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A European spine registry

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Abstract New joint replacement registries are being widely implemented across national and international organizations. The need for a continuous long-term post-market surveillance of implants has been recognized, and has become increasingly important to ensure the quality of prosthetic components. Registry data with large case numbers represent an acceptable alternative to controlled randomized clinical trials, which are often difficult to conduct in orthopedic surgery. The variety of implants and procedures in spinal surgery not only induces the same need for long-term monitoring of post-surgical product performance as in the joint replacement subspecialties, but also renders essential the establishment of a comprehensive spine registry for all major pathologies and interventions. In cooperation with the M.E. Müller Institute

for Evaluative Research in Orthopedic Surgery (MEM-CED) at the University of Berne, Switzerland, the Spine Society of Europe (SSE) has launched Spine Tango: the first modular and multilevel European online registry for spinal surgery. Within Spine Tango, the major challenge in registry design and structure is the definition of and agreement upon a core set of questions as a common European dataset. Additional questions for national or individual interest can also be dynamically added to the core dataset. An automated implant tracking system has also been setup, which allows highly precise product documentation without additional work for clinical staff members.

Keywords Spine · Registry · Documentation · Implants

Introduction

All over the world, efforts are being made to set up registries on regional, state, or even national levels, and consequently the number of articles in the literature reflects the establishment and activity of all these new and young institutions [1, 3, 7, 11, 12]. The Swedish hip registry is considered one of the oldest and best functioning registries. It has already proven valuable in eliminating poorly performing materials and implants, and was key in changing treatment practices on an evidence-based background [4]. Imitating the Swedish model, registries have

been, or are in the process of being, set up in Germany [7], Canada [1], New Zealand [12], Norway [3], Finland and England, as well as in many young eastern European countries. With their focus enlarged beyond major joint replacements, such as total hip and knee arthroplasty, new registries are being setup for joint replacement procedures that are less frequently performed, like shoulder and elbow arthroplasties [11].

All authors stress the fact that their registry questionnaires are to be considered as a minimal dataset, in order to avoid overworking the surgeon and thereby lowering response rates [3, 7, 12]. In addition, many registries try to construct their questionnaires in such a way that data col-

lection is rendered a team effort involving operating room staff, surgeons, secretaries and residents.

Spine surgery represents a challenge for all registry endeavors. The variety of levels, pathologies, accesses, and surgical techniques confounds all attempts to invent a short yet comprehensive questionnaire. Therefore, institutions that have developed questionnaires or registries have focused on certain main aspects of spine surgery. The North American Spine Society has developed mainly patient-based questionnaires for cervical and lumbar spine problems in addition to scoliosis [2, 9]. The Swedish spine registry was even named “The Swedish National Register for Lumbar Spine Surgery”, indicating that the focus was only on lumbar pathologies and interventions [14]. As compared to older registration and documentation initiatives in other orthopedic subspecialties [6], the outcomes movement has led to a dramatic shift towards patient-based documentation [5, 15]. This has taken the burden of answering large and detailed questionnaires away from the busy clinician and put it on the patient, who has been empowered with more responsibility to participate in decision-making and quality assessment. The essence of a modern surgeon-based documentation system was described by one of the authors of the Swedish spine registry in three words: “simplicity, simplicity, simplicity” (personal communication, B. Stromqvist, 2002).

Spine Tango: the European initiative

Under the auspices of the Spine Society of Europe (SSE), a project was launched for the design and implementation of a documentation system for spinal surgery in 2000. This effort was introduced as the “Spine Tango”, and was conducted in collaboration with the M.E. Müller Institute for Evaluative Research in Orthopedic Surgery (MEM-CED) at the University of Berne, Switzerland. The former Department of Education and Documentation of the M.E. Müller Foundation has built up a great expertise in documentation and data collection due to the fact it hosts arguably the oldest and most detailed hip arthroplasty registry in the world. Its first records date back to 1968, and there are currently over 48,000 primary interventions, 12,000 revisions, and roughly 71,000 follow-up controls archived in the database. Data collection took place on a voluntary basis, and was standardized according to the International Documentation and Evaluation System (IDES) [10]. Data was collected at over 40 hospitals in various European countries, including Austria, Belgium, Switzerland, Germany, Great Britain, France, Italy, and the Netherlands.

Spine Tango is probably the first spine registry initiative to face the challenge of developing a comprehensive questionnaire covering all major spine pathologies and interventions, as well as spanning all anatomical levels. To accomplish this task, a technically demanding computer

application was a prerequisite. The need for such an application coincided with the prototype release of an online tool for data collection developed by the MEM-CED. The decision to employ Internet technologies to enhance centralized data collection seemed obvious to the Spine Tango team, given the cumbersome and inaccurate paper-based methods utilized to date. Paper-based forms are traditionally filled in by clinical users, sent to the central data collection office, and then entered into a database using various customized local software solutions, which are sometimes optionally interfaced to optical character or mark readers. The enormous human and financial resources needed to read in paper-based data, and especially to correct and complete invalid datasheets, were the driving force behind conceptually changing these outdated methods by technologically shifting data entry back to the peripheral user. At the same time, new documentation features and interfaces have been introduced to further alleviate the burden of registering data.

