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The evolving role of clinical registries: Existing practices and opportunities for orthopaedic surgeons

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The Evolving Role of Clinical Registries: Existing Practices and Opportunities for Orthopaedic Surgeons

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Orthopaedic surgery has historically been a leader in using clinical data registries (CDRs) to improve the effectiveness of care, primarily relating to arthroplasty. The Patient Protection and Affordable Care Act (PPACA) has dramatically altered the quality-reporting landscape in the U.S., and registries are now at the center of several intersecting national health policy initiatives. Moreover, other surgical specialties have established registries with proven success in improving care quality, and lessons can be learned from these efforts. In order to effectively utilize registries for innovation, quality assessment, and demonstration of value, orthopaedic surgeons need a clear understanding of how registries and mandated quality reporting are increasingly linked.

CDRs prospectively track outcomes among patients with a unifying disease or treatment. Over the past decade, CDRs have been expanded to include overlapping roles in health services research, quality improvement, and now pay-for-performance initiatives. The Physician Quality Reporting System (PQRS) implemented by the Centers for Medicare & Medicaid Services (CMS) has begun attaching financial incentives to CDR reporting to increase physician participation in national quality-improvement efforts[1]. An up-to-date knowledge of developments in CDR creation and utilization is vitally important for orthopaedic surgeons. CDR participation can meaningfully contribute to increasing value in musculoskeletal care through quality improvement and cost-effectiveness research, in addition to complying with payer mandates.

An Updated Rationale for Registry Participation

The evolution of CDRs has been shaped by several landmark health-policy changes during the past decade. The Institute of Medicine's reports on patient safety and health-care disparities in the early 2000s forced stakeholders to examine the quality and variability of care delivered to patients[2,3], while the PPACA brought the issues of cost containment and value to the forefront[4]. Accordingly, the structure and goals of registries have been expanded to meet these objectives.

Within orthopaedic surgery, CDRs have historically been used for surveillance of implants, typically in hip and knee arthroplasty. Prospective arthroplasty registries trace their origins to Dr. Mark Coventry of the Mayo Clinic, who started a computerized registry soon after implanting the first Charnley hip arthroplasty in the U.S. in 1969; this registry now includes more than 100,000 total joint procedures, all from the Mayo Clinic[5,6].

Because of the challenge of obtaining longitudinal follow-up data in a multiple-payer system, much of the pioneering work in orthopaedic registries has since been performed outside the U.S. The first national arthroplasty registries were not created

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until nearly a decade later, first with Sweden in 1975, then in Finland and Norway in the 1980s, followed by many more national registries throughout the 1990s to 2000s[7,8]. Outcomes of interest have traditionally centered on implants, such as catastrophic failures and revision rates. Registries have been useful in this capacity; the Norwegian arthroplasty registry has detected implant failures within three years of product introduction[9]. Although device surveillance continues to be a critical function of CDRs, incorporating patient-reported outcomes (PROs) such as pain, function, health-related quality-of-life scales, and validated functional outcome scales will strengthen the utility of registries for detecting truly clinically relevant differences in implant performance[10,11].

In a competitive environment of cost containment and value-based purchasing, efforts to measure and improve cost-effectiveness in orthopaedics are critical to maintaining care access. CMS has recently stated a goal of having 30% of all Medicare payments tied to "value" by the end of 2016[12]. CDRs have several advantages over other commonly employed clinical research methodologies, making them robust vehicles for conducting comparative effectiveness research. CDRs can provide timely data to compare rapidly developing interventions that may not be optimally evaluated in randomized clinical trials (RCTs) due to ethical concerns, logistical challenges, and time frame constraints[13]. RCTs can be limited by difficulties with enrolling adequate numbers of patients at a single center, particularly in a specialty field such as orthopaedics. Registry data are often superior to administrative claims data, which are not prospectively collected for research and are prone to coding errors. Absence of detailed clinical information in claims data precludes rigorous risk adjustment and limits definitive conclusions, both of which are critical to ensuring appropriate interpretation of outcomes. CDRs, however, are capable of demonstrating the performance of a clinical intervention under variable conditions, translating into greater generalizability. For example, orthopaedic registries implemented by the Kaiser Permanente health system provide meaningful, actionable information to clinicians and administrators regarding clinical best practices, device performance, at-risk populations, and practice variation among providers and centers[14].

