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

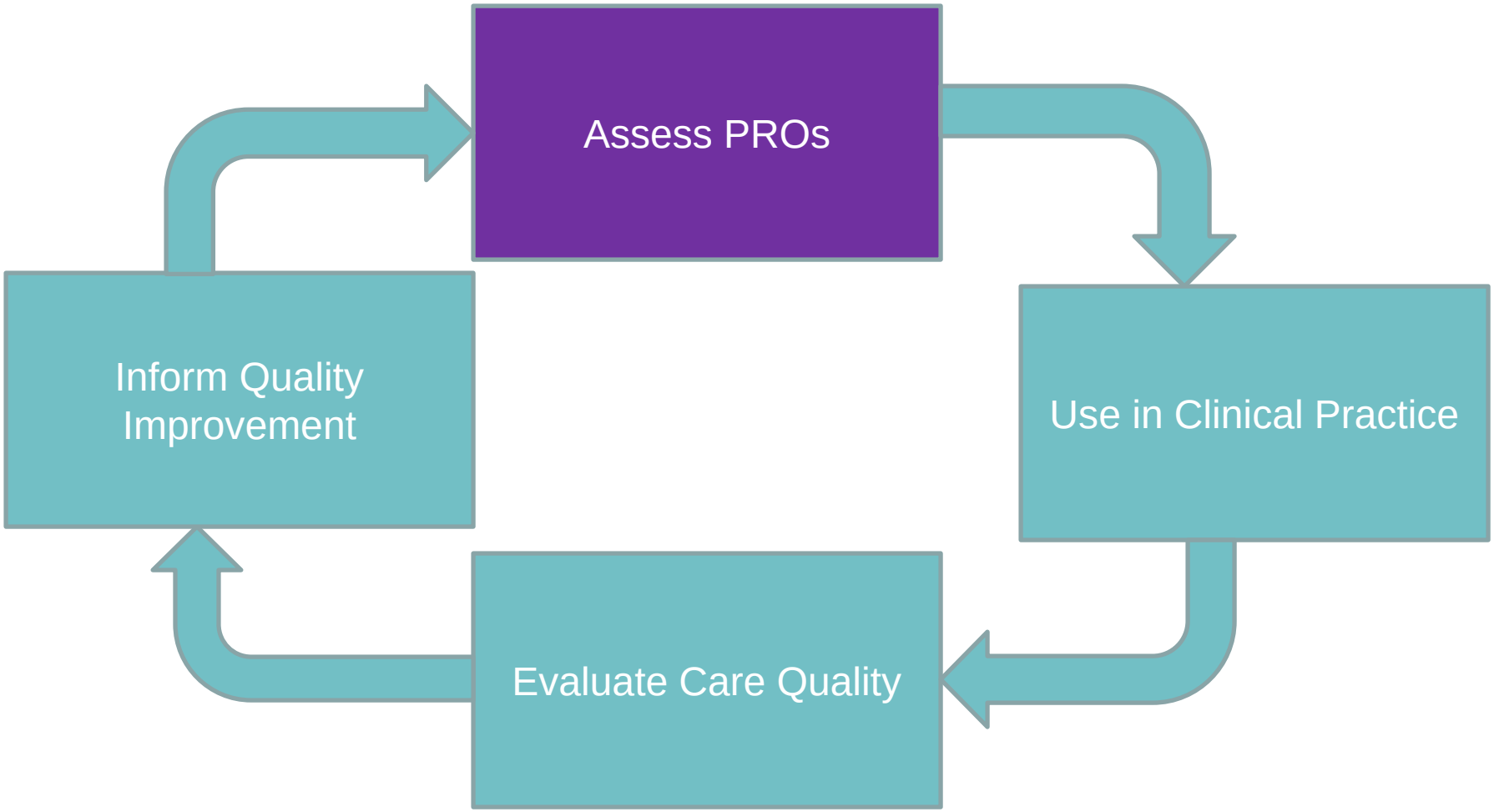
Claire Snyder, PhD, Principal Investigator
Albert Wu, MD, MPH, Co-Principal Investigator

NIH Collaboratory/PCORNet Grand Rounds
October 13, 2017

Funded by the Patient-Centered Outcomes Research Institute


SURVEY
Your EMR
Differential Diagnosis
Treatment
Peptic Ulcer Disease, General
Prescribe

Multi-Purpose PROs



ELSEVIER

Journal of Clinical Epidemiology 66 (2013) S12–S20

Journal of Clinical Epidemiology

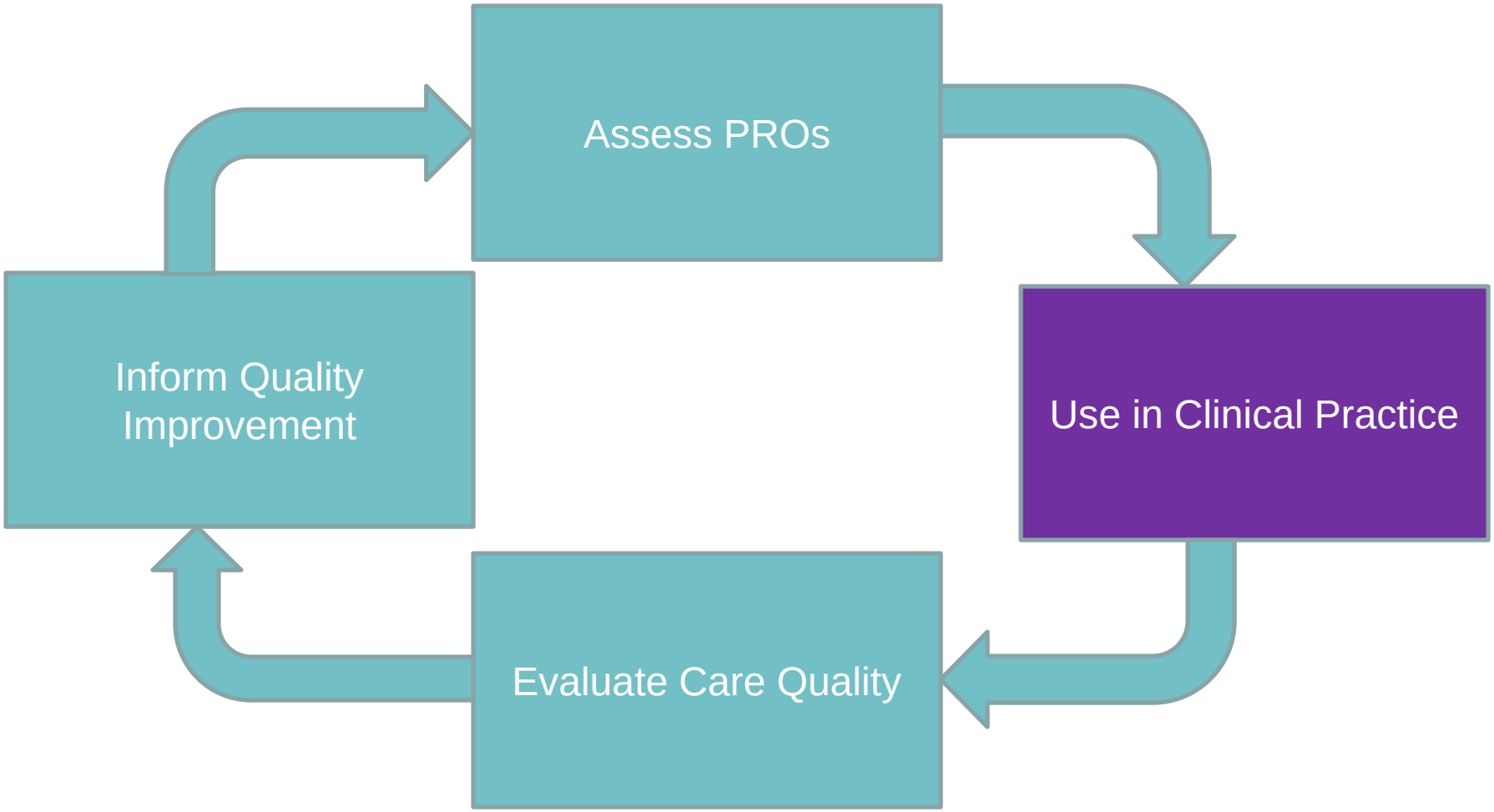
Measure once, cut twice—adding patient-reported outcome measures to the electronic health record for comparative effectiveness research

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

Multi-Purpose PROs



Clinician & Patient View Report

Comments View All

Is there one problem in particular you'd like your doctor or nurse to address during your next visit?

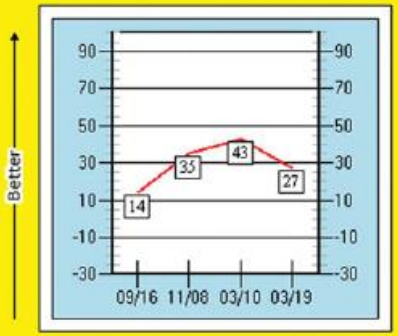
I am having trouble doing the things I need to do.

Enter any other comments or questions for your doctor or nurse.

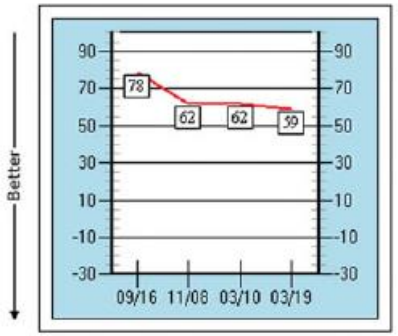
It's helpful answering these questions.

The results for the most recent and four previous surveys are graphed below. Graphs highlighted in yellow represent either a significant worsening or a score that is likely to be a problem. For a summary of the items in each score, click What is this? For an explanation of the scoring, click Score meaning. For suggestions for how to address potential problems, click What can I do?

