Navigating the Use of Patient-Reported Outcomes in Research and Practice: The PROTEUS Consortium

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Project Scientists

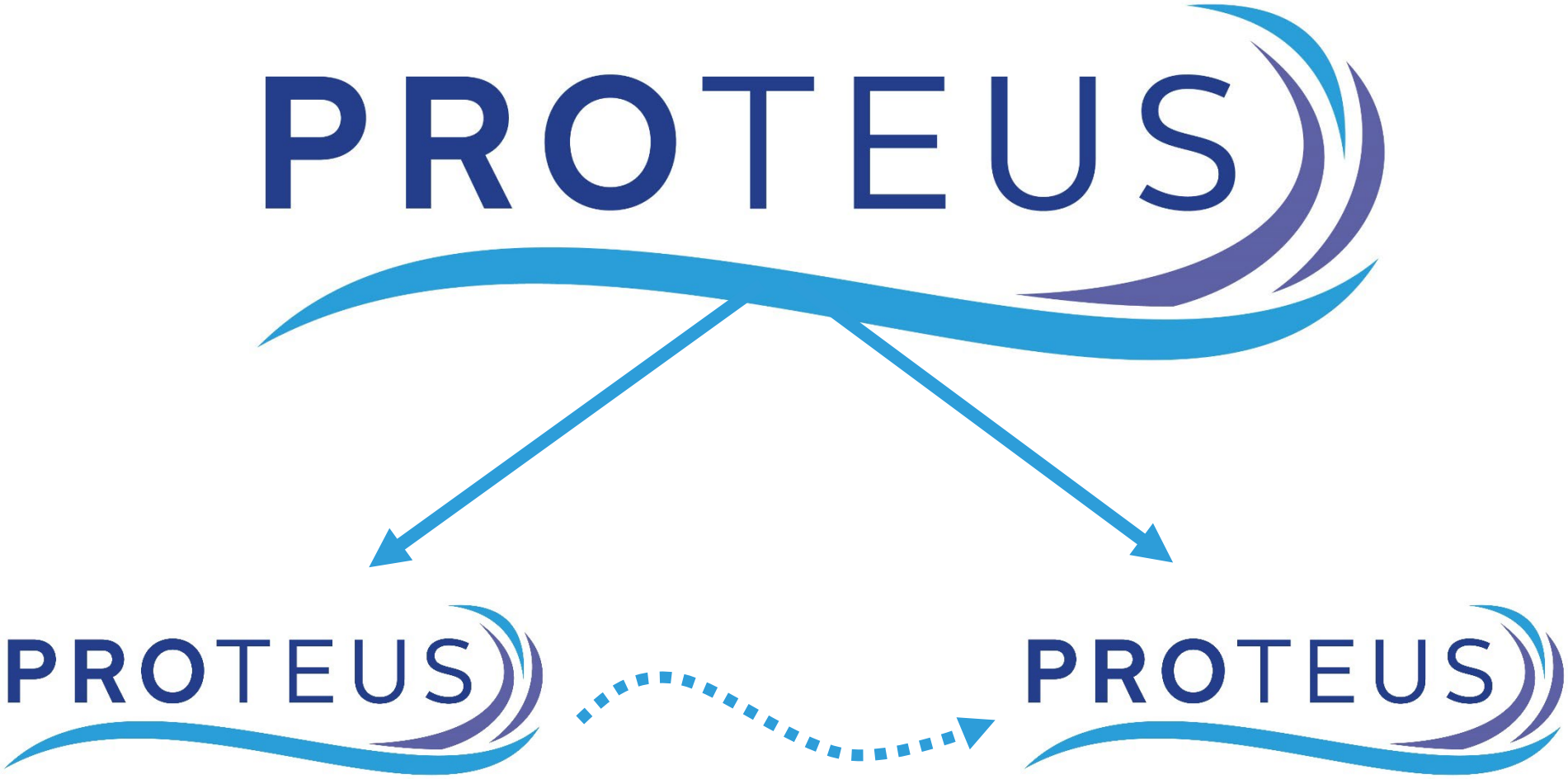
PROTEUS

CONSORTIUM

Patient-Reported Outcomes Tools: Engaging Users & Stakeholders

TheProteusConsortium.org

Originally funded by the Patient-Centered Outcomes Research Institute and unrestricted funding from Genentech
Ongoing unrestricted support from Pfizer


PROTEUS
PROTEUS
PROTEUS
Trials
Practice

Today's Agenda

- Introduction to the PROTEUS Consortium
- Tools and Resources to Navigate the Use of PROs in Clinical Trials
- "Measuring Once and Cutting Twice"
- The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice: A Synthesis of Resources
- Initiatives to Improve the Use of PROs in Clinical Practice

PROTEUS

The PROTEUS Consortium

- **OBJECTIVE**

  Ensure that patients, clinicians, and other decision-makers have high-quality PRO data from **clinical trials** and **clinical practice** 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 and clinical practice

PROTEUS

Organizations with PROTEUS Participants

Clinician & Patient Advocates

1. American Cancer Society
2. American Society for Radiation Oncology
3. American Society of Clinical Oncology
4. Canadian Association of Radiation Oncology
5. National Coalition for Cancer Survivorship
6. Oncology Nursing Society
7. Patient perspective

Research & Methods Organizations

8. AcademyHealth
9. Consolidated Standards for Reporting of Trials (CONSORT)
10. International Society for Quality of Life Research
11. ISPOR
12. Society for Clinical Trials
13. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
14. International Consortium for Health Outcomes Measurement (ICHOM)
15. medical journal editor perspective

Clinical Trials Groups

16. Australian Clinical Trials Alliance
17. Critical Path Institute PRO Consortium
18. European Organization for the Research and Treatment of Cancer
19. Industry (GSK)
20. National Clinical Trials Network PRO representatives

PROTEUS

**Participation in PROTEUS does not imply endorsement of any particular PRO tools or guidance documents*

Organizations with PROTEUS Participants

Funding & Govt. Agencies

21. European Medicines Agency-Scientific Advice Working Party / Dutch Medicines Evaluation Board
22. Food & Drug Administration - Oncology Center of Excellence
23. HealthCanada
24. Medicines and Healthcare Products Regulatory Agency
25. National Cancer Institute
26. National Institute for Health and Care Excellence
27. Patient-Centered Outcomes Research Institute

Universities & Health Systems

28. AmbuFlex Center for Patient Reported Outcomes (Denmark)
29. Amsterdam University Medical Center and the KLIK PROM Portal
30. CancerAustralia
31. Cancer Care Alberta
32. Centre for Patient Reported Outcomes Research, University of Birmingham (UK)
33. Children's Hospital of Philadelphia
34. Dartmouth Health and The Dartmouth Institute for Health Policy and Clinical Practice
35. Emory University
36. George Washington University
37. Kettering Health
38. MD Anderson
39. Memorial Sloan Kettering Cancer Center
40. Moffitt Cancer Center
41. Northwestern University
42. PROMPT-Care (Australia)
43. PROVE Center at Brigham Health
44. Thomas Jefferson University
45. University of California-Los Angeles
46. University of California-San Francisco
47. University of Michigan
48. University of North Carolina-Chapel Hill
49. University of Rochester
50. University of Utah Health
51. Washington University in St. Louis
52. West Virginia University

PROTEUS

**Participation in PROTEUS does not imply endorsement of any particular PRO tools or guidance documents*

The PROTEUS Trials Objective

- Ensure that patients, clinicians, and other decision-makers have high-quality PRO data from clinical trials

- Requires a **SMART** approach:
  - **Specifying** the PRO methods appropriately
  - **Measuring** the PROs effectively
  - **Analyzing** the PRO data properly
  - **Reporting** the PRO results clearly
  - **Translating** the PRO findings in practice

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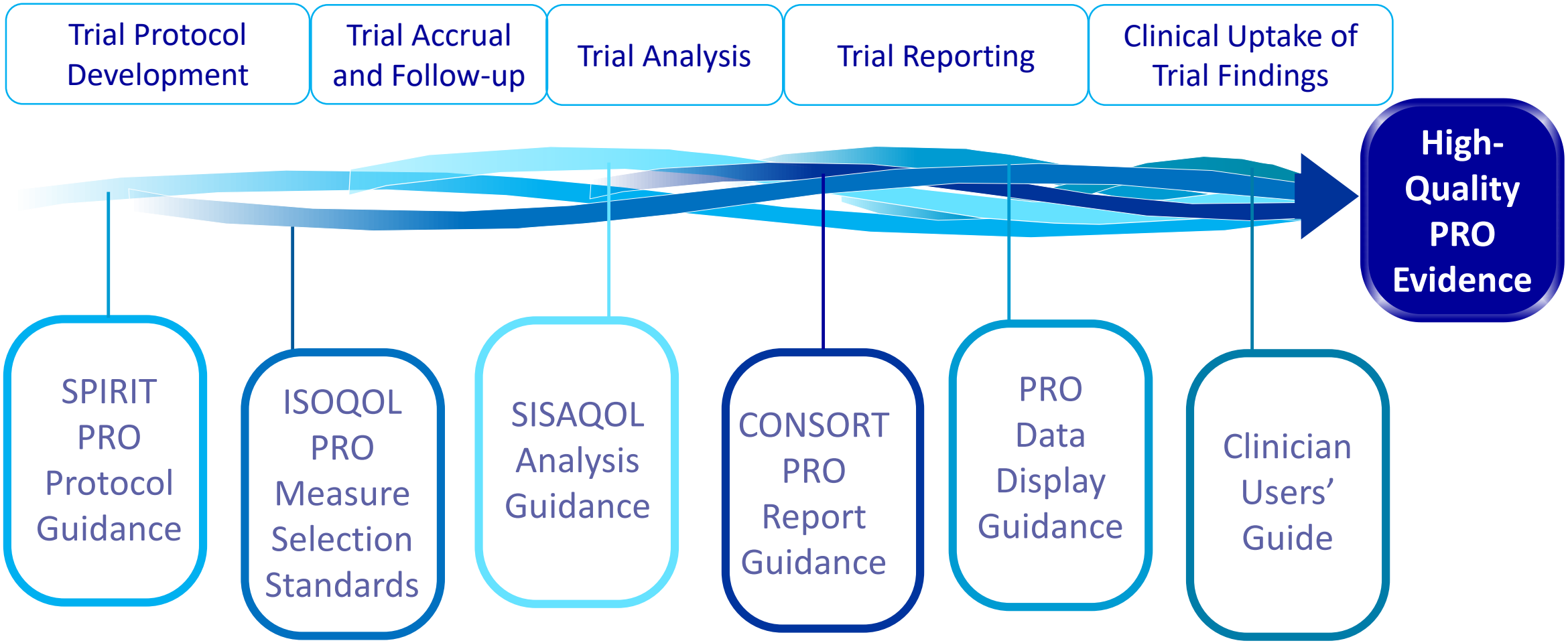
PROTEUS Trials Roadmap



PROTEUS

Clinical Review & Education

JAMA | Special Communication

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).

Editorial page 450

Supplemental content

CME Quiz at jamanetwork.com/learning

Calvert et al, JAMA 2018, 319(5), 483-494

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

Accepted: 17 December 2012 / Published online: 4 January 2013

Reeve et al, Qual Life Res 2013, 22, 1889-1905

Quality of Life Research
https://doi.org/10.1007/s11136-020-02625-z

REVIEW

International guidance on the selection of patient-reported outcome measures in clinical trials: a review

Norah L. Crossnohere[1] · Michael Brundage[2] · Melanie J. Calvert[3] · Madeleine King[4] · Bryce B. Reeve[5] · Elissa Thorner[6] · Albert W. Wu[1,7] · Claire Snyder[1,6,7]

Domain	ISOQOL minimum standards	COSMIN Initiative	EMA appendix 2	FDA PRO	FDA PFDD[a]	MOT review criteria	Red-IRYSS EMPRO[b]
Conceptual & measurement model	√	√	√	√	√	√	√
Reliability	√	√	√	√	√	√	√
Content validity	√	√	√	√	√	√	√
Construct validity	√	√	X	√	√	√	√
Responsiveness	√	√	√	√	√	√	√
Interpretability of scores	√	±	√	√	√	√	√
Translation	√	√	√	√	√	√	√
Burden	√	±	√	√	√	√	√
Additional domains		• Structural validity • Quality assessment	• Alternative mode of admin • COAs • Special patient populations	• Alternative mode of admin • Special patient populations • Context of use	• COAs • Context of use, fit-for-purpose • Special patient populations • Alternate modes of admin	• Alternative mode of admin	• Alternative mode of admin • Global assessment of instrument by rater

Crossnohere et al,
Qual Life Res 2021;30:21-40

Policy Review

International standards for the analysis of quality-of-life and patient-reported outcome endpoints in cancer randomised controlled trials: recommendations of the SISAQOL Consortium

Corneel Coens, Madeline Pe*, Amylou C Dueck, Jeff Sloan, Ethan Basch, Melanie Calvert, Alicyn Campbell, Charles Cleeland, Kim Cocks, Laurence Collette, Nancy Devlin, Lien Dorme, Hans-Henning Flechtner, Carolyn Gotay, Ingolf Griebsch, Mogens Groenvold, Madeleine King, Paul G Kluetz, Michael Koller, Daniel C Malone, Francesca Martinelli, Sandra A Mitchell, Jammbe Z Musoro, Daniel O'Connor, Kathy Oliver, Elisabeth Piault-Louis, Martine Piccart, Chantal Quinten, Jaap C Reijneveld, Christoph Schürmann, Ashley Wilder Smith, Katherine M Soltys, Martin J B Taphoorn, Galina Velikova, Andrew Bottomley; for the Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data Consortium*

Patient-reported outcomes (PROs), such as symptoms, function, and other health-related quality-of-life aspects, are increasingly evaluated in cancer randomised controlled trials (RCTs) to provide information about treatment risks, benefits, and tolerability. However, expert opinion and critical review of the literature showed no consensus on optimal methods of PRO analysis in cancer RCTs, hindering interpretation of results. The Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data Consortium was formed to

Lancet Oncol 2020; 21: e83-96

*Joint first authors

European Organisation for Research and Treatment of Cancer, Brussels, Belgium (C Coens Msc, M Pe PhD,

Coens, et al Lancet Oncol 2020, 21, e83-96

Reporting of Patient-Reported Outcomes in Randomized Trials

The CONSORT PRO Extension

Melanie Calvert, PhD
Jane Blazeby, 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 end points. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypothesis 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.

JAMA. 2013;309(8):814-822 www.jama.com

THE CONSORT (CONSOLIdated Standards of Reporting Trials) Statement, first published in 1996 and most recently revised in 2010,[1,2] provides evidence-based recommendations to improve the completeness of reporting of randomized controlled trials (RCTs). The statement focuses on parallel-group trials, but a number of extensions for reporting other trial designs (cluster, noninferiority, and equivalence), interventions (nonpharmacologic and herbal therapies), and for specific data, such as harms have been developed.[3] The CONSORT Statement is endorsed by major journals and

Calvert et al, JAMA 2013, 309(8), 814-822

Quality of Life Research
https://doi.org/10.1007/s11136-018-2020-3

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

Claire Snyder[1,2,3] · Katherine Smith[2,3] · Bernhard Holzner[4] · Yonaira M. Rivera[2] · Elissa Bantug[3] · Michael Brundage[5] · PRO Data Presentation Delphi Panel

Accepted: 29 September 2018

Snyder et al, Qual Life Res 2019, 28(2), 345-356

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 Velanovich, 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.

