National
Arthroplasty
Registers

EPRD
Endoprothesenregister
Deutschland

The German Arthroplasty Register EPRD

Structure, Procedures and Organisation

An Overview presented at the 2012 EFORT Congress in Berlin

Joachim Hassenpflug

EAR
European Arthroplasty Register

The German Arthroplasty Register (EPRD)

EPRD
Endoprothesenregister Deutschland

The participants of the constituent EPRD Executive Committee meeting in Berlin on 14 March 2011

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1. Summary

The German Arthroplasty Register (EPRD – Endoprothesenregister Deutschland) was established as a wholly-owned subsidiary of the German Association of Orthopaedics and Orthopaedic Surgery (DGOOC – Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie e.V.). As a not-for-profit limited liability company ("gGmbH"), the German Arthroplasty Register exclusively adheres to scientific principles and is a guarantor of independent and neutral evaluations. The Register will record the performance of artificial joint replacements in everyday clinical practice, and – as opposed to previous clinical studies, which usually only examine a highly selected study population – will thus reflect the actual outcome and effectiveness of arthroplasty.

Although artificial joint replacement with about 390,000 surgeries per year is one of the most frequent interventions performed in Germany, there is lack of comprehensive data as regards prosthesis survival, outcome quality and patient safety. Quality assurance measures in Germany so far only consider in-patient stays and routine data from health care and health insurance providers. However, no conclusion is possible on relevant parameters, such as type of prosthesis and surgical technique.

The German Arthroplasty Register will for the first time allow for nationwide implant survival records and implant-specific evaluations, making it possible to identify prostheses with conspicuously short survival times at an early stage. To this end, selected routine data from hospitals and health insurance funds are linked with implant-specific data from a product database. After sophisticated analysis the results will be made available to the partners involved, the expert audience and also to the general public in due form.

The source population will initially consist of those insured with the AOK *[the largest health insurance company in Germany; translator's note],* as well as the patients insured with the substitutional social health insurance funds having opted for participation in the Register. This accounts for about 70 % of patients covered by statutory health insurance in Germany. The Register is intended to be expanded to all insured patients and their health insurance companies.

An independent Advisory Council is responsible for the centrally organised evaluation and interpretation of data according to scientific principles and involving the scientific and clinical expertise of the German Association of Orthopaedics and Orthopaedic Surgery (DGOOC).

2. Background

Artificial joint replacement is one of the biggest success stories of modern medicine. Pain, functional disorders and restricted mobility can be treated effectively and durably in particular in the hip and knee joint. In the eyes of the public joint replacement has meanwhile become a sort of standard intervention that is associated with high expectations. In many studies the success rate in terms of implant survival is reported to be approximately 95 % at 10 years.

Hip and knee replacement rank among the most common surgical procedures throughout Germany. In 2010, for instance, in summary about 390,000 joint replacements were performed in Germany. Of these 157,712 interventions were total hip arthroplasties, 24,948 hip revision surgeries, and about 50,000 hip replacements after femoral neck fractures. In the same year 146,233 knee prostheses were implanted and 12,215 artificial knee joints revised (1).

The prevalence of both hip and knee arthroplasty interventions is exceptionally high in Germany (2; 3). In view of an increasingly aging population several authors expect a further increase in joint replacement surgery in Western industrialised nations (4-6).

As evaluations from the Finnish Register have shown, a considerable proportion of revision surgeries actually become necessary not only 10 to 15 years after implantation, but sometimes far earlier (7). These findings are also true for Germany: in 2010 the revision rates even during primary in-patient stay were 1.6 % for primary hip prostheses, 5.6 % for hip revisions, 1.4 % for knee replacements, and 3.4 % for knee revision surgeries.

In spite of the – relatively speaking – low failure rates, due to the high number of implantations a very large number of patients actually have to undergo serious revision surgery, many of them at an advanced age with additional general risk factors. Apart from the personal distress due to pain and lack of mobility, there are also associated annual costs of about 370,000,000 euros that have to be taken into account, based on an estimate of 10,000 euros per revision surgery.

Starting in 1979, Sweden certainly has the longest experience with arthroplasty Registers run with significant involvement of the National Orthopaedic Society. Since the introduction of the Register the revision rate has been reduced decisively, i.e. by almost half. The main effect was already observed early after launch of the Register (8;9). Multifactorial parameters, such as the type of prosthesis, surgical technique, but also patient-specific factors are supposed to affect implant survival times until revision surgery. The German Arthroplasty Register will allow for in-depth analysis of the effects of these variables.