Medical IT innovations

The MEM-CED new online documentation system is slowly being recognized as a powerful generic centralized documentation application. Along with its numerous simplified tools for collecting medical, implant, radiological, and patient data, a true information technology innovation has been developed. Embedded in an orthopedic portal (see Fig. 1), called Orthoglobe, the academic online joint registry application currently offers a wide array of questionnaires and online tools for data collection and administration. In addition to the Spine Tango, it offers the orthopedic community the European Federation of National Associations of Orthopedics and Traumatology (EFORT) and IDES registries for total hip arthroplasty and the IDES total knee arthroplasty registry, as well as several ongoing multicenter studies for restricted user communities, which deal with spine trauma, pediatric fractures, motion-preserving spine stabilization, and meniscus implants.

Data can be collected and extracted using several complementary solutions (see Fig. 2). While the most direct method of data entry is using the online interface, an alternative, offline, solution employs handheld barcode read-



Fig. 1 The Orthoglobe portal (www.orthoglobe.com)

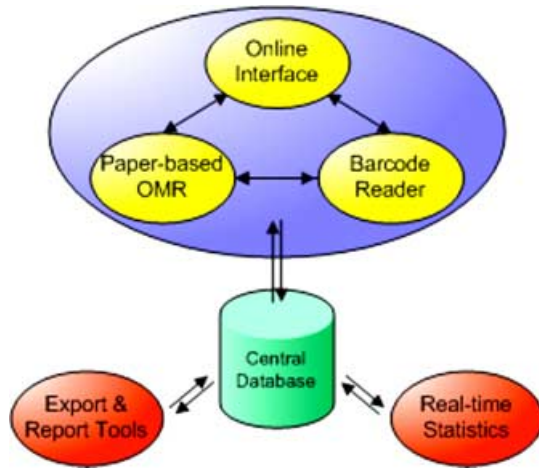


Fig. 2 Overview of documentation IT solution

ers. A third possible method of data collection is based on a MEM-CED proprietary online interface to traditional paper-based data registration using an optical mark reader. Regardless of the preferred method by which data are registered, all data are finally routed back to the online-accessible central database, where the user can verify, edit, and submit data. Online validation rules guarantee that only medically and logically valid and complete datasets are submitted. Otherwise, the dataset is rejected and users are advised to perform corrections. This ensures the quality and integrity of data stored in the database. Once data are submitted, they cannot be altered. Various online features are in place for online data analysis to recuperate time spent for documentation. Forms can be printed out in a rough question-answer format, and soon the documented information will be available within an editable text body, so that the collected data can be used to create user-customizable reports and letters. Direct online-accessible real-time queries of personal user statistics and comparison with the data pool for benchmarking are also possible. Moreover, data can be downloaded to the user's own computer for further customized statistical analysis. An online tool to upload up to six digital radiographs per documented case is also available.

Due to the nature of the doctor/patient relationship and the sensitivity of healthcare data, exchanging and collect-

ing information on the web brings with it many concerns regarding privacy and confidentiality. As such, the official security policy of the MEM-CED and the Orthoglobe portal is to take every measure possible to guarantee the security and integrity of entrusted data. This is accomplished by using only ISO compliant systems with a physically secure and segregated network setup, protected by firewalls and antivirus filtering. In addition, all transfer of data is conducted via 128-bit encrypted channels conforming to the highest levels of security, similar to those utilized in e-business solutions.

A European registry: unity in diversity

The biggest obstacle in establishing a European registry is the heterogeneity of interests and ideas regarding content and techniques of documentation. There is no doubt that the Internet represents the ideal and cheapest solution possible to network all players, and to gather datasets in a central database. In addition, no costly hardware and software purchases are necessary to run or maintain the installation, since system upgrades and maintenance are only conducted at the central control unit. Nevertheless the amalgamation of different sets of questions into a single questionnaire to satisfy various European, national and regional, or even individual needs, while still ensuring that it is possible to extract only the data of interest to the respective user, remains the insurmountable obstacle of any documentation system.