 ■ Mayo Clin Proc. 2014;89(5):653-661

Wu et al, Mayo Clin Proc 2014, 89(5), 653-661

“6 Tools-1 Paper” Paper

Short Communication

CLINICAL TRIALS

Clinical Trials
1–8

DOI: 10.1177/17407745221077691
journals.sagepub.com/home/ctj
SAGE

The PROTEUS-Trials Consortium: Optimizing the use of patient-reported outcomes in clinical trials

Claire Snyder[1,2,3] Norah Crossnohere[4] Madeleine King[5] Bryce B Reeve[6] Andrew Bottomley[7] Melanie Calvert[8,9,10,11,12] Elissa Thorner[1,3] Albert W Wu[1,2] and Michael Brundage[13]; for the PROTEUS-Trials Consortium

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PROTEUS CONSORTIUM

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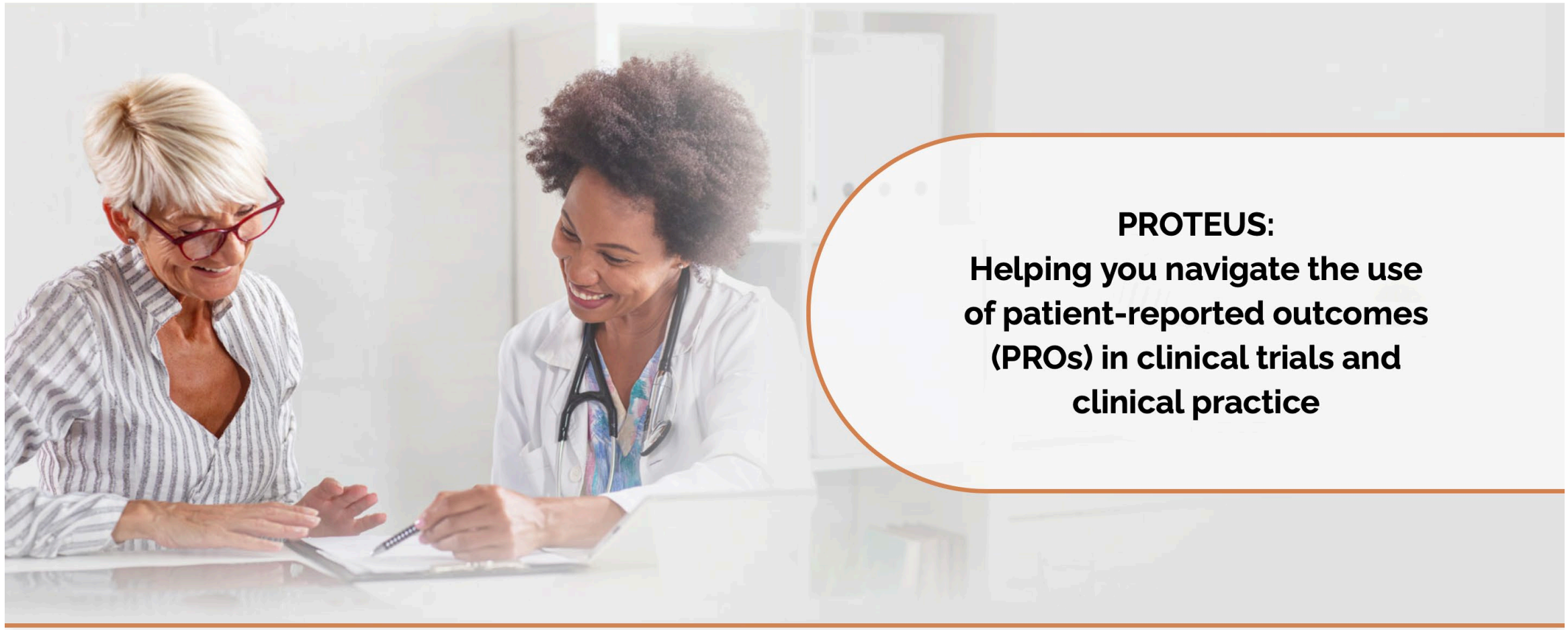


PROTEUS:
Helping you navigate the use of patient-reported outcomes (PROs) in clinical trials and clinical practice

DISPLAYING RESULTS

Determining the best way to display PRO findings graphically, so that patients and clinicians can easily and accurately interpret them, is a critical step in reporting clinical trial results.

Stakeholder-driven, evidence-based recommendations to promote consistent presentation of PRO data and improve understanding of what PRO scores mean are available in the paper **Making a Picture Worth a Thousand Numbers: Recommendations for Graphically Displaying Patient-Reported Outcomes Data**.

CORE RESOURCES

ARTICLE

Making a Picture Worth a Thousand Numbers: Recommendations for Graphically Displaying Patient-Reported Outcomes Data

Learn more →

CHECKLIST

PRO Data Display Guidance Checklist: Research Results Presented to Patients

Learn more →

CHECKLIST

PRO Data Display Guidance Checklist: Research Results Presented to Clinicians and Researchers

Learn more →

VIDEO

Displaying PRO Results Graphically: Overview of Recommendations (Overview)

Learn more →

VIDEO

Displaying PRO Results Graphically: Applying the Recommendations (Advanced)

Learn more →

POWERPOINT

Displaying PRO Results Graphically: Recommendations PowerPoint (Overview)

Learn more →

POWERPOINT

Displaying PRO Results Graphically: Applying the Recommendations PowerPoint (Advanced)

Learn more →

HANDBOOK CHAPTER

Displaying Results (Trials): Handbook Chapter

Learn more →

Objective of Resource

- To provide evidence-based recommendations for research PRO data display to facilitate ease of interpretation for presenting results to:
  - Patients (i.e., educational materials and decision aids)
  - Clinicians/researchers (i.e., peer-reviewed publications)

[Also addresses display for individual patient data, to be covered later]

Communicating patient-reported outcome scores using graphic formats: results from a mixed-methods evaluation

Michael D. Brundage[1] · Katherine C. Smith[2,3] · Emily A. Little[4] · Elissa T. Bantug[2] · Claire F. Snyder[2,3,4] · The PRO Data Presentation Stakeholder Advisory Board

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

Katherine C. Smith[1,4] · Michael D. Brundage[2] · Elliott Tolbert[3] · Emily A. Little[3] · Elissa T. Bantug[4] · Claire F. Snyder[3,4] · PRO Data Presentation Stakeholder Advisory Board

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

Elissa T. Bantug[a,*], Theresa Coles[b], Katherine C. Smith[a,c], Claire F. Snyder[a,c,d], Julie Rouette[e], Michael D. Brundage[e] On the behalf of:the PRO Data Presentation Stakeholder Advisory Board

What Do These Scores Mean? Presenting Patient-Reported Outcomes Data to Patients and Clinicians to Improve Interpretability

Claire F. Snyder, PhD[1,2,3]; Katherine C. Smith, PhD[2,3]; Elissa T. Bantug, MHS[3]; Elliott E. Tolbert, PhD[1,2]; Amanda L. Blackford, ScM[3]; and Michael D. Brundage, MD, MSc[4]; and the PRO Data Presentation Stakeholder Advisory Board

Original Article

MDM Medical Decision Making

Medical Decision Making
1–12

DOI: 10.1177/0272989X18791177
journals.sagepub.com/home/mdm
SAGE

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

Quality of Life Research
https://doi.org/10.1007/s11136-018-2065-3

In proportion: approaches for displaying patient-reported outcome research study results as percentages responding to treatment

Elliott Tolbert[1,2] · Michael Brundage[3] · Elissa Bantug[4] · Amanda L. Blackford[4,5] · Katherine Smith[2,4,6] · Claire Snyder[1,2,4,7] · PRO Data Presentation Stakeholder Advisory Board

Accepted: 22 November 2018

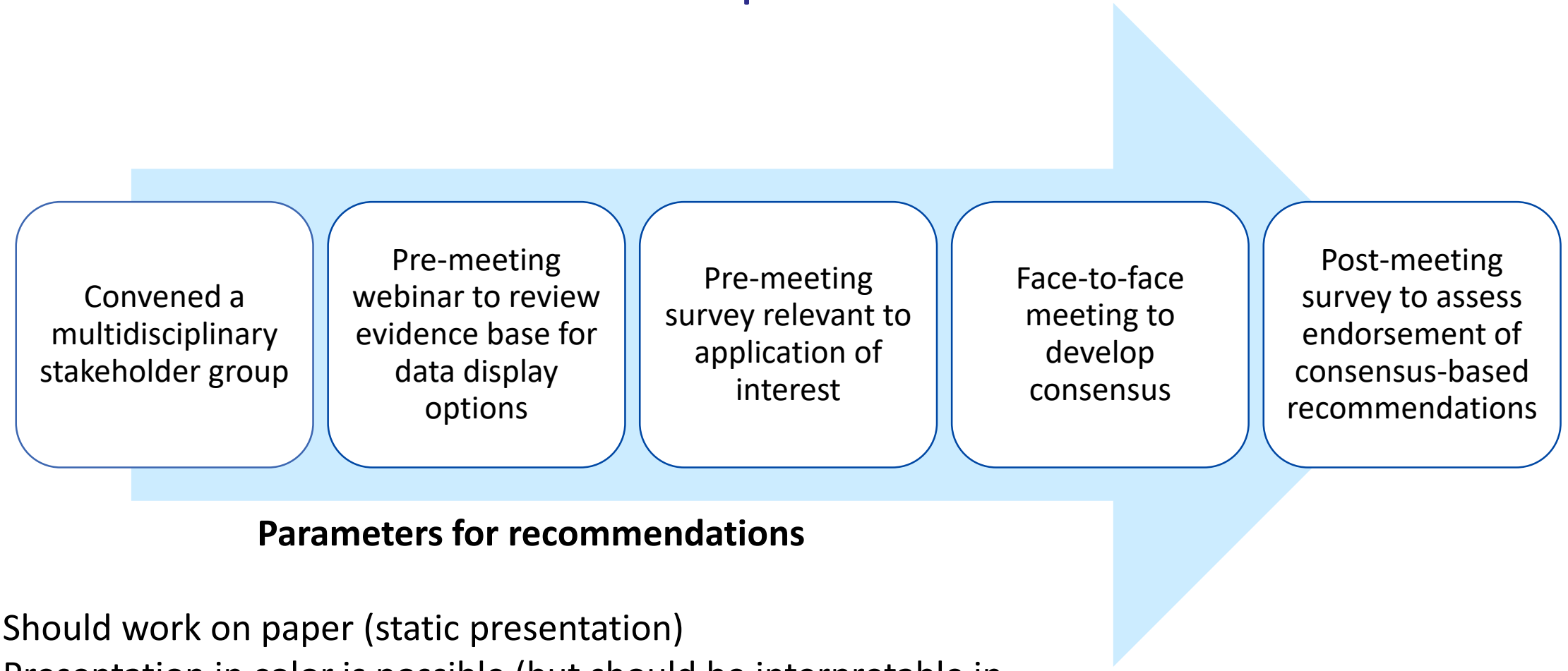
Qual Life Res
DOI 10.1007/s11136-017-1710-6

CrossMark

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

Michael Brundage[1,8] · Amanda Blackford[2] · Elliott Tolbert[3,4] · Katherine Smith[5,7] · Elissa Bantug[7] · Claire Snyder[3,6,7] · PRO Data Presentation Stakeholder Advisory Board (various names and locations)

Methods: Modified-Delphi Process



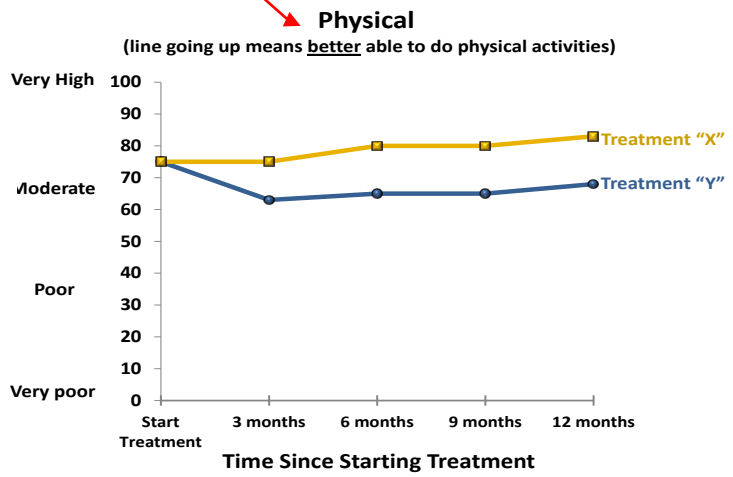
- Should work on paper (static presentation)
- Presentation in color is possible (but should be interpretable in grayscale)
- Additional functionality in electronic presentation is possible (but not part of standards)

