4.11. MedtecHTA

Project	MedtecHTA – Methods for Health Technology Assessment of Medical Devices: A European Perspective
Organisation	Università Commerciale Luigi Bocconi
Research location	Milan, Italy
Cooperation partners	Hamburg Centre for Health Economics of the University of Hamburg; University of York Centre for Health Economics; Technology Assessment Group of the Peninsula College of Medicine & Dentistry University of Exeter; Institute of Public Health, Medical Decision Making and Health Technology Assessment of the University for Health Sciences, Medical Informatics and Technology in Austria; the Institute for Economic Research in Slovenia and the European Society of Cardiology of the European Heart Rhythm Association in France
Team	One director, one deputy director, one scientific advisor, one product manager in addition to five Bocconi researchers and several researchers from the partners' institutions
Funding sources	European Union FP7 grant agreement HEALTH-F3-2012-305694
Website	www.unibocconi.it

ORGANISATIONAL BACKGROUND

The research project is led by Rosanna Tarricone from the Bocconi University. She is Associate Professor and Director of CERGAS (Centre for Research on Health and Social care Management) at Bocconi University. Five research fellows from Bocconi University are involved. A full professor and three research fellows from the group of Centre of Health Economics from York University are also consortium members. From Hamburg Centre for Health Economics there is a full professor, three research fellows and the director of the programme on Economic Evaluation and Health Technology. At the University of Exeter Medical School two researchers are involved including one full professor, one full professor and two researchers from UMIT in Austria, two researchers from the Institute for Economic Research, Ljubljana in Slovenia and three researchers from the European Society of Cardiology.

FUNDING

Funding for the research comes from the European Union Seventh Framework Programme under grant agreement HEALTH-F3-2012-305694.

PROBLEM BEING ADDRESSED

MedtecHTA aims to improve the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices and to develop this framework into a tool that provides structured, evidence-based input into health policies. Medical devices are different from drugs but are currently assessed using the same methods. This poses a risk to decision-makers and they may generate biased recommendations preventing patients from accessing cost-effective procedures.

The objective of MedtecHTA project was to investigate improvements in HTA methods to allow for more comprehensive economic evaluation of medical devices. It consisted of seven work packages (WPs) that investigated: the regulatory process of MDs in Europe and its impacts on the diffusion of medical devices; current methods used in HTA for medical devices and whether these are different from other technologies; comparative effectiveness of medical devices; value of information and the characterisation of uncertainty surrounding the development of new devices and the drivers of diffusion of medical devices.

RESEARCH DESIGN AND SOLUTION

The research team has involved several stakeholders at various stages in the research. From the very beginning an Advisory Board has helped to shape the entire project's methods and aims, and throughout the three-year study duration preliminary findings were discussed with different target audiences such as patient organisations, scientific communities, policymakers, payers, regulatory authorities and the industry. The continuous and open exchange of views and perspectives has greatly helped to improve the project and more importantly, to make its findings relevant and useful for society as a whole.

Assessment of MDs is more challenging than that of drugs in several respects: they are often diagnostic tools (e.g. multiple indications, value of information); the performance of MDs often depends on end-users (learning effect); and experimental studies (e.g. RCTs) are often unethical, difficult, or impossible to conduct. Although these challenges are widely recognised, regulatory and HTA bodies do not consider them when assessing MDs.

GRAND CHALLENGE BEING ADDRESSED

Technological innovation in healthcare is one of the key determinants of better health outcomes but also a driver of healthcare expenditure. Among health technologies, medical devices (MDs) represent a very dynamic sector which is advancing at a fast pace. Governments struggle to maintain a fair balance between patients' access to modern care and economic sustainability of healthcare systems and in doing so they endeavour to select the most cost-effective devices at the lowest possible price. Moreover, the recent economic crisis has threatened the health of people who are less advantaged. This has happened partly because governments were not equipped with the most appropriate tools to assess the inequality of access facing patients. The present research investigates the drivers of diffusion and how these can be managed in order to reduce inequalities across and within European countries and appropriate methods developed to make the right choices in the best interests of patients.