In developing an online tool for a European mission, the MEM-CED has engineered an IT solution that measures up to the expected complexity of several levels of content within one and the same questionnaire. After a core dataset for a European register has been adopted, each participating nation can define additional questions that it would like to incorporate into its national documentation system. Participating surgeons can consequently still choose their national registry questionnaire, but also fulfil European standards. Moreover, they are provided with an online tool to generate questions for their individual in-house interests. This is accomplished by introducing a new scheme of real-time retrospective and prospective documentation. In such a system, each study questionnaire is divided into subforms that best emulate the

Fig. 3 Breakdown of study forms into sizeable subforms

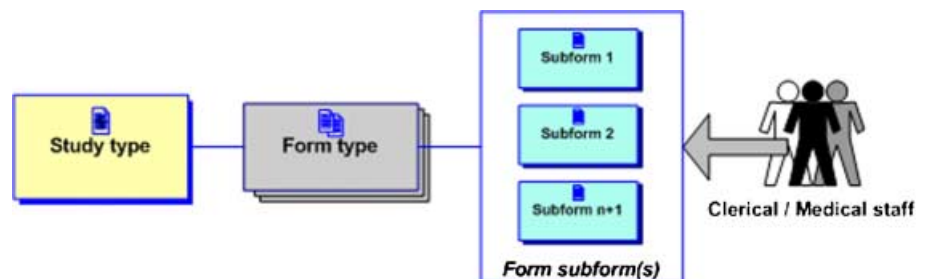


Fig. 4 Spine Tango primary intervention questionnaire

data collection workflow in hospitals (see Fig. 3). The overwhelming advantage of such a model is that subforms can potentially be filled out by different users independently of one another, while validation rules built into the generic system ensure that data are logically and medically validated before submission.

Since data sharing is defined at the departmental level, all surgeons within a given department can make use of the individually created sets of added-on questions, whereas users outside the department or the hospital can neither see nor use these extensions. To increase flexibility and application tidiness, the various sets of additionally created questions are provided in the form of a menu of optional packages that can be actively selected and linked to the European and national questions, thereby enabling the concept of a multilevel documentation. The European core data are anonymously pooled at the central data collection unit, and benchmarks are created. Hospitals are given the opportunity to compare their core parameters with the European or national averages by performing online live queries to the database. The national datasets belong to the society, under whose auspices the registry was established. Only the surgeon who entered the data is able to retrieve the complete set of parameters, including patient-based information.

Far more difficult than constructing this complicated IT architecture is the definition of a core dataset for the various orthopedic subspecialties. Regarding a core questionnaire for the Spine Tango, an initiative was taken in cooperation with the Spine Department at the Schulthess Clinic, Zurich, Switzerland, to work out a set of questions suitable for a European Spine Registry. For reasons of

data validation, possibilities for real-time documentation, and sharing of documentation workload, the core questions are subdivided into five subforms: admission, main pathology, surgery, surgical measures and discharge (see Fig. 4). Under the “additional” menu, several optional modules are also available: social, clinical assessment cervico-thoracic, clinical assessment lumbar, imaging, functional tests and invasive imaging, and the Oswestry score. Moreover, a second intervention surgery and surgical measures subform for combined access or two-step intervention can be activated for a precise documentation of cases with two accesses or even two interventions within one hospital stay. The intention is to provide users who have an interest in documenting information beyond the core dataset with standard add-on modules.

Implant documentation: high tech for precision and time saving

One of the main reasons for setting up joint replacement and implant registries is the fact that many implants enter the market with only laboratory testing. However, the real testing arenas for implants are the patients themselves, where all factors affecting implant performance, such as design, choice of materials, manufacturing issues, patient characteristics, and surgical techniques, come into play [8]. A minimum follow-up of 10 years is normally required to realistically judge a joint replacement as successful [13]. However, many institutions that are in possession of such data are often not able to compare it with data of other authors, because of the technological and

content limitation of the different methods of data collection and analysis utilized.

Implants are also an essential part of modern spine surgery, and the increased use of artificial materials over the past years makes post-market surveillance of products as necessary as it is in the joint replacement sector. To finally overcome the compatibility problems of documentation techniques and parameters of interest, and thereby make it possible to follow new or questionable product and implant designs over extended postoperative periods, the MEM-CED has integrated a unique implant-tracking tool to complement the online documentation system.

A major European implant producer has introduced a barcode-based implant tracking system for ordering and stocking purposes. The so-called SEDICO (secure data integration concept) system is marketed in an open partner concept, as other large implant producers are already participating and using the new technology. All materials with article and lot numbers in barcode format are registered with a barcode scanner when they are unwrapped by the operating room staff and delivered to the surgeon. Via

telephone modem, the article and lot numbers are sent to the producers for restocking. Hospitals that are part of the fast-growing SEDICO user community and document with the MEM-CED online system can rely on the automated background linking of article and lot numbers of implants to their documented cases.

Hence, a unique and proprietary interface is in place ensuring that a copy of all implant datasets is independently sent to the registry database and made available online within minutes. As a result, not only can a single product be evaluated precisely, but an early warning system for poorly performing implants is also established, as all other implants belonging to any given production run can be recalled using the lot numbers. Users that do not want to or cannot install the SEDICO system are offered updated online product catalogues of all participating implant suppliers within the documentation system. With the search tools in place, an implant can be selected and also linked to the respective case. However, lot numbers are not registered with this implant-tracking search option.

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