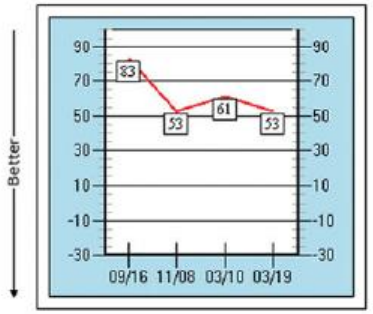
Physical Function - Score meaning
What is this? What can I do?



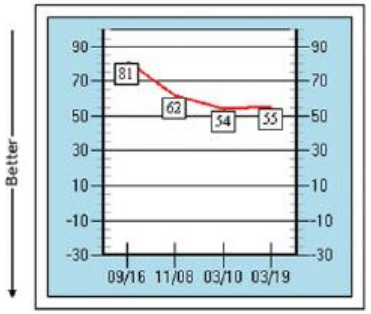
Pain Impact - Score meaning
What is this? What can I do?



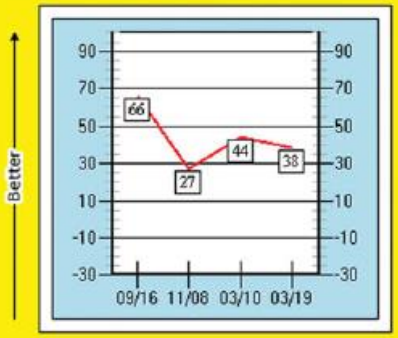
Anxiety - Score meaning
What is this? What can I do?



Depression - Score meaning
What is this? What can I do?



Social Roles - Score meaning
What is this? What can I do?



Fatigue - Score meaning
What is this? What can I do?

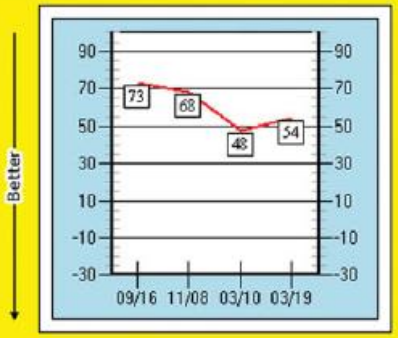


Table Chart

	03/19/2012	03/10/2012	11/08/2010	09/16/2010
Physical Function	27.1	42.6	35.0	14.1
Pain Impact	59.1	61.8	61.8	78.3
Social Roles	38.2	44.4	27.0	65.6
Fatigue	53.7	47.6	67.8	72.9
Anxiety	52.6	61.3	52.6	82.7
Depression	55.3	54.3	61.6	81.1
Comments	Yes	Yes	No	No

Original Contribution

Review of Electronic Patient-Reported Outcomes Systems Used in Cancer Clinical Care

By Roxanne E. Jensen, PhD, Claire F. Snyder, PhD, Amy P. Abernethy, MD, Erhan Basch, MD, Arnold L. Potosky, PhD, Aaron C. Roberts, Deena R. Loeffler, MA, and Bryce B. Reeve, PhD

Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, DC; The Johns Hopkins University School of Medicine and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; Duke Comprehensive Cancer Center, Duke University Medical Center, Durham; Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC; and Health Outcomes Group, Memorial Sloan-Kettering Cancer Center, New York, NY

Abstract

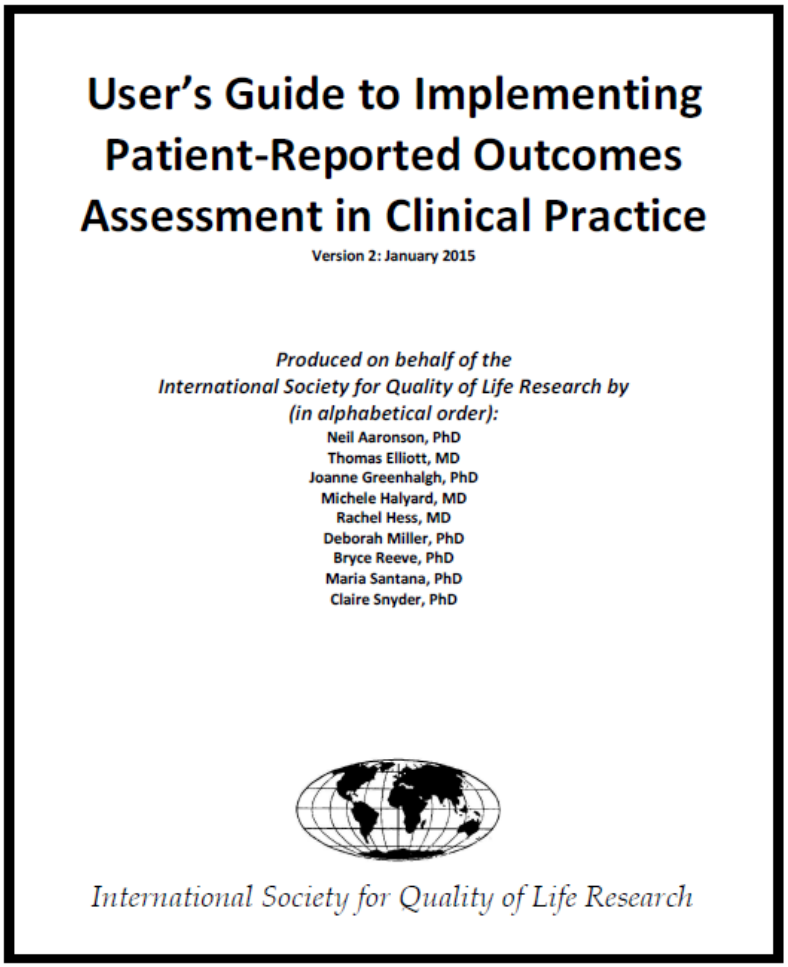
Purpose: The use of electronic patient-reported outcomes (PRO) systems is increasing in cancer clinical care settings. This review comprehensively identifies existing PRO systems and explores how systems differ in the administration of PRO assessments, the integration of information into the clinic workflow and electronic health record (EHR) systems, and the reporting of PRO information.

Methods: Electronic PRO (e-PRO) systems were identified through a semistructured review of published studies, gray literature, and expert identification. System developers were contacted to provide detailed e-PRO system characteristics and clinical implementation information using a structured review form.

Results: A total of 33 unique systems implemented in cancer clinical practice were identified. Of these, 81% provided detailed information about system characteristics. Two system classifications were established: treatment-centered systems designed for patient monitoring during active cancer treatment (n = 8) and patient-centered systems following patients across treatment and survivorship periods (n = 19). There was little consensus on administration, integration, or result reporting between these system types. Patient-centered systems were more likely to provide user-friendly features such as at-home assessments, integration into larger electronic system networks (eg, EHRs), and more robust score reporting options. Well-established systems were more likely to have features that increased assessment flexibility (eg, location, automated reminders) and better clinical integration.

Conclusion: The number of e-PRO systems has increased. Systems can be programmed to have numerous features that facilitate integration of PRO assessment and routine monitoring into clinical care. Important barriers to system usability and widespread adoption include assessment flexibility, clinical integration, and high-quality data collection and reporting.

Source: Jensen et al, J Oncol Pract. 2014;10:e215-222.



Available at:
http://www.isoqol.org/UserFiles/2015UsersGuide-Version2.pdf

- Helps clinicians and researchers interested in implementing PRO assessment to aid patient care
- Includes
  - Considerations
  - Options
  - Resource requirements
  - Relative advantages and disadvantages

Qual Life Res
DOI 10.1007/s11136-011-0054-x

REVIEW

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

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

Accepted: 18 October 2011

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.

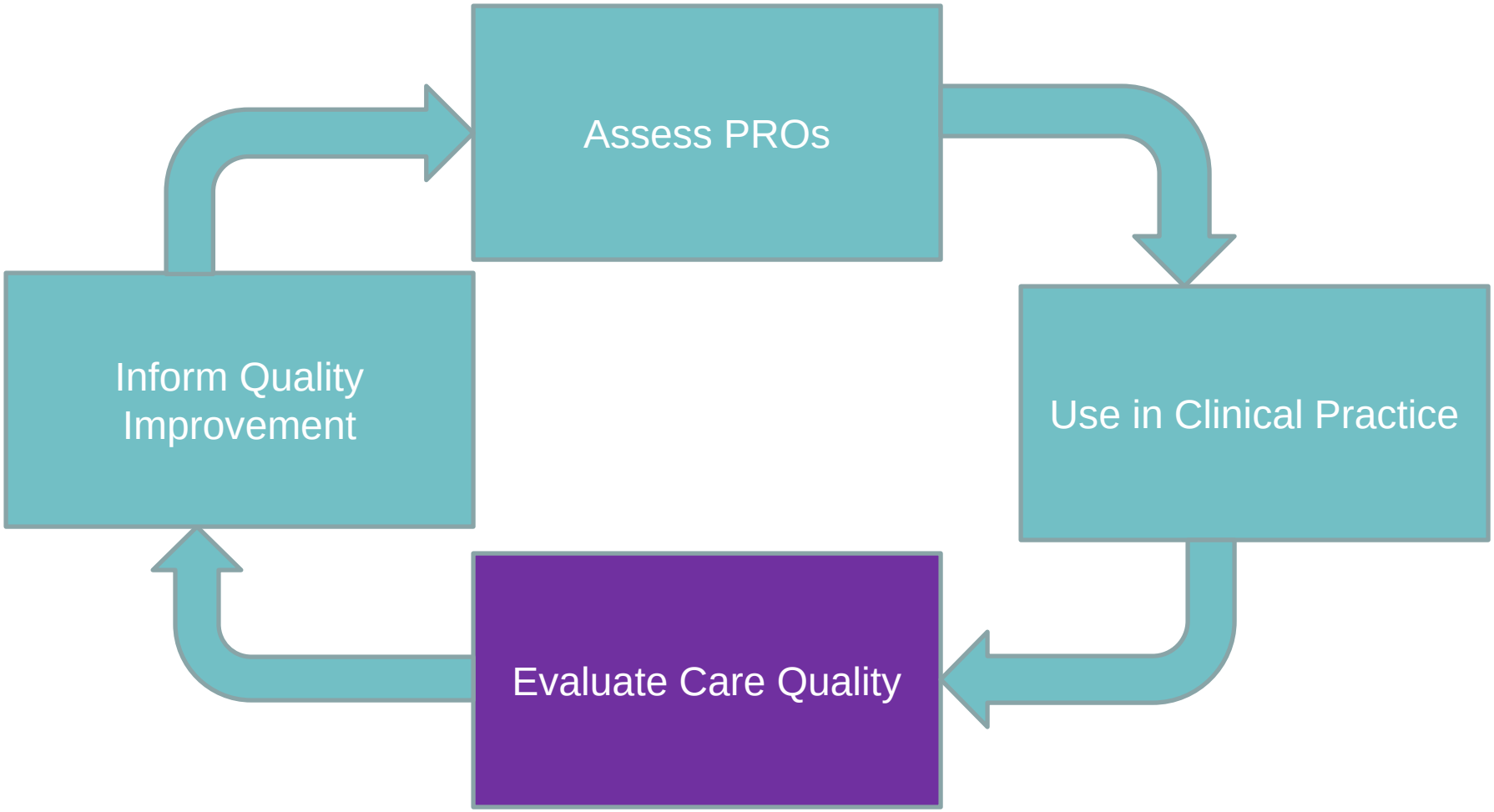
Conclusions Integrating PROs in clinical practice has the potential to enhance patient-centered care. The online version of the *User's Guide* will be updated periodically.

