The Promise of PROs (Patient-Reported Outcomes)

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Johns Hopkins Schools of Medicine and Public Health
November 1, 2018
Claire Snyder, PhD

• Research funding to institution from Genentech
• Travel support from Optum (to present at the 2017 ISPOR European Congress)
Objectives

At the conclusion of this activity, the participant should be able to describe the role of PROs for:

1. Monitoring and managing individual patients
2. Conducting clinical trials and comparative effectiveness research
3. Evaluating the quality of care
Patient-Reported Outcomes (PROs)

• “Patient-reported outcomes represent the patient’s report of a health condition and its treatment” (Acquadro et al. Value in Health 2003;5:522-531)

• “Any report coming directly from patients (i.e., study subjects) about a health condition and its treatment” (FDA Draft PRO Guidance)
1. Individual Patient Monitoring

- Promote patient-clinician communication
- Monitor progress
- Inform management
- Improve outcomes
Improved Quality of Life

Fig 2. Proportion of patients with health-related quality-of-life changes at 6 months compared with baseline. The proportion of patients in each study arm who showed improvement or deterioration in the EuroQol EQ-5D Index scores improved, remained unchanged, or worsened by any amount at 6 months compared with baseline. This analysis was repeated using a threshold for change of six or more points, an amount considered to be clinically meaningful in US cancer populations.

Basch et al. JCO 2015;34:557-565
More Efficient Resource Use

Basch et al. JCO 2015;34:557-565
Improved Survival

Figure. Overall Survival Among Patients With Metastatic Cancer Assigned to Electronic Patient-Reported Symptom Monitoring During Routine Chemotherapy vs Usual Care

Crosses indicate censored observations. Enrollment in the patient-reported symptom monitoring group was enriched for a preplanned subgroup with low baseline computer experience as part of a feasibility substudy with a 2:1 randomization ratio in that subgroup (N = 227) and a 1:1 ratio in the computer-experienced subgroup (N = 539), yielding 441 participants in the patient-reported symptom monitoring group, and 325 in the usual care group. With a minimum follow-up of 5.4 years, median follow-up was 6.9 years (interquartile range, 6.5-7.7) for the electronic patient-reported symptom monitoring group and 7 years (interquartile range, 6.6-8.1) for the usual care group.

JAMA Published online June 4, 2017

Basch et al. JAMA 2017 [Epub June 4]
• US national cluster RCT comparing usual care vs. weekly symptom reports with alerts to nurses for severe/worsening symptoms

• 50 community oncology sites, N=1000 patients with metastatic cancers

• Outcomes: physical function, survival, symptom control, ER/hospitalization, chemotherapy use, satisfaction

• Assessment of implementation strategies for PROs in practice

Slide courtesy of Sydney Henson and Ethan Basch, MD, MSc-University of North Carolina at Chapel Hill
• Helps clinicians and researchers interested in implementing PRO assessment to aid patient care

• Includes
  – Considerations
  – Options
  – Resource requirements
  – Relative advantages and disadvantages

Available at:
Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations

Claire F. Snyder · Neil K. Aaronson · Ali K. Checair · Thomas E. Elliott · Joanne Greenhalgh · Michele Y. Halyard · Rachel Hess · Deborah M. Miller · Bryce B. Reeve · Maria Santana

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Abstract
Purpose While clinical care is frequently directed at making patients “feel better,” patients’ reports on their functioning and well-being (patient-reported outcomes [PROs]) are rarely collected in routine clinical practice. The International Society for Quality of Life Research (ISOQOL) has developed a User’s Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice. This paper summarizes the key issues from the User’s Guide.
Methods Using the literature, an ISOQOL team outlined considerations for using PROs in clinical practice; options for designing the intervention; and strengths, weaknesses, and resource requirements associated with each option.
Results Implementing routine PRO assessment involves a number of methodological and practical decisions, including (1) identifying the goals for collecting PROs in clinical practice, (2) selecting the patients, setting, and timing of assessments, (3) determining which questionnaire(s) to use, (4) choosing a mode for administering and scoring the questionnaire, (5) designing processes for reporting results, (6) identifying aids to facilitate score interpretation, (7) developing strategies for responding to issues identified by the questionnaires, and (8) evaluating the impact of the PRO intervention on the practice.
Conclusions Integrating PROs in clinical practice has the potential to enhance patient-centered care. The online version of the User’s Guide will be updated periodically.

