MedtecHTA

Methods for Health Technology Assessment of Medical Devices: a European Perspective

Improving the process for HTA of Medical Devices

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Bocconi

WP1 overview

Cross country analysis of HTA for medical devices

Task 1

To undertake a review of current licensing practice for medical devices

Task 2

To review HTA practices for medical devices

Task 3

To assess how current guidelines are applied in HTA reports of drugs and medical devices

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EDITORIAL

Rethinking medical device regulation

*J R Soc Med 2012: **105**: 186–188.*

Carl Heneghan • Mathew Thompson

Invited Commentary

Improving Medical Device Regulation
A Work in Progress

JAMA Internal Medicine November 2014 Volume 174, Number 11

Elisabeth M. Dietrich, MPH; Joshua M

Improving Medical Device Regulation: The United States and Europe in Perspective

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The Milbank Quarterly, Vol. 92, No. 1, 2014 (pp. 114-150)

Task 1

Regulatory Framework for MDs

Methods

- 1) literature review
- 2) content analysis of the relevant websites
- 3) semi-structured interviews with key informants from agencies

Jurisdiction	Regulatory Agency/Body	Website
United States	FDA (Food and Drug Administration)	www.fda.gov
European Union	EU Commission and Notify Body	http://ec.europa.eu/health/medical-devices/
Australia	TGA (Therapeutic Goods Administration)	www.tga.gov.au
Canada	Health Canada	http://www.hc-sc.gc.ca/
Japan	PMDA (Pharmaceutical & Medical Devices Agency)	www.pmda.go.jp/english
Brazil	ANVISA (Agência Nacional de Vigilância Sanitária)	http://portal.anvisa.gov.br/wps/portal/anvisa-ingles
China	CFDA (China Food & Drug Administration)	www.eng.sfda.gov.cn

Tarricone R, Torbica A, Ferré F, Drummond M. Generating appropriate clinical data for value assessment of medical devices: what role does regulation play? Expert Rev Pharmacoecon Outcomes Res. 2014 Oct;14(5):707-18

Regulatory Framework for MDs

Findings

- Regulatory principles for drugs and MD are similar in that they seek to ensure the appropriate balance of **patient benefit and ha**
- All jurisdictions relate their evidential requir**ed system** of device classificati
- Regulator**n pr**oth**e-**o
- Ma**juris**in Eu**ket** requirements across high risk devices have received a CE mark ps, only to be rejected by US FDA approval process
- Reliance on **passive adverse event collection** for marketed devices e.g. US (MAUDE) by the FDA and EU (EUDAMED)

Lack of clinical evidence generated to respond to regulatory requirements leads to difficulties in conducting HTAs of MDs and create delays in funding and patient access.

