REVIEW OF INTERNATIONAL HTA ACTIVITIES ON MEDICAL DEVICES

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About MedtecHTA

The MedtecHTA project (Methods for Health Technology Assessment of Medical Devices: a European Perspective) aims at improving 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. The research h activities are conducted by a consortium of six European Universities and one Scientific Association. The project is funded under the European Union's 7th Framework Programme as Small or Medium-Scale Focused Research Project (2013-2015).

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality (Washington DC, USA)
AHTA	Adelaide Health Technology Assessment (Adelaide, Australia)
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (Adelaide, Australia)
BCBSA	Blue Cross Blue Shield Association (Chicago & Washington DC, USA)
BSCF	Blue Shield of California Foundation (San Francisco, CA)
CADTH	Canadian Agency for Drugs and Technologies in Health (Ottawa, Ontario)
CDE	Center for Drug Evaluation (Taipei, Taiwan)
CENETEC	Centro Nacional de Excelencia Tecnológica en Salud (Mexico City, Mexico)
CMeRC	Charlotte Maxeke Research Consortium (Parktown, South Africa)
DECIT	Coordenação Geral de Avaliação de Tecnologias em Saúde, Departamento de Ciência e Tecnologia (São Paulo, Brazil)
ECRI	Emergency Care Research Institute (Plymouth Meeting, USA)
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
EXCITE	MaRS Excellence in Clinical Technology Evaluation
HITAP	Health Intervention and Technology Assessment Program (Nonthaburi, Thailand)
HQO	Evidence Development and Standards, Health Quality Ontario (Toronto, Ontario - Canada)
HSAC	Health Services Assessment Collaboration (Christchurch, New Zealand)
HTA	Health Technology Assessment
HTAi	Heath Technology Assessment International
ICER	Institute for Clinical & Economic Review (Boston, USA)
IECS	Institute for Clinical Effectiveness and Health Policy (Buenos Aires, Argentina)
IETS	Instituto de Evaluación Tecnológica en Salud (Bogotá, Colombia)
IHE	Institute of Health Economics (Edmonton, Alberta - Canada)
INAHTA	International Network of Agencies for Health Technology Assessment
INESS	Institut national d'excellence en santé et en services (Québec, Québec - Canada)
MaHTAS	Health Technology Assessment Section, Ministry of Health Malaysia (Putrajaya, Malaysia)
MD	Medical Device

MedtecHTA	Methods for Health Technology Assessment of Medical Devices
MoH, Singapore	Ministry of Health, Singapore (Singapore)
MSAC	Medical Services Advisory Committee (Canberra, Australia)
MSP	Ministry of Public Health of Uruguay (Montevideo, Uruguay)
MTU-SFOPH	Medical Technology Unit - Swiss Federal Office of Public Health (Berne, Switzerland)
NECA	National Evidence-based healthcare Collaboration Agency (Seoul, Korea)
NHC	New Zealand National Health Committee (Wellington, New Zealand)
NHG	National Healthcare Group (Singapore)
NHMR CTC	NHMRC Clinical Trials Centre (Camperdown, Australia)
NOKC	Norwegian Knowledge Center for the Health Services (Oslo, Norway)
OHTAC	Ontario Health Technology Advisory Committee (Toronto, Ontario - Canada)
PATH	Programs for Assessment of Technology in Health Research Institute (Hamilton, Ontario - Canada)
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PLAC	Prostheses List Advisory Committee (Canberra, Australia)
RCHD-CS	Ministry of Public Health of the Republic of Kazakhstan, Republican Centre for Health Development, Centre of Standardization, HTA department (Astana City, Kazakhstan)
SHS	Singapore Health Services (Singapore)
SME	Subject Matter Expert
SUS	Brazilian Public Health System
UCEETS	The National Coordination Unit of Health Technology Assessment and Implementation (Buenos Aires, Argentina)
UoC	University of Calgary (Calgary, Alberta)
WHO	World Health Organization

Executive Summary

Background

Policymakers increasingly rely on Health Technology Assessment (HTA) to make decisions about health technology coverage and reimbursement. While there have been a number of previous surveys of international HTA agency practice few have specifically assessed medical device evaluation.

Objective

The overarching objective of this study was to review and compare current HTA activities for medical devices across non-European HTA agencies with particular reference to their structure, processes, and methods.

Methods

The identification of agencies for inclusion in this study was based on their membership (as of February 2013) in: Heath Technology Assessment International (HTAi), European network for Health Technology Assessment (EUnetHTA), International Network of Agencies for Health Technology Assessment (INAHTA) and World Health Organization (WHO) Collaborating Centers for HTA.

Included agencies' HTA procedures for medical devices were evaluated from three organisational perspectives:

1) Structure: How is the agency organised?
2) Process: What are the agency's HTA standard operating procedures?
3) Methods: What scientific methodologies underpin the assessment process?

Data collection consisted of two phases: web-based survey of all included agencies and semi-structured interviews with those agencies identified to have medical device specific procedures.

Key Findings

Our final sample included 36 HTA agencies across 19 non-EU countries. In accordance with good practice principle #3 for HTA agencies proposed by Drummond and colleagues (i.e., 'HTA should include all relevant technologies'), the majority (36/41, 88%) of agencies identified included the assessment of medical devices alongside drugs, and other medical technologies, such as diagnostic tests. In addition, 27 out of the 36 (75%) agencies evaluating medical devices have also developed approaches specific to the assessment and appraisal of medical devices. Seventy-eight (21/27) and sixty-seven percent (18/27) of agencies have developed specific structural and procedural processes respectively for the evaluation of medical devices. Only one agency, the Department of Science and Technology in Brazil, reported that they developed specific methodological guidance for the HTA medical devices.

Interviews with agencies confirmed a number of commonly cited challenges in the HTA of medical devices, including relatively poor quality of evidence for medical

devices, problems with generalising the medical device evidence obtained in a specific setting to another, the 'learning curve' (i.e., the clinical outcomes of medical devices depend on training and experience of operator or the clinical setting in which the device is being used), and difficulty scoping the decision problem for HTA of medical devices.

The vast majority of agencies appeared to apply the same methodological approach to assessment of medical devices as non-devices. However, we did identify some innovative approaches to evidence generation and HTA assessment for medical devices such as the MaRS Excellence in Clinical Technology Evaluation (EXCITE) programme recently established in Ontario, Canada. This programme seeks to assist medical device manufacturers with the design of studies and collection of evidence that would allow them to fulfill the requirements for both regulators and HTA decision-making authorities.

Policy Implications

In contrast to regulatory requirements that are fairly consistent across international settings, HTA procedures for medical devices appear to vary widely across countries.

It is well accepted that medical devices differ from drugs and other health technologies in a number of specific ways (e.g., learning curve, incremental technology innovation). However, we found little evidence of differentiation in the methods used by HTA agencies to assess devices compared to non-device technologies. Our findings therefore raise the question of whether the differences are such to demand that HTA procedures (i.e., structure, processes and methods) be tailored specifically to meet the needs of medical devices.