This paper is produced on behalf of the International Society for Quality of Life Research (ISOQOL). All authors are members of ISOQOL. All authors participated in writing the paper and reviewing the drafts. The manuscript was reviewed and approved by the ISOQOL Board of Directors as an ISOQOL publication and does not reflect an endorsement of the ISOQOL membership.
Topics Covered

1. Identifying the goals for collecting PROs in clinical practice
2. Selecting the patients, setting, and timing of assessments
3. Determining which questionnaire(s) to use
4. Choosing a mode for administering and scoring the questionnaire
5. Designing processes for reporting results
6. Identifying aids to facilitate score interpretation
7. Developing strategies for responding to issues identified by the questionnaires
8. Evaluating the impact of the PRO intervention on the practice
3-Part Mixed Methods Study

1. To what extent do current practices of PRO reporting limit clinician and patient understanding and use? What are the most/least desirable attributes of current practices?

2. What are novel ways to present PRO results to clinicians and patients to improve their usefulness?

3. Are these novel ways of presenting PROs effective in improving understanding and use of the data?
Communicating patient-reported outcome scores using graphic formats: results from a mixed-methods evaluation

Michael D. Brundage⁠¹. Katherine C. Smith⁠²,⁴. Emily A. Little⁣⁴. Elissa T. Bantug⁡. Claire F. Snyder⁠²,⁳,⁴. The PRO Data Presentation Stakeholder Advisory Board

Engaging stakeholders to improve presentation of patient-reported outcomes data in clinical practice


Graphical displays of patient-reported outcomes (PRO) for use in clinical practice: What makes a pro picture worth a thousand words?

Approach: Part 3

Individual Patient Data

- Presented to Patients & Clinicians
  - Internet Survey (n=1113)
    - Patients (n=627)
    - Clinicians (n=236)
    - Researchers (n=250)
  - 1-on-1 Interviews
    - Patients (n=10)
    - Clinicians (n=10)

Research Study Data

- Presented to Patients
  - Internet Survey (n=1017)
    - Patients (n=629)
    - Clinicians (n=139)
    - Researchers (n=249)
  - 1-on-1 Interviews
    - Patients (n=10)
    - Clinicians (n=10)

- Presented to Clinicians
  - Internet Survey (n=481)
    - Clinicians (n=233)
    - Researchers (n=248)
  - 1-on-1 Interviews
    - Clinicians (n=10)
What Do These Scores Mean? Presenting Patient-Reported Outcomes Data to Patients and Clinicians to Improve Interpretability

Claire F. Snyder, PhD1,2,3; Katherine C. Smith, PhD2,3; Elissa T. Bantug, MHS1; Elliott E. Tolbert, PhD1,2; Amanda L. Blackford, ScM3; and Michael D. Brundage, MD, MSc4; and the PRO Data Presentation Stakeholder Advisory Board

Original Article

Medical Decision Making
1–12
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journals.sagepub.com/home/mdm

Picture This: Presenting Longitudinal Patient-Reported Outcome Research Study Results to Patients

Elliott Tolbert, Michael Brundage, Elissa Bantug, Amanda L. Blackford, Katherine Smith, Claire Snyder, and PRO Data Presentation Stakeholder Advisory Board

Presenting comparative study PRO results to clinicians and researchers: beyond the eye of the beholder

Michael Brundage1,2; Amanda Blackford2; Elliott Tolbert3,4; Katherine Smith5,7; Elissa Bantug2; Claire Snyder3,4,7; PRO Data Presentation Stakeholder Advisory Board (various names and locations)
Modified-Delphi Process

• Conduct Pre-Meeting Webinar
  – Orient to meeting process
  – Review evidence base for choices
• Develop Delphi Survey
• Administer Delphi Survey
  – Assess initial levels of agreement
• Share Survey Results
  – Summarize areas of agreement/disagreement
• Meet in Person to Develop Consensus
• Post-Meeting Survey
Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data

Claire Snyder¹,²,³ · Katherine Smith²,³ · Bernhard Holzner⁴ · Yonaira M. Rivera² · Elissa Bantug² · Michael Brundage⁵ · PRO Data Presentation Delphi Panel

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Patient's results for levels of function

**Physical Function**
(Line going up means better able to do physical activities)

- Very High
- Moderate
- Poor
- Very Poor

Results below the red line are possibly concerning.