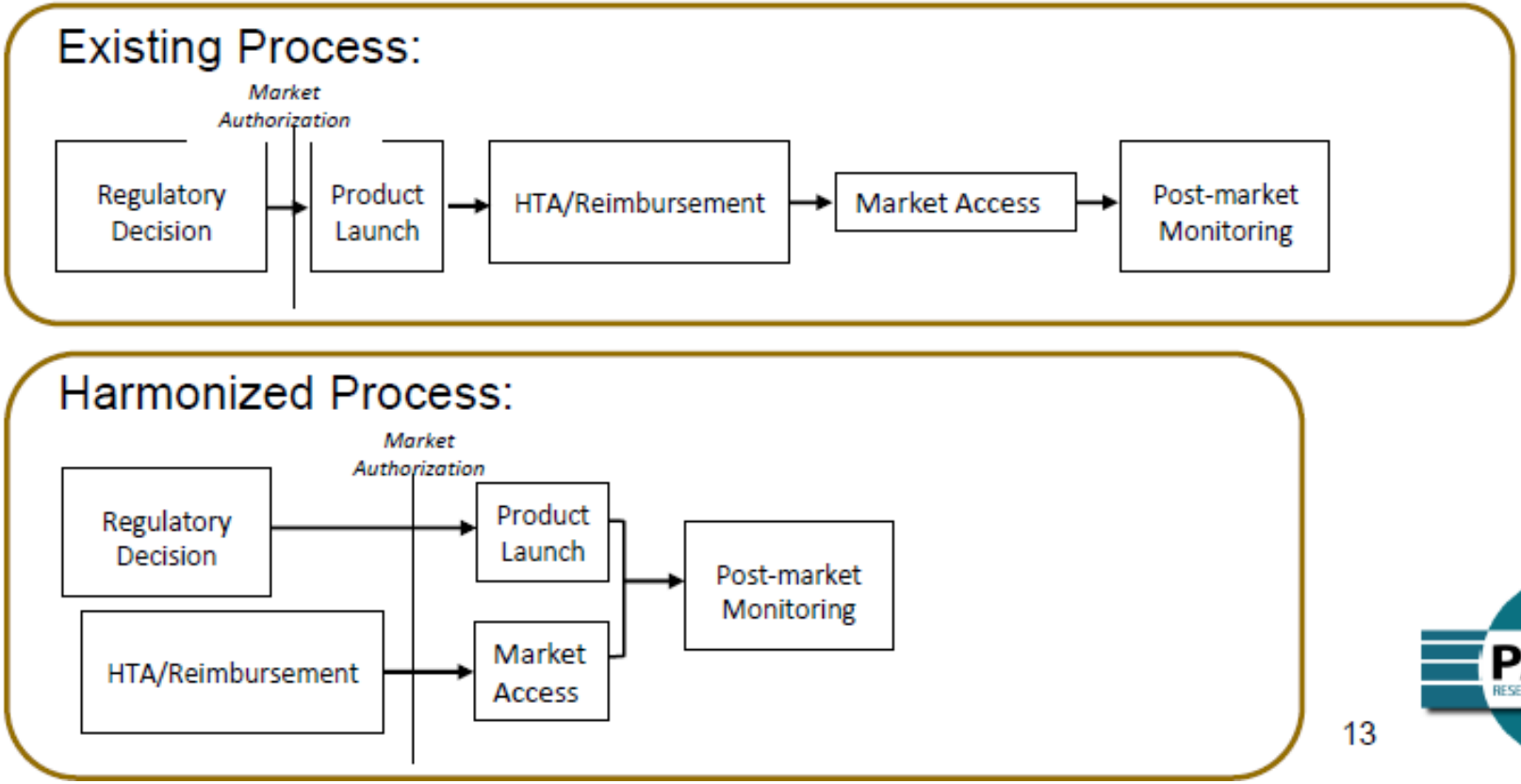
Regulatory Framework for MDs

Potential ways forward

- the type of evidence required prior to **approval match the potential risk of new device** & more **stringent requirements to provide clinical trials for the efficacy and safety** for high risk devices
- need for **international harmonisation of regulatory requirements**, with efforts to set common risk classification rules
- post-marketing surveillance opportunity not just for safety monitoring, but to go beyond efficacy (seen in a trial setting) and assess effectiveness in regular use, and **provide data on device/user learning curve and the organisational impact of medical devices**
- Need for **innovative models of collaboration between regulators, HTA/reimbursement agencies** e.g., Canada EXCITE; Europe SEED

Regulatory Framework for MDs

Potential ways forward



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HTA practices for MDs

To describe and compare non-EU HTA agencies' activities for MDs in terms of:

- organisational structure
- operating procedures
- scientific methods

How is HTA organised and governed? (e.g. separate unit, allocation of resources, deployment of people)

How is HTA conducted? (e.g. degree of stakeholder interaction, priority-setting, transparency)

What methodologies underpin HTA? (i.e., specific scientific method guidelines for assessing evidence)

Ciani O, Wilcher B, Blankart CR, Hatz M, Rupel VP, Erker RS, Varabyova Y, Taylor RS. Health technology assessment of medical devices: a survey of non-European union agencies. Int J Technol Assess Health Care. 2015 Jan;31(3):154-65.