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

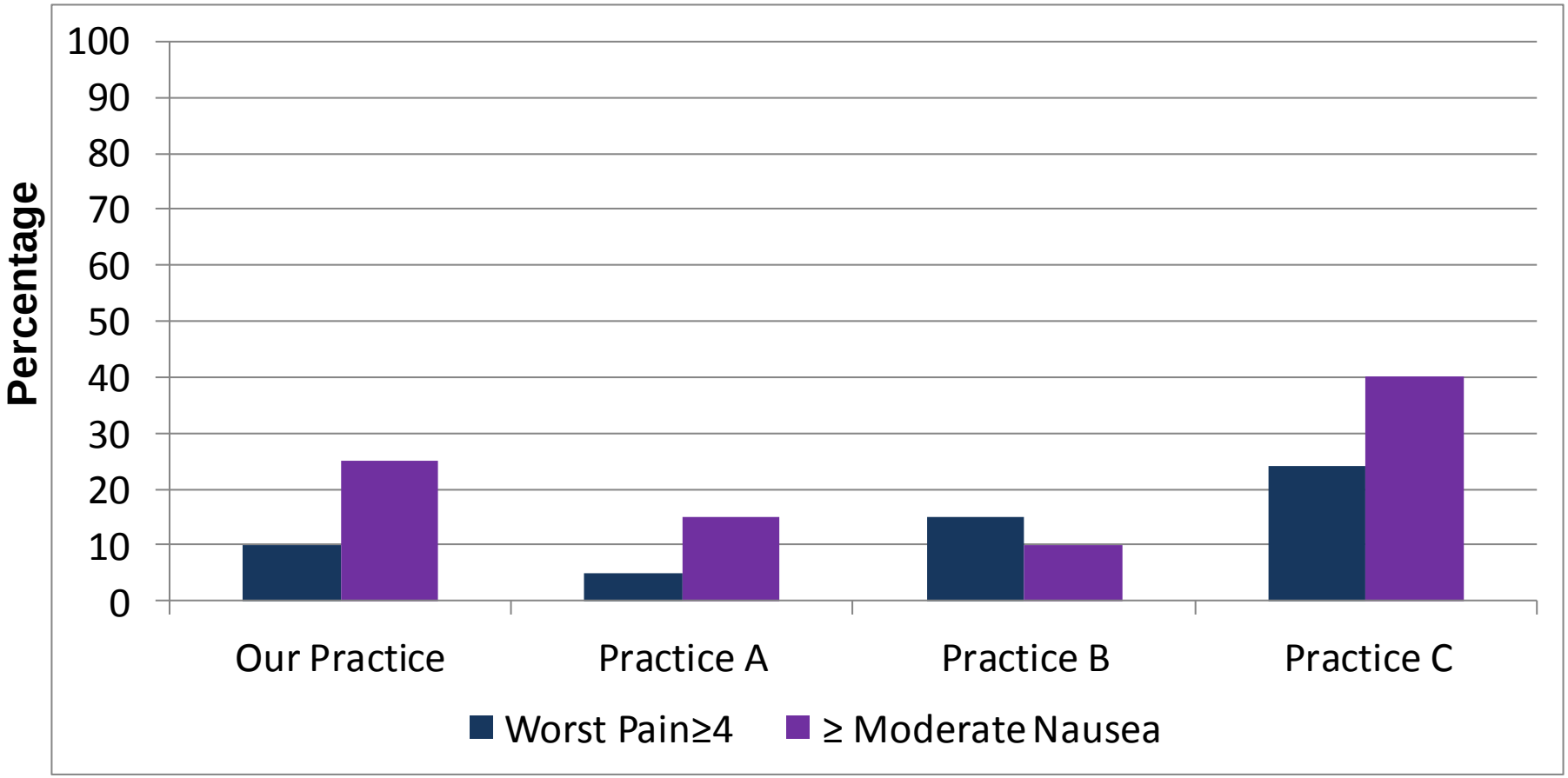
1. Identifying the goals for collecting PROs in clinical practice
2. Selecting the patients, setting, and timing of assessments
3. Determining which questionnaire(s) to use
4. Choosing a mode for administering and scoring the questionnaire
5. Designing processes for reporting results
6. Identifying aids 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

Multi-Purpose PROs



Aggregate Data Across Patients

Quality Reporting to Compare Providers



ASCO Pilot-Test of PRO Performance Measures

Special Series: Quality Care Symposium

Perspective

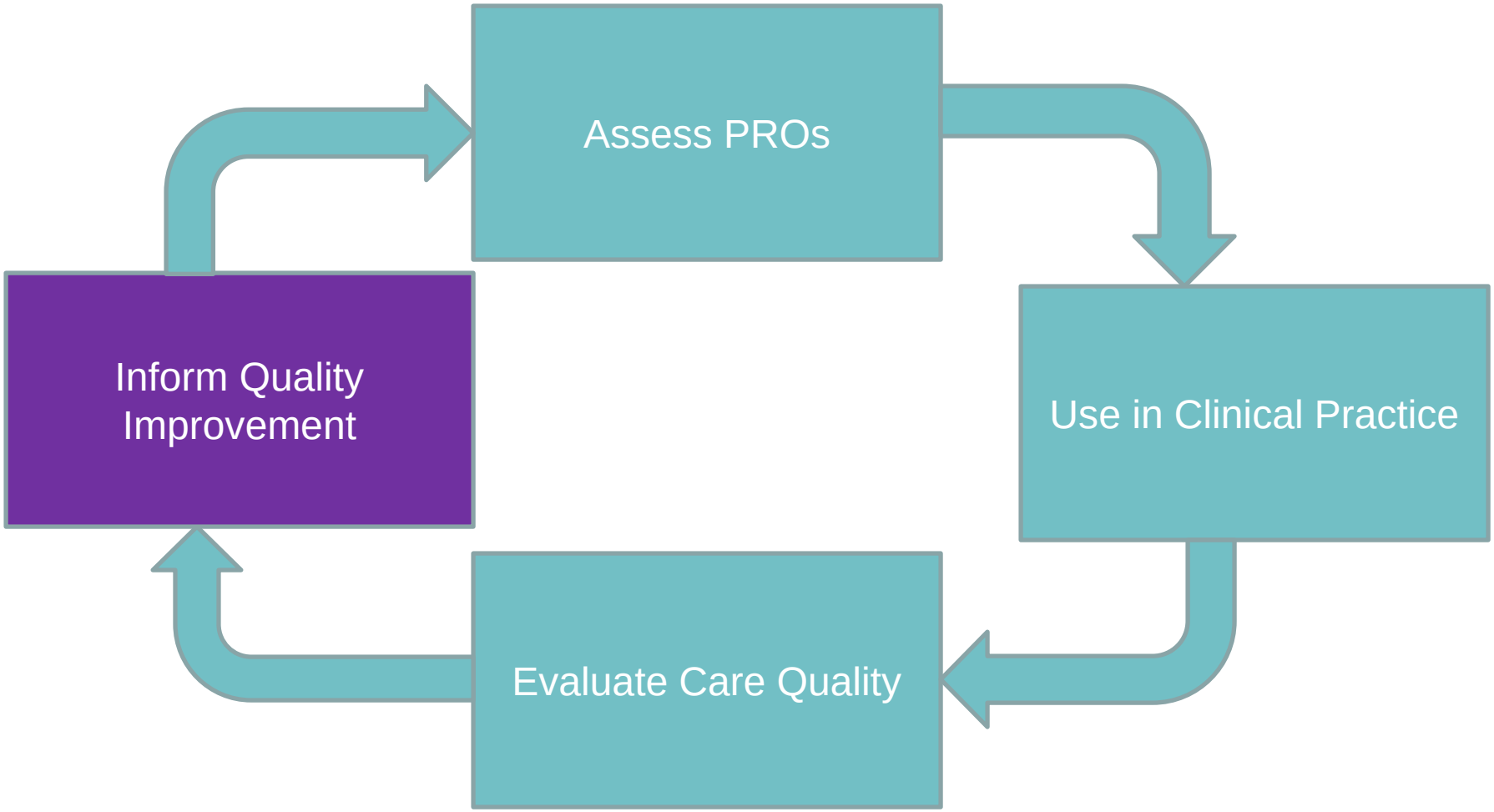
Patient-Reported Outcome Performance Measures in Oncology

