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Beyond Joint Implant Registries: A Patient-Centered Research Consortium for Comparative Effectiveness in Total Joint Replacement

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Despite the proven effectiveness of total joint replacement (TJR) surgery in relieving advanced knee and hip arthritis pain, TJR outcomes have come under intense public scrutiny in recent years. The 2010 recall of ASR metal-on-metal hip implants[1] heightened awareness of the importance for implant safety surveillance for this high-cost and high-use procedure and exposed the need for a national systematic patient-centered outcomes monitoring system. These safety concerns and the exponential growth in TJR use— given the demographics of the baby boomer generation— emphasize the need for systematic comparative effectiveness research (CER) to inform patients, physicians, and policy makers about the optimal practices in TJR surgery.

Recent estimates suggest that up to 500 000 US patients received a metal-on-metal hip implant between 2003 and 2010.[2] Prior to the recall, case reports from across the globe documented unusually high rates of early postoperative revision surgery among patients with these implants. National registries of England and Wales, Australia, and New Zealand reported greater revision surgery rates with metal-on-metal implants[3] compared with conventional metal-on-polyethylene implants. In hindsight, the first sign of implant failure was atypical patient-reported pain, followed by pathologic soft tissue changes. However, at the time, registries were not systematically documenting longitudinal patient-reported symptoms (eg, pain and physical function) after knee and hip surgery. The existence of such systematic patient-reported data may have brought attention to these implants earlier. There is a current need, in the United States in particular, for an efficient monitoring infrastructure of population-based, longitudinal, patient-reported outcomes to provide evidence to inform patient and clinician decisions about optimal TJR timing, implant selection, surgical technique, and likely functional outcomes.

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To address this need, the Agency for Healthcare Research and Quality funded a 4-year $12 million research program, Function and Outcomes Research for Comparative Effectiveness in TJR (FORCE-TJR).[4] Led by a team of researchers at the University of Massachusetts Medical School in cooperation with a national network of surgeons, FORCE-TJR assembled a consortium of orthopedic practices to serve as a research laboratory to generate CER to guide surgeon and patient decisions. The FORCE-TJR has a national scope, is representative of US practices, includes longitudinal patient-reported outcomes, and has the ability to measure implant failure as well as important clinical outcomes and complications.

The FORCE-TJR Approach

The FORCE-TJR model goes beyond the traditional implant failure or revision registry and integrates the principles of population-based prospective research based on patient-centric outcomes. The FORCE-TJR is planning to enroll more than 30 000 diverse patients receiving care from more than 100 orthopedic surgeons representing all regions of the country and varied hospital and practice settings to ensure that data reflect typical US practice. Specifically, the study will include the following:

Diverse Orthopedic Practice Settings

Typically, TJR outcomes research is conducted in high-volume practices, often in academic medical centers. However, the majority of TJR surgeries in the United States are performed by general orthopedic surgeons in community practices. By design, 67% of the 101 surgeons who have joined the FORCE-TJR consortium to date practice in community settings in 27 states. In aggregate, consortium surgeons perform more than 14 000 TJR procedures each year using devices made by each of the 5 leading device manufacturers.[5] With more surgeons joining the study each month, FORCE-TJR is expected to exceed target patient enrollment. Varied practice size, financing (eg, private, health maintenance organization, Medicare), and geographic settings will ensure that this consortium includes diverse patient populations, practice settings, and health care delivery and financing models.

Patient-Centric Outcomes

Patient-reported arthritis symptoms of pain, stiffness, and limited physical function are central to TJR timing and outcome. To capture patient symptoms, scannable paper and web-based standardized surveys are completed by patients before and after surgery as well as annually for years into the future. In the first months of the study, more than 6000 patients consented to participate and completed the surveys.

Postoperative Events

Patients are the primary source of longitudinal data and will report concerns with their knee or hip implants. Reports of unusual pain or other symptoms that require medical evaluation initiate a centralized clinical record review to confirm (or dismiss) the presence of a postoperative adverse sequela. Although prior longitudinal research such as the Women's Health Initiative has used a similar design, this model has not been implemented in TJR registries. Most other US registries rely on the patient's return to the same hospital or health system to identify postoperative events. Given that patients may change location or surgeon,

the FORCE-TJR model should help ensure that all postoperative events, including issues that do not require return to the index hospital, can be identified and monitored to detect early evidence of postoperative concerns. Patient reports will be supplemented by surgeon reports and Medicare claims analyses for those TJR patients older than 65 years.

The FORCE-TJR design may be a useful model for future CER and patient-centered research consortia. Consistent patient risk factors and clinical data are collected from community-based orthopedic practices and augmented by collection of patient-reported symptoms at regular intervals before and after surgery. In addition to the patient metrics, FORCE-TJR collects traditional TJR surgical and implant details allowing estimates of implant failure or revision. The comprehensive data set should help researchers perform analyses to address questions important to all stakeholders while ensuring that the patient perspective remains central. The inclusion of clinical data may allow refined answers to questions of importance to patients, surgeons, and public health professionals. For example, the relative contributions of patient risks, surgical approach, and implant factors on total knee replacement or total hip replacement functional outcomes as well as revision rates will be evaluated.

The Future

Patients and surgeons participating in FORCE-TJR will contribute important new information that will inform guidelines to optimize patient care and TJR outcomes. The design of this surgical consortium and database shifts the primary TJR outcome from a single surgical event, implant revision, to an array of patient-defined outcomes, pain relief and functional improvement, and clinician-defined postoperative sequelae. Because postoperative adverse events are consistently defined through rigorous expert chart review, precise postoperative complication estimates will inform individual patient risks. In the future, the FORCE-TJR infrastructure will help support diffusion of best practices across the consortium members and through orthopedic professional societies and government agencies who participate in the FORCE-TJR National Stakeholder Committee. Also, FORCE-TJR is committed to transforming new research into patient-centric decision tools to allow patients to self-assess arthritis symptoms before and after surgery, ensuring that the patient's health and function are the critical elements in assessing TJR outcomes.

Data analyses from patients enrolled in 2012 are expected to be available by 2013. With the commitment of future federal and private funds, the FORCE-TJR infrastructure could be sustained for years to come to measure and disseminate early, mid-term, and long-term TJR patient outcomes. Beyond total joint replacement, lessons learned from the FORCE-TJR cohort and consortium may help inform future models for postmarketing surveillance of other devices and high-risk medications to guide clinician and patient decisions and health care policy.

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