Task 2

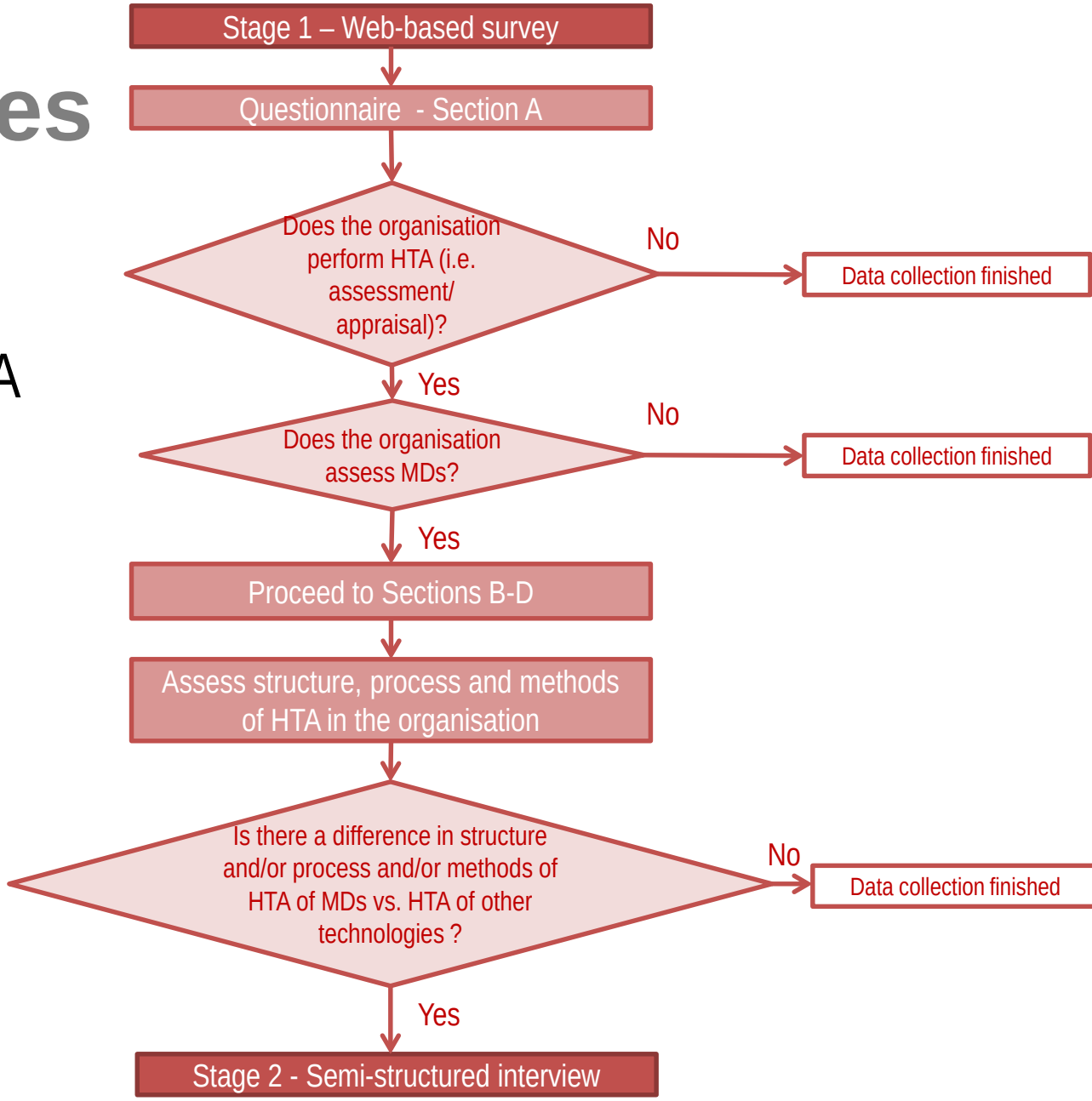
HTA practices for MDs

Methods

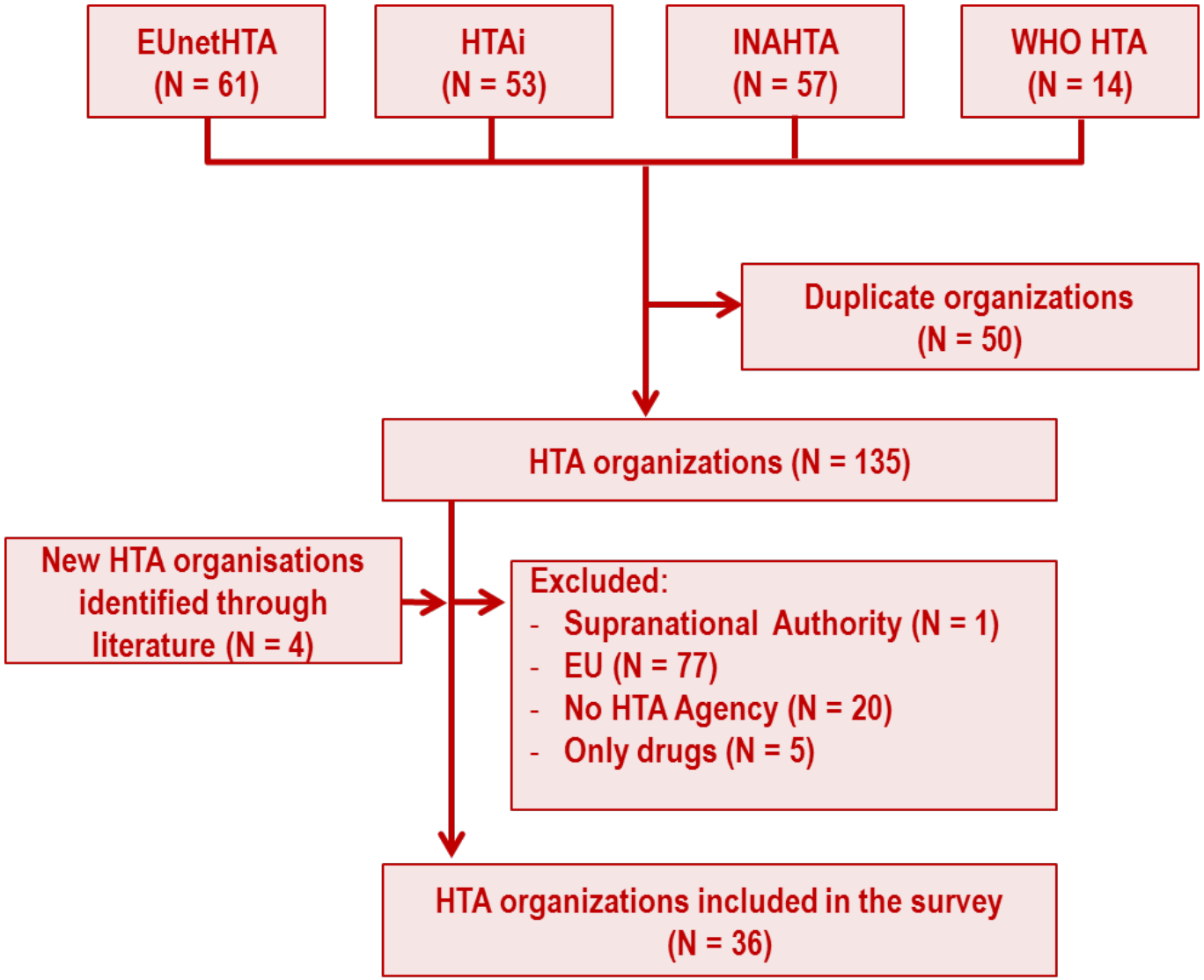
1) identification of HTA agencies

2) content analysis of the relevant websites

