The German Arthroplasty Register

RP Pitto[1], I Lang[2], H Kienapfel[3], H-G Willert[2]

Departments of Orthopaedic Surgery, [1] University of Erlangen-Nuremberg, [2] University of Göttingen, and [3] University of Marburg, Germany.
Correspondence: Rocco Paolo Pitto, MD, PhD, Department of Orthopaedic Surgery, University of Erlangen-Nuremberg Waldkrankenhaus, Rathsbergerstr. 57, D-91054 Erlangen, Germany. Tel #49 9131 822 275. Fax #49 9131 852 3657. E-mail: pitto@ortho.med.uni-erlangen.de. http\\www.endoreg.de

Since 1989, as a result of the Health Reform Act, German hospitals have been obliged to participate in measures for external quality assurance. The objective is to document and assess selected services—including the use and check of artificial hips and knee joints—within the framework of quality assurance measures. The organisation of this documentation was transferred to the Quality Assurance Office (Servicestelle Qualitätssicherung, SQS) in Düsseldorf. Documentation started in some States (Länder) in 1997. Despite the extensive and expensive SQS documentation in the area of arthroplasty, however, the project did not fulfil the expectations (Griss 1998). A new organisation, the Bundesgeschäftsstelle für Qualitätssicherung (BQS) recently started a new documentation project, but the structure for the analysis of data does not exist at the moment, and it is unknown how this will be achieved. The Verein Endoprothesen-Register was founded in 1994 with the objective of quality assurance for members of the biomaterial working group of the German Society of Orthopaedics and Traumatology (Deutsche Gesellschaft für Orthopädie und Traumatologie), the association of surgeons for biomaterials of the German Society of Surgery (Deutsche Gesellschaft für Chirurgie) and the German Society of Trauma Surgery (Deutsche Gesellschaft für Unfallchirurgie), as well as representatives of the industry. In 1997, the association started to set up an arthroplasty register based on the Scandinavian model (Lang and Willert 2001). In 1999 it joined the so-called Institut Eingetragenes Endoprothesen-Register (IDEE), founded in 1997 in Bad Mergentheim, to form the German Arthoplasty Register (Deutschen Endoprothesen-Register, DER).

Patients and methods

Set up and structure of the German Arthroplasty Register

Clinics, private individuals and representatives from the implant producing and distribution industries can join according to the constitution. Participation in the documentation is voluntary. The documentation is currently financed exclusively from members' contributions. In order to record the quality, it is necessary to document the implant types used, with their exact descriptions, and to calculate their survival rate. This can be best done by collecting data from the primary operation together with the data of the revision operation, a procedure which the Scandinavian arthroplasty register has been using successfully for more than 15 years (Lang and Willert 1997, Malchau and Herberts 63rd AOOS Meeting). The German register has developed two documentation files, one for documentation of the primary operation and one for the revision operation. The type and extent of the questions is closely based on the Scandinavian register (Havelin et al. 1994, Knutson et al. 1994, Malchau and Herberts 63rd AOOS Meeting) and was agreed with members of the arthroplasty register in 1996. All the information recommended by the European Implant Register Committee (Lang and Willert 2001) was collected (Table 1)

The data of arthroplasty of hip, knee, shoulder, elbow and ankle joint as primary operation, as well as revision operation, are registered prospectively. The criterion for failure of the implants is the revision operation, i.e. the exchange or removal of a implant component or even the complete removal or exchange of the implant. Documentation is by

Table 1. Minimum data documentation according to the suggestions of the European Implant Register Committee (EIRC)

Patient demographic	Data related to operation
ID-Number	Date of operation
Gender	Primary / revision
Age	Implant identification
Diagnosis	Type of cement / cement application
Site of operation	Hospital

paper and pencil and is sent by post. Details of the implants used are provided, ideally, by including the manufacturer's labels. In the database they are identified by manufacturer, catalogue number and implant name. In addition, each implant is given a key word which characterises the implant type and allows groups to be formed. For subsequent allocation of the revision operation to the data from the primary operation, it is necessary to introduce a clear case identification which also satisfies data protection requirements. The register follows a proposal from the German Federal Office for Data Protection and generates a patient-based ID number from the first, third and fifth letter of the patient's surname and first name and from the date of birth. In addition, the operated side serves as an identification criterion. The time required to fill in the forms is about one minute. The documentation forms are sent by post at intervals (quarterly) to the data centre of the arthroplasty register. A copy is kept with the patient's records in the hospital. The forms are checked for completeness of the data, plausibility and legibility. Where there is doubt, the management of the data centre asks the sender for completion. The data is then entered into the database by typists. The database is currently held in the Department for Medical Statistics at the Göttingen University and is based on the Oracle database system. It is not possible for the register to check whether all the relevant operations are reported by the clinics. In this respect, the reliability of the clinics must be mentioned. The forms do not contain any information about the surgeon. The specific data about the individual clinics are treated confidentially according to the constitution. Each clinic receives a confidential yearly report about the current status of its results compared to the average.

