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Implementation of Patient-Reported Outcome Measures in U.S. Total Joint Replacement Registries: Rationale, Status, and Plans

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Investigation performed at the University of Massachusetts Medical School, Worcester, Massachusetts, Mayo Clinic, Rochester, Minnesota, University of California, San Francisco, San Francisco, California, University of Michigan, Ann Arbor, Ann Arbor, Michigan, and Virginia Commonwealth University, Richmond, Virginia

Background: In the U.S. and abroad, the use of patient-reported outcome measures to evaluate the impact of total joint replacement surgery on patient quality of life is increasingly common. Analyses of patient-reported outcomes have documented substantial pain relief and functional gain among the vast majority of patients managed with total joint replacement. In addition, postoperative patient-reported outcomes are useful to identify persistent pain and suboptimal outcomes in the minority of patients who have them. The leaders of five U.S. total joint replacement registries report the rationale, current status, and vision for the use of patient-reported outcome measures in U.S. total joint replacement registries.

Methods: Surgeon leaders of the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement registry, American Joint Replacement Registry, California Joint Replacement Registry, Michigan Arthroplasty Registry Collaborative Quality Initiative, and Virginia Joint Registry report the rationale supporting the adoption of patient-reported outcome measures, factors associated with the selection and successful implementation of patient-reported outcome measures, and barriers to complete and valid data.

Results: U.S. registries are at varied stages of implementation of preoperative surveys and postoperative total joint replacement outcome measures. Surgeon leaders report unified rationales for adopting patient-reported outcome measures: to capture data on pain relief and functional gain following total joint replacement as well as to identify suboptimal implant performance. Key considerations in the selection of a patient-reported outcome measure include its ability to measure both joint pain and physical function while limiting any burden on patients and surgeons related to its use. Complete patient-reported outcomes data will be associated with varied modes of survey completion, including options for home-based completion, to ensure consistent timing and data capture.

Conclusions: The current stage of implementation of patient-reported outcome measures varies widely among U.S. registries. Nonetheless, evidence from the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement registry supports the feasibility of successful implementation of patient-reported outcome measures with careful attention to the selection of the outcome measure, mode and timing of postoperative administration, and minimization of any burden on the patient and surgeon.

Patient-reported outcome measures (PROs) are validated surveys that assess health and health limitations, including pain, physical function, and quality of life. Global PROs assess general health status, including physical health, emotional

health, and general vitality¹. The results of total joint replacement research indicate that, on average, patients undergoing total joint replacement surgery achieve overall significant improvement in global health status during the first six to twelve months following

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surgery^{2,4}. In addition, total joint replacement research commonly evaluates joint-specific PROs or patient-reported surveys that assess symptoms such as pain, stiffness, and limitations in physical activity related to a knee or hip pathology. Research findings on these joint-specific measures also document pain relief and improved physical function in the immediate period following total joint replacement^{3,4}.

The use of PROs by total joint registries and policy makers extends beyond for research purposes. International arthroplasty registries use PROs today in the surveillance of suboptimal total joint replacement outcomes, payment refinement, and assessment of patient-reported total joint replacement value^{4,5}. For example, reports from both the New Zealand Joint Registry and the National Joint Registry for England and Wales indicate that considerable, persistent pain at six months following total joint replacement surgery is associated with subsequent implant failure and revision^{6,7}. In addition, in the United Kingdom PROs are administered across four surgical procedures (hip replacement, knee replacement, surgery for varicose veins, and surgery for inguinal hernias) to assess the relative value of each procedure, and there are plans to link reimbursement to PROs^{8,9}. In the U.S., the Centers for Medicare & Medicaid Services are exploring the potential value and implementation of PROs in total joint replacement¹⁰. Finally, real-time patient-reported survey collection and review can support shared decision-making between the surgeon and patient before a total joint replacement procedure¹¹.

Because of the emerging importance of PROs in assessing total joint replacement outcomes, we report the status of PRO implementation as well as perceived barriers and facilitators of PRO use among five U.S. registries.

Current PRO Use in U.S. Registries

For this report, U.S. registries are defined as independent entities not associated with a single hospital, delivery system, or health insurer that collect data to assess the safety and outcomes of total joint replacement procedures. Surgeon leaders from the five U.S. registries that meet this definition participated. The contributors to this report include surgeon leaders from FORCE-TJR (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement), American Joint Replacement Registry, Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI), California Joint Replacement Registry, and Virginia Joint Registry.

The current status of PRO use is briefly summarized below for each of these registries.

