Developing and Implementing a Patient Reported Outcomes Network in Canada: Potential Benefits and Challenges
Montreal, QC, Canada

Integrating PROMIS in Arthritis Clinical Care: Feasibility, Impact, and Content Validation

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Rheumatoid Arthritis

• Rheumatoid arthritis (RA) is a chronic, systemic, and frequently disabling disease that affects up to 1% of the population.

• Associated with considerable disease- and treatment-related morbidities and premature mortality.

• Multiple aspects of physical, emotional, and social health are impacted.

• **Current measures** used in clinical care to guide treatment decisions have limited inclusion of patient-valued outcomes.
Current Outcome Measures Used in RA Clinical Trials and Decision Making

• RA Core Set: Swollen Joints, Tender Joints, Patient Global Assessment, MD Global Assessment, Patient Assessment of Pain, HAQ-DI, ESR/CRP

• DAS— Swollen Joints, Tender Joints, ESR/CRP, Patient Global Health

• CDAI—Swollen Joints, Tender Joints, Patient Global Assessment of Disease, MD Global Assessment

• SDAI— CDAI+ CRP
Outcome Measures in Rheumatology
Established in 1992 to Develop, Improve, Validate Outcome Measures for Clinical Trials
- RA Core Set, RA Remission, OA Response, MRI RAMRIS, Psoriatic arthritis Core Set, etc
Evolved to encompass spectrum of rheumatic diseases and settings (RCT, LOS, practice)

Filter 1.0: Truth, Discrimination, Feasibility
Filter 2.0: Framework for developing Core Outcome Sets

Patient inclusion in research process since 2002
- Resulted in addition of Fatigue to recommended RA Core Set
RA Patients and Providers have Different Perspectives When Rating the Importance of Disease Signs and Symptoms: RA Flare

Patient-Reported Outcome Measurement Information System (PROMIS®)
www.nihpromis.org

• Developed to improve the precision of evaluating Health Related Quality of Life (HRQoL) across multiple areas of physical, mental, and social health

• Tested mostly in research settings
• Limited evaluation in clinical care settings
• Limited evaluation in specific disease states

• Domains identified by RA patients are included in PROMIS

• Evaluation of PROMIS in RA has been limited to assessments of physical function
  – Addresses floor and ceiling effects of HAQ and SF12
PCORI Pilot Project Objectives

• Hypothesis tested:
  – Integrating PROs into routine care will improve the assessment of patient-valued symptoms and influence medical decision-making

• Objective:
  – To evaluate the feasibility and impact of integrating PROMIS® in RA patients seen in a busy clinical practice setting
    • Acceptability to Patients and Providers
    • Integration within Practice Workflow
    • Patient-Care Team Interactions
    • Shared Decision-Making
    • Validity and Responsiveness of PROMIS measures
People with RA seen in routine clinical care are eligible

Assessment Center programmed with PROMIS instruments and legacy measures

In waiting room, patient given an iPAD linked to online AC module

PROMIS SFs, CATs, and other measures completed
• Routine clinic visit with provider takes place
• Review/discussion of PROMIS results
• Patient and provider rate “value” of information, and impact on clinical decision-making (survey)
• Interviews and focus groups with patients, providers, clinic and research staff
Mixed Methods Analytic Approach

- Qualitative (Surveys, Interviews, Focus Groups)
  - Patients
  - Providers
  - Clinic Staff
  - Research Staff
  - Stakeholders

- Quantitative
  - PROMIS Data
  - “Legacy” PROs
  - Standard Clinical Outcomes
  - Validation
## Selection of Domains

