# Assessing and Advancing Progress in the Delivery of High-Quality Cancer Care:

# The Role of Patient-Reported Outcomes

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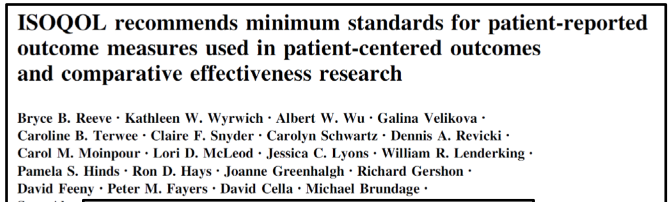
Principal Investigator
The PROTEUS Consortium

# “clinical trials and comparative effectiveness research must include data collection that reflects patient-reported outcomes”



**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 ·
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Sara Ahm

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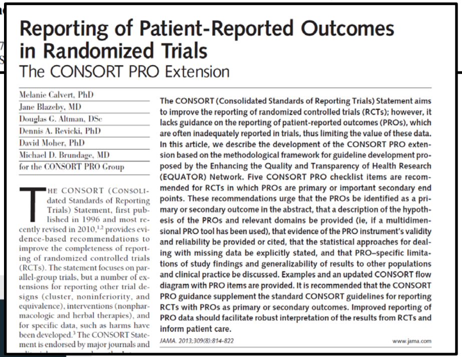

**Reporting of Patient-Reported Outcomes in Randomized Trials**
The CONSORT PRO Extension

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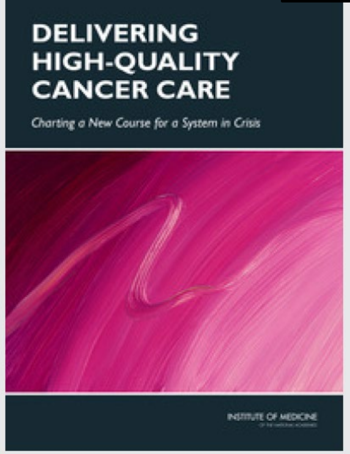
David Moher, PhD
Michael D. Brundage, MD
for the CONSORT PRO Group

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



DELIVERING HIGH-QUALITY CANCER CARE
*Charting a New Course for a System in Crisis*
INSTITUTE OF MEDICINE

2013

2014

**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 S
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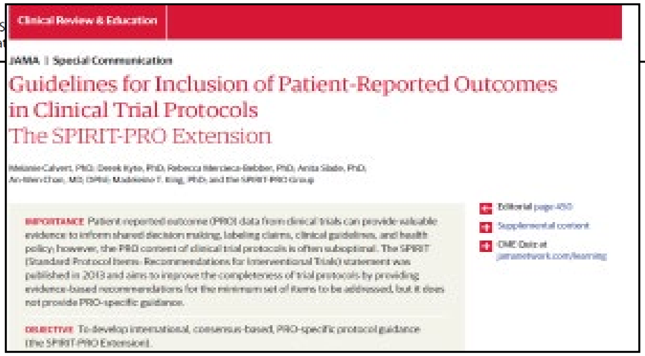


Clinical Review & Education

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

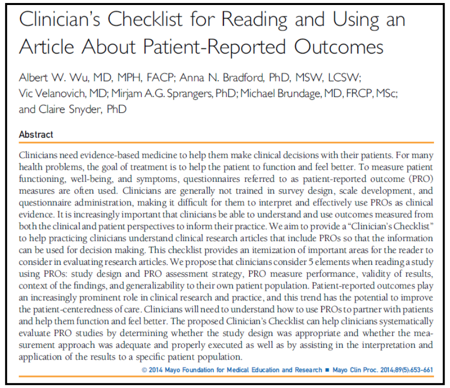
**IMPORTANCE** Patient-reported outcome (PRO) data from clinical trials can provide valuable evidence to inform shared decision making, labeling claims, clinical guidelines, and health policy; however, the PRO content of clinical trial protocols is often suboptimal. The SPIRIT (Standard Protocol Items: 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

2018

2020



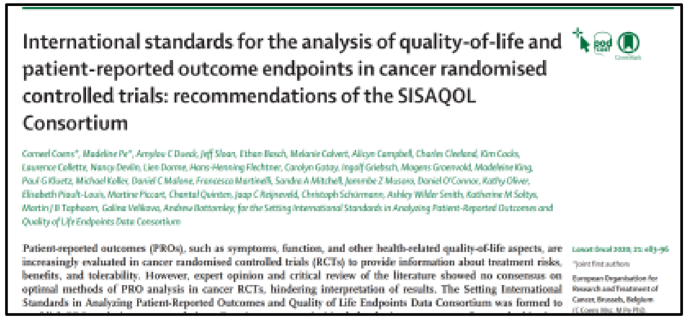
Clinician’s Checklist for Reading and Using an Article About Patient-Reported Outcomes

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.

