The Swiss Orthopaedic Registry

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Abstract
Following the tradition of the IDES European Hip Registry inaugurated by M. E. Müller in the 1960s, the Institute for Evaluative Research in Orthopaedic Surgery at the University of Bern started a new era of data collection using internet technology (www.memdoc.org). With support of the Swiss Orthopaedic Society, the pilot of the Swiss Orthopaedic Registry was conducted, and in cooperation with different academic and non-academic centers the practicability of integrating the various data collection instruments into the daily clinical workflow was evaluated. Three different sizes of hip and knee questionnaires were compiled, covering the individual demands of the participating hospitals whereby the smaller questionnaires always represent a subset of the next larger one. Different types of data collection instruments are available: the online interface, optical mark reader paper questionnaires, and barcode sheets.

Precise implant tracking is implemented by scanning the implant barcodes directly in the operating theaters and linking them to the clinical data set via a central server. In addition, radiographic information can be linked with the clinical data set. The pilot clinics suggested enhancements to the user interface and additional features for data management. Also, recommendations were made to simplify content in some instances and diversify in others. With a new software release and adapted questionnaires the Swiss Orthopaedic Registry was officially launched in Summer 2005.

Many orthopaedic and non-orthopaedic registries have been established throughout the world.1-9 The Swedish Hip Registry remains the best example for a well-functioning national registry. It has had an impact on the number and types of hip implants used by eliminating poorly performing implants, on the quality of cemented component fixation in Sweden, and it has helped detecting problems with new cement types at an early stage. As a result the revision rates for total hip arthroplasties (THA) have been decreased,10 the overall quality of treatment increased,11 and valuable insights have been gained regarding the influence of patient characteristics on loosening of THA.

The need for documentation of interventions and their outcomes was, however, described many years earlier. In 1931, Codman published his end-result idea which stated that in order to assess the benefits or complications of a certain treatment every patient must be followed long enough to determine whether or not the treatment has been successful.12 Medical documentation also has a long tradition in Switzerland. The AO founders, Müller, Allgöwer, and Willenegger, described their philosophy in 1963: a centralized documentation of clinically relevant information by means of standardized code sheets and additional collection of radiographs. They considered this concept necessary for surgeon self-assessment and evaluation of treatment methods.13

In 1965, Prof. M.E. Müller (MEM) started a systematic collection of THA outcome data and developed a documentation system which culminated in the IDES,14,15 the International Documentation and Evaluation System for total hip and knee arthroplasty. With IDES and precursors, information concerning about 48,000 primary THA, 12,000 revision THA, and 77,000 follow-ups has been collected from 65 hospitals in Europe.

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The team of the Institute for Evaluative Research in Orthopaedic Surgery (IEFO) at the University of Bern set out to continue the 40-year tradition of outcome documentation. Based on the previously gained expertise, a new generation of data collection using Internet technology was developed (www.MEMdoc.org). In parallel, the systematic analyses of the MEM hip database quickly lead to national and international recognition.

With the new portfolio of data collection instruments and the academic status of a neutral data-clearing house, the institute initiated the pilot phase of the Swiss Orthopaedic Registry (SOR) with support from the Swiss Orthopaedic Society (SGO). Several academic and non-academic centers of different size were involved in order to evaluate the feasibility of integrating the various data collection instruments into the daily clinical workflow and gain experience concerning the size of the case report form (CRF) that is most preferred by various types of hospitals.

