The PROTEUS Guide

to Implementing Patient-Reported Outcomes in Clinical Practice

A Synthesis of Resources

A Resource from the

PROTEUS

CONSORTIUM

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The Guide is also available online at: theproteusconsortium.org/proteus-practice-guide.

INTRODUCTION

The **PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice: A Synthesis of Resources** offers guidance on designing, implementing, and managing PRO systems and related data when using PROs in clinical care. This Guide was developed by the PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders), which helps navigate the use of PROs in clinical trials and clinical practice. PROTEUS partners with key stakeholder groups to disseminate and implement tools that have been developed to optimize the use of PROs in clinical trials and routine care.

This Guide focuses specifically on the use of PROs in clinical practice for individual patient management (i.e., my clinician using my data to inform my own care). While individual-level patient data collected to inform that patient's own care can be aggregated for use as real-world evidence, in quality assessment efforts, and in other ways, this Guide focuses primarily on the use of PROs in individual patient-clinician interactions.

As described by the U.S. Food & Drug Administration and others, PROs are patients' own reports of how they feel, function, live their lives, and survive. A growing evidence base suggests using individual patients' PRO data to inform their care facilitates patient-clinician communication, helps identify symptoms, informs patient monitoring and management, can improve efficiency, and sometimes, increases survival.

Using PROs in clinical care effectively requires addressing a range of considerations. Several established resources provide guidance on specific aspects of using PROs in clinical care, such as how to display PRO results or how to integrate PRO data into the electronic health record. This Guide collates and synthesizes the guidance from these foundational resources to create a unified, comprehensive document that covers all stages of the process. For the most comprehensive and detailed information on a topic, we encourage you to review the relevant foundational resources listed at the end of each section. We also suggest you cite these resources directly, in addition to the Guide, as noted in Acknowledgements & Referencing.

Throughout the Guide, we refer to both patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). We refer to PROs when discussing the outcome itself, or more generally to refer to the field of collecting patient-reported outcomes. We refer to PROMs when we are describing the standardized, validated questionnaire or survey used to elicit information from the patient about a given outcome. Both concepts are distinct from patient-reported experience measures (PREMs), which are questionnaires used to assess patients' perceptions of their care, although many of the considerations that apply to PROs and PROMs also apply to PREMs.

The Guide is organized into 16 sections which span three overarching stages of using PROs in practice: Design, Implementation, and System & Data Management. Within each section we present a high-level overview, and then expand upon this information. 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. As such, 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.

Finally, while the Guide draws primarily from the foundational resources, Appendix 2 describes selected other relevant references (not an exhaustive bibliography).

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
Visualizations	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			

Nothing in this Guide should be construed to represent or warrant that persons using this Guide have complied with all applicable laws and regulations. All individuals and organizations using the Guide have the responsibility for complying with the applicable laws and regulations or regulatory requirements for the relevant jurisdiction.

Each chapter of the Guide lists the key foundational resources that informed its content. To appropriately recognize the foundational resources, we encourage you to cite both the Guide and the relevant foundational resource(s). Recommended citations are provided in Acknowledgements & Referencing.

ACKNOWLEDGEMENTS & REFERENCING

This Guide was developed by the PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders), which helps navigate the use of patient-reported outcomes (PROs) in clinical trials and clinical practice. This Guide focuses specifically on the use of PROs in clinical practice and builds on a range of foundational resources. These foundational resources cover different aspects of the use of PROs in clinical practice; this Guide synthesizes information across the foundational resources to create a unified, comprehensive guide.

Each chapter of the Guide lists the foundational resources that informed its content. To appropriately recognize the foundational resources, we encourage you to cite both the Guide and the relevant foundational resource(s). Recommended citations are provided below.

We are grateful to the many Consortium members who participated in the development of this document, especially the Advisory Committee who provided critical input regarding the structure and content of this Guide (See Appendix 1).

TO CITE THE GUIDE
The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice: A Synthesis of Resources. Prepared by Crossnohere N, Brundage M, Snyder C, and the Advisory Group, 2023. Available at: www.TheProteusConsortium.org.

TO CITE THE FOUNDATIONAL RESOURCES
ePROs in Clinical Care: Guidelines and Tools for Health Systems
LeRouge C, Austin E, Lee J, Segal C, Sangameswaran S, Hartzler A, Lober B, Heim J, Lavallee DC. ePROs in Clinical Care: Guidelines and Tools for Health Systems. Seattle, WA: CERTAIN, University of Washington. May 2020. Available at: http://epros.becertain.org/

Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Snyder C, Wu AW [Eds.]. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Patient-Centered Outcomes Research Institute, 2017. Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records.
> Working group members: Joseph Ali, Ethan Basch, Judy Baumhauer, Jim Bellows, Arlene Chung, Michele Halyard, Andrea Hartzler, Rachel Hess, Erin Holve, Roxanne Jensen, Irene Katzan, Carolyn Kerrigan, Danielle Lavallee, Esi Morgan, Greg Pawlson, Lucy Savitz, Dean Sittig, Galina Velikova, Neil Wagle, Kevin Weinfurt, Danielle Whicher, Adam Wright

<u>Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data</u>
Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. Making a picture worth a thousand numbers: Recommendations for graphically displaying patient-reported outcomes data. Quality of Life Research. 2019;28:345-356

<u>International Society for Quality of Life Research User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice</u>
International Society for Quality of Life Research (prepared by Aaronson N, Choucair A, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). Users Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version 2015. Available at: <u>https://www.isoqol.org/wp-content/uploads/2019/09/2015UsersGuide-Version2.pdf.</u>

<u>PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes</u>
A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: <u>https://journals.lww.com/lww-medicalcare/toc/2019/05001.</u>
Contributing authors: Kate Absolom, Alex Alexander, Anthony Arnold, Lisa Barbera, Ethan Basch, Susan Beck, Antonia Bennett, Jakob Bjorner, Amanda Blackford, John Browne, Michael Brundage, Stefan Cano, Philip Carr, David Cella, Charles Cleeland, Karon Cook, Katrina Croghan, Allison Deal, Geoff Delaney, Amylou Dueck, Ivana Durcinoska, Briant Fruth, Andrea Gibson, Afaf Girgis, Martha Grootenhuis, Karen Hammelef, Lotte Haverman, Sydney Henson, Jennifer Jansen, Roxanne Jensen, Carolyn Kerrigan, Madeleine King, Jennifer Le-Rademacher, Tito Mendoza, Lesley Moody, Kathi Mooney, Eugene Nelson, Brant Oliver, Bryce Reeve, Dennis Revicki, Yonaira Rivera, Qiuling Shi, Jeff Sloan, Claire Snyder, Angela Stover, Angelina Tan, Carrie Tompkins Stricker, Maud van Muilekom, Hedy van Oers, Galina Velikova, Rahma Warsame, Meagan Whisenant, Albert Wu, David Zahrieh

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1 DEFINING GOALS

KEY POINTS

- *Defining the goal(s) of patient-reported outcome (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:*

  - *Enhancing individual patient care (i.e. screening for problems, monitoring symptoms, assessing needs, promoting patient-centered care, assessing outcomes, informing shared decision-making)*

  - *Improving population health*

  - *Facilitating research and enhancing clinical datasets*

  - *Informing health system reporting, billing, and value-based purchasing*

OVERVIEW

An essential first step when implementing PROs in practice is defining the goals for the PRO system. There are numerous reasons to collect PROs at the point of care, and PRO systems can be designed to meet multiple objectives.

Leaders of health systems are increasingly interested in using PRO data to support diverse goals. It is important to consider opportunities for aligning the collection of PROs to enhance the multiple goals of a healthcare system. The goals should drive how PRO systems are designed and implemented.

A. What are potential goals for PRO systems?

To enhance individual patient care
- Patient-care goals are often the primary focus of PRO systems
- Patient-care goals are diverse in nature and can include objectives related to screening for problems, monitoring symptoms, assessing needs, promoting patient-centered care, assessing outcomes, and informing shared decision-making. These goals are further described in <u>Table 1.1</u>

To improve population health
- PRO data can be used to support predictive analytic algorithms and other approaches to explore risks within and between groups, including equity analyses

To facilitate research
- PRO data can be used to answer important research questions about the health of individuals cross-sectionally, over time, or in response to interventions
- PRO data collected from clinical settings can be used to inform understanding of real-world effectiveness rather than efficacy

To improve quality (beyond using individuals' PRO data to aid in their management)
- To improve care and quality, such as by comparing pooled data from one patient population to another or to normative benchmarks
- To facilitate multidisciplinary team communication by providing a common data source that diverse providers can use to discuss a patient's health status as reported by the patient themselves. This approach requires that team members of multiple disciplines be able to interpret PRO findings
- To identify strengths and weaknesses in the care a patient has been provided, for example, through use of audit/benchmarking data
- To serve as a useful indicator for clinicians regarding how their practice compares to other practices or normative data
- To provide comparative provider data to payers
- To compare the quality of care, though notably, this can be challenging due to confounders and limitations in case-mix adjustment

To inform billing, reporting, and value-based purchasing
- To inform automatic billing and coding of specific services
- To provide an outcome measure for value-based purchasing

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

B. How do you determine your PRO systems goal(s)?

- Define the clinical goals of the PRO system before selecting the specific content to inform the development of a more robust PRO system
- Address multiple stakeholder needs, when possible, to economize organizational resources (see Chapter 3, Identifying, Engaging, and Training Users and Stakeholders)
- Consider healthcare setting characteristics that might influence PRO goals, including target population(s), urban vs. rural location, where the collection of PRO data will occur (e.g. inside or outside of healthcare setting), resources available
- Consider healthcare setting characteristics that might influence PRO goals, including target population(s), urban vs. rural location, where the collection of PRO data will occur (e.g., inside or outside of healthcare setting), resources available, likelihood of compliance (both by the health providers and the patients and/or caregivers)

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of defining goals for the PRO system. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- ePROs in Clinical Care Website

2 IDENTIFYING BARRIERS AND FACILITATORS

KEY POINTS

- *Barriers to the use of patient-reported outcomes (PROs) in clinical practice occur at the patient-, provider-, administrator-, and system-level*

- *While there may be similarities in the barriers experienced, the facilitators to alleviate these barriers may vary depending on the unique context of the healthcare setting*

OVERVIEW

PRO data has tremendous potential benefit to patient care, but barriers in the collection, analysis, interpretation, and integration of this data can hinder its application in practice. PROs are often treated as a separate data set. The systems and workflow are different. While not insurmountable, the change management needed to support integration is important to address.

