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JOINT REGISTRY UPDATE

Joint Replacement Registries in the United States: A New Paradigm

David C. Ayers, MD, and Patricia D. Franklin, MD, MBA, MPH

This commentary serves as an introduction to an upcoming series of articles about orthopaedic registries, in general, with an emphasis on lessons learned from the evolving U.S. and international total joint replacement registries. This paper provides an overview of total joint replacement registries and the current expansion of data collection beyond implant attributes and survival to include postoperative complications and patient-reported outcomes.

Osteoarthritis is the most common cause of physical disability in the U.S.¹ The combination of osteoarthritis prevalence and the success of total joint replacement in relieving pain and improving function in patients with advanced osteoarthritis has resulted in total joint replacement becoming the most common and costly inpatient procedure among Medicare beneficiaries. Moreover, the fastest growing subgroup of patients undergoing total joint replacement consists of those less than sixty-five years of age². More than one million total joint replacements are performed annually in the U.S., making measurement of total joint replacement outcomes a public health priority. To measure and monitor the outcomes of total joint replacement, state and national total joint replacement registries are emerging that incorporate lessons learned from long-standing international implant registries as well as integrate new methods to quantify perioperative quality and patient-reported outcomes.

International total joint replacement registries have traditionally focused on implant revision rates and tracked the length of time between the initial total joint replacement and implant removal. In this model, national registries incorporate large numbers of arthroplasties to identify relatively low annual failure rates and the focus is on device longevity. However, today's total joint replacement registries are broadening their focus to include perioperative complications and patient-reported

outcomes following surgery. While the implant revision rate remains an important outcome, implant materials and technology have matured and patients and insurers want to understand the quality of care of the vast majority of patients who do not have a revision each year. Our health-care system is transforming from a volume-based system to a value-based system. Value is defined as outcome divided by cost. Measurement of patient outcomes after total joint replacement is increasingly emphasized.

The 2010 recall of metal-on-metal hip implants brought total joint replacement into the public eye and reinforced the importance of recording symptoms such as pain and physical limitations over time to assess the success of the surgery³. Early substantial pain in the operatively treated joint was the first sign of metal-on-metal problems. For decades, joint registries only reported implant data and revision rates, so any implant that remained in the patient was considered a "success." However, as was clear with the metal-on-metal situation, patients who have not undergone revision may experience symptoms or complications that must be quantified. In 2013, the Centers for Medicare & Medicaid Services (CMS) began publicly reporting thirty-day hospital readmission rates following total joint replacements. In early 2014, the CMS added ninety-day all-cause complications to the hospital reports on total joint replacements. Finally, the CMS convened a technical expert panel to evaluate the role of patient-reported outcomes in monitoring outcomes of total joint replacement in the U.S. Medicare population⁴.

To meet emerging clinical and policy needs, U.S. total joint replacement registries must expand beyond implant tracking to include postoperative complications and patient-reported pain and function. This same evolution can be observed internationally as the capture and reporting of patient-reported outcomes following total joint replacement has expanded greatly over the

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past decade. The New Zealand joint registry has been reporting patient-reported outcome data since 2002 and the Swedish hip registry, since 2005^{5,6}. The U.K. National Health Service (NHS) began the mandatory collection of patient-reported outcomes in 2009 in an effort to refine the reimbursement system. Patient-reported outcomes were collected after four types of surgical procedures, including knee and hip replacement surgery. The U.K. implant registry first integrated the NHS's patient-reported outcomes into its 2013 annual report⁷.

In the U.S., the Agency for Healthcare Research and Quality awarded a \$12 million competitive program project award to the Department of Orthopedics and Physical Rehabilitation at the University of Massachusetts Medical School in 2010 to build both a total joint replacement registry and a total joint replacement comparative-effectiveness research program^{1,8}. This initiative (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement [FORCE-TJR]) defines patient-reported outcomes as the primary outcome of total joint replacement. In addition to patient-reported outcomes, the FORCE-TJR data include postoperative quality measures (e.g., thirty-day readmissions, ninety-day complications, and surgical site infections) as well as implant outcomes (e.g., revision). All of these measures are important to ensure that U.S. patients receive the best possible surgical and perioperative care and achieve optimal outcomes. FORCE-TJR is a patient-centered total joint replacement registry. Patients choose elective total joint replacement to relieve pain and improve physical function. Using patient-reported outcomes to specifically measure pain and physical function before and after total joint replacement is a logical method of measuring treatment outcomes from the patients' perspective. To date, FORCE-TJR has successfully collected patient-reported outcome surveys before and after total joint replacement to 20,000 patients in diverse orthopaedic practice settings, including low and high-volume and urban and rural settings, and supports the importance of patient-reported outcomes in monitoring total joint replacement outcomes. Ultimately, the FORCE-TJR 30,000-patient cohort will be the largest national group of patients for whom complete patient-reported outcome data before and after total joint replacement will be available. To parallel current U.S. arthroplasty practice, community-based orthopaedic surgeons represent 75% of the cohort and are drawn from twenty-two states. Primary elective total knee and total hip replacements as well as revision surgery with diverse implant materials and designs are included. FORCE-TJR has collected surveys from 96% of the patients scheduled to undergo total joint replacement and patient-reported outcomes from 90% of the patients who have undergone total joint replacement. Thus, FORCE-TJR can serve as the reference cohort with which future hospital and physician outcome data can be compared. Comparative data are returned to participating surgeons through a secure web site allowing practices to compare their outcomes with national norms.