FORCE-TJR

The Agency for Healthcare Research and Quality awarded a \$12 million grant in 2010 to the Department of Orthopedics and Physical Rehabilitation at the University of Massachusetts Medical School to establish the FORCE-TJR registry. FORCE-TJR is enrolling a national cohort of more than 30,000 total joint replacement patients from over 130 orthopaedic surgeons, representing all regions of the U.S. and varied hospital and surgeon practice settings (urban, rural, low volume, and high volume)¹². Consistent with 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 PROs from 90% of the patients who have undergone total joint replacement. Registry staff contact patients as needed to ensure submission of complete data. Both the Short Form-36 (SF-36) and the Hip disability and Osteoarthritis Outcome Score (HOOS) or the Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire are collected at each time point. In addition to PROs (level-III data), data on adverse events (level II) and implants (level I) are collected on all patients, and radiographic (level-IV) data are collected on a subset of patients. Data capture via direct-to-patient surveys is supported by web-based and scannable paper options. In addition, longitudinal adverse event tracking captures events at all hospital or office visits, and it is not limited to the hospital where the surgery was performed. FORCE-TJR provides risk-adjusted, actionable comparative outcome reports to all of its participating surgeons through a secure surgeon web portal that can be aggregated to hospital, insurance plan, procedure, or implant manufacturer-level data¹³.

American Joint Replacement Registry

The American Joint Replacement Registry is a multi-stakeholder, independent, not-for-profit organization. Its goal is “to foster a national center for data collection and research on total hip and knee replacement with far-reaching benefits to society including reduced morbidity and mortality, improved patient safety, improved quality of care and medical decision-making, reduced medical spending, and advances in orthopaedic science and bioengineering”¹⁴. Currently, 249 hospitals have agreed to participate in the initiative. Nearly 140 of these participating institutions submit implant and basic procedural (level-I) data on primary and revision total joint replacement procedures, and the remaining hospitals are in the onboarding process (C. Etkin [Director of Research, American Joint Replacement Registry], personal communication, February 24, 2014). Initially, the American Joint Replacement Registry is gathering patient-identification, basic procedural, and implant (level-I) data from hospitals, but the registry will soon expand to include options for submitting adverse event (level-II) and PRO (level-III) data¹⁴. A pilot program of PRO collection and submission began in November 2013 with fifteen participating sites. Hospital staffs document procedures in their electronic medical record system and submit results through the American Joint Replacement Registry’s secure online portal. The American Joint Replacement Registry staff will compile data into an aggregate format for reports individualized by hospital, surgeon, procedure, implant, manufacturer, or other criteria.

MARCQI

Founded in 2010, MARCQI is a consortium of Michigan hospitals that is funded through the Blue Cross Blue Shield of Michigan and the Blue Care Network Value Partnerships

program. MARCQI will be used to address variations in patient outcomes related to hip and knee joint replacement surgery in the state of Michigan. The MARCQI consortium consists of the Coordinating Center at the University of Michigan, Ann Arbor; the Data Management Center at St. Joseph Mercy Ann Arbor Hospital; and a network of forty-four participating hospitals in Michigan. MARCQI's goals include improving patient safety and the quality of hip and knee joint replacement procedures performed in Michigan by promoting continuous quality-improvement activities. The registry will be used to report results and identify devices and techniques associated with inferior outcomes through the analysis of its data, with the aim of improving the value of arthroplasty services at MARCQI institutions¹⁵. While MARCQI hospitals focused initially on collecting implant data (level I) and reporting adverse events (level II), a subset of the hospitals are collecting PROs (level III). MARCQI has collected 2200 PROs from 20% of all pre-total joint replacement patients and 10% of the postoperative patients in the registry. PROs can be collected at postoperative visits, or they can be submitted by patients through a web portal to the database after they receive e-mail reminders. Staff from member hospitals report difficulty in collecting PROs from patients postoperatively for multiple reasons, including varying settings for postoperative follow-up, differing levels of surgeon involvement, and limited use of e-mail and the Internet by arthroplasty patients.

California Joint Replacement Registry

The California Joint Replacement Registry is a collaborative initiative of the California HealthCare Foundation, Pacific Business Group on Health, and California Orthopaedic Association to collect and share information about hip and knee replacement arthroplasties performed in California. The California Joint Replacement Registry collects and incorporates clinical information and direct feedback from patients about the outcomes of hip and knee replacement surgeries. Twenty-four hospitals and their affiliated surgeons are now contributing data to the California Joint Replacement Registry. These hospitals perform nearly 25% of the total knee and total hip replacement procedures in California. Primary elective total knee and total hip replacements as well as revision surgery with various implant designs in a diverse group of patients from different practice settings are included. The California Joint Replacement Registry collects the Short Form-12 (SF-12), the HOOS and KOOS, and the University of California, Los Angeles (UCLA) activity score for patients before surgery as well as at three months, at one year, and annually thereafter postoperatively. In addition to PROs (level III), adverse event data (level II) and implant data (level I) are collected on all patients. Data capture from direct-to-patient measures is supported by web-based and scannable paper options. As well as the implant data that have been collected, PROs and adverse event data have been reported by more than 3000 patients. The California Joint Replacement Registry reported that approximately 70% of patients who are scheduled to undergo joint replacement and 30% of patients who have undergone the procedure complete PROs¹⁶.

