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Electronic Data Capture through Total Joint Replacement Registries

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Abstract
There has been a move toward adoption and implementation of electronic health records. In the U.S. there exists the potential to use electronic data capture to better understand patient outcomes and improve the quality and efficiency of medical care. Within orthopaedics, national joint replacement registries have been shown in other countries to improve clinical decision-making and outcomes after joint arthroplasty. As such, there is increasing interest among U.S. clinical investigators and policy makers to utilize electronic clinical data to develop national and regional joint replacement registries. We discuss our experience with integrating electronic data capture and reporting methodology into the California Joint Replacement Registry (CJRR) and American Joint Replacement Registry (AJRR) initiatives. The use of electronic clinical data for joint replacement registries will better facilitate multi-stakeholder collaboration, improve the quality of care, reduce medical spending and foster customized evidence based clinical decision-making.

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Electronic Data Capture through Total Joint Replacement Registries

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Abstract

The move toward adoption and implementation of electronic health records (EHR) provides an opportunity in the United States to use electronic clinical data (ECD) to better understand patient outcomes and to improve the quality and efficiency of medical care. Within the field of orthopedics, national joint replacement registries have been shown in other countries to improve clinical decision-making and outcomes after joint arthroplasty. Thus, there is increasing interest among U.S. clinical investigators and policymakers to utilize ECD to develop national and regional joint replacement registries. We discuss our experience with integrating electronic data capture and reporting methodology into the California Joint Replacement Registry and American Joint Replacement Registry initiatives. The use of ECD for joint replacement registries will better facilitate multi-stakeholder collaboration, improve the quality of care, reduce medical spending, and foster customized evidence-based clinical decision-making.

Introduction

Provider incentives and the specter of financial penalties have driven increased utilization of electronic health records (EHR).[1,2] Widespread adoption and implementation of EHR provide rich opportunities to use electronic clinical data (ECD) to better understand patient outcomes and to improve the quality and efficiency of medical care.

Within the field of orthopedic surgery, there is increasing interest in utilizing ECD to assess outcomes and guide clinical decision-making. Specifically, because total joint arthroplasty (TJA) is a high-volume and costly procedure for the U.S. health care system, a sophisticated and coordinated electronic method of surveillance has been of interest for many years. In other fields, electronic data capture has allowed physicians to collect data in parallel to clinical practice, and to use these data to obtain expeditious answers to clinical questions.[3,4] Deployment of electronic data capture through joint replacement registries can improve our understanding of outcomes after TJA, by providing continuous monitoring; the data gained through such monitoring can guide surgeon practices.

In this paper, we present the rationale and evidence for joint replacement registries as a feasible form of electronic data capture within orthopedics. We also describe experiences using ECD in the setting of a regional and national joint replacement registry in the United States.

Rationale for Electronic Registries in TJA

Joint replacement registry data provide the opportunity to prospectively assess outcomes in patients undergoing TJA. Although registry studies do not permit for robust analysis of endpoints beyond survivorship, nor do they allow for identification and control of risk factors associated with failure, they do hold great promise for driving clinician behavior and improving patient safety. Registry studies also provide surgeons with important implant surveillance and survivorship data.

Unlike randomized controlled trials, registries have no predefined control over inclusion criteria or implant type used. As such, registry studies provide the opportunity to more easily gather long-term data on a wide range of patients across multiple institutions. Some authors have suggested that because of strict inclusion criteria and subgroup analyses performed in formal therapeutic studies, these more formally structured studies likely have inherent preselection biases and may thus have less fidelity than registry data when portraying *average* outcomes.[5] Less restrictive joint replacement registry inclusion criteria across multiple centers and surgeons provide the orthopedic community with evidence at a very high level of generalizability.

There is currently no international consensus on a minimal data set required for the establishment of a joint replacement registry, but the International Society of Arthroplasty Registries suggests that an essential minimum data set should include such details as prosthe-

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sis (catalog number and lot number); patient (name, age, gender, address, unique identifier); surgery (site and side, diagnosis, primary vs. revision); surgeon (name or identifier number); and hospital. The complexity of data collected within registries is often referred to in the context of levels (Levels I–IV): Level I includes the simplest data (essential minimum data set), and data complexity increases at each level up to Level IV, which consists of imaging diagnostics (see table).

