State-Based and National U.S. Registries

The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI), California Joint Replacement Registry (CJRR), and American Joint Replacement Registry (AJRR)

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Abstract: The concept of a total joint registry as a tool to gather and compare longitudinal clinical outcome data emerged in the early 1970s; although initially begun as a single-institution effort, it soon spread to the development of large nationwide registries, first in Scandinavia and subsequently around the world. These national registries established the value of population-wide results, large cohorts, and the importance of ongoing implant surveillance efforts, as detailed elsewhere in this series. In the United States, concerted efforts to establish a national total joint registry for the hip and knee began in earnest in the early 2000s and culminated with the incorporation of the American Joint Replacement Registry (AJRR) in 2009. Parallel efforts soon followed to establish state-based total joint registries, either as stand-alone entities or in affiliation with the AJRR. Some of these state-based efforts succeeded, and some did not.

In the first section of this article, Brian Hallstrom, MD, details the highly successful Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI). This state-based effort was made possible by a unique partnership between a single dominant statewide private payer and the Michigan orthopaedic surgery community; it has already successfully advanced the quality of care for patients in Michigan, and efforts are ongoing.

The second section, by James I. Huddelston, MD, details a different path to the establishment of a focused state-based registry. The California Joint Replacement Registry (CJRR) was the result of a partnership with representatives of the statewide business community and resulted in a pioneering effort to successfully collect and publicly report patient-reported outcome measures as part of the registry data set. Further discussed are the establishment, development, and status of the AJRR and its current place among the family of American Academy of Orthopaedic Surgeons (AAOS) registries, which were inspired by the AJRR and span a range of orthopaedic specialties.

The Michigan Arthroplasty Registry Collaborative Quality Initiative

The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) is a statewide quality improvement project for primary and revision hip and knee replacement that is funded by Blue Cross Blue Shield of Michigan (BCBSM) but retains independent control of the data and quality improvement work[1]. MARCQI received funding, established our coordinating center, and began recruitment in 2011. Data collection began in 2012. The registry has multiple data sources but is anchored by direct chart abstraction, by trained data abstractors, of 100% of cases at participating sites. This data validation and analysis are done by the MARCQI Coordinating Center. The abstracted data are supplemented with automated file-based uploads from each site as well as administrative billing data from the Michigan Inpatient and Outpatient Databases provided by the Michigan Health & Hospital Association. As a quality improvement program, MARCQI operates under a designation of a "not-regulated" activity according to the "Common Rule" (45 CFR 46) that governs human subjects research.

MARCQI currently has 79 participating sites consisting of 59 hospitals, 5 affiliate hospitals, and 15 outpatient surgical centers, with approximately 350 active surgeons. The registry currently contains >375,000 cases. The data collection is guided

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by a detailed specifications manual that defines each of the 150 data elements. The data elements are categorized as demographics, operative data, hospitalization, and follow-up. The administrative data are supplemented with comorbidities and postoperative events. This statewide administrative data allows the capture of events that occur at other hospitals, such as emergency department visits, readmissions, or reoperations, which are then linked back to the primary surgical case.

Data elements were carefully selected at the inception of the patient registry, with an emphasis on quality improvement and pragmatic data collection. The development and maturation of the registry have resulted in changes in data collection over time. Data elements that have been added to the registry include the use of topical antibiotic powder, the use of irrigation solutions, and the type of fixation of each individual component. Because questions have arisen, the registry has considered adding other data elements, including tourniquet use, more detailed information on the reason for revision, and data on other types of cases such as hip hemiarthroplasty for a fractured neck of the femur. The MARCQI Coordinating Center works diligently to balance the retirement of old data elements with the introduction of new ones. Additionally, the possibility of incorporating radiographs or other visual data into the registry has been explored.

MARCQI began data collection in February 2012. For the purposes of perioperative quality improvement, MARCQI case abstraction extends to 90 days postoperatively. This allows the collection of detailed data on postoperative outcomes and complications (e.g., transfusion, non-home discharge, and venous thromboembolism). The 90-day event data are the core of the collaborative quality initiative (CQI) model that is funded by BCBSM. Shewhart statistical process control charts are constructed for each participating site and made available to them on a quarterly basis. Risk-standardized forest plots are also generated so that sites can compare themselves with the overall collaborative.

