



A CENTRALIZED TOTAL JOINT REPLACEMENT REGISTRY USING WEB-BASED TECHNOLOGIES

BY C. RÖDER, MD, A. EL-KERDI, MSC, S. EGGLI, MD, AND M. AEBI, MD, FRCSC

Investigation performed at the Institute for Evaluative Research in Orthopaedic Surgery, University of Bern, Bern, Switzerland

There are three current formats for reporting the performance of orthopaedic implants: prospective, randomized clinical trials; meta-analyses; and retrospective case series. Maloney¹ argued that none of these approaches is suitable as an early warning system for problems related to total joint implants because of the long delays between the performance of the studies and the publication of the results. To address this problem, he proposed the creation of a national joint registry that would accomplish three goals: it would define the epidemiology of joint replacement surgery in a particular patient population, provide timely information to the orthopaedic community on the outcomes of joint replacements, and identify risk factors for a poor outcome and then improve results through continuous feedback to participating centers and surgeons.

The Swedish hip registry is often cited as an example of a well-functioning national joint registry that fulfills these three goals². Nonetheless, the establishment of a national joint registry, whether with or without governmental support, presents important practical and legal considerations. Legal considerations include complying with applicable laws relating to confidentiality,

privacy, and discoverability. Practical challenges include the cost of the technology infrastructure, management of the data, governance, and selective access to the database.

Centralized Documentation

On the basis of the pioneering work in the field of orthopaedic and trauma documentation initiated by Professor M.E. Müller in the 1960s, the University of Bern Institute for Evaluative Research in Orthopaedic Surgery has advanced the concept of centralized documentation to enable the establishment of national registries. It builds on the earlier work with the International Documentation and Evaluation System^{3,4}. One of the first objectives of the institute was to analyze systematically the existing International Documentation and Evaluation System database. Over the past forty years, data from more than fifty hospitals from different countries, including Switzerland, Germany, Italy, France, Austria, Belgium, and Canada, were centrally collected within the International Documentation and Evaluation System database. Currently, the database holds data sets for approximately 50,000 primary total hip arthroplasties, 12,000 revision arthroplasties, and 77,000 follow-up evaluations. They form one of the richest and most valuable data collections in the field of orthopaedic surgery. The value of the systematic data retrieval from the In-

ternational Documentation and Evaluation System hip registry, which was begun in 2001, has been recognized with awards from the Swiss Orthopaedic Society (Marathon Award, 2002) and The Hip Society (Frank Stinchfield Award, 2003) and in several peer-reviewed publications⁵⁻⁷.

We have now built on our experience of more than four decades and have devised a new methodology in centralized data management, the Clinical Documentation Technology System, which uses the latest innovations in medical informatics. This system allows data management with use of various tools that include a web interface, optical mark readers, and mobile barcode readers that record, validate, and transmit data to and from a central server. Furthermore, both the implant characteristics (article and lot numbers) and the radiographic data are integrated by means of dedicated interfaces to commercially available systems.

The striking advantage of this technology is that the end user is not required to purchase, install, or maintain software and hardware. All technical servicing is performed only at the central server. Consequently, clinical protocols can be easily and quickly distributed to a large user community, while data retrieval and analysis can be conducted locally or centrally. Such a system will facilitate the setup of any regional, national, and supranational registry.



A commentary is available with the electronic versions of this article, on our web site (www.jbjs.org) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

Content

Europe represents a challenging laboratory for building such a registry because of the heterogeneity of regional interests and national characteristics. We addressed this problem by creating three levels of content: supranational (e.g., Europe or the United States), national (e.g., individual European countries or states in the United States), and individual (participating clinics). The core data set, i.e., the minimum essential data for all participants, is implemented on the supranational level. Registries on national or state levels can then be designed to use the core data, but they can add content that is specifically interesting or important for the respective participant. An online question generator gives individual centers the possibility to design a third level of content that is of unique interest to that center. Thus, while maintaining their own research interests in day-to-day documentation, all participating clinics contribute core data sets to the supranational and national data pool. Also included in the database are standard patient-based, disease-specific, and general health questionnaires. For those questionnaires, automatic, system-integrated score calculations are available.

Documentation in a Clinical Setting

Documentation is considered a time-consuming task and must compete with the multiple and more immediate demands of a busy hospital and its busy clinicians. Currently, in many centers, data are collected retrospectively, captured on paper in a nonvalidated or incomplete fashion, and eventually entered into a local database. Final analysis or consolidation of data in a common pool is often not achieved. To standardize data collection and make it a successful team effort, the process must be compatible with the hospital working environment. Our data collection technology divides content into smaller, manageable task-oriented entities. These so-called subforms typically include data

collected at admission, clinical evaluation, surgery, and discharge. The subform structure allows real-time documentation, i.e., data can be recorded at the time and place where they are generated. Different users theoretically can fill in one or more subforms at a different time and place even with use of a different technology.

