

The Use of Real-World Evidence (RWE) to Support Market Access of Medical Devices: Implications for the German Setting

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BACKGROUND

- Changes in German healthcare regulation strengthen the need for real-world evidence (RWE) analyses to support market access of medical devices.
- From 2016 on, the Act to Strengthen Health Care Provision within the Statutory Health Insurance System (Gesetz zur Stärkung der Versorgung in der gesetzlichen Krankenversicherung, §137h SGB V) requires high-risk or implantable, highly invasive medical devices (regulatory risk classes IIb and III) that are based on a new theoretical-scientific concept to undergo a benefit assessment.
- A benefit assessment will be mandatory if a hospital requests reimbursement under a special funding system that exists to cover additional resource use for new technologies. This funding scheme named the "New Diagnostic and Treatment Methods" (Neue Untersuchungs- und Behandlungsmethode [NUB]) system addresses, among other technologies, medical devices not yet covered by the G-DRG system.
- A 1-month period will be given to the manufacturer and hospitals seeking additional funding for using the respective medical device to provide information on its clinical benefits.
- Within the following 3 months, the Gemeinsame Bundesausschuss (GBA) will perform a benefit assessment that forms the basis for a decision on additional reimbursement.
- RWE offers various opportunities to address different information needs by diverse stakeholders on medical devices, and consequently, RWE analyses may act as an important instrument in supporting market access of medical devices.

OBJECTIVE

- The aim of this systematic literature review was to assess the current status of RWE studies in the field of medical devices for Germany.

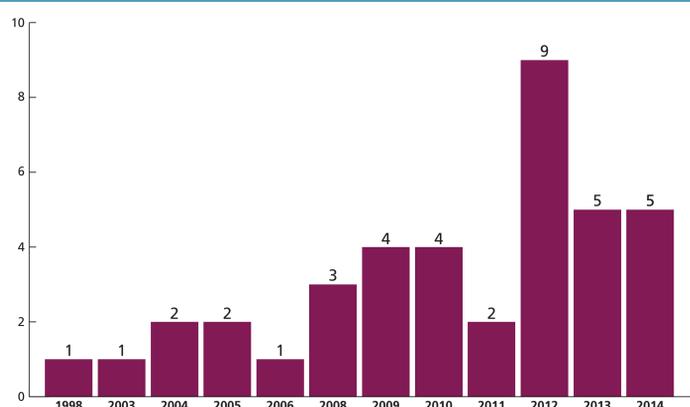
METHODS

- A systematic literature review was conducted to depict the status quo of RWE studies in the field of medical devices for Germany.
- Relevant articles were identified via PubMed by keywords and MeSH terms linking various related terms for RWE and medical devices in the MEDLINE database of the United States National Library of Medicine (NLM).
- Titles and abstracts of potential studies were separately screened by 2 independent researchers. Studies were excluded if they did not describe the use of medical devices in a real-world setting in Germany in German/English language.
- Included studies were stratified by type of RWE data (registry data, administrative/claims data, medical charts, and other data sources), study design (prospective vs. retrospective), and research questions (brand-specific vs non-brand-specific).

RESULTS

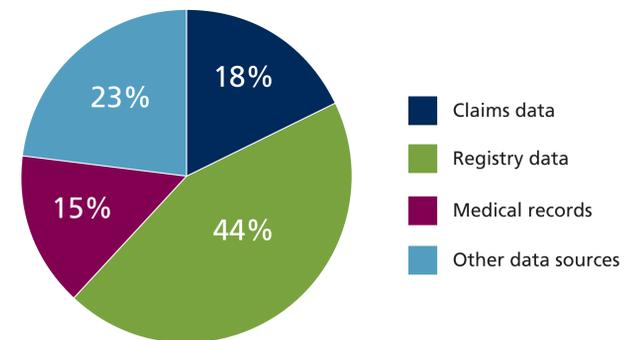
- Thirty-nine publications met the inclusion criteria and were included in the analyses.

Figure 1. Number of Publications on Medical Devices Referring to RWE



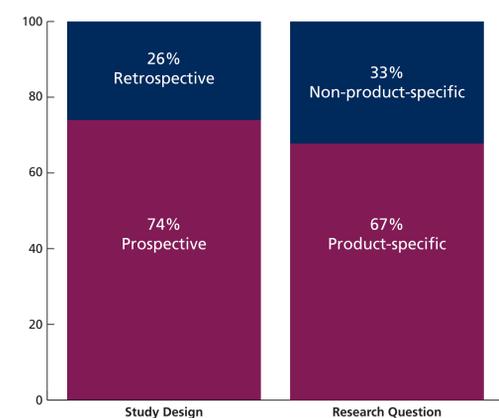
- RWE studies on medical devices have steadily increased over the past 2 decades.
- Most studies (44%) used registry data while administrative/claims data were used in 18% of the cases. Medical records were used in 15% and other data sources, such as questionnaires or the database of the mandatory national quality control program for hospitals, were represented in 23% of the studies.

Figure 2. Types of Data Used in RWE Studies on Medical Devices



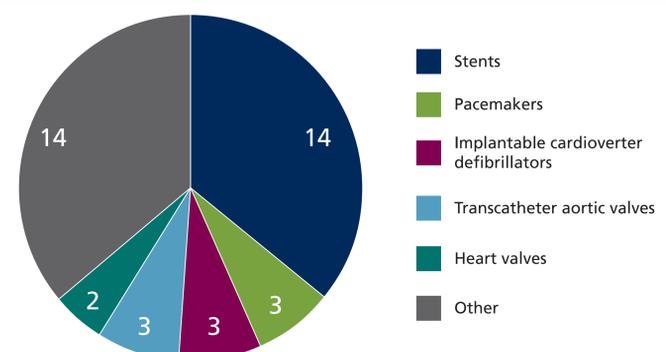
- The majority of publications, about 74%, used a prospective study design (compared to retrospective studies at 26%).
- Two-thirds (66%) of the studies analyzed data on a product-specific level, whereas the remainder mainly distinguished between different categories of medical devices.

Figure 3. Perspective and Focus of RWE Studies on Medical Devices



- Registry data were mostly used to address product-specific research questions (88%), while all claims data-based studies investigated research questions on a non-product-specific level.
- Stents are the most prominent research topic in RWE studies on medical devices. Most of these studies are based on 2 existing stent registries (DES.DE and Cypher).

Figure 4. Product Classes Assessed in RWE Studies on Medical Devices



- Common research questions were cost comparisons, survival analyses, and burden of disease.

CONCLUSIONS

- Given the wide spectrum of product classes for medical devices, RWE is used only to a limited extent in the German setting.
- After the most recent changes in German healthcare regulation, it is expected that the use of real-world data will gain momentum as it provides a valuable means to answer a multitude of different research questions.
- However, careful considerations have to be made regarding whether existing data sources can be utilized or new data need to be generated to address specific research questions.
- Especially studies on real-world effectiveness and cost-consequence studies may become more prominent, as these topics form the majority of upcoming regulatory questions and payer-related discussions.