

Real World Evidence (RWE) In Oncology – Status Quo In Germany

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BACKGROUND

- In Germany, cancer is the second most common cause of mortality and almost 0.5 million people are diagnosed annually.¹
- Various data sources have been established over the past few years. Since 1995, the Federal Cancer Registration Law obligates the establishment of epidemiological cancer registries. In addition, some hospitals have clinical registries for oncologic diseases.²
- RWE research is diverse in this segment and studies are conducted, eg, to estimate the prevalence and incidence of the underlying disease and the target populations, eg, as support for market access of new medications.³
- Observational studies, eg, with claims data or registries, might be used to fill in gaps of randomized studies or when these cannot be conducted. RWE publications are able to give an overview of the status quo of oncological research eg, epidemiology or the treatment situation.

OBJECTIVE

- The aim of this study was the identification and categorization of available RWE in oncology. Furthermore, based on the identified publications research gaps for Germany were shown.

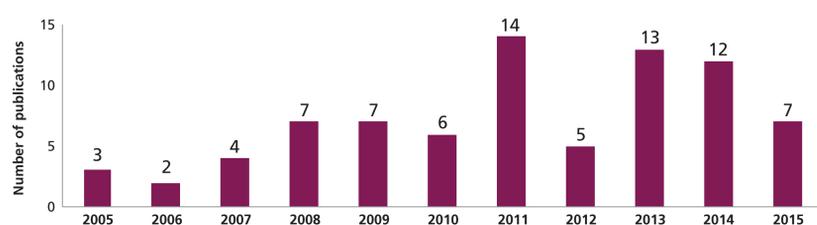
METHODS

- A systematic literature search was conducted to evaluate the status quo of RWE in the field of oncology in Germany.
- Key words identifying health services research in combination with oncology were used in a search performed in the DIMDI (German Institute of Medical Documentation and Information) meta-database including all years up to 2015.
- The identified publications were screened for relevance based on the assessment of RWE.
- All selected publications were classified by type of RWE study and further categorized by cancer types.
- Specific outcomes such as prevalence, incidence and patient reported outcomes, were assessed to analyze the field of oncology from different perspectives.

RESULTS

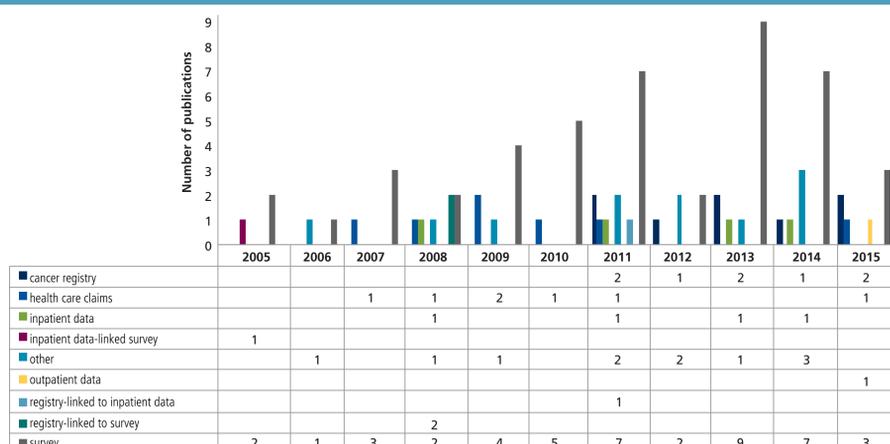
- The systematic search yielded 137 publications of which 80 publications from 2005-2015 were included (**Figure 1**).
- The identified publications were stratified by RWE approach, cancer type and year of publication.