At the **patient leve**l, common barriers include those related to accessibility of PRO systems, lack of patient buy-in to the use of PROs, lack of familiarity with electronic collection (if electronic collection used), literacy in the language of collection, and burdensome PRO collection processes. At the **provider level**, barriers include technological and logistical challenges, disruption to workflow, time and resource constraints, and uncertainty regarding how to integrate PRO data in clinical care. At the **administrative level**, barriers include cost, lack of shared values/purpose, uncertainty in how to assess the impact of PRO collection on quality, and legal/regulatory concerns. Finally, at the **system level**, barriers include (a sometimes limited) technical capacity and the fact that there is no "one-size-fits-all" approach for integrating PROs into practice. In this section we explore the general barriers identified for using PROs in clinical care and highlight potential solutions or facilitators, where they exist, to help overcome these challenges.

A. What are potential patient-level barriers and facilitators to the collection and use of PRO data in clinical care?

	BARRIERS	FACILITATORS
Accessibility	• Some patient populations may have trouble completing PROMs (patient-reported outcome measures) due to physical or cognitive impairments, low literacy, and language/translation issues • Not all patients have access to or choose to use technology (e.g. computer, internet, patient portal account), through which PROs are often collected • Patients may be confused or burdened if PRO data is collected using a separate system from the clinic's other systems such as those used for billing, scheduling, messaging, or clinical trials	• Providing additional support to patients • Offering alternative modes of PROM administration as requested by patients • Having clear protocols for proxy reporting
Lack of buy-in	• Patients may not complete PROs if it is unclear how these measures are relevant to them and their care team or how the data will be used	• Communicating a clear purpose to patients regarding why PRO information is being collected and how it will be used • Using measures that have face validity and are relevant to the patient population of interest • Demonstrating how the measures affect patient care (e.g. clinicians should explicitly state that they have reviewed the patient's PRO data)
Burden reporting PROs	• Poor organization of PRO systems may lead to patients being asked to complete the same PROMs multiple times or for different purposes without explanation, which may be frustrating and burdensome • Many PRO collection systems, particularly those that are web-based or electronic, can be complex to navigate; it can be difficult to know when to complete the PROMs, where in the system the PROMs are located, and how to review and submit PROMs • Multi-item PROMs can be time consuming to complete • PROs are often collected alongside other outcome measures, so it is important to consider the burden of PRO collection within the full context of patients' care	• Unifying PRO collection as much as possible across healthcare settings, • Implementing intuitive PRO systems that use principles of user-centered or human factors design • Purposefully selecting succinct measures that address the needs of the target population

B. What are potential clinician-level barriers and facilitators to the collection and use of PRO data in clinical care?

	BARRIERS	FACILITATORS
Technologic and logistical challenges	• Logistical challenges such as difficulty finding the PRO system, remembering when to check the system, or being able to access the system pose barriers to the use of PROs – particularly if the PRO data is not fully integrated in the electronic health record • Features of systems such as requiring additional logins or redirecting clinical teams to platforms outside of their typical workflow or which have an atypical 'look and feel' can deter PRO system use	• Co-designing PRO systems with clinical and patient input to promote integration with the routine workflow and established systems • Providing training to familiarize clinical staff with PRO system features
Disruption to workflow	• Integrating PROs into clinical care in any systematic way is likely to disrupt preexisting workflows • These disruptions can be burdensome to address, requiring the adoption of new administrative and clinical patterns • PRO information can complicate a visit if additional health concerns are identified as a result of PRO data collection, particularly if those concerns are outside of the clinical scope of the provider the patient is seeing	• Integrating the PRO data in the existing workflow to the extent possible • Consulting with the clinical team on how best to incorporate new workflows • Embedding resources and decision support to promote efforts to address identified concerns • Providing resources to patients for self-management (see Chapter 11, Responding to Issues)
Time and resource constraints	• Providing healthcare is notoriously demanding, and clinicians are already routinely stretched thin. Clinical teams likely require training to use PRO systems and integrate PRO data into clinical decision-making. Staff turnover requires a regular training program • Adding responsibilities, such as collecting and integrating PRO data into decision-making daily is time and resource consuming • PRO collection may compete with the demands of collecting other quality metric data that are required and tied to reimbursement	• Designing PRO systems so that they inform rather than impede the clinical encounter (e.g. helping to focus discussion by identifying clinically relevant issues requiring attention, streamlining the review of systems) • Automating the process
Uncertainty with integrating data into clinical care	• Clinicians may be hesitant to use PRO data if they are uncomfortable in how to interpret the information or if there is no clear management strategy for the identified issue	• Presenting data to promote understanding and use • Embedding resources and decision support to promote efforts to address identified concerns (see Chapter 9, Presenting Results, and Chapter 11, Responding to Issues)

C. What are administrative-level barriers and facilitators to the collection and use of PRO data in clinical care?

	BARRIERS	FACILITATORS
Cost	• Upfront and maintenance costs when developing or purchasing PRO systems • Costs associated with training clinical teams and staff and having staff on hand to support completion by patients	• Outlining how collecting and integrating PRO information will be cost-saving to the administration, or facilitate new billable expenses for reimbursement, or meet quality standards
Lack of shared values/ purpose	• Various stakeholder groups may disagree on the purpose and value of collecting and integrating PRO information into clinical care • It can be difficult to foster buy-in for PRO systems across the many stakeholders potentially impacted by these systems	• Facilitators to promote shared values include having a PRO champion who has expertise in and passion for the collection of PROs at the point of care
Uncertainty in how to assess the impact of PRO collection on quality	• Upon integrating a new PRO system there should be efforts to review and evaluate its performance. These evaluations may require additional resources and new approaches	• Planning for the evaluation at the time of implementation • Considering quasi-experimental/ quality improvement approaches, in addition to more traditional evaluation designs (see Chapter 12, Evaluating the Intervention)
Legal/ regulatory concerns	• Legal and regulatory issues around the use of PRO information have been raised; for instance, it is unclear who is responsible for medical decisions made based on PRO data that have risks for patient health	• Consulting with the legal/ regulatory officials of the healthcare system prior to implementing new PRO projects • Providing information to patients on how data will be used/managed (see Chapter 16, Considering Ethical/ Legal Issues)

D. What are system-level barriers and facilitators to the collection and use of PRO data in clinical care?

	BARRIERS	FACILITATORS
No "one-size-fits-all" approach	• PRO systems cannot be one-size-fits-all, but rather must be made based on the unique goals of the healthcare setting, resources available, and specific context • There is no single governance structure that can be uniformly applied across settings	• Adapting the PRO intervention approach to meet the institution's specific goals, resources, and context
Technical capacity	• Different PRO systems have various features • While some systems may be easily integrated with existing electronic medical records, others cannot be • Systems may not allow for monitoring of missing data, present results in real time, or be able to map onto results benchmarks and other normative values • Some systems are more customizable than others	• Selecting an existing PRO system • Developing a new PRO system guided by the goals of the program and the resources available
Lack of in-house expertise	• Lack of expertise of individuals who can inform the design, implementation, or evaluation of PRO systems • Lack of expertise on specific patient populations, or on diversity, equity, and inclusion topics in general	• Toolkits and resources from PROTEUS and other relevant groups • Collaboration and partnerships across institutions

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of barriers and facilitators. For more detailed information please see the following sources:

• International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). <u>User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice</u>, Version: January 2015.

• ePROs in Clinical Care <u>Website</u>

• Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. <u>Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data</u>. Quality of Life Research. 2019;28:345-356.

• <u>PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes</u> A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: https://journals.lww.com/lww-medicalcare/toc/2019/05001.

• Snyder C, and Wu, A.W., eds. <u>Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records.</u> Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

3   IDENTIFYING, ENGAGING, AND TRAINING END USERS AND STAKEHOLDERS

KEY POINTS

- *Numerous relevant perspectives should be engaged in the design, development, and implementation of a patient-reported outcome (PRO) system*

- *Training activities can build capacity for robust engagement with PRO systems*

- *The content and modality of training might vary based on the goals of the training and the role of the stakeholder*

- *Participation in PRO systems can be motivated by demonstrating the value of PROs to clinical care, and reducing barriers to effective system use*

OVERVIEW

There are numerous relevant perspectives to consider when developing a PRO system: those who provide and may directly benefit from the use of PROs in clinical care, such as patients and their clinical teams; those who design PRO systems, such as electronic health records (EHR) and PRO specialists; and those who use PRO data to inform organizational or research initiatives, such as patients, clinical team members, and administrators. Including the perspectives of these stakeholders contributes to improved PRO systems. Stakeholders can advise on topics ranging from what outcome data to collect and what measures to use to collect them, to the development and design of the PRO system itself, including how data is collected, stored, and integrated into care.

Achieving the benefits of diverse stakeholder participation often requires training to build capacity so that their perspectives can be most meaningfully integrated. If patients are included in the co-design it is important to reflect on how they are similar to or different from the representative population. Common goals of training include educating stakeholders on the value of PROs in clinical care, teaching specific functionalities of a PRO system, and determining

how and when to collect and integrate PRO data into clinical care. Training can occur through predeveloped materials and/or live training sessions, depending on the goals of the training and the level of familiarity and engagement stakeholders have with the PRO system. In conjunction with training, stakeholders can also be engaged in the process of designing PRO systems.

Motivating stakeholders to participate in PRO systems is essential to system sustainability. The optimal motivational approach to encourage use of a PRO system may vary based on the type of stakeholder. For instance, for clinical team members, motivators might include identifying local champions of the system, and building a system that seeks to reduce, rather than increase, burden. For patients, motivation to use the PRO system may come from clear communication around how and why PRO data will be used to inform care, prompting patients to use the PRO system, making the PRO system easy-to-use, and providing patients with incentives for doing so.