A web interface provides the common data entry, query, and administration site. In addition to direct data entry or retrieval, data can be recorded with portable barcode readers employing special questionnaire templates defined in barcode format. Alternatively, a hybrid solution between paper-based data collection and paperless data administration—the preferred data collection mode in Europe—allows data capture with pencil on optical mark reader questionnaires, which are read locally with an optical mark reader scanner. The scanner is hooked up to a local personal computer by means of a standard interface and is remotely connected to the central database by means of the local network. Data also can be collected on paper questionnaires for later entry with use of the online user interface.

The Clinical Documentation Technology System is a workflow-based methodology that validates the quality of the collected data. All validation checks are performed at the point of data entry so that the user cannot submit incomplete, invalid, or inconsistent data sets. Error messages pointing out missing or contradictory answers are displayed until the preprogrammed standards are met. This setup eliminates the need for retrospective data correction, and it guarantees the desired integrity, validity, and completeness of the data in the central database.

Technology—High Tech for Flexibility and Additional Features

In addition to providing modularity of data collection, the generic information technology architecture allows the implementation of new content quickly and efficiently. Consequently, the effort to design and distribute a new ques-

tionnaire by means of a web interface is minimal, and costs can be kept low. In contrast, new optical mark reader forms or barcode questionnaire templates are more cumbersome to design, and the necessary hardware, such as barcode readers or optical mark reader scanners, must be purchased. Radiographs and implant identification and lot numbers, as well as patient objective scores, are easily integrated into the system. Our server allows submission of up to six digitized radiographs per questionnaire. After transfer to the central unit, digitized radiographs are converted to a standardized format, and they can be viewed and manipulated by means of web-enabled imaging tools. Also, an automated implant-tracking system can capture implant information directly from operating rooms. The unique implant and lot numbers are captured with a specialized barcode reader by the operating-room staff, and data are forwarded by means of a dedicated telephone modem connection. A unique interface allows linking of a copy of all captured implant and lot numbers with the respective clinical data set for the patient. Thus, precise implant tracking becomes possible without any additional documentation efforts by the physicians.

The reporting and the statistical packages are powerful data retrieval tools. Clinical reports or patient responses to questionnaires can be printed out in a customizable text template. The statistics package allows real-time queries of the data and presents results as tables and graphs within seconds. For registries with a sufficient caseload, benchmarking mechanisms can be implemented. Consequently, comparisons of performance between departments and peers on regional, national, or supranational levels become possible, depending on the application level of the registry. For personal statistical analysis, data can be downloaded in standard worksheet formats. That way, all required data sets for the outcome of total hip arthroplasty, such as clinical, surgical, patient, implant, and radiographic data sets, are centrally

stored and accessible from any networked terminal worldwide.

Moreover, implant usage statistics at various levels (patient, physician, or department) can be generated and, in case of implant recall scenarios, a list of all patients in whom the respective component has been implanted is immediately available. Finally, the open partner concept has facilitated a steady growth in the number of participating implant manufacturers, which makes the implementation of an early warning system for implant-related problems, as required by Maloney¹, technically feasible.

Privacy Issues

The exchange of medical data sets across regional or state boundaries by means of the World Wide Web presents important challenges with regard to the protection of patient privacy. Additionally, participating physicians may be uncomfortable sending data to a central server that is not located within their institution. To address this problem, we developed a personal computer-based web server that acts as a filter between the user and the central database and deletes all identifiable information from the data sets. With this module, a community of hospitals can access the system through their own web site, administer the module autonomously, and hence keep full control and responsibility for all data sets that identify users or patients. Only the anonymous "raw" medical data sets are passed on to the central server.

Participation Setup and Cost

To minimize the cost to participants, we used low-cost software packages and provided interfaces to commercially available systems. Participation costs in the Clinical Documentation Technology System can accommodate departments, large centers, and specialty societies. Private physicians are also welcome to participate with pricing models based on caseload. The Clinical Documentation Technology System fees (in United States dollars) are calculated per department per study (e.g., hip,

knee, or spine study), regardless of the number of entered cases, as follows:

- \$50 monthly for the basic web interface
- \$25 monthly add-on for a barcode interface
- \$25 monthly add-on for an optical mark reader interface
- \$0.10 add-on for each digital radiograph

For example, an orthopaedic department participating in a national hip registry using the optical mark reader interface incurs a flat cost of \$75 per month, excluding the one-time purchase cost of optical mark reader scanners and paper questionnaires. The module that ensures privacy of communication (the so-called MEMdoc Module) is offered to large centers or medical societies at a price of \$25,000, with an optional service and support fee of \$6000 annually. Finally, all consulting work in the electronic setup or statistical analysis of registries is invoiced hourly, according to the University of Bern rates.

In conclusion, we have developed a centralized data management and evaluation instrument for establishing registries that meet the documentation needs of nations or individual clinics. This tool is offered to the orthopaedic and nonorthopaedic communities for testing and usage. Interested users can freely explore the test environment of the web application by accessing our web site, www.memdoc.org, and clicking on "Demo Tour." The brochure, which describes the complete functionalities, can also be downloaded. We can be contacted personally for further information regarding the terms and conditions of participation.