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

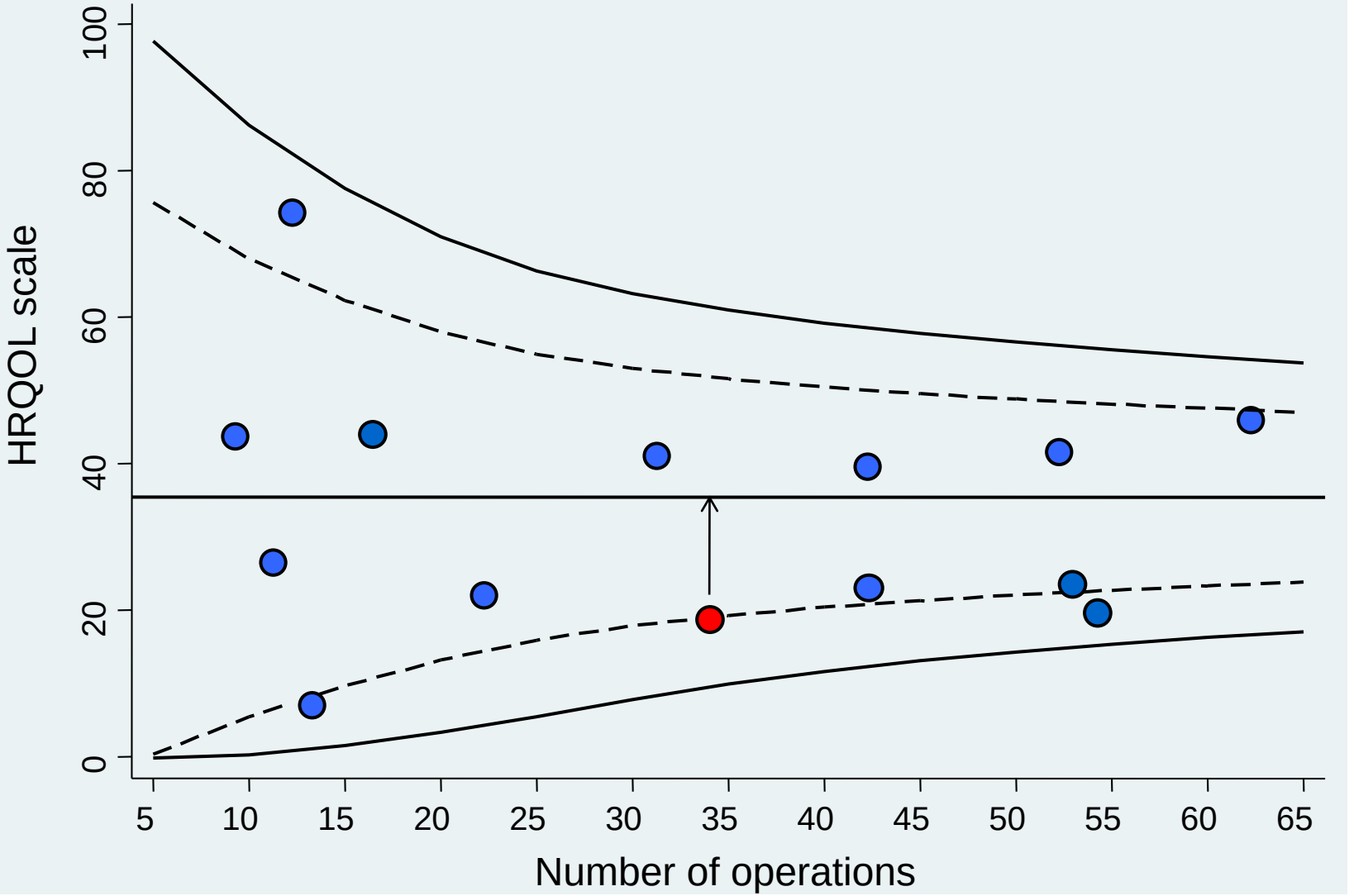
Source: Basch et al, J Oncol Pract. 2014; 10:209-211.

Multi-Purpose PROs

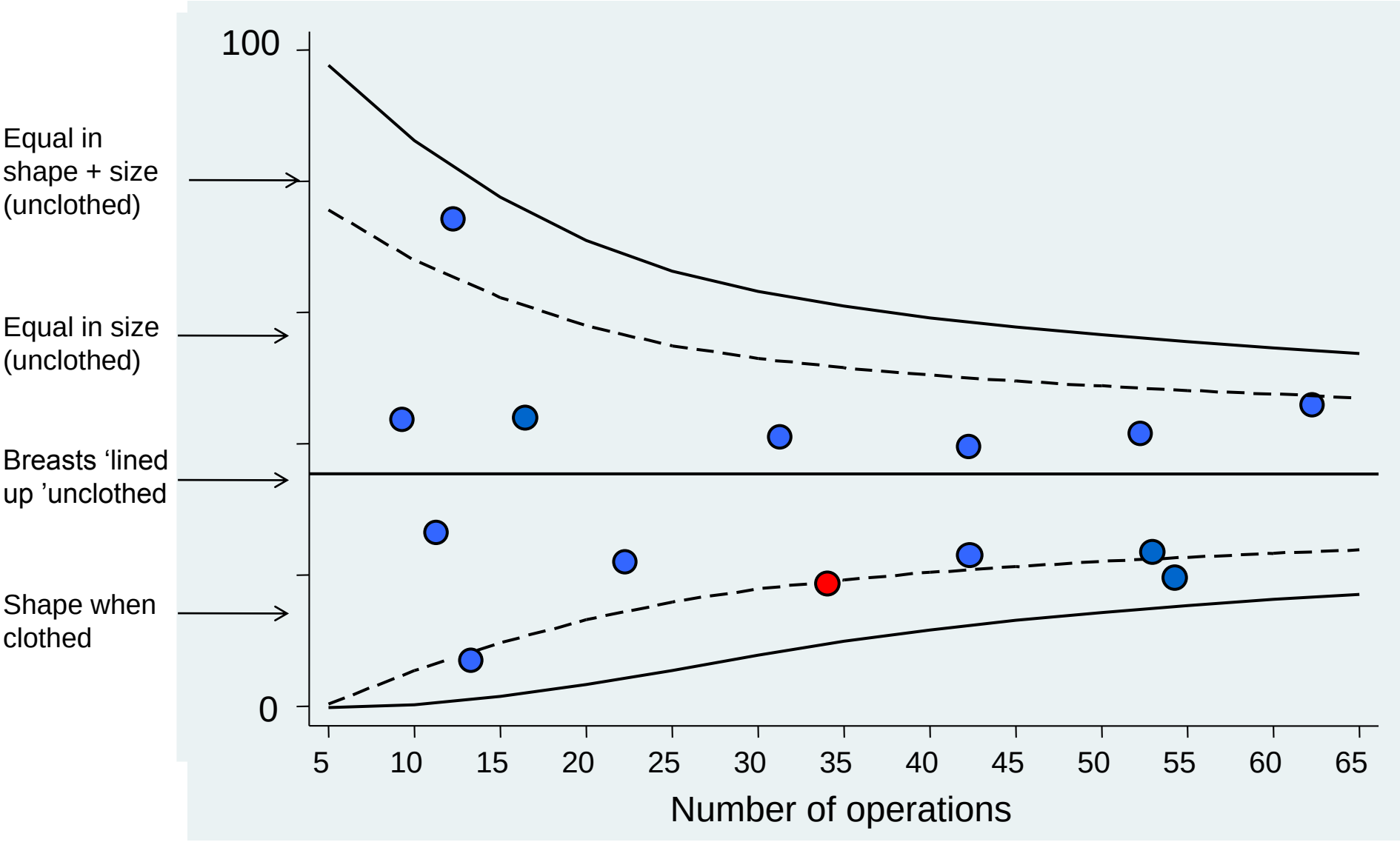


How do we turn PROMs into remedies?

