

Update on Internet-Based Orthopedic Registries

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Abstract

With healthcare costs rising and health-care value being emphasized, physicians now, more than ever, must capture and track patient care outcomes. Already burdened with electronic medical records, they must now collect outcomes data, as this information ultimately will be tied to reimbursement. Advances in Internet-based systems can facilitate the process. Not only is outcomes collection better for patient care, but the feedback that physicians receive from peer comparisons can enhance quality improvement.

In a 2012 review of database tools, Lubowitz and Smith¹ examined Internet-based applications that arthroscopic surgeons could use to record and monitor patient-reported outcome (PRO) data and potential adverse effects. In this article, we update orthopedic surgeons on the registries and monitoring software mentioned in that earlier publication and in other publications that have since become available.

Most orthopedic surgery candidates are seeking pain relief and improved function. Many patients expect their pain to be completely relieved by surgical intervention and their function to return to what it was before they became stricken.^{2,3} Therefore, PRO measures (PROMs) are now standard in post-orthopedic surgery outcome reporting.⁴ PROMs, which include any measurement that assesses a patient's health, illness, or benefits from the perspective of the patient, are often administered as a questionnaire or survey.⁵ The collection of PROMs continues to increase and evolve, creating a need for data storage and analysis. Registries, large collections of patient

information and outcomes, allow for evaluation of patient outcomes, monitoring of adverse effects, identification of procedure incidence, understanding of predictors of prognosis, generation of feedback for quality of care, monitoring of the safety of implantable devices, and the conducting of hypothesis-driven scientific research.^{6,9}

Orthopedic surgery has registries at regional, national, and international levels. Although the United States has fallen well behind other countries in establishing a national registry,⁹ it has made some recent progress. The United States now has several national registries, including the American Joint Replacement Registry (AJRR), Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR), the Kaiser Permanente National Total Joint Replacement Registry (TJRR), the Veterans Affairs (VA) and American College of Surgeons (ACS) National Surgical Quality Improvement Programs (NSQIPs), and the National Trauma Data Bank (NTDB).⁹ AJRR currently has 960 hospitals participating and is tracking 1,084,664 hip and knee replacements.¹⁰

These orthopedic registries, however, are limited in 2 ways. First, the majority are joint replacement registries. Second, though registries are established to determine patterns of care and predict patient outcomes, many are not set up to report care data back to healthcare providers.⁷ For procedures other than joint arthroplasty and for providers interested in tracking their patients' PROs, systems are available for establishing clinical quality registries in orthopedics.

Registry Systems

CareSense

CareSense (Medtrak) is an Internet-based care management and data collection system designed for patient engagement, which results in fewer missed appointments, increased patient adherence, enhanced patient education, and improved

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patient satisfaction.¹¹ CareSense features email/text reminders for data entry, custom and standard reports, import and export of electronic medical record (EMR) information, and tools for running research studies.¹² CareSense emphasizes care navigation by helping hospitals educate and guide patients through their care by sending exercise videos to patients for home rehabilitation, transferring messages from post-acute care facilities to surgeons and caregivers, and alerting the care team to any potential readmission symptoms.^{11,13} CareSense is also a Centers for Medicare & Medicaid Services (CMS) approved qualified clinical data registry (QCDR). QCDRs collect data for Merit-Based Incentive Payment System (MIPS) clinicians and submit the data to CMS.¹²

KareOutcomes

KareOutcomes, a healthcare technology and support firm founded in 2009, advocates transparency and trust among providers and patients, and aims to optimize PROs.¹⁴ The KareOutcomes team incorporates patient follow-up personnel, administrators, engineers, physicians, software developers, and technicians. The KareOutcomes software, which is backed by a 6-month guarantee, includes system design and implementation, data collection and entry, methods of submitting data to statewide or nationwide registries and sending standardized and customized surveys, and accessible and meaningful data presentation. KareOutcomes allows patient follow-up through automated reminders by telephone, SMS text message, and email. Patients can respond to surveys or questionnaires whichever way is most convenient—by telephone, Internet, SMS text message, or on paper, either in the office or by mail.

