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HTA goes Europe

Collaboration of Assessments of Medical Devices
Chances & Challenges

The Austrian Perspective

HTAN-Meeting, Brussels
March 23rd

PD Dr. Claudia Wild

Environmental Analysis: 8 devices

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	TAVI	HIFU	MitraClip	Barricaid	Zephyr	Renal denervation	IORT	Rheofilter
Spain (AETSA)		2013						
Spain (AVALIA-t)	2014					2013	2010, 2013, 2014	
Austria (LBI-HTA)	2008, 2009, 2010, 2011	2010, 2012	2010, 2012 In progress	2013	2008, 2010	2010, 2012	2009, 2012	2008
Spain (CAHIAQ)		2008, 2010						
England (NICE)	2012, 2014	2005, 2006, 2012	2009	In progress	2013	In progress	In progress	2010
Belgium (KCE)	2011	2014			2009		2013	
Netherlands (ZIN)		2007, 2013			2012			2010
Lithuania (VASPVT)		In progress						
Italy (Agenas)	2009	2009	In progress			2012		
France (HAS)	2012	2011						
8 devices:	10	14	4	2	5	4	8	3

6/8 times Austria 1st assessor

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Collaboration and Re-use on MedDevices

Figure 1. Levels of evidence

HTA

Maturing of evidence:
CTs, RCTs, Registries

Early Assessments

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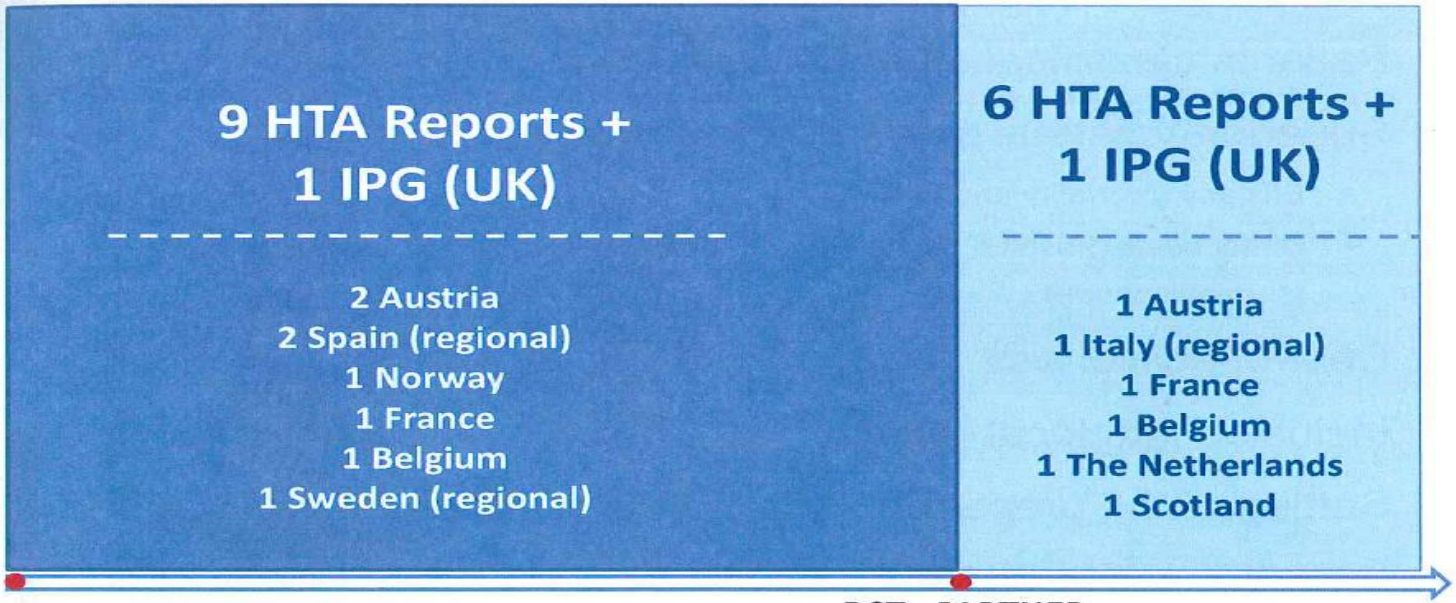
How many HTA reports on TAVI?