<table>
<thead>
<tr>
<th>Patient Identified Domain</th>
<th>Legacy Measure</th>
<th>PROMIS SF, Scale or Score</th>
<th>PROMIS Item</th>
<th>PROMIS CAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Assessment</td>
<td>VAS</td>
<td>Global 1.1</td>
<td>G1, G2</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>VAS</td>
<td>Pain Intensity 3a</td>
<td>G7</td>
<td>Pain Interference</td>
</tr>
<tr>
<td>Physical Function</td>
<td>MHAQ</td>
<td>Global Physical Score</td>
<td>G6, G3</td>
<td>Physical Function</td>
</tr>
<tr>
<td>Participation</td>
<td>None</td>
<td></td>
<td>G9r G5</td>
<td>Participation satisfaction</td>
</tr>
<tr>
<td>Fatigue</td>
<td>VAS</td>
<td>Fatigue</td>
<td>G8</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Systemic Features</td>
<td>Global VAS</td>
<td></td>
<td>G1, G2</td>
<td></td>
</tr>
<tr>
<td>Sleep</td>
<td>None</td>
<td></td>
<td></td>
<td>Sleep Disturbance Sleep Interference</td>
</tr>
<tr>
<td>Emotional Distress</td>
<td>None</td>
<td>Global Mental Score</td>
<td>G4, G10</td>
<td>Depression Anxiety Anger</td>
</tr>
</tbody>
</table>

**Other Measures:** Patient assessed disease change, Minimal important difference, Patient acceptable symptom state, Flare assessment, Stiffness, Self-management
Multilevel Mixed Methods Approach with Patient Incorporation throughout Research Process

PCORI Pilot Project: Integrating PROMIS in Arthritis Clinical Care

Input
- RA Patients
- OMERACT
- CPATH/FDA
- NIH/PROMIS
- EULAR
- RA Patients

Outcomes
- Feasibility and Acceptability
  - RA Patients
- Truth, Relevance, and Content Validity
  - RA Patients
- Effects on Communication and Decision Making
  - RA Patients
- Ability to Detect Change/Discrimination
  - RA Patients
- “Value” and Implications of Study Results
  - RA Patients

Research Team

Stakeholders

RA Patients
Preliminary Results
PROMIS In Clinic: Feasibility

- 12 PROMIS Instruments Administered:
  - Global health, Pain (Intensity, Interference), Fatigue, Physical function, Sleep (Disturbance, Interference), Depression, Anxiety, Cognition general concerns, Social roles (Participation, Satisfaction)

<table>
<thead>
<tr>
<th>(n=107)</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Complete (minutes)</td>
<td>12.1</td>
<td>4.5</td>
<td>10.8</td>
<td>5.7</td>
<td>32</td>
</tr>
<tr>
<td>Number of Questions</td>
<td>67.8</td>
<td>9.5</td>
<td>65.0</td>
<td>58</td>
<td>98</td>
</tr>
</tbody>
</table>

- Time for completion includes clinic interruptions (moving to rooms, vital signs, etc.)
- Interviews ongoing with patients, providers, and clinic staff to determine effect on clinic flow
Example PROMIS Reports

Your scores for the CATs you completed are shown below.

<table>
<thead>
<tr>
<th>Your Score</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Interference</td>
<td>67</td>
</tr>
<tr>
<td>Fatigue</td>
<td>65</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>61</td>
</tr>
<tr>
<td>Sleep-Related Impairment</td>
<td>47</td>
</tr>
<tr>
<td>Depressive Symptoms/Sadness</td>
<td>35</td>
</tr>
<tr>
<td>Anxiety/Fear</td>
<td>46</td>
</tr>
<tr>
<td>Anger</td>
<td>34</td>
</tr>
</tbody>
</table>

**Active RA**

Your scores for the CATs you completed are shown below.