**Emotional Function**
(Line going up means better emotional well-being)

- Very High
- Moderate
- Poor
- Very Poor

Results below the red line are possibly concerning.

Patient's results for symptoms

**Fatigue**
(Line going up means worse fatigue)

- Severe
- Moderate
- Mild
- None

Results above the red line are possibly concerning.

**Pain**
(Line going up means worse pain)

- Severe
- Moderate
- Mild
- None

Results above the red line are possibly concerning.
A PRO-cision Medicine Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes

- Identify and evaluate approaches to aid interpretation of PRO scores
- Identify and evaluate methods to develop guidance for acting on PRO issues

Funded by Genentech
Topics Covered

1. Identifying the goals for collecting PROs in clinical practice
2. Selecting the patients, setting, and timing of assessments
3. Determining which questionnaire(s) to use
4. Choosing a mode for administering and scoring the questionnaire
5. Designing processes for reporting results
6. Identifying aids to facilitate score interpretation
7. Developing strategies for responding to issues identified by the questionnaires
8. Evaluating the impact of the PRO intervention on the practice
Advances in the Use of Patient Reported Outcome Measures in
Electronic Health Records

Including Case Studies

Albert W. Wu, MD, MPH
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Roxanne E. Jensen, PhD
Lombardi Comprehensive Cancer Center
Georgetown University, Washington, DC

Claudia Salzberg, MS
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Claire Snyder, PhD
Johns Hopkins University School of Medicine, Baltimore, MD

In support of the PCORI National Workshop to Advance the Use of PRO measures in
Electronic Health Records
Atlanta, GA. November 19-20, 2013

<table>
<thead>
<tr>
<th>#</th>
<th>System Affiliation (Name)</th>
<th>Initial Population</th>
<th>Multiple Sites/Clinics</th>
<th>Multiple Populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Epic Systems Corporation (MyChart, EpicCare)</td>
<td>Epic Users</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>Dartmouth Spine Center</td>
<td>Spine</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>3</td>
<td>Cleveland Clinic (Knowledge Program)</td>
<td>Neurological Disorders</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>4</td>
<td>Group Health Cooperative (Health Profile e-HRA)</td>
<td>General</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>5</td>
<td>Cincinnati Children’s Hospital</td>
<td>Rheumatology</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>6</td>
<td>Kaiser Permanante Colorado (PATHWAAY)</td>
<td>Older Adults</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>7</td>
<td>Essentia Health (MN Community Measurement)</td>
<td>Depression</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>8</td>
<td>University of Pittsburgh Medical Center</td>
<td>Primary Care</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>9</td>
<td>Duke University (Patient Care Monitor)</td>
<td>Cancer</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>10</td>
<td>UCLA/Michigan (My GI-Health)</td>
<td>GI Disorders</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>11</td>
<td>University of Washington/ Centers for AIDS Research Networks of Clinical Systems</td>
<td>HIV</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>
Need for Guidance

• Increasing interest in the topic of PROs in EHRs
  – PCORI-sponsored meeting reviewing the use of PROs in EHRs (November 2013)
  – NIH collaboratory meeting on barriers to routine collection of PROs for EHRs (January 2015)

• Need for:
  – Guidance on the steps involved in integrating PROs in EHRs
  – Opportunity for voluntary consortia to collect PRO-EHR data to enable pooling
Users’ Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

Prepared For PCORI By:
Johns Hopkins University, Baltimore, MD

May 2017

Steering Group

Ethan Basch, MD, MSc Lineberger Comprehensive Cancer Center at the University of North Carolina-Chapel Hill

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Ashley Wilder Smith, PhD National Cancer Institute

*We appreciate the previous service on the Steering Group of Jamie Skipper, PhD, and Caroline Coy, MPH, from the ONCHIT
Covering…

- Strategy for Linkage
- Governance
- Training & Engaging
- Patients/Populations
- Outcomes
- Measure Evaluation
- Questionnaire Administration
- Score Display
- Acting on Results
- Data Pooling
- Ethical/Legal Issues

- Including…
  - Considerations
  - Options
  - Relative advantages and disadvantages