Content

The IDES hip questionnaires (1992 version) and the knee questionnaires (1998 version) were both updated and restructured in a 2005 version. Definitions for radiographic aseptic component loosening were adapted to those in the current literature and the Harris Hip Score (HHS) and Knee Society Score (KSS) were integrated into the CRFs. Further evolving the MEM concept of three different levels of content, an additional level I was defined, representing the minimal data set for a European hip registry proposed by the European Federation of Orthopaedics and Traumatology (EFORT). The structure of the minimal knee questionnaires was adapted from the hip content. The minimal questionnaire can be expanded to so-called scientific questionnaires (level II) with all the mandatory IDES questions as previously defined by MEM and published by Paterson. Moreover, optional yet standardized subsets of questions can be added by the user as a third level III and an individual subform with customizable questions can be programmed by each clinic (level IV). This structure follows the principle of the Russian Matroschka puppets, whereby the smaller questionnaire always represents a subset of the next larger one. That way, a common core dataset is included in all four questionnaire sizes and consequently filled in by all participants. This core dataset represents the most basic form of an orthopaedic registry, namely a pure implant registry where survival times are calculated based on primary and revision interventions and no clinical outcomes are documented from follow-up examinations. The obvious advantage of the level I questionnaires is that completion of a paper form takes no longer than 30 seconds.

Technical Set-Up

The Swiss Orthopaedic Registry employs a multi-tier client-server electronic documentation system for data collection and storage. Integral to this system is a central Oracle 8i database, which stores patient demographics, clinic and physician information, protocol question/answer definitions with validation rules, as well as collected datasets. Several information technologies, such as PHP/PERL/JAVA scripting, JAVA, C/C++, and so forth are utilized in the overall architecture of the system, providing a balance between development efficiency and application performance. Furthermore, all Internet applications are embedded within a web content management system for ease in web mastering by non-technical staff members. Similarly, proprietary application interfaces are researched and developed to facilitate the integration of third-party systems that further enrich the overall potency of the SGO documentation system, such as...
as interfaces to digitized DICOM-compatible radiographic archives, SAS statistical engine, SEDICO implant tracking, and multiple data collection instruments (Fig. 1).

Data Collection Instruments
There are three different types of data collection instruments: the online interface, optical mark reader (OMR) paper questionnaires, and barcode sheets that are scanned with a barcode pen in pocket size (Fig. 2). The online interface is the common basic mode of data entry and all CRFs are available in the online version. All but the minimal CRF are broken-up into subforms, which represent the amount of data that has to be entered in one documentation step in order to be able to save the information. Incomplete subforms are not accepted by the underlying validation and completeness checks of the system. The subforms represent an entity of information that occurs at a given point in time during the patient’s treatment pathway so that real-time data collection at source becomes possible. The four mandatory clinical subforms of the IDES scientific version are Admission, Clinical Evaluation, Surgery, and Discharge. The IDES minimal version is composed of parts of the admission and surgery subforms.

The CRFs are also available as paper questionnaires that can be completed with pencil and fed into an OMR, which is hooked up to a PC. The user operates the OMR via the online interface that also displays the error messages about invalid or incomplete CRFs or the confirmation about the successful transfer of the data into the central database. Immediately after successfully uploading a paper CRF, it also becomes available online for further use.

As a third possible mode of data collection, the IDES minimal CRF was laid-out as double-sided barcode sheet, where one side displays the primary CRF and the other side the revision CRF. The sheets are laminated for long-lasting use.

Implant Tracking
An implant registry’s most valuable data sets are those describing the implanted components. In the previous versions of the IDES system, the questionnaires contained a section for description of components, materials, and sizes. Despite a comprehensive and time consuming capture of details, a precise definition of implants and their outcomes remained difficult since many changes in design throughout a component’s lifetime could not be reproduced. The new IDES generation was equipped with a valuable tool that solves this problem. The Swiss implant industry has introduced SEDICO (secure data integration concept) into the Swiss orthopaedic operating theaters. SEDICO serves for automatic component re-ordering after usage. Therefore, the implant article and lot numbers are captured with a barcode scanner and transferred to a central server. For purposes of documentation, the scanners can also be operated in ordering and tracking or solely tracking mode. That way the article and lot numbers are transferred to the MEMdoc server and linked to the clinical data sets with linking parameters like patient medical record number, date of surgery, and anatom-

Figure 2 The three different types of data collection instruments: the online interface, optical mark reader (OMR) paper questionnaires and barcode sheets.
In addition, the clinical administrator needs about one documentation. This allows the assignment of each single implants due to use of the wrong medical record number (there are three per patient) and to keep the database in a comprehensible condition. To correct these errors as well as to register implants from night and weekends, a “SEDICO-tool” was developed, enabling the administrator to manually link and unlink implants to and from a patient. In order to regain the time invested for documentation, Basel makes use of the MEMdoc print tool that generates customizable standard letters from the collected information replacing the dictation and typing of operative and discharge reports.

