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# WP 3: Comparative effectiveness of medical devices

## Deliverable 3.1:

**A framework and recommendations for comparative effectiveness research for medical devices based on a review of current methods for comparative effectiveness research**

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## Executive Summary

Guidelines for Health Technology Assessment (HTA) and Comparative Effectiveness Research (CER) largely focus on pharmaceuticals and only few explicitly consider other health care technologies. CER of medical devices (MD) faces some challenges that raise questions about how adequate current CER methods account for the specific features of MD and how well MD fit in the paradigm of drug evaluation. The underlying question is where the framework of CER and HTA methods needs specifications to deal with the specific challenges by MD and which methods can be applied.

The aim of WP3 - Methods for Comparative Effectiveness Research of Medical Devices- was to identify challenges and gaps in current methods for CER of MD and to derive a comprehensive framework for CER of MD with focus on high-risk implantable MD. Our review investigates primary and secondary research methods to address all relevant steps for the evaluation of technologies, because informative CER results can only be achieved when sound primary data are available. Therefore our recommendations also consider the generation of appropriate evidence. The basis of our comprehensive framework is a targeted literature review for CER methods and specific features of MD. An electronic database search was combined with systematic screening of tables of content of selected journals in the fields of epidemiology, HTA, statistics, and evidence-based medicine, which have a strong focus on methods. Additionally, we screened the reference lists of the most relevant papers.

More than 200 publications about the general evaluation of MD and about specific CER methods were included.

The MD's physical mechanism of action, the dynamic development and regulatory evidence requirements are the driving features that suggest the increased use of certain methods for the evidence generation, finding of information for HTA, data analysis and synthesis, and interpretation of results. The challenges for the design of randomized controlled trials and the increased use of observational studies for MD suggest that rather than following the paradigms of drug evaluation, MD resemble more the notion of complex interventions. A major factor to understand the extent and quality of evidence available is the consideration of the life cycle of the technology.

The evaluation of MD with CER differs in several aspects from the evaluation of pharmaceuticals. It is usually not as straight forward as for drugs and follows more the paradigms of evaluation of complex interventions. In primary research the IDEAL framework gives concrete advice for study types in the different development phases of the life-cycle of surgery which can be applied to implantable MD. The CER assessment phase can be differentiated further according to the market situation. Therefore MD specific features of non-inferiority studies should be further examined. In systematic reviews of CER of MD the approach of the Working Group preparing the chapter for evaluation of complex interventions for the Cochrane handbook can be adapted to implantable MD. Methods for analyzing and synthesizing observational data and cross-design synthesis are needed more frequently in systematic reviews and HTA of MD. The lack of incentives for manufacturers to generate high quality evidence was also identified as an important challenge to improve the evaluation of MD.