Defining an Outcome Measure Set for a National TJR Outcome Registry: FORCE-TJR

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Today’s Goals

1. FORCE-TJR: Patient-Centered registry
   PROs and outcome metric lessons

2. Outcome benchmarks for QI
   Lessons for risk-adjustment

3. Lessons for real-world evidence, learning healthcare system
Traditional TJR registries: surgical revision is primary outcome

UK and Australia - two of world’s largest TJR registries

“Unlike tumour registries, which use death as an endpoint, joint registries are focused on the outcome of the device: anyone with any amount of joint damage can be admitted, only device-related surgical procedures are reported as failures, and death is counted as a success.”

The Lancet, Volume 384, Issue 9952, Pages 1405 - 1407, 18 October 2014

• If patients die, no revision; success?
• If patient has persistent pain, no revision; success?
TJR Failure: persistent pain, post-op complication, or implant revision

- Metal on metal hips demonstrated unusual pain and disability associated with soft tissue pathology; precedes implant failure.

- New Zealand TJR registry reported a direct relationship between increased patient-reported pain at 6 and 12 months post-TJR and early revision.
  - Pain at 12 months: 7 times greater risk of 5 year revision.

  Patient-reported PAIN (PRO) is key outcome for patient and implant surveillance.
Patient reported outcome measures

• PROs: "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else." NQF

• PROs: two major groups
  1. **Global health status**: physical, mental, and social well-being.
  2. **Diagnosis-specific** patient reported symptoms, e.g., knee, hip, shoulder, spine.
“…a patient gets used to not being able to bend the knee, or tie my shoes. The [PRO]questions reminded me by the time I got into the surgeon’s exam room and there it was: ‘What do you mean I’m only a 20 [very low function]?’ My primary care doctor thought I was too young for surgery.”
Alison, TKR patient, 51 years

“It [PRO survey] gave you something to go in there with, evidence that I really need this. I’m not just being a baby. A patient needs to be committed and have no doubts that surgery is the right way to go.”
Meg, THR patient, 63 years
FORCE-TJR: Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement

University of Massachusetts Medical School

PRO is Primary Outcome

AHRQ P50 Grant (2010-2015)

Member FDA TJR Clinical Research Network (Cornell U01)

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

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 ARS metal-on-metal hip implants highlighted awareness of the importance for implant safety surveillance for this high-end 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—

To address this need, the Agency for Healthcare Research and Quality funded a 5-year $12 million research program, Function and Outcomes Research for Comparative Effectiveness in TJR (FORCE-TJR), 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 surgeons 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
FORCE-TJR Principles

Inform quality improvement and comparative effectiveness research in clinical care:

– Assess benefits and risks that are patient-priorities
  1. PROs: pain relief, functional gain;
  2. Absence of complication (Adverse event rate);
  3. Implant longevity (Revision rate)
– Follow patient over time (with device)
FORCE-TJR cohort: PROs and clinical risk data >30,000 patients

• Patient information (age, sex, race, living situation)
• Medical co-morbidities (ICD)
• BMI, smoking
• Musculoskeletal co-morbidities- low back pain, contralateral hip/knee pain
• Outcomes: Patient priorities
  1: Patient Reported Outcomes (pre- and post-op)
  2: Complications/Readmissions at any facility
  3: Implant longevity

Complete risk data for risk-adjusted outcome comparisons; Over half of measures not consistently in EMR (blue).
FORCE: National Representative Network

>200 Surgeons in 28 States

- 75% of surgeons are community-based
- Fellowship-trained, general orthopedic surgeons
- High and low volume surgeons/hospitals; urban and rural
- Teaching hospitals, non-teaching
- Private, public and HMO insurance
- All major implant manufacturers

National norms, benchmarks to guide quality improvement
FORCE: Prospective data collection

**Data source:**
- **PATIENT**
- Before Surgery

**Timing:**
- **Before Surgery**
- **Hospital**
- Surgery
- 90 days
- **PATIENT**
- 9-12 months

**Measures:**
- PRO VR12/PROMIS
- HOOS/KOOS
- CLINICAL Medical & MSK risks
- Demographic
- OR Surgery and implant data
- PRO Pain
- CLINICAL Complication (if any)
- PRO VR12/PROMIS HOOS/KOOS
- CLINICAL Complication (if any)

**Reports:**
- Real-time, scored and trended PRO and risk factor reports
- Clinical /OR data and complications validated with CMS, claims, and EMR data.

Direct-to-patient data capture (web) in-office or in-home for consistent data and timing.
Ease of patient data capture; Web, APP
PRO capture through EMR Portal vs. Tethered Web Survey?

• EMR Portals collect PROs; may lack real-time trended data, norms, complete risk factors, and predicted outcomes.

• Why limitations?
  – Data: EMR data inconsistent as patients use diverse healthcare settings; office visits based on need.
  – Analytics: PRO data must be merged with risk factors, norms, and statistical models to generate real-time guidance.

*FORCE web-survey system collects and analyzes data.*

*Returns data to surgeon, patient, and EMR for storage.*
Individual Patient Summary for shared decision making, risk stratified care

Real-time, scored, trended pain and function using national norms for TJR.

Key clinical factors affecting risk of complication, readmission, and poor post-TJR outcomes

Early complete adverse event tracking.

BMI: 36.6 Obese
Smoker: No
Diabetic: Yes
Charlson Index: 2
LBP: Moderate
Emotional health score: 37 low

ER visit: 4/5/16 XXXX Hospital
Readmission: Reoperation:
1. How do my patients’ pre-operative risks compare?
2. How do my patients’ pre-operative pain and function (disability) compare?
3. How do my risk-adjusted patient outcomes (pain, function, readmissions) compare to other sites?
PRO and patient-reported comorbidity enhances readmission prediction

- Demographics and Medical comorbidities (ICD)
- CMS (ICD) = 0.65

- Patient reported: BMI, smoking, pre-op Function and MSK comorbidities (Mod/Severe pain in low back, hips, knees)
  
  C= 0.79 (TKR); 0.86 (THR)

Area under ROC curve = 0.7881
TKR brings significant gains in mean 12 month KOOS ADL and pain; 15% lag
Pain as ‘signal’ for underperforming implant profile; at risk patients

• Understand PRO/pain as an indicator for poorly performing implants at risk for revision.
• Supporting post-market surveillance
FORCE Lessons Real World Evidence

– Engage patients as active participants in data generation - hold many of the key metrics
– Collect comprehensive risk factors for predictions
– Representative network of community orthopedic surgeons can generate data
– Integrate data capture at key points in care
– Follow the patient for longterm outcomes, quality measures, device surveillance
– Transparent data for patient-surgeon decisions
Data Harmonization

• CMS Comprehensive Joint Replacement bundled payment pilot
  – Parallel 30day readmission, 90day complication, 9-12 month PROs, HCAHP as quality measures.
  – Mandatory in 67 regions; 800 hospitals.

• International Consortium of Health Outcome Measures: OA/TJR panel

• QCDR/MIPS- meet regulatory goals

• American Board of Orthopedic Surgeon
  – Recertification standards
SUMMARY: Patient-centered registry for QI and patient care

1. Patient-generated, combine with clinical, data guide care decisions and QI.

2. Consistent measurement of key risk factors is important to refine outcomes and focus on improvement priorities.

2. Patient-centered registries offer efficient, effective infrastructure for future device evidence generation.
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