<table>
<thead>
<tr>
<th>Your Score</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>25</td>
</tr>
</tbody>
</table>

**Mild RA**

Breakup w/ Sig Other

<table>
<thead>
<tr>
<th>Your Score</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA in Remission</td>
<td>3</td>
</tr>
</tbody>
</table>

Poor Sleep 2° Sinus Surgery
Preliminary Observations: Clinical Decision-Making

- New comorbidities and symptoms have been identified by PROMIS measures that did not surface during the usual clinical encounter
  - E.g., fatigue, sleep, depression, anxiety

- Some of these resulted in changes in RA therapy to address symptoms, referrals for evaluation of symptoms, and/or treatment of comorbidities
## Participant Characteristics (n=107)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yrs.)</td>
<td>55.5 ± 13.0</td>
<td>22-85</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>53 (77%)</td>
<td></td>
</tr>
<tr>
<td>Minority race (%)</td>
<td>17 (16%)</td>
<td></td>
</tr>
<tr>
<td>Completed some college</td>
<td>74%</td>
<td></td>
</tr>
<tr>
<td><strong>RA Characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease duration (yrs.)</td>
<td>12.0 ± 9.3</td>
<td>1-41</td>
</tr>
<tr>
<td>CDAI</td>
<td>8.8 ± 8.7</td>
<td>0-33.5</td>
</tr>
<tr>
<td>MD Global Assessment (VAS)</td>
<td>15.7 ± 17.1</td>
<td>0-75</td>
</tr>
<tr>
<td><strong>Patient Reported Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Global (VAS)</td>
<td>29.8 ± 26.6</td>
<td></td>
</tr>
<tr>
<td>Pain (VAS)</td>
<td>33.2 ± 28.6</td>
<td></td>
</tr>
<tr>
<td>MHAQ (0-3)</td>
<td>0.3 ± 0.4</td>
<td></td>
</tr>
</tbody>
</table>

Values are mean ± SD, unless otherwise indicated
Preliminary Results
Distribution of Selected PROMIS CAT T-Scores in RA Patients (n=107)

*Scores inverted for demonstration
### Regression coefficient, effect sizes and mean scores by CDAI disease activity level for legacy and PROMIS measures: Global and General Health

