National joint registry in the US makes progress, but faces obstacles in execution

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Although many regional and institutional joint arthroplasty registries exist, many look to the development of a national joint registry in the United States to improve patient care and identify early device warnings and adverse events in real-time. However, debate on the formation of a national total joint registry continues concerning data collection, funding sources, safeguards to protect patient privacy and methods to avoid potential litigation.

Efforts to create a U.S. national joint registry have grown with the progress of the American Joint Replacement Registry (AJRR), which currently collects data from over a dozen hospitals and has that same number poised to submit data in the next few weeks. Another 80 hospitals and health care systems are working with AJRR and have the required paperwork under review or in process, AJRR Chair David G. Lewallen, MD, told Orthopedics Today.

The organization seeks to address the need for basic level 1 data analysis of hip and knee devices by benchmarking the Swedish knee and hip registries' technique of reporting level 1 data first, and then progressing to level 2 or 3 data in the future.

“There are over 3 decades of experience with national registries,” Lewallen, of the Mayo Clinic and Mayo Foundation in Rochester, Minn., said. “They began in Sweden, spread across Scandinavia and have cropped up around the rest of the world with over 20 national registries now. The advantages they provide are contemporary information about the experience with total joint arthroplasty in a broad population of patients as performed by a variety of surgeons in a variety of practice situations in a diverse range of hospitals.”

Henrik Malchau, MD, PhD, of Massachusetts General Hospital, highlighted the benefit of groups such as the International Consortium of Arthroplasty Registries (ICOR) and the International Society of Arthroplasty Registries, which share the goal of pooling national registry data for surveillance of existing and new implants.

“It is a world movement now with registries,” Malchau said.

ICOR met with the FDA last year to discuss reports of adverse events related to metal-on-metal hip replacements, he said.

“The FDA could not, based on their post-market surveillance, tell [us] anything about what happened in the United States,” Malchau told Orthopedics Today.

Regional and institutional registries

Current regional registries from Michigan, Virginia and California plan to contribute information to the AJRR and some of the largest institutional registries, such as those at Mayo Clinic, Kaiser Permanente, Stanford University and the Harris Joint Registry at Harvard Medical School, will follow suit, according to Thomas C. Barber, MD, American Academy of Orthopedic Surgeons (AAOS) representative to the AJRR.

“Right now, a lot of information is reported for billing purposes about the patient, the doctor and the hospital, but there is not information about the bar code for the [polyethylene] PE liner for the socket and that may be important in survivorship of
an implant; we need that information," Lewallen said. “Some of the level 1 information is going to be harder to get.”

“That is why the question comes up, ‘Why would you need the regional registry when you have the national registry?’” John J. Callaghan, MD, a former AJRR committee member, told Orthopedics Today. “There are a lot of differences in geographic practice [and it is] probably more applicable to compare people in your region than a more global or national scale. In addition, due to the smaller size of these registries, more data (including outcome data) can be collected.”

AJRR Vice Chair William J. Maloney, MD, also noted the limitations of institutional and regional registries.

“Institutional registries are not really registries, as they are research databases, so they were never meant to function in real time,” he told Orthopedics Today. “They gather data, but people do not analyze it continuously. Someone will develop a hypothesis and then go to the institutional research database to answer that question.”

**A massive undertaking**

The AJRR will gather data including the patient identifier number, date of birth, age at surgery, diagnosis, hospital, surgeon and implant type, to simplify data collection and allow for an early detection system for any adverse risks of hip or knee implants, according to Maloney. The problem with a national registry, Lewallen noted, is the massive undertaking that requires participation from the 5,000 hospitals that perform total joint arthroplasty in the United States.

“Think of the initial top level information as a trip wire or a smoke alarm,” Lewallen said. “It is something to raise an alert to performance that does not fit with that observed with other implants, institutions, surgeons or other groups. For example, if there is a particular device that is being used across the country that looks like, from the survivorship curve perspective, it is performing well and fits in with the average of all similar devices, that is great. But if we look at the data and subdivide it by gender and by age, and we find out that the failure rate for males who are 50 years and younger is five times higher than the failure rates of similar devices in that same subset of patients. We do not know why that is, but we can start asking interesting questions and we can delve into it further.”

“We do not have the resources to look in to every patient subset, every patient group and every way you can parse the data,” Lewallen continued. “But, what we can do is survey the information and subdivide the overall survivorship curves so we know where the most interesting sort of observations are occurring, either devices that are vastly outperforming their competition or those that are not.”

**Garnering participation**

However, some have questioned whether a U.S. joint registry with thousands of participants can achieve compliance without government regulation when compared to smaller countries like Sweden that have 80 hospitals.