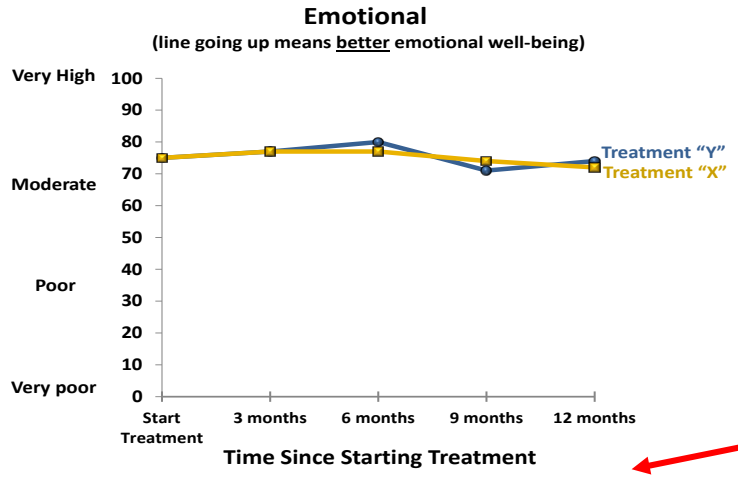
Reporting Mean (Changes) to Patients

Labels for directionality

Y-axis descriptive anchor labels

Patients' Functioning

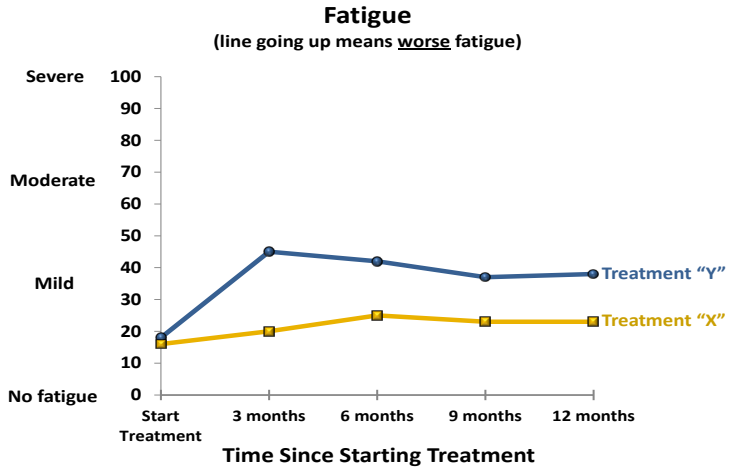


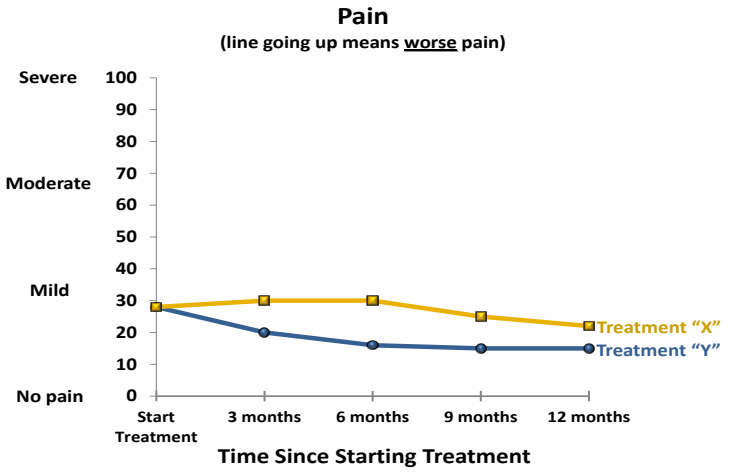


Visually Separate domains with different directionality

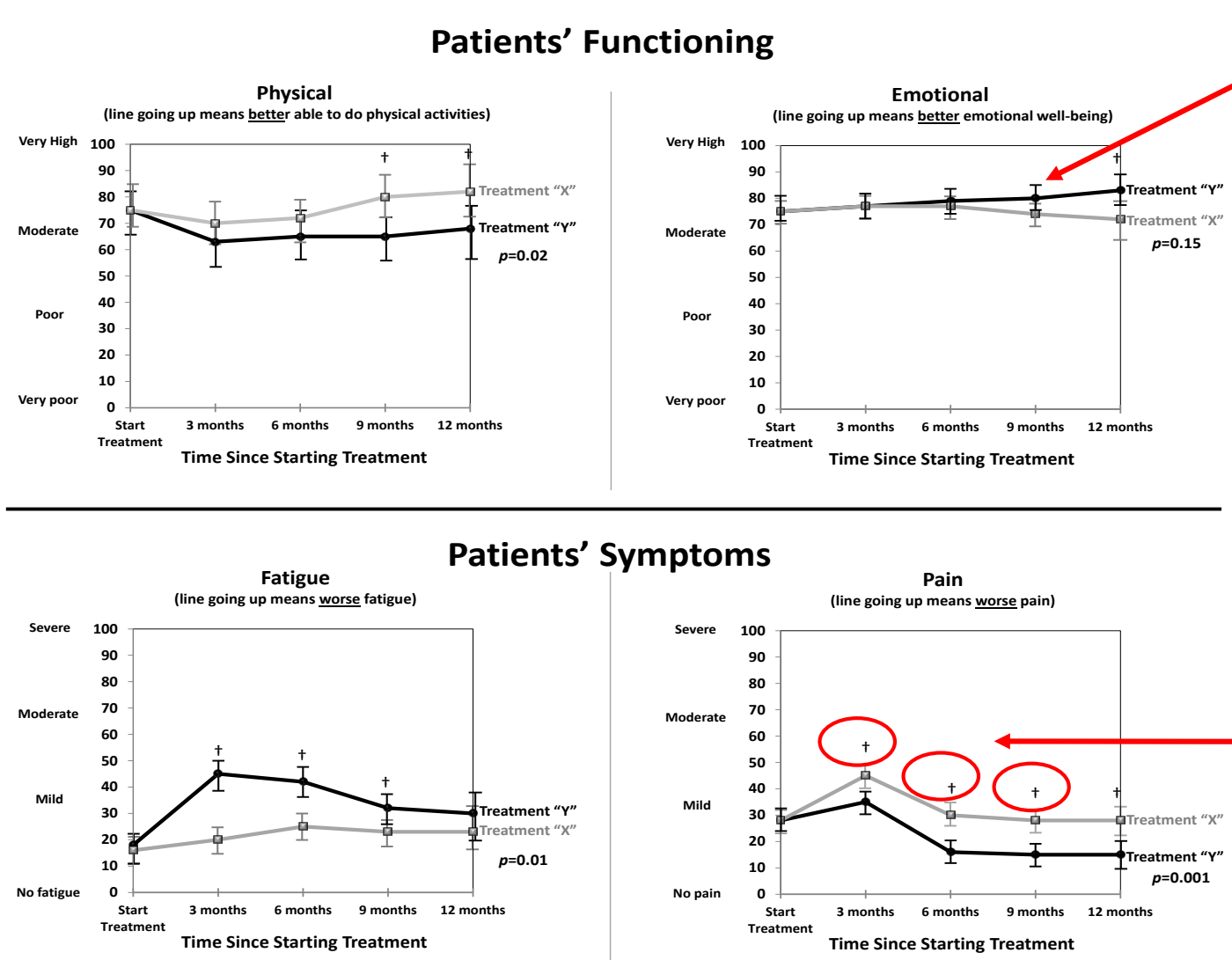
Patients' Symptoms

Y-axis labels reinforce directionality





Reporting Mean (Changes) to Clinicians/Researchers



Confidence limits should always be shown

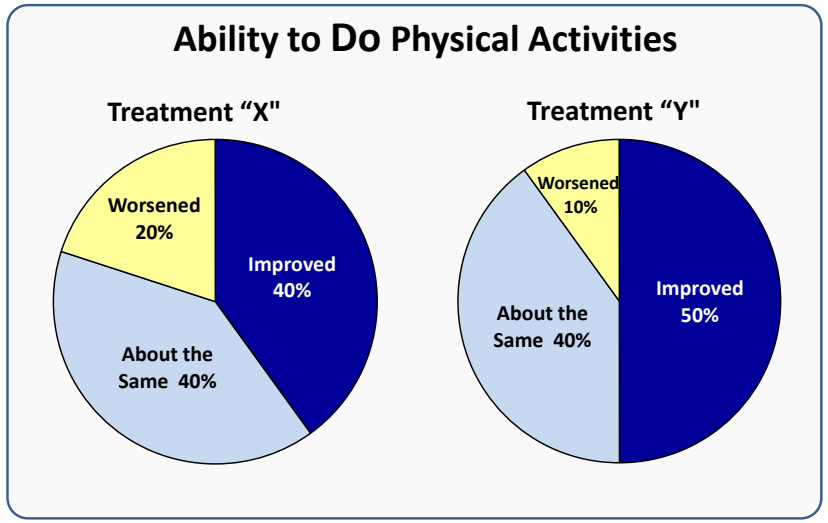
Symbols illustrating clinically important differences between group scores

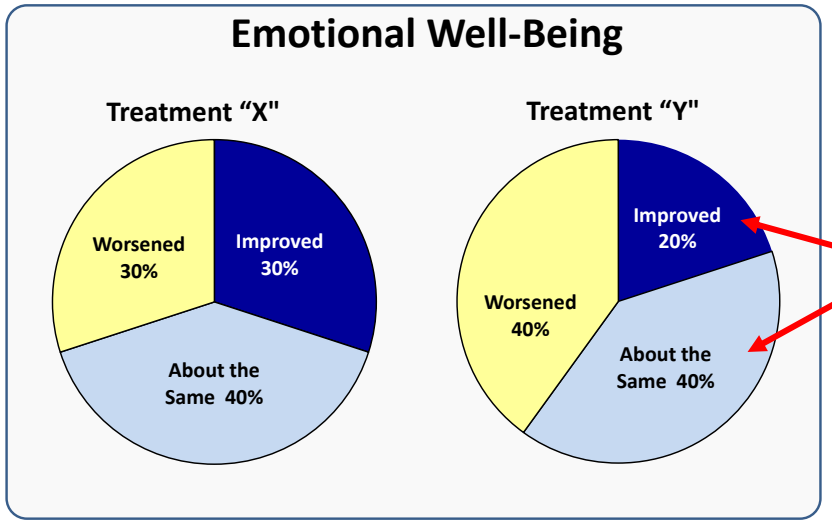
Legend explanation

Legend: For all graphs, *p*-values are for between-treatment differences over time, and vertical lines indicate 95% confidence limits at each time point.
† indicates differences between treatments that are clinically important.

Reporting Proportion Responding to Patients (and Clinicians/Researchers)

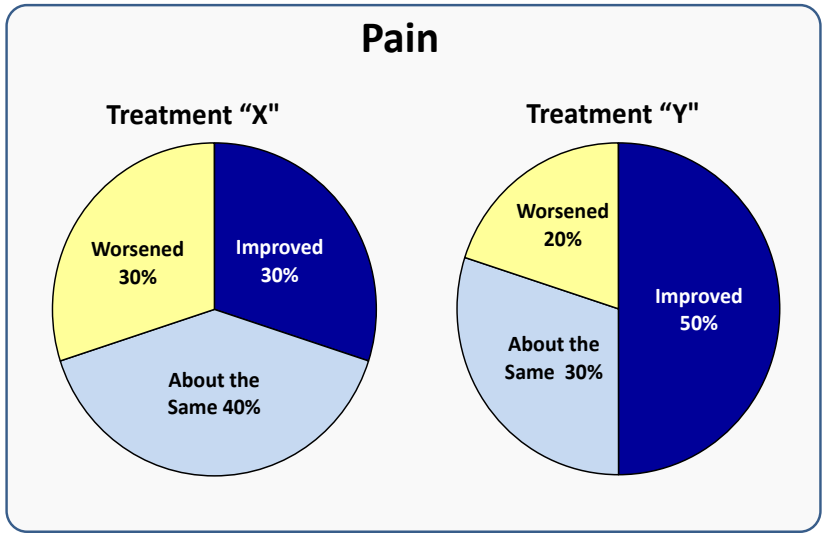
Status of 100 patients 9 months after starting treatment

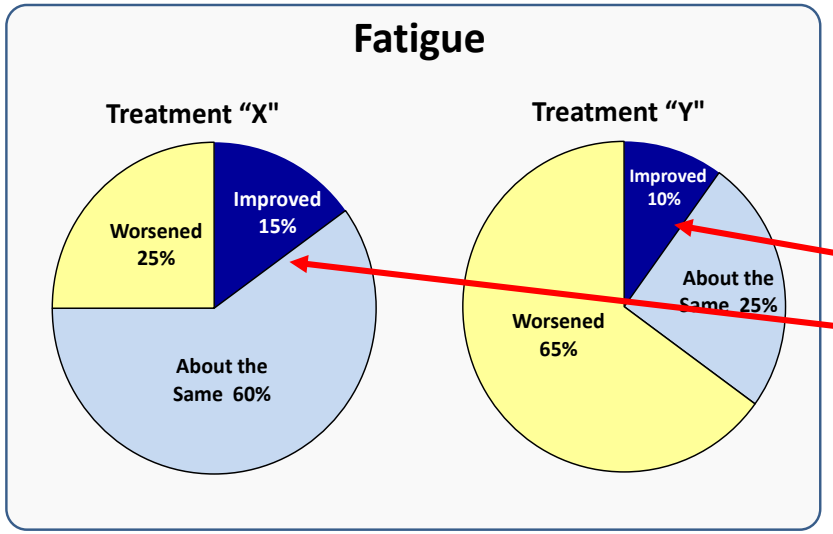




Data labels annotated on each slice

No horizontal line separating domains since directionality not relevant with proportions

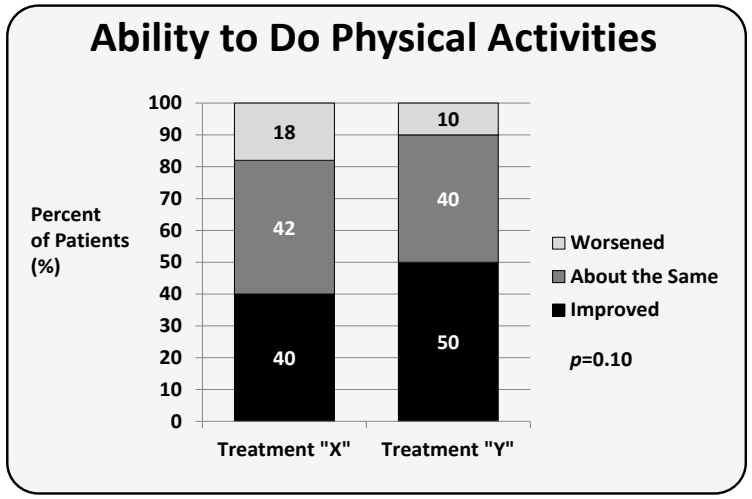


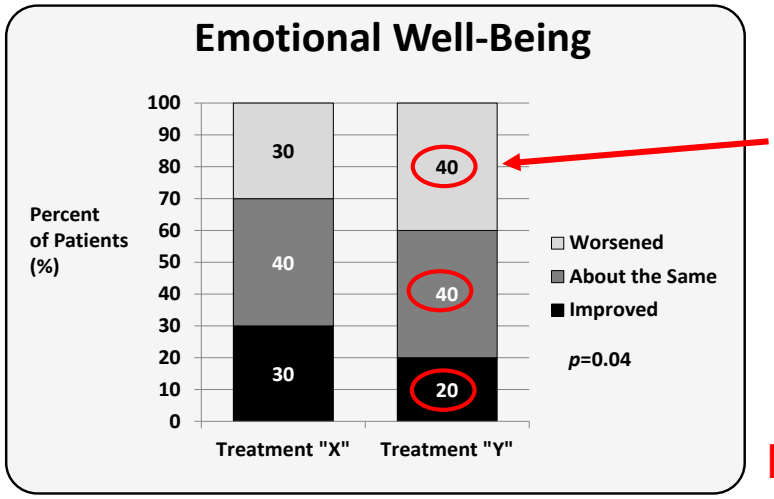


"Improved" slice consistently starts at 12:00 position

Reporting Proportion Responding to Clinicians/Researchers

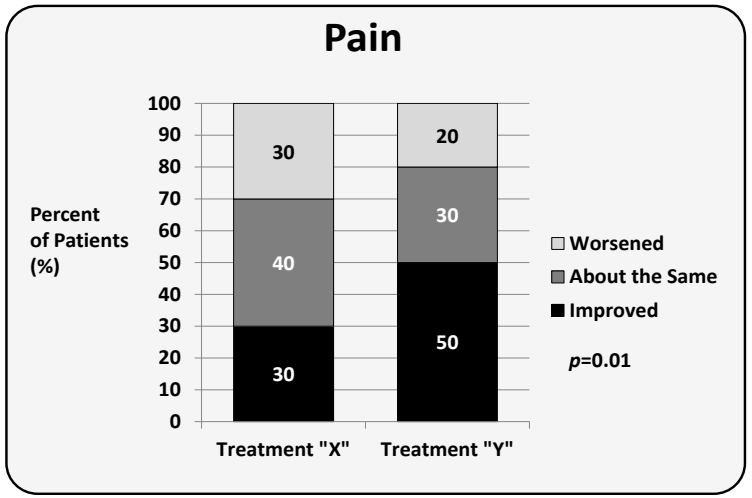
Status of 100 patients 9 months after starting treatment

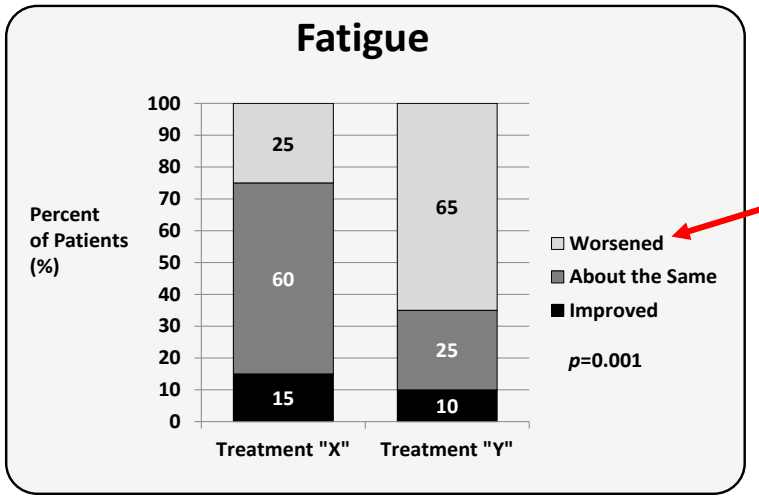




Data labels annotated on each slice so stacked proportions can be read directly

No horizontal line separating domains since directionality not relevant with proportions





Legend replicated for easy access and order is the same as stacked bar sections

PRO Data Display Guidance Checklist: Research Results Presented to Patients

Issue	Consensus Statement	Notes/ comments
Directionality of PRO Scores	The Consensus Panel warned against trying to change current instruments–even if only how the data are displayed (e.g., "flipping the axes" where required for symptom scores so that lines going up are always better). PRO data presentation should avoid mixing score direction in a single display.	
Conveying Score Meaning	Descriptive labels (e.g., none/mild/moderate/severe) along the y-axis are helpful and should be used when data supporting their location on the scale are available. In addition to the descriptive y-axis labels, reference values for compa considered for inclusion if they are available.	
Normed Scoring	PRO data presentation needs to accommodate instruments the way th without normed scoring. One can decide if/when to show the reference population norm visuall understanding that displaying it might provide additional interpretive va greater complexity. Comparison to the norm might be less relevant in the context where th between treatments. If a norm is displayed: • It is necessary to describe the reference population and label the nor (recommend "average" rather than "norm") • It also requires deciding what reference population to show (to the ex • It will need to be explained to patients that this normed population ma patient.	
Clinically Important Differences	Patients may find information regarding clinically important differences confusing, but it is important for them to know what differences "matter informed decision.	
Proportions Changed	Pie charts are the preferred format for displaying proportion meeting a stable, worsened), so long as the proportion is also indicated numerica	

Snyder C, Smith K, Holzner B, et al. Making a picture worth a thousand numbers: recommendations for graphically 2019;28(2):345-356. doi:10.1007/s11136-018-2020-3

PRO Data Display Guidance Checklist: Research Results Presented to Clinicians

Issue	Consensus Statement	Notes/ comments
Directionality of PRO Scores	PRO data presentation should avoid mixing score direction in a single display. In cases where this is not possible, authors should consider changing the directionality in the display to be consistent. There is a need for exceptionally clear labelling, titling, and other annotations.	
Conveying Score Meaning	Descriptive labels (e.g., none/mild/moderate/severe) along the y-axis are helpful and should be used when data supporting their location on the scale are available. In addition to the descriptive y-axis labels, reference values for comparison populations should be considered for inclusion if they are available.	
Normed Scoring	PRO data presentation needs to accommodate instruments the way they were developed, with or without normed scoring. One can decide if/when to show the reference population norm visually (e.g., with a line on the graph), understanding that displaying it might provide additional interpretive value, but potentially at the cost of greater complexity. Display of the norm might be less relevant in the context where the primary focus is the choice between treatments. If a norm is displayed: • It is necessary to describe the reference population and label the norm as clearly as possible (recommend "average" rather than "norm") • It also requires deciding what reference population to show (to the extent that options are available).	
Clinically Important Differences	Clinically important differences between treatments should be indicated with a symbol of some sort (described in a legend). The use of an asterisk is not recommended (as it is often used to indicate statistical significance). If there is no defined clinically important difference, that also needs to be in the legend and/or the text of the paper.	
Conveying Statistical Significance	The data suggest that clinicians and others appreciate p-values; however, the Consensus Panel recognizes a move away from reporting them (and toward the use of confidence limits to illustrate statistical significance). Regardless of whether p-values are reported, confidence intervals should always be displayed.	
Proportions Changed	Reasonable options include bar charts, pie charts, or stacked bar charts.	

Snyder C, Smith K, Holzner B, et al. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. *Qual Life Res.* 2019;28(2):345-356. doi:10.1007/s11136-018-2020-3

The PROTEUS-Trials Consortium

Patient-**R**eported **O**utcome **T**o
Engaging **U**sers & **S**takehold

PROTEUS

Handbook

ThePROTEUSConsortium.org

Contents

Overview of the SPIRIT-PRO Guidance

- To be used in conjunction with the SPIRIT 2013 Statement and related extensions
- 5 elaborations on existing SPIRIT 2013 checklist items as applied to PROs in trial protocols
- 11 extensions – additional PRO-specific items recommended for trial protocols where PROs are a primary or important secondary outcome

The SPIRIT-PRO guidance constitutes an extension to the SPIRIT 2013 statement that guides the reporting of various parts of the trial protocol sections. The key items relevant to the reporting of PROs include the following:

Introduction

- Describe PRO-specific research question, rationale, and relevant previous findings
- State PRO-specific objectives or hypotheses (including relevant PRO concepts/domains)

Methods – Participants, Interventions, Outcomes

- Specify any PRO-specific eligibility criteria
- Specify the PRO concepts/domains used to evaluate the intervention and related analysis metric

Methods – Data Collection, Management and Analysis

- Describe the PRO measure and its psychometric characteristics
- Include a data collection plan (e.g., time points, mode, setting)
- Specify language versions available
- State and justify use of proxy reporting, if relevant
- Specify strategies to minimize missing data and address missing data in analysis

Harms

- State whether PRO data will be monitored to inform clinical care

The specific elaborations and extensions are detailed below.