Several experts have argued for robust registry data entry beyond a minimum data set.[7] The use of electronic data capture will more easily allow registry coordinators to capture minimum data sets as well as other potentially relevant data points such as operative technique details, patient demographics (e.g., race and socioeconomic status), patient comorbidities, patient-reported outcomes (PROs), and radiographic studies. PRO measures are highly relevant within the U.S. context; since the passage of the Patient Protection and Affordable Care Act (ACA) there has been increased interest in understanding patient-centric outcomes. As part of the ACA, the Patient-Centered Outcomes Research Institute was formed with the goal of funding and increasing the dissemination of patient-centered outcomes research. Thus there is a pressing need, perhaps beyond that of other international joint registries, for PRO measures to be incorporated into any U.S. joint replacement registry effort.

Levels of Data for a Joint Registry[5, 6]

Data Level	Data Collected
Level I	**Patient-related data** Personal identification Gender Laterality Primary diagnosis Incidence of death **Procedural data** Date of surgery Type of procedure Implant information Hospital identification Surgeon identification Reoperation and/or revision
Level II	Comorbidities Surgical complications Height and weight Prophylactic measures Surgical measures (technique, approach, fixation method, and timing)
Level III	Patient-reported outcome Socioeconomic status Adverse events Costs
Level IV	Imaging diagnostics

An exciting application of electronic data capture is with regard to PRO measures and the development of platforms to capture data in an inexpensive and less burdensome way. A meta-analysis found that the psychometric properties between electronic and paper-and-pencil methods for delivering PROs are equivalent[8] Because these methods have been found to be equivalent electronic PRO methods are being increasingly deployed in various medical fields. Notably, within oncology there has been a focus on developing software solutions to allow for the capture of a variety of electronic PRO measures during routine clinical practice.[9]

There is no literature on the implementation of electronic PROs within orthopedics. Because joint replacement registry data can be potentially flawed by inconsistent follow-up and follow-up protocols, PRO measures and the use of revision as a firm endpoint provide a degree of consistency for joint replacement registry data.[6] Electronic means of PRO data capture in orthopedics are particularly appealing because patients can enter data remotely without the need to present to a clinic. Enabling patients to enter outcomes data remotely makes the collection of data more feasible and reduces associated costs through reductions in human resource consumption. Electronic outcomes reporting also provide the opportunity for patients to answer outcomes questionnaires at intervals more frequent than the typical schedule of follow-up clinic visits.

Evidence from Joint Replacement Registries

Outside of the United States, national joint replacement registries have long been established. The first such registry was the Swedish Knee Arthroplasty Register established in 1975, which was followed by the Swedish Hip Arthroplasty Register in 1979.[10,11] Since the early 1980s, several national registries have been established in Europe, Canada, and Australasia. The Nordic Arthroplasty Register Association, which was established in 2007, represents a novel effort to transcend the typical national bounds in data and outcomes sharing.[12,13]

The importance of registries for understanding and improving outcomes after joint arthroplasty has been well recognized. For example, since the Swedish Hip Arthroplasty Register was implemented in 1979, data obtained from the registry have improved total hip arthroplasty (THA) practice by identifying individualized patient risks, identifying implant safety issues, and highlighting the efficacy of improved surgical and cementing techniques.[14] Similarly, the Australian Orthopaedic Association National Joint Replacement Registry serves as the country's monitoring and warning system; it has helped surgeons monitor new implants and identify appropriate patients for specific implants.[15] More recently, data from the National Joint Registry of England, Wales and Northern Island allowed experts in the United Kingdom's National Health Service to warn against the use of metal-on-metal implants for THA. Implant surveillance as part of the registry found that more than 6 percent of patients with metal-on-metal implants required revision within 5 years, compared with 2 percent in patients with metal-on-polyethylene or ceramic-on-ceramic.[16] As a result of these findings in the United Kingdom, other countries have begun

to more closely scrutinize data for metal-on-metal hip implants. Although the U.S. Food and Drug Administration has tightened regulation of metal-on-metal hip implants, the lack of registry data in the United States has prevented meaningful data reporting beyond institutional records and implant device manufacturer postmarket surveillance.