A. Whose perspectives should be included in the development of a PRO system?

A range of stakeholders
- Relevant perspectives on PRO systems can include anyone involved in the development, collection, or use in clinical settings
- Including individuals with a range of perspectives will facilitate better PRO systems that meet the needs of diverse groups
- Consider guidelines for promoting diversity, equity, inclusion, and accessibility when identifying and engaging with stakeholders
- Examples of potentially relevant perspectives to include in developing PRO systems include:
  - Patients
  - Caregivers
  - Administrators
  - Administrative support staff
  - Providers
  - Clinical champions
  - Clinical staff
  - Electronic health record designers
  - Informaticians
  - Operation leads
  - PROM specialists
  - Researchers

B. What topics can stakeholders advise on?

- Identifying how data can be used to support care
- Selecting symptoms/experiences to assess by PRO system
- Determining appropriate frequency of assessment
- Selecting specific PROMs
- Identifying clinically concerning PROM scores
- Identifying appropriate alert thresholds
- Developing recommendations for acting on PRO results
- Creating a 'wish list' of attributes for a PRO system
- Identifying barriers and proposing solutions to overcome them
- Optimizing presentation/visualization of PRO data
- Co-designing the system/interface
- Using PRO data for clinical decision-making
- Developing guidelines for PRO system design
- Addressing accessibility issues for the target population
- Considering the cultural acceptability of PROMs

C. What are common goals of PRO system training?

To understand the value of PROs
- Collective understanding of why PROs are being collected at a clinical/organizational or other level may foster buy-in

To understand how to use a PRO system
- Provide the technical knowledge to operate a PRO system, such as how to collect and input data, retrieve data records, visualize results

To understand how to interpret and integrate PROs into clinical decision-making
- Using PRO data to inform shared decision-making conversations between patients and providers
- Providing notifications/alerts for concerning results
- Referring patients/clinicians to decision support tools within the electronic health record
- Integrating score interpretation into the PRO report/electronic health record

To specify the context for PRO use
- Determining, for instance, which patients, what setting, and what timepoints PRO data are being collected
- Considering whether and how current practices within a specific context might need to be adapted to accommodate a PRO system, or vice versa

D. What modalities are available for training?

Live training modalities
- Group sessions may be appropriate when initiating a PRO system as it may not yet be clear what questions users typically have
- One-on-one sessions may be useful to teach specific or advanced PRO system features

Pre-developed modalities
- Pre-developed modalities can be useful if there is high staff turnover or if the training program is resource intensive. Pre-developed materials can be easily shared without the need for one-on-one training
- These modalities may include videos, decision-trees, and information summary sheets, for example

E. How do you motivate provider and staff end-users to use PRO systems?

Identify local champions
- Identify a champion who has a long-term interest in the success of PRO use and who will help sustain the PRO strategy over time
- Champions may be individuals with experience using PROs and PRO data
- Champions may also become trainers who can administer trainings internally and reduce the need to hire outside trainers

Reduce burdens
- Engage stakeholders to suggest approaches for bundling PRO collection with other data collection to lessen burden
- Continue to support existing users and train new providers
- Optimize PROM data display within electronic health records to allow for easy access and inclusion of other clinical data (e.g. vital signs, procedure dates) (see Chapter 10, Visualizations to Aid Interpretation)

Continuous quality improvement
- Audit PRO systems and provide feedback such as benchmarking to other clinics/ organizations
- Incentivize providers to collect, view, and use PROs in care, by, for example, offering PRO use as a quality project or malpractice reduction credit
- Redesign the workflow iteratively as needed to optimize the system
- Engage providers and teams to evaluate the PRO program

Publicly celebrate successes
- Demonstrate how use of PROs improved quality of care and outcomes
- Convey the benefits and successes of the program at clinical/organizational meetings

F. How do you motivate patient end-users to use PRO systems?

Demonstrate to patients the value of PROs for their care
- Most importantly, review and discuss results with patients
- Develop informational materials like pamphlets or flyers that describe why PRO data are collected and how they are used to inform clinical decision-making
- Develop scripts about the value of PROs and tailor them for different members of the care team

Incentivize patient participation in PRO systems
- Ensure that patients' results are discussed with them by a member of the care team
- Create patient friendly reports and data displays that can be effectively used in care, such as by displaying results over time
- Make sure patients can access their PRO results
- Demonstrate how PROs can be used for self-management
- Encourage patients' personal motivation to complete PROs

Prompt patients to use PRO systems using these mechanisms
- Scheduler prompts when making the appointment
- Reception staff prompt upon arrival at the appointment
- Nurse champion/medical assistant/clinical support staff prompt during appointment
- Electronic systems prompt via reminders, patient portal messages
- Provider prompts when seeing the patient
- Research coordinator prompts, if patient is part of a study
- Patient navigator prompts

G. How might stakeholders be engaged in developing PRO systems?

Using methods for engagement
- Interviews or conversations with stakeholders about how to design and develop systems
- Delphi-methods to reach decisions across groups
- User-centered design strategies to inform the development of reports/visualizations that are informative and interesting
- Provider discussions with patients at the point of care regarding the value of PRO data to inform the patient's individual care

Following a philosophy of engagement
- Create a "feedback loop" to increase transparency, improve trust, foster bi-directional conversation, and demonstrate how stakeholder input informs decision-making
- Engage stakeholders throughout the entire lifecycle, from conceptualization to implementation, evaluation, and sustainment
- More generally, advance health system capacity for patient engagement

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of how to engage stakeholders. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- ePROs in Clinical Care Website

- Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. Quality of Life Research. 2019;28:345-356.

- PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: https://journals.lww.com/lww-medicalcare/toc/2019/05001.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

4 IDENTIFYING PATIENTS

KEY POINTS

- *Identifying which patients will complete PROMs (patient-reported outcome measures) is a critical step in the design of a PRO (patient-reported outcome) system*

- *Examples of groups who might be asked to complete PROMs include all patients in a healthcare system or specific clinic, patients with a defined condition, or patients receiving a specific treatment/intervention*

- *Special accommodations should be made for proxy-report PROs when patients are unable to complete themselves (e.g. pediatric patients)*

OVERVIEW

Determining which patients will complete PROMs (patient-reported outcome measures) is a critical step in the design of a PRO (patient-reported outcome) system. The target audience for PROM completion depends on the overarching goals of the PRO system, as well as the technical and logistical resources available to support the collection and use of this data.

Some PRO systems may decide that it is valuable to collect PRO information from all patients within its purview, be that the broader healthcare system or a specific clinic. This routine collection of PRO information has benefits including promoting a culture of routine data collection. Another approach is to collect PROMs from patients with a specific condition or patients who have undergone a specific treatment/intervention. This targeted approach may facilitate the collection of PRO data that is more clinically relevant to the patient's current health status.

Not all patients may be able to self-complete PROMs, such as pediatric patients or patients with mental/cognitive impairment. Report of the patient's health by a proxy, such as by caregivers or physicians, can provide important information about the patient's health in lieu of self-reported data. However, proxy report comes with several limitations, including being less valid than patient self-report.

A. What patients should complete PROMs?

All patients in the healthcare system
- Creates a culture of PRO assessment for patients, providers, and staff within a healthcare system
- In addition to informing individual-level care, can be used to inform research or population health
- Provides an opportunity to incorporate screening measures (e.g. depression) required to comply with quality reporting programs mandated by payers
- Allows for a known expected denominator when determining PROM response rates
- Uniform questionnaire collection across all patients may be easier to implement and require less decision-making for the front desk staff and/or clinical team responsible for collecting PROMs
- May result in low response rates and high amounts of missing data if patients are not seen at regular intervals
- May reduce patient and provider engagement if PROs are automatically collected without a clear connection to patient care
- Could require more modalities of PROM completion to accommodate the diverse needs of all patients across a healthcare system

All patients in a specific clinical setting
- Creates a culture of routine assessment within the specific setting (e.g. primary care clinic)
- Allows for the opportunity to collect both generic and specific PROMs relevant to the care setting
- Allows for a known expected denominator of patients (i.e. all patients in setting) which can be used to consider response rates and better understand missing data

Patients with a defined condition
- May be straightforward to collect and interpret as many PROMs are developed and validated in condition-specific contexts
- May have clearer clinical interpretations, including through the availability of predefined benchmarks, anchors, and comparisons to normative population scores
- Requires consideration of patient burden and redundancy of PROM collection across settings as many patients have multiple conditions; advisable to implement a coordinating PRO system that is accessible to all who provide care to the patient
- Can pose challenges because not all conditions have well-validated PROMs
- May benefit from additional reminders to staff and providers to administer and integrate PROs into workflow if PROs are only collected for a specific group of patients

Patients who receive a specific treatment
- Provides information about patient outcomes following specific procedures or treatments
- Can be collected at specific timepoints pre- and post-intervention to understand the impact of the intervention
- Informs whether patients have achieved a clinically meaningful improvement after receiving the treatment, providing actionable information for clinical care
- Facilitates comparison of health outcomes across different courses or treatments or across different providers
- May require patient completion of PROMs between healthcare visits
- May not be well-validated PROMs with clear interpretation

B. What considerations should be made when collecting PROMs from patient proxies?

- Many patients may not be able to self-complete PROMs or may request support to complete them. This includes pediatric patients and patients with mental/cognitive impairment
- Proxies can include parents, other caregivers, and physicians
- Proxy reporters can provide important information in cases where the patient is unable to provide responses themselves
- Proxy reports may be more valid to assess observable outcomes than unobservable ones (e.g. physical functioning as opposed to pain)
- Proxies may have a difficult time differentiating their own assessment of the patient's health from how they think the patient would report
- Proxy responses may be impacted by their experience caring for the patient
- There is often limited agreement between child/adolescent and parent proxy report
- It should be explicitly noted what the proxy's relationship to the patient is and if the proxy reporter is different at different administrations (e.g. one parent completes a PROM during visit A, another parent completes the PROM during visit B)

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of identifying patients. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

5 ⟩ SELECTING PROS AND PROMS

KEY POINTS

- *At the outset, there should be a clear rationale for patient-reported outcome (PRO) assessment and plan for use of the data. The outcomes selected should be relevant to patients and advancing the goals of the PRO system*

- *After identifying the outcomes of interest, stakeholders then select specific patient-reported outcome measures (PROMs). The ideal PROM has several characteristics, including that data from the PROM can be used to meet the goals of the PRO system, is psychometrically robust, and can be feasibly implemented in the context of interest*

OVERVIEW

At the outset, stakeholders should consider what outcomes to collect in the PRO system. The information to collect depends on the relevance of the content to advancing the goals of the overarching PRO system, and to patients and other stakeholders. In addition to identifying what clinical area the outcome data is tied to, stakeholders should also consider whether they are interested in aspects such as symptoms, physical function, treatment, tolerability, or broader quality of life, as well as the type of outcome they are interested in (e.g. frequency, severity, bother).

After identifying the outcomes of interest, stakeholders can then select specific PROMs. The ideal PROM addresses the goals of the PRO system, is psychometrically robust, and can be feasibly implemented into the context of interest. Decision-makers must balance their interest in using a specific measure with measurement properties of that measure. In some cases, there may be many PROMs from which to choose. In other cases, no "perfect" PROM is available; this is especially the case when trying to use a single measure to meet multiple goals (e.g. it may be hard to find a measure that is relevant, psychometrically robust, and feasible to collect, and which also meets both the goals of informing patient care and value-based purchasing).

Outside of the content area, other attributes of PROMs that might influence their selection include whether the measure is generic or disease-specific, whether the measure is profile or preference-based, how burdensome it is for patient to complete, how burdensome it is to collect and integrate into the PRO system, and the costs/licensing agreements required for use.

Harmonizing PROMs across the healthcare system can be useful to avoid including multiple PROMs within the same domain, minimize data collection and processing, and streamline PRO efforts. However, harmonizing approaches produce challenges, including less flexibility in measure selection by clinicians and researchers, and potentially less relevance to patients.