Participation in CDRs allows for surgeon benchmarking, enabling peer comparisons of clinical performance including utilization of health-care services, indications for surgery, and patient outcomes[15]. Benchmarking will be increasingly important for individual physicians to understand their performance and opportunities for improvement; CMS is already publishing physician-specific quality data on the Physician Compare web site[16]. Widespread participation in CDRs will contribute to the development of appropriate and realistic expectations of care delivery, providing a critically important context as payers move toward public reporting of individual physicians' outcomes.

CDRs are not without limitations. They are expensive to establish, requiring an information technology infrastructure as well as administrative staffing. Data quality control necessitates substantial effort because there are many more participating physicians and hospitals than those in RCTs. Ensuring that participants are submitting all cases is difficult; thus, a CDR may not represent a true consecutive series, and selection and reporting bias may still be present.

Current Use of Registries by Orthopaedic Surgeons

Current European efforts are focusing on improving data integration among national registries. The Nordic Arthroplasty Register Association was created in 2007 by Norway, Sweden, Denmark, and Finland[17], and the larger European Arthroplasty Register has a membership of twenty-five registries in twenty-one countries[18]. Analyses of European registry data have resulted in marked reductions in revision rates and substantial national health-care cost savings[9,19]. The Swedish joint registry alone has created an estimated $140 million in savings over ten years in a population one-thirtieth the size of the U.S.[19].

In the U.S., Kaiser Permanente started the first multicenter orthopaedic registry in 2001 (Tables I and II). More than 192,000 patients are now included, encompassing arthroplasty, hip fractures, anterior cruciate ligament (ACL) reconstructions, and spine procedures[20,21]. Recently, Kaiser Permanente has begun collaborating with the Norwegian arthroplasty registry, serving as a model for inter-registry cooperation[22].

State-based arthroplasty registries have been started in California, Michigan, and Virginia[23,24]. The California Joint Replacement Registry (CJRR) was initiated in 2010, and has focused on measuring PROs. As of 2015, forty-seven hospitals participated in the CJRR, representing 39% of arthroplasty procedures in the state[25]. The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) was started in 2011 by Blue Cross Blue Shield of Michigan and the Blue Care Network to reduce complications and revision rates for arthroplasty procedures in the state. Currently, MARCQI includes fifty hospitals and has captured data on more than 73,000 arthroplasty cases[23,26].

The American Joint Replacement Registry (AJRR) is the first nationwide orthopaedic registry effort in the U.S. The AJRR was founded in 2011, and as of 2015 it included more than 500 participating hospitals in forty-eight states, with the goal of enrolling 90% of all U.S. hospitals performing arthroplasty[27]. More than 250,000 procedures have been captured thus far; in 2015, the CJRR was absorbed into the AJRR, with the goal of translating CJRR's expertise in PROs to AJRR participants throughout the country[28,29]. The AJRR is a nonprofit collaboration among orthopaedic professional associations, insurers, and implant manufacturers. In addition to patient demographics and data on implant type, the AJRR is working to expand data collection to capture complications, PROs, and PQRS measures[30].

In 2010, funding from the Agency for Healthcare Research and Quality enabled the creation of another U.S. national joint registry, the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR). Data are gathered from more than 150 surgeons across different practice settings (community practices and high-volume academic centers) in twenty-three U.S. states[31,32]. FORCE-TJR aims to enroll 33,000 patients, accumulating PROs and complication and implant data[10,31]. This represents an important pilot effort to establish methodologies for capturing data on a larger portion of the