<table>
<thead>
<tr>
<th>Variable</th>
<th>Source</th>
<th>B</th>
<th>Effect Size (β/SE)</th>
<th>Remission N=29</th>
<th>Low N=45</th>
<th>Moderate N=21</th>
<th>High N=12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Global VAS</td>
<td>17.8</td>
<td>8.4</td>
<td>5.5 + 6.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>29.6 + 23.2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>50.0 + 21.4&lt;sup&gt;c&lt;/sup&gt;</td>
<td>53.4 + 27.8&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>MD Global VAS</td>
<td>13.2</td>
<td>11.1</td>
<td>3.4 + 3.8&lt;sup&gt;a&lt;/sup&gt;</td>
<td>10.9 + 9.5&lt;sup&gt;b&lt;/sup&gt;</td>
<td>26.9 + 13.0&lt;sup&gt;c&lt;/sup&gt;</td>
<td>43.8 + 22.6&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>PROMIS Global Physical</td>
<td>Score -5.6</td>
<td>-7.4</td>
<td>53.8 ± 6.9&lt;sup&gt;a&lt;/sup&gt;</td>
<td>44.1 ± 8.2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>39.2 ± 5.6&lt;sup&gt;c&lt;/sup&gt;</td>
<td>38.4 ± 6.3&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>PROMIS Global Mental</td>
<td>Score -3.1</td>
<td>-3.6</td>
<td>54.7 ± 8.1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>48.2 ± 8.2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>48.6 ± 8.2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>44.1 ± 8.6&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>Pain</td>
<td>VAS</td>
<td>17.6</td>
<td>7.4</td>
<td>6.2 ± 8.2a</td>
<td>35.7 ± 25.3b</td>
<td>54.1 ± 26.8c</td>
<td>52.4 ± 25.7c</td>
</tr>
<tr>
<td>PROMIS Pain Intensity</td>
<td>SF</td>
<td>4.1</td>
<td>5.7</td>
<td>38.4 ± 7.3a</td>
<td>46.3 ± 6.4b</td>
<td>48.7 ± 6.6b</td>
<td>50.3 ± 8.4b</td>
</tr>
<tr>
<td>PROMIS Pain Interfere</td>
<td>CAT</td>
<td>4.9</td>
<td>5.8</td>
<td>46.6 ± 7.9a</td>
<td>55.4 ± 8.4b</td>
<td>59.2 ± 4.7b</td>
<td>60.1 ± 10.7b</td>
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<tr>
<td>Fatigue</td>
<td>VAS</td>
<td>16.8</td>
<td>6.2</td>
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<td>PROMIS Fatigue</td>
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<td>5.1</td>
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<td>58.0 ± 5.2b</td>
<td>58.1 ± 8.1b</td>
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<td>PROMIS Fatigue</td>
<td>CAT</td>
<td>5.6</td>
<td>6.2</td>
<td>46.2 ± 8.8a</td>
<td>55.3 ± 8.7b</td>
<td>60.0 ± 6.8c</td>
<td>62.0 ± 11.3c</td>
</tr>
<tr>
<td>mHAQ*</td>
<td>Scale</td>
<td>.2</td>
<td>5.2</td>
<td>0.1 ± 0.4a</td>
<td>0.3 ± 0.3a</td>
<td>0.5 ± 0.4b</td>
<td>0.7 ± 0.6b</td>
</tr>
<tr>
<td>PROMIS PF</td>
<td>CAT</td>
<td>-5.2</td>
<td>-6.7</td>
<td>50.4 ± 9.0a</td>
<td>43.0 ± 7.5b</td>
<td>38.7 ± 5.6c</td>
<td>35.2 ± 7.1c</td>
</tr>
<tr>
<td>PROMIS Anxiety</td>
<td>CAT</td>
<td>2.2</td>
<td>2.6</td>
<td>48.0 ± 7.5a</td>
<td>52.0 ± 9.1b</td>
<td>51.9 ± 7.3a,b</td>
<td>55.6 ± 8.2b</td>
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<td>CAT</td>
<td>2.2</td>
<td>2.6</td>
<td>48.0 ± 7.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>52.0 ± 9.1&lt;sup&gt;b&lt;/sup&gt;</td>
<td>51.9 ± 7.3&lt;sup&gt;a,b&lt;/sup&gt;</td>
<td>55.6 ± 8.2&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>PROMIS Depression</td>
<td>CAT</td>
<td>2.4</td>
<td>2.6</td>
<td>47.1 ± 8.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>49.5 ± 9.3&lt;sup&gt;a&lt;/sup&gt;</td>
<td>51.5 ± 9.1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>54.4 ± 9.1&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>PROMIS Anger</td>
<td>CAT</td>
<td>2.0</td>
<td>2.1</td>
<td>45.2 ± 8.4</td>
<td>46.8 ± 9.7</td>
<td>49.5 ± 11.1</td>
<td>51.1 ± 8.9</td>
</tr>
<tr>
<td>PROMIS Participation</td>
<td>CAT</td>
<td>-4.9</td>
<td>-5.9</td>
<td>55.9 ± 9.3&lt;sup&gt;a&lt;/sup&gt;</td>
<td>50.0 ± 8.4&lt;sup&gt;b&lt;/sup&gt;</td>
<td>46.2 ± 6.3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>40.7 ± 8.6&lt;sup&gt;b,c&lt;/sup&gt;</td>
</tr>
<tr>
<td>PROMIS Satisfaction</td>
<td>CAT</td>
<td>-5.0</td>
<td>-5.2</td>
<td>55.3 ± 10.0&lt;sup&gt;a&lt;/sup&gt;</td>
<td>47.3 ± 10.1&lt;sup&gt;b&lt;/sup&gt;</td>
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Conclusions

- Our preliminary data suggest that the integration of PROMIS CATs and short forms is possible within clinical care settings.
- The immediate availability of results allows for evaluation and discussion with patients at the time of the clinic visit.
- Our preliminary assessments indicate that PROMIS measures demonstrate considerable impact of RA across multiple areas of HRQL.
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  - Brandy Miles
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  - Bonnie Hebden

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  - David Cella PhD
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  - Sarah Hewlett RN PhD
  - Enkeleida Nikai
  - Amye Leong MBA
  - Kelly Young
  - Ernest Choy MD PhD