A.   How do you decide what PROs to collect?

Ensure that the outcomes are relevant to stakeholders (see Chapter 3, Identifying, Engaging, and Training, Users and Stakeholders)
- Engage stakeholders in the process of identifying what outcomes to assess
- Include patients and caregivers in the PRO selection process for the co-production of healthcare
- Involve the clinical team to foster buy-in to collect and use the PRO data
- Involve research/analyst early in planning to support the selection of measures with evaluable data
- Challenges with engaging stakeholders include:
  - Different perspectives across stakeholders on the relevance, purpose, and value of a given PRO/PROM and its ability to advance the goals of the PRO system
  - Time and resource requirements
  - Limitations in generalizability of input

Ensure that information on the outcomes will advance the goals of the PRO system
- If the goal of the system is to improve patient care, then the outcomes to be measured should be relevant to patients, and be useful to providers to inform clinical decision making (see Chapter 1, Defining Goals)
- If the goal of the system is tied to billing and payment, certain outcome measures might be required and/or recommended to enable economic analyses (See Figure 5.1)

Ensure content relevance
- Determine whether symptoms, functioning, quality of life, or a combination of these is of interest and relevant
- Evaluate what aspects are relevant (e.g. severity, frequency, interference, bother)
- Consider the preferences of patients and clinicians and the goals of the PRO system

Consider the use of core outcome sets
- Core outcome sets are standardized groups of outcomes/measures that are often designed through expert consensus and which are collected and reported together
- They are often inclusive of PROs, clinician reported outcomes, and clinical measures which together provide a more cohesive picture of patient health
- As they are standardized there is often greater opportunity to compare outcomes across settings and populations
- Numerous core outcome sets exist which span specific conditions and patient populations

Figure 5.1 **Process of selecting a PROM**

SELECTING GOALS	SELECTING OUTCOMES	SELECTING PROMs
• To enhance individual patient care • To improve population health • To facilitate research • To improve quality (beyond using individuals' PRO data to aid in their management) • To inform billing, reporting, and value-based purchasing	• To enhance individual patient care • Ensure that the outcomes are relevant to stakeholders • Ensure that information on the outcomes will advance the goals of the PRO system • Ensure content relevance • Consider the use of core outcome sets	• Generic vs. disease-specific measures • Profile vs. preference based • Single item vs. multi-item • Static vs. computer adaptive test (CAT) measure

B. What are the different types of measures that can be used to collect PROs?

Generic vs. disease-specific measures
- Generic measures may capture the more common health-related quality of life domains and allow comparison to population norms, but might not be sensitive to changes over time
- Disease-specific measures may be more sensitive to specific symptoms but might miss domains of health that are important to patients but unrelated to the specific condition

Profile vs. preference based
- Profile measures usually provide scores across multiple domains and are often longer to complete
- Preference measures use a single score aggregated across multiple PRO domains. Often the score is weighted based on the preferences of a set of stakeholders (e.g. general population, patients). Often, but not always, preference-based measures are generic rather than disease-specific

Single item vs. multi-item
- Multi-item scales typically provide more reliable and valid estimates but are also more burdensome
- Single item measures are quick to complete but less reliable, particularly at tracking changes over time

Static vs. computer adaptive test (CAT) measures
- CAT measures require the presence of and access to a validated item bank, and CAT software to facilitate the adaptive nature of the assessment
- CAT measures are more efficient and typically allow more domains to be assessed with a similar number of questions
- Static measures can be used on paper and computers but might lack the high degree of discernability of CAT measures and may take longer to complete

C. What response format should be used?

Response option formats
- Verbal descriptions of response options may be preferred if the outcome is difficult to describe numerically or if the population of interest has lower numeracy
- Numeric ratings may be preferred if the outcome is related to frequency, can otherwise be meaningfully explained numerically, or is commonly assessed using a rating scale (e.g. visual analogue scale for pain)
- If using multiple measures, consider the potential cognitive burden of differing response options

D. What are other desirable features of PROMs?

Robust psychometric properties in the context of interest
- Evidence of validity in the patient population(s) of interest
- Low measurement error such that the scores give a precise picture of the patient's status
- Conceptually clear with published evidence on reliability, feasibility, and utility
- Appropriate reading level for the target population; generally lower is usable by a broader range of patients
- Normative values such as thresholds, severity values, and other reference values that can be used to contextualize patient health and functional status
- Responsive to changes over time and in response to clinically significant changes in health
- Recall periods that are appropriate for the outcome of interest (i.e. short enough to reflect current health status, but not so short that they miss the outcome of interest)

Feasible to implement
- Respondent burden: How difficult is a measure to complete? While shorter measures are often regarded as better to reduce burden, patients are willing to complete longer measures if there is a clear purpose and the concepts are meaningful to them
- Cost/licensing: Some measures may require permission to use or have fees associated with their use
- Proxy versions: Some measures may have validated proxy versions, which is important if there is concern about the patient population's ability to report for themselves (see Chapter 4, Identifying Patients)
- Translations: Availability of linguistic and cultural translations of instruments
- Compatibility with PRO system: Feasibility to program, collect, store, and feedback the PROM data within PRO system
- Clinical champions: Stakeholders may have positive experiences with a given PROM

E.　Should PROs/PROMs be harmonized across the system?

Benefits to PRO/PROM harmonization
- Reduces the total number of PROMs that need to be programmed into a system, and increases the feasibility of PROM adoption
- Decreases duplication of effort to identify relevant severity thresholds, normative values
- Reduces respondent burden if fewer PROs can be used to inform medical decisions in multiple clinical contexts
- Streamlines training of end-users as all are training on the same system and with a pre-defined set of measures
- Facilitates research and other non-patient care goals by contributing to common data elements, allowing for information sharing within and across systems

Burdens to PRO/PROM harmonization
- Requires buy-in and participation of multiple stakeholder groups to agree on a set of harmonized measures
- Requires top-down guidelines on the harmonization system
- Decreases clinician/researcher autonomy in measure selection
- Limits utility if harmonized measures do not address the specific clinical needs of a population or are not relevant to decision-making in each context

F.　Is the PRO/PROM a good or poor fit for a given health system?

*Indicators that a PRO/PROM is a **good fit** for the health system*
- Information on the outcome will advance the goals of the PRO system
- The outcome is relevant and meaningful to patients and other stakeholders
- The types of measures and/or response options available to evaluate the outcome are feasible for the patient population and setting
- The PROM has evidence of psychometric validity in the context of interest
- The PROM is feasible to integrate into the PRO system

*Indicators that a PRO/PROM is a **poor fit** for the health system*

- Information on the outcome will not advance the goals of the PRO system
- The outcome is not necessarily relevant and/or meaningful to patients and other stakeholders
- The measures and/or response options are not feasible for the patient population and setting
- The PRO measure does not have evidence of psychometric validity in the context of interest
- The PRO measure may be difficult to integrate into the PRO system

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of how to select PROs and PROMs. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- ePROs in Clinical Care Website

6 DETERMINING ADMINISTRATION TIMING/FREQUENCY

KEY POINTS

- *Patient-reported outcome measures (PROMs) can be completed at a single clinical visit, at multiple clinical visits, between visits through remote monitoring, or some combination of the above*

- *The best timing and frequency of collecting PROMs will vary depending on the PRO system's data collection goals*

OVERVIEW

The optimal timing and frequency of collecting PROMs will vary depending on the PRO system's data collection goals. PROMs can be collected in the clinic at a single visit or over repeated visits. While collecting information at a single visit can be useful in screening for problems and unexpected conditions, it does not allow for monitoring over time.

Collecting PROMs at multiple visits is useful for evaluating a patient's trajectory over time and may be particularly useful to inform clinical care if a patient is symptomatic. However, increasing the number of instances of PROM collection requires an incremental increase in resources, and can be burdensome to patients.

PROMs can also be collected remotely between clinic visits, and while this approach may decrease disruptions to the clinical workflow at the visit, it requires patients to have both the willingness to complete PROMs outside of the clinical encounter and to have the ability to access the patient portal or other PRO collection system. It also requires a process for managing the incoming PRO data outside of the clinic visit workflow.

A. When can PROMs be completed?

At a clinic visit: single visit
- Provides an opportunity to screen for problems and unexpected health conditions with relatively low burden to patients
- Provides the care team information about what is important to the patient
- Does not allow for monitoring changes over time
- May be more appropriate for patients with stable health

At a clinic visit: multiple visits
- Allows for better understanding of the patient's trajectory and can provide a more complete picture of the patient's health. This information may be especially useful for patients who are symptomatic or in treatment
- May help patients better understand the interpretation of the PRO scores and how they align with their health and functional status
- Increases the resources required to collect PROMs incrementally based on the frequency of PROM collection
- May be more burdensome to patients, but may also provide information that is valuable to patients about their health over time

Between visits (remotely)
- Generally, requires patients to have access to the internet for completion via the patient portal or other platform outside of the clinical setting; can also be done via telephone administration (live or automated); use of mailed surveys limits ability to act on data in real-time
- Has the potential to help patients connect with care as needed between visits, and can help inform whether a patient needs care even when not being seen by the clinical team
- Requires a workflow to monitor PROM responses to determine whether they are clinically actionable or necessitate an alert to a member of the care team
- Creates the potential for burdensome alerts to the clinical care team, if they are triggered too often or for changes that are not clinically meaningful
- Requires patient willingness to engage with the PRO system outside of the clinic, and may result in decreased completion rates

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of PROM administration timing/ frequency. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). <u>User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice</u>, Version: January 2015.

- Snyder C, and Wu, A.W., eds. <u>Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records</u>. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

7　ADMINISTERING AND SCORING PROCESS

KEY POINTS

- *The available modalities to administer and score patient-reported outcome measures (PROMs) depend on whether collection is taking place during a clinical visit or remotely between visits*

- *In the clinic, PROMs can be collected through self-administration on paper, interviewer administration, or computer-assisted administration. Remotely, PROMs can be collected by mail, by telephone, or online*

- *Including quality and error checks in PROM administration can reduce missing data and invalid entries*

OVERVIEW

PROMs can be administered across different settings and using different modalities. PROMs can be completed in the clinic, either through self-administration by the patient with paper-and-pencil, administration by an interviewer, or computer-assisted administration. PROMs can be completed remotely through the mail, by telephone, or online. While it is possible (and frequently advisable) to offer multiple approaches for PRO data collection, it is essential that data collected from the different approaches are merged.

In recent years, electronic collection has become the most common approach. For data collection that occurs online, such as through a patient portal, quality and error checks can be included in PRO administration to reduce missing data or invalid entries. Systems can monitor missing data and provide reports to care teams summarizing missing PROM responses from either individual patients or groups of patients. Systems can also alert the patient or care team when a particular PROM has not been completed by the patient.