TABLE I Orthopaedic-Related Clinical Data Registries in the U.S.*

Registry	Year Founded	Geographic Inclusion	Procedures Captured	Integration with Other Registries?	2015 PQRS-Qualified Registry[59]?	2015 QCDR[47]?
Kaiser Permanente[21,22]	2001	California, Hawaii, Northwest, Colorado, Ohio, Georgia, Mid-Atlantic	THA, TKA, TSA, ACLR, hip fracture, spine	Collaboration w/ Norwegian arthroplasty registry	N	N
AJRR[29]	2011	Nationwide	THA, TKA	AJRR has absorbed CJRR; collaboration w/ other U.S. and international registries in planning stages	N	Y
FORCE-TJR[32]	2010	22 states	THA, TKA		N	Y
CJRR[25,28]	2010	California	THA, TKA	CJRR integrated into AJRR in 2015; cooperation w/ Kaiser and FORCE-TJR	N	N
MARCQI[23,26]	2011	Michigan	THA, TKA	Some participants also submit Level I data to AJRR	N	N
Virginia Joint Registry[24]	2005	Virginia	THA, TKA	Collaboration w/ AJRR in discussion	N	N
N^2QOD[44-46]	2012	Nationwide	Cervical, lumbar, scoliosis spine cases		N	Y
ACS SSR[40,41]	2005	Nationwide	Non-specific; perioperative measures		Y	Y

* PQRS = Physician Quality Reporting System, QCDR = Qualified Clinical Data Registry, THA = total hip arthroplasty, TKA = total knee arthroplasty, TSA = total shoulder arthroplasty, ACLR = anterior cruciate ligament reconstruction, AJRR = American Joint Replacement Registry, CJRR = California Joint Replacement Registry, FORCE-TJR = Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement, MARCQI = Michigan Arthroplasty Registry Collaborative Quality Initiative, N^2QOD = National Neurosurgery Quality and Outcomes Database, NASS PSI = North American Spine Society Patient Satisfaction Index, and ACS SSR = American College of Surgeons Surgeon Specific Registry.

estimated 1.5 million arthroplasty procedures currently performed annually in the U.S[33].

In an effort to better integrate CDRs and expand their analytic power, the U.S. Food and Drug Administration initiated the International Consortium of Orthopaedic Registries in 2010. Current membership exceeds forty registries, spanning North America, Europe, Africa, and Australia and New Zealand. Research efforts include creating a universal total joint database, with a focus on comparing arthroplasty bearings. In total, member registries have data on more than 3.5 million arthroplasty procedures, encompassing essentially all currently available implants[34].

Current Use of Registries by Other Surgical Specialists

Other surgical specialists are successfully using CDRs to collect and analyze data on common procedures and patient populations. Challenges, strategies, and best practices learned from these efforts can inform the continued development of orthopaedic CDRs.

American College of Surgeons (ACS)

The ACS operates two registry reporting programs: the National Surgical Quality Improvement Program (NSQIP), which is a hospital-based registry for surgical procedures, and the Surgeon Specific Registry (SSR), which is a case-reporting database for individual surgeons. The NSQIP has helped hospitals achieve notable reductions in surgical morbidity and mortality, as well as cost savings[35-38]. Hospitals are able to voluntarily report NSQIP data on the CMS Hospital Compare web site, but individual surgeon data are not available through NSQIP and thus cannot be submitted to the PQRS[39].

The SSR allows ACS member surgeons as well as nonmember subscribers to report individual surgical case data (Tables I and II). Orthopaedic surgeons who are ACS members can participate; the SSR tracks forty-five perioperative measures—some of which are relevant to orthopaedics. Because the SSR does track individual physicians, registry data can be submitted to the PQRS[40,41]. In addition to satisfying PQRS reporting, the SSR is notable as an easy method for surgeons to benchmark their outcomes and obtain maintenance of certification.

Neuropoint Alliance

The National Neurosurgery Quality and Outcomes Database (N^2QOD) is a U.S. neurosurgical registry initiated in 2012 by the Neuropoint Alliance (NPA), a joint nonprofit organization formed by two neurosurgical professional societies (Tables I and II)[42]. The registry now includes modules for lumbar, cervical, and scoliosis surgeries; more than 17,000 spine cases from more than sixty-five hospitals have already been submitted[43-46]. N^2QOD will establish risk-adjusted benchmarks, report procedure-related costs, and facilitate comparative effectiveness research. Surgeons can use N^2QOD to report individual data to CMS for PQRS requirements[47].

