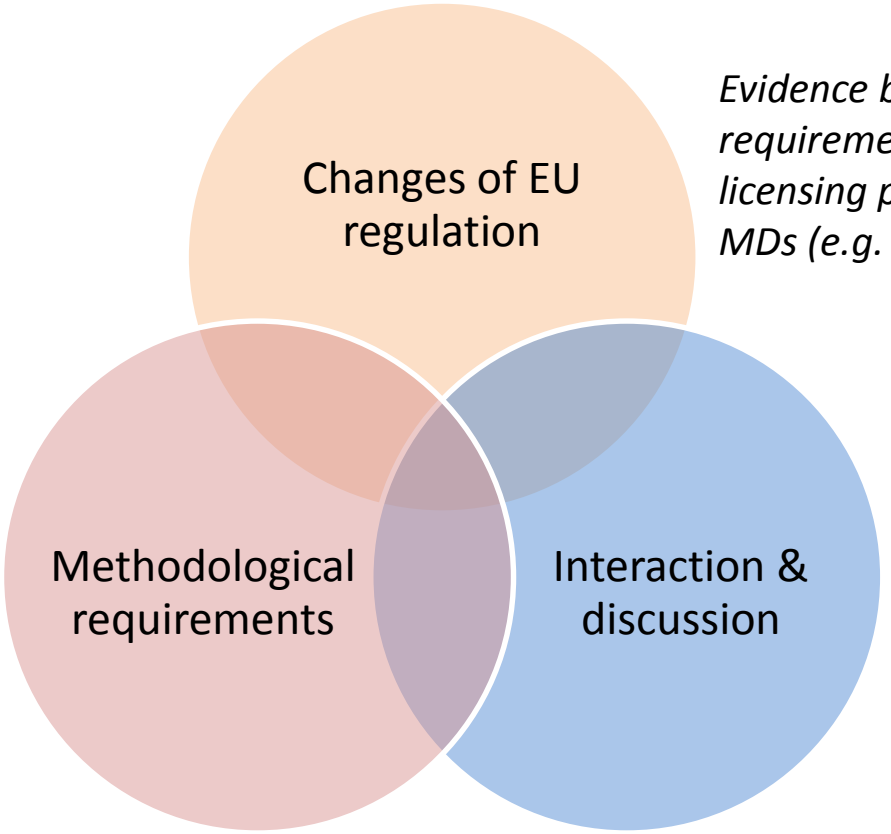
Solving challenges

- Approaches identified during the interviews (n=16):
  - Use of Horizon Scanning programs (e.g. Austria)
  - Set up post-introduction monitoring (e.g. Spain)
  - Set up patient safety programme (e.g. Netherlands)
  - Implementation of new approaches such as coverage with evidence development (CED; e.g. Germany)
  - Creation of a proposal for change at national level: guided introduction of high risk MDs with measures (Belgium)

Solving challenges

- Approaches identified during the interviews (n=16):
  - Facilitate the conduct of research studies/set up of a register (e.g. UK / England & Wales)
  - Improve flexibility during the assessment process (e.g. Italy)
  - Set up own instruction rules (evidence weak → no full assessment) (Austria)
  - Create own guidance for assessment based on EUnetHTA and own questions (Italy, Spain)

Impulses for change from the perspective of interviewed agencies (n=16)



Evidence based requirements for licensing process of MDs (e.g. efficacy)

Common understanding on methodological requirements and specific tools needed (e.g. GRADE for prognostic studies)

Dialogue & consiousness from policy side and between different stakeholders

WP5 recommendations

WAYS FORWARD

Ways forward - WP5 recommendations

- European regulation is currently being revised:
  - opportunity for insights from our work to contribute to the discussions and hopefully help ameliorate the current situation
    - e.g. through incorporate the opinions of 16 HTA institutions

Ways forward - WP5 recommendations

(1) Taxonomy can be useful for HTA institutions and decision makers (e.g. MoH, insurers)

- can serve as a support tool to
  - (a) select topics for assessment and
  - (b) identify certain aspects/particularities that require tailored (methodological) approaches

(2) 'Pointers' addressing certain methodological aspects that may be applicable to different device types (and therefore taxonomic cells) and could/should be considered along with the regular methodological approach adopted by each institution