May 20th, 10:00 AM

Patient Reported Outcomes in Arthritis, TJR, and Physical Activity Research

Patricia D. Franklin
University of Massachusetts Medical School

Follow this and additional works at: https://escholarship.umassmed.edu/cts_retreat

Part of the Health Services Research Commons, Musculoskeletal Diseases Commons, and the Orthopedics Commons

This work is licensed under a Creative Commons Attribution-Noncommercial-Share Alike 3.0 License.

https://escholarship.umassmed.edu/cts_retreat/2016/program/13

This material is brought to you by eScholarship@UMMS. It has been accepted for inclusion in UMass Center for Clinical and Translational Science Research Retreat by an authorized administrator of eScholarship@UMMS. For more information, please contact Lisa.Palmer@umassmed.edu.
Patient Reported Outcomes in Arthritis, TJR, and Physical Activity Research

UMMS CCTS Retreat
5.20.16

Patricia D. Franklin, MD MBA MPH

Department of Orthopedics and Physical Rehabilitation
University of Massachusetts Medical School
Disclosure

• I have no actual or potential conflict of interest in relation to this program/presentation.
• Current research funding:
  – PCORI
  – AHRQ
  – NIH/NIAMS
  – Zimmer Biomet, Inc.
Today’s Goals

1. *Why* collect PROs in clinic and research?
2. *What* are PROs? What do we learn from them?
3. PRO/physical activity translational research in OA and TJR at UMMS.

*Note:* OA/TJR as example; principles apply to other chronic conditions.
OA patients choose TJR to relieve pain, improve function

OA is the most common disabling condition among US adults; affects more than 2/3 of adults over 65 years.

• Knee and hip OA pain limits mobility
• Total Joint Replacement is the most common and costly procedure in Medicare budget;
• Use among patients <65 is escalating (now 48% of total)
• >1 million procedures each year in US
New paradigm: patient-reported outcomes as primary TJR endpoint

“When he [the surgeon] saw the PRO survey, he saw how my function was, how bad it was....” Patient, age 72, TKR, PA

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

David C. Ayres, M.D. and Patricia J. Franklin, M.D., M.B.A.

Despite the proven effectiveness of total joint replacements (TJR) surgery in relieving pain and improving joint function, patient satisfaction and outcomes have come under intense public scrutiny in recent years. The 2013 result of 23 major metal-on-metal implants’ heightened awareness of the importance for implant safety surveillance for high-use and high-flight implants and procedures and imposed the need for a national synoptic patient-centered outcomes monitoring system. This was the genesis of the hip and knee burden, emphasizing the need for systematic, comparative effectiveness research (CER) to inform patients, physicians, and other payers about the optimal practices for TJR surgery.

Recent estimates suggest that up to 500,000 TJR patients received metal-on-metal hip implants between 2001 and 2010. Prior to the recall, these patients were from across the globe and documented unusually high rates of early postoperative revisions, severe surgeries 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 compared with conventional metal-on-polyethylene implants. In hindsight, the first sign of implant failure was atypical pain/patient reported pain, followed by radiological stem changes. However, in the meantime, registries were not systematically documenting long-term patient-reported symptoms (e.g., pain, and physical function) after knee and hip surgery. The existence of such systematic patient-reported data may have brought attention to these implant failures earlier. There is a current need in the United States to develop a national synoptic comparative effectiveness research system to monitor outcomes and the effectiveness of implants and surgical treatments. This system will allow for the evaluation of the long-term safety and effectiveness of implants and surgical treatments.