TABLE II Data Collected by Orthopaedic-Related Clinical Data Registries in the U.S.*

	Data Collected							
	Level I		Level II		Level III			
Registry	Patient Demographics	Surgical Data	Patient Risk Factors	Surgical Complications	PROs	Risk-Adjusted Output?	Public Reporting?	Notes
Kaiser Permanente[21,22]	Y	Y	Y	Y	Y (HOOS/ KOOS, PROMIS-10)	Y	N	Public reporting is possibly beginning in late 2015.
AJRR[29]	Y	Y	Y	Y	Y (HOOS/ KOOS, SF-36, HHS, Knee Society, OHS/ OKS)	N	N	Efforts are underway to risk-stratify data, as well as to add VR-12 and PROMIS-10 PRO modules.
FORCE-TJR[32]	Y	Y	Y	Y	Y (HOOS/ KOOS)	Y	N	
CJRR[25,28]	Y	Y	Y	Y	Y (VR-12, HOOS/ KOOS, UCLA)	Y	Y	
MARCQI[23,26]	Y	Y	Y	Y	Y (WOMAC, SF-12, UCLA)	Y	N	MARCQI may apply for 2016 PQRS qualification. There is currently a 3-site trial to collect HOOS/ KOOS and PROMIS-10 PROs.
Virginia Joint Registry[24]	Y	Y	N	N	N	N	N	
N^2QOD[44-46]	Y	Y	Y	Y	Y (pain scores, NDI, EQ-5D, mJOA, NASS PSI, ODI)	Y	N	
ACS SSR[40,41]	Y	Y	Y	Y	N	Y	N	The PQRS-qualified registry option is available via both a measures group and an individual measures format; the latter can be used by orthopaedic surgeons. The QCDR option is only available for general trauma surgeons.

* PQRS = Physician Quality Reporting System, QCDR = Qualified Clinical Data Registry, PRO = patient-reported outcome, HOOS/ KOOS = Hip disability and Osteoarthritis Outcome Score/ Knee injury and Osteoarthritis Outcome Score, PROMIS-10 = Patient Reported Outcomes Measurement Information System 10-item survey, AJRR = American Joint Replacement Registry, CJRR = California Joint Replacement Registry, SF-36 = Short Form 36-item survey, HHS = Harris hip score, OHS/ OKS = Oxford Hip Score/ Oxford Knee Score, VR-12 = Veterans RAND 12-item survey, FORCE-TJR = Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement, UCLA = University of California Los Angeles activity score, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index, SF-12 = Short Form 12-item survey, MARCQI = Michigan Arthroplasty Registry Collaborative Quality Initiative, N^2QOD = National Neurosurgery Quality and Outcomes Database, NDI = Neck Disability Index, EQ-5D = EuroQol 5D survey, mJOA = modified Japanese Orthopaedic Association myelopathy score, NASS PSI = North American Spine Society Patient Satisfaction Index, ODI = Oswestry Disability Index, and ACS SSR = American College of Surgeons Surgeon Specific Registry.

Society of Thoracic Surgeons (STS)

The STS National Database was developed in 1989 in response to public reporting of U.S. hospital cardiac surgery mortality data with inadequate risk adjustment[48]. The STS's cardiothoracic surgery database houses more than 5 million surgical records, representing over 4000 surgeons at approximately 95% of all cardiac centers[49]. The STS database has had a profound impact on quality reporting in thoracic surgery, resulting in more than 100 peer-reviewed publications. Recently, the STS partnered with Consumer Reports to rate institutions performing cardiothoracic surgeries using risk-adjusted outcomes as documented in the database[50]. The STS experience has demonstrated that a surgical registry can achieve near-universal surgeon participation and drive care quality to the extent that collaborations with mainstream media are sought to highlight success. However, it must be recognized that this registry reports process measures such as pump times, blood component utilization, and mortality, which are somewhat easier to collect and report than patient-oriented outcomes data.