“We have a much more fragmented health care system,” Lewallen said. “There are a wide range of payers, hospitals, groups, networks, surgeons and others involved in health care in this country. [It is] different from a single payer system as for example Norway, where everybody understands who you talk to, because there is one national health care system. It also simplifies tracking patients when everyone is in the same program, and everybody gets a number and that number is the same throughout their lives.”

Augusto Sarmiento, MD, of the University of Miami School of Medicine, added, “The current system is alleged to have been beneficial to the respective countries. This could probably be explained by their smaller size when compared to that of the United States, where a laissez faire, non-socialized system currently exists. The Scandinavian countries are highly disciplined nations where compliance is readily obtained, making possible the inclusion of every hospital and surgeon in the project.”
Currently, Scandinavian countries do not require that hospitals participate in registries, but they do have mandates that surgeons cannot take patients or get reimbursed through the public health care system if they do not participate in Sweden’s national registry, Malchau said.

“That is one way to move it in United States too. Medicare says fine you will get reimbursed Medicare rates if you report, otherwise deductions of 2% to 4% and that is a significant reduction in reimbursement,” he said.

**Incentives, government involvement**

The AJRR, however, is not federally regulated.

“Our idea in the United States is that we would rather have our profession and Academy do this in the volunteer way,” Callaghan said. “The idea is we would rather have carrots than sticks. The stick is that if the government did this, and they could, it would be a whole lot different and much more onerous.”

Participation in the AJRR does not currently affect surgeon payment, but the AJRR plans to implement surgeon incentives for participation in the future, according to Lewallen and Barber. It may require health care information technology professionals to report to the AJRR as a part of meaningful use criteria for level 2 and 3 data, for which hospitals may receive reimbursement from Medicare if they qualify under meaningful use, Barber said.

Another way to garner participation is by inspiring surgeons to improve their performance, Callaghan said.

“If the surgeon is not good enough, he takes remedial training,” he said. “Or he or she stops doing joint replacements because the results are not as good. You can self-regulate with good data from registries.”

Lewallen hopes the registry data will help improve patient outcomes and, in turn, lower costs.

“By improving patient care, the payer in question ends up spending less over the long term because they are on the hook for the complications,” Lewallen said. “They obviously have an incentive for reducing them.”

The aim to improve patient care while reducing costs is aligned with federal initiatives such as the Patient Protection and Affordable Care Act (PPACA’s) initiatives.

“With the new PPACA and the new trend toward trying to cut cost and keep up quality, registries seem like a no brainer,” Callaghan said. “One way of showing value to our procedures is to have data from AJRR showing the revision burden is reduced and relatively low, and we were working on it to improve quality, which is the whole point of PPACA. There are at least 30 or 40 areas talking about quality improvement.”

“We have run some of the calculations, and simply for the Medicare population, there are tens to hundreds of millions of dollars to be saved annually by [the Centers for Medicare & Medicaid Services] CMS by reducing the revision burden here in the United States,” Lewallen said. “If we just move the bar down a little bit in terms of the percentage of revisions occurring each year, it has a huge economic benefit to our health care system. There is a good argument to be made that payers stand to benefit from such a system if it is able to provide trusted data back to surgeons, hospitals and manufacturers, such that they alter their behavior and improve the care provided to patients when they see that their performance is not optimal.”

A. Seth Greenwald, DPhil (Oxon), noted that registry data and government interpretation could be “a double-edged sword.”

“I am sure that CMS will be guided by the results of what they see from registry data,” he told *Orthopedics Today*. “If they have a system that has terrible results with lots of revisions, that is the system they are going to look at carefully.”
To counter this, the registry would need to drill down information to account for surgeon proficiency, patient selection and implant design — all variables that influence outcomes, he said.

**Funding of a national registry**

Many worry industry-backed funding of a national joint registry would lead to data reporting that is biased toward specific devices and, therefore, resulting in erroneous data. In the established national registries in the United Kingdom are funded by industries with tariffs on implants, according to Maloney.

“Our current position at the head table will further increase their control to unimaginable degrees,” Sarmiento explained. “They will, probably from the outset, finance the needs of some or all the participating surgeons and, in that manner, kill once and for all any dreams of true evidence-based orthopedics.”

To address these concerns, the AJRR adopted a multi-stakeholder structure receiving financial support from industries, orthopedists, orthopedic societies such as the AAOS and the American Association of Hip and Knee Surgeons, and private payers such as WellPoint, United and Blue Cross Blue Shield, Lewallen said. Every stakeholder has a seat at the table during deliberations and data analysis.

The multiple stakeholders serve as “checks and balances” to the system because all of the “people on board will be able to see the data and make sure it is not misinterpreted,” Callaghan said.

**Liability, data collection**

Another concern with starting a national registry in the United States centers on collecting data without violating patient privacy laws such as the Health Insurance Portability and Accountability Act (HIPAA).

“Many facilities in the United States have some concerns legally about sharing the patient identifiable information with a registry entity,” Barber said. “Even though there can be legal protections, it is not clear from the federal laws what can be shared. In order for a total joint registry to work, you have to share information about a patient that is specific to that patient such as an identifier, which might be the social security number, which is covered under HIPAA, because you want to be able to track it over time. If something fails down the road, you have to have some way of identifying that patient.”

Liability also poses a barrier to hospital participation in the AJRR because the organizations must meet with lawyers to discuss the business service agreement with hospitals.

“As we approach hospitals about reporting, they all see the value in this. The surgeons are enthusiastic,” Lewallen said. “We get agreement from decision makers that they wish to participate. Then the discussions occur with the legal department and the [information technology] IT security people at those hospitals. That is where things bog down.”

Randolph Meinzer, BS, CS/EE, information technology director at AJRR, told *Orthopedics Today* that the data collection for the registry is HIPAA-compliant.

“It is secure and each user needs to be authenticated,” Meinzer told *Orthopedics Today*. 
In addition, he said, hospitals — not surgeons — will submit the data. Hospitals with existing electronic medical records can extract the existing information from their medical IT systems into one large file, which they then upload to a secure file transfer protocol (FTP) site. The AJRR then downloads the data to its database.

“The AJRR is working with each site to ensure that we can conduct the batch download because we believe it is more efficient in the long run if people are not re-entering information that already exists in patients’ files,” Meinzer said.

Next steps

The AJRR is working with more than 200 hospitals to incorporate their data into its national registry and has 80 hospitals and health care systems working to complete the enrollment process, Lewallen said. They have 13 hospitals already submitting data, and another 12 with signed business agreements and other paperwork complete, but AJRR has not yet received data from these institutions as they work through the finer details of data transfer.

“It takes work, effort and some time, but we are working hard to try to achieve our 5-year goal of 90% penetrance within the United States in the 5,000 hospitals that do arthroplasty,” Lewallen said. “That is an aspirational goal, but we are going to work hard to do it. We have a plan and some metrics, and we are going to work hard to hit those.” – by Renee Blisard

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Disclosures: Barber, Greenwald, Meinzer and Sarmiento have no relevant financial disclosures. Callaghan receives royalties from DePuy for intellectual property for hip and knee implants. Lewallen works for Mayo Clinic and develops implants for Zimmer, OrthoSonic and Medtronic in association with Mayo Clinic. Malchau receives lab support from Zimmer, Biomet, DePuy and Mako, has a consultant agreement with Smith & Nephew and Mako, and owns stock and is a board member in RSA Biomedical for radiographic examinations. Maloney develops hip implants for Zimmer and knee implants for Wright Medical, is the device chairman for AJRR and serves on the board of directors of the Western Orthopaedic Association.

Should patient-reported outcomes be included in a US national joint registry?

POINT

Not a practical route

I do not recommend patient-recorded outcomes for the U.S. national joint registry. From a cost and practicality standpoint, efforts should be made first to obtain level 1 data (patient age, diagnosis, laterality, surgical procedure, implants, surgeon case volume, hospital case volume, complications and re-operations). National registries from other countries have made significant scientific contributions and demonstrated improved patient outcomes and safety, using level 1 data. Level 2 data collection, such as patient body mass index, comorbidities, and detailed surgical and postoperative interventions, may one day be possible, with a network of electronic health records sharing aggregate data behind secure firewalls. The logistics and costs associated with collecting level 3 data, such as patient-reported outcome measures, would be prohibitive on a national scale.

Robert S. Namba
Outcomes are appropriate

Patient-reported outcomes (PROs) convey knowledge of the patient’s health condition, without a third party being allowed to interpret or modify the data. PROs are already being monitored by the Centers for Medicare & Medicaid Services (CMS) and will contribute up to 30% of CMS’ evaluation of quality of care in determining reimbursements for inpatients. Given that our ultimate aim as physicians is to improve our patients’ health and satisfaction, it is entirely appropriate that we measure whether our interventions are successfully matching their health needs.

Design and sensitivity of a PRO instrument in measuring what is truly important is the paramount issue. Health-related quality of life PRO measures commonly used by most orthopedic surgeons are too generic to adequately inform us on whether patient expectations of a specific orthopedic intervention have been met or exceeded. Meaningful information from a PRO instrument will only be obtained if it straddles both patient expectations and information on specific utility of the intervention provided.

It only makes sense that the joint replacement registry develops the capacity to include PROs in its database. Logistical roadblocks to this effort will include the development of a validated outcome instrument specific to the needs and expectations of our joint replacement patients, de-identification of data that is included in the national registry, the ability to longitudinally track patients in this de-identified fashion, software programs that facilitate easy input by our patients and the ability to obtain this information easily without disrupting physician clinic workflows.