3) semi-structured interviews with key informants from “MD specific” agencies

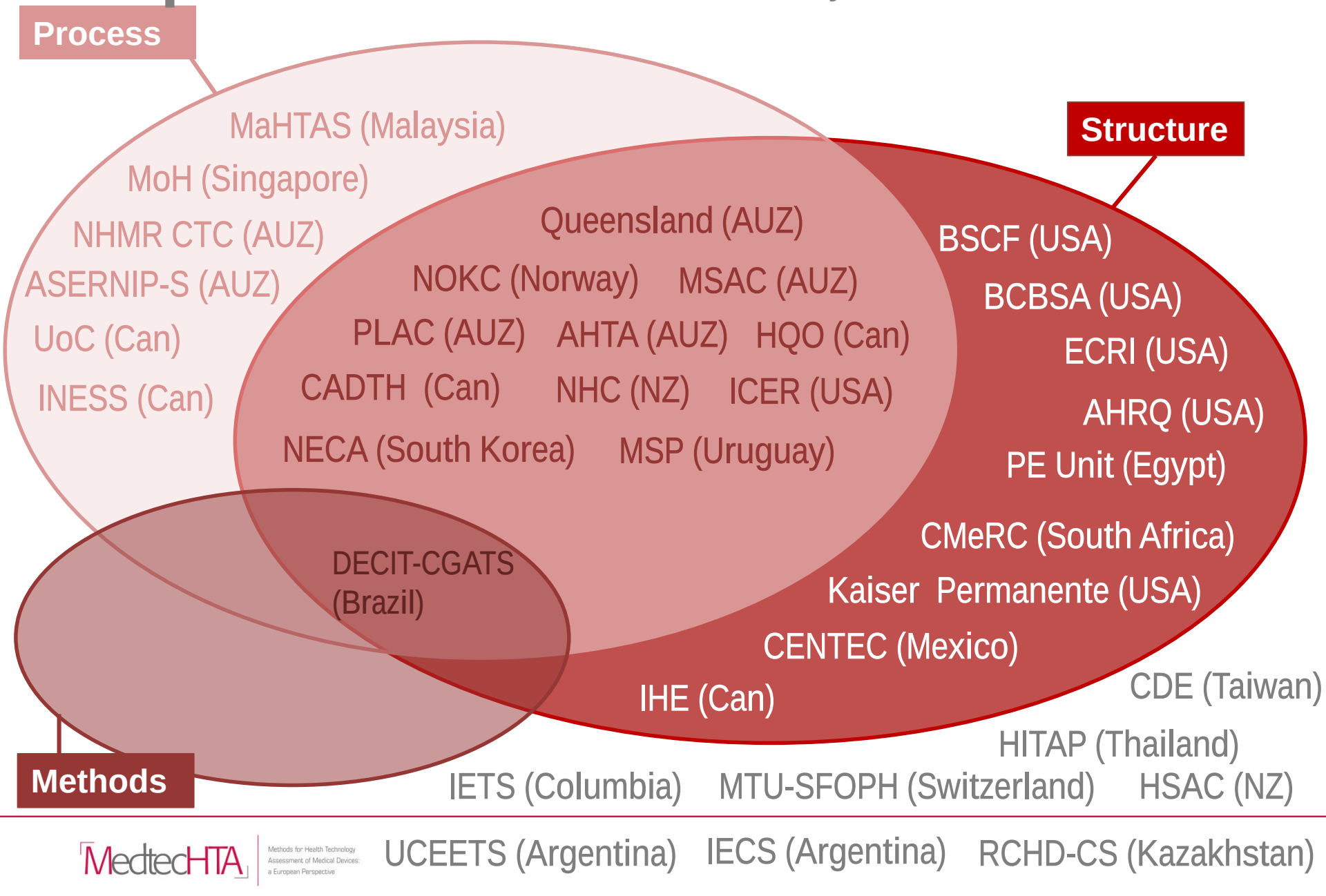


HTA practices for MDs *Selection of HTA agencies*

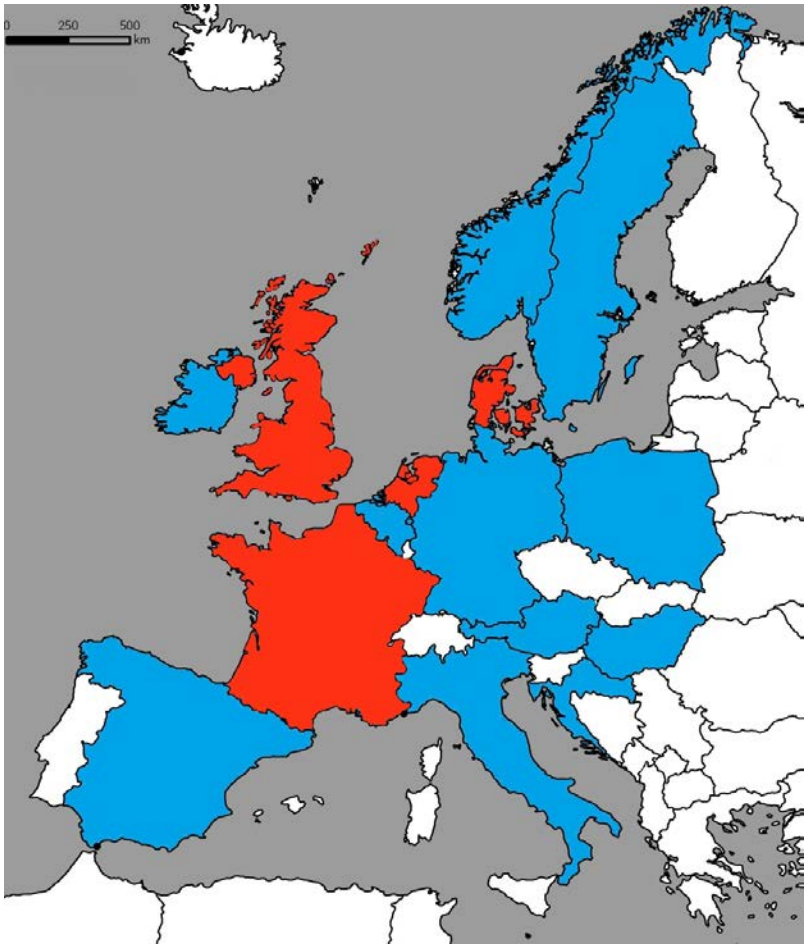


Task 2

HTA practices for MDs *Survey Results*



EU HTA practices on MDs



39 methodological documents from 20 agencies in 16 countries

4 agencies with separate documents for the assessment of medical devices:

- ✓*NICE (UK)*
- ✓*HAS (FR)*
- ✓*CVZ (NL)*
- ✓*DACEHTA (DK)*

Fuchs S et al. Health Technology Assessment of Medical Devices in Europe. Results from Advance HTA. 2014 Washington, HTAi

HTA practices for MDs *Interview themes*

Quality of evidence

- "The fact of having an evaluation of sanitary registration for marketing that does not use the same principles are considerable obstacles in HTA for MD."

Capacity

- "Not enough [MD] experts – there is a very large gap there."

Fragmented system

- "So, for devices we have an extremely fractured system for entry points. Because of that, we have different kinds of evidence requirement at different kinds of levels. I would go so far to say at some levels there is no rigorous evidence assessment taking place."

Transferability

- "…for instance the performance of devices in clinical practice can be very different from that assessed in controlled setting."

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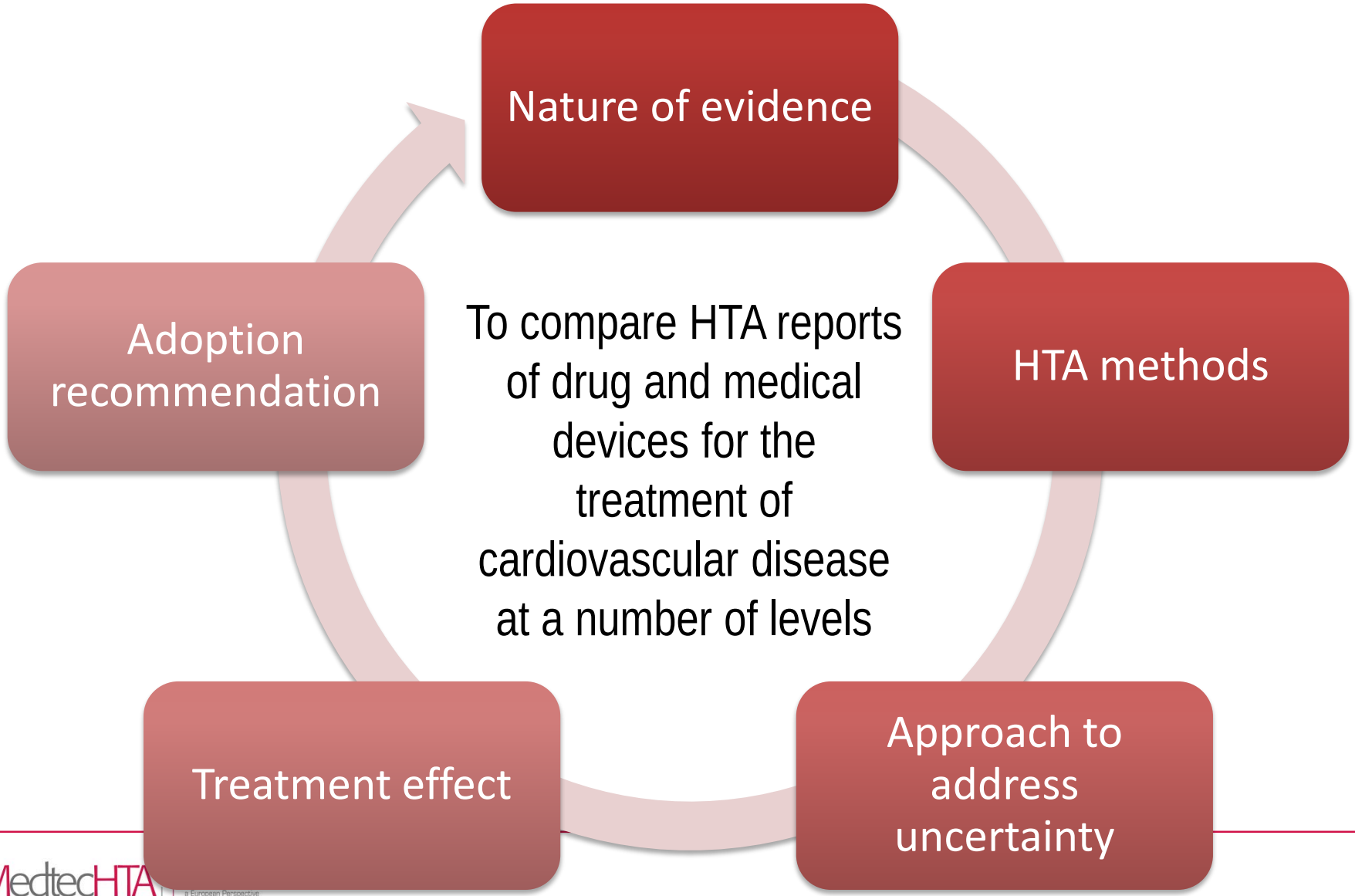
Comparison of HTA reports of drugs and MDs

