

Advancing Methods of Health Technology Assessment for medical devices: the EU MedTechHTA project

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Premise

1. Health Technology Assessment is undoubtedly the most widespread approach to set priorities and help supporting the allocation of scarce resources in the health care sector
2. Health Technology Assessment has diffused having pharmaceuticals in mind
3. Assessment of medical devices are more challenging than drugs in several respects*:
 - They are often diagnostics (e.g. multiple indications, value of information)
 - Medical devices' performance often depends on end-users (learning effect and timing of assessment)
 - Experimental studies (e.g. RCTs) are more challenging (e.g. unethical, difficult, impossible)
 - Medical devices have wider economic implications (e.g. organisational impact)
 - Pricing strategies also depend upon country-based procurement policies

*Drummond M, Griffin A, Tarricone R. Economic evaluation for devices and drugs: same or different? Value in Health 2009;12(4):402-406

Did we really need MedtecHTA?

1. Although these challenges are widely recognised, regulatory and HTA bodies rarely seem to consider them when assessing MDs*
2. Does this matter?
3. Would recommendations drawn from HTA change had medical devices been treated differently from drugs?
4. If yes, what would the impact be? Patients not accessing cost-effective innovations? Industry not rewarded for cost-effective innovations? Missed opportunities for healthcare systems and health professionals?
5. Too much important questions to be left unanswered.....

*Tarricone et al., Generating appropriate clinical data for value assessment of medical devices: what role does regulation play? Expert Opinion on Pharmacoeconomics and Outcome Research 2014; 14(5):707-718

Ciani et al., Health Technology Assessment of Medical Devices: a survey of non European Agencies. IJTAHC 2015;31(3):154-165.

MedTechHTA at-a-glance...

- European Commission 7th Framework Programme, Small or Medium-Scale Focused Research Project Call identifier: FP7-HEALTH-2012-INNOVATION-1
- Overall Value of the Project: 2.5 mln€
- EC contribution: 2,055,134.00€
- Duration: 36 months
- Period: 01/01/2013 – 31/12/2015

THE CONSORTIUM

COORDINATOR



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Institute for Economic Research

**Institute for Economic
Research**
Slovenia



**European Society of
Cardiology**
European Heart Rhythm
Association - France

Aims

1. To improve the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices
2. To investigate:
 - **regulatory process** of medical devices in EU & abroad & impacts onto medical devices' uptake and diffusion
 - **current methods used for HTA** of medical devices & whether these differentiate from other technologies (i.e. drugs); **comparative effectiveness** of medical devices
 - value of information and the **characterisation of uncertainty** surrounding the development of new devices
 - **Drivers of diffusion** of medical devices
3. To provide recommendations for methods in conducting HTA on medical devices

Methods

Seven Work Packages investigating the key themes of MedtechHTA through a combination of mixed methods (quantitative and qualitative) approach:

- Systematic literature reviews
- Analysis of case-studies (e.g. fEVAR)
- Interviews (e.g. HTA Agencies, Regulatory bodies)
- Surveys (e.g. clinicians)
- Experiments (e.g. elicitation of bias)

Final Results and Recommendations (I)

9.45 – 11.15: **Improving the process for HTA of Medical Devices**

Chair: **Aleksandra Torbica** (Università Bocconi, MedtecHTA)

Speakers: **Rod Taylor** (University of Exeter Medical School, MedtecHTA) and **Oriana Ciani** (Università Bocconi and University of Exeter Medical School, MedtecHTA)

Discussants: **John Wilkinson** (Medicines and Healthcare Products Regulatory Agency, UK) and **Claudius Griesinger** (European Commission, Joint Research Centre)

Final Results and Recommendations (II)

11.30 – 13.00: **Developing methods for the HTA of Medical Devices**

Chair: **Mike Drummond** (Centre for Health Economics University of York and Bocconi University, MedtecHTA)

Speakers: **Uwe Siebert and Petra Schnell-Inderst** (UNIT University for Health Sciences, Medical informatics and Technology, MedtecHTA) and **Mark Sculpher** (Centre for Health Economics, University of York, MedtecHTA)

Discussants: **Mark Campbell** (NICE Medical Technologies Evaluation Programme, UK) and **Finn Børlum Kristensen** (EUnetHTA)

Final Results and Recommendations (III)

14.00 – 15.00: **Optimising the diffusion of Medical Devices**

Chair: **Rosanna Tarricone** (Bocconi University, MedtecHTA).

Speakers: **Aleksandra Torbica** (Università Bocconi, MedtecHTA) and **Jonas Schreyögg** (Hamburg Centre for Health Economics, MedtecHTA)

Discussants: **Maurizio Lunati** (ESC, Niguarda Cà Granda Hospital, Italy) and **Pascale Brasseur** (Eucomed HTA Working Group, MedtecHTA Advisory Board).

15.00 – 15.30: **Recommendations and Conclusions**

Mike Drummond (Centre for Health Economics University of York and Bocconi University, MedtecHTA)

Thank You.

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