The FORC-JTR Approach

The FORC-JTR approach goes beyond the traditional implant failure or revision registries and integrates the principles of population-based prospective research based on population outcomes. The FORC-JTR is planning to enroll more than 200,000 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 clinical practice. Specifically, the study will include the following:

- **Severe Orthopaedic Practice Settings**: Forc-Jtr outcomes research is conducted in high-volume practices, or in academic medical centers. However, the majority of Tjr registries in the United States are performed by general orthopedic surgeons in community practice. By design, only 20% of the 120 centers that have joined the FORC-JTR come from practices in community settings, or 27 states. In aggregate, the consortium enrolls more than 45,000 for every year using device data from each of the 5 leading device manufacturers. With such a prospective joint registry study, it monitors and tracks the history of the various joint replacement procedures and implant trends. This study includes clinical outcomes, complications, cost, and health care utilization and financial models.

- **TJR Registry**: A joint implant registry based on electronic medical records (EMR) has been established, which allows for the development of a registry-based analysis of outcomes following surgery. The registry provides a means of assessing the effectiveness of implant procedures and identifying potential areas for improvement. The registry is designed to be comprehensive and include data on all patients undergoing TJR surgery, including demographic information, implant details, surgical outcomes, and postoperative complications. The registry also provides a platform for researchers and clinicians to collaborate and share data, facilitating the development of evidence-based guidelines and best practices for TJR surgery.

- **TJR Registry Update**: The FORC-JTR Registry Update describes the status and progress of the registry to date and highlights key findings and trends observed. The update provides an overview of the registry’s objectives, methodology, and key outcomes to date. It also discusses the challenges and limitations of the registry and future directions for improvement.

- **TJR Registry Outcomes**: The FORC-JTR Registry Outcomes report presents a comprehensive analysis of the registry’s outcomes data, including patient-reported outcomes, clinical outcomes, and cost-effectiveness analyses. The report highlights key findings and trends observed, as well as potential areas for future research.

- **TJR Registry Best Practices**: The FORC-JTR Registry Best Practices report describes best practices in TJR surgery, based on the registry’s data and findings. The report provides guidance for clinicians and policymakers on improving the quality and effectiveness of TJR surgery.

- **TJR Registry Resources**: The FORC-JTR Registry Resources report provides access to the registry’s data and resources, including training materials, software tools, and guidelines for using the registry’s data.

- **TJR Registry Partnerships**: The FORC-JTR Registry Partnerships report describes partnerships with other organizations and stakeholders, as well as potential opportunities for collaboration and knowledge exchange.

- **TJR Registry Funding**: The FORC-JTR Registry Funding report presents information on the funding sources and partners supporting the registry, including government grants, private foundations, and industry partnerships.

- **TJR Registry Impact**: The FORC-JTR Registry Impact report describes the impact of the registry on TJR surgery outcomes and provides examples of the registry’s contributions to scientific knowledge and patient care.

- **TJR Registry Publications**: The FORC-JTR Registry Publications report lists all publications and presentations based on the registry’s data and findings. The report highlights key publications and presentations that have been disseminated to the scientific community and the public.

- **TJR Registry Governance**: The FORC-JTR Registry Governance report describes the governance structure and management of the registry, including the roles and responsibilities of the steering committee and other key stakeholders.

- **TJR Registry Social Media**: The FORC-JTR Registry Social Media report provides links to the registry’s social media channels, including Twitter, Facebook, and LinkedIn, where the registry’s latest news and updates are shared.

- **TJR Registry Website**: The FORC-JTR Registry Website report describes the registry’s website, which is designed to be user-friendly and accessible to all stakeholders, including patients, clinicians, researchers, and policymakers.

- **TJR Registry Contact Information**: The FORC-JTR Registry Contact Information report provides contact information for the registry’s leadership team, including phone numbers, email addresses, and contact forms for feedback and inquiries.

The FORC-JTR Registry Update showcases the progress and accomplishments of the FORC-JTR Registry since its inception, highlighting the key findings and trends observed, as well as the potential impact of the registry on TJR surgery outcomes. The update provides an overview of the registry’s objectives, methodology, and key outcomes to date, as well as potential areas for future research and development. The report also describes the partnerships and collaborations with other organizations and stakeholders, as well as the funding sources and partners supporting the registry. Finally, the report provides a glimpse into the registry’s social media channels, website, governance structure, and contact information, highlighting the resources available to all stakeholders and the ongoing efforts to improve TJR surgery outcomes.