PROTEUS

ELSEVIER

Journal of Clinical Epidemiology 66 (2013) S12–S20

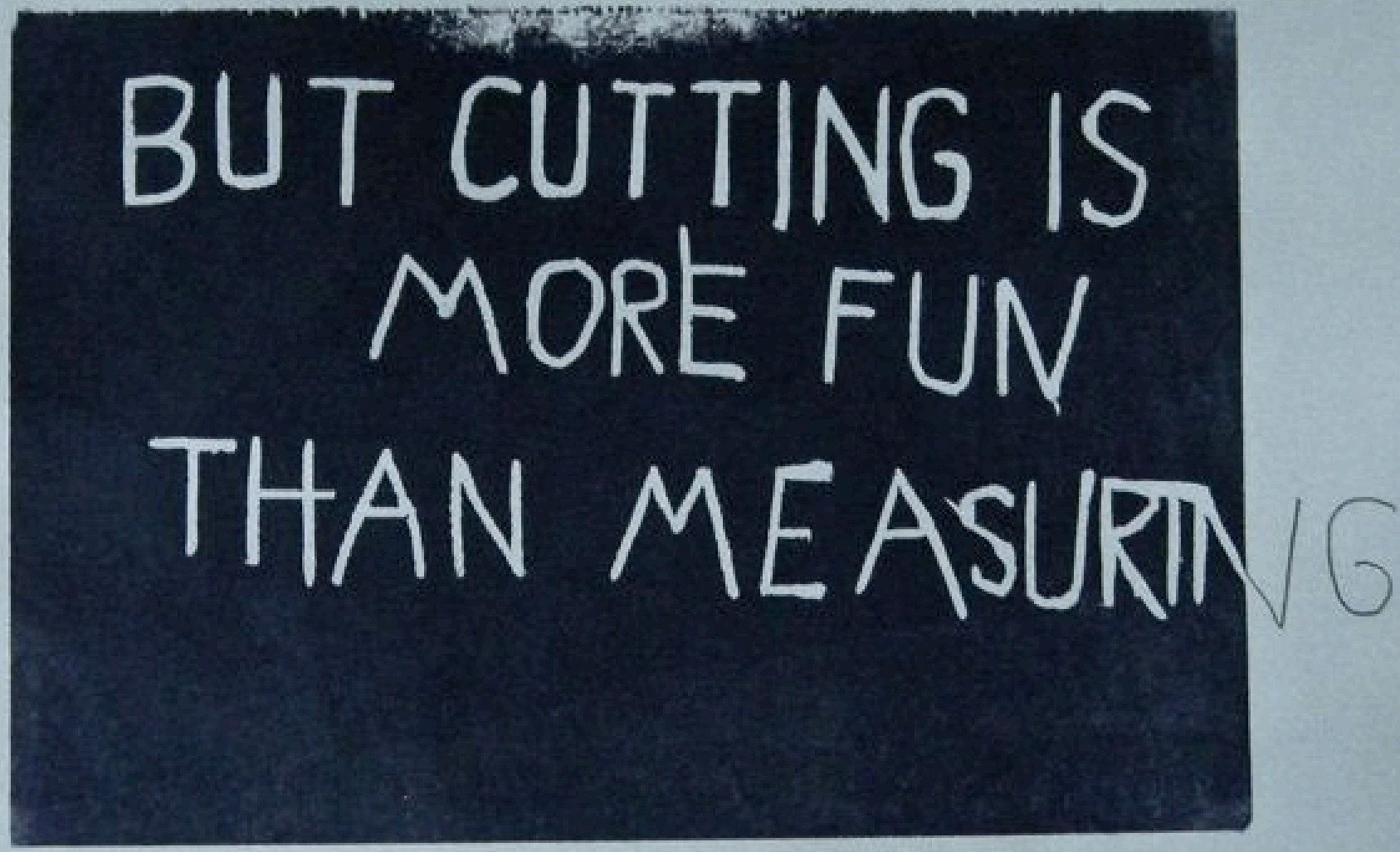
Journal of Clinical Epidemiology

Measure once, cut twice—adding patient-reported outcome measures to the electronic health record for comparative effectiveness research

Albert W. Wu*, Hadi Kharrazi, L. Ebony Boulware, Claire F. Snyder

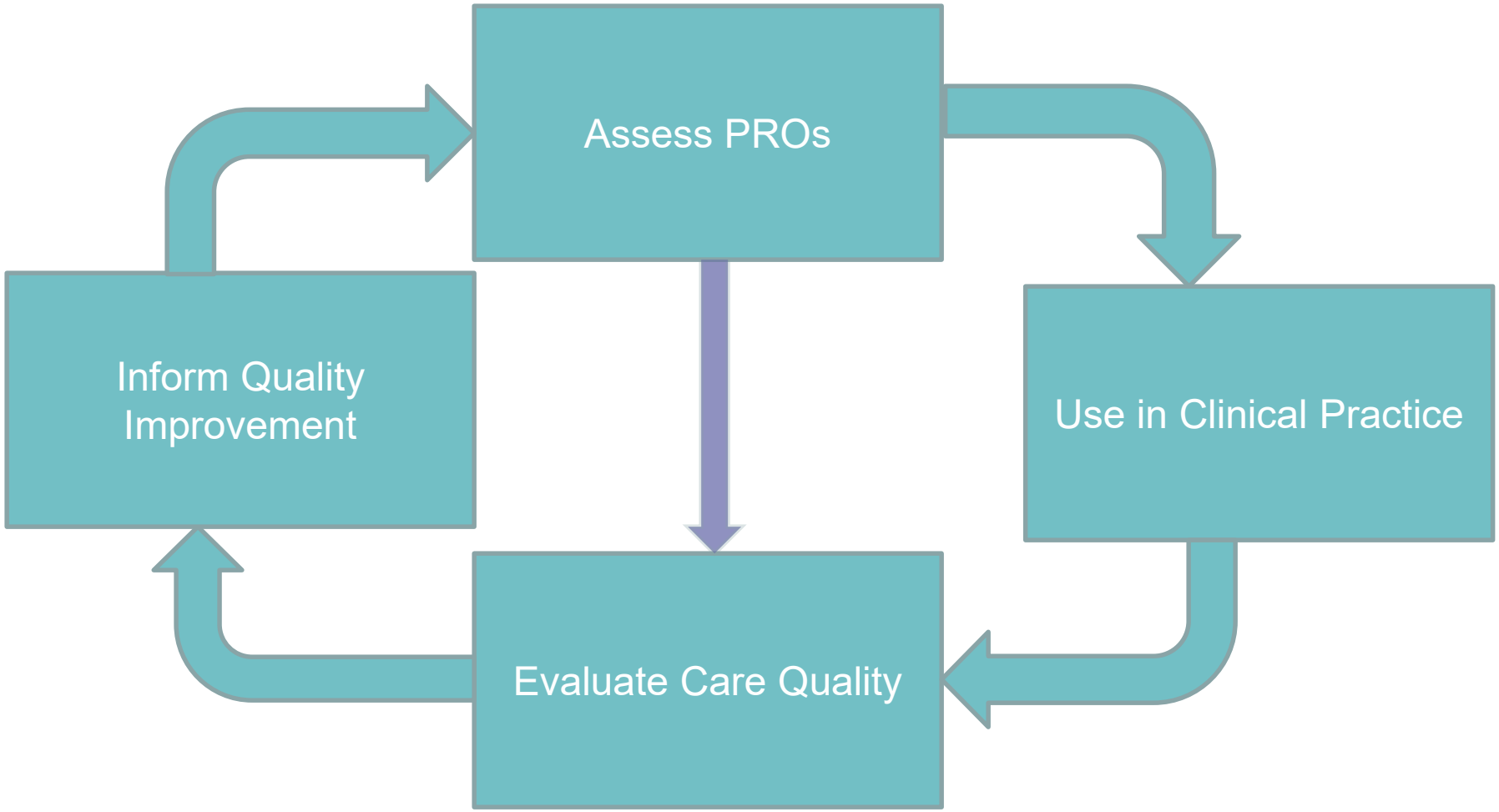
Departments of Health Policy & Management and Medicine, Johns Hopkins University, Baltimore, MD, USA

Accepted 19 April 2013

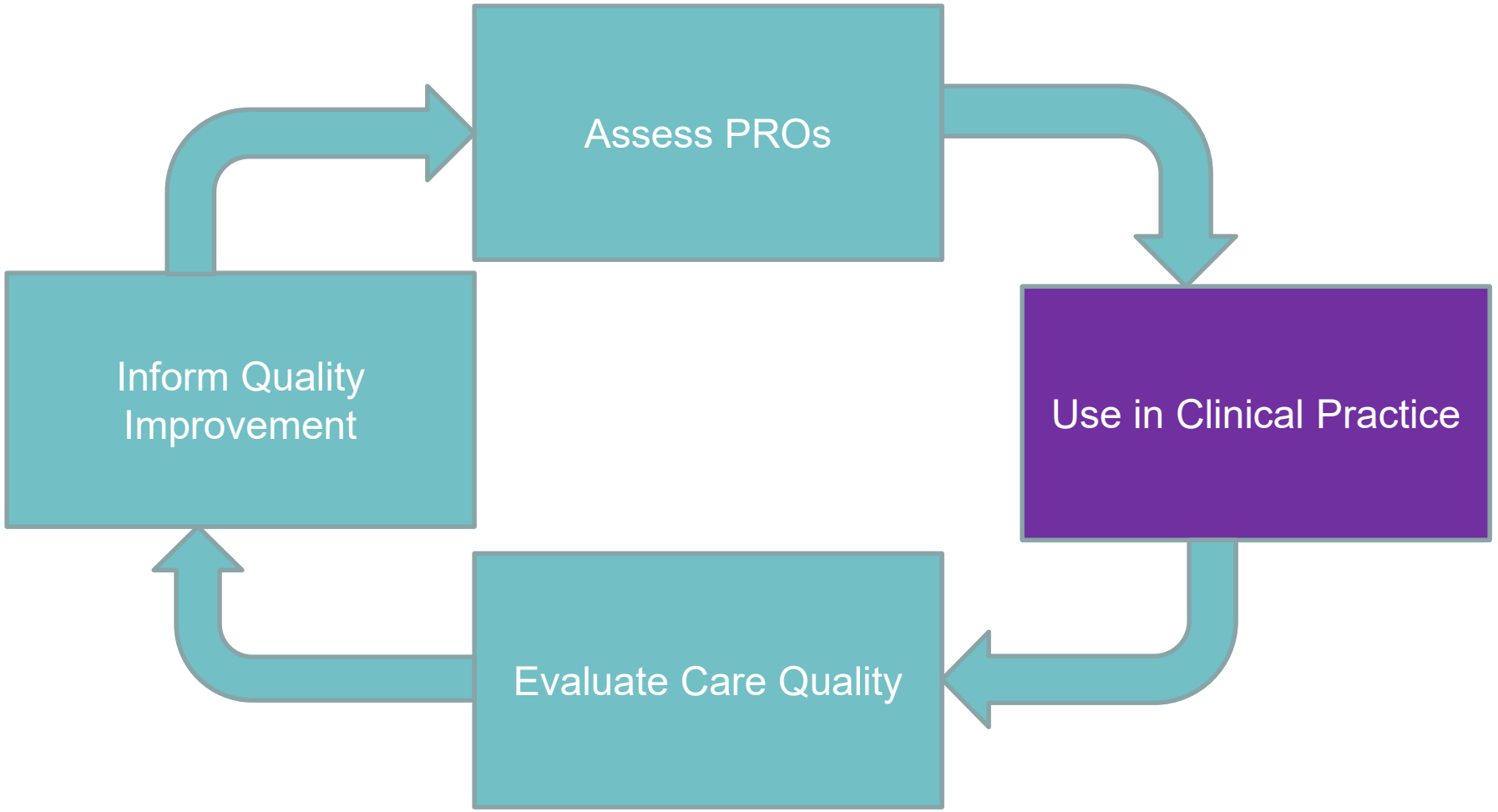


PEACHEY
MMX

Multi-Purpose PROs

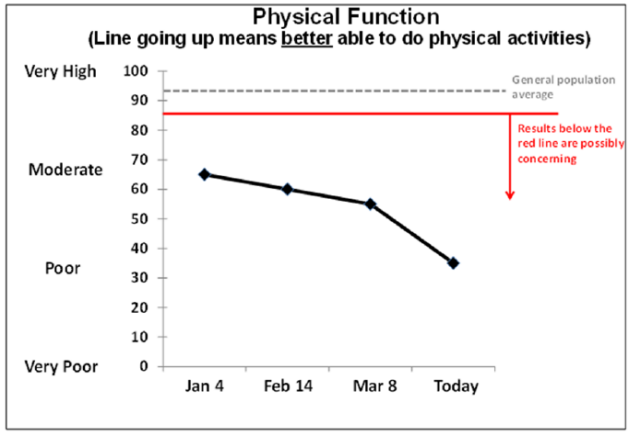


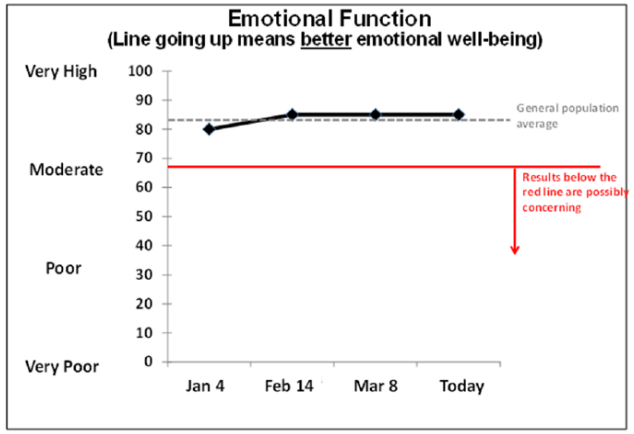
Multi-Purpose PROs



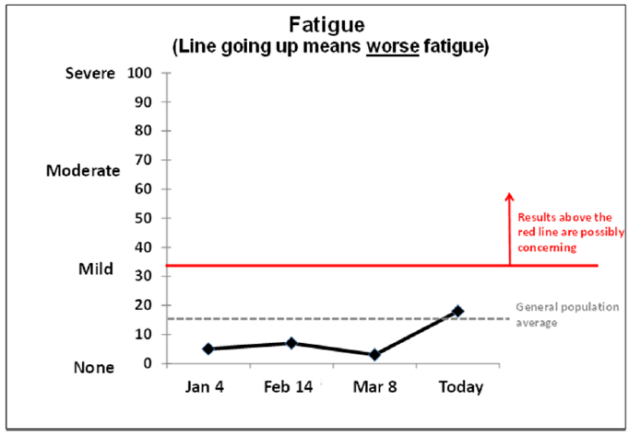
Clinicians and Patients Use Data to Inform Care

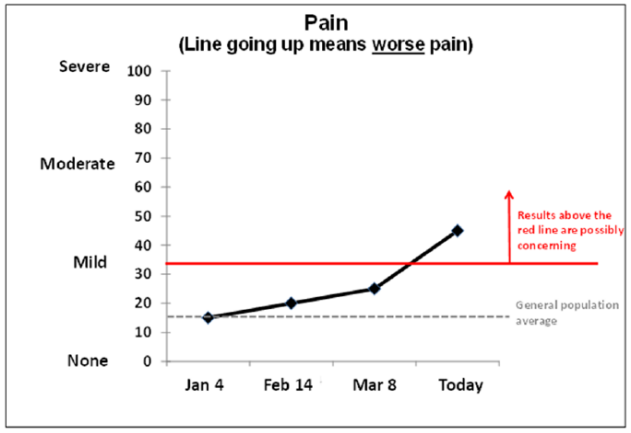
Patient's results for levels of function