On a global scale, the necessity of Arthroplasty Registers is recognised by an increasing number of countries (10). Arthroplasty Registers have already been established in various Scandinavian countries (11;12), Australia (13), Canada (14) and New Zealand, but also the Orthopaedic Societies of the USA, Great Britain, France and South Africa support the development and maintenance of Arthroplasty Registers (15). Particular efforts in promoting a National Arthroplasty Register are presently being made in the USA (16). However, the results from foreign Registers are not exactly transferable to the German situation (17).

3. Aims and Organisational Structure

The German Arthroplasty Register is supposed to provide a nationwide record of implant survival times. Data collection is organised in such a way as to keep additional administrative processing at a minimum, which was an essential goal in project planning, and strictly adheres to the existing data protection regulations (18). As important stakeholders in health care, apart from the Orthopaedic Society also major health care insurance providers, impant manufacturers, and the BQS Institute *[Institute for Quality and Patient Safety; translator's note]* are directly involved to ensure long-term operation of the Register and cross-functional cooperation.

The German Association of Orthopaedics and Orthopaedic Surgery (DGOOC) had been trying to establish an arthroplasty register for nearly two decades. From 1997 the Deutsche Endoprothesenregister e.V. *["German Arthroplasty Register Association"; translator's note]* collected arthroplasty data on a voluntary basis (19). However, when BQS started nationwide collection of structural and process quality data, this register was ceased not least due to lack of systematic funding. Subsequently comprehensive concepts were drawn up for a statutory Arthroplasty Register organised through External Quality Assurance. In 2009, after the German External Quality Assurance provider had been changed, the implementation of a National Arthroplasty Register could no longer be expected to be realised in the short to medium run.

In 2010 the German Association of Orthopaedics and Orthopaedic Surgery (DGOOC) therefore initiated the foundation of the German Arthroplasty Register "Endoprothesenregister Deutschland gGmbH" (EPRD). The EPRD is a not-for-profit society and a subsidiary of the scientific National Orthopaedic Association DGOOC (see p.11). Structured cooperation was built up across long existing sectoral boundaries among the Orthopaedic Society (DGOOC), the Arthroplasty and Implants Division within the German Medical Technology Association (BVMed), and the hospitals. On the initiative of the DGOOC the essential key partners in health care – the Federation of Local Health Insurance Funds (AOK-Bundesverband), the Association of Substitute Health Insurance Funds (vdek – Verband der Ersatzkassen), implant manufacturers via the BVMed, as well as the BQS Institute – joined forces in a common project, the EPRD. As Members of the Executive Committee all partners have a decisive share in steering the German Arthroplasty Register. They are supported by a Council composed of high-ranking personalities from the public, political and scientific sector.

To give appropriate consideration to all requirements including statutory provisions, the EPRD has concluded mutual, long-term agreements with all partners. The financing concept provides balanced contributions from health insurance providers, manufacturers and the hospitals.

The findings obtained will be made accessible to the scientific community as well as to the general public through regular evaluations, publications and presentations. Through close feedback via the Orthopaedic Society these findings can be implemented in everyday treatment practice directly and in the short run, which will lead to an increase in patient safety.

4. Register Design

The Register is based on the use of routine accounting data for arthroplasty implantations and revisions, which are forwarded to the Register as a part of the routine accounting procedures between the hospitals and the health insurance providers. Moreover, the Register has a globally unique product database at its disposal developed by implant manufacturers in cooperation with the EPRD. The implants are registered in the hospitals by means of their barcodes and identified through automatic collation with the product database.

The German Arthroplasty Register records every arthroplasty implantation and every revision. The two events are linked with each other in order to define the survival time of the implant until it is revised as a "hard parameter". The data are then matched with the mortality data of the health insurance providers. Due to the use of routine data the time and expense for record in the Register is kept at a minimum:

- The time of primary and of revision surgery is determined from the routine data according to Article 301 SGB V *["SGB V" refers to Book V of the German Social Security Code, which contains the regulations for statutory health insurance in Germany; Article 301 regulates data provision between hospitals and health insurance funds; translator's note]*, which are transferred from the hospitals to the health insurance funds on a regular basis anyway. The health insurance funds in turn transmit the relevant extracts from these data to the Register using asymmetrically pseudonymised patient and case tokens.

- Implants are recorded through barcode scanning in the hospitals, and identified by collating the barcode with a product database that has been provided and is continuously updated by the implant manufacturers. The description of the implant is transmitted to the Register by the hospital together with a patient token, which, as with the health insurance funds, is created by an independent trust agency.