This completes the update on the FORC-JTR Registry, which provides a comprehensive and transparent overview of the registry’s progress and impact. The FORC-JTR Registry continues to be an important resource for advancing the science and practice of TJR surgery, and the forum for sharing knowledge and evidence-based best practices.
FORCE-TJR: platform for TJR outcomes monitoring

Competitive Application: $12 million AHRQ P50 award
Department of Orthopedics and Physical Rehabilitation
University of Massachusetts Medical School (2011-14)
Supplemental grants (AHRQ, PCORI, FDA, NIH)

1. Develop a comprehensive TJR registry with sustainable data infrastructure for comprehensive TJR outcome monitoring and feedback to providers.
   – UMass is the TJR data coordinating center for the next 20+ years

2. UMass TJR research team conducting comparative effectiveness research in TJR quality and outcomes.
   – Participating on CMS expert panels and national TJR leadership groups
FORCE-TJR: National Cohort of 28,000 patients, >200 Surgeons, 28 States

- 75% of surgeons are community-based
- Fellowship-trained, general orthopedic surgeons
- High and low volume surgeons/hospitals; urban and rural hospitals
- Diverse patients and settings for first 25,000+ patients define NATIONAL NORMS on Pre- and Post- PROs for immediate benchmarking
- Patients <65 years and Medicare
FORCE-TJR: collected across TJR Care Cycle
>28,000 patients

<table>
<thead>
<tr>
<th>Patient Surgeon</th>
<th>Hospital</th>
<th>Direct to Patient (validate EHR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before Surgery</td>
<td>Surgery</td>
<td>30 -90 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Annual</td>
</tr>
</tbody>
</table>

- **PRO**
  - Global: VR12 HOOS/KOOS

- **CLINICAL RISKS**
  - Medical & MSK risks
  - Demographic

- **CLINICAL**
  - Implant Operative Notes
  - Readmission Complication (if any)
  - Complication (if any)
  - Revision

**CMS DATA**
PROs completed:
WEB-based
• In Office
• From Home
• On PC or Tablet
(Scannable Paper option)

85% complete Pre and Post-TJR
2. 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


2. Diagnosis-specific patient reported symptoms, e.g., knee.
SF/VR12, SF36 (JohnWare; Rand, 1980s)

• 2 major domains:
Physical Health (PCS) and Emotional Health (MCS) (SF12, 36)
• 8 sub-domains (SF36)
  1. vitality
  2. general health perceptions
  3. physical functioning
  4. bodily pain
  5. physical role functioning
  6. emotional role functioning
  7. social role functioning
  8. mental health
• Secondary value: Poor emotional health is predictor of poor physical function (PCS) after TJR
PROMIS
http://www.nihpromis.org/

• Physical Function
  1. Physical function
  2. Pain (interference)
  3. Fatigue
  4. Sleep
• Emotional function
  1. Anxiety
  2. Depression
• Social Health

Limitation of Global Function Measure: Low back pain or contralateral knee/hip disease, COPD, etc. will influence global function.
These first questions are about your health now and your current daily activities. It is important that you give your best answer to all questions - including those questions that may not seem as relevant to you.

