MedtecHTA
Methods for Health Technology Assessment of Medical Devices: a European Perspective

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WP5: Uncertainty and value of information analysis for medical devices

Deliverable 5.1:

Evaluation of uncertainty and value of further research for devices – key methodological issues

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Executive summary

The evaluation of clinical effectiveness and cost-effectiveness of medical devices relies on evidence which is typically less extensive and lower in quantity than evidence for pharmaceutical products. In these circumstances, further evidence may be particularly valuable as it can reduce uncertainty, improve patient outcomes and/or reduce resource costs. However, a decision to adopt (fund, cover or reimburse) a technology early in its life cycle when the evidence base is least mature will often have an impact on the prospects of acquiring further evidence to support its use. This general issue of balancing the value of additional evidence about the performance of the technology and the value of access to the technology is central to policy decisions on whether and when to adopt a medical device into clinical practice.

A general framework for health technologies has recently been developed to inform policy choice regarding conditional coverage and evidence development decisions (Claxton et al, 2012).[1] The key principles and assessments needed fall into four broad areas: i) the value of the technology; ii) the need for and value of additional evidence, and whether the type of evidence required can be conducted once a technology is approved for widespread use; iii) whether there are sources of uncertainty which cannot be resolved by research but only over time; and iv) whether there are significant (opportunity) costs which once committed by approval of the technology cannot be recovered. These assessments lead to different types of guidance about the use of health technologies: Only in Research (OIR), Approval with Research (AWR), Approve or Reject.

This work extends the existing framework for health technologies to address the conceptual issues that arise when dealing with uncertainty in the evaluation of devices. A set of analytic principles specifically for medical devices is established which focuses on the characteristics of devices which differ most from pharmaceuticals. In particular, the impact of learning curves, capital investment costs, price changes and incremental device modifications over time are examined. The impact on the value of the technology and the future value of research is quantified. This forms an important component of the policy decision on whether to adopt the medical device based on the current state of evidence and/or wait until further research is conducted to support its use. The development of the framework promotes rapid and consistent adoption of innovative clinically and cost-effective medical technologies and identifies when research might reasonably be expected to be provided by sponsors or when publically funded research might be needed.

The framework also highlights many of the complexities associated with the evaluation of medical devices: i) the difficulty of identifying and disentangling the mechanisms underlying the learning curve; ii) the interactions between the different device characteristics, e.g. incremental developments of the device to improve effectiveness and user experience; iii) circular circumstances when the effects of the learning curve impact on policy choice and policy choice impacts on uptake and learning; iv) identifying the 'optimal' timing of adoption or reimbursement decisions in the technology's life cycle; and v) how the link between price, value and the need for additional evidence creates incentives to manufacturers for the conduct of research.

SEVENTH FRAMEWORK PROGRAMME

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