C. Röder, MD
A. EL-Kerdi, MSc
M. Aebi, MD, FRCSC
Maurice E. Müller Center for Research in Orthopaedic Surgery, Institute for Evaluative Research in Orthopaedic Surgery, University of Bern, Stauffacherstrasse 78, 3014 Bern, Switzerland. E-mail address for C. Röder: christoph.roeder@memcenter.unibe.ch

S. Eggli, MD

Department of Orthopaedic Surgery, Inselspital, University of Bern, 3010 Bern, Switzerland

The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

References

1. Maloney WJ. National joint replacement registries: has the time come? *J Bone Joint Surg Am.* 2001;83:1582-5.
2. Herberts P, Malchau H. Long-term registration has improved the quality of hip replacement: a review of the Swedish THR Register comparing 160,000 cases. *Acta Orthop Scand.* 2000; 71:111-21.
3. Paterson D. The International Documentation and Evaluation System (IDES). *Orthopedics.* 1993;16:11-4.
4. Röder C, Eggli S, EL-Kerdi A, Müller U, Ambrose T, Rössli E, Busato A, Aebi M. The International Documentation and Evaluation System (IDES)—10-years experience. *Int Orthop.* 2003; 27:259-61.
5. Röder C, Parvizi J, Eggli S, Berry DJ, Müller ME, Busato A. Demographic factors affecting long-term outcome of total hip arthroplasty. *Clin Orthop.* 2003;417:62-73.
6. Röder C, Eggli S, Aebi M, Busato A. The validity of clinical examination in the diagnosis of loosening of components in total hip arthroplasty. *J Bone Joint Surg Br.* 2003;85:37-44.
7. Müller U, Gautier E, Roeder C, Busato A. The relationship between cup design and the radiological signs of aseptic loosening in total hip arthroplasty. *J Bone Joint Surg Br.* 2003;85:31-6.

Commentary

Total joint replacement offers patients with end-stage degenerative joint disease a solution to disabling joint pain that results in a marked improvement in quality of life. As with all mechanical devices, failure can and will occur. The survival of the implant is multifactorial. Patient-related factors, surgical technique, and implant design as well as manufacturing all play a role in failure. Despite an extensive investment in research and development by implant manufacturers to improve implant performance, unintended consequences of a change in design may result in premature failure. Regardless of the amount

of premarket testing done with any given device, it is important to remember that the final testing ground is in our patients. Only there will all of the factors noted above come into play. With that in mind, it seems a reasonable goal to track outcomes at least at a high level to potentially identify poorly performing designs or surgical techniques at the earliest possible point.

In this paper, Röder et al. offer a strategy for the documentation of outcomes of total joint arthroplasty. They reestablished the concept of central documentation utilizing the newest documentation technology, including web interface, optical mark readers, and mobile barcode readers. This system allows immediate usage and tracking statistics for all captured implant data. In addition, digitized radiographs can be automatically transformed into a standardized format. They noted that the advantage is that the purchase, installation, maintenance, and updates of local software are no longer necessary. All technical servicing is done at the central server. This has obvious potential benefits from the standpoint of the user.

As it relates to a national registry

in the United States, the system of Röder et al. has several complicating issues. First, it is important to remember that there is a fundamental difference between a registry and a database. A registry simply keeps track of what goes in and what goes out. For a registry to be valid, it has to be in widespread use to eliminate or minimize the potential for bias. In the United States, that represents a potential problem. According to the 1997 data, approximately 50% of the total hip replacements in Medicare patients were done by surgeons who did ten or fewer such procedures per year. Most surgeons have never participated in clinical research and thus are not likely to be motivated to submit data. To have a valid registry in the United States, it is my opinion that the level-one data (that is, the basic data that keeps track of what goes in and what goes out) must be an institutional responsibility with identifiable, dedicated personnel responsible for data entry. That person is not likely to be an orthopaedic surgeon but a hospital employee. Second, the new guidelines of the Health Insurance Portability and Accountability Act make tracking of identifiable information very difficult.

The primary purpose of a registry in the United States must be to improve patient safety and quality assurance and not to provide a research tool. This may in the future allow some leeway as it relates to data collection. Currently, with the pilot project for the American Joint Registry, we plan to obtain consent prior to entry into the registry project. As an ongoing issue, this is costly and burdensome. It is possible that in the future, with appropriate protections of identifiable information, a registry such as this may be able to be housed under the umbrella of a patient-safety organization. This certainly would make the project more feasible on a large-scale basis.

Finally, it is quite clear that the data must be protected. The stakeholders in this matter include the patients, the surgeons, and the hospitals as well as the manufacturers. Inappropriate release of data prematurely is in no one's best interest and may do more harm than good.

—William J. Maloney, MD
Washington University
School of Medicine
St. Louis, Missouri