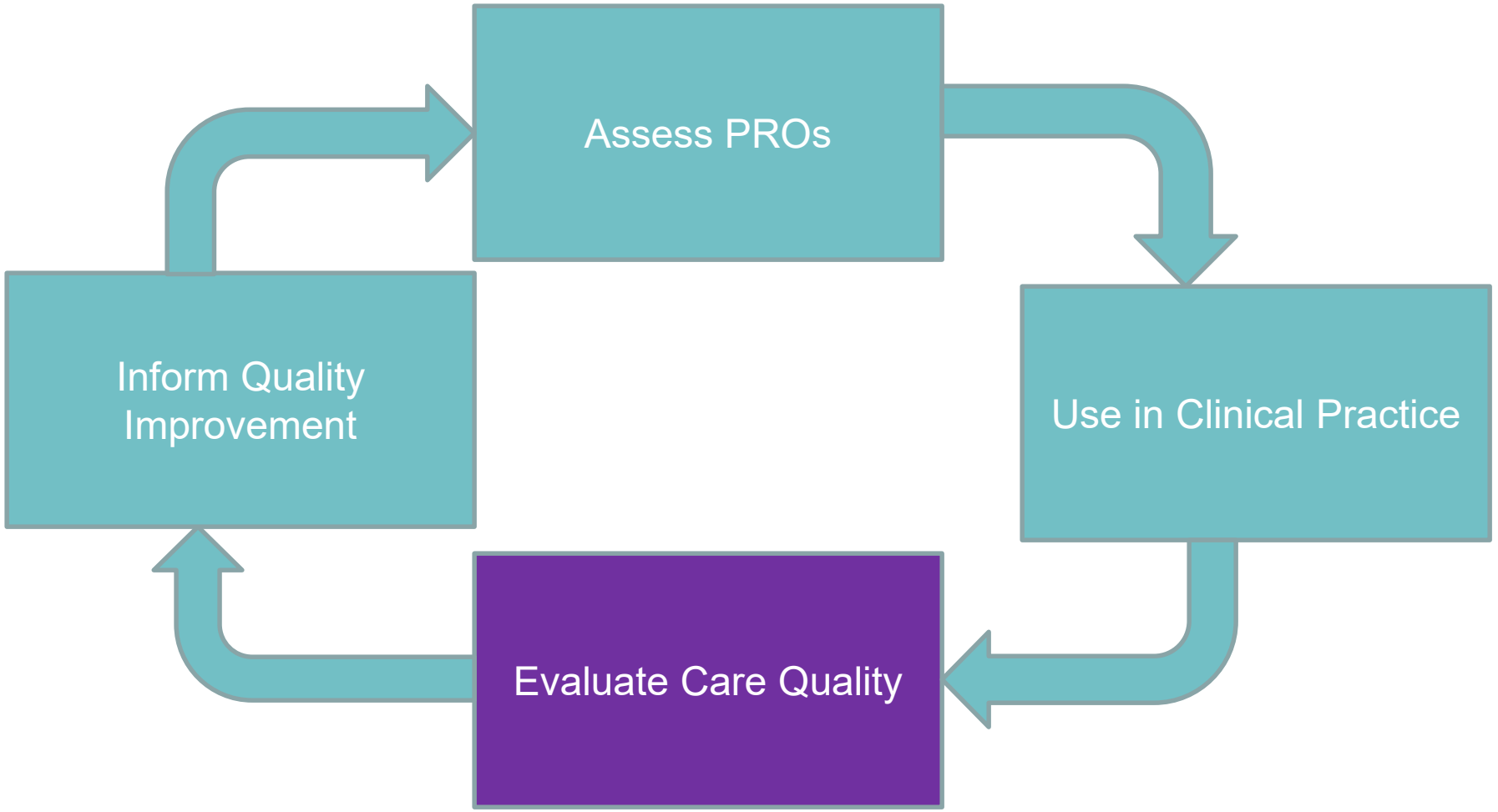


Patient's results for symptoms

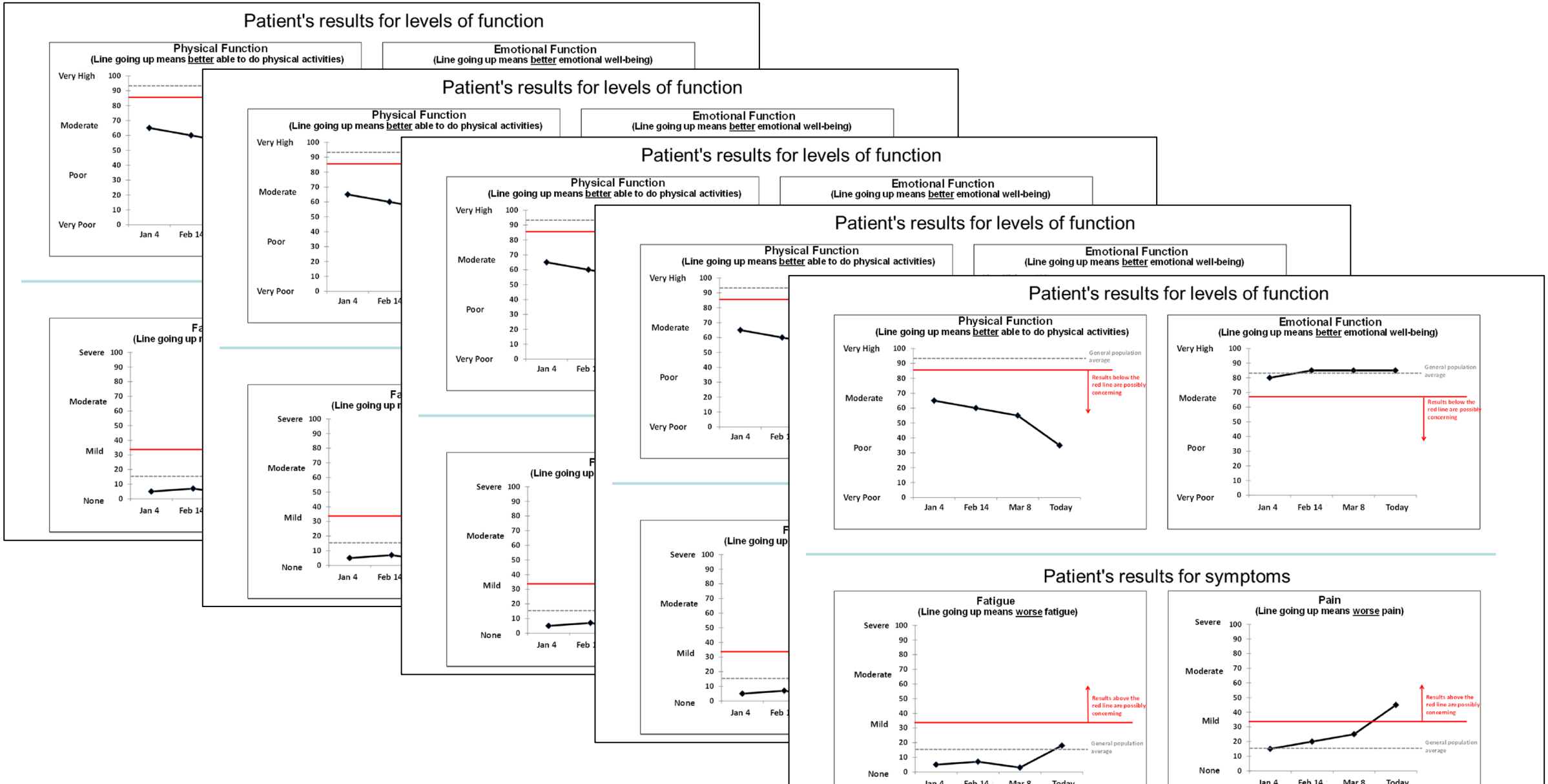




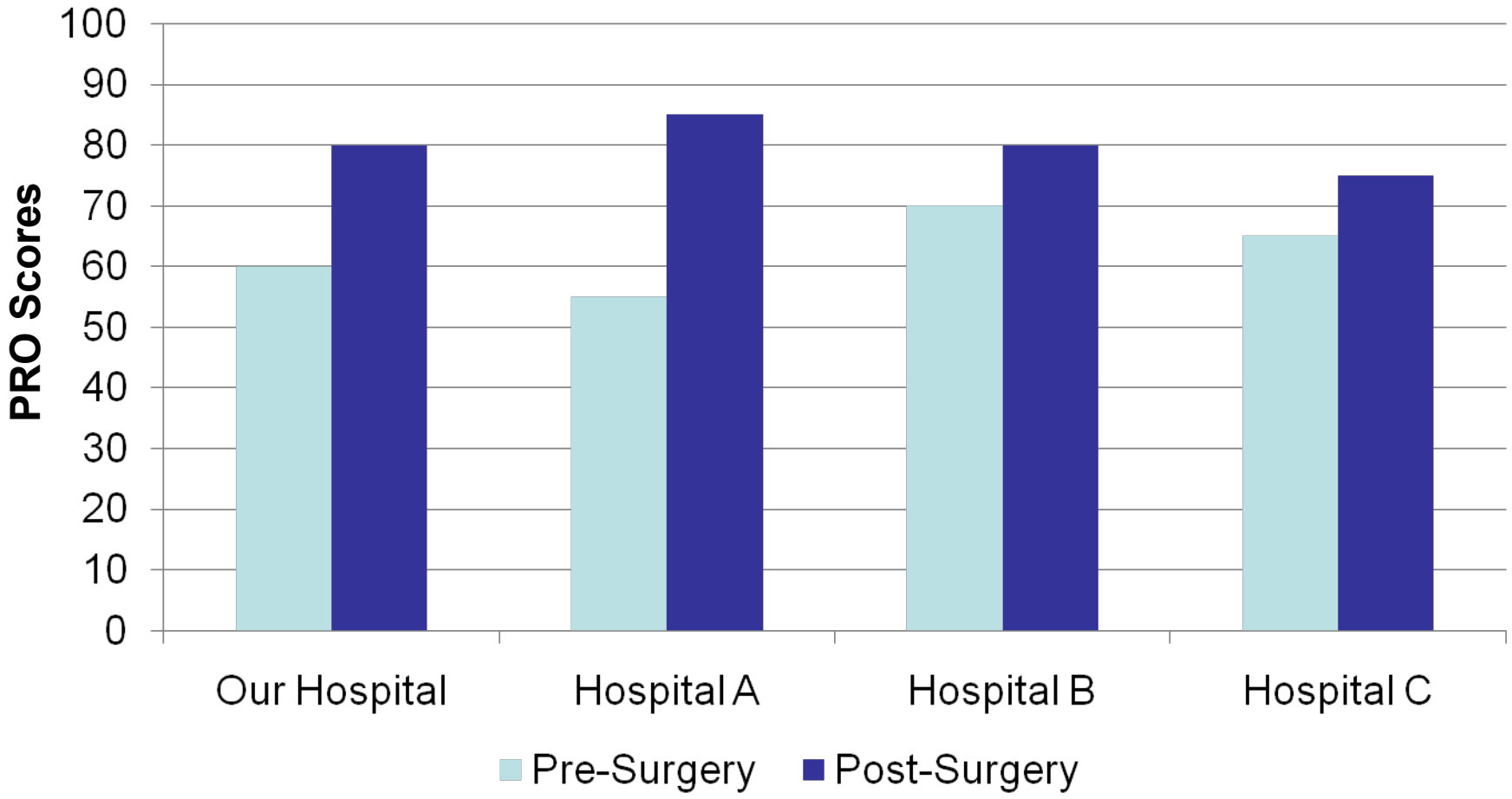
PROs: From Assessment to Quality Improvement



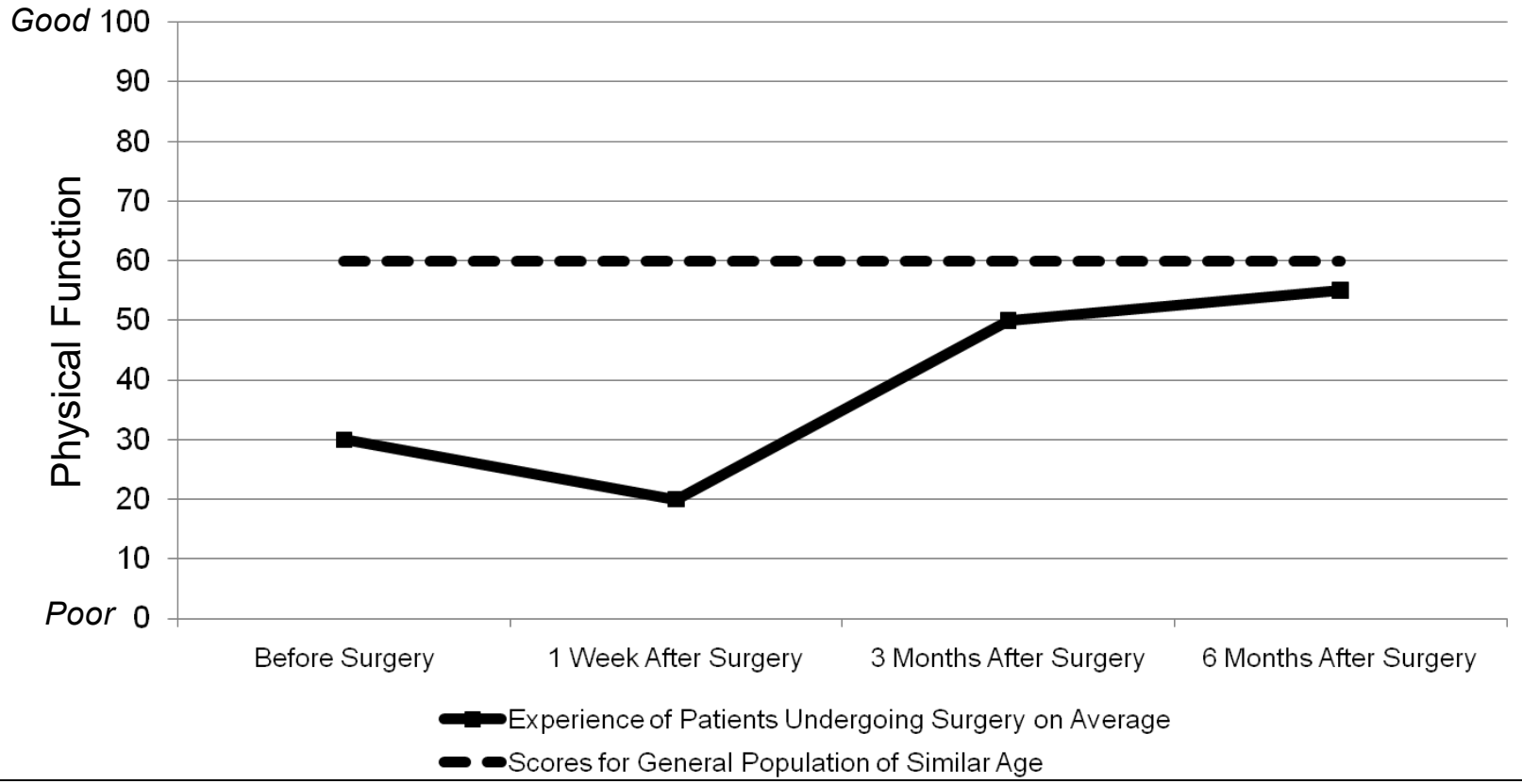
Aggregate Data Across Patients



Quality Reporting to Compare Providers



Describing Impact of Treatment

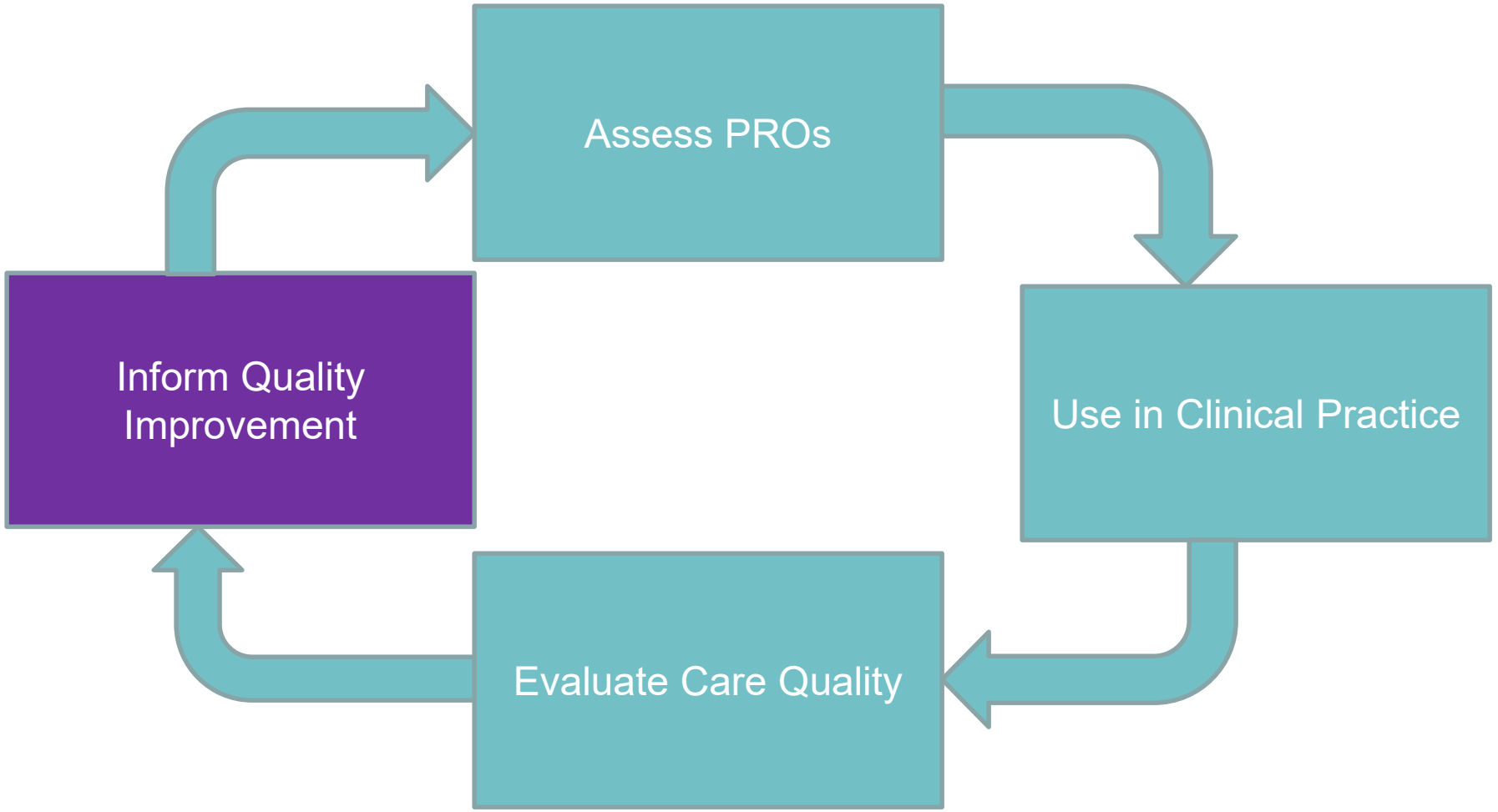


This figure describes the physical function of patients who undergo this procedure on average. Scores of 0 represent poor physical function, and scores of 100 represent good physical function. On average, patients who undergo this surgery have a score of 30 before the procedure. Immediately following the procedure (1 week after surgery), their function has decreased a little to a score of 25. However, physical function then improves over the next 3 months to achieve a score of 50, with a little additional improvement to 55 at the point 6 months after surgery.