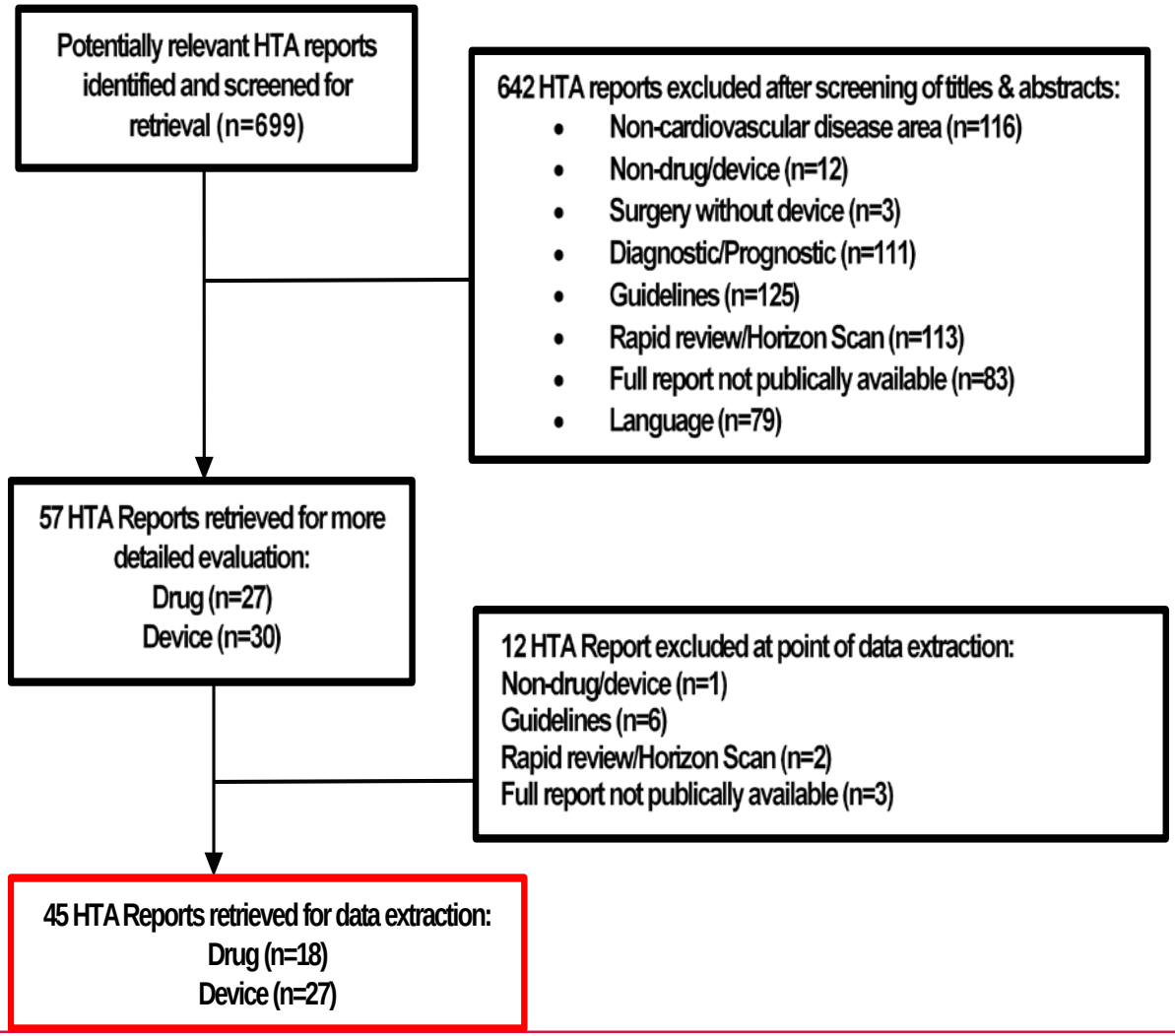


Comparison of HTA reports of drugs and MDs

Methods

- A Systematic Review of HTA reports from CRD database
- Exclusion criteria:

1. Primary indication non cardiovascular disease
2. Surgical procedure w/o device
3. Diagnostic/Prognostic
4. Guidelines
5. Abbreviated review
6. Not publically available
7. Not in English



Comparison of HTA reports of drugs and MDs

Results

	Drug (N = 18)	Device (N = 27)	P-value[1]
Type of clinical study	n (%)	n(%)	
RCTs	17 (94)	18 (67)	0.03
non RCTs	4 (22)	12 (44)	0.13
Observational studies	3 (17)	13 (48)	0.04
Evidence synthesis[2]	6 (33)	8 (30)	0.79
Other[3]	1 (6)	2 (7)	0.81
Number of patients	Median	Median	
RCTs	4203	1482	0.23
non RCTs	4917	836	0.18
Observational studies	7636	646	0.51
Recommendations	n (%)	n(%)	
Unrestricted	1 (20)	0 (0)	
Optimised	1 (20)	5 (83)	
Only in research	1 (20)	0 (0)	
Not recommended	2 (40)	1 (17)	

1. Calculated with Mann-Whitney/ Fisher's/Chi-square tests
2. Includes systematic reviews, pooled analyses, meta-analyses, and previous HTA reports
3. Includes rapid reviews and sources of evidence that do not fall into the above mentioned hierarchy of evidence categories

Comparison of HTA reports of drugs and MDs

Results

	Drug (N = 18)	Device (N = 27)	P-value
HTA dimensions considered	n (%)	n(%)	
Health problem and current use of technology	15 (83)	10 (37)	0.003
Description and technical characteristics of technology	15 (83)	8 (30)	0.001
Safety	12 (67)	17 (63)	0.8
Clinical effectiveness	17 (94)	24 (89)	0.64
Cost and economic evaluation	13 (72)	20 (74)	1
Ethical aspects	1 (6)	1 (4)	1
Organisational aspects	1 (6)	12 (44)	0.006
Social aspects	5 (28)	3 (11)	0.235
Legal aspects	1 (6)	1 (4)	1
Quality	Mean	Mean	
AMSTAR checklist total	7.47	5.5	0.04
Drummond checklist total	7.56	5.29	0.02

Conclusions

- Regulatory and HTA processes for devices need to become more aligned with respect to data requirements
- Need for increased harmonisation in the HTA evaluative framework (collection & synthesis of clinical evidence and economic evaluation) for devices across international HTA agencies
- Need to refine and foster uptake of methods for handling the common ‘complexities’ of devices and start approaching these technologies as complex interventions
  - Number of interacting components
  - Number and difficulty of behaviours required by those delivering or receiving the intervention
  - Number of groups or organisational levels targeted by the intervention
  - Number and variability of outcomes
  - Degree of flexibility or tailoring of the intervention permitted

Craig et al. BMJ 2008

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Thanks for your attention

Results

Characteristics	MD Agencies (N= 36)
Yr funding (mUSD$)	2.1 (0.01 - 24.20)
Nr staff	25 (3 - 150)
Length assessment (mo)	9 (1 - 18)
%HTA reports on MD	25% (5 - 100)
Government body	16 (44%)
Performs assessment	36 (100%)
Performs appraisal	15 (42%)
Funded by Govt	31 (86%)
Priority-setting	23 (64%)
In-house HTA staff	25 (69%)
Re-assessment	15 (42%)

Characteristics	MD Agencies (N= 36)
HTA available online	26 (72%)
Methods guidance	22 (61%)
Methods guidance online	15 (42%)
Emerging/new MD	33 (92%)
Organisational aspects	20 (56%)
Systematic review	31 (86%)
Model based EE	27 (75%)
MDs specific attributes	17 (47%)
Use foreign HTA reports	18 (50%)
National data mandatory	8 (22%)