Like other arthroplasty registries, revision is a key outcome of interest at MARCQI. Revisions are tracked indefinitely beyond the 90-day window that is used for other events. Revision cases are linked to primary cases even when the revision occurs at a different site than the primary surgery. While MARCQI is unable to record revisions that occur outside of Michigan, Etkin et al. estimated that only 4% of patients undergoing primary hip or knee arthroplasty in Michigan migrate out of state within 5 years[2]. The catalog numbers of all implanted devices are captured for each case, and a device library (Curvo Laboratories) is used to convert them into the product name, dimensions, and materials. These data are used to produce publicly available annual reports that provide 5-year revision risk by implant product name (https://marcqi.org/marcqi-registry-reports-marcqi-annual-reports/).

Data completeness in MARCQI is confirmed by comparing reported cases to validated, statewide administrative billing data. MARCQI collects data on approximately 96% of primary and revision hip and knee arthroplasties performed in Michigan. The cases that are missed are performed at small hospitals and surgical centers that do not participate in MARCQI. Audits are performed to ensure that 100% of cases at participating sites are abstracted. Most data elements have a hard-stop requirement to complete abstraction of a case. Reviews of return on investment performed by BCBSM have consistently demonstrated substantial cost savings, above secular trends, related to the MARCQI quality improvement projects.

The primary strength of the registry is collaboration across the entire state. Surgeons and hospitals that otherwise compete with each other come together in cooperation, share data openly, collaborate on quality improvement projects, and develop collegial relationships. Since the beginning of MARCQI, the registry has had 36 collaborative meetings. During that time, sites have worked on quality improvement projects and shared site visits, and together have improved the quality of care for all patients undergoing hip and knee replacement surgery in Michigan.

As noted above, the best uses of the registry have been to collaborate across the state toward the MARCQI goal of making Michigan the best place in the world to undergo joint replacement surgery. This is made possible through transparent hospital-level data sharing at collaborative meetings. MARCQI also publicly reports implant survivorship data by product name and summaries of quality improvement progress. MARCQI produces individual reports for each active surgeon in the state, which are distributed to the surgeon for the purposes of practice review and benchmarking to others in the state. These reports include funnel plots of the surgeon's aggregate data relative to his or her peers and corresponding cumulative sum (CUSUM) graphs to track changes over time.

The weaknesses of the MARCQI project are similar to those of many observational registries. Because detailed data abstraction on a high volume of cases is extremely labor-intensive, and long abstraction times would result in long lag times between the performance of cases and the reporting of their results, data are only abstracted out to 90 days postoperatively. The registry is also limited by the scope and definition of each individual data element. Analytically, the chief limitation of MARCQI is the inability to definitively determine causality from the registry data. To minimize bias from confounding, MARCQI uses modern tools from the field of causal inference. These include the selection of covariates based on graphical causal models[3,4], propensity score matching[5], and inverse probability of treatment weighting (IPTW)[6] modeling. The size of the MARCQI team results in substantial issues with analytic bandwidth. This requires frequent careful prioritization and limits the registry's ability to pursue all priorities. The "not-regulated" status and data protection agreements of MARCQI place restrictions on the performance of research projects. The registry is focused on reporting and publishing the quality improvement work that it performs[7-13].

The structure of MARCQI has resulted in a group of very active, involved surgeons representing each of the surgical sites across the state, but there are surgeons with little or no involvement with MARCQI. This represents a goal and an opportunity to increase the engagement of surgeons across the state. Providing surgeons with their individual reports is one step toward involving them in the quality improvement journey.

The overall pitfalls and lessons that have been learned over the first decade of MARCQI have emphasized the importance of building trust and transparency. These 2 concepts are related, as hospitals and providers require trust in order to share their outcome results transparently in front of their peers. It takes considerable time and effort to build trust among a group of skeptical surgeons and hospital administrators. Surgeons in a private setting must not feel that the database is simply a tool to advance academic careers. To counter this, opportunities to publish on MARCQI work are shared widely across the collaborative. It is also imperative that MARCQI data not be used for commercial competitive purposes such as marketing, which is restricted by MARCQI agreements with participating sites. The success of a registry like this relies on the trust of the participants to contribute data and feel comfortable that the data will be used for them rather than against them. Only then can we come together to achieve the improvements in care that our patients deserve when they place their lives and limbs in our hands.