The general population of a similar age has a physical function score of 60.

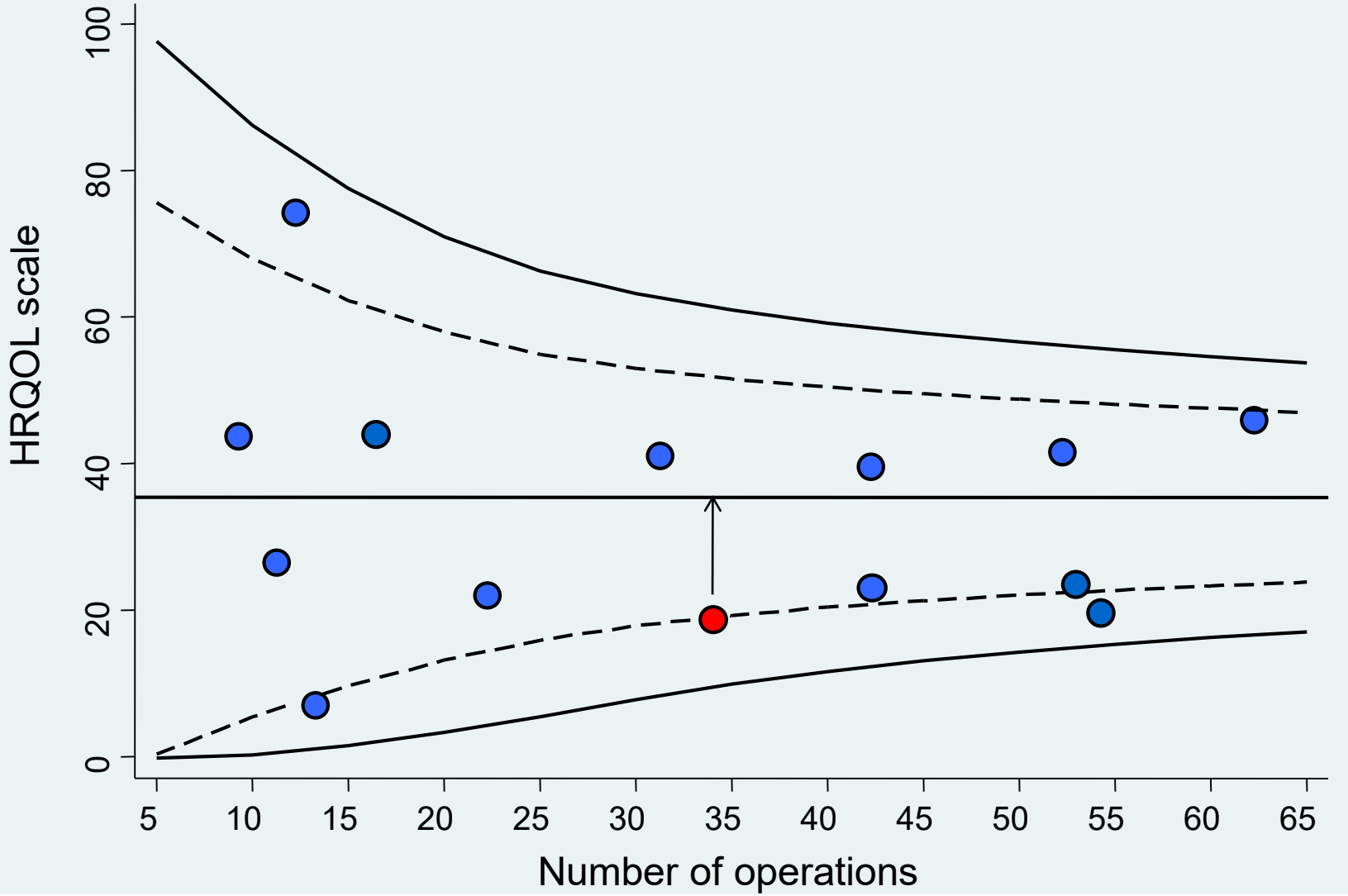
Thus, on average, this procedure improves patients' physical function substantially, but not quite to the level of the general population.

Multi-Purpose PROs

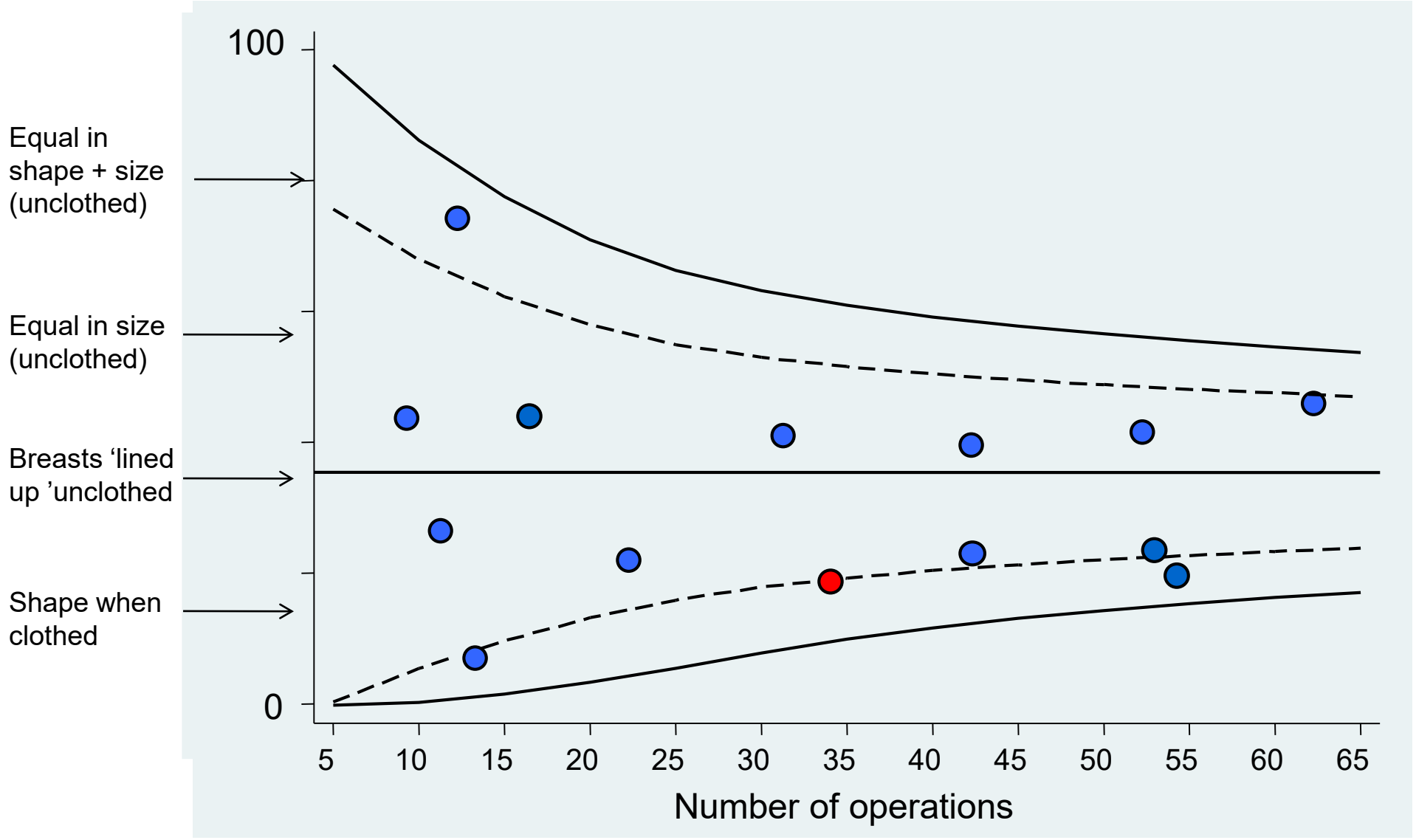


How do we turn PROMs into remedies?

Slide courtesy of John Browne, PhD, University College – Cork

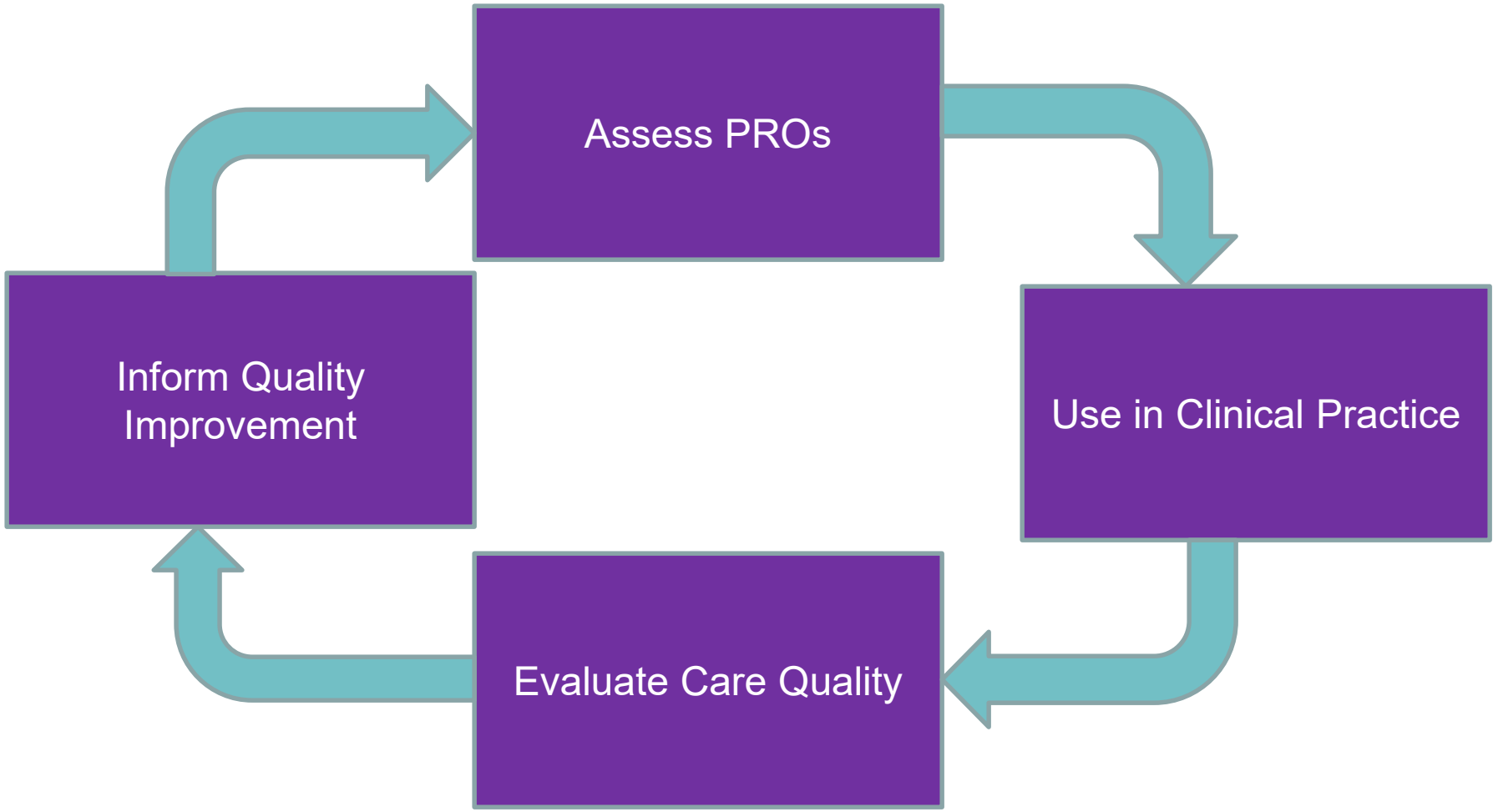


An interpretable PROM for breast reconstruction? The Breast-Q.



Slide courtesy of John Browne, PhD, University College – Cork

Multi-Purpose PROs



The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice:

A Synthesis of Resources

Norah L Crossnohere, PhD
Assistant Professor, General Internal Medicine
The Ohio State University College of Medicine

Imperative

Engagement with members of the PROTEUS Consortium highlighted the need for unified, comprehensive resources to inform the implementation of using PROs in diverse clinical settings

"Develop step-by-step guides and frameworks for initiating a program to use PROMs in clinical practice."

"Differences in healthcare systems internationally make it challenging to develop a 'one size-fits-all' approach to using PROs in clinical care."

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Foundational resources

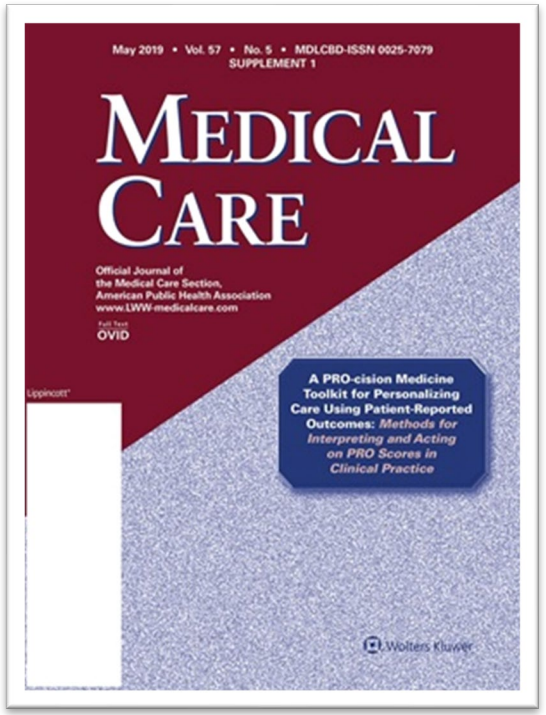
User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice

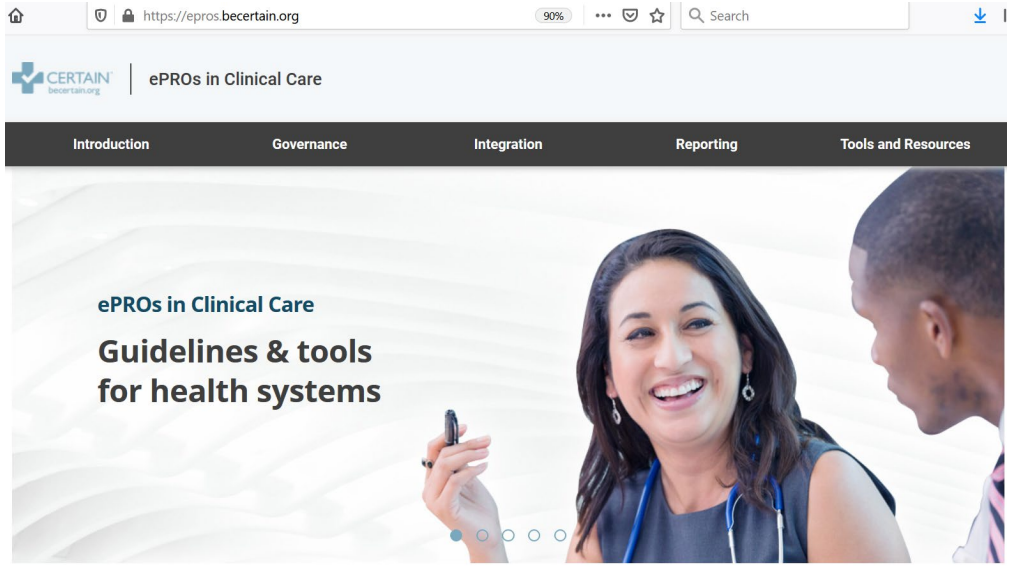
Version 2: January 2015

Produced on behalf of the International Society for Quality of Life Research by (in alphabetical order):