Oberd

Oberd (Universal Research Solutions) offers a comprehensive package of solutions for collecting optimal PRO data. The package has several modules: outcomes, education, registry, operative notes, data import and export, and data reporting.¹⁵ Oberd Outcomes allows convenient and engaging data collection. For example, users can send both standardized and customized forms. Oberd Education allows patients to receive information in an interactive, narrated format that is specific to their physician's techniques and practices. Oberd Registry allows users to input multiple datasets into a registry, compare data, and generate reports with visuals. Like CareSense, Oberd is a CMS-approved

QCDR. Oberd's MIPS Dashboard helps providers collect and report patients' reported outcomes, and use that information to modify and improve their practice.

Ortech

Ortech is a web-based data registry system that allows physicians and administrators to mine the data they own, track key metrics in their data, and improve reporting.¹⁶ Users can collect PROMs, use them to measure and analyze patient progress, and add to their collection of information that helps support their evidence-based decision making. They can capture intraoperative and implant data through barcode scanning, which then registers the data in an implant product code library that allows quick identification of patients with a specific implant in the event of a product recall. Ortech also allows automatic generation of customized operative reports on data entered from the operating room and populated into the EMR. Ortech offers 2 versions of its data collection platform, phiDB and phiDB Lite. The phiDB Lite version is for smaller practices and focuses mainly on PROMs but lacks many of the other features that phiDB offers, such as operating room modules, automated operative reports, barcode scanning, and unlimited data reporting.

Socrates

Socrates (Standardised Orthopaedic Clinical Research and Treatment Evaluation Software; Ortholink) is dedicated orthopedic software that facilitates following patient outcomes and conducting high-quality research.¹⁷ Socrates is fully customizable to fit each user's needs. It allows for tracking of outcome scores, intraoperative details, nonoperative procedures, clinical examinations, therapies, and adverse effects. Users can also create reports from this information, which is inputted to Socrates and can be exported into EMR. Socrates data are stored on the user's server, on site; the software generates patient summaries, collective summaries, and follow-up reports through its built-in descriptive statistics module. Raw data can be extracted for

Take-Home Points

- PRO data collection can provide feedback for improvements in patient care and physician performance.
- Many options exist for orthopedic physicians to establish clinical data registries.
- Registry systems can help improve patient follow-up with system monitoring and patient reminders.
- Clinical registries can offer many advantages to observational research.
- With registry use becoming more prevalent, work needs to be done to establish standards for validity and reliability.

statistical analysis. Socrates can catalogue images, radiographs, documents, and videos.

Surgical Outcomes System

Surgical Outcomes System (SOS; Arthrex) is a cloud-based orthopedic and sports medicine global registry that focuses on monitoring and evaluating the outcomes of various orthopedic and sports medicine surgical procedures, as well as nonoperative interventions, to contribute to evidence-based protocols for patient treatment.¹⁸ SOS can be fully customized with desired PROMs for arthroplasty and for surgical procedures for extremity joints and even the spine. SOS includes real-time reporting on PROs for individual patients, summary PROMs for all of the physician’s patients who are receiving the same treatment, and comparisons with all registry patients (from global de-identified registry data) who had the same treatment or surgery. This real-time analysis provides immediate patient and physician feedback on treatments and products used. A patient portal for education on surgical procedures is also available. SOS is approved for use in 21 countries and is a benefit included with Arthroscopy Association of North America (AANA) membership. SOS is listed on the National Quality Registry Network (NQRN) website and, as a specialized registry as defined by CMS, can accept data generated by EMR technology.

Discussion

Delaunay¹⁹ indicated that successful registry management depends on several factors, including “use of a single identifier for each patient to ensure full traceability of all procedures related to a given implant; a long-term funding source; a contemporary, rapid, Internet-based data collection method; and the collection of exhaustive data, at least for innovative implants.” The registry systems reviewed in this article are Internet based and allow healthcare providers to monitor the clinical outcomes of their patients in the hope of improving clinical decision-making and overall patient care. From the provider perspective, many registry systems allow for integration of outcome data reporting into EMRs, including generation of operative reports. In turn, registries can improve documentation efficiency, as it was estimated that a US physician without a registry spends more than 15 hours a week reporting quality measures,²⁰ or almost 800 hours and \$15 billion each year.^{20,21} It remains to be seen whether registry systems will optimize the documentation process, but there is

potential improvement in time and cost-efficiency with registry use.

