Title: Incorporating Patient-Centered Outcomes into Real World Data

Abstract

Patient-reported outcomes (PROs) are reports of health conditions that come directly from patients and gathering PROs are an important component to improve the health of individuals and populations. In this lecture, the definition of PROs will be discussed and placed in the context of diabetes care. Additionally, best practices for collecting PROs and implementing the use of PROs in clinical care will be discussed. Lastly, future challenges to the collection and use of PROs in clinical care will be introduced.

Reference List


Incorporating Patient-Centered Outcomes into Real World Data

ADA Research Symposium – November 2018

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Chicago Center for Diabetes Translational Research
Section of General Internal Medicine

Funding / Disclosures

• Member of Chicago Center for Diabetes Translation Research (NIDDK P30)
• ADA Junior Faculty Development Award
• AHRQ U18HS026151 (PORTAL-Depression)
• UChicago Bucksbaum Institute for Clinical Excellence
• UChicago Center for Healthcare Delivery Science and Innovation
Outline

- What are patient-reported outcomes (PROs)?
- How to collect PROs?
- What do you do with PROs?
- Future challenges

What are patient-reported outcomes (PROs)?
Definition

“A PRO is 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”
Definition

“A PRO is 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”

Integrating PROs into clinical care has been associated with:
- Increased patient satisfaction with care
- Better communication
- Better symptom management
- Better health quality
- Fewer hospitalizations / ER visits
- Longer survival

"PROs provide a complementary perspective to that of clinician assessments, and may provide greater insights into health status, function, symptom burden, adherence, health behaviors, and quality of life”
Patient-Reported Outcomes

Chair: Kevin Weintraub
NHS Representatives: Susan Czajkowski, William Riley
Members: Anne Berk, M. Fernanda Belloso, Gloria Coronado, Richard Deyo, Janna Friedly, Erik Hess, Tamara Isakova, Francis Keefe, Chris Kneipke, Margaret Kuikinksi, Amy Lorre, Dana Miskulin, Brett Moran, Ashih Owen-Smith, Pamela Peterson, Stacy Sterling, Jon Tiburt, James Tubby, Doug Zlock
Project Manager: Mario Mencini

rethinkingclinicaltrials.org/cores-and-working-groups/patient-reported-outcomes-2/

Patient-Reported Outcomes in Diabetes

Neuroscience Center Building
6001 Executive Boulevard
Rockville, MD

November 6 - 7, 2017

• Depression, anxiety, suicidality
• Distress
• Fear of hypoglycemia
• Health-related quality of life
How to collect PROs?

How (perhaps) NOT to collect PROs

1. Ask physicians to collect PROs
How (perhaps) NOT to collect PROs

2. Collect the same PRO for every patient at every visit (IMO)
   CAVEAT: if the status of the PRO changes frequently

NAMCS: https://www.cdc.gov/nchs/data/databriefs/db212_fig1.png
How TO collect PROs

1. Leverage Health IT

If PHQ-9 score ≥ 10, Smart Set option appears

How TO collect PROs

Effects of Faculty Peer Comparison Feedback

2. Encourage collection
Medical Assistant screening:
27.3% (n=53569) to 59.0% (n=19129), $p<0.0001$

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How TO collect PROs

3. Assign medical assistants to collect data during triage

4. Move it outside of the 15 minute clinical visit
   - Patient portals (pre-visit)
   - Telephone calls (pre-visit)
   - Waiting areas (pre-visit) (tablets)
   - Patient portals (population health?)

PORTAL-Depression (AHRQ U18HS026151)
Randomized trials:
1. To test whether using MyChart can increase rates of population-level depression screening
2. To test whether using MyChart can increase depression remission in patients with active depression
What do you do with PROs?

Depression Screening and Management

- **PHQ-2**
  - **PHQ-2 ≤ 3**
    - Negative screen
    - Use suicide screener OR Escort to ER
  - **PHQ-2 ≥ 3**
    - Positive screen
    - PHQ-9
    - **Suicidal OR homicidal / psychosis**

1. **Mild**
   - PHQ-9: 5-9
   - **CAT-DI: 30-49**
   - Patient education

2. **Moderate**
   - PHQ-9: 10-14
   - **CAT-DI: 65-79**
   - Patient education

3. **Moderately Severe**
   - PHQ-9: 15-19
   - **CAT-DI: 65-79**
   - Patient education

4. **Severe**
   - PHQ-9: ≥ 20
   - **CAT-DI: ≥ 80**
   - Patient education

**Measures**

- PHQ-9 every 4-6 weeks via MyChart, phone, or in person

**Options**

- Continue antidepressant ≥ 6 mo
- Increase, augment, or switch antidepressant AND/OR initiate therapy
- If ≥3 months, consider Psychiatry

**Medications**

- **SSRIs**
  - Escitalopram (Lexapro) 10 mg/d → 10-20 mg/d
  - Sertraline (Zoloft) 50 mg/d → 50-200 mg/d
  - Fluoxetine (Prozac) 20 mg/d → 20-60 mg/d
  - Paroxetine (Paxil) 20 mg/d → 20-60 mg/d