Neil Aaronson, PhD
Thomas Elliott, MD
Joanne Greenhalgh, PhD
Michele Halyard, MD
Rachel Hess, MD
Deborah Miller, PhD
Bryce Reeve, PhD
Maria Santana, PhD
Claire Snyder, PhD

International Society for Quality of Life Research





Quality of Life Research
https://doi.org/10.1007/s11136-018-2020-3

CrossMark

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

Claire Snyder[1,2,3] · Katherine Smith[2,3] · Bernhard Holzner[4] · Yonaira M. Rivera[2] · Elissa Bantug[3] · Michael Brundage[5] · PRO Data Presentation Delphi Panel

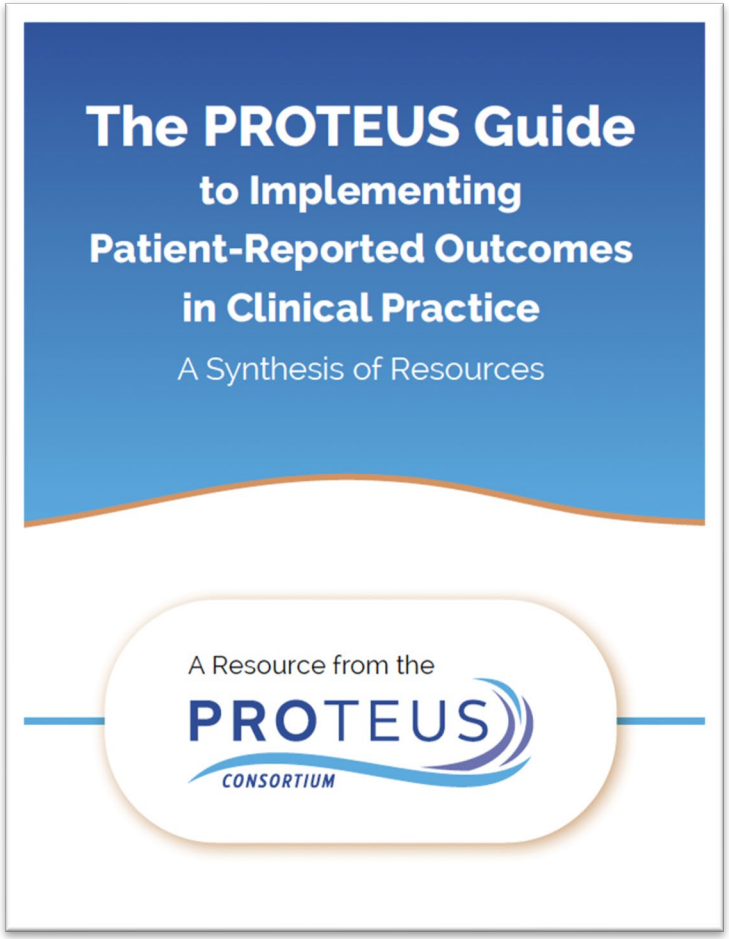
Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

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

May 2017

The PROTEUS-Practice Guide

- Using PROs in clinical care effectively requires addressing a range of considerations
- The Guide:
  - Offers support for designing, implementing, and managing PRO systems in clinical care
  - Collates and synthesizes foundational resources to create a **unified**, **comprehensive** resource



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No “one size fits all” approach

- For each consideration, the Guide provides a range of options rather than one “right” way
- In almost all cases, the options are not mutually exclusive, and it is advisable to adopt multiple approaches
- The Guide is applicable to a broad range of health systems, from solo practices to large group practices, from outpatient to inpatient settings, and from small clinics to large, integrated health systems

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Topics covered in the Guide

Relevant Primary Resources by Topic for PROs in Clinical Care

	ISOQOL Users Guide	PRO-EHR Users Guide	Recommendations for PRO Data Display	PRO-Cision Medicine Methods Toolkit	ePROs in Clinical Care Toolkit
DESIGN					
Goals	X				X
Barriers & Facilitators	X	X	X	X	X
Training & Engagement		X			X
Identifying Patients	X	X			
Outcomes & Measures	X	X			
Frequency & Timing	X	X			
IMPLEMENTATION					
Administering & Scoring	X	X			
Workflow					X
Results Presentation	X	X	X	X	X
Interpretation	X	X	X	X	X
Responding to Issues	X	X		X	
SYSTEM & DATA MANAGEMENT					
Evaluating	X				
EHR Integration		X			X
Governance		X			X
Data Pooling/Exchanging		X			
Ethical/Legal Issues		X			

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Defining Goals (Ch. 1)

- Defining the goal(s) of PRO collection upfront is critical to inform the design of robust PRO systems
- PRO systems can be designed to meet multiple goals
- Examples of these goals include:
  - Enhance patient care
  - Improve population health
  - Facilitate research
  - Quality improvement

Table 1.1 Patient-care goals for PRO systems

Patient-care goal	PRO system application
Screening tools	Identify unknown health problems using one-time assessments. Note that this approach does not describe changes in health over time.
Symptom monitoring and management	Track patient outcomes over time to inform whether treatments and interventions are effective, or how they should be modified.
Self-monitoring and management	Allow patients to track and evaluate their own health over time. This information can be used for self-management as well as to facilitate conversations with the clinical care team.
Needs assessment	Identify and evaluate symptoms, functional impairment, and health risks.
Patient-centered care	Understand a patient's own experiences and use this information to inform treatments and interventions.
Outcomes assessment	Evaluate the effectiveness of an intervention or a treatment.
Shared decision-making and decision aids	Facilitate discussion between providers and patients about patients' priorities for life and care. PRO data can be included in decision aids to inform patients' medical choices and help clarify patient values. Decision aids can include PROs and sometimes evaluate the impact of using a decision aid on PROs.

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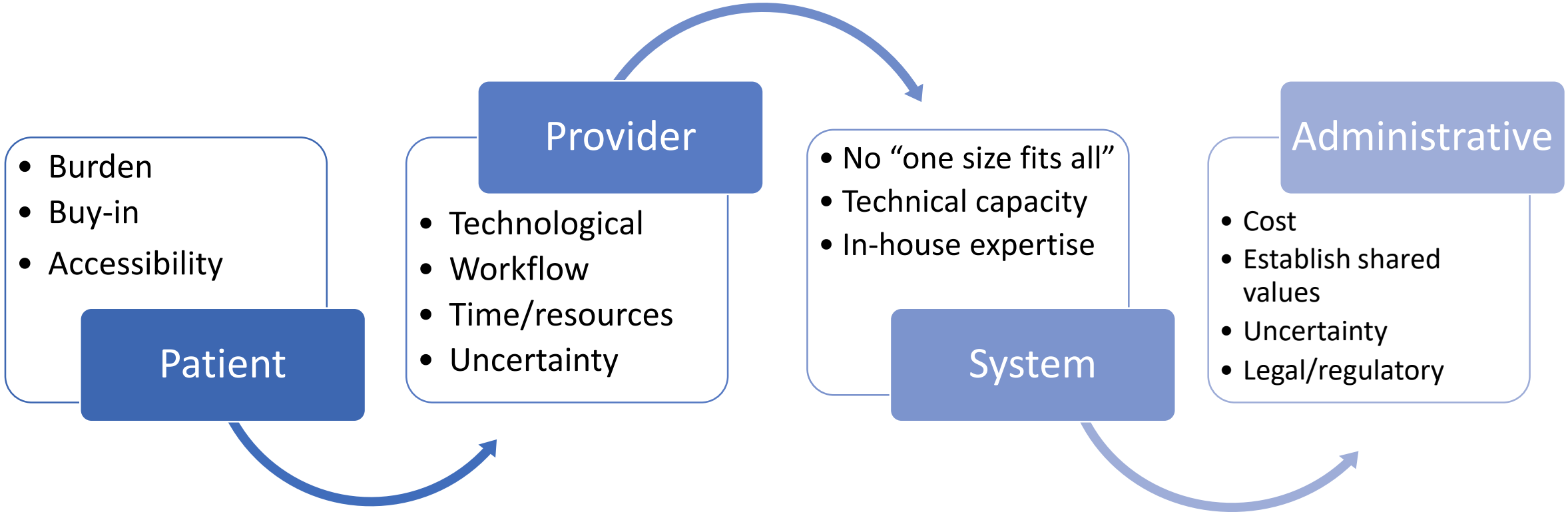
Barriers and Facilitators (Ch. 2)



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Identifying, Training, and Engaging Users and Stakeholders (Ch. 3)

Patients	Providers	Administrators
Administrative support staff	EHR managers	Informaticians
PROM experts	Researchers	Operation leads

- Numerous perspectives should be engaged in the design, development, and implementation of PRO systems
- Training activities can build capacity for robust engagement
- Participation in PRO systems can be motivated by demonstrating the value of PROs to clinical care

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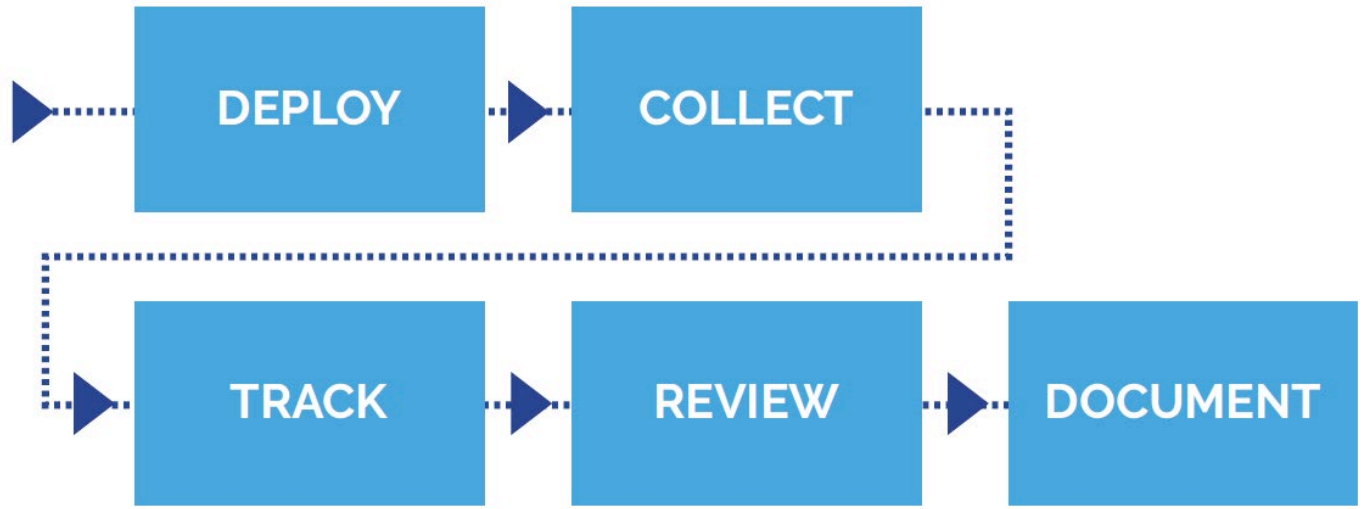
Incorporating in Clinical Workflow (Ch. 8)

- Specifics tasks for PROs will vary across settings, but 5 step process is universal

- When designing a workflow, start by identifying how PRO data will be used, and identify resources needed to integrate PROs

- Implementation science and user-centered design approaches can improve the quality of integration



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Presenting Results (Ch. 9)

- When PROs will be presented impacts how they should deployed, collected, and tracked
- Results can be displayed visually or numerically, in static or dynamic systems
- Reference values can be included to inform interpretation of PRO results
  - Baseline
  - Comparison to reference

Before Visit

- Allows for review the prior to visit
- Requires patient willingness to complete PROMs outside of the clinic

During Visit

- Most up-to-date information
- May be difficult to deploy, collect, and analyze

After Visit

- May be easier to implement
- Does not allow PROM use to inform clinical decision-making at the visit

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Aiding Interpretation (Ch. 10)

- Optimizing visualization can help patients and providers interpret results more easily and accurately

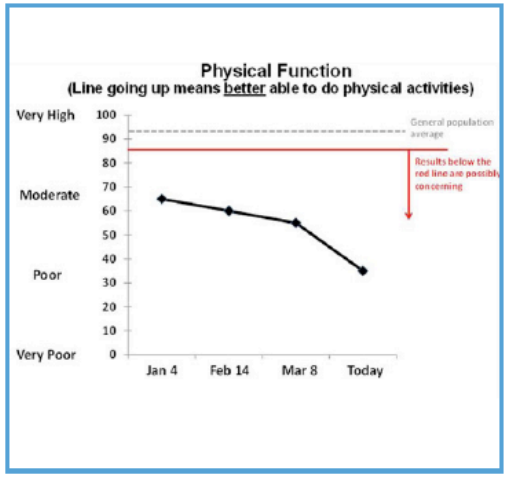
- Visualization should depend upon the purpose and context in which PROM information is being used

- Color, **bolding**, hover-over text can be used to draw attention to PROM data display

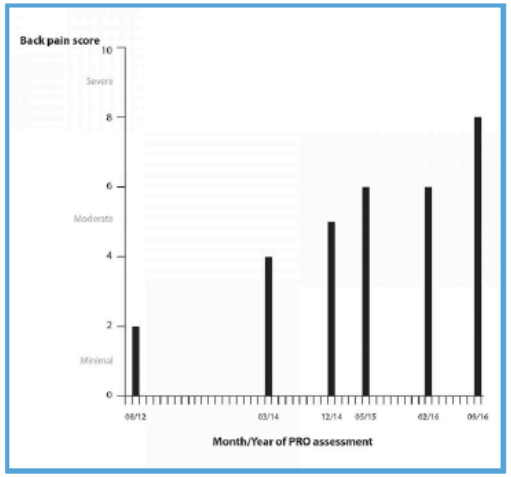
TABLE

	Scores on Each Visit Date			
Date	3/12	3/26	4/9	4/23
Physical Function	70	75	68	56
Emotional Function	80	80	85	80
Overall Quality of Life	75	70	70	65
Nausea or Vomitting	10	15	15	25
Pain	5	5	5	10
Fatigue	20	25	25	35

LINE GRAPH



BAR GRAPH



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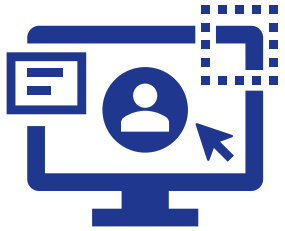
EHR Integration (Ch. 13)



Full integration

- PROMs collection and display entirely contained in EHR
- Typically, the most convenient and trusted
- Limited customization options

Partial integration

- Collect PROMs in stand-alone system which may be sent to EHR
- User-friendly interfaces designed for PROMs specifically
- May require patients to access a separate portal outside of EHR

Minimal Integration

- Scan or manually enter paper-collected PROMs into EHR
- Low upfront costs, but manually burdensome
- Automatic scoring, tracking features not available

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Approach for Governance (Ch. 14)

- Governance provides strategic input on the structure and process of implementing the PRO system
- Centralized, distributed, or a hybrid
- Should include individuals with multi-disciplinary perspectives

Governance Activities

- Define system scope
- Establish decision-making process
- Guidance on selection of PROs
- Disseminate good practices for PRO system
- Identify PRO system needs

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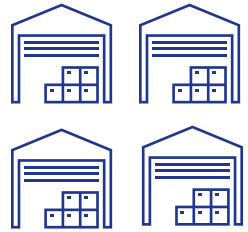
Pooling/Exchanging Data (Ch. 15)

- Identifying an appropriate data model and associated meta-data is an important aspect of maximizing the utility of pooled PRO data

- Pooled data can be stored either in centralized data warehouses or in distributed data warehouses

Centralized

- Store data from sites
- Return data for own analysis
- Easier record linkage
- Greater data sharing/privacy concerns



Distributed

- Store only local data
- Return data summaries
- More difficult record linkage
- Fewer data sharing/privacy concerns

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Addressing Legal and Ethical Issues (Ch. 16)

- Equitable and inclusive PRO systems are vital to ensuring the utility of PROMs for diverse patient populations
- Have appropriate disclosures and consents in place to ensure that PRO data can be ethically used for multi-purposes
- Liability concerns, especially regarding responses to PROM alerts, should be considered when designing PRO systems

QUESTIONS AND CONSIDERATIONS

A. WHAT ARE THE DIVERSITY, EQUITY, AND INCLUSION CONSIDERATIONS FOR PROM DATA USE IN CLINICAL CARE?

- Collecting PROMs from diverse patient populations can inform understanding of how patient experiences vary across these groups
- When selecting a PROM for data collection, it is important to ensure it is valid and relevant for the patient population of interest
- While the use of electronic PRO capture may be useful to some, it may exacerbate disparities in care for others, such as those who lack internet access, or have low technology and/or health literacy

B. WHAT DISCLOSURES COULD BE PRESENTED TO PATIENTS WHEN COLLECTING AND USING PROMS?

NO DISCLOSURE

- Patients would be asked to complete PROMs but receive no information about how the data will be maintained/managed
- No verbal/written authorization from patients is requested
- May be easiest for individual fielding and completing the surveys, but may also decrease motivation to complete the survey if it is unclear how/why this data will be used
- May not comply with local laws and research regulations, and ability to use and publish data collected using this approach for research may be limited