The California Joint Replacement Registry and the American Joint Replacement Registry

Discussions regarding the development of a national hip and knee arthroplasty registry in the United States started in earnest in 2001 between William J. Maloney, MD, and Richard H. Gelberman, MD, who at the time was president of the American Academy of Orthopaedic Surgeons (AAOS), and led to a consensus conference later that year in Washington, D.C., regarding the potential benefits and challenges of establishing a national registry in the U.S. In 2002, the AAOS board established a National Arthroplasty Registry committee to work on defining the core data elements that are required to track these procedures and to establish a plan for piloting methods of data collection from surgeons or hospitals. These efforts were fueled in part by previous implant recalls as well as by the success of national registries in Australia, England and Wales, Sweden, and others. In 2004, the governance structure for what was then called the American Joint Replacement Registry (AJRR) was developed. Due in part to the complexities and size of the health-care delivery system in the U.S. and the need to define costs and a sustainable financial model, building the required consensus on core data elements, finalizing the plans and processes for institution-based data submission, and building a successful multistakeholder collaboration among hospitals, surgeons, implant manufacturers, private payers, and patient representatives took several years (from 2004 to 2009). A core strategy of the initial perioperative data reporting by participating hospitals was chosen with important guidance from the American Hospital Association (AHA). This unique multistakeholder collaboration from across the entire orthopaedic community was successful in producing a secure funding model and an independent governance structure with representation from all of the participating groups (including patients); it ultimately succeeded in transforming the dream of a nationwide registry into reality.

Thus, in 2009, the AJRR was formally incorporated with financial support from the AAOS, the American Association of Hip and Knee Surgeons (AAHKS), The Hip Society, The Knee Society, and orthopaedic industry via representation from the Advanced Medical Technology Association (AdvaMed). David G. Lewallen, MD, who had led the initial AAOS registry oversight committee, served as the inaugural chair of the board of the AJRR, which had representation from all of the supporting groups listed above, as well as hospitals via the AHA, insurance companies via America's Health Insurance Plans (AHIP), and patients via a patient advisory committee. Subsequent chairs of this multistakeholder endeavor have included William J. Maloney, MD; Daniel J. Berry, MD; Kevin J. Bozic, MD, MBA; and the current chair, Bryan D. Springer, MD. Pilot sites began data submission into the production registry platform in 2010.

In 2011, sufficient funding had been secured from industry, the AAOS, the AAHKS, The Hip Society, and The Knee Society to enable a full launch for any willing participants across the country. By 2012, the 100th site began submitting data, and the AJRR became an independent entity. This unique multistakeholder board of directors, with representatives that included patients, surgeons, hospitals, industry, and health plans, determined that the mission statement for the AJRR should be to improve arthroplasty care for patients through the collection, analysis, and reporting of actionable data. An expansion of the data elements occurred in 2013. The AJRR released its first annual report in 2014, the same year it earned distinction as a Qualified Clinical Data Registry (QCDR) by the Centers for Medicare & Medicaid Services (CMS). Designation as a QCDR enables participants to earn credit for promoting interoperability in the Merit-based Incentive Payment System (MIPS) of the Quality Payment Program (QPP). In 2016, the merger with the California Joint Replacement Registry (CJRR)[14-16] (Tables I and II) facilitated the launch of the AJRR platform for collecting patient-reported outcome measures (PROMs) later that year. The AAHKS designated the AJRR as its official registry in 2016. In 2017, a busy year for the AJRR, the registry surpassed 1 million procedures, launched its surgeon-user

TABLE I CJRR Standard Data Elements

Hospital size
Case volume
Procedure type
Age
Gender
Body mass index
Diagnosis
Comorbidities
Length of stay
Postoperative adverse events (90 days)
Surgical approach
Femoral head size
Bearing couples
Level of constraint

TABLE II CJRR PROMs

Short Form-12
Veterans RAND-12
Western Ontario and McMaster Universities Osteoarthritis Index
University of California at Los Angeles Activity Index

dashboard, and was reintegrated into the AAOS as the cornerstone of the overall AAOS orthopaedic registry initiative, which was championed by Dr. Maloney, the AAOS president that year. Currently, the AJRR receives approximately two-thirds of its funding from site licensing fees and one-third from the hip and knee implant industry.

Sources of Data in the AJRR

The AJRR is populated by administrative coding data that are pulled directly from the electronic health record. Some data elements, such as surgical approach, require manual entry. AJRR data include patients with private insurance as well those with Medicare coverage. At the present time, information on revisions and postoperative adverse events are limited to Medicare patients only, unless patients are treated at an AJRR-participating facility. Efforts to obtain these data on all patients with private insurance, regardless of the service site, are ongoing. As of December 2021, the AJRR housed nationally representative[17] data on approximately 2.5 million procedures contributed by 14,000 surgeons from 1,400 hospitals and ambulatory surgery centers in all 50 states. The data have been widely disseminated through 7 annual reports. It is estimated that these data represent approximately 40% of the total volume of hip and knee replacements performed annually in the U.S.

