

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

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

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> Final Conference Bocconi University Milan, November 13th, 2015



Premise

- 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.



MedTecHTA at-a-glance...

- European Commission 7th Framework Programme, Small or Medium-Scale Focused Research Project Call identifier: FP7-HFALTH-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



Università Commerciale Luigi Bocconi

Centre for Research on Health and Social Care Management (CERGAS) - Italy

PARTNERS



University of Hamburg Hamburg Centre for Health

Hamburg Centre for Health Economics - Germany



University of York

Centre for Health Economics -United Kingdom



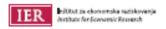
University of Exeter Medical School

Peninsula Technology Assessment Group - United Kingdom



University for Health Sciences, Medical Informatics and Technology

Institute of Public Health, Medical Decision Making and Health Technology Assessment - Austria



Institute for Economic Research

Slovenia



European Society of Cardiology European Heart Rhythm



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
- To provide recommendations for methods in conducting HTA on medical devices



Methods

Seven Work Packages investigating the key themes of MedtecHTA 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** (UMIT 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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