Workflow Example of a Clinic with Paper-Based Documentation

At the department of Orthopaedic Surgery at the Spitalzentrum Biel the paper-based documentation started in the beginning of 2004. Additionally, all knee arthroplasties from 2003 were documented retrospectively. All implants are recorded with the SEDICO-Scanner. Due to the insufficient IT infrastructure (slow Internet connection, lack of hardware) the paper-based documentation was the preferred solution. The treating physician completes the primary form during the course of hospitalization. The follow-up forms are filled out at postoperative controls in the ambulatory department. The first follow-up documentation is routinely conducted one year after operation. A scientific researcher feeds the completed forms into the OMR scanner and administers the records online. The learning curve proved to be flat; advanced resident doctors need approximately 8 minutes for the completion of the level II primary form and 5 minutes for the level II follow-up form. Scanning and submitting the data takes the administrator an additional 3 minutes per case.

Discussion

A Swiss Orthopaedic registry is indispensable for quality assurance in orthopaedic departments and for fostering evidence-based orthopaedic research in Switzerland. The former Department of Evaluation and Documentation of the MEM foundation has accumulated 40 years of experience in the field of registry set-up and hosting. This experience has been picked up by the Institute for Evaluative Research in Orthopaedic Surgery of the University of Bern and has been incorporated into a newly developed documentation system with web technology. Based on the MEMdoc technology, a pilot for a national registry was initiated. Within 18 months, 6 pilot clinics have collected a multitude of case report forms and linked them with implant data in an automated fashion. Not only was medical content of the IDES version 2005 discussed during the pilot, but also constant feedback was achieved regarding system deficiencies, work-flow problems and necessary new functionalities to successfully integrate the documentation into the daily routines of the pilot clinics. Finally, a survey was conducted where all pilot clinics completed a standardized questionnaire and commented upon the feasibility and future use of the system. Based on the positive feedback and pilot results, the SGO quality assurance working group has approved the system and content as the basis for building the Swiss Orthopaedic Registry.

Participation remains voluntary, however it will be highly recommended by the SGO to its members. While all cost for system and content development was covered by IEFÖ, the pilot study was co-sponsored by the most important implant suppliers in the Swiss marketplace. Negotiations between the SGO and industry are ongoing in regard to their continued sponsorship of the system. Based on the estimated 15,000 total hip and 8,000 total knee arthroplasties performed annually, cost will range between $20 to $30 per case (an estimate in which the development costs of the system are excluded and a paper-based documentation of about two thirds of the cases is assumed). All financing
entities, however, have no data ownership. The anonymous data pool is exclusively owned by the Swiss Orthopaedic Society; the hospital specific data sets are owned by the hospitals themselves and can be downloaded (i.e., copied) for their own use at any time.

A crucial point to be resolved remains the unequivocal identification of patients across the system. Currently, a medical record number (MRN), gender, and year of birth are the sole mandatory parameters to create a patient record on the system. With this anonymous demographic data set, patient consent is not required. As soon as additional information like names, addresses, social security numbers, and so forth are stored, informed written consent becomes mandatory. Since the majority of participating clinics prefers entering anonymous data, these patients cannot be recognized by the evaluative center if a revision procedure has been performed in a different hospital where patients receive a new hospital-specific MRN. Consequently, a unique identifier issued and administered by a national governmental body is a still unfulfilled key factor for providing the Swiss Orthopaedic registry with data of a similarly high validity as the Scandinavian Orthopaedic registries. Cross-validation of Swiss data becomes possible by analysis of other national databases, like the Swiss hospital discharge master file and the Swiss hospital statistics that the IEFO uses for other evaluative research endeavors.

References