Although the factors involved in management are important, clinical data registries must have systems in place to help ensure patient adherence and minimize selection bias, as adherence is crucial in data accuracy.³ What helps with adherence is the ability to send automated email or SMS text message reminders to patients. According to a review, email reminders increased the completion of PROM datasets by 26%.²² When the new national quality register (NQR) HAKIR (Handkirurgiskt kvalitetsregister) was established in Sweden, it was found that when only 1 type of reminder was used (SMS text message, in this case), only about 30% of participants completed their questionnaires.²³ However, after the system was changed to send both SMS text message and email reminders, the response rate increased from 50% to 60%. Using 2 types of automated reminders might minimize lost data more effectively than 1 type alone.

Another benefit of outcome monitoring through a registry is potential reduction of interviewer-related errors. Interviewer bias can occur in many different ways. Interviewers might not follow the same instructions or administer questionnaires or surveys the same way for different patients,²⁴ the interviewer’s presence might cause the patient to alter responses based on social norms,²⁵ and the patient might report better outcomes in the presence of a physician or interviewer.^{26,27} Given that clinical registries allow electronic capture of self-administered surveys, interviewer bias is reduced because all patients receive a standardized set of questions and instructions. In addition, electronic questionnaires and surveys prompt users to add or fix missed or incorrectly completed items, further reducing potential data inaccuracies.

Healthcare costs continue to rise in the United States. In 2015, the total cost of healthcare expenditure in the United States was \$3.2 trillion, or almost 18% of the US gross domestic product.²⁸ In addition, in the first half of 2016, an estimated 16.2% of people under age 65 years were in families that were struggling to pay medical bills.^{29,30} Healthcare reform provides a financial incentive to healthcare providers to collaborate to reduce unnecessary costs and procedures and improve the quality of healthcare.³¹ Porter and Teisberg³² defined value as health outcomes achieved per dollar spent. Registry monitoring of PROMs, which are the numerator in this critical value formula, allows providers to track patient outcomes over time to

determine which interventions produce the best outcomes.²² Therefore, clinical registries play an important role in improving health outcomes and reducing the cost of healthcare.⁷

Since the Swedish Knee Arthroplasty Register (SKAR) was established 40 years ago, NQRs have been commonplace in Scandinavian countries, Australia, and the United Kingdom.²³ Between 2001 and 2014, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) documented a decline in the financial burden of hip and knee arthroplasty revision in Australia—in comparison with the United States, which did not have a full national registry at the time and showed a revision rate increase.²⁴ The economic benefit of reducing hip and knee arthroplasty revisions in Australia during that period was an estimated \$65 million to \$143 million.²⁴ Besides having financial benefits, national registries allow early identification of flawed implantation products and methods, leading to a further reduction in the burden associated with recall and future use of such defective implants—including patient harm.

In addition to monitoring existing techniques and devices, registries can also follow new techniques and, compared with publication in clinical journals, more expeditiously provide clinical data for outcome expectations and treatment methods. This timeliness is particularly valuable given that publication of clinical trials with the usual mandatory 2-year follow-up can take 4 years or longer.^{33,34} For instance, in the expanding field of hip arthroscopy, data from registries in both Sweden and Denmark are being analyzed.^{35,36} These data are important in new fields such as hip arthroscopy, in which clinical indications and treatment techniques may vary considerably between locations.³⁵ In 2012, the Danish Hip Arthroscopy Registry (DHAR) was started as a web-based prospective registry.³⁶ Between 2012 and December 2014, DHAR added 2000 procedures, which included all hip arthroscopy procedures performed at 11 centers in Denmark.³⁶ DHAR tracks PROM, surgical procedure, operative, and radiologic data.