GENERAL NON-SPECIFIC DISCLOSURE AND OPT-OUT

- All patients in the healthcare system are informed that PROMs are generally collected for use in clinical care, quality improvement, and research
- Patients can, for example, opt-out of completing PROMs, or opt-out of PROM data being linked to other databases
- This general disclosure may be insufficient for some types of research use, which would then require future consent

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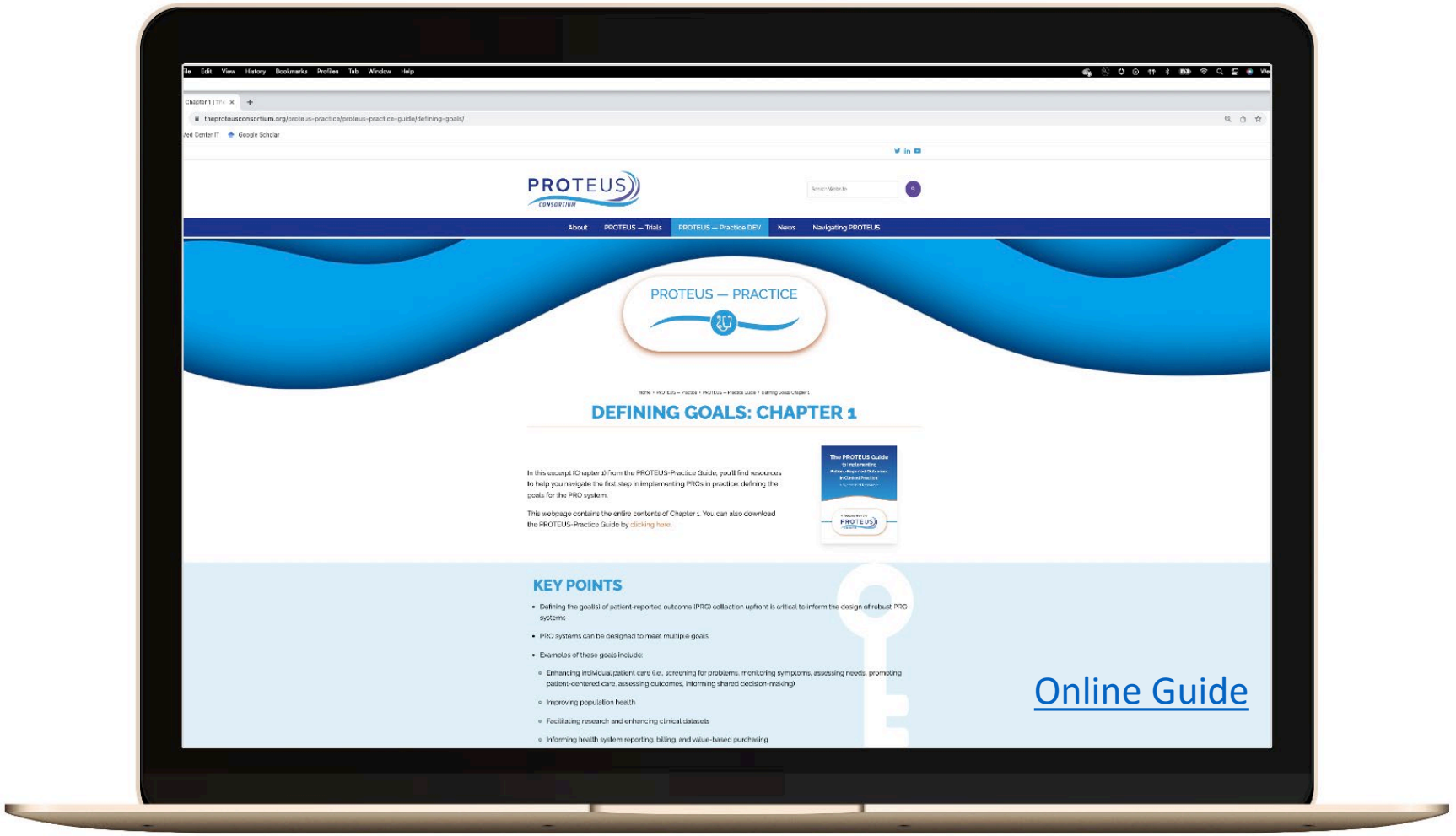
Web Tool



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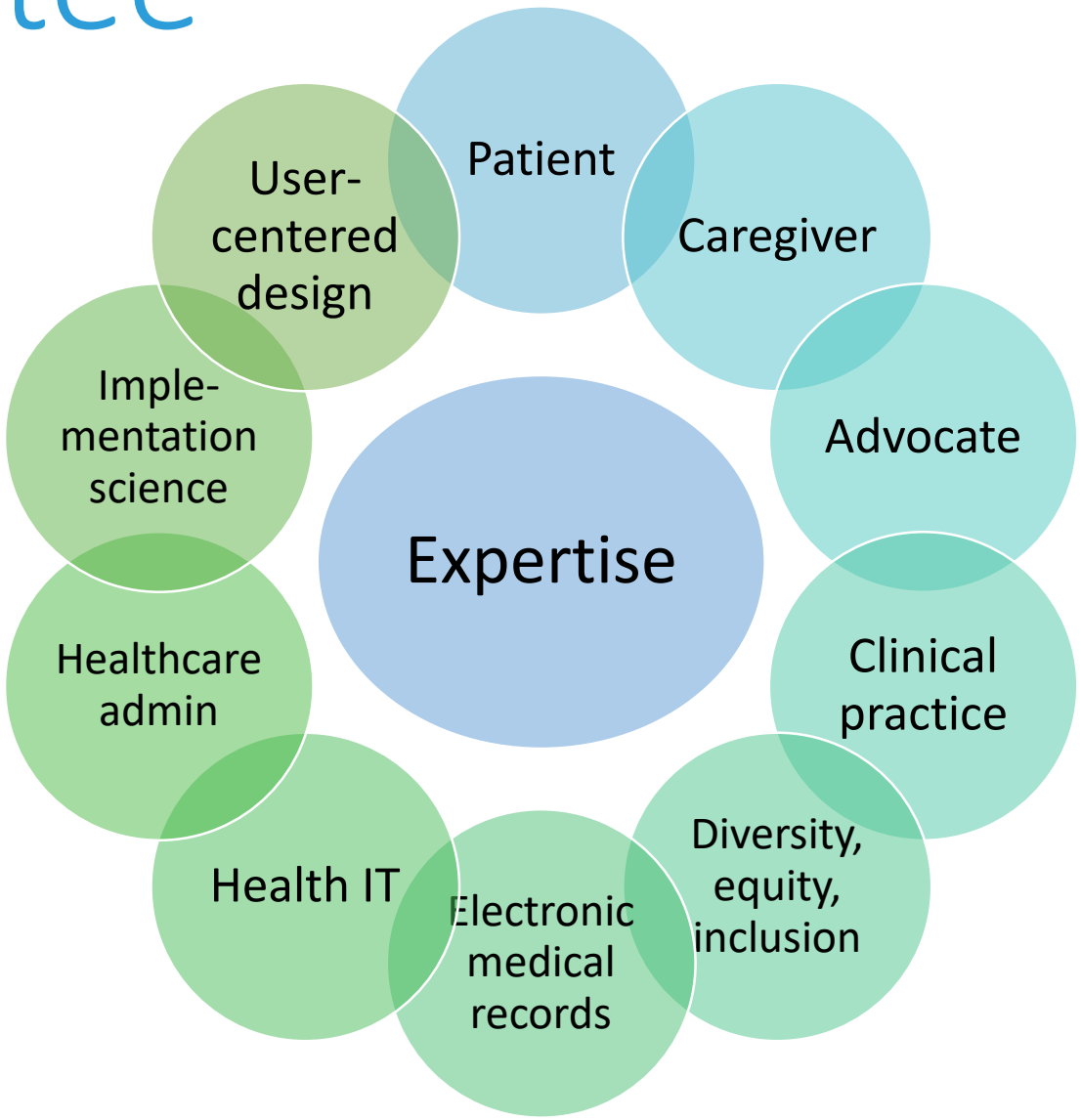
Advisory Committee

- Nicola Anderson, PhD, MSc
- Judy Baumhauer, MD
- Michael Brundage, MD, MSc
- Mel Calvert, PhD
- Norah Crossnohere, PhD
- Rebecca Esparza
- Christopher Gibbons, PhD
- Yuchen Li, MD
- Carolyn Petersen, MS, MBI
- Ameeta Retzer
- Claire Snyder, PhD
- Angela Stover, PhD
- Elissa Thorner, MSPH
- Elliott Walker
- Garrett Ursin
- Galina Velikova, MD



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The PROTEUS – Practice Initiatives:

Learning Health Network & Underserved Advisory Group

Anne L R Schuster, PhD
Research Scientist, Department of Biomedical Informatics
The Ohio State University College of Medicine

Learning Health Network

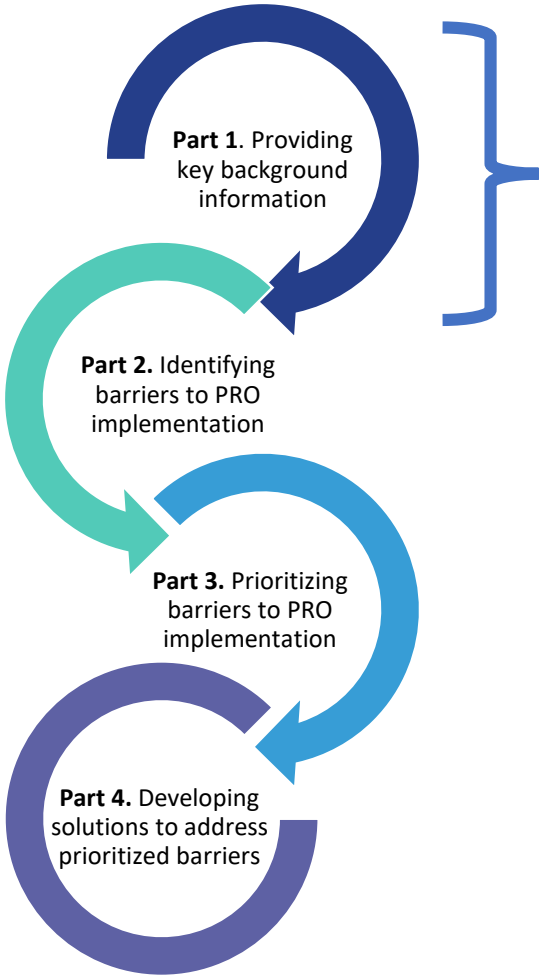
- There is a recognition that using PROs in clinical practice is not easy, despite growing evidence of the benefits of using them in routine practice such as:
  - Patient-clinician communication
  - Detection and management of problems
  - Efficiency
  - Symptom control, quality-of-life, survival
- PROTEUS & Pfizer partnered and issued a Request for Proposals for projects that support the implementation of PROs in oncology clinical practice
- Learning Health Network includes 10 funded projects who come together with members across the PROTEUS Consortium for monthly meetings hosted by PROTEUS that provide a forum to share experiences and lessons learned

Underserved Advisory Group

- Building off Learning Health Network Request-for-Proposals, recognition that institutions caring for vulnerable and underserved populations* may face unique challenges when aiming to implement PROs in routine care
- PROTEUS & Pfizer partnered to explore these issues by forming and meeting with an Advisory Group that aimed to:
  - Improve our understanding of the facilitators of and barriers to implementing routine PRO assessments in vulnerable and underserved populations
  - Build capacity for PRO implementation to improve care for cancer patients who are vulnerable or underserved
- 26 individuals invited from 86 submissions received from PROTEUS-Pfizer Request for Expressions of Interest

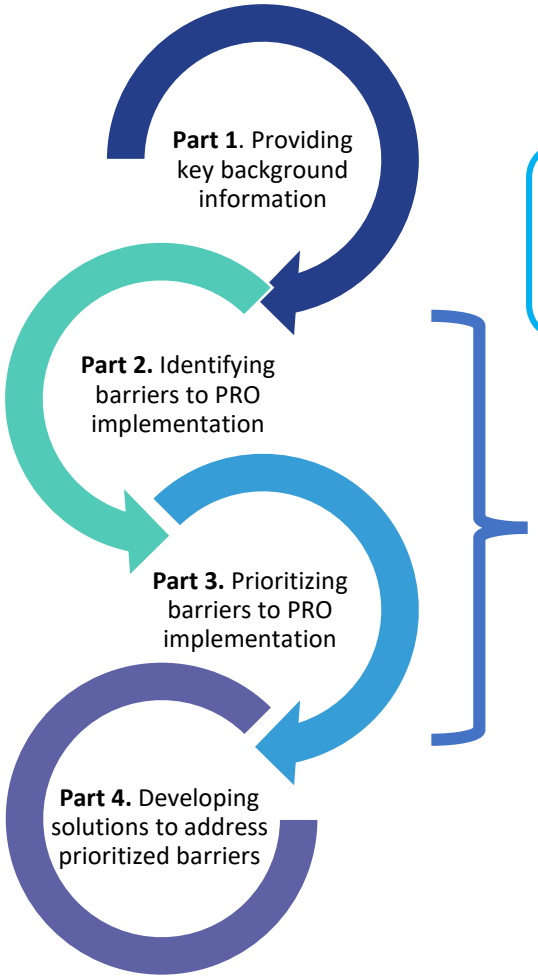
**Based on definitions from the U.S. Department of Health & Human Services and Centers for Medicare and Medicaid Services*

Underserved Advisory Group Meeting: Process and Outcomes



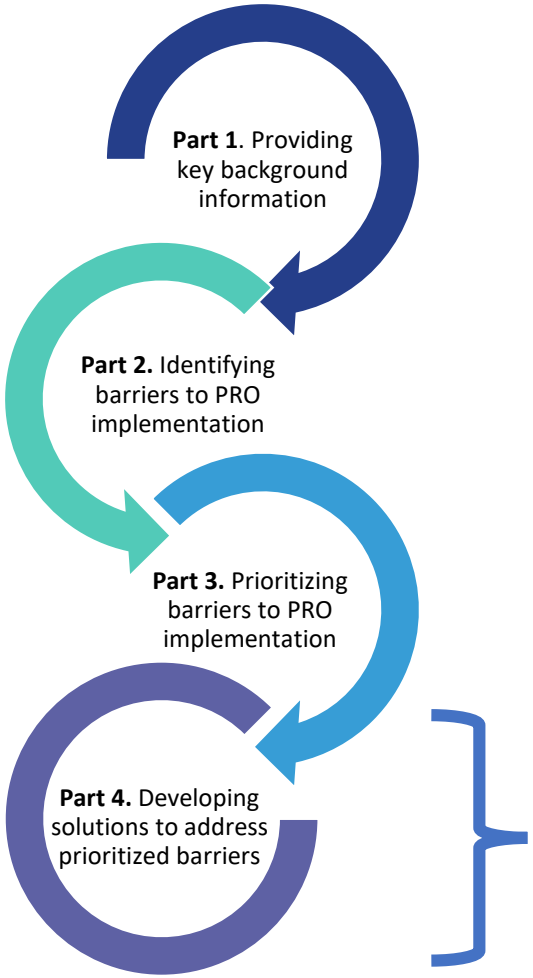
- PROTEUS team leaders presented:
  - Background on PROTEUS
  - Rationale for establishing the Underserved Advisory Group
  - Goals of developing solutions to advance the use of PROs in vulnerable and underserved populations
- Included three orienting presentations that highlighted:
  - A patient's experience
  - Current literature on implementing PROs in routine clinical care for diverse and underrepresented patients in the U.S.
  - Known barriers to integrating PROs in clinical care

Underserved Advisory Group Meeting: Process and Outcomes



Barrier	Number of votes
Systems' commitment among competing priorities as demonstrated through resources and staffing	17
Systems and clinicians' ability to address patients' culture, language, literacy and numeracy	12
Investment required to collect data among vulnerable populations	9
Patient-level technology capability (broadband access, willingness/capability to use)	8
Clinician resistance / lacking appreciation of value	7
Patient not seeing value if not seeing PROs used	5
Trust and respect	4
Availability of PRO measures in multiple language and literacy levels	4
Lack of reimbursement to systems trickles to clinicians and then patients	4
Concerns about technology security and data privacy	3
Actionability (not asking about things that can't be addressed)	3
PROs not patient-centered because not patient informed	3
Sustainability in a dynamic environment	2
Responsibility to act on data	1
Inequitable impact of PRO data benefits	1
Lack of engagement of these populations in healthcare generally	1
Time and transportation	0

Underserved Advisory Group Meeting: Process and Outcomes



- The Advisory Group identified 47 different potential solutions to address the top barriers
- Following the meeting, the PROTEUS leaders reviewed and categorized the solutions into four categories:
  - Education and engagement (included 48% of all solutions)
  - Information technology or technological resources (included 22% of all solutions)
  - Incentives, mandates, and marketing (included 15% of all solutions)
  - Research (included 15% of all solutions)

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