



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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# MedTechTA 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

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# Project Recommendations

- Improving the process for HTA of medical devices
- Developing methods for HTA of medical devices
- Optimising the diffusion of medical devices

# Improving the Process for HTA of Medical Devices (1)

- Align regulatory and HTA processes for devices with respect to data requirements
  - joint scientific advice by regulatory and reimbursement bodies for data collection for the device industry
  - design studies that allow collection of data that jointly fulfill the requirement of regulators and payers
- Harmonize the HTA evaluative framework (collection & synthesis of clinical evidence and economic evaluation) for devices across international HTA agencies

# Improving the Process for HTA of Medical Devices (2)

- Assessment of expected cost-effectiveness is not sufficient: conditional coverage and evidence development decisions are recommended
  - value of the device and future value of research needs to be quantified and used to identify the optimal timing of reimbursement decisions in the device's life cycle
  - implementation may commit resources that cannot be recovered
- Consideration should be given to the implications of the learning curve (LC) on policy decisions (and vice versa)
  - LC does not only change the estimate of effectiveness but also affects the uncertainty
  - identify the mechanisms of learning likely to cause change over time and assess the profile of investment risk according to user experience affected by the rate of uptake of the device in practice

# Improving the Process for HTA of Medical Devices (3)

- Consideration should be given to the likely prospects of research and who should pay for it
  - is it priority for public funding or for manufacturers to undertake?

# Developing Methods for HTA of Medical Devices(1)

- Refine existing methods (for collection & synthesis of clinical & economic data) for handling the common ‘complexities’ of devices
  - synthesis of observational and trial evidence
  - incorporating learning curves into decision analytic models
  - incremental innovation
- Consider the MD-related intervention as a complex intervention; in particular, include the intervention’s components and the relation between intervention, modifying factors and outcome in the formulation of the research question.

# Developing Methods for HTA of Medical Devices (2)

- Consider specific study designs and analysis methods, in addition to general recommendations for RCTs, to assess the comparative effectiveness of MDs
- Disease-based or device-based registries of high quality should be established for the long-term study of the effectiveness and safety of MDs.
- Such registries should be designed to allow comparative analyses. Information on possible confounding factors should be routinely collected.
- Comparative effectiveness or safety analyses must use appropriate methods for confounder adjustment and should try to address residual confounding

# Developing Methods for HTA of Medical Devices (3)

- If data from large registries are available for inclusion in the evidence synthesis in HTA, bias-adjustment based on expert elicitation should be considered as one scenario in the sensitivity analysis.
- Document research using suitable existing reporting guidelines.
- Consider MD-specific application of guidance on the methods for evidence synthesis from the framework on complex interventions.
- Assess the applicability of findings considering the challenges arising from patient eligibility, user dependence, study design, and rapid evolution of the technology.

## Developing Methods for HTA of Medical Devices (4)

- An iterative process to the evaluation of devices may be required as additional evidence and learning emerges over time
- Consideration should be given to the likelihood of future price changes
  - price influences the benefits of early approval and the benefits of research
  - may be useful to identify effective price thresholds for which guidance changes
- Determine whether manufacturers should be expected to conduct the research based on assessment of:
  - the commercial value to manufacturers of early evidence
  - the potential for AWR and for improving research timelines

# Optimising the Diffusion of Medical Devices (1)

- Leverage routinely collected data (administrative data) to investigate the adoption and diffusion of MDs, provided that coding system allows for valid and reliable identification of the technology
- Endorse the use of a common classification for medical devices (unique identification code) across countries to facilitate international comparisons
- Systematically include factors driving adoption of medical devices in HTA reports to estimate the impact of the interplay of:
  - physician characteristics,
  - organizational, regional, and environmental factors and manufacturers' actions

## Optimising the Diffusion of Medical Devices (2)

- Consider divergent effects by stratifying by medical devices type (e.g. “old” and “new” cardiovascular devices)
- Concentrate on the identification of key opinion leaders in hospital to better understand the adoption and the diffusion process
- Focus on developing the understanding of physicians’ personal goals and motivation and their role in the adoption of (cardiovascular/medical) devices

# Optimising the Diffusion of Medical Devices (3)

- Monitor manufacturers' actions, as they seem to be very relevant for the adoption of “new” cardiovascular devices
- Consider regional (e.g. rural vs urban hospital location) and environmental factors (e.g. GDP and out-of-pocket payment) to understand where the diffusion process is likely to take place
  - large hospitals, with relatively large cardiology departments in agglomerations and highly developed countries with lower shares of out-of-pocket payments