American Academy of Ophthalmology (AAO)

The AAO's Intelligent Research in Sight (IRIS) Registry integrates data acquisition with existing electronic health record (EHR) systems, allowing participants to satisfy PQRS reporting requirements through their EHR systems. One of the strongest

TABLE III Summary of Current PQRS Reporting Options for Orthopaedic Surgeons[55,56]*

Individual Providers	Group Practices
Medicare Part B claims	Web interface†
EHR data via direct submission	EHR data via direct submission
EHR data via data submission vendor	EHR data via data submission vendor
PQRS-qualified registry	PQRS-qualified registry
QCDR	CAHPS via CMS survey vendor†

* EHR = electronic health record, QCDR = qualified clinical data registry, and CAHPS = Consumer Assessment of Healthcare Providers and Systems. PQRS relates only to Medicare patients. †Only for groups of ‡25 providers.

attributes of the registry is its ability to provide practitioners with real-time benchmarking metrics, such as the frequency of examination result notifications to primary care doctors and the rates of return to surgery for patients following cataract surgery[51]. The IRIS registry is notable for its efforts to integrate existing EHR systems, its focus on self-assessment, and its adaptability to multiple practice settings.

Registries and Pay-for-Performance

Payers are beginning to base reimbursements partly on registry participation. CMS's PQRS is the largest quality-reporting program in the U.S.; although the PQRS only involves Medicare patients, it will increasingly be a central model for how payers employ registry data to evaluate and reimburse health-care services. Established in 2006, the PQRS is a pay-for-performance program that seeks to reward value of care. Failure to participate in the PQRS results in a 1.5% penalty on Medicare Part B claims for 2015 and a 2% penalty for 2016[52].

CMS has incrementally expanded the breadth of approved reporting measures, with 382 individual measures and twenty-five groups of measures available in 2014, including some relevant to orthopaedics (see Appendix). Specialty societies have successfully worked with CMS to add additional measures relevant to their practice areas. For example, the American Association of Hip and Knee Surgeons (AAHKS) developed the Total Knee Replacement group of measures, and the ACS developed the General Surgery group of measures, both of which were new in 2014[53]. CMS has acknowledged that the majority of individual measures used during the early PQRS program years were process-based measures, and it is working with medical specialty societies to develop, implement, and encourage a transition to outcomes-based reporting measures. In particular, CMS is emphasizing PROs as components of registries and alternative payment models to drive improvements in health-care value.

Expansion of available reporting measures has come with increased reporting requirements. CMS is attempting to encourage use of the EHR and registry mechanisms rather than claims-based reporting, as evidenced by the removal of a claims-based reporting option for many individual measures and for any type of measures group[54]. Table III summarizes physician PQRS reporting options[55,56]. Two of these pathways involve CDRs: PQRS-qualified registries and qualified clinical data registries (QCDRs). Because both the nomenclature and structure of these two reporting pathways are similar, an explanation of the key differences is merited to help U.S. physicians best decide on how to combine registry participation with PQRS compliance. Of note, per current CMS rules, both individual physicians and group practices can report via PQRS-qualified registries, whereas only individuals can report via QCDRs.

PQRS-Qualified Registries

In 2008, CMS first approved PQRS reporting via approved registries, expanding this to group practice reporting in 2013. At a minimum, a PQRS-qualified registry must collect nine individual PQRS measures spanning three National Quality Strategy (NQS) domains[57] (see Appendix) or at least one measures group and must have at least twenty-five participating physicians. Registries seeking CMS approval to submit PQRS measures on behalf of subscribers must complete an extensive application process detailed on the CMS web site, including demonstration of a validation strategy to audit the accuracy of submitted data from providers[58].

Table I summarizes approved PQRS-qualified registries applicable to orthopaedic surgeons[59]. One advantage of PQRS-qualified registries is that physicians who were already reporting to these registries can satisfy PQRS reporting without duplicating their reporting. Also, the registries have some flexibility to select PQRS measures relevant to their subscribing physicians. However, participating registries are still restricted to using only existing PQRS-approved measures, many of which may not be relevant to the specific field of medicine the registry represents.