A. Where and how can PROMs be administered and scored?

In the clinic: self-administered on paper
- Has low technology requirements and can be implemented in any clinical setting. Completion is relatively low-cost but requires more time and resources for data entry and processing
- Can be challenging for patients with low literacy or those with other limitations that make it difficult to self-complete a survey
- Has a higher chance of returning missing/unusable data as patients independently complete the forms without a validity check from an interviewer or computer system

In the clinic: interviewer administered
- Offers a more personal experience to patients
- Largely overcomes barriers of self-administration for in-clinic completion
- Requires a private physical space in which to administer the PROM, as well as trained personnel to administer and score the PROMs
- Requires significant additional human resources
- May introduce social desirability bias

In the clinic: computer assisted
- Offers a standardized approach for collecting PROMs with less potential for bias than live interviewers
- Simultaneously captures and stores responses
- Requires personnel to provide support with the data collection device (computer, tablet) and a private space for completion
- Can lead to challenges dealing with technological malfunctions (e.g. device, internet access, etc.)
- May have higher costs than paper administration as it requires purchasing the PRO software and the devices to run it on, but fewer resources for data input and processing

By mail: self-administered
- May be simpler than administration during clinic visits and has low-technology requirements
- Likely has a higher non-response rate and is subject to other limitations of self-administered surveys in the clinic and may be subject to lower data quality caused by transcription error
- Less likely that the care team can respond in a reasonable time frame if the patient has clinically actionable results

By telephone: interview administered
- Offers a more personal experience to report PROs
- Largely overcomes barriers to completing PROMs caused by low-literacy or visual impairment
- Requires trained personnel to administer survey

By telephone: voice activated prompts
- Offers a standardized approach for collecting PROMs with less potential for bias than live interviewers
- Largely overcomes barriers to completing PROMs caused by low-literacy or visual impairments
- Requires upfront costs to develop/purchase an interactive voice response system that can return PRO results to the clinic, but once established has a relatively low cost
- May decrease patient satisfaction
- Potentially limits data completeness for PROMs that are lengthy or have complex responses as they may take substantial time to complete

Online: self-administered on patient's personal device outside of clinic
- Simultaneously captures and stores responses
- Allows for flexibility in timing of data collection
- Can be developed to immediately alert staff regarding completion and possible alerts on scores
- Requires a secure platform to house and collect data on PROMs
- Requires personnel to manage the system

Using a combination of approaches
- Accommodates the different preferences or abilities of patients to complete PROMs
- Uncertainty amongst staff as to what system each specific patient is using
- Requires that data collected from different approaches are merged and housed in an integrated fashion

B. What quality and error checks can be included in computer assisted/online PRO administration?

- Range and format checks can be used to reduce invalid entries
- Requiring responses before moving to the next question can reduce missing data, but prevents individuals from opting-out of questions they would prefer not to answer

C. How can the system monitor compliance/alert to missing questions?

Reports of completion rates
- Can be generated to report how many/often a patient or group of patients (e.g. all patients in a particular practice) complete PROMs
- Can be used to inform quality improvement of the PRO system
- Depends on having technological capability to aggregate material for reports and distribute them

Automated messages when patients do not complete PROMs
- Sends notification or email to the patient and/or clinical care team alerting that a patient's PRO questionnaire is missing
- Provides a prompt to go back and capture missing information
- Depends on having technological capability to identify when to flag a questionnaire as incomplete, and alert the patient/care team

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of administration and scoring. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

8　INCORPORATING IN CLINICAL WORKFLOW

KEY POINTS

- *Designing a clinical workflow that efficiently captures and addresses patient-reported outcome (PRO) data requires evaluating the current workflow and identifying the points where the workflow must be altered to facilitate the use of patient-reported outcome measures (PROMs)*

- *While the specific tasks associated with any given PRO system will vary across settings, universal activities include deploying, collecting, tracking, reviewing, and documenting PROMs and PROM scores*

- *Following implementation science frameworks and approaches can improve the quality of PRO system integration into a clinical workflow*

OVERVIEW

There are numerous considerations for integrating a PRO system into an existing clinical workflow. At the broadest level, initiatives to incorporate PROs into the workflow should start by clarifying how PRO data will be used (including to inform decisions within and outside of direct patient care), and identifying resources needed for integrating PROs into the workflow. Designing a workflow that efficiently captures PRO data requires evaluating the current workflow and identifying points in this workflow requiring modification for PRO system integration.

Some examples of good practices in the development of PRO systems include incorporating principles of user-centered design, connecting with people with relevant skills/experience in systems engineering or workflow design, conferring with other institutions that are using a similar system, and conducting pilot testing and formative evaluation of the system before full implementation.

While the specific tasks associated with a PRO system will vary across settings, there are five universal key activities. These include deploying PROMs to patients for completion, collecting PROMs from patients, tracking whether PROM data is missing, reviewing how the clinical team accesses PRO information, and documenting how PRO data are catalogued for future reference. These core activities may be adapted to align with the existing clinic workflow. Potential barriers to address, as well as metrics to evaluate the effectiveness of the PRO system, can be considered for each of these activities.

Incorporating PROs into a clinical workflow is largely an exercise in implementation. Common stages in the implementation of any new intervention include planning, designing, developing, implementing, and sustaining. Several implementation science frameworks can be applied to improve the integration of a PRO system into a clinical workflow.

A. What are the initial considerations for incorporating PROs into the clinical workflow?

    Clarify why and how PRO data will be collected for patient care
- Knowing the goals and purpose of a PRO system can inform the workflow design (see Chapter 1 on Defining Goals)

    Identify resource needs for integrating PROs into workflow
- Typical resources needed include training, decision response resources, personnel, financial support, information technology/technical support, and physical space

    Consider whether/how PRO data will be used outside of direct patient care
- For instance, if using PROs for billing and contractual reporting, they must be reflected in patient records

B. How do you design a workflow that efficiently captures PRO data?

    Begin by planning
- Document existing workflows
- Identify updates needed to current workflow to include PROM collection
- Develop protocols for how PRO data will be communicated to care team members
- Collect feedback and iterate process as needed

Use good practices in designing the PRO system
- Incorporate principles of user-centered design
- Present and display PRO data to promote the clinical team's ability to include it efficiently and meaningfully in their decision making
- Conduct usability testing of the PRO system across different end-users (patients, clinical care teams, information technology)
- Conduct formal pilot testing prior to system-wide rollout
- Allow time for modification based on experience, or develop a clear plan for receiving feedback and adapting accordingly
- Confer with other institutions who have developed similar systems to understand their experiences
- Work with information technology to understand technological functionalities available
- Design a system that does not require end-users to log into a new system/platform

Design a system around five key activities
- There are five key activities that should occur in any PRO system implementation (Figure 8.1):
  - **Deploy** PROMs to patients for completion
  - **Collect** PROMs from patients
  - **Track** whether PROM questionnaire forms are missing
  - **Review** how the clinical team accesses PRO information
  - **Document** how PRO data are catalogued for future reference
- These core activities may be adapted to align with the existing clinic workflow

Figure 8.1 **Steps to incorporate PROs into the clinical workflow**
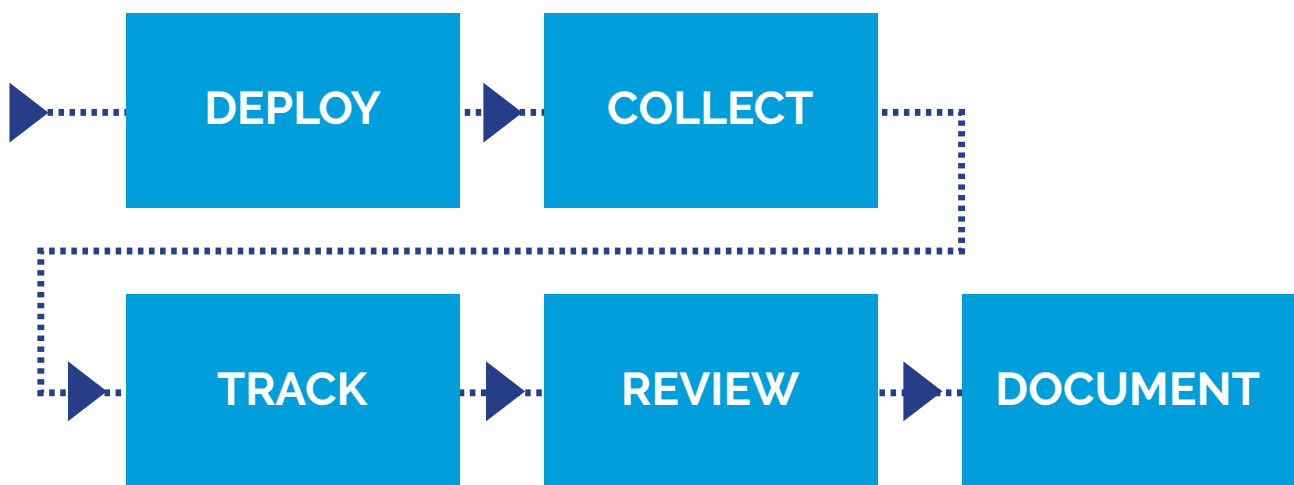
Adapted from ePROS in Clinical Care website (epros.becertain.org)

C. What are potential barriers to integrating PROs into the workflow?

Barriers to integrating PROs into the workflow vary across the PRO system implementation activities. Below are example barriers for each activity:

- **Deploy:** clinical team member does not know that PROM is due; team member does not send PROM to patient
- **Collect:** patient does not have access to patient portal/electronic materials or ability to complete PROMs
- **Track:** PROM scores do not go to the appropriate team member; results do not get updated in time to inform clinical care
- **Review and Document:** care team does not know how to locate PROM scores; PROMs do not contain relevant clinical information; PROMs scores are not saved in the record

D. How do you evaluate whether the PRO system is well integrated into the workflow?

- Engage in routine implementation monitoring to improve workflow over time
- Evaluate the system using quantitative metrics, including:
  - **Deploy:** Percent of patients who receive notification to complete PROM
  - **Collect:** Percent of patients who submit PROMs
  - **Track:** Percent of PRO items missing within questionnaires and total questionnaires missing
  - **Review and Document**: Percent of PROM questionnaires that are correctly documented by the clinical team
- Evaluate the system using qualitative methods: conduct formal interviews, usability tests
- Evaluate the system using informal methods: ask patients, clinical team members, administrators, information technology specialists what is and is not working for them

E. What can implementation science teach us about incorporating PROs into a clinical workflow?

- Incorporating PROs into a clinical workflow is an implementation strategy. Common stages in the implementation of any new intervention include planning, designing, developing, implementing, and sustaining
- Several implementation science frameworks can be applied to integrating a PRO system into a clinical workflow. Examples include:
  - Structured Analysis and Design Technique (SADT): approach to modeling a workflow that looks for commonalities across diverse environments; describes the core workflow activities, inputs, outputs, controls, and mechanisms for how activities are accomplished
  - Lean Management: performance improvement tools that can optimize complex workflows
  - Institute for Healthcare Improvement Model for Improvement: guides teams to improve outputs using repeated, small-scale Plan-Do-Study-Act cycles
  - Proctor's Outcomes for Implementation Research Model: provides a framework for aligning implementation process, healthcare, and patient experience outcomes
  - Consolidated Framework for Implementation Research (CFIR) Model: identifies implementation factors that impact program adoption and outcomes
  - Non-adoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) Framework: guides identification of challenges and approaches for addressing them using non-adoption, abandonment, and sustainability principles

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of incorporating PROs into the workflow. For more detailed information please see the following sources:

- ePROs in Clinical Care Website

9 PRESENTING RESULTS

KEY POINTS

- *Patient-reported outcome (PRO) results can be presented before, during, or after a clinic visit, or some combination of the above*

- *Results can be displayed using numeric or visual modalities, and across systems that range from being simple and static to those that are complex and dynamic*

- *There are multiple reference values that can be included to inform the interpretation of a patient's PRO results. These include baseline measures, comparisons to reference groups, and comparison across time*

OVERVIEW

Presenting PRO results is an important step in using the information to inform care. When PRO results are presented has implications in terms of how they must be deployed, collected, and tracked. Who receives the PRO results may also vary. Patients and providers are typically the primary audiences for PRO scores, but the two groups may use the information in different ways. Additionally, other audiences such as administrators, public health practitioners, and payers may use PRO data to inform research, pricing/reimbursement, or to meet other goals of the PRO system. Who is accessing PRO data has implications for how to optimally display results.