Joint replacement registries have also been shown to provide significant economic benefit by reducing the rate of revision TJAs and thus the economic burden associated with these procedures (revision TJAs are more costly than primary procedures). One study using the Australian National Joint Replacement Registry found that the identification of implants with a higher-than-expected rate of failure led to 25.8 percent fewer revision procedures.[17] The Healthcare Cost and Utilization Project (HCUP) estimated the economic burden of revision joint arthroplasty in 2012 at $2.7 billion. Thus, even a 2 percent reduction in the U.S. national revision rate would represent a $54 million annual cost savings for the Centers for Medicare & Medicaid Services.[18]

Discussion

With the demonstrated value of national registries, there has been significant attention paid to developing a national registry in the United States. Several institutions and regions within the United States have developed their own registries, but there has yet to be a fully implemented national registry.

Joint Replacement Registries in the United States

The California Orthopaedic Association, the California HealthCare Foundation, and the Pacific Business Group on Health have partnered in developing a California state registry, the California Joint Replacement Registry (CJRR); this registry is still in the pilot phase. As part of data collection efforts, CJRR collaborators augmented the minimum recommended data set with information on patient comorbidity, socioeconomic data, prophylactic measures, costs, and adverse events. Furthermore, CJRR institutions administered three PRO measures to each patient: the SF-12 Health Survey, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the University of California, Los Angeles (UCLA) Activity Index. Questionnaires were administered preoperatively and at intervals of six months, one year, and five years postoperatively.

As of April 2013, the CJRR had enrolled more than 5,000 individual patients and the registry institutions included 12 participating sites, with 19 additional facilities in the process of joining. By the end of 2013, CJRR sites are projected to account for more than 30 percent of the California TJA volume.[19]

On a national level, several key stakeholders have come together to establish the American Joint Replacement Registry (AJRR)—a major effort toward developing a national registry.[20] The AJRR was incorporated in 2009; a successful pilot project collecting data on 3,600 joint replacements was completed in June 2011, and active recruitment of additional hospitals began soon thereafter. The AJRR has made significant progress in scaling up the project and aims to create a national footprint through contracts and collaborations, with the goal of reaching a critical mass of institutions by 2014. Thus far, AJRR funding has largely been achieved through various stakeholder/collaborator contributions; however, as the financial model evolves, AJRR will look to transition to a self-sustaining model drawing funds from hospitals, industry, payers, governmental agencies, and other parties potentially interested in AJRR data.

There are currently no published data from the CJRR or the AJRR. On its website, the CJRR provides preliminary preoperative and six-month WOMAC scores for over 2,000 primary TJAs performed from April 2011 to November 2012. For THAs at six months follow-up, patients had an average score of 78.4 on the WOMAC compared with 42.8 preoperatively. For total knee arthroplasty (TKA), patients had an average score of 75.9 on the WOMAC compared with 52.9 preoperatively. With continued longer-term follow-up, the CJRR will have the opportunity to report medium- to long-term PROs from a state-based U.S. registry.

Electronic Data Capture in U.S. Registries

Both the CJRR and the AJRR have employed electronic data capture to better facilitate data collection and collaboration among key stakeholders. As part of the CJRR collaboration, registry developers created a Web interface through which patients could access PRO questionnaires from home and which was also available in physician offices on kiosks or handheld devices such as smartphones and tablets. Our goal was to use electronic data capture to facilitate the collection of patient-centered outcomes and to increase the ease of participation for patients as well as the ease of data collection and collation for registry administrators. Thus far in the pilot phase, CJRR developers have reported a response rate greater than 50 percent for preoperative PRO questionnaires among the 5,000 enrollees. Improving electronic PRO response rates will likely be achieved by polling patients to understand patient preference and system issues related to nonresponse to electronic PRO. Understanding and responding to these factors will likely improve response rates and add to the strength of reported outcomes measures.

Electronic data capture has also played an important role in the rapid pace of national rollout and stakeholder collaboration involved in establishing the AJRR. The AJRR organizers have successfully leveraged ECD collection systems to coordinate and streamline the process of coordinating a multiregional joint replacement registry effort. For example, during the pilot phase, registry leadership received feedback from pilot sites regarding the time-consuming nature of current electronic data entry processes. As a result, the AJRR implemented an automated system with new software products that utilized batch data rather than individual data, thereby allowing smoother data entry.[21]

Electronic data capture in the AJRR has not been without difficulty. A key technological challenge that was recognized and addressed early on was patient privacy and the protection of data.

