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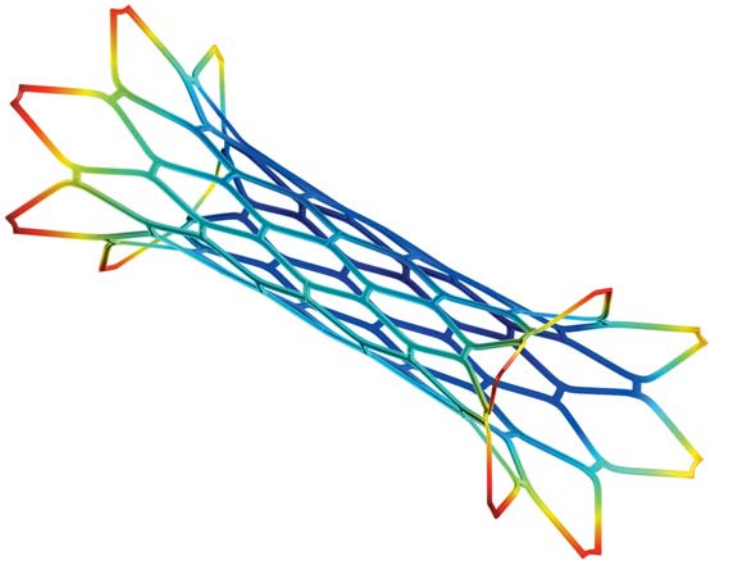

MedtecHTA

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

SEVENTH FRAMEWORK PROGRAMME

Funded under FP7 - HEALTH Grant Agreement no. 305694

THE PROJECT

Health Technology Assessment (HTA) is widely accepted as a multidisciplinary approach studying the clinical, economic, social and ethical implications of development, diffusion and use of health technologies. In addition, its role in policy making is increasingly established in EU countries. However, the currently adopted methodological framework for HTA does not fully meet the challenges rising from intrinsic differences between different types of health technologies, and in particular medical devices.

The general objective of the **MedtecHTA** project is to investigate improvement of HTA methods to allow for more comprehensive evaluation of medical devices by acknowledging complexities arising from their integration into clinical practice and to develop this framework into a tool that provides structured, evidence-based input into health policies.

The **MedtecHTA** project will provide more than 280 person-months of scientific research effort to:

- explore current differences in methods used for HTA of medical devices in EU and non-EU countries;
- investigate within- and between-country variations in utilization of innovative medical devices (e.g. implantable devices in cardiology) that have important implications on equity;
- develop improved methods for satisfying three main pillars of HTA: comparative effectiveness, economic evaluation and organizational impact of medical devices;
- investigate uncertainty surrounding the development of new devices and investments in research.

MedtecHTA is expected to make a substantial contribution to the development of methodologies and practices of HTA for medical devices for a wide range of key stakeholders: policy makers, the scientific community, HTA agencies, healthcare providers, the medical device industry and patients.

MedtecHTA is funded under the European Commission's 7th Framework Programme as a Small or Medium- Scale Focused Research Project. The project started on 1 January 2013 and will run for 3 years with a budget of over €2 million.

MedtecHTA consists of seven related work packages, each implemented by an international team of researchers under the coordination of Università Commerciale Luigi Bocconi (UB): Project Director Professor Rosanna Tarricone, Project Scientific Advisor Professor Mike Drummond and Deputy Project Director Professor Aleksandra Torbica.

OVERVIEW OF PROJECT WORK PACKAGES

1st Part **Cross-country analysis of HTA practices and utilization of medical devices**

- WP 1 Cross-country analysis of HTA agencies
  Led by: Rod Taylor, UNEXE
- WP 2 Geographic variation in access to medical devices
  Led by: Giuseppe Boriani, ESC/EHRA

2nd Part **Methodological issues in HTA of medical devices**

- WP 3 Comparative effectiveness of medical devices
  Led by: Uwe Siebert, UMIT
- WP 4 Economic evaluation of medical devices: Overview of different approaches
  Led by: Giovanni Fattore, UB
- WP 5 Uncertainty and value of information for medical devices
  Led by: Mark Sculpher, YORK
- WP 6 Organizational impact of medical devices
  Led by: Jonas Schreyöegg, HCHE

3rd Part **Conclusions, synthesis and recommendations**

- WP 7 Recommendations on HTA methods for medical devices
  Led by: Rosanna Tarricone, UB

Expected results:

By reviewing current licensing and HTA guidelines for medical devices in Europe, the first WP will make policy makers more aware of the state of the art and potential benchmarks. By exploring variation in utilization rates of selected medical technologies in the field of electrophysiology across and within member states, WP2 will provide new evidence about access and appropriateness to care across and within member states.

Such evidence is pivotal to sustaining policy action at both the national and the EU level. WPs 3-7 will review the state of the art about the methodologies used in HTA and will make recommendations for improvements. In particular, they will offer policy makers methodological reflections and advancements on comparative effectiveness, cost-effectiveness and economic analysis in general, uncertainty and value of information, and organizational impact of new technologies.