Various information about the PRO scores may be presented, such as how current scores compare to prior scores, or to other patients/groups of patients. Information about how a patient's health compares to other patients can be meaningful. Comparisons can be made to specific groups or populations, such as other patients in a provider's panel, to reference values from the general population, or to the patient's own health over time.

A. When should you present the PRO results?

Before a clinic visit
- Allows more time for the responses to be scored, and for the patient/clinical team to review the results and prepare for a discussion
- Requires patient willingness to complete PROMs outside of the clinic, and resources to deploy the PROMs outside of the clinical setting

During a visit
- Provides patients and clinicians with the most up-to-date information
- Alerts clinicians to areas of patient/family caregiver concern, enhances patient-clinician communication, and can clarify priorities for care
- May be difficult to deploy, collect, and analyze the PROM data within the brief period between when the patient enters the clinic and when they are seen by their care team unless an electronic system is used

After a visit
- May be easier to collect PROMs at the time of the visit and score them later; may also be easier to integrate into the clinical workflow
- Does not allow PROM use to inform clinical decision-making at the visit
- Provides no opportunity for patients to discuss PROM results with their care team, which may reduce the usefulness of these results and make them more challenging for the patient to interpret

B. Who receives the PROM results?

Patients
- Patients can use PROMs for monitoring and managing their own health, informing shared decision-making, and empowering them to discuss symptomatic problems with their care team or loved ones
- Returning results to patients promotes transparency and helps patients understand the different pieces of information that a clinical team uses to inform decision-making
- Results should be presented with context and appropriate interpretations to meaningfully inform the patient and prevent confusion

Providers
- PRO data can be treated like other clinical data to inform care, and alert the care team to adverse events
- Historical PRO data can be shown to discuss expected symptom trajectories based on the experiences of past patients (e.g. chemotherapy or surgery discussion)
- PROs can help providers engage patients in symptom and side effect monitoring
- Feedback to providers requires integration into the clinical workflow, including customization to a specific practice
- Personnel other than the doctor (e.g. nurse, other clinical team members) may be better positioned to respond to PRO information

Other audiences
- Administrators may want to receive aggregated PRO results if data will inform quality improvement efforts, or billing and reimbursement
- Payers, public health practitioners, or others might benefit from receiving PRO results to inform reimbursement, research, or population health
- Particular attention to data privacy and security protocols must be in place to uphold confidentiality and protect patients when data collected for clinical care is re-used in non-clinical settings

C. What PRO data from the patient can be presented?

Individual item, sub score, instrument scores
- Depending on PROM scoring guidelines, PROM data presented can include the individual item, the subscale/domain score, and the overall instrument score
- Having the ability to drill down/up allows users to review information at differing levels of granularity

Summary statistics
- A variety of summary statistics can be displayed to provide additional context to the PRO results. These can include descriptive statistics (mean, median, frequency, range), quartiles, and confidence intervals

Transformed, standardized, and normed scoring
- Transformed scores can be obtained by converting the scoring range for the scale
- Normed scores can be obtained by aligning the PROM scale to normative values for a particular population. Normed scoring can be used to compare the results of PROMs with different raw scores
- Data presentation should accommodate instruments as they were developed, be that with or without normed scoring
- Examples include using z-score standardization or t-scores
- Normed scoring may be less relevant when assessing changes within a patient over time
- If a norm is displayed, it is necessary to describe the reference population in the display, and indicate to the patient how this normed score may or may not be applicable to a specific patient

Comparison to reference values
- When data from specific groups are aggregated, they can be used as reference values
- Individual patient's PRO scores can be compared to many different types of reference values. These include:
  - Reference to public can be used to evaluate the level of patient impairment
  - Reference to a group of people within the same patient panel, with similar demographic or other information
  - Reference to a group of patients with similar clinical experiences such as having the same condition, receiving similar treatment, having undergone the same procedure

Comparison groups/populations
- Individual level scores reflect PRO scores from a particular patient, whereas group or population level scores are aggregated across multiple patients
- Individual level information is useful for patient monitoring and management, as well as screening and other outcomes
- Group or population level scores can be useful for providing reference values against which to compare a patient
- When comparing individual and population scores it is important to consider differences in clinical context (e.g. clinical specialty, inpatient vs. outpatient setting of data collection)

Longitudinal data
- Presenting longitudinal results can help describe trends and inform expectations about a patient's trajectory
- Time spans and intervals to display can be selected to align with treatments, clinical benchmarks, or office visits
- Longitudinal data can also be used to describe health status pre/post specific interventions
- Change scores describe the difference in PRO scores from one time to another, with an indication of whether the patient's health is improving, worsening, or staying the same
- Patients value indications of how scores are changing as well as if that change is concerning

D. What are additional desirable functionalities of PRO presentations systems?

- Augment with other information about the patient
- Able to filter data, e.g. for a particular window of time
- Personalize platforms, e.g. providers and patients can customize the display to provide the information most relevant to them or their decision-making process

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of how to present results. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- ePROs in Clinical Care Website

- Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. Quality of Life Research. 2019;28:345-356.

- PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: https://journals.lww.com/lww-medicalcare/toc/2019/05001.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

10 VISUALIZATIONS TO AID INTERPRETATION

KEY POINTS

- *Optimizing patient-reported outcome measure (PROM) visualization can help patients and providers interpret PROM results with greater ease and accuracy*

- *Numerous graphical approaches for visualizing PROM data exist, and the selection of an approach should depend upon the purpose of the visualization and the context in which the PROM information is being used*

- *Information such as score directionality, meaning, and possibly concerning results can be effectively conveyed through visual cues*

- *Color, bolding, symbols, and hover-over text can be used to meaningfully draw attention to aspects of the PROM data display*

- *Including supplemental information such as clinical data about the patient or practice guidelines in the PROM visualization can help contextualize PROM results*

OVERVIEW

For PROM data to be useful in clinical care it must be understood by providers and patients. PROM results can be presented in several different formats. They can be presented numerically, through text and tables, or visually, through charts, pictographs, and other graphics. While visual formats are typically more intuitive and enhance appropriate interpretation, they are also more challenging and costly to design and integrate, especially into EHRs.

As users increasingly access results with their mobile devices, visualizations should be designed for optimal use on both computer and mobile device screens. Formats readable by screen readers make PROM results accessible to patients with visual limitations.

PROM results can be displayed at varying levels of complexity. Simple displays may describe PRO scores in a static format. Complex displays can be more interactive, and include functionalities such as representing change scores, comparing individual PRO scores to population PRO scores, and incorporating other forms of benchmarking.

There are different methods to improve the ease and accuracy with which PROM data is interpreted. The selection of a particular visualization approach for PROM data should depend upon the purpose of visualization, and the context in which the PROM information is being used (i.e. for a patient encounter vs. analytic/research purposes). Optimal approaches for displaying individual-patient level data are line graphs of scores over time, which can be supplemented with features such as arrows and descriptive text to better convey the results. Other visualization approaches include bar graphs, tables, color bars, pictographs, scatterplots, pie charts, and floating column bars, though many of these are better suited to group-level data. Many of these methods are appropriate for comparisons across groups or to reference values.

Different types of information can be included in and alongside a display of PROM results, such as score directionality (i.e. whether higher scores are better or worse), descriptive labels indicating score meaning and/or severity thresholds, scores that are possibly concerning, and indications of clinically important changes. Visual cues, such as lines, color and shading, symbols and pictures, bolding/highlighting/arrows, and hover-over text/annotation, can draw attention to specific aspects of the PROM data display.

PROM data can be organized in various ways within the display window depending on the functionalities of the PRO system or the electronic system within which it is embedded. These options include presenting visuals of PROM results in separate tabs, within the same window, in a dashboard, or overlaying PROM results onto one graphic. Display windows can also be organized to include supplemental information that can help contextualize PROM scores, such as clinical information about the patient or practice guidelines.

A. What are different ways to display the data?

Numeric
- Presented in text or tables
- Can be relatively easy to configure, including in electronic health records and patient portals
- Does not require data manipulation
- Reflects format for clinical results care teams are already accustomed to reviewing
- May make it difficult to quickly identify problematic results or significant changes if only numbers are presented

Visual/graphical presentation
- Includes charts, graphs, and pictographs
- Can be more intuitive and promote accurate interpretation of the data
- May be preferred for displaying information about changes in health
- Can more effectively communicate health to low literacy groups with specific visualization methods, such as pictographs
- May be harder to integrate into electronic health records

Simple displays
- Lack contextual details
- Typically static and require no user interaction
- Easier and less expensive to develop
- May be easier to interpret by both patients and clinicians
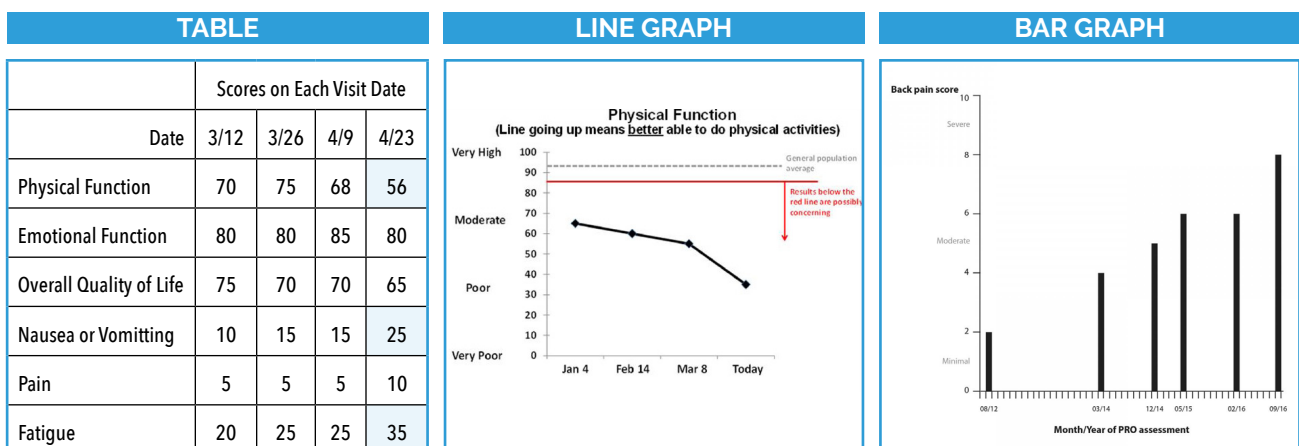- Can lead to potentially inaccurate interpretation due to less detail provided

Complex displays
- May include descriptive text (possibly personalized), change scores, comparisons to population values, and other forms of benchmarking
- Increase ability to contextualize PRO scores and use them to inform care decisions
- Require more resources to develop/maintain and more energy to interpret due to their sophistication

B. What graphics are appropriate for visualizing different types of PROM results?

Below is a figure describing different types of graphs that can be used to visualize individual-level PRO data with examples.