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

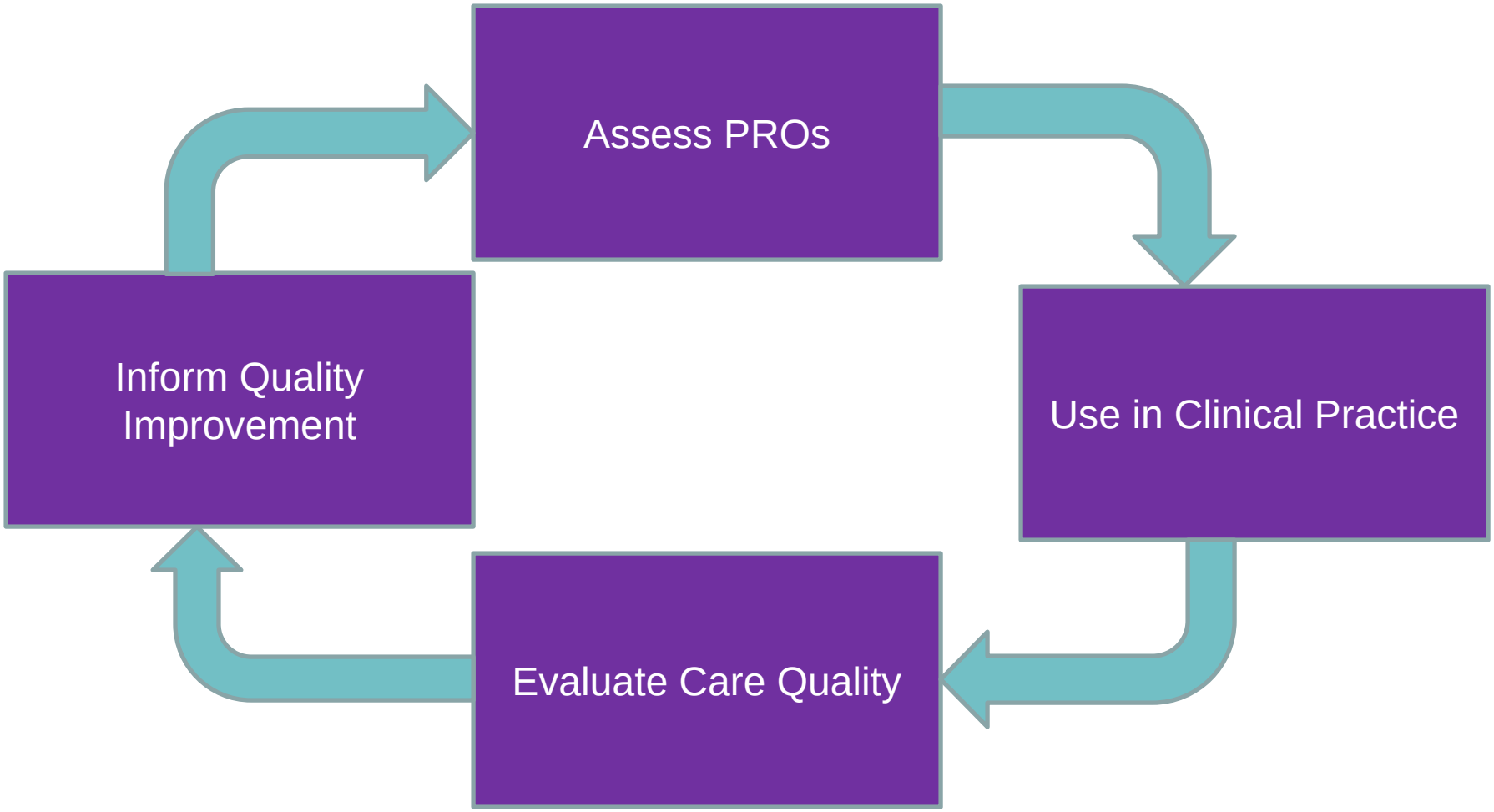


An interpretable PROM for breast reconstruction? The Breast-Q.

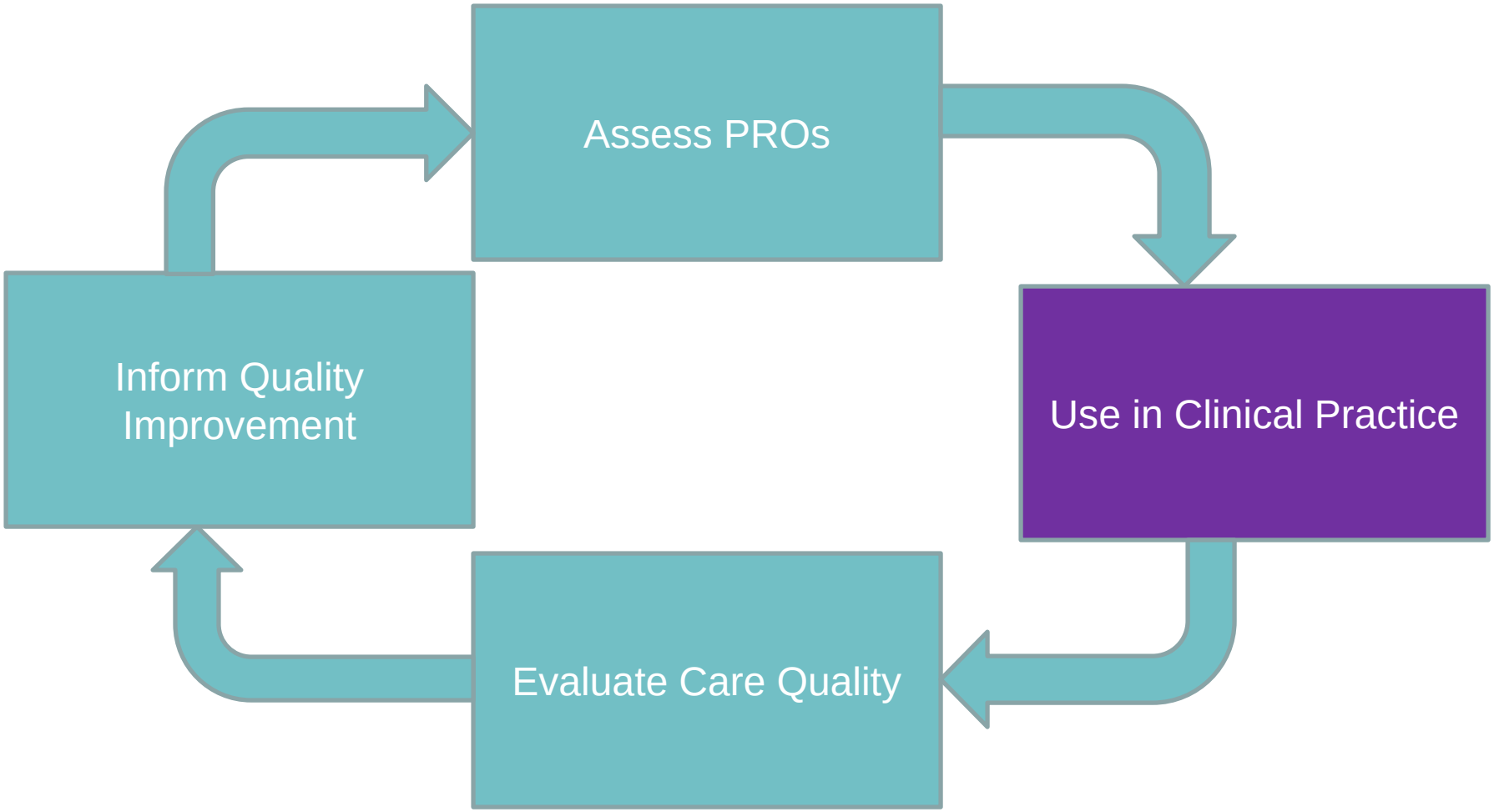


Slide courtesy of John Browne, PhD, University College – Cork

Multi-Purpose PROs

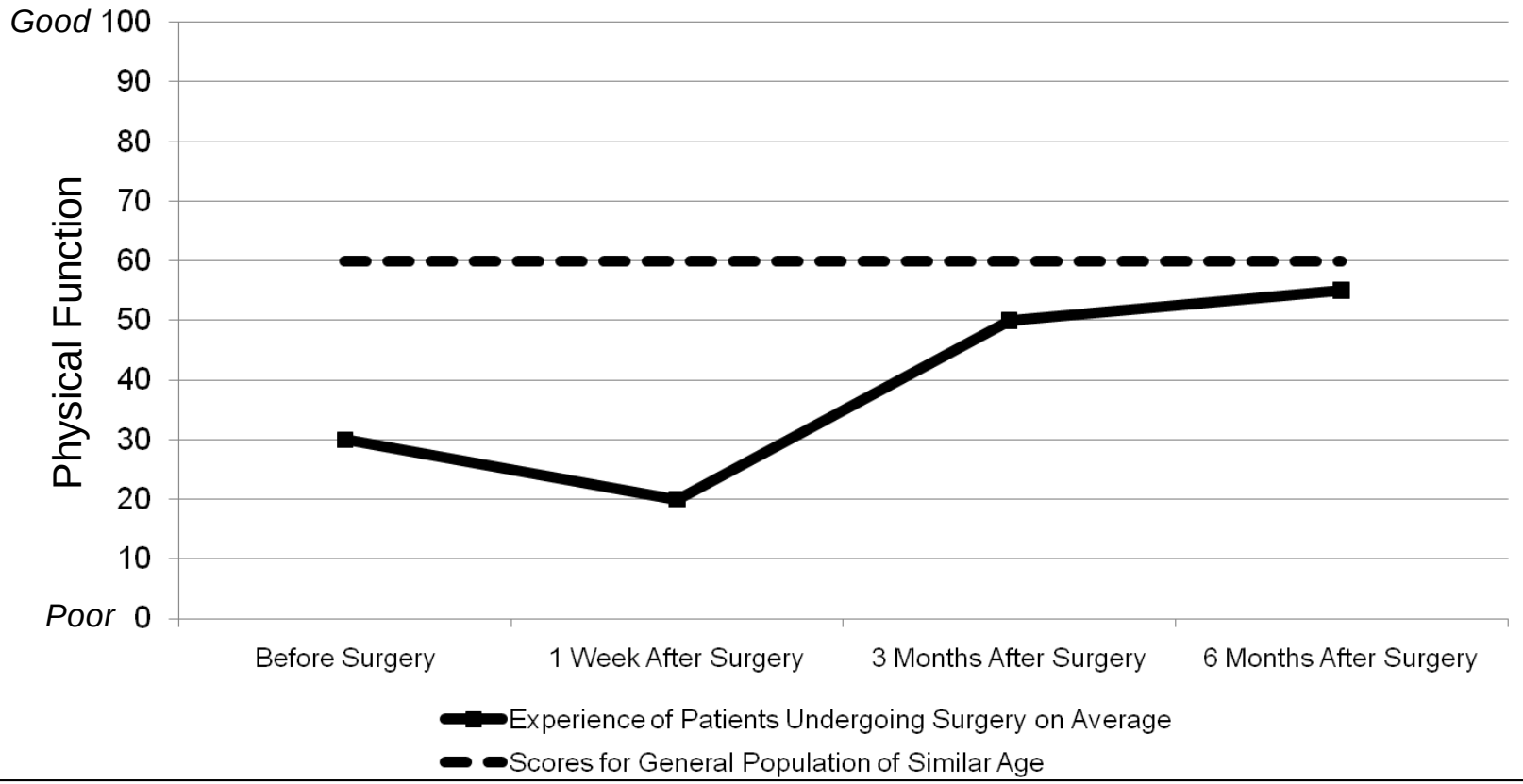


Multi-Purpose PROs



Aggregate Data Across Patients

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.