Increased use of clinical registries has led to use of their data in clinical research. Registry-based randomized controlled trials (RCTs) are lower in cost than other types of research, allow for rapid enrollment of patients, offer larger population sizes and multi-institutional sampling, and can provide a more diverse patient population.^{19,37} Although non-registry RCTs remain the gold standard of clinical research, registry RCTs have several advantages

given the abilities and structure of registries. Because of resources and cost, nonregistry RCTs are usually limited in the number of examined exposures and typically focus on only 2.⁶ Registry RCTs, on the other hand, can monitor multiple exposures, typically at minimal cost difference.⁶ Another disadvantage of nonregistry RCTs is that they are often performed at institutions providing care that might not be indicative of the quality most patients expect, as these institutions might be selected for a specific clinician or specialty service.

Registry RCTs also have their limitations with respect to clinical research. A major one is their lack of validity standards or accepted benchmarks for accuracy, adherence rates, registry completeness, and data collection.^{37,38} In addition, lack of standardization across national and international registries could produce conflicting data. Another limitation is that data in most registries are not subjected to any third-party checks or independent auditing.^{9,39} Furthermore, evaluating the impact of registries is difficult because it is difficult to find comparable outcome data on nonregistry patients.⁴⁰ A final limitation involves the ethics of including registry data in RCTs. Although data are often added to a registry without patient consent, should the same data be used for research without patient consent? Should patients be able to disallow use of their data for research, or require a notification each time their data are used? These issues must be addressed.

Review Limitations

One limitation of this review of clinical Internet-based outcome systems is that it might not have identified comparable systems. In addition, specific costs associated with each system were not addressed, as they depend on PROM licensing fees, total institutional access, other proprietary costs, and other variables. Another limitation, in terms of creating a national or international registry, continues to be Internet access. The Pew Research Center estimated that 84% of US adults used the Internet in 2015.⁴¹ Although 84% represents most of the adult population, the other 16% typically is over age 65 years, where only 58% of adults reported using the Internet, or come from lower income households, where access was <75%. For registries in European countries and North America, where Internet usage typically is >70%, this is not a significant problem. However, worldwide, only 47% of the population used the Internet in 2016.⁴² Internet usage by Asian and Arab states citizens was 41.6% and 41.9%,

respectively, and usage by African citizens was only 25.1%. As a significant benefit of registry use is that researchers can obtain larger sample sizes, it is a problem that some populations—elderly people, people of lower socioeconomic standing, people living where the Internet is unavailable—might be underrepresented in registry data.

As mentioned, patient adherence is an ongoing issue for clinical registries. As adherence tends to decrease as more time passes after a patient's treatment date, it is important to account for and encourage continued patient participation with outcome monitoring. Missing data lessen the validity and accuracy of a registry, increasing the likelihood that certain groups will be underrepresented. Although registry systems can reduce the cost of following PROMs, doing so requires monitoring and following up on issues of patient adherence. In other words, many clinicians will need the help of a research assistant. Makhni and colleagues²¹ found that adding a research assistant for this task increased survey adherence from 65% to 94% before surgery, from 65% to 72% 6 months after surgery, and from 38% to 56% 12 months after surgery.

Even though studies continue to use clinical data from registries, there is not much research on the impact of these registries on improvement in healthcare. Again, many factors are involved: lack of standardized benchmarks for accuracy and adherence, lack of an accepted method of data auditing and validation, and difficulty evaluating the impact of registries owing to the difficulty obtaining comparable data on nonregistry patients. Registries must adopt accepted forms of standardization in order to allow better comparisons of registries, because comparing data across registries can be useful in determining the strengths and weaknesses of different registries.^{27,43} As registries support decision making at clinical, institutional, and governmental levels, it is vital that their clinical data be accurate and reliable.³⁸

Conclusion

Rising healthcare costs, and government and third-party pressures are making patient outcomes collection a standard of care. Going forward, orthopedic surgeons must be proactive, and Internet-based registries provide technological advances that facilitate the process.

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