Virginia Joint Registry

The Virginia Joint Registry was organized in 2005 by interested hip and knee surgeons to address the need for utilization data for joint replacement services as well as to provide surveillance data on the function of these replacements. The registry is a 501(c)3 public service corporation dedicated to improving the quality of hip and knee reconstructive services within the Commonwealth of Virginia. The registry partnered with the Virginia Orthopaedic Society and primarily collects implant (level-I) data¹⁷.

Rationale for PRO Integration in U.S. Total Joint Replacement Registries

Each of these five U.S. registries collects identical data to track implant performance (level I). Data elements include limited patient identification as well as implant lot and catalog numbers. In the future, these common data definitions will enable proactive surveillance of implant survival across all registries.

While revision rates are a critical marker of implant performance, new information⁶ from the New Zealand Joint Registry and National Joint Registry for England and Wales indicates that each year a subset of the implants that remain in place (such as prior to revision) are associated with substantial pain and limited function. Thus, PROs can serve as both a measure of outcome of total joint replacement in the first year after surgery and as a surveillance tool to identify symptoms of suboptimal implant performance prior to revision. Of importance, findings from the New Zealand Joint Registry and the National Joint Registry for England and Wales indicate that patients with substantially poorer PRO scores at six months after total joint replacement are more likely to have revision surgery within two or five years^{6,8}. This growing evidence that PROs can quantify both successes and suboptimal outcomes following total joint replacement procedures motivates U.S. registries to capture PROs.

Criteria for Selecting Specific PROs

These U.S. registries either currently collect or plan to collect a global health status measure such as a version of the SF-36¹⁸ (rather than the EuroQol five-dimension [EQ-5D] measure used abroad). They also collect or plan to collect a joint-specific measure such as the HOOS and KOOS, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)¹⁹⁻²², or the knee and hip-specific Oxford index²³. All five of these U.S. registries plan to use PROs to assess joint-specific pain and function to measure the impact of total joint replacement on pain and function and to assess suboptimal outcomes as represented by persistent pain after surgery.

Registry leaders believe that the three most common patient-related barriers to PRO completion are a perception that the survey is too long, its content is confusing or not relevant, and its administration via computer limits the participation of older adults. Leaders from all five of the registries report that the length of the PRO is critical when selecting which one to administer. Long completion times for a PRO can be a disincentive to both

patients and surgeons. While the FORCE-TJR registry administers the SF-36 and the HOOS and KOOS long forms, its leaders report excellent completion rates, with an item missing less than 3% of the time. Thus, the length of the survey alone does not necessarily determine completion rates, as direct-to-patient e-mail and postal mailings are associated with high response rates. FORCE-TJR illustrates the value of using a proven patient and surgeon-friendly PRO process to ensure high completion rates for PROs.

The leaders of these U.S. registries report that, in addition to the length of the survey, its content influences PRO selection. In particular, the registry leaders value the ability to assess joint-specific pain improvement independently from functional gains after total joint replacement. The value that U.S. surgeons place on joint-specific measures is reflected in the choice of PRO by each registry: the WOMAC (California Joint Replacement Registry), the HOOS and KOOS (FORCE-TJR and MARCQI), and these options plus the new Knee Society Score (American Joint Replacement Registry). Because the HOOS and KOOS include all of the WOMAC items, all U.S. registries could potentially report identical joint-specific pain and physical function metrics.

Some registry leaders advocated providing options for both web-based and paper PRO surveys because today's total joint replacement cohort has a mean age of sixty-five years and includes patients who may not be web literate. For example, the majority of patients in FORCE-TJR prefer the paper survey option even when they have an e-mail account. However, in the near future, technology-enabled total joint replacement patients will effectively complete web-based PROs by computer and phone.

In contrast to the perceived patient-related barriers, the surgeon-related barriers that the registry leaders believe are major hurdles to adopting PROs in the surgeon's office are the costs of PRO administration and, more importantly, the fact that patients do not return to the office at routine intervals. Finally, if a dedicated staff member is required to support high-quality PRO data collection, the additional costs are a further disincentive for surgeons' practices to collect PROs.