Figure 10.1 **Graph types to visualize PROM results**

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

Adapted from ePROS in Clinical Care website (epros.becertain.org) and from Recommendations for PRO Data Display

C. What information can be included in visuals to aid PROM interpretation?

Directionality of PROM scores
- Indicate the directionality of PROM scores clearly to improve the interpretation of their meaning. Depending on the specific PROM, improvement in health outcomes might be a numeric increase or decrease in score
- Avoid mixing score directions within a specific display
- Use labels, titles, and other annotations to make clear which scores indicate "better" and which indicate "worse" scores on the PROM

Score meaning / Severity thresholds
- Include descriptive labels and/or color-code (e.g. mild, moderate, severe) on graphs when there is data to support their placement; anchors at the extremes (e.g. none, severe) can be used even if information on the middle categories (e.g. mild, moderate) are not available
- Select PROMs that have validated severity thresholds, if available
- Use PRO-bookmarking, Rasch measurement theory, anchor-based methods, and other approaches to identify severity thresholds, if not available for a given PROM

Possibly concerning results
- Possibly concerning results can be generated either from absolute scores, or from changes in scores over time
- Possibly concerning PRO results can often be displayed in a manner consistent with how other concerning results (such as for biomedical data like blood tests) are displayed
- Examples of possibly concerning results include scores outside of a target range, or scores that require attention or intervention by the medical team

D. What visual cues can be used to enhance key information in PROM visualizations?

Lines on the graph
- Can be used to visualize discrimination of scores (e.g. lines can indicate the threshold for mild, moderate, severe scores)
- Can be used to visualize a clinical cut-off, e.g. cut-off scores for a psychological screening
- Can be used to reflect reference values such as those from the general population or another comparator group

Color and shading
- Traffic light colors (green, yellow, red) can be used to designate severity
- Pairings of color and shading should consider the needs of people with visual impairments such as color blindness/color confusion
- Cultural associations of patient populations should be considered when relevant as colors have different meanings in different cultures

Symbols and pictures
- Pictures/symbols can be used to make results more interpretable

Bolding/highlighting/text size/arrows
- Can be used to draw attention to a particular aspect of the visual

Hover-over text/annotation
- Can provide description or definition of key terms within the graphic

E. What different ways can PROM data displays be organized?

- Tabs: present different PROM results in different tabs. Tab systems require toggling between different screens and can make it more challenging to compare results across different PROMs and more difficult to manage on mobile devices
- Dashboards: present different PROM results, often each using different graphical styles
- Overlay of multiple PROM results on the same graphic: makes it easier to observe symptom clustering
- Not all systems may have the ability to offer all displays
- There is a tradeoff in selecting any given option for presenting PROM scores. For instance, dashboards may be easy to use but are challenging to design and integrate

F. What additional information can be included alongside visualizations to improve interpretability of PROM data?

- Contextual information can provide a more holistic view of the patient's health. Examples of this information include interventions received, demographic information, lifestyle information, medical events, and vital signs
- Practice guidelines can be provided alongside PROM data to inform decision-making

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of aiding interpretation of PROM results. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- ePROs in Clinical Care Website

- Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M; PRO Data Presentation Delphi Panel. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. Quality of Life Research. 2019;28:345-356.

- PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: https://journals.lww.com/lww-medicalcare/toc/2019/05001.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

11 RESPONDING TO ISSUES

KEY POINTS

- *Clinical teams must be equipped to respond to alerts or refer to other support services prior to integrating patient-reported outcome measures (PROMs) into clinical care*

- *Evidence-based cut points are already established for some measures, and these cut-points can be used to inform when providers are notified about possibly concerning scores*

- *Scores that may be critical in some contexts might be normal or expected in other contexts, and this context is important when determining how to respond*

OVERVIEW

It is important to establish a plan for responding to PROM data prior to integrating PROMs into clinical care. Groups must first consider how PROM data will be integrated into the patient record, and specifically whether providers need to actively accept the PROM information, or whether that information can be passively added to records or pushed to patient portals without additional provider vetting. It is also important to consider what notifications a provider should receive about new PROM data, including no notification at all, notification for everything, or notification only for specific alerts. These alert systems should be co-designed with the patient and clinical team.

It is important to differentiate what is typically considered a critical score from that which is critical (or normal) for a particular patient when determining a response. Determining what threshold constitutes an alert is a significant challenge, and both patients and providers want to maximize the chance that providers see possibly concerning results while also minimizing the number of alerts they receive.

Evidence-based cut points are already established for some measures, and these cut points can be used to inform when providers are notified about possibly concerning scores. For the many PROMs that do not have established cut points, there are rigorous quantitative and qualitative approaches that can be used to establish cut points, or more rule-of-thumb values that might be used.

The clinical team must be equipped to respond to alerts. Discussing possibly concerning scores with patients is advised. Some validated thresholds may be mapped onto a need for specific clinical actions. Establishing clear pathways can reduce uncertainty in clinical decision-making. When clear pathways do not exist, clinical team members should explore the identified issue(s) with the patient and can engage multidisciplinary care team members to inform next steps. In some instances, reassurance and acknowledgement of difficult-to-manage symptoms may be helpful.

PROM data can be communicated to patients, their proxies, primary care providers, the provider "ordering" the PROM, patient navigators, or any combination of these groups. Who receives the PROM data has implications for how the information will be included in care. Modalities for communicating about PROM data include email, secure clinical notes, and text/page.

A. Should providers have to "accept" PROM data into the record?

   No
   - In this configuration, PROM data can be moved into the health record without it being actively "accepted" by a provider
   - This approach allows for the easy integration of data into a patient-reported outcome (PRO) system
   - This approach reduces burden on the healthcare provider as they do not need to accept potentially large volumes of data that do not require a response
   - This configuration may lead to more regular and meaningful use of the data
   - The medical record should reflect what information was provider-input in comparison to what data was patient-input
   - Concerning results need to be flagged for provider review

   Yes
   - In this configuration, providers are required to review and accept PROM data when it is included in the record
   - This approach increases the likelihood that PROM data is correct and ensures that providers see all the PROM data
   - Reviewing and incorporating PROM data into the record is time consuming, and may inadvertently lessen the utility of this information

B. What kinds of notifications should providers receive about PROM data?

No notification
- One approach is to consider PROM data like vital sign or other information that gets imported into the system without notification
- Potentially concerning data could be flagged, but the provider would not get a pushed notification of the flag
- This approach does not incur any added workload and does not interfere with workflow, but runs the risk of providers missing important clinical information
- There are potential liability concerns if the patient believes that data will be reviewed when this might not be the case

Notification of all PROM information
- Providers receive a notification every time new PROM information is entered into the system
- Notification modality is usually not flagged as urgent, and is delivered as an email or clinical message
- Ideally notification should include the PROM results themselves
- As compared to receiving no notification at all, receiving notifications makes it less likely that PROM data will be missed. However, at high volumes it may be possible that results are ignored
- This approach may be most effective in a low-volume setting

Notification of "alert" PROM information
- Alert notifications can be used to indicate to a clinician that a patient requires follow-up, such as if the alert indicates they are experiencing chest pain or severe depression
- Systems should carefully consider whether they want to assess symptoms that would require immediate action
- Open-ended alerts will notify the provider but do not require that the provider electronically close the alert
- Closed-loop alert notifications require that the provider electronically close or address the alert
- Alerts to providers can be sent at the same time as notifications are sent to patients advising them on next steps for their care; it is also recommended that patients be warned not to report urgent issues via the PRO system and to contact their provider directly for urgent issues
- Notifications to patients should be co-designed with patients and follow user-centered design practices
- As compared to receiving a notification of all PROM information, only notifying providers with alerts may be more likely to bring attention to a given PROM finding
- Notification of an alert requires that some sort of action be taken to address the alert. It is not always clear what this action should be

C. What approaches can be used to select alert and other clinical thresholds?

Select measures with existing, validated severity thresholds
- PROMs that have validated severity thresholds can be purposively selected
- Depression and anxiety measures are more likely to have thresholds compared to other PROMs

Develop severity thresholds for measures without them
- Validated severity thresholds have not been established for many PROMs
- PRO-bookmarking, Rasch measurement theory, anchor-based methods, and other approaches can be used to identify severity thresholds
- Consensus-based approaches, such as Delphi panels, are increasingly used to identify appropriate cut points

Use rule-of-thumb cut points
- Re-scaled PROs with scores that can be mapped onto a 0-10 scoring system can be very generally grouped as: 0 = none, 1-3 mild, 4-7 moderate, and 8-10 severe
- >=4 or >=5 are often used as a cut point for general alert to a provider

D. What modality is used to communicate a result?

Email
- Non-secure email is not typically recommended, but may be acceptable when using a 3rd party PRO system that is not integrated with the electronic health record or other clinical messaging systems
- In cases when email can be used securely, email can be beneficial as it does not need to be integrated with the electronic health record and can be accessed with routine login information

Secure clinical messages within the electronic health record
- Clinical messages within the electronic health record can be easily used if the PRO system is embedded within the electronic health record
- Clinical messages are secure, automatically documented, non-interruptive, and are easily accessible within the electronic health record platform
- Clinical messages require access to a specific network or login through a virtual private network

Texts, secure texts, page
- Both 3rd party and electronic health record systems can often be integrated with a text/paging platform
- These options are secure, and present information in real time
- The real-time delivery of results can be either useful or interruptive

E. What methods can be used to respond to alerts identified by PROMs?

Discuss PROM scores with patients to better understand their experiences
- Generally recommended to better understand patients' PROM scores. In some cases PROM scores may be related to issues outside of the specific clinical context (e.g., limited physical function related to a broken ankle rather than a cancer diagnosis is more relevant to the orthopedist than the oncologist)
- This approach can be time-consuming but may also help patients holistically