Health Technology Assessment (HTA) is undoubtedly playing an increasing role in decision-making on the introduction and diffusion of technological innovation in healthcare with the aim of balancing access to innovation and cost containment. HTA is "a multidisciplinary field of policy analysis which studies the medical, social, ethical, and economic implications of the development, diffusion, and use of health technology" and is traditionally conceived as an effective approach to guide the decision-making process for the allocation of scarce resources. Nevertheless HTA has been developed with pharmaceuticals in mind.

It has been claimed that HTA for devices raises special challenges which require the HTA community to reflect on whether the current methods adequately take account of their specific features. Two major salient features of devices deserve special attention: the device-operator interaction that can generate learning curve effects and therefore risks the presence of bias in estimating the size of the benefits and the incremental nature of innovation (e.g. longer battery life, improvements in software systems, smaller size) that needs to be addressed by adequate and reasonable licensing procedures, but also by careful identification of alternatives for comparative and incremental cost-effectiveness analysis.

RESPONSIBLE RESEARCH AND INNOVATION

Besides academics, MedtecHTA has involved relevant stakeholders: clinicians, policymakers, providers, regulators and the industry. These actors have different backgrounds and different objectives, sometimes with opposing goals. Given the ultimate aim of MedtecHTA (i.e. to recommend a methodological framework to assess medical devices), it was fundamental to gather stakeholders' opinions to ensure that all possible aspects that might impact the way in which MDs are assessed are taken into account. The rationale is that research can translate into policy action only if shared and agreed by relevant stakeholders. The stakeholders were involved at several points during the study period. Regulators and policymakers were interviewed several times in order to elicit their preferences in terms of process and procedures for assessing MDs but also to understand their difficulties and perplexities. Clinicians have been part of a large European survey aimed at investigating the key motivational factors that predict diffusion of MDs and equality of access for patients. Hospitals have been compared to measure their performance in providing MDs and identify key success factors. The industry has been consulted in order to fully understand how MDs are developed and the challenges in carrying out clinical studies.

Target groups were involved in the research project from the start of MedtecHTA through an Advisory Board, composed of people from industry, policymakers, the scientific community, EUnetHTA and clinicians. The objectives and methods were shared with them and feedback was gathered in order to better shape the research proposal and improve the methods and materials. A website was developed on which key milestones were posted and circulated via a newsletter sent to all subscribers. Preliminary results have been presented as soon as they were ready to several conferences and workshops covering different target groups (e.g. HTAi which is widely attended by regulators, policy-makers and payers; iHEA at which academics are well represented; ISPOR with a strong industry presence; HAS-Haute Autorité de la Santé which is attended by many patients' organisations, industry, regulators and payers). The final results were presented to a large audience consisting of patients, clinicians, payers, hospital managers and the industry and discussed with HTA Agencies, Scientific Associations, the Department of Health and EunetHTA.

The MedtecHTA project made a substantial contribution towards the development of HTA methodologies and practices for medical devices for a wide range of key stakeholders and towards informing policy in the European Union, which in turn will impact on public health in the Region. The objective of the MedtecHTA project was to bring the research to the attention of various target audiences interested in methodological developments in health technology assessment: these include researchers, policymakers, the industry, and patients' associations. It aimed to demonstrate the ways in which research is contributing to a European 'Innovation Union' and to show its openness. This was done by providing tangible proof that collaborative research adds value by showing how European collaboration has achieved more than would have otherwise been possible in helping to solve the challenges facing society.

EVALUATION AND DISSEMINATION

The research originates from a paper by Drummond, Tarricone and Torbica from 2013, entitled "Alternative approaches for assessing the socioeconomic benefits of medical devices: a systematic review", published in the journal *Value in Health* (16,1: S7-S13). The article raised the issue that new approaches are needed to access the benefits of devices. This article initiated the project and on the basis of the project, the research team refers to eight journal articles since 2013. Two important changes have been accomplished. First, the results on comparative effectiveness (i.e. bias adjustment, use of real-world evidence) have been incorporated in the recommendations made by EunetHTA, the European network of HTA Agencies. Second, the Italian government has decided to constitute a National Plan for HTA in relation to MDs, with a process and methods that are differentiated from those used for drugs.