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Conclusion 1

- Rough estimation of 30-40 products (class III+ IIb, IVD C+D) per year = overseeable quantity
- Enourmous overlap in European assessments: 1-2 overlaps equal time/ 4-14 within 6 years

European collaboration within EUnetHTA

Challenges & lessons learned

Published EUnetHTA Assessments

	Duodenal-jejunal bypass sleeve for the treatment of obesity with or without type II Diabetes mellitus	Renal denervation for treatment resistant hypertension	Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dsyfunction
Duration	January 2013 – August 2013	April 2013 – December 2013	April 2014 – February 2015
Pilot team agencies, n	8	8	5
(Co-)Authoring HTA bodies	LBI-HTA (Austria) AAZ (Croatia)	NOKC (Norway) Avalia-t (Spain) CFK (Denmark)	FinOHTA/THL HIQA (Ireland)
Dedicated reviewing HTA bodies	GYMEZSI (Hungary) HIQA (Ireland) HVB (Austria) ISCIII (Spain) NOKC (Norway) Charles University Prague (Czech Republic)	HIS (UK) FinOHTA/THL (Finland) AHTAPol (Poland) GYMEZSI (Hungary) IQWiG (Germany)	GYMEZSI (Hungary) HVB (Austria) AHTAPol (Poland)

Ongoing Assessments

	Biodegradable stents for benign refractory esophageal stenosis	Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation	?
Duration	April 2014 – May 2015	November 2014 – September 2015	March 2015 - ?
Pilot team agencies, n	5	8	?
(Co-)Authoring HTA bodies	ISCIII (Spain) SAGEM (Turkey)	Agenas (Italy) AAZ (Croatia) MoH (Slovak Republic)	HIQA (Ireland)
Dedicated reviewing HTA bodies	VASPVT (Lithuania) Slovak Ministry of Health (Slovakia) LBI-HTA (Austria)	HAS (France) GÖG (Austria) AETSA (Spain) AAZ (Croatia) HIQA (Ireland) HIS (Scotland)	

Challenges & solutions 1

Topic selection: determines relevance for and thus uptake by members

- indication-specific, not technology-specific
- authors provide a rationale for topic selection
- mini-prioritisation: authors suggest two potential topics out of their own work-programme, members asked to rank them

Challenges & solutions 2

Timing of assessment: at what stage of life-cycle of technology, in absence of a clear point of market entry throughout Europe

- CE mark as selection criterion
- topic selected out of work-programme of authors

Unsolved:

- assessment too early with no comparative evidence; lack of comparative studies as “stopping rule”?
- too late and already widely used in practice?
- updates of assessments?

Challenges & solutions 3

Quality assurance: participation of HTA agencies (in WP5 51 partners) with different backgrounds, expertise, experiences, methods

- first authors responsible for overall quality of assessments
- several quality assurance mechanisms in place: internal review, external review, involvement of stakeholders

Unsolved:

- Selection criteria for different roles?? differentiation between „experienced“ and „less experienced“ agencies/individuals?

Challenges & solutions 4

Methods: differences in methods for HTA production between HTA institutes, prone to inconsistencies

- 10 EUnetHTA Guidelines currently published
- more in development (e.g. for literature search, non-randomised trials, etc)
- Update of HTA Core Model for Rapid REA (ongoing)

Unsolved:

- How to grade the overall strength of evidence – GRADE?

Challenges & solutions 5

Timelines: „rapid“ ~ 6 months, but so far ~ 8 months were needed, even more time needed with piloting the submission file template for medical devices

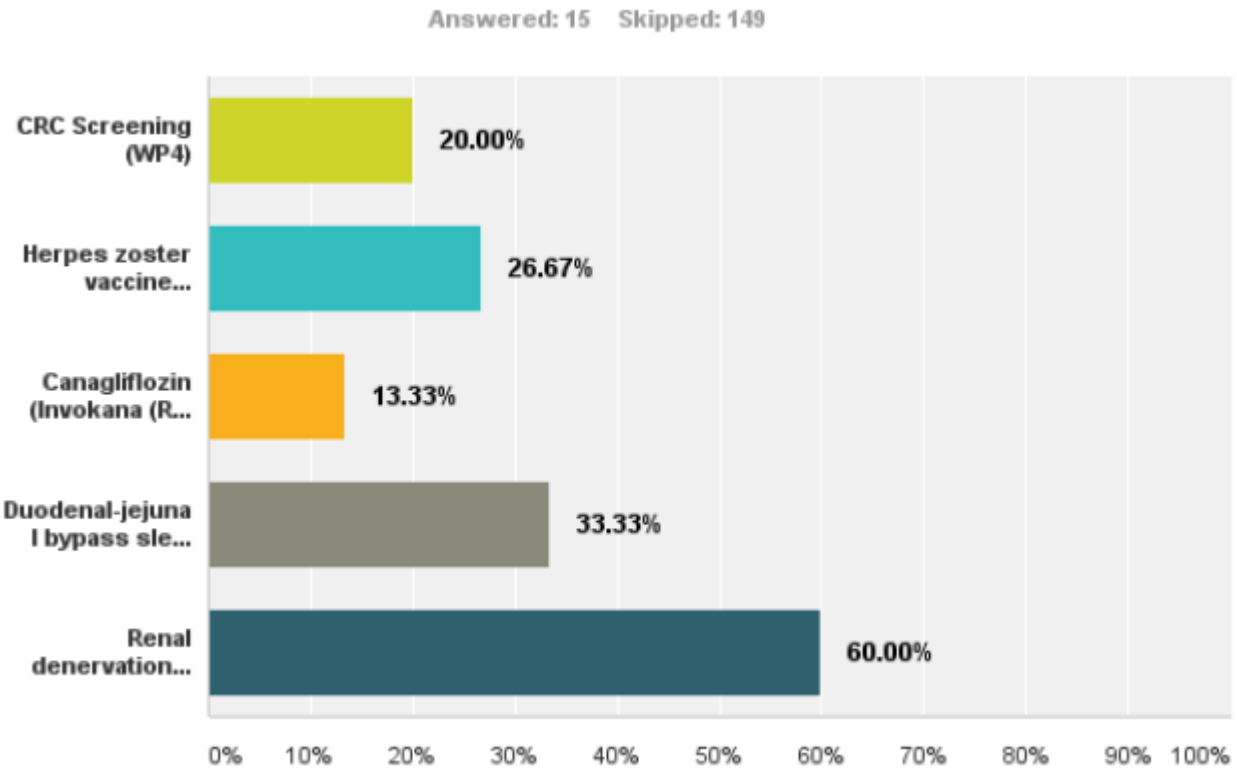
Unsolved:

- routine use of submission file template in future collaborations? First experiences positive from both sides (authors and manufacturers)
- Logistics of scoping meetings with several manufacturers

National Re-Use JA2

EUnetHTA output	Past adaptation/uptake	Planned adaptation/uptake
Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus Published: August 2013	1. LBI-HTA (2013, Austria) *(http://eprints.hta.lbg.ac.at/1008/)* 2. ISCIII (2014, Spain) *http://gesdoc.isciii.es/gesdoccontroller?action=download&id=29/09/2014-ef80379f51*	1. MoH Czech Republic (no date indicated) 2. NOKC (Norway) (no date indicated) 3. HIQA (Ireland) (no date indicated)
Renal denervation systems for treatment-resistant hypertension Published: December 2013	1. CR.DK (full assessment used, Denmark) 2. NOKC (directly used, Norway) 3. ZIN (directly used, Netherlands, 2013)	1. HIS (Scotland, UK) (no date indicated)
Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction Published: February 2015	1. FinOHTA/THL (2015, Finland) 2. ? 3. ?	1. LBI-HTA (April 2015, Austria) 2. ? 3. ?

WP3 Survey results – Has your organisation used HTA information?



Conclusions 2

- European collaboration associated with many challenges
- Many challenges have overcome, several not (yet?)
- Reduction of redundancy needed!
- High potential for efficiency gains by re-use of joint assessments but also by usage of EUnetHTA tools on national/local basis

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Example 1: Re-use

In reimbursement/ hospital benefit catalogue

1. EndoBarrier (March 2013)
2. Tuboplasty (April 2015)
3. Biodegradable Stents – Oesophagus (November 2015)

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Example 2: uptake at LBI

LBI started to use Core Model & EUnetHTA Guidelines for HTAs on extra medical services in 2015

Horizon Scanning in Oncology: will follow

B0001b - What is the comparator for the prophylaxis of VOD?

For the prophylaxis of VOD in transplant recipients, there is no standard therapy available, but several experimental agents have been tested including heparin, low-dose heparin, danaparoid, ursodeoxycholic acid or glutamine [4]. Of these, clinical use of two agents that is ursodeoxycholic acid and low-dose heparin is supported by randomized trials. They are applied depending on the type of hematopoietic stem cell transplantation (HSCT) regimen [5]:

- Ursodeoxycholic acid (UDCA) for patients undergoing allogeneic HSCT. It is administered at a daily dosage of 12 mg/kg (in two doses) from the day preceding the preparative regimen and is continued for the first 3 months of transplantation.
- Low-dose heparin for patients undergoing autologous HSCT. Patients receive heparin at a dosage of 100 units/kg per day (continuous intravenous infusion) from the first day of preparative regimen until hematopoietic engraftment.

B0001c - What is the comparator for the treatment of VOD?

For the treatment of VOD no standard therapy is available. The mainstay of VOD therapy is supportive care, including fluid restriction and diuretics, and avoidance of hepatotoxic medications [6]. Other agents which have been used in clinical practice include: tissue plasminogen activator (t-PA), N-acetylcysteine or methylprednisolone [7].

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Example 3: uptake at LBI

- POP is part of SOP before starting project

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Conclusio 3

- Challenges:
  - acceptance of English HTAs by decision-makers (despite comprehensive German summary)?
  - Aquaintaince of Core Model by researchers, but structure according to research questions contained in the Model was eventually found very useful
- Opportunities:
  - Transparency & comparability
  - Potential for adaptation/re-use of reports by other agencies

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Overall Conclusion 1/2

Benefits for all

- for HTA-agencies: less work !!!!
- for Health Policy: efficient use of HTA resources, faster and more output due to re-use.
- for Patients: transparent assessments on effectiveness/ safety, early access to true innovative technologies (ev. under documentation/ evidence generation).

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Overall Conclusion 2/2

Benefits for all

for Manufacturer:

- End of diverse requirements of information, but 1 submission template to fill in (reduction of workload),
- Possibility to contribute to scope of assessment from the start,
- Building trust + understanding.

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