Similar to ISOQOL Users’ Guide

• ISOQOL Users’ Guide focuses on use of PROs in Clinical Practice, in general
• PRO-EHR Users’ Guide focuses specifically on integrating PROs in EHRs
• ISOQOL was a collaborating partner

Available at:
2. Clinical Trials/Comparative Effectiveness Research

- Clinician understanding of treatment impacts and patient counseling
- Patient educational materials/decision-aids
- Shared decision-making
A knowledge translation challenge: clinical use of quality of life data from cancer clinical trials

Michael Brundage • Brenda Bass • Ringash Jolie • Kimberley Foley

42% Feel comfortable interpreting quality of life data from the clinical trial literature

67% Feel need to improve/increase use of clinical trial quality of life data in clinical practice
More willing to have chemotherapy

Strength of Treatment Preference

Less willing to have chemotherapy

Small-magnitude HRQL difference  Large-magnitude HRQL difference

Mean Pre = 5.3  Mean Post = 5.5  Mean Pre = 5.1  Mean Post = 4.6

Pre-HRQL Post-HRQL Pre-HRQL Post-HRQL
The PROTEUS Consortium - 

**Patient-Reported Outcome Tools:** 
**Engaging Users & Stakeholders**

**Objective:** Ensure that patients, clinicians, and other decision-makers have PRO data from clinical trials to make the best decisions they can about treatment options.

**Approach:** Partner with key stakeholder groups to disseminate and implement tools that have been developed to optimize the use of PROs in clinical trials.
# PRO Tools for PROTEUS

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<th>PURPOSE</th>
<th>TOOL</th>
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<td>Writing PRO protocols</td>
<td>Standard Protocol Items: Recommendations for Interventional Trials-PRO Extension (SPIRIT-PRO)</td>
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<td>Selecting PRO measures</td>
<td>ISOQOL Minimum Standards for PRO Measures in Patient-Centered and Comparative Effectiveness Research</td>
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<tr>
<td>Analyzing PRO data</td>
<td>Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data (SISAQOL) Consortium</td>
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<tr>
<td>Reporting PRO findings</td>
<td>Consolidated Standards of Reporting Trials-PRO Extension (CONSORT-PRO)</td>
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<tr>
<td>Displaying PRO results</td>
<td>Stakeholder-Driven, Evidence-Based Standards for Presenting PROs in Clinical Practice</td>
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<td>Interpreting PRO papers</td>
<td>Clinicians Checklist for Reading and Using an Article about PROs</td>
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Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols
The SPIRIT-PRO Extension

Melanie Calvert, PhD; Derek Kyte, PhD; Rebecca Mercieca-Bebber, PhD; Anita Slade, PhD; An-Wen Chan, MD, DPhil; Madeleine T. King, PhD; and the SPIRIT-PRO Group

**IMPORTANCE** Patient-reported outcome (PRO) data from clinical trials can provide valuable evidence to inform shared decision making, labeling claims, clinical guidelines, and health policy; however, the PRO content of clinical trial protocols is often suboptimal. The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement was published in 2013 and aims to improve the completeness of trial protocols by providing evidence-based recommendations for the minimum set of items to be addressed, but it does not provide PRO-specific guidance.

**OBJECTIVE** To develop international, consensus-based, PRO-specific protocol guidance (the SPIRIT-PRO Extension).
ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research

Bryce B. Reeve · Kathleen W. Wyrwich · Albert W. Wu · Galina Velikova · Caroline B. Terwee · Claire F. Snyder · Carolyn Schwartz · Dennis A. Revicki · Carol M. Moinpour · Lori D. McLeod · Jessica C. Lyons · William R. Lenderking · Pamela S. Hinds · Ron D. Hays · Joanne Greenhalgh · Richard Gershon · David Feeny · Peter M. Fayers · David Cella · Michael Brundage · Sara Ahmed · Neil K. Aaronson · Zeeshan Butt

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Analysing data from patient-reported outcome and quality of life endpoints for cancer clinical trials: a start in setting international standards