- Revision surgery data are compiled in the same way and transferred to the Register.

- The Register determines the survival time by merging the datasets referring to the implantation of the prosthesis, the implant code digits, as well as potentially relevant influencing paramenters (e.g. co-morbidities).

- Any transfer of data from the hospitals and health insurance providers to the Register is subject to the intervention of a trust agency so that also long-term requirements of efficient data protection are met.

4.1 Basic Data

The patients' declaration of consent is a prerequisite for use of their data in the Register. From the various data sources only those data are transferred to the Register that are relevant for the actual event. The following data sources are used:

1. Accounting data according to Article 301 SGB V

2. Barcode aquisition for implant identification

3. Health insurance funds data

4. Manufacturers' product database

5. Supplementary question regarding previous surgeries and reasons for revision

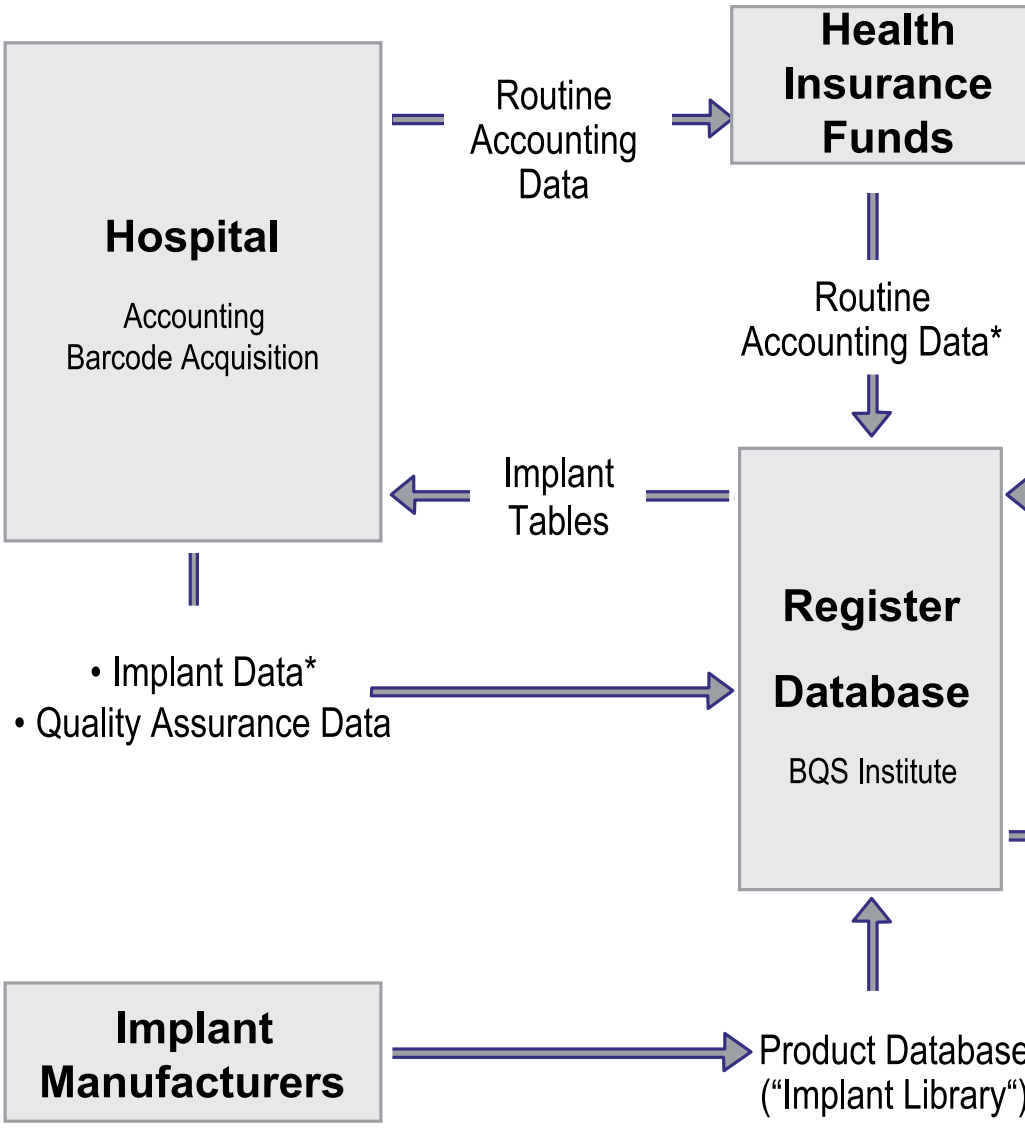
6. External Quality Assurance data according to Article 137a SGB V

