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

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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

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

Karen D. Franklin, MD, MCH, MRA
David C. Ayers, MD

Despite the proven effectiveness of total joint replacements (TJR) surgery in relieving pain and improving function for hip and knee arthroplasty patients, TJR outcomes have come under intense public scrutiny in recent years. The 2013 recall of 33,000 metal-on-metal hip implants highlighted awareness of the importance for implant safety surveillance for high-risk and high-morbidity procedures and sparked the need for national prospective, patient-centered, outcomes monitoring systems. To address this need, the Agency for Healthcare Research and Quality funded a 4-year, U.S. million research project, Patient- and Outcomes Research for Comparative Effectiveness in TJR (FORCE-TJR).Led by a team of researchers at the University of Massachusetts Medical School in conjunction with a national network of surgeons, FORCE-TJR assembled a consortium of orthopedic practices to serve as a research laboratory to generate evidence of patient and surgical outcomes. The FORCE-TJR has a national scope, a representation of U.S. practices, includes longitudinal patient-reported outcomes, and has the ability to measure implant failures as well as important clinical outcomes and complications.

The FORCE-TJR Approach

The FORCE-TJR project goals beyond the traditional implant failure or revision registry and integrates the principles of population-based prospective research based on outcomes. The unique perspective of the FORCE-TJR is planning to enroll more than 30,000 diverse patients receiving care from more than 100 orthopedic centers representing all regions of the country and varied health care practice settings to ensure that data reflect clinical practice. Specifically, the study will include the following:

- BHERS Orthopaedic Practice Settings: The FORCE-TJR outcomes research is conducted in high-volume practices, selected in academic medical centers. However, the majority of TJR registries (BHERS and others) are performed by general orthopedic surgeons in community practice. By design, 47% of the 121 centers that have joined the FORCE-TJR consortium are in data practice in community settings in 27 states. In aggregate, consortium centers perform more than 14,000 TJR procedures each year using devices made by each of the leading devices manufacturers. With more surgeons joining the study each month, FORCE-TJR is expected to expand beyond patient enrollment. Vailed practice site, State and local provider input, prospective patient enrollment, and geographic settings will ensure that the consortium includes diverse provider populations, practice settings, and health care delivery and financing models.

See also pp 1277 and 1279.

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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

Map of Participating Core Centers and Community Sites

Core Clinical Centers
- UMass Medical School, Worcester, MA
- Connecticut Joint Replacement Institute, Hartford, CT
- The University of Rochester Medical Center, Rochester, NY
- Medical University of South Carolina, Charleston SC
- Baylor College of Medicine, Houston, TX

Community Sites
- Community Sites currently enrolled
FORCE-TJR: collected across TJR Care Cycle
>28,000 patients

**Patient Surgeon**
- Before Surgery
  - PRO Global: VR12 HOOS/KOOS
  - CLINICAL RISKS Medical & MSK risks Demographic

**Hospital**
- Surgery
  - PRO Pain
    - CLINICAL Implant Operative Notes
- 30 -90 days
  - PRO Global: VR12 HOOS/KOOS
  - CLINICAL Readmission Complication (if any)
- 6 months
  - PRO Global: VR12 HOOS/KOOS
  - CLINICAL Complication (if any)
- Annual
  - PRO Global: VR12 HOOS/KOOS
  - CLINICAL Complication (if any)

**Direct to Patient (validate EHR)**
- PRO Global: VR12 HOOS/KOOS
- CLINICAL 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 (John Ware; 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.
General: VR12; PROMIS
No attribution to disease

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 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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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>Activity</th>
<th>Limited A lot</th>
<th>Limited A little</th>
<th>Not Limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<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>Problem</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>ACCOMPLISHED LESS than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>Problem</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>ACCOMPLISHED LESS than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did work or other activities LESS CAREFULLY THAN USUAL</td>
<td></td>
<td></td>
<td></td>
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<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>
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</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>
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<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>
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</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 ($6.3 million)
- 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?