The German Arthroplasty Registry (EPRD)

1. Structure of the EPRD

The German Arthroplasty Registry (Endoprothesenregister Deutschland, in short "EPRD") has been set up 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") together with the two biggest German public health insurance companies (AOK-Bundesverband GbR and Verband der Ersatzkassen e.V. vdek), together covering some 70% of all public health-insured German people, and together with industry represented by Bundesverband Medizintechnologie e.V. (in short "BVMed"), a German association of medical device manufacturers.

Together with its member companies, BVMed provides an implant database that is updated continuously. Implant manufacturers, vdek and the AOK-Bundesverband support the registry financially. 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 setup of the EPRD several times through subsidies.

The success of hip and knee arthroplasty operations has led to their widespread acceptance by both the general public and orthopaedic surgeons. In the hope of improving the quality of service, new implants are constantly being introduced. The EPRD aims to improve the quality of care delivered by monitoring arthroplasty procedures in Germany over time, with the long-term goal of reducing 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 elective knee and hip arthroplasty surgery in Germany (>450,000 surgeries p.a.) is comparable to that documented in other national joint registries.

Data collection by the EPRD in Germany is on a voluntary basis for all parties, i.e., patients (consent necessary), hospitals, manufacturers, and public health insurers. Through the collection of pseudonymized patient data and implant data via barcode scanning from hospitals, linked to information from industry´s product database, and supplemented with follow-up clinical data from the two participating public health insurers, a closed system of audit and survival analysis is thus established between participating hospitals, insurers and patients.

The EPRD is run by the management company EPRD Deutsche Endoprothesenregister gGmbH (in short "EPRD gGmbH") which is a non-commercial entity. DGOOC is 100% shareholder of EPRD gGmbH, but all major decisions are made by a supervisory board called Executive Committee (in short "EC"). The EC is comprised of equal number of representatives of the DGOOC, of BVMed and of the two public health insurance companies. The EC may form committees from among its members, define their tasks and competency, and delegate decision-making competency to them. At the time being, committees include six permanent working groups.

2. *Summary of Statistical Methodology and Data Linkage*

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

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

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), and 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. This system is currently restricted to publicly insured patients (90% of all patients). As there is no way to pseudonymize privately insured patients for a process of longitudinal follow up, their data cannot be included in the registry without compromising European privacy laws. It is anticipated that in the next 2-3 years a system for the pseudonymization of private patient data will be introduced, allowing long-term follow-up of these patients in the future.

II. **EPRD Product Library.** This library is maintained by industry providers primarily engaged in orthopaedic product manufacturing. The library currently comprises more than 61,000 individual articles. Each article is precisely described and classified, according to its design parameters. The classification process is highly granular to enable refined analysis of arthroplasty performance. The library itself is continuously updated, as new articles enter the German market.

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.

III. **Public Health Insurer Clinical Data Collection.** The data collected by the public health insurer supplements that obtained from the hospital at the index operation. To afford completeness in the case of revision of arthroplasty components performed outside the above-described closed system of EPRD-participating German hospitals, data is supplemented by revision operation data collection from either of the two major public health insurers (AOK Bundesverband GbR and Verband der Ersatzkassen e.V. vdek). These two umbrella organizations comprise 17 public health insurance companies that cover some 70% of the German publicly insured population (i.e., about 65% of the entire German population).

Through routine billing documentation based on DRG clinical coding and OPS coding systems, insurance companies can provide clinical data for cross-referencing with and validating hospital acquired data. This ensures that the EPRD will be informed of any relevant revision procedure, amputation or death of the patient within this closed data system.

Using DRG codes, supplementary health data regarding relevant comorbidities are 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 [GDPR]). Linked supplementary health data enables substratification for

relevant confounding factors, as is routinely performed in many of the long-standing national joint registries.

3. *Coverage and Representation*

For the year 2018, more than 300,000 hip and knee arthroplasty procedures have been reported to the EPRD from 716 independent institutions (for the year 2019 approximately 320,000 cases are expected in total). Included are bipolar hips, total hip replacements, partial/total knee replacements, and revision procedures.

At present, participation in the EPRD in Germany is voluntary. To calculate the proportion of all hip and knee arthroplasty operations performed in Germany that are submitted to the EPRD for long-term analysis, data is provided by the independent quality assurance body Institute for Quality Assurance and Transparency in Healthcare (in short "IQTiG"). The IQTiG confirms that 448,000 hip and knee arthroplasty operations were performed in German hospitals in 2018. Thus, when approximately 300,000 operations are submitted to the EPRD, a national coverage rate of some 67% (expected to rise to some 70% for 2019) is calculated.

EPRD participation is voluntary for clinics (individual surgeons cannot report individual data). Currently about 750 of the about 1,200 clinics implanting hip and knee arthroplasties participate in EPRD case collection. These clinics perform a disproportionately high share (82%) of all hip and knee primary and revision operations that are performed in Germany. That is to say, clinics that perform a higher-than-average number of arthroplasty operations are more likely to participate in the EPRD: hospitals with >500 hip & knee implant procedures per annum are overrepresented (>90% of this group take part) while hospitals with <100 surgeries per annum are underrepresented (<20% of this group take part).

4. *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 four years from the date of the index operation. Due to the large volume of implants, trends are none-the-less discernible even in this early phase.

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 40% 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. Henceforth 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.

5. *National German implant registry on the horizon*

Towards the end of 2019, German parliament passed a law setting up a national German implant registry called Implantateregister Deutschland (in short "IRD"). The IRD is planned to start its nation wide data collection for hip and knee implants beginning of 2024. It is anticipated that all major medical implants will eventually be followed-up under the IRD within ten years. The existing structure of the EPRD has served as a blueprint for the comprehensive and compulsory IRD and will be subsumed within it. EPRD data transfer to the IRD is planned in 2025, thus enabling seamless continuity of follow-up of EPRD cases.

Participation in IRD will be mandatory for all parties involved in surgery. This means that all patients (without consent), hospitals, public & private health insurance companies, and manufacturers selling implants in Germany must comply with sharing data to the IRD. All arthroplasty products available on the German market will be profiled in the German IRD product library.

The German Ministry of Health (BMG) will be the responsible public body overseeing the IRD.

Berlin, July 06th, 2021

EPRD Deutsche Endoprothesenregister gGmbH, Straße des 17. Juni 106-108, 10623 Berlin, Germany
Phone: +49 (30) 340 60 36 40, E-Mail: info@eprd.de