SURVEY
Your EMR
Differential Diagnosis
Current Medications
Treatment
Interaction Alerts
Prescribe

Advances in the Use of Patient Reported Outcome Measures in Electronic Health Records

Including Case Studies

Albert W. Wu, MD, MPH
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

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

http://www.pcori.org/assets/2013/11/PCORI-PRO-Workshop-EHR-Landscape-Review-111913.pdf

TABLE 1: SUMMARY OF CASE STUDIES

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

http://www.pcori.org/assets/2013/11/PCORI-PRO-Workshop-EHR-Landscape-Review-111913.pdf

Rationale

- Increasing interest in the topic of PROs in EHRs
  - PCORI-sponsored meeting reviewing the use of PROs in EHRs (November 2013)
    - http://www.pcori.org/assets/2013/11/PCORI-PRO-Workshop-EHR-Landscape-Review-111913.pdf
  - 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

Project Phase 1: Planning

- Formed a Steering Group to advise on the overall project plan
- Developed strategy for meeting long-term goals
- Identified questions to be addressed in the PRO-EHR Users' Guide
- Circulated question list for comment
- Outlined next steps

Steering Group

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

Jason Gerson, PhD, Patient-Centered Outcomes Research Institute

Mellanie True Hills, CSP Patient Advocate

Kevin Weinfurt, PhD Duke Clinical Research Institute

Nancy Smider, PhD Epic

Albert Wu, MD, MPH Johns Hopkins Center for Health Services and Outcomes Research

Claire Snyder, PhD Johns Hopkins School of Medicine

Matt Stiefel, MS, MPA Kaiser Permanente Care Management Institute

David R. Hunt, MD, FACS Office of the National Coordinator for Health Information Technology*

Erin Holve, PhD, MPH, MPP Department of Health Care Finance in the Government of the District of Columbia

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

Project Phase 2: Implementation

- Identify Working Group Members
- In-Person Meeting to Discuss Section Outlines
- Develop Draft Sections
- Working/Steering Group Review and Comment on Draft Sections
- Circulate Draft for Comment
- Hold Public Meeting

Working Group

Joseph Ali, JD Johns Hopkins Berman Institute of Bioethics

Jim Bellows, PhD, MPH Kaiser Permanente Care Management Institute

Erin Holve, PhD, MPH, MPP Department of Health Care Finance in the Government of the District of Columbia

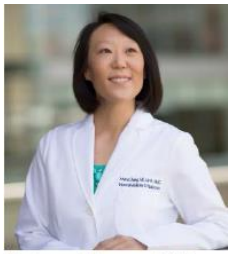
Esi Morgan, MD, MSCE Cincinnati Children's Hospital Medical Center

Lucy Savitz, PhD, MBA Institute for Healthcare Delivery Research, Intermountain Healthcare

Dean Sittig, PhD University of Texas at Houston Health Science Center

Rachel Hess, MD, MS University of Utah

Judy Baumhauer, MD, MPH University of Rochester Medical Center



Arlene Chung, MD, MHA, MMCi University of North Carolina-Chapel Hill

Roxanne Jensen, PhD Georgetown Lombardi Comprehensive Cancer Center

Greg Pawlson, MD, MPH P&M Healthcare Insights

Michele Halyard, MD Mayo Clinic

Galina Velikova, MBBS, PhD Leeds Institute of Cancer and Pathology, University of Leeds

Kevin Weinfurt, PhD Duke Clinical Research Institute

Irene Katzan, MD Cleveland Clinic

Adam Wright, PhD Harvard Brigham & Women's Hospital

Carolyn Kerrigan, MD, MSc Dartmouth School of Medicine

Danielle Lavallee, PharmD, PhD University of Washington

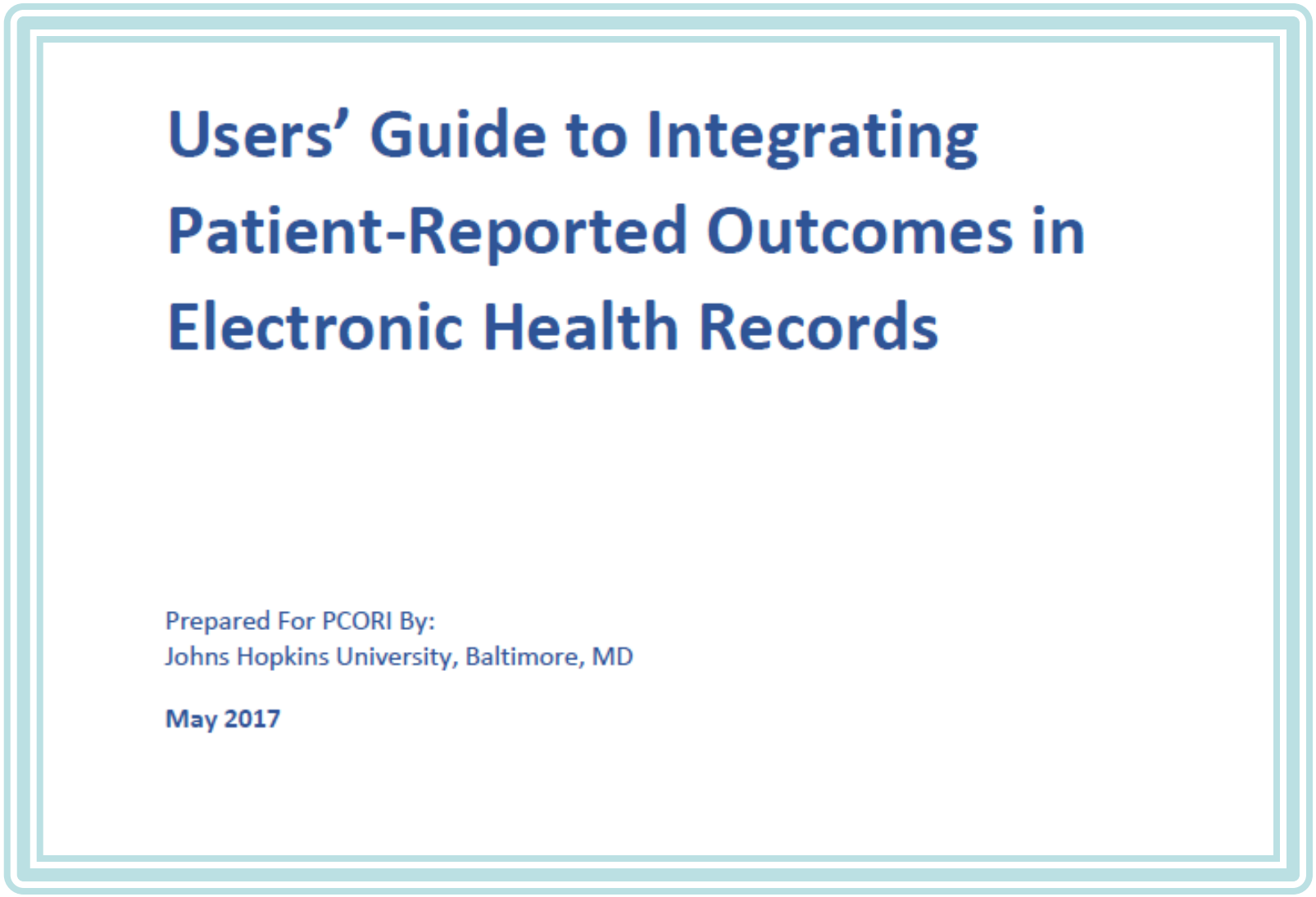
Danielle Whicher, PhD, MHS Patient-Centered Outcomes Research Institute

Andrea Hartzler, PhD Kaiser Permanente Washington Health Research Institute

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

Neil Wagle, MD, MBA Partners Healthcare

Special Thanks



Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records

Content

- Considerations involved in integrating PROs in EHRs
- Options offered for each consideration
  - Don’t have to pick just one!
- Relative advantages/disadvantages described for each option
- Case example descriptions *(optional)*
- Key information gaps/research questions
- Useful references/resources

Topics Covered

1. What strategy will be used for integrating PROs in EHRs?
2. How will the PRO-EHR system be governed?
3. How can users be trained and engaged?
4. Which populations and patients are most suitable for collection and use of PRO data, and how can EHRs support identification of suitable patients?
5. Which outcomes are important to measure for a given population?
6. How should candidate PRO measures be evaluated?
7. How, where, and with what frequency will PROs be administered?
8. How will PRO data be displayed in the EHR?
9. How will PRO data be acted upon?
10. How can PRO data from multiple EHRs be pooled?
11. What are the ethical and legal issues?