The hospitals forward standardised accounting data to the health insurance providers for every hip or knee arthroplasty and every revision surgery. The AOK and vdek centralised data networks proved particularly favourable in reducing the time and efforts for EPRD data collection. The use of routine data also minimises the documentation burden within the hospitals. One additional question complements the essential contents of the EFORT Minimal Dataset as appropriate. In the case of primary interventions the supplementary question comprises a list of previous operations, in the case of implant removals the reasons for revision. The time of implantation and revision surgery, but also all re-operations are evident from the routine data in Germany as specified in Article 301 SGB V without additional documentation being required.

A big advantage of the secondary use of accounting data is that they are available without additional documentation efforts, and that they are to a large extent routinely verified on a regular basis. Moreover, hospitals themselves of course have a strong interest in correct accounting data.

Participation of the AOK system and the Association of Substitute Health Insurance Funds (vdek) ensures high representativeness even at this stage. To further increase external validity – with the aim of achieving full coverage of all prostheses implanted – talks are being held with further health insurance providers.

German Arthroplasty



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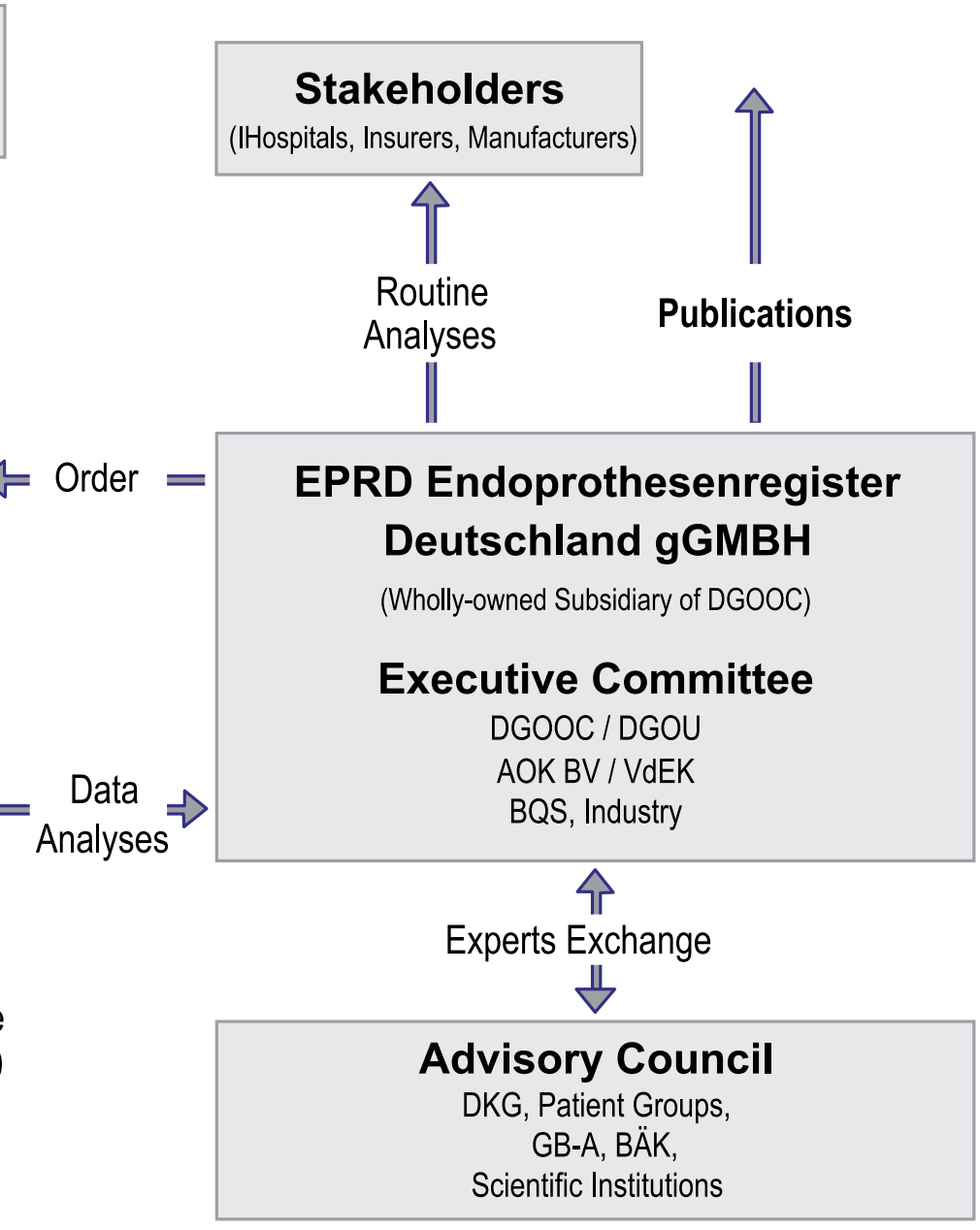
Register – Data flow