Follow a disease management pathway
- Established disease management pathways can be used to easily identify clinical next steps
- Having established pathways reduces uncertainty and creates uniform responses to address patient needs
- Creating new pathways is a time consuming and challenging process

Engage multidisciplinary team members
- Healthcare professionals from different disciplines, including different medical specialties as well as from groups such as social workers, nutritionists, and counselors, can be engaged to troubleshoot patient problems or identify next steps for care
- It can be time-consuming and difficult to coordinate multidisciplinary team members to address patient problems

F. Who should be notified of PROM results?

The patient, their proxy, or their choice of providers
- As the ones experiencing the outcome, patients are the ultimate owners of their data and may be interested in receiving their PROM results
- It can be difficult to provide the full context of the results to patients when not accompanied by contextual information
- Patients can also select who they would like the PROM results to be shared with, including who within their clinical care team they would like to inform

Ordering provider
- The provider who requested the patient complete the PROM could be the individual alerted in the event of a problem
- Typically, the problem detected would be relevant to the ordering provider, and ordering providers would like to see the results
- It can at times be difficult to identify the ordering provider within the PRO system

Primary care providers
- Primary care providers are often considered responsible for a patient's overall health and therefore may be more likely to do something when presented with a potentially concerning result
- Patients have preexisting relationships with their primary care providers, which may increase primary care providers' willingness to address the concerning health problem
- It may be overwhelming for primary care providers to be tasked with addressing results from PROMs for all patients

Navigator or administrator
- Patient navigators or administrators sometimes take on the role of organizing information across many patients and ensuring that information is relayed to the correct clinical party
- Navigators or administrators can be notified of the results and can then route this information to the appropriate member of a patient's care team
- This approach can be administratively challenging

G. Are PROMs ready to drive clinical decision-making?

Yes, if PROM scores can be meaningfully interpreted and tied to an action
- Translating PROM responses into actions is valuable
- Requires that that there is sufficient evidence supporting linking a clinical action to a PROM score
- When used correctly, PROM scores can be used to improve clinical decision support and can increase likelihood of completed PROMs in the future

Not yet, if PROM scores are unclear or cannot be tied to a clinical action
- Most PROMs have not been used widely enough to be associated with clearly defined clinical actions
- More experience with using a given PROM to inform clinical care may be required before using the measure to inform clinical action
- Urgent alerts should not be sent for PROM data that does not have an associated action
- If a PROM is directly tied to a clinical action, it may be considered a medical device in some countries and subject to regulatory requirements
- PROMs can still be used to inform discussions, even if not tied to a clinical action

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of responding to PROMs. For more detailed information please see the following sources:

- International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: January 2015.

- PRO-cision Medicine Toolkit for Personalizing Care Using Patient-Reported Outcomes A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes. Available at: https://journals.lww.com/lww-medicalcare/toc/2019/05001.

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

12 EVALUATING THE INTERVENTION

KEY POINTS

- *Evaluate both implementation and patient clinical outcomes to consider the full impact of a patient-reported outcome measures (PROMs) program*

- *Consider the pros/cons of experimental and non-experimental designs*

- *Communicate findings about the intervention back to the health system and use them to improve future iterations of the program*

OVERVIEW

Evaluating an intervention is a crucial aspect of gauging its success and determining areas for improvement. Measuring the PROM intervention's effect on both implementation outcomes, such as acceptability and appropriateness, as well as on patient clinical outcomes, such as symptom burden, survival, and quality of life, can provide a fuller picture of how well the intervention met its objectives.

Different methods can be used to evaluate the implementation of PROM systems. These include both experimental and non-experimental designs. These methods span more controlled methods (e.g. randomized controlled trials) to more flexible and adaptive methods (e.g. quality improvement studies). Quality improvement studies may be more appropriate during the initial implementation phases while more rigorous designs may be more appropriate to evaluate the impact of established programs. Just as implementations science frameworks can be used to guide the incorporation of PROs into the workflow (see Chapter 8, Incorporating in Clinical Workflow), they can also inform an evaluation strategy for the intervention.

A. What outcomes can be evaluated?

Implementation outcomes
- Implementation outcomes describe how well a program is delivered and received
- Examples include acceptability, appropriateness, feasibility, adoption/uptake, fidelity, reach/penetration, costs, sustainability (See Figure 12.1)

Patient clinical outcomes
- Patient clinical outcomes include those related to the patient's health and health service use
- Examples of clinical outcomes for evaluation include symptom burden, use of emergency services, survival, quality of life, physical function, satisfaction with care

Figure 12.1 **Example implementation and clinical outcomes**

IMPLEMENTATION OUTCOMES	CLINICAL OUTCOMES
• Acceptability • Appropriateness • Feasibility • Adoption/Uptake • Fidelity • Reach/Penetration • Costs • Sustainability	• Symptom burden • Use of emergency services • Survival • Quality of life • Physical function • Satisfaction with care
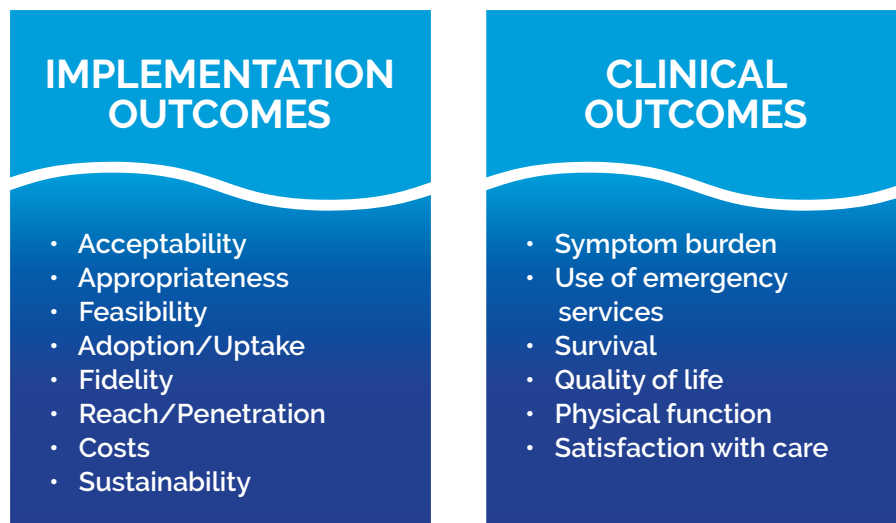
B. What evaluation methods can be used?

Experimental designs
- Experimental designs include randomized controlled trials, cluster-randomized trials, and similar approaches
- These designs are considered the 'gold standard' in evaluating an intervention as they are typically rigorous and maximize internal validity
- Experimental designs typically test efficacy rather than effectiveness, but some implementation science experimental designs have been adapted to evaluate effectiveness
- Conducting an experimental evaluation requires substantial monetary and professional resources, typically requires grant support, and often needs institutional review and approval including ethical review
- These studies may be more appropriate to evaluate established programs

Feasibility studies, quality improvement designs, quasi-experimental designs, and observational studies

- Includes improvement research, plan-do-study-act cycles, cross-over, case-control, and time series research. These approaches may be better suited to capture effectiveness of an intervention as they are evaluating a hybrid of its implementation and its effect on patient outcomes
- These studies may be more appropriate to evaluate initial implementations but can also be used to continuously improve established programs
- The non-experimental nature of the design increases risk of bias and decreases generalizability
- Both qualitative and quantitative methods can be used to evaluate the system
- These approaches are typically lower cost but may still require some monetary and personnel resources to administer, as well as possibly requiring institutional and ethical approval

C. What should you do with the results of the intervention evaluation?

- Inform PROM system improvement
- Communicate learnings throughout the organization
- Share learnings with the field. Consider disseminating results of the intervention through conferences, publications, or other communication channels to increase awareness of both the PROM program and efforts to evaluate it
- Consider whether the outcomes meet the goals of the PROM system – and adjust the PROM strategy if they do not

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of evaluating the intervention. For more detailed information please see the following sources:

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

13 INTEGRATING WITH ELECTRONIC HEALTH RECORDS

KEY POINTS

- *Full electronic health record (EHR) integration describes a system wherein patient-reported outcome (PRO) collection is contained entirely within the pre-existing EHR*

- *Stand-alone collection systems capture patient-reported outcome measures (PROMs) using a bespoke or 3rd party system and can relay this information to the EHR*

- *There is a continuum of levels of integrating externally collected data with the EHR, ranging from minimally integrated systems with limited patient-reported outcome (PRO) data uploaded to the health record in a non-modifiable format and more extensively integrated systems where external data are uploaded to the health record as discrete and manipulable values*

OVERVIEW

Integrating PROs in the EHR is an important aspect of making sure that PRO information is well-documented and available to inform clinical care, research, or any other goals of the PRO system. Several strategies are available for integrating PROs into the EHR. One is full PROM integration, wherein the PROM collection and display both take place within the EHR, often via the patient portal.

Another option is stand-alone PROM collection systems, wherein PROMs are collected in a system purchased from a 3rd party or developed specifically for the clinic. These systems communicate bi-directionally with the EHR to a varying extent.

At the most basic level, PROMs can be collected and then entered in the EHR by uploading a scanned copy of the completed PROM or manually entering values.

A. What methods can be used to integrate PROMs with the EHR?

Full integration
- Full integration describes a system wherein PRO collection is contained entirely within the EHR
- Benefits:
    - An integrated system is typically more convenient for patients and providers, as it uses an existing platform to collect and store PROM information alongside other patient data
    - PROMs can be pulled from/pushed to and scored in real-time, and can generate alerts for potentially concerning scores
    - The integrated nature means that PROM completion can benefit from other EHR functionalities, such as patient reminders
    - PRO system data collection can be tied to specific medical events (e.g. automatically timed to procedures or treatments)
    - This approach may reduce redundant completion of PROMs as they are contained within a single record that all providers within a health system can access
    - Scoring and visualization of PROM data can be presented alongside other health information (e.g. vital signs, laboratory tests, clinical notes)
    - It may be more efficient to develop a PRO system within an existing system with an already approved vendor
    - Outcomes can be used to analyze trends across patient populations (e.g. determining how a particular demographic is responding to a pertinent health measure, how effective certain treatments are)
    - For research purposes, PROM data can be easily extracted along with other EHR data
    - Asynchronous collection of PROMs is possible
- Drawbacks:
    - Requires that patients complete the questionnaire via the patient portal or other system tied to the EHR
    - Limits customization options for data collection and results display
    - Any customization requires involvement of EHR and information technology teams
    - The standard PROMs integrated in the EHR system may be more relevant to clinical use rather than for research or administrative goals of PRO systems

Partial integration: PROM collection in stand-alone system
- PROM collection can be conducted in a system that is either bespoke to the healthcare setting or has been purchased from a 3rd party
- These systems can be fully or partially integrated with the EHR
- Many of the benefits and drawbacks of this approach are determined by the specific system being