© 2014 Mayo Foundation for Medical Education and Research ■ Mayo Clin Proc. 2014;89(5):653-661



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, Madeline 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
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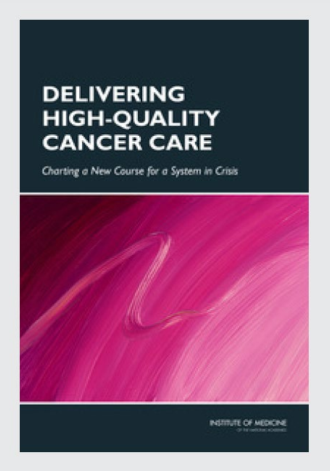
PROTEUS
CONSORTIUM

# “A high-quality and efficient information technology infrastructure is critical to collecting these outcome data from ongoing clinical practice at the point of care,”



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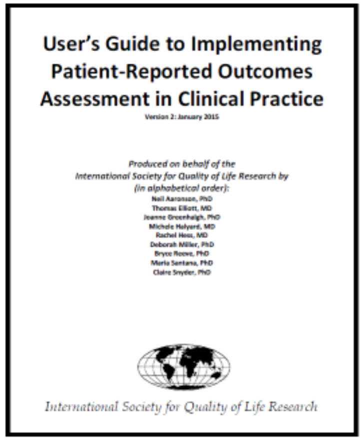
2015



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

Version 2: January 2015

*Produced on behalf of the*
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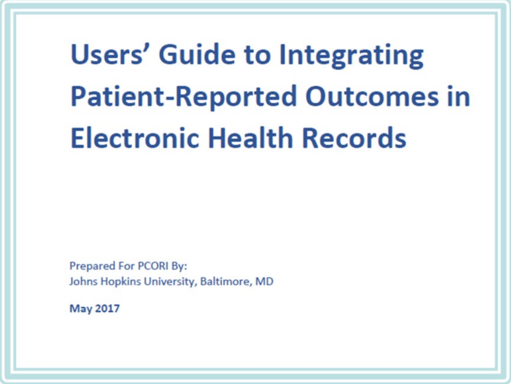
Claire Snyder, PhD

*International Society for Quality of Life Research*

2017



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

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

May 2017

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

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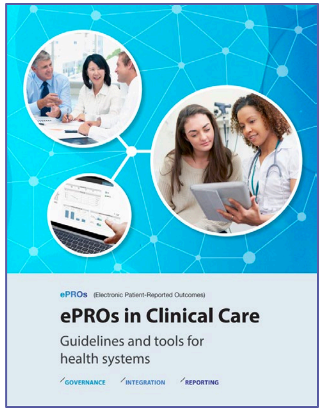
2018

2019

MEDICAL CARE



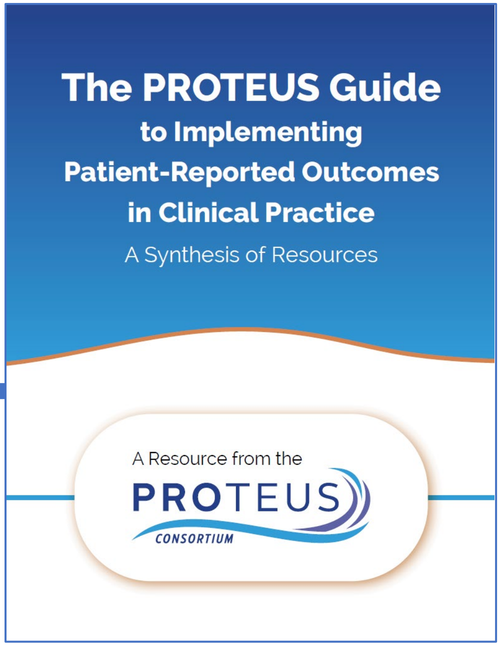
ePROs (Electronic Patient-Reported Outcomes)