4.2 Product Database

Since the type of prosthesis implanted – as one of the various multifactorial influencing factors – potentially affects the survival time, implant identification has to be documented in addition. To this end, manufacturers make available a comprehensive product database via BVmed, the German Medical Technology Association, that contains all individual implant components. Each single component is stored including its manufacturer, its item and batch number as well as its product description, and systematically classified accor-ding to a comprehensive standardised classification system. Such a database is unprecedented worldwide to date, and it could serve as a model for further international Registers.

As a standard procedure, implants are scanned by means of a barcode reader in the operating theatre areas of the hospitals. In the process different barcode systems are taken into account allowing for the unambiguous assignment of implants. Implant components used are identified through collation with the product database using special software, and stored in the Register along with the pseudonymised data of the individual patient. Additional information is gathered by asking for previous surgeries at primary interventions and the reasons for revision at revision surgeries. Thus, all essential pieces of information contained in the EFORT Minimal Dataset are reproduced in the Register data pool.

5. Evaluation

The data collected are analysed according to a previously agreed evaluation concept involving experts from the Orthopaedic Society and all other Register partners, the central outcome being prosthesis survival. The times of prosthesis implantation and revision surgery are determined from the health insurance provider's routine data. The participating health insurance funds regularly forward the datasets referring to prosthesis implantations to the Register point at the BQS Institute for the calculation of implant survival times. Allocation of later re-operations and hence linking of primary and revision interventions is made possible through pseudonymisation in compliance with the requirements of German Data Protection legislation. To determine the survival time, parts of the routine datasets, implant codes as well as other relevant parameters (e.g. co-morbidities) are linked longitudinally at the Register. The vital status of patients, which is important for calculating implant survival, can be verified from health insurance fund data.

Implant survival times are comparatively analysed using the Kaplan-Meier estimator as well as the Cox regression model. Among other things, these methods serve to estimate the probability of a patient requiring revision surgery within a certain time interval. The Cumulative Revision Rate (CRR) indicates the percentage of patients who are expected to undergo revision surgery as a function of time.

The data are carefully adjusted involving the scientific and practical expertise of the specialty societies. Risk adjustment is performed based on essential influencing factors, such as age, gender, weight or principal diagnosis. Furthermore, the type of prosthesis (e.g. unicondylar vs. bicondylar), bone cement, retropatellar replacement and implant model, as well as the hospital, department or institution performing surgery are evaluated in due consideration of the incidence and prevalence of arthroplasty treatment.

By sophisticated analysis of implants and implant components with high failure rates, for example, treatment problems and deficits in outcome can be identified. Thus, an assessment is taking place of the treatment and outcome quality, patient safety, and efficiency of the medical device "endoprosthesis".

6. Discussion and Outlook

Even though, according to the criteria of evidence-based medicine, randomised controlled studies are considered to have the highest scientific value, they are not suited for analysis of the results of nationwide arthroplasty treatment in Germany (20). After all randomised controlled studies, at great expense, are aimed at comparatively analysing selected, different therapeutic procedures. Thus, a randomised controlled clinical trial is not a suitable instrument to describe or analyse the comprehensive and long-term quality of treatments as achieved in routine patient care (10;21).

In this context Register data provide a sound basis for highly representative comparative evaluations using Comparative Effectiveness Research (CER) (10;22). Register data and results from controlled clinical trials are complementary ways to obtain conclusive evidence of outcome quality in arthroplasty; they do not compete but sensibly complement each other.
The Register data obtained are evaluated for epidemiological and clinical research projects, to provide support and advice in innovative products development, as well as to enhance transparency in the presentation of outcome quality in arthroplasty.