Dr Andrew Bottomley, PhD, Madeline Pe, PhD, Jeff Sloan, PhD, Ethan Basch, MD, Franck Bonnetain, PhD, Melanie Calvert, PhD, Aca A, PhD, Charles Cleeeland, MD, Kim Cocks, PhD, Laurence Collette, PhD, Amylau C Dueck, PhD, Nancy Devlin, PhD, Hans-Henning Flechtn, MD, Carolyn Gotay, PhD, Eva Greimel, PhD, Ingolf Griebisch, PhD, Mogens Groenvold, MD, Jean-Francois Hamel, PhD, Madeleine King, PhD, Paul G Kluetz, MD, Michael Koller, PhD, Daniel C Malone, PhD, Francesca Martinelli, MSc, Sandra A Mitchell, PhD, Carol M Moinpour, PhD, Jamilje Musoro, PhD, Daniel O'Connor, MBChB, Kathy Oliver, BA, Elisabeth Piault-Louis, PharmD, Martine Piccart, MD, Francisco L Pimentel, MD, Chantal Quinten, MSc, Jaap C Reijneveld, MD, Christoph Schürmann, PhD, Ashley Wilder Smith, PhD, Katherine M Soltys, MD, Martin J Taphorn, MD, Galina Velikova, MD, Corneel Coens, MSc for the Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data (SISAQOL) consortium

Published: 18 October 2016

Abstract

Background: There is currently a lack of consensus on how health-related quality of life and other patient-reported outcome measures in cancer randomized clinical trials are analyzed and interpreted. This makes it difficult to compare results across randomized controlled trials (RCTs) and synthesize scientific research, and use that evidence to inform product labeling, clinical guidelines, and health policy. The Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data for Cancer Clinical Trials (SISAQOL) Consortium aims to develop guidelines and recommendations to standardize analyses of patient-reported outcome data in cancer RCTs.

Methods and Results: Members from the SISAQOL Consortium met in January 2017 to discuss relevant issues. Data from systematic reviews of the current state of published research in patient-reported outcomes in cancer RCTs indicated a lack of clear reporting of research hypothesis and analytic strategies, and inconsistency in terms of the data, including missing data, health-related quality of life, and patient-reported outcome.

Conclusion: The quality of the Consortium guidelines and recommendations is informed and enhanced by the broad Consortium membership, which includes regulators, patients, clinicians, and scientific research.
Reporting of Patient-Reported Outcomes in Randomized Trials
The CONSORT PRO Extension

Melanie Calvert, PhD
Jane Blazey, MD
Douglas G. Altman, DSc
Dennis A. Revicki, PhD
David Moher, PhD
Michael D. Brundage, MD
for the CONSORT PRO Group

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials (RCTs); however, it lacks guidance on the reporting of patient-reported outcomes (PROs), which are often inadequately reported in trials, thus limiting the value of these data. In this article, we describe the development of the CONSORT PRO extension based on the methodological framework for guideline development proposed by the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network. Five CONSORT PRO checklist items are recommended for RCTs in which PROs are primary or important secondary endpoints. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypotheses of the PROs and relevant domains be provided (ie, if a multidimensional PRO tool has been used), that evidence of the PRO instrument’s validity and reliability be provided or cited, that the statistical approaches for dealing with missing data be explicitly stated, and that PRO-specific limitations of study findings and generalizability of results to other populations and clinical practice be discussed. Examples and an updated CONSORT flow diagram with PRO items are provided. It is recommended that the CONSORT PRO guidance supplement the standard CONSORT guidelines for reporting RCTs with PROs as primary or secondary outcomes. Improved reporting of PRO data should facilitate robust interpretation of the results from RCTs and inform patient care.

Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data

Claire Snyder¹,²,³ · Katherine Smith²,³ · Bernhard Holzner⁴ · Yonaira M. Rivera² · Elissa Bantug² · Michael Brundage⁵ · PRO Data Presentation Delphi Panel

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Clinician’s Checklist for Reading and Using an Article About Patient-Reported Outcomes

Albert W. Wu, MD, MPH, FACP; Anna N. Bradford, PhD, MSW, LCSW; Vic Velandovich, MD; Mirjam A.G. Sprangers, PhD; Michael Brundage, MD, FRCP, MSc; and Claire Snyder, PhD