While some regional and institutional registries use de-identified data to circumvent privacy issues, they lose the ability to track patients over time. De-identified patient data were a suboptimal choice for the AJRR given that longitudinal prospective tracking had been an explicit goal for the registry. The AJRR addressed this issue by creating a data-encrypted interface for institutional access. Further, through the Western Institutional Review Board, the AJRR was granted a waiver of Health Insurance Portability and Accountability Act (HIPAA) authorization and Common Rule consent. These efforts toward protection of ECD provide the AJRR with an opportunity not only to longitudinally track TJAs in various individuals but also to identify revisions that occur in AJRR patients.

Applications for Joint Replacement Registry ECD

Currently, the AJRR collects only Level I data elements. An initial focus on Level I data has allowed the AJRR to compile complete data sets within a relatively short time frame. However as the registry becomes more established, there will be an increasing need for higher levels of clinical data to facilitate richer data analysis. To meet this need, the AJRR has developed an interface that allows for data file upload from remote servers, thereby allowing registry coordinators to begin compiling some of these more complex data elements from existing data sets. Specifically, the AJRR data management software has a variety of built-in methods to avoid duplicating work. Software capabilities include extraction of registry data from administrative claims forms, automated data submission from existing orthopedic registries and custom interfaces linking to EHR and other available health care information technology systems.[22]

Capturing higher levels of ECD is of interest to various stakeholders involved in TJA. For example, Level II data, which include patient comorbidities and surgical complications, is of particular interest to payers and policymakers. Patient comorbidity data collected in large volume on a broad scale will provide a unique opportunity to begin risk-adjusting particular regions, institutions, and/or providers. Similarly, in a value-centric health care climate, complication and revision data provide a reliable metric that value-based purchasing programs can use to determine remuneration.

Joint replacement registry ECD has the potential to influence decision-making across multiple other stakeholder groups, beyond payers and government agencies. Joint replacement registries are well established as an effective postmarket surveillance system and have been shown to decrease national revision rates. In the U.S. context, data collected through joint registries could potentially serve as a feedback mechanism to device manufacturers. A proper assessment of implant failures by device manufacturers can lead to more expeditious implant design improvement and more responsible adoption of new medical technologies.

Patient interest groups and surgeon specialty organizations have also expressed tremendous interest in joint registry efforts; many believe that the public reporting of joint replacement registry ECD will allow patients to better engage in collaborative decision-making with their surgeons. Registry data could potentially provide patients with greater transparency into outcomes at multiple levels—device, provider, and institution. Furthermore, compilation of a large-scale outcomes data set will allow surgeons to better understand patient-specific factors that are associated with an increased risk of failure. Currently, the AJRR provides publicly available annual reports with de-identified data on procedure frequency, device utilization, device-specific survivorship, and volume effects by surgeon and hospital type (e.g., academic or community). Custom reports with identifiable data are available on demand for participating hospitals and surgeons. Similarly, the CJRR provides a publicly available progress update that gives an overview of TJA volumes and utilization as well as some Level I, II, and III data on enrolled patients. In addition to this publicly available data, participating CJRR hospitals, medical centers, and surgeons receive confidential reports benchmarking performance by institutions and surgeons to the overall performance of participants. On both the patient and the provider sides, the availability of those data has great potential to aid in clinical decision-making and improve patient safety.

Initial AJRR recruitment efforts have been focused on enrolling large medical centers and hospital networks with regional databases, the goal being to scale up the number of joint replacement patients tracked in the registry through high-volume acquisitions. Such high-volume targets (compared with smaller institutions) often have more sophisticated means of internally tracking their TJA data. However, as ECD and data management practices become more ubiquitous, medium- and smaller-size institutions will become better equipped to collate their data and more easily contribute to the AJRR. Tracking of outcomes in the AJRR database for these small- and medium-size practices will provide new levels of clinical outcomes transparency.

Conclusion

Utilization of ECD in the management and assessment of health outcomes is expanding. Within orthopedics, there is an opportunity to use electronic data capture capabilities to develop efficient and integrated registries. ECD is currently being integrated into U.S. joint replacement registry efforts. Thus far electronic data capture has allowed for more efficient data collection and aggregation of implant, patient, surgeon, technical, and institutional information. Outside of the United States, joint replacement registry data have already been shown to play an important role in improving patient safety and outcomes through tracking of implant survivorship and surveillance of new technologies. In the United States, joint replacement registry data will provide not only implant-specific information but also patient-reported outcomes and quality-related data. Greater transparency into national TJA results will allow for more appropriate benchmarking and risk adjustment/attenuation. Use of ECD for joint replacement registries serves as an appropriate model for registry efforts in other subspecialties within orthopedic surgery.

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