Results

Forty-one hospitals are currently involved in the documentation, of these, 19 are orthopaedic and 22 emergency surgery departments. About 7000 primary implant operations on hips and 3000 primary operations on knees, as well as 1100 hip revision operations and 250 knee revision operations are documented by these clinics each year. The majority (95%) of the hip revision operations are revisions of implants which were made before the arthroplasty register was set up or which were performed in other hospitals. The remaining (5%) revision operations were performed on implants which were implanted by member hospitals between 1997 and mid 2000. Of these, only 4 types are represented in larger amounts.

The register documents all modular parts of a joint replacement separately so that surveys about, inlays, heads and knee joint modular components are possible along with the usual surveys about the prosthesis. This was only possible after an extensive implementation of a in-house prosthetics catalogue of all manufacturers present in the marketplace. This arthroplasty register prosthesis type catalogue is the basis of all assessments, it covers about 25,000 entries and has to be constantly updated as new types of implant are introduced.

The forms for the arthroplasty register facilitate an immediate response, when filled in immediately after the operation, without additional inspection of the patient's files. The analysis of the data already entered has mainly revealed careless mistakes when filling in the form. All hospitals now use the manufacturer's labels to identify the implants. However, not all of these have barcodes in order to allow entry via a barcode scanner.

The free text entries about the removed prosthesis is not completed in 11% of cases, and 20% only give summary details such as "cemented cup or shaft", or the response is the manufacturer's details such as "Aesculap cup" or "stem Endoplus". In another 6% of cases, the date of the implant was missing so that the life of the implant could not be calculated. The analysis of the retrospective revision section had a high proportion of so-called third party revisions. Thirty of the 41 hospitals carry out 50% or more of their revisions on implants which they did not implant originally. These revisions

Table 2. Number of different implants used in primary and revision hip surgery (1998–1999)

	Primary n = 14359	Revision n = 2308
Hip joint, stems	127	75
Hip joint, cups	107	86

formed the classic contingent of "lost-to follow-up cases". These records reveal the indisputable benefit of the retrospective section of the register. Another noteworthy aspect of the analysis of the data stock is the range of implants (Table 2), especially for revision surgery. Although this allows an epidemiological description, for many types of implant there are no relevant statistical data, as the numbers are so small.

Discussion

A register in which all primary implants and all revisions are prospectively recorded across the country and in which they can be assigned to one another, is still an essential measure for external quality assurance of the results of joint implants (Fitzpatrick et al. 1998, Havelin et al. 2000). A national organisation like the German Arthroplasty Register can not only be financed from members' contributions, however. Cost calculations have shown that a contribution of just 0.05% of the appropriate case payment (i.e. 0.05 % of about 7500 Euro for one hip arthroplasty) is sufficient to guarantee a complete prospective documentation. The economic savings potential has been recognised by the Scandinavian health insurers.

Two requirements for the register seems to contradict each other. The greatest security in encoding the name as required for data protection, and the easy and reliable identification of a revision case (Finck-Krämer et al. 1998). According to its plan, the arthroplasty register is designed to allow revision operations to be allocated without a trace of doubt to the primary operations, even 10 or 15 years after they were performed. Nations with standardised, constant and life-long social security numbers have a simpler task in setting this up. A comparison between different registers doesn't seem to present problems (Havelin et al. 2000). Whether the path selected by the German Arthroplasty Register with respect to case identification is practicable, remains to be seen as no statistician was able to say how many unnecessary double entries will appear in the register in the expected report incidences. The first indications for the success of the procedure will be provided by the data comparison after the first three years have been fully entered by the end of 2000.

The large variety of implants does not produce any relevant statistics for the numerous implant types due to the small case amount. Although the arthroplasty register has already reached 60% of primary operations and 80% of the revision operations with only 41 clinics, compared to the total amount of data in the Scandinavian register (Söderman 2000), more participants must be obtained for the documentation. According to a prognosis by Kleimann et al (1996) up to 180,000 hip replacements and 50,000 knee replacements are performed by about 1,900 specialised departments in Germany every year. These figures make clear the large potential which is currently being lost. This amount of data can only be managed with computer-supported recording in the clinics. The universal introduction of barcodes on manufacturer's labels without computer-supported recording does not appear sensible, but is the unavoidable requirement for the implant industry. Moreover, questions regarding data protection must be answered. In many clinics there are physically separate networks for patient-related data (pat-lans) and for scientific data exchange in the Internet. A direct exchange between networks is not possible.

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