Abstract

Clinicians need evidence-based medicine to help them make clinical decisions with their patients. For many health problems, the goal of treatment is to help the patient to function and feel better. To measure patient functioning, well-being, and symptoms, questionnaires referred to as patient-reported outcome (PRO) measures are often used. Clinicians are generally not trained in survey design, scale development, and questionnaire administration, making it difficult for them to interpret and effectively use PROs as clinical evidence. It is increasingly important that clinicians be able to understand and use outcomes measured from both the clinical and patient perspectives to inform their practice. We aim to provide a “Clinician's Checklist” to help practicing clinicians understand clinical research articles that include PROs so that the information can be used for decision making. This checklist provides an itemization of important areas for the reader to consider in evaluating research articles. We propose that clinicians consider 5 elements when reading a study using PROs: study design and PRO assessment strategy, PRO measure performance, validity of results, context of the findings, and generalizability to their own patient population. Patient-reported outcomes play an increasingly prominent role in clinical research and practice, and this trend has the potential to improve the patient-centeredness of care. Clinicians will need to understand how to use PROs to partner with patients and help them function and feel better. The proposed Clinician's Checklist can help clinicians systematically evaluate PRO studies by determining whether the study design was appropriate and whether the measurement approach was adequate and properly executed as well as by assisting in the interpretation and application of the results to a specific patient population.
3. Evaluating Care Quality

- Providing performance indicators based on patient perspectives
ASCO Pilot-Test of PRO Performance Measures

Patient-Reported Outcome Performance Measures in Oncology

By Ethan Basch, MD, Claire Snyder, PhD, Kristen McNiff, MPH, Rebecca Brown, Suzanne Maddux, RN, Mary Lou Smith, JD, MBA, Thomas M. Atkinson, PhD, Doris Howell, PhD, RN, Anne Chiang, MD, William Wood, MD, MPH, Nathan Levitan, MD, Albert W. Wu, MD, MPH, FACP, and Monika Krzyzanowska, MD

Lineberger Cancer Center, University of North Carolina, Chapel Hill, NC; Johns Hopkins School of Medicine, Baltimore, MD; American Society of Clinical Oncology, Alexandria, VA; Research Advocacy Network, Plano, TX; Memorial Sloan Kettering Cancer Center, New York, NY; Princess Margaret Hospital, Toronto, Ontario, Canada; Yale Cancer Center, New Haven, CT; University Hospitals Seidman Cancer Center, Cleveland, OH; and Dana-Farber/Harvard Cancer Center, Boston, MA
Development of Cancer PRO-PMs

- ASCO PRO Committee mixed methods work (systematic reviews, stakeholder interviews, surveys, consensus)
- Developed *outcome* measure specifications:
  - % of patients receiving moderately/highly emetogenic chemotherapy with moderate or worse nausea 1 week after treatment (+/- 3 days)
  - % of patients with metastatic cancer with moderate or worse pain
  - % of patients receiving systemic cancer treatment with moderate or worse constipation
- Developed *process* measure specification:
  - % of patients receiving systemic cancer treatment who provide self-reported symptoms 1 week following chemotherapy (+/- 3 d)

Slide courtesy of Ethan Basch, MD, MSc-University of North Carolina at Chapel Hill
Testing Cancer PRO-PMs in U.S.

- PCORI-funded project
  - Led by UNC (PI: Stover & Basch); partnered with ASCO, American Cancer Society, and Research Advocacy Network
  - Mixed methods development work to refine metrics
  - Prospective multicenter U.S. implementation study to:
    - Test feasibility
    - Collect data for adjustment variables
Funding from the Patient-Centered Outcomes Research Institute

- Stakeholder-Driven, Evidence-Based Standards for Presenting Patient-Reported Outcomes in Practice (PI: Snyder & Brundage)
- Integrating the Patient’s Voice in Electronic Health Records (PI: Snyder & Wu)
- Presenting Patient-Reported Outcomes to Promote Patient and Clinician Understanding and Use (PI: Snyder & Brundage)
- Patient-Reported Outcomes in Electronic Health Records: A Landscape Review (PI: Wu)
- Development and Evaluation of a Patient-Centered Approach to Assess Quality of Care: Patient-Reported Outcomes-based Performance Measures (PRO-PMs) (PI: Stover & Basch)
- Electronic Patient Reporting of Symptoms during Outpatient Cancer Treatment: A US National Randomized Controlled Trial (PI: Basch)
Objectives

At the conclusion of this activity, the participant should be able to describe the role of PROs for:

1. Monitoring and managing individual patients
2. Conducting clinical trials and comparative effectiveness research
3. Evaluating the quality of care
Questions?