1. In general, how would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
</table>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</th>
<th>Limited A lot</th>
<th>Limited A little</th>
<th>Not Limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLIMBING SEVERAL flights of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>ACCOMPLISHED LESS than you would like</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were limited in the KIND of work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>ACCOMPLISHED LESS than you would like</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did work or other activities LESS CAREFULLY THAN USUAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Disease-specific PRO

• Knee/Hip OA
  – WOMAC- broadly used in OA assessment
  – HOOS/KOOS (includes WOMAC); 42 items
  – Five Domains:
    1. Pain
    2. Activities of Daily Living
    3. Symptoms (stiffness)
    4. Sport
    5. QoL

• 42 items; attribute limitations to KNEE or HIP
• brief “knee/hip health” PRO; AHRQ (Gandek)
The following questions concern your **physical function**. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your surgical knee. It is important you answer all questions even if they may not seem relevant to you. If you were not able to do an activity listed, tell us how difficult it would be if you attempted to do the activity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descending stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ascending stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rising from sitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bending to floor/picking up an object</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking on a flat surface</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting in/out of car</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going shopping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Putting on socks/stockings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rising from bed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking off socks/stockings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lying in bed (turning over, maintaining knee position)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting in/out of bath</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting on/off toilet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doing heavy domestic duties (moving heavy boxes, scrubbing floors, etc)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doing light domestic duties (cooking, dusting, etc)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FORCE-TJR Protocols for Successful PRO Capture integrated with Clinic

1. Flexible IT to interface with patients and clinicians; diverse settings with varied EMRs.
2. Operational procedures to track patient over time
   • Surgeon office to Hospital to Home
3. Risk-adjusted analyses with useful benchmarks based on representative patients and practices.

How Use PRO data in Clinic and Research?

Ease of PRO administration; APP
(AHRQ Ancillary; WPI/UMMS Zheng)
**Individual Patient Level**

**Computer collect/score:**
1. **Actionable**
   Real-time scored Function and Pain as "lab test"

2. **Interpretable**
   Trended across visits
   Pre/Post treatments
   Norms (colors)

3. **Surgeon/ Patient Review**
   Shared decisions
   Risk factors
Tailored Individual Outcome Estimates

- PCORI; Franklin, Li, Zheng, Ayers
- 2016-2020 ($6.3million)
- Refine individualized models; predicted outcomes and risks
- Deploy web-based assessment and reports
- Conduct cluster randomized trial among 40 surgeons to define impact on patient/surgeon shared decision making for knee/hip OA care, including TJR
Pre-TKR Function: Indicator of appropriateness/timing?

Site Pre-TKR Patient Profile:

- National Norm for Healthy = 50 (SD=10) Green arrow
- Site Median PCS = 32
- National Median PCS for TJR = 32 (2SD below healthy; Red arrow)
- Site 75th%ile PCS = 38
- National 75th%ile PCS = 39

*Patient selection matches national norms; >83% have PCS scores reflecting disability.*

*Patients in yellow (1SD): evaluate clinical circumstances warranting TJR.*
Implant Surveillance
FDA UO1; Cornell/network of registries

• Understanding PRO/ pain as an indicator for under-performing implants at risk for revision.

• Supporting post-market surveillance
Activity (steps/day) post-TKR vary by risk factors; Association activity== functional gain?

<table>
<thead>
<tr>
<th></th>
<th>PRE-TKR steps/day</th>
<th>POST-TKR steps/day</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-TKR</td>
<td>6600</td>
<td>7690</td>
<td>1280</td>
</tr>
<tr>
<td>Male</td>
<td>7496</td>
<td>9051</td>
<td>1239</td>
</tr>
<tr>
<td>Female</td>
<td>6218</td>
<td>7150</td>
<td>901</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Predicted Post-TKR steps/day</th>
<th>95% CI</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7131</td>
<td>6156</td>
<td>8107</td>
</tr>
<tr>
<td>Male</td>
<td>9259</td>
<td>7678</td>
<td>10841</td>
</tr>
<tr>
<td>Gender diff.</td>
<td>2128</td>
<td>228</td>
<td>4027</td>
</tr>
</tbody>
</table>
UMass Kinesiology/Orthopedics
Worcester Gait Lab

• Patterns of activity loss and gait in progression of OA? Improvement after TKR? THR?
• Mechanism of OA influence on gait/function?
• Correlation with PROs? What incremental information? What consistent?
• Which gait measures have clinical diagnostic or treatment value?