The German Arthroplasty Registry (EPRD)

1. *Structure of the Registry*

The German Arthroplasty Registry (Endoprothesenregister Deutschland, in short "EPRD") was established as an initiative of the German Society of Orthopaedics and Orthopaedic Surgery e.V. (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie e.V., in short "DGOOC") in cooperation with the two biggest German public health insurance companies (AOK-Bundesverband GbR, in short "AOK" and Verband der Ersatzkassen e.V. vdek, in short "vdek"). These two umbrella organizations comprise 17 public health insurance companies that cover roughly 70% of all Germans with public health insurance, and 65% of the overall population. The medical device industry is represented by the Bundesverband Medizin-technologie e.V. (in short "BVMed"), a German association of medical device manufacturers. BVMed provides an implant database that is updated continuously.

The EPRD is run by the management company EPRD Deutsche Endoprothesenregister gGmbH, a non-commercial entity. DGOOC is the parent company and sole shareholder of EPRD gGmbH, but all major decisions are made by a supervisory board (Executive Committee, in short "EC"). This board is comprised of an equal number of representatives from the DGOOC, BVMed, as well as the AOK and vdek. The EC may form committees from among its members, define their tasks and competences, and delegate decision-making competency to them. At present, these committees include six permanent working groups.

The registry is financially supported by implant manufacturers, as well as the vdek and AOK. The Deutsche Arthrose-Hilfe e.V. supported the establishment of the EPRD as part of its research funding. Furthermore, the German Federal Ministry of Health (BMG) supported the establishment of the EPRD through several subsidies.

2. *Aims of the Registry*

The success of hip and knee arthroplasty operations has led to their widespread acceptance by both the general public and orthopaedic surgeons. To improve the quality of service, existing and new implants are developed constantly. The EPRD's goal is to contribute to the improvement of the quality of care by monitoring arthroplasty procedures in Germany over a long time span, with the long-term goal of reducing the rates of revision arthroplasty operations.

With the establishment of the EPRD, Germany commits to the scientific principle of auditing one of the most frequently performed public health procedures in the field of elective surgery. The prevalence of hip and knee arthroplasty surgery in Germany is comparable to that documented in other national joint registries.

3. *Study population*

Prospective data collection by the EPRD in Germany is on a voluntary basis for all parties, i.e., patients, hospitals, implant manufacturers, and public health insurance companies. Hospitals collect pseudonymized patient data and implant data via barcode scanning. This data is linked to information from the industry´s product database and supplemented with follow-up clinical data from the two participating public health insurance companies. In this way, a closed system of audit and survival analysis is established between participating hospitals, insurance companies, and patients.

4. Summary of Statistical Methodology and Data Linkage

Data collected for analysis by the EPRD is gathered from three separate sources:

I. **Participating Hospitals.** Index arthroplasty case data are submitted to the EPRD by participating hospitals and include:

   a) decoding of implanted components using web-based barcode scanning: identifies the brand, type and design of components used;

   b) patient-specific demographic data (electronic case report form [eCRF]): age, sex, relevant prior operations, height and weight (as of Jan. 1st, 2017), as well as ASA classification (as of Jan. 1st, 2020).

   c) procedure-specific data (eCRF): date of procedure, the clinic performing the operation, operation site, laterality, primary or revision surgery, primary diagnosis, and revision diagnosis.

   Publicly insured patient data are pseudonymized using a unique lifelong patient identifier. As there is currently no such unique lifelong identifier for privately insured patients (10 % of all patients), their data cannot be used for longitudinal follow up. It is expected that a system for the pseudonymization of private patient data will be introduced in the nearer future, allowing long-term follow-up of these patients.

II. **EPRD Product Library.** This library is maintained by industry providers primarily engaged in orthopaedic product manufacturing. It currently comprises more than 75,000 individual product components. Each component is precisely described and classified, according to its design parameters. The classification process is highly granular to enable refined analysis of arthroplasty performance. Barcode scanning results are matched with the information from the eCRF. A plausibility test is run against the specifications of the product library to validate the implanted components. In the case of incomplete data, size or laterality mismatch, a warning is sent to the participating hospital. The library itself is continuously updated as new products and components enter the German market.