Levels of Integration

LOW INTEGRATION

- Secure external web platform
- Patients and providers can only access the PRO functionalities via the external system
- Images of PRO data can be linked with the EHR on the back-end via linkage by patient identification number

HYBRID

- Secure external web platform for PRO data collection
- Interfaces with (bolts on to) an EHR's clinical test results and patient identification databases
- Providers find patients and assign questionnaires either through a linkage to the external system or directly in the external system
- Patients complete PROs and view results via the external system

FULL INTEGRATION

- Secure, tethered web portal
- Patients can view portions, communicate with providers and complete PRO questionnaires
- PRO measures can employ several core functions of the EHR

Example: Low Integration

PROVIDERS

•Order PRO questionnaires via external system; ordering PROs for patients with specific characteristics (e.g., diagnoses) requires entry of this information in the external system

•Can view results in hard copy, or image files within EHR; cannot manipulate PRO data within EHR or plot PROs with other clinical information

•Out of range scores can trigger alerts (+/- advice) via external system

PATIENTS

•Complete PROs via external system at home or in clinic

•Can use kiosks/ tablets/smart phone/interactive voice response

•Results displayed via external system (+/- advice)

IT PROFESSIONALS

•PRO measures programmed in external system

•Programmers must be familiar with external system's design

•External system programmers control which PRO questionnaires are available

ANALYSTS/ RESEARCHERS

•PRO and EHR data extracted separately and require linkage on the back-end

Example: Hybrid Integration

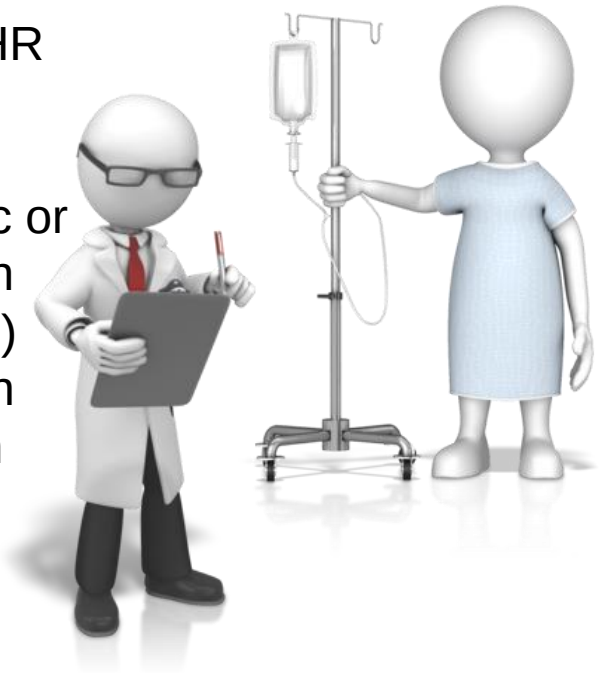
PROVIDERS

•Limited access to PRO data within EHR (visible as blocks of text/image files), broader access via external system

•Can order PRO questionnaires ad hoc or automatically triggered for patients with specific characteristics (e.g., diagnosis)

•Limited manipulation of PRO scores in EHR possible, but can't be plotted with other clinical data

•Out of range PRO scores can trigger alerts (+/- advice) via external system



PATIENTS

•Complete PROs via external system at home or in clinic

•Can use kiosks/ tablets/smart phone/interactive voice response

•Results displayed via external system (+/- advice)

IT PROFESSIONALS

•PRO measures programmed in external system

•Programmers must be familiar with external system's design

•Technical interface between PRO and EHR system must be set up and maintained and requires shared patient identifiers for linkage

ANALYSTS/ RESEARCHERS

•PRO and EHR data extracted separately and require linkage on the back-end

Example: Full Integration

PROVIDERS

•Can order PRO questionnaires ad hoc or automatically triggered for patients with specific characteristics (e.g., diagnosis)

•Results displayed within EHR and can be plotted with other clinical data (e.g., laboratory tests)

•Out of range PRO scores can trigger alerts (+/- advice)

PATIENTS

•Complete PROs via tethered portal at home or in clinic

•Can use kiosks/ tablets/smart phone

•Results displayed within EHR and can be plotted with other clinical data (+/- advice)

IT PROFESSIONALS

•Require specific training to work with the EHR

•Some PRO questionnaires built into EHR

•New PRO questionnaires added within EHR constraints

ANALYSTS/ RESEARCHERS

•Can extract PRO and EHR data for individual patients or groups of patients

Strategies for Integration: Strengths & Weaknesses

LEVEL	STRENGTHS	WEAKNESSES
LOW	-Easier to build a system with limited integration -Easier to tailor	-No bidirectional exchange between PRO and EHR -No ability to manipulate PRO data based on EHR data
HYBRID	-User interface designed specifically for PROs -Greater flexibility in which PROs are included -Can design PRO data display	-Requires patients and providers to use system outside of EHR to order/complete PROs -Requires upkeep of system separate from EHR
HIGH	-PRO data and clinical data collected in the same system in real-time -Facilitates presentation of PRO data with other clinical data -Can use clinical data to trigger PROs	-Limited flexibility for tailoring questionnaire or report format in system -Number of PRO measures built in system may be limited -Requires patients be engaged with EHR portal

Levels of Governance

DISTRIBUTED

- Decisions about implementation, oversight, and PRO use is left to individual or group (e.g., department) users
- Enables tailoring of content to direct clinical needs, as well as small-scale pilots
- Lack of coordination could lead to confusion or duplication, and makes aggregation challenging

HYBRID

- Core, central entity provides a set of rules, which are implemented at the user level
- Balances flexibility and need for tailoring
- Could lead to disputes regarding responsibility for final decisions

CENTRALIZED

- Appointed individual or group has oversight on implementation and use
- Facilitates coordination, use of best practices, compliance with regulations, and data aggregation
- Could be bureaucratic and use PROs that do not meet specific clinic's needs

Training & Engaging

Who activates patients?

- Appointment schedulers
- Receptionist
- Nurse/medical assistant/flow staff champion
- Care manager/navigator
- Provider
- Research coordinator
- Automated system

How is value conveyed?

- Scripts
- Patient marketing/information materials
- Review and discussion of results with patients

Facilitators

- Easy-to-use technology
- Review and discussion of results with patients
- Patient-friendly reports/data displays
- Self-management decision support
- Enable patient self-initiation

Training Approaches

- Introduce rationale at department meetings/forums
- Ongoing support to users and training new providers
- Local champions/super users
- Qualitative debriefs for individuals/teams
- Audit and feedback
- Engage stakeholders to design workflows and training
- Ensure understanding of PRO score meaning

Patients, Outcomes, Measures

EHR CAN HELP SELECT

- All patients for whom a provider/system is accountable
- Defined clinical setting (e.g., primary care)
- Defined condition (e.g., Parkinson's disease)
- Specific treatment (e.g., knee replacement)

OUTCOMES

MEASURE EVALUATION CRITERIA

- Availability
- Attributes (e.g., validity, length)
- Standardization
- Ability to pool
- Integration in EHR/stand-alone system
- Stakeholder engagement
- Resources and workflow impact

How, Where, When

POSSIBLE EHR ROLES

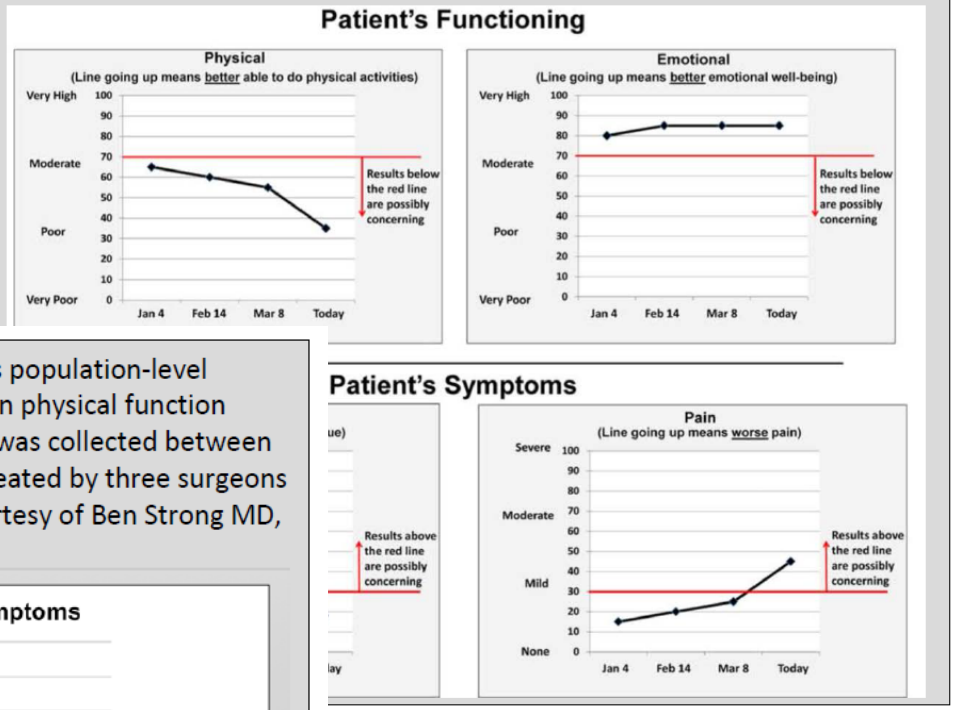
- Synchronizing questionnaire administration
- Build-in quality/error checks
- Combine PRO data collected across multiple modes
- Meta-data collection (e.g., how PRO was completed and by whom)
- Monitor compliance/alert to missing questionnaires
- Deploying questionnaires in clinic or remotely