In addition to FORCE-TJR, other U.S. total joint replacement registries have emerged. The American Joint Replacement Registry (AJRR) is an independent, not-for-profit organization currently collecting implant and basic procedural data from

nearly 140 institutions⁹. AJRR is now piloting programs to collect patient-reported outcomes at fifteen sites and postoperative event data collection. Three state-based total joint replacement registries have also been established. The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) is a consortium of Michigan hospitals funded by Blue Cross Blue Shield of Michigan. While MARCQI hospitals focused initially on collecting implant and adverse-event data, a subset of the hospitals collects patient-reported outcomes. To date, patient-reported outcomes have been collected from 20% of patients scheduled to undergo total joint replacement and 10% of those who have undergone the procedure. The California Joint Replacement Registry (CJRR) is a collaborative initiative of the California HealthCare Foundation, Pacific Business Group on Health, and California Orthopaedic Association to collect total joint replacement outcomes performed in California. Twenty-four hospitals that perform about one-quarter of the total joint replacement procedures in California participate. Patient-reported outcomes and adverse-event data have been reported by more than 3000 California patients. This represents approximately 70% of patients scheduled to undergo total joint replacement and 30% of those who have undergone total joint replacement enrolled in this registry¹⁰. Thus, the U.S. total joint replacement registries have addressed the need for broader post-procedure outcome measurement.

The majority of total joint arthroplasties are performed to relieve pain and disability of advanced osteoarthritis when comprehensive medical and rehabilitation treatments have been exhausted. Patient-reported outcomes offer an objective means to quantify the trajectory of pain and function both before and after total joint replacement. In the orthopaedic office, osteoarthritic pathological changes are documented with use of radiographs and physical examination. While these clinical metrics can quantify osteoarthritis-related cartilage loss and bone changes, neither can quantify the patient's experience of pain or the functional impact of the osteoarthritis. This void is critical because the timing and importance of total joint replacement are often dictated by the severity of pain and the extent of disability. To fill this void, patient-reported outcomes can serve as a new "lab test" that will complement the radiographs and physical examination by documenting the patient's symptoms.

Patient-reported outcomes were developed to be validated, standardized measures of outcomes that are meaningful to patients and help surgeons to assess the progression of symptom severity and effectiveness of treatment across time. Patient-reported outcomes are collected directly from patients. Some are generic (global) measures that are used for all patients regardless of their medical conditions. An example of a generic patient-reported outcome is the Short Form-36 (SF-36¹¹), a thirty-six-item health questionnaire that includes a global physical component summary (SF-36 PCS) in which a patient rates how well he/she performs everyday tasks and a global mental component summary (SF-36 MCS) in which a patient reports challenges in emotional health. Of interest, the National Institutes of Health (NIH)-funded Patient Reported Outcomes Measurement Information System (PROMIS) is establishing a generic core set of patient-reported outcomes (item bank) that will ultimately

be available through the Internet and smartphones to reach large numbers of patients in the future. These types of patient-reported outcomes are not specific to a medical condition or treatment and thus allow comparisons across diverse conditions or treatments.

Other patient-reported outcomes are specific to a disease or medical condition and have been validated in specific patient populations. For instance, the proprietary Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)¹² has been validated for patients with osteoarthritis, including those undergoing total hip or total knee replacement. The WOMAC assesses clinical changes (pain, stiffness, and function) over time. The Hip disability and Osteoarthritis Outcome Score (HOOS) and the Knee injury and Osteoarthritis Outcome Score (KOOS) are also used for patients undergoing total hip or knee replacement, and include the WOMAC items plus additional items. The non-proprietary HOOS and KOOS^{13,14} both include subscores for pain, symptoms, activities of daily living, sports/recreation function, and quality of life. In the HOOS/KOOS pain score, for instance, a patient reports how much pain he/she experiences while performing tasks of daily living, and in the HOOS/KOOS activities of daily living score (function), a patient reports how well he/she can perform those tasks. The U.S. FORCE-TJR registry uses the HOOS/KOOS to measure joint-specific symptoms and performance. The Oxford¹⁵ hip or knee score is a proprietary disease-specific patient-reported outcome used in many European total joint replacement registries. It provides a summed score that reflects the severity of pain and function limitations in patients treated with total hip or knee replacement. It does not allow separation of a joint-specific pain score from a physical function summary of the same joint and is not used often in the U.S.

Patient-reported outcomes have been validated in various populations to inform population-based norms in the general population as well as in patients with a specific disorder or medical condition. Condition-specific norms for patients before and after surgery are helpful for assessing the timing and outcomes of the procedures. For example, because FORCE-TJR has a large national sample of patient-reported outcomes, risk-adjusted preoperative and postoperative norms can be used by surgeons to compare his/her patient populations.

In conclusion, total joint replacement registries are emerging as important surveillance tools with which to assess both short-term postoperative events and long-term pain relief, functional gain, and revision rates. Over time, this series of reports will review critical issues related to the use of registry data, including representative data capture in clinical practice, risk-adjusted data analysis, and reporting to inform surgeon and patient clinical decisions. Total joint replacement registries are rapidly evolving to serve both clinical and public-health information needs and offer important templates to inform orthopaedic registries across subspecialties. ■

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