Figure 1. Number of RWE publications from 2005 to 2015



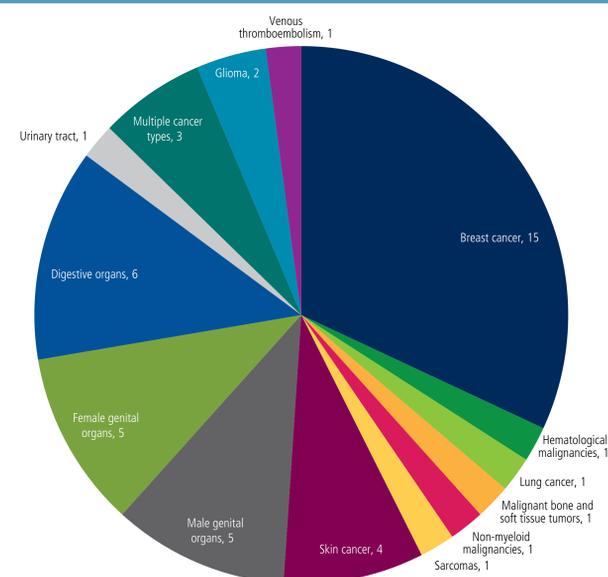
- In total, nine RWE categories were determined, including cancer registries, health care claims, inpatient and outpatient data, surveys, registry-linked data with inpatient data or surveys, inpatient data linked to surveys, and "other RWE" referring to specific evaluations such as secondary analyses of evaluation programs (**Figure 2**).

Figure 2. Type of RWE category assessed from 2005 to 2015



- Most observational studies assessed healthcare in oncology by conducting surveys (56%), followed by cancer registries (10%) and health care claims (9%).
- Over time, most observational studies were published in 2011 (18%), followed by 16% in 2013 and 15% in 2014.
- Assessments with cancer registries were published as of 2011, whereas there were no studies with claims data from 2012-2014. The first available claims data publication was issued in 2007.
- The use of surveys increased from 2005 onwards.
- Regarding evaluated cancer types, 32 studies (40%) explored cancer in general without focusing on a specific cancer type.
- Breast cancer was assessed in 15 studies (19%), whereas 5 (6%) addressed prostate and female genital organ cancer and 8% digestive cancer (**Figure 3**).

Figure 3. Publications stratified by cancer type



- Summarizing, various cancer types were assessed including malignant neoplasms affecting digestive organs and gender-specific cancer types.
- Breast cancer was mostly assessed with surveys from 2006 onwards, which might be linked to the integration of Disease Management Programs (DMP) for breast cancer in Germany which exist since 2002.⁴
- Specific care and treatment of cancer patients, including palliative care was considered in 23 (29%) publications.
- Quality of care and treatment was an important outcome both prospectively and retrospectively assessing the patterns of care and the need for specific care.
- Only a few publications (11%) aimed at assessing incidence and prevalence for various outcomes.

CONCLUSIONS

- Cancer registries, health insurance claims data, and surveys present a comprehensive view of the healthcare system and epidemiology and are preferably used in the assessed publications in Germany.
- Information such as prevalence, incidence, mortality as well as demographics, diagnoses, prescriptions, sick leave payments, health care cost, and patient needs were estimated with various RWE data.
- The use of RWE in observational studies provides complementary data to randomized trials for missing study/label populations or research findings.
- Furthermore, observational studies can represent a large number of patients. By using claims data analyses, big sample sizes can be realized in one study and therefore might be a more valid approach for assessments of disease burden.
- Screening programs are widely established for the early detection of cancer, of which the efficiency might also be evaluated with observational studies. Additionally missing data, accordance to present guidelines, health service gaps and needs for improvement might be identified.
- Finally, observational studies can reflect the applied treatment patterns as well as the occurrence of treatment effects in a real world setting as this represents a link between clinical research and medical practice.
- Research gaps exist in terms of RWE treatment with new concepts, drugs, and in some cancer fields. Further research is warranted to compare the use of RWE in other countries.

1. https://www.gkv-spitzenverband.de/krankenversicherung/qualitaetsicherung_2/klinisches_krebsregister.jsp Available October 2015.
 2. http://www.gekid.de/origin_aims_tasks.html Available October 2015.
 3. Use of Real World Evidence in German AMNOG Applications, Value in Health, May 2015, Volume 18, Issue 3, page A95.
 4. <http://www.bundesversicherungsamt.de/druckversion/weitere-themen/disease-management-programme/zulassung-disease-management-programme-dmp.html> Available October 2015.