Direct feedback to the Register participants should help reduce the revision rate of implants. Early indications of irregularities are identified through statistical process control of the results so as to trigger off an early warning mechanism in a systematically graduated procedure if necessary. In the case of severe irregularities the responsible bodies and project partners may use Register data – in accordance with strict rules – to inform the patients concerned, provided the patients have previously complied with the transfer of their data.

In interpreting the variance in implant survival times one must discern whether the irregularities observed are related to treatment or implant-associated problems. Apart from the reasons of revision queried, conclusions can, for example, also be drawn from the geographic distribution pattern of the revisions observed.

Data analysis is published at regular intervals. Thus, patients will be informed about the quality of health care; health insurance providers will have transparent information available about the quality of treatment; health care providers will have a comparative value for benchmarking their own quality; scientific societies will be provided with basic information to assess the performance of new techniques, new implants and new areas of application and enabling them to give support and advice during the innovation process; policy-makers and the BfArM *[Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Drugs and Medical Devices; translator's note]* will be able to rely on largely comprehensive records as regards long-term quality; and manufacturers finally, in terms of an early warning system, will receive early feedback about potential problems, innovation risks and shortcomings in results, as well as data on the outcome quality of their products.

From an international perspective, the data of the German Arthroplasty Register will form the basis for a long-term target: the participation in a European Joint Replacement Register, which is currently at the planning stage. The Minimal Dataset proposals for primary and revision hip and knee arthroplasty as previously published by the European Arthroplasty Register have been taken into account in their entirety (23-26), enabling the EPRD to make its full contribution to the common European project.

Abbreviations

AOK ..... Allgemeine Ortskrankenkasse – Local Health Insurance Fund

AOK Bundesverband ..... Federal Association of Local Health Insurance Funds; Federal Association of the AOK

BÄK ..... Bundesärztekammer – German Medical Association

BfArM ..... Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Drugs and Medical Devices

BQS (BQS-Institut) ..... Institut für Qualität und Patientensicherheit – Institute for Quality and Patient Safety

BVMed ..... Bundesverband Medizintechnologie – German Medical Technology Association

DGOOC ..... Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie – German Association of Orthopaedics and Orthopaedic Surgery

DGOU ..... Deutsche Gesellschaft für Orthopädie und Unfallchirurgie – German Association of Orthopaedics and Traumatology

DKG ..... Deutsche Krankenhausgesellschaft – German Hospital Federation

EAR ..... European Arthroplasty Register

EFORT ..... European Federation of National Associations of Orthopaedics and Traumatology

EPRD ..... Endoprothesenregister Deutschland – German Arthroplasty Register

GB-A ..... Gemeinsamer Bundesausschuss – Federal Joint Committee

Abbreviations

SGB ..... Sozialgesetzbuch – German Social Security Code

SGB V ..... Book V of the German Social Security Code
[This fifth of twelve Books of the German Social Security Code deals with Statutory Health Insurance regulations; translator's note.]

VdEK (vdek) ..... Verband der Ersatzkassen – Association of Substitute Health Insurance Funds

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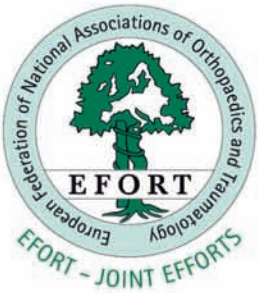
Contact Information

Prof. Dr. med. Joachim Hassenpflug
Geschäftsführung EPRD gGmbH
Langenbeck-Virchow-Haus
Luisenstr. 58/59
10117 Berlin
Germany

Geschäftsstelle EPRD gGmbH
Langenbeck-Virchow-Haus
Luisenstr. 58/59
10117 Berlin
Germany

Tel.: +49 – (0)30 – 847 12 131
Fax: +49 – (0)30 – 847 12 132
E-Mail: eprd@dgooc.de
Website: http://www.eprd.de



Contact:

Prof. Dr. med. J. Hassenpflug
Dir. der Klinik für Orthopädie
Universitätsklinikum
Schleswig-Holstein, Campus Kiel
Michaelisstr. 1
24105 Kiel, Deutschland

Phone +49 (0)431/597-2430
Fax +49 (0)431/597-2456
hassenpflug@orthop.uni-kiel.de
www.uni-kiel.de/orthop

European Arthroplasty Register (EAR)

Innsbruck Medical University
Dept. of Orthopaedic Surgery

Anichstrasse 35
6020 Innsbruck, Austria

Phone +43 (512) 504 22695
Fax +43 (512) 504 22701
gerold.labek@efort.org
www.ear.efort.org