   Implant classifications for this product library were originally developed by the EPRD, and were further refined and harmonised in collaboration with the British National Joint Registry (in short, "NJR"), so that the two largest European arthroplasty registries are now intercompatible. It is planned to make this classification available for all implant registries through a project with the International Society of Arthroplasty Registries (in short, "ISAR").

III. **Public Health Insurer Data Collection.** The accounting data collected by the public health insurance companies (AOK and vdek) is based on clinical coding of the 10th International Classification of Diseases (in short, "ICD-10") and operating procedure classification (in short "OPS"), and is linked to the pseudonymised case data from the participating hospitals. It is used for cross-referencing and validating the directly provided registry-data from the hospitals at the index operation (starting point of the follow up). In case of a subsequent arthroplasty revision of the same joint performed in a German hospital, the event of revision is documented by the accounting data from the AOK and vdek, even if this hospital does not provide data to the EPRD. This procedure ensures that the EPRD will be informed of any relevant revision procedure, amputation, or death of the patient within this closed data system, avoiding an underestimation of revision rates. Relevant comorbidities are also made available to the EPRD. This information is linked to the pseudonymized case data and conforms to EU data and privacy protection laws (General Data Protection Regulation (EU) 2016/679, in short, "GDPR"). Linked supplementary health data (such as relevant comorbidities etcetera) enables additional substratification and risk adjustment for relevant confounding factors, as it is routinely performed in many of the long-standing national joint registries.

5. *Coverage and Representation*

   Since November 2012, more than 2,630,000 hip and knee arthroplasty procedures have been reported to the EPRD. Included cases are primary and revision procedures of hemi/total hip replacements, partial/total knee replacements.

   Since 2019 the national coverage is more than 70 % p.a. At present, participation in the EPRD in Germany is voluntary. To define the proportion of all hip and knee arthroplasty operations performed in Germany that are submitted to the EPRD, data is provided by the independent quality assurance body Institute for Quality Assurance and Transparency in Healthcare (in short "IQTiG"). According to the IQTiG latest report, in total about 460,000 hip and knee arthroplasty operations were performed in German hospitals in 2022. Thus, when approximately 350,000 operations are submitted to the EPRD, a national coverage rate of some 76 % for the year 2022 is calculated.

   EPRD participation is voluntary for clinics (individual surgeons cannot report individual data). Currently 774 of the total of about 1,200 clinics implanting hip and knee arthroplasties actively participate in EPRD case collection. These clinics represent a disproportionately high share (80 %) of all hip and knee primary and revision operations performed in Germany. Hospitals that perform a higher-than-average number of arthroplasty operations are more likely to participate in the EPRD: Hospitals with more than 500 hip & knee implant procedures per annum are overrepresented (more than 90 % of this group take part), while those with less than 100 surgeries per annum are underrepresented (less than 20 % of this group take part).

6. *Survival Analysis of Arthroplasty Components and "Completeness of Revision"*

   Survival analysis is essential to assessing the quality of hip and knee replacement surgery in Germany. Currently, the EPRD supplies follow-up data for up to ten years from the date of the index operation. Due to the large volume of implants, clearly discernable trends have emerged in the mid-term phase of data follow-up.

   The collaboration between public health insurance companies and registry enables a closed system of observation for a subset of patients, ensuring the inclusion of data on patients who may otherwise have been revised at a German hospital not actively contributing to the EPRD. Following exclusion of inconsistent/incomplete data (e.g., mismatch of operating side between hospital and health insurance company data) approximately 50 % of all data gathered by EPRD per year can be used for survival analysis.

   Because of the linkage between health insurance and EPRD data, loss of follow up revision surgery is reduced to an absolute minimum for those patients who meet the inclusion criteria.

   With the death of the patient, or amputation of the affected lower limb, the observational follow-up is concluded. From this point, the case is considered "censored" and excluded from implant follow-up to avoid an underestimation of the revision rate. In conclusion, the cross-validation process ensures high data quality with a closed system for completing revision surgery data for the studied subpopulation.

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