

Comparative assessment of HTA reports on drugs and medical devices for the treatment of cardiovascular disease

WORK PACKAGE 1 – DELIVERABLE D 1.3

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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 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).

About the authors & their contribution to the report

Oriana Ciani (OC) PhD student and Research Fellow based at the Institute of Health Research, University of Exeter Medical School. Contributed to the drafting of the protocol and the final report and data extraction.

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Rod Taylor (RT) is Work Package 1 (WP1) lead based at the Institute of Health Research, University of Exeter Medical School. Responsible for the overall oversight of deliverable 1.3 and the final report. Co-led the protocol and final report drafting.

Britni Wilcher (BW) is a contracted researcher on MedtecHTA WP1 and Associate Research Fellow based at the Institute of Health Research, University of Exeter Medical School. Responsible for coordination of deliverable 1.3. Led the drafting of the protocol and final report, undertook the initial data extraction, and conducted the data analysis.

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Executive Summary

Background

Policymakers increasingly rely on Health Technology Assessment (HTA) to inform their decisions about health technology coverage and reimbursement. However, given the differences between medical devices and drugs (i.e. more rapid changes in technology, outcomes that often depend on training and experience of operator, and more dynamic pricing), the traditional HTA evaluative framework, primarily developed for drugs, may not be as applicable to medical devices.

Aim

The overarching aim of this study was to compare HTA reports of drug and medical devices for the treatment of cardiovascular disease.

Methods

Reports were identified for inclusion by searching the University of York's Centre for Reviews and Dissemination HTA Database for the 10 year period of 2003 to 2013 for evaluating medical device or drug interventions for cardiovascular disease (i.e. cerebrovascular, cardiac or peripheral vascular disease).

Included HTA reports were reviewed at four levels: (i) nature of evidence included (i.e. study design considered, quality of evidence), outcomes (e.g. use of surrogate endpoints); (ii) methods applied by reports (e.g. systematic review, meta-analysis), consideration of device specific factors (e.g. learning curves and incremental evolution); (iii) approaches and methods used to address uncertainty; (iv) magnitude of treatment effect. Quantitative outcome data for drug and medical device reports were summarised and compared using descriptive and inferential statistics. Textual data was thematically analysed, and where possible, comparisons were made across device and drug reports.

Main Findings

Of the 699 HTA reports identified, a total of 45 HTA reports (18 drug and 27 medical device) were included across cardiac (31), peripheral vascular (12) and cerebrovascular (2) indications. Reports were primarily undertaken by agencies in Canada, UK and US.

Compared to drug HTA reports, medical device HTA reports were: (i) less likely to include RCT evidence but are similar in their consideration of economic evidence; (ii) of poorer quality evidence synthesis methods (i.e. systematic review and de novo economic modelling); (iii) more likely to consider organisational issues; and (iv) were equally as likely to handle uncertainty. Due to the heterogeneity of type and nature of outcome reporting it was not possible to compare directly magnitude of treatment effects of device and drug reports. Whilst medical device HTA reports often acknowledge technology specific issues (including organisational factors, learning curve, and technology evolution), few reports formally assessed impact of these issues on clinical or economic outcomes. Although reports stated a policy recommendation, based upon a review of clinical and economic evidence, the conclusions of drug and device report appeared equally positive.

Implications

Our results support the view that quality of clinical data available to allow policymakers to make robust reimbursement and coverage decisions for medical devices can be inferior to that of drugs. This discrepancy is probably a reflection of less stringent regulatory approval pathways for medical devices, particularly in Europe. However, the mismatch in the quality and nature of evidence included in HTA reports for drugs and medical devices in the particular case of cardiovascular disease is perhaps less than expected.

The potentially generalisability of these findings requires further comparative analyses of drug versus medical device HTA reports in other clinical areas. Research is also needed into the application of quantitative methods to formally assess the impact medical device technology specific issues in HTA.