Data Elements Collected by the AJRR

The AJRR has 2 modules: hip arthroplasty and knee arthroplasty. The procedural data for the modules incudes patient name/date of birth/Social Security Number, diagnosis (ICD 9/10 [International Classification of Diseases, Ninth and Tenth Revisions] and CPT [Current Procedural Terminology]), gender, race/ethnicity, height/weight/body mass index, payer status, site of service (TIN [Taxpayer Identification Number] and NPI [National Provider Identifier]), surgeon, trainee status, procedure, date of operation, length of stay, surgical approach, surgical technique, laterality, implant data (manufacturer and lot number), and type of anesthesia.

Comorbidities and postoperative adverse events include common comorbidities, American Society of Anesthesiologists score, Charlson Comorbidity Index, and postoperative complications (e.g., myocardial infarction, cerebrovascular accident, venous thromboembolic event, etc.)

The recommended PROMs include the PROMIS (Patient-Reported Outcomes Measurement Information System) Global-10, the Veterans RAND-12 (VR-12), and the Hip disability and Osteoarthritis Outcome Score, Joint Replacement (HOOS JR) or Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS JR), but all other PROMs are accepted.

Data on deaths are available through linkage with the National Death Index (NDI).

Important Data Elements Not Collected by the AJRR

There are many important data elements relative to AJRR stakeholders that we are unable to collect. These include information on blood transfusion, physical therapy, postoperative day 0, the use of regional anesthesia, the delivery of appropriate preoperative prophylactic antibiotics, the use of tranexamic acid, and the type and duration of use of various anticoagulants. Perhaps most importantly, we are currently unable to collect postoperative adverse event and revision data on patients with private insurance unless they have been treated at an AJRR-participating institution.

Completeness of Data Collection

Given that data completeness for some important data points is modest, efforts to improve data completeness are ongoing. We anticipate introducing a minimum data set, similar to those used by other national registries, in the near future. Registry data are audited annually for accuracy. This process, conducted by an independent entity, surveys 20% of participating AJRR institutions. The audit routinely returns an accuracy rate of at least 95%. The capture of linked data (patients who completed both preoperative and postoperative surveys) remains a challenge. We anticipate great improvement in collection rates in the near future as these data become mandated by payers.

Strengths of the AJRR

It is estimated that the AJRR currently captures approximately 40% of the annual volume of hip and knee arthroplasty in the United States. These data are now considered a nationally representative sample[18]. The AJRR data set includes 100% follow-up for Medicare patients whose index procedure was performed at an AJRR-participating facility. AJRR participation provides many benefits and allows for many opportunities for data reuse, including, but not limited to, comparison with national benchmarks through the RegistryInsights surgeon dashboard, credit in the American Board of Orthopaedic Surgery Maintenance of Certification program, waiver of preauthorization for Blue Shield of California, credit in the Blue Cross Blue Shield Blue Distinction Specialty Care Program, inclusion in the Accreditation Association for Ambulatory Health Care Advanced Orthopaedic Certification, facilitation of the transfer of patient-reported outcome data for participants in advanced alternative payment models such as the Comprehensive Care for Joint Replacement model and the Bundled Payments for Care Improvement Initiative, credit for Aetna Institutes of Quality, credit for the Surgical Treatment Support Program by Cigna, and credit toward achieving Certification for Advanced Total Hip and Knee Replacement from The Joint Commission. As part of its core objective, AJRR participants can request custom reports and have access to early warnings for poorly performing implants. The current AJRR data set represents the largest repository of PROMs in the world for hip and knee arthroplasty patients. Implant-specific survivorship curves also are now available.

Weaknesses of the AJRR and Potential Pitfalls of AJRR Data Use

While the AJRR contains a tremendous amount of data, it is important to emphasize that these are observational data. As such, insights into causation are limited. As with any database that is populated with administrative coding data, AJRR data are limited by inherent inaccuracies in the coding process. Data completeness, including linked PROMs, has ample room for improvement. Data on revisions and postoperative adverse events are only captured 100% of the time for Medicare patients. This type of data for patients with private insurance is only captured if the patient is treated at an AJRR-participating institution. Without a complete data set, any conclusions on the value of delivered care must be tempered on account of these deficiencies.

Summary

In 2022, the AJRR is well on its way to achieving its vision of being the U.S. national registry for hip and knee arthroplasty through comprehensive data and technology, and resulting in optimal patient outcomes.

Work in the future will focus on optimizing data completeness, minimizing the burden of data collection through smart forms and natural language processing, expanding enrollment, exploring expanded data sets to provide data that are actionable for all stakeholders, introducing risk adjustment, exploring data use for international regulatory bodies, helping to further optimize the international prosthetic library, and sharing our experiences with other AAOS registries. ■

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