May 20th, 10:00 AM

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

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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

Patient-reported outcomes (PROs) are an indispensable part of comprehensive care for total joint replacement (TJR) and have been shown to improve clinical decision-making and increase patient satisfaction. However, the adoption of PROs in TJR has been slow due to the lack of standardized and validated instruments. The CLEAR registry, a national PRO registry, was established in 2014 to address these challenges and promote the use of PROs in TJR. The registry is a collaborative effort between academic institutions and clinical practices, and it uses a standardized PRO survey to collect patient-reported data. The CLEAR registry has shown that PROs can provide valuable information for both clinicians and patients, and it has been successful in increasing the use of PROs in TJR.

The CLEAR registry also provides valuable insights into the outcomes of TJR procedures. For example, the registry has shown that patients who undergo elective TJR procedures have better outcomes than those who undergo urgent or emergency procedures. Additionally, the registry has demonstrated that patients who undergo TJR procedures at academic institutions have better outcomes than those who undergo procedures at community hospitals. These findings highlight the importance of continuing to invest in PRO research and the importance of using PROs to inform clinical decision-making in TJR.

In conclusion, the CLEAR registry has shown that PROs can provide valuable information for both clinicians and patients and can improve clinical decision-making in TJR. The registry has also demonstrated the importance of investing in PRO research and the importance of using PROs to inform clinical decision-making in TJR.
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>
<tr>
<td>• PRO Global: VR12 HOOS/KOOS</td>
<td>• PRO Pain</td>
<td>• PRO Global: VR12 HOOS/KOOS</td>
</tr>
<tr>
<td>• CLINICAL RISKS Medical &amp; MSK risks Demographic</td>
<td>• CLINICAL Implant Operative Notes</td>
<td>• CLINICAL Complication (if any)</td>
</tr>
<tr>
<td>• CLINICAL Readmission Complication (if any)</td>
<td>• CLINICAL Complication (if any)</td>
<td>• CLINICAL Complication (if any)</td>
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</tbody>
</table>

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>
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</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>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>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>CLIMBING SEVERAL flights of stairs</th>
<th>Limited A lot</th>
<th>Limited A little</th>
<th>Not Limited at all</th>
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</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>
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<tbody>
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<table>
<thead>
<tr>
<th>WERE LIMITED IN THE KIND of work or other activities</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>
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</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>
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</thead>
<tbody>
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</table>

<table>
<thead>
<tr>
<th>DID WORK OR OTHER ACTIVITIES LESS CAREFULLY THAN USUAL</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>
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</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>
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<tr>
<td>Rising from sitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Standing</td>
<td></td>
<td></td>
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<tr>
<td>Bending to floor/picking up an object</td>
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<tr>
<td>Walking on a flat surface</td>
<td></td>
<td></td>
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<tr>
<td>Getting in/out of car</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Going shopping</td>
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<tr>
<td>Putting on socks/stockings</td>
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</tr>
<tr>
<td>Rising from bed</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Taking off socks/stockings</td>
<td></td>
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<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>
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<td></td>
</tr>
<tr>
<td>Sitting</td>
<td></td>
<td></td>
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<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>
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</tr>
<tr>
<td>Doing light domestic duties (cooking, dusting, etc)</td>
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</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?