Qualified Clinical Data Registries

Beginning in 2014, CMS established QCDRs as a second registry-based PQRS reporting mechanism. The primary difference between PQRS-qualified registries and QCDRs is that non-PQRS measures can be reported in QCDRs while still satisfying requirements for PQRS participation. Introduction of QCDRs is intended to encourage participation in specialty-driven, patient-oriented registries, allowing participating physicians to avoid the burden of otherwise-redundant data reporting to meet PQRS requirements. CMS has stated that a QCDR should "serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data"[60], anticipating that participation by medical specialty societies in QCDR development will accelerate the shift within PQRS from collecting process measures to PROs.

QCDRs have the flexibility to determine which nine quality measures are reported for its participants. The measures must span three NQS domains, and at least two of the measures must be outcomes-based (as opposed to process-based)[60]. Although the QCDR can report PQRS measures if desired, the following options are also available: Consumer Assessment of Healthcare Providers and Systems Clinician & Group (CG-CAHPS) survey scores, National Quality Foundation (NQF)-endorsed measures, measures used by American Board of Medical Specialties (ABMS) certifying boards or specialty societies, and measures

used in regional quality collaborations[61]. This initial battery of accepted measures represents progress and a willingness by CMS to allow medical societies a greater role in determining what data are important to achieve real gains in quality. Several medical societies, including the American Academy of Orthopaedic Surgeons (AAOS), have called for even greater flexibility and an initial requirement of only three reported measures[62,63]. Existing QCDRs relevant to orthopaedics are summarized in Table I[47].

QCDRs must meet several additional criteria: inclusion of data from multiple payers, capacity to benchmark providers in relation to their peers, provision of quarterly feedback to providers on the quality measures collected, and risk-adjustment of the quality measures data submitted to CMS[60]. Like PQRS-qualified registries, QCDRs are required to submit patient-specific data to CMS on behalf of the provider, which may be an obstacle to participation for some surgeons and health systems because of data security concerns.

Opportunities for Orthopaedic Surgeon Participation in Registries: Current and Future

CDRs are rapidly becoming an intersection point for several major health policy initiatives in the U.S.: (1) an emphasis on tracking health outcomes via increased reporting requirements for physicians and hospitals, (2) a focus by payers on increasing value in healthcare by increasing quality and lowering cost, and (3) restructuring of reimbursement for physicians and hospitals to incentivize improving value.

In the current environment, CMS and private payers are willing to accept physician input regarding registries. By designing and participating in CDRs, physicians can exert substantial influence in these key policy arenas and help achieve real improvements in care value. With a long history of registry use, orthopaedic surgeons are well-positioned to continue as leaders in these efforts. In order to do so, however, several key action steps are needed.

Orthopaedic CDRs need to continue moving toward a patient-centered focus by including PROs. Table II summarizes which U.S. orthopaedic registries currently track PROs; currently, there is little alignment of which PROs are tracked. As registry development continues, selecting the most useful PROs and then integrating these into CDRs is essential to achieving significant gains in care value. The National Institutes of Health (NIH) created the Patient Reported Outcomes Measurement Information System (PROMIS) to facilitate this transition across medicine, and orthopaedic surgeons are increasingly using and adapting PROMIS[64-66].

In addition, collaboration between the AAOS and orthopaedic subspecialty societies is essential to expand CDR participation. Substantial investment of time and resources will be needed to integrate the input of physicians and policy experts. Although most current orthopaedic registries center on arthroplasty, other common orthopaedic procedures, such as ACL reconstruction and rotator cuff repair, are amenable to registry recording. Moreover, collaboration with CDRs such as the ACS SSR and the N^2QOD may allow more orthopaedic surgeons to participate in registry-based PQRS reporting by capitalizing on the infrastructure that these registries have already established.

In conclusion, orthopaedic surgeons are increasingly using registries to improve quality through research, benchmarking, and rapid recognition of surgical innovation effectiveness. Registries are influential tools for orthopaedic surgeons to answer the public mandate to improve the value of care in this era of health-care reform.

Appendix

eA Tables showing relevant items from the 2015 PQRS measures list and the National Quality Strategy domains are available with the online version of this article as a data supplement at jbjs.org. n

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