- **SNRIs**
  - Venlafaxine ER (Effexor XL) 37.5-75 mg/d → 75-375 mg/d

- **NDRIs**
  - Buproprion XL (Wellbutrin XL) 150 mg/d → 150-300 mg/d

**Other Treatments**

- **AUGMENT**
  - Buspirone 7.5-15mg BID
  - Aripiprazole 5-10 mg daily

**Development**

- Developed by the UChicago Medicine Primary Care Group- Behavioral Health Integration Program
- Primary Care Behavioral Health Integration Director: Neda Laiteerapong, MD, MS
- Last updated 11/14/2018
## Behavioral Health SmartSet

**2. Integrate decision support into day to day clinical care**

<table>
<thead>
<tr>
<th>From BestPractice</th>
<th>Your patient screened positive for depression (on a PHQ-9). Please utilize the following SmartSet to address the issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orders, Dx and Instructions</strong></td>
<td><strong>Orders</strong></td>
</tr>
<tr>
<td></td>
<td>Consult to Behavioral Health - Individual</td>
</tr>
<tr>
<td></td>
<td>Consult to Psychiatry</td>
</tr>
<tr>
<td><strong>Patient Instructions</strong></td>
<td>Behavioral Medicine Intake Line</td>
</tr>
<tr>
<td></td>
<td>Depression (Discharge Care) (English)</td>
</tr>
<tr>
<td></td>
<td>Anxiety (Discharge Care) (English)</td>
</tr>
<tr>
<td></td>
<td>Stress (Discharge Care) (English)</td>
</tr>
<tr>
<td></td>
<td>Community Mental Health Resources</td>
</tr>
</tbody>
</table>

## Co-located BMED Clinic

**3. Advocate for more resources as necessary**

### Curbside Consults

- Warm hand-offs

During warm hand-offs, patients will often get a full therapy session

<table>
<thead>
<tr>
<th>Fabiana Araujo, Ph.D.</th>
<th>Nancy Beckman, Ph.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Health Consultant</td>
<td>Behavioral Health Consultant</td>
</tr>
<tr>
<td>Monday Afternoons &amp; Tuesday Mornings</td>
<td>Wednesday Afternoons</td>
</tr>
</tbody>
</table>
Results: Screening by Demographics

Gender
- Female

Age
- 40-64

Race
- Asian
- Black/AA
- Other

4. Examine for disparities in PROs data collection

Odds Ratio

p = 0.001, Ho rejected using Hochberg multiple comparisons adjustment

Future challenges
Challenge 1: Content Validity

• Unclear match between PRO and intended claim

• Lack of direct patient input into PRO content from target population

• No evidence that most relevant and important item content is contained in instrument

• Lack of documentation to support modifications to PRO instrument

Challenge 2: External Validity

Validation of the Computerized Adaptive Test for Mental Health in Primary Care

Andrea K. Graham, PhD\textsuperscript{1}, Alexa Minc, BA, BFA\textsuperscript{2}, Erin Staab, MPH\textsuperscript{3}, David G. Beiser, MD, MS\textsuperscript{4}, Robert D. Gibbons, PhD\textsuperscript{5}, and Neda Laiteerapong, MD, MS\textsuperscript{5}

<table>
<thead>
<tr>
<th>Major Depressive Disorder</th>
<th>CAD-MDD</th>
<th>PHQ-9</th>
<th>PHQ-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.77</td>
<td>0.75</td>
<td>0.58</td>
</tr>
<tr>
<td>Specificity</td>
<td>0.93</td>
<td>0.94</td>
<td>0.93</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>0.57</td>
<td>0.62</td>
<td>0.52</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>0.97</td>
<td>0.97</td>
<td>0.95</td>
</tr>
<tr>
<td>AUC [95% CI]</td>
<td>0.85 [0.76-0.94]</td>
<td>0.84 [0.75-0.94]</td>
<td>0.76 [0.65-0.87]</td>
</tr>
</tbody>
</table>

Accepted in Annals of Family Medicine
Challenge 3: Volume

- PROMIS® measures
  - over 300 measures of physical, mental, and social health
  - Short forms, unidimensional CATs, profiles

- PROMIS® measures in EPIC
  - 2012 – limited short-forms
  - 2017 – CATs
  - Doesn’t come for free

- Multi-dimensional CATs can decrease question burden without sacrificing precision

Challenge 4: Stagnation

- EHR Access to Seamless Integration of PROMIS®
  - 6.3 M NCATS grant
  - Justin Starren, PI (Northwestern)
  - David Liebovitz, site PI (UChicago)
  - 9 universities

  Northwestern
  University of Chicago
  University of Illinois at Chicago
  University of Alabama at Birmingham
  University of Kentucky

  University of Florida
  University of Utah
  Harvard Catalyst CTS
  Southern California CTSI
Summary

• PROs are important outcomes to integrate into diabetes care and research
• PROs collection should consider
  – Time and timing
  – Staffing
  – Seamless integration, clinical decision support tools
  – Leveraging health IT
• Many future challenges
  – Validity – content, external
  – Stagnation – implementation, volume

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