Data Display

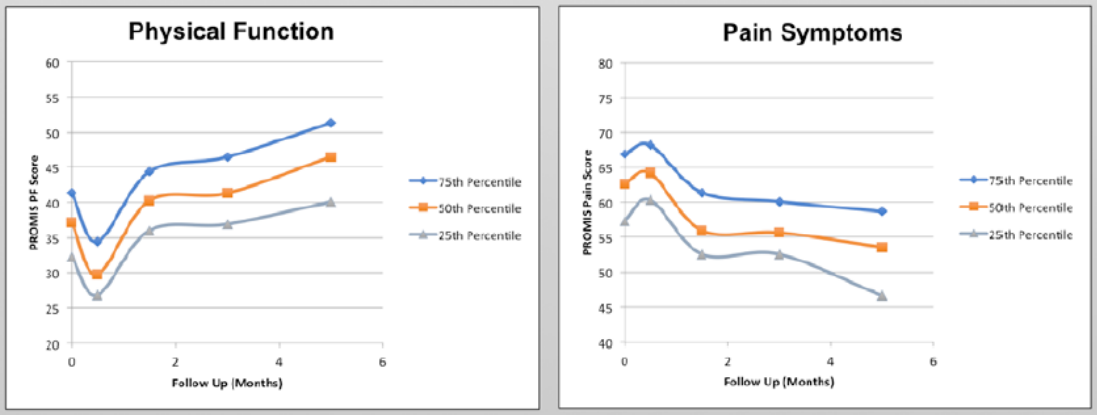
CONSIDERATIONS

- Target audience (patients, clinicians, administrators, researchers, others)
- Format (numeric, visual)
- Type of scores (longitudinal, cross-sectional, change)
- Level (individual, population)
- Complexity (simple, complex)

Use Case Example 1: Individual-Level Display: This report illustrates individual-level scores formatted visually in a line graph to show longitudinal trends in a patient's functioning and symptoms. The target audiences of this report are clinicians and patients who can use the PRO data for patient care. This example is from an external PRO system that is not tethered to an EHR. This organization chose to create reports due to limitations of their current EHR functionalities for displaying PRO data. (Image reproduced from Snyder CF, et al. Cancer. 2017 Jan 13.)



Use Case Example 2: Population-Level Display: This report illustrates population-level scores formatted visually in a line graph to show longitudinal trends in physical function (left) and pain (right) scores for use in predictive analytics. PRO data was collected between April and December 2015 from 215 total hip replacement patients treated by three surgeons with a minimum 3-month follow up (mean 4.7 months). (Images courtesy of Ben Strong MD, and John Ginnetti MD, University of Rochester Medical Center)



Acting on PRO Data in the EHR

WHEN SHOULD THERE BE PRO COMPLETION NOTIFICATION

- Never
- Always
- Only for certain scores (with or without requirement to “close the loop”)

WHO SHOULD BE NOTIFIED

- Primary care provider
- “Ordering” provider
- Provider with upcoming appointment
- Navigator or administrator
- Patient or designee
- Patient choice

HOW SHOULD NOTIFICATIONS BE SENT

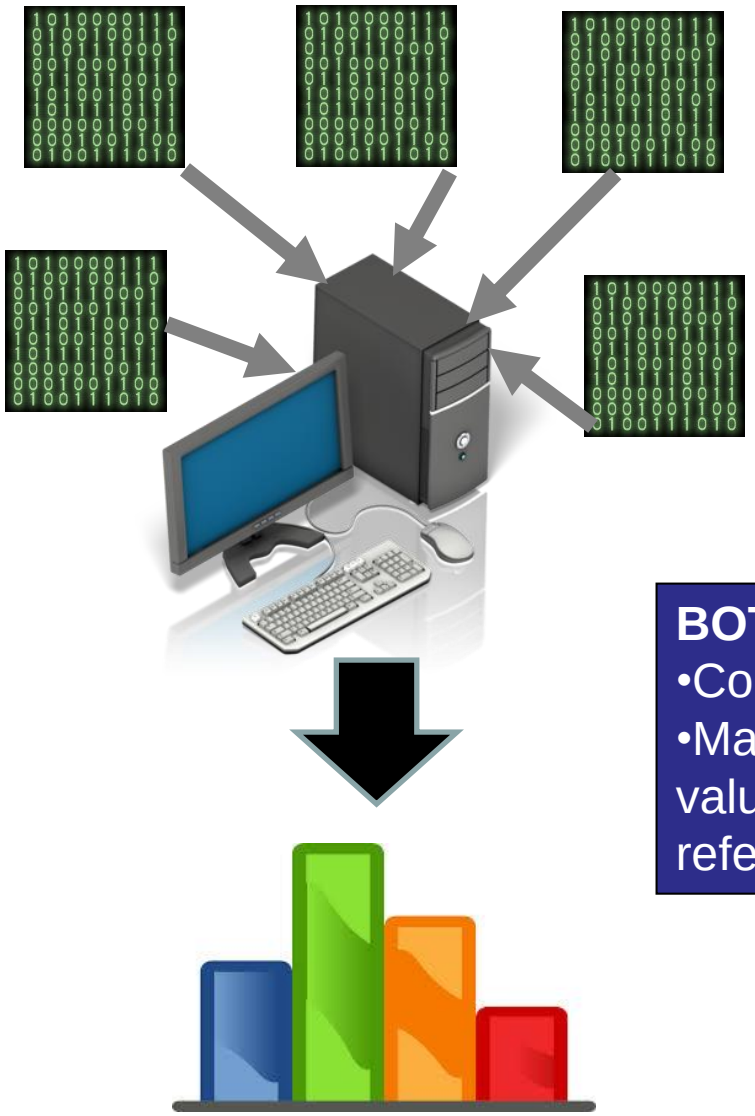
- Email
- Clinical message within EHR
- Text message/secure text message/page

DECISION SUPPORT

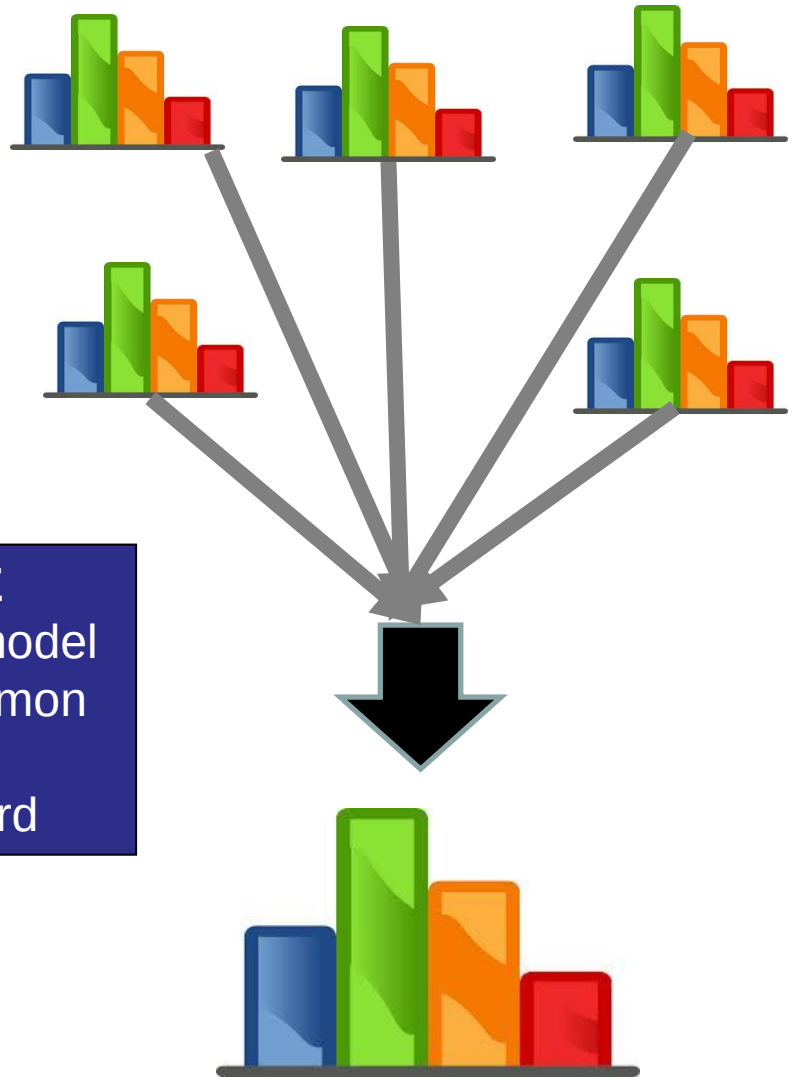
- Useful when there is consensus on what to do for which patients
- Evidence base for decision support is increasing

Pooling PRO Data Across EHRs

CENTRALIZED



DISTRIBUTED



BOTH REQUIRE

- Common data model
- Mapping to common values/shared reference standard

Levels of Consent: Collection & Use

NONE
- No specific consent
- Easy to implement and consistent with other clinical data
- Does not emphasize patient autonomy
- May not comply with laws, depending on the purpose of collection and use

GENERAL DISCLOSURE/OPT-OUT
- Explains PRO collection and use in general, with ability to opt-out
- Relatively efficient but still allows opt-out
- Have to track opt-outs and participation rates may be lower
- May not be sufficient depending on the purpose of collection and use

SPECIFIC DISCLOSURE/OPT-OUT
- Explains collection and use of specific PRO
- Provides patients with clearest understanding of PRO purpose and allows opt-out; could be written to enable multiple data uses
- May be burdensome
- Have to track opt-outs and participation rates may be lower

ROBUST SPECIFIC DISCLOSURE/ OPT-IN
- Most robust informed consent
- Provides the greatest amount of information and is consistent with most data uses
- Could be burdensome and lead to lower participation rates

Key Steps for Moving Forward

- Create and use open source data standards (e.g., put PROs in Consolidated Clinical Document Architecture [CCDA]; Logical Observation Identifiers Names and Codes [LOINC])
- Develop guidelines for interpretation and action for patients and clinicians
- Identify stakeholders and develop marketing plan with value proposition for each
- Produce evaluation framework to address cost, burden, efficiency, quality, transparency, care, and patient outcomes
- Establish rules of engagement for a central data repository and network of sites
- Provide crosswalk across PRO instruments and meta-data for deep learning
- Implement policies to give more access/control to patients and reimbursement/incentives for patients

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

Discussion