ePROs in Clinical Care

Guidelines and tools for health systems

GOVERNANCE INTEGRATION REPORTING

2020



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

A Synthesis of Resources

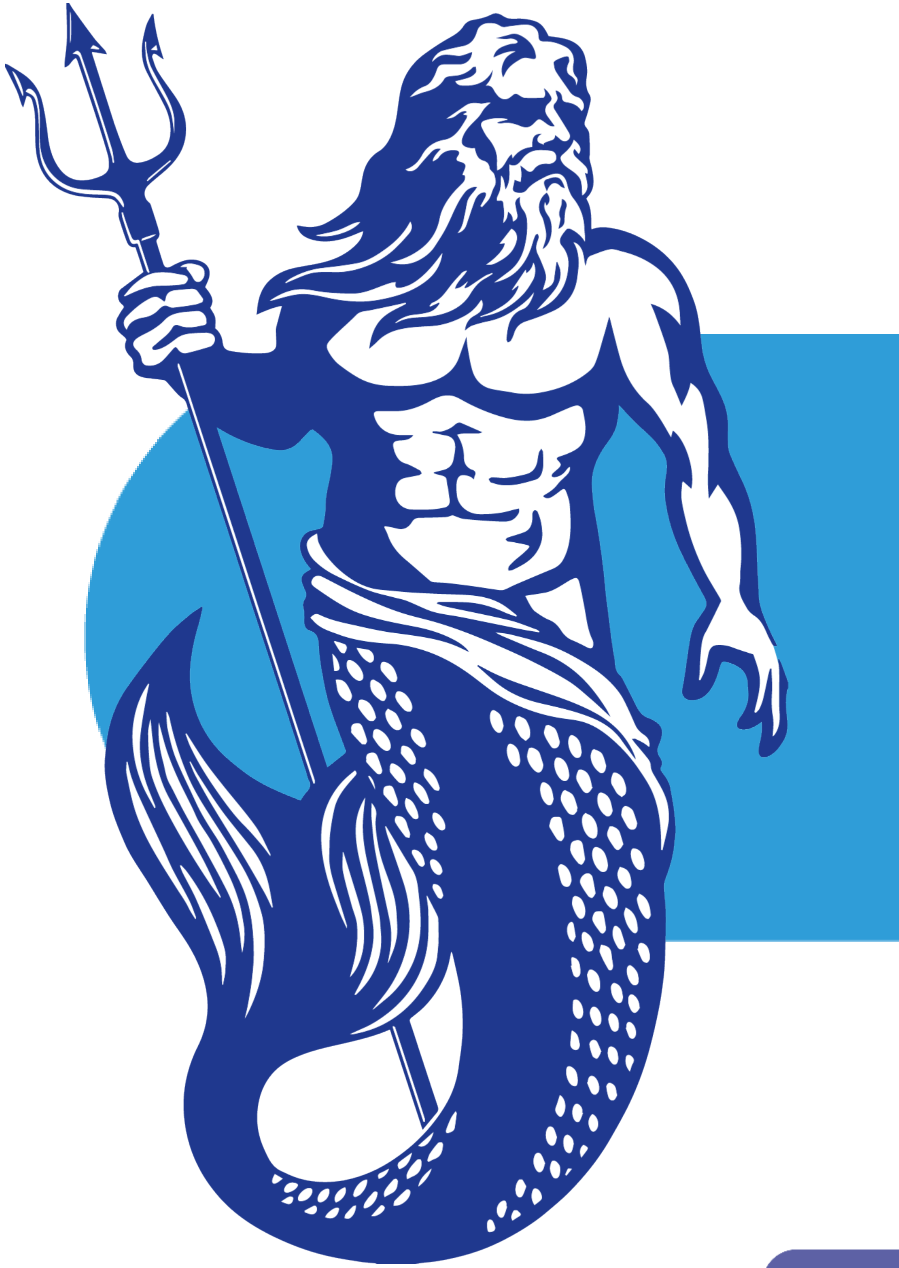
A Resource from the PROTEUS CONSORTIUM

# PROTEUS

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

# PERSONAL

- Consulting fees from Janssen and Shionogi
- Anticipated honorarium from Boehringer-Ingelheim



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