Key Considerations for PRO Implementation

U.S. registries administer preoperative surveys in a clinical setting, the hospital, or the surgeon's office, but they capture data via direct-to-patient surveys after surgery. In FORCE-TJR, patient enrollment takes place in the surgeon's office, where patients are educated about the need for complete data both before and after the total joint replacement procedure. In addition, repeat mailings and phone calls are used after total joint replacement to prompt patients to complete the postoperative PROs that are mailed or e-mailed to their homes. This model requires a dedicated clerical staff member to place reminder telephone calls each week but results in excellent completion rates. The California Joint Replacement Registry also enrolls patients in the surgeon's office and administers preoperative surveys electronically. The California Joint Replacement Registry administers postoperative surveys via e-mail, with reminders given via mailed postcards and phone calls. Leaders from both the California Joint Replacement Registry and the

MARCQI registry report more difficulty getting patients to complete postoperative surveys than preoperative surveys. These registries are hospital-based; while they do have direct-to-patient web surveys available for completion postoperatively, to date, the response rates have been suboptimal.

For context in assessing collection methods and response rates, international registries reported successful PRO completion rates following total joint replacement. Both the Swedish and the United Kingdom postoperative surveys are distributed directly to the patients at their homes. The Swedish hip registry uses the brief EQ-5D and reported completion by more than 90% of patients²⁴, while the United Kingdom uses the twelve-item Oxford assessment and reported completion by 79% to 85% for various postoperative intervals and patient subgroups²⁵⁻³¹. Beyond for total joint replacement, similar PRO completion rates have been reported for a cancer-survivor registry: 85% at six months and 66% at fifteen months postoperatively³².

The timing and location of PRO collection postoperatively are important to ensure valid outcome assessment following total joint replacement. Reaching patients in their homes after surgery is an important option because substantial variation exists in the timing of orthopaedic office visits following total joint replacement; also, most patients do not return to the original hospital, making hospital collection of PROs unlikely. The degree of pain relief and functional gain following total joint replacement differs depending on the postoperative interval. If postoperative visits to the surgeon's office vary between three and six months, PROs collected in the office cannot be effectively compared across surgeons, as patients are at different stages of recovery at these times. Moreover, data for patients with the most successful outcomes may not be captured with office-based PROs, as patients with optimal pain relief and functional gain are more likely to miss a postoperative office visit than are patients with persistent pain or limitations. Thus, PRO data collected in the office postoperatively may be skewed toward patients with the poorest outcomes. For these reasons, the FORCE-TJR, California Joint Replacement Registry, MARCQI, and international registries distribute postoperative PROs directly to patients at uniform, pre-determined intervals to ensure valid comparisons across sites.

Finally, the leaders of the five registries agree that PRO data collected at twelve months postoperatively are the best for capturing the full benefits of total joint replacement surgery, with data collected at six months as the second best. Six-month data from FORCE-TJR indicate that hip replacement patients report almost all functional gains by six months postoperatively and that total knee replacement patients achieve approximately 85% of the recovery by six months postoperatively. The registry leaders also report that data from the five and ten-year postoperative intervals are valuable for assessing long-term outcomes, particularly implant-specific survival (level-I data). An important potential future use of PRO data may be to screen patients to determine which ones might benefit from in-office clinical and radiographic follow-up and which ones do not need to return to the surgeon's office. This approach would focus surgeons' long-term postoperative care on the patients with suboptimal implant performance.

Conclusions

U.S. registries are at various stages of implementation of preoperative and postoperative patient-reported surveys of total joint replacement patients. Surgeon leaders report unified rationales for adopting PROs: to capture pain relief and functional gain following total joint replacement as well as to identify suboptimal implant performance. Key considerations in PRO selection include its ability to measure joint pain and physical function while minimizing any burden on patients and surgeons. Complete PRO data will be associated with various modes of survey completion, including options for home-based completion, to ensure consistent timing and data capture.

Measuring the change in pain and physical function between the levels before and after total joint replacement makes sense to patients and surgeons and supports the Institute of Medicine's vision to use information technology to support patient-centered care and evidence-based decisions. The authors of a recent review of PRO use in arthroplasty registries concluded that "omitting patient-reported outcomes precludes us [registries] from having a full understanding of the factors that contribute to pain relief, restoration of function, and patient satisfaction."³³ Total joint replacement registries in the U.S. are moving from an implant-centered model to a patient-centered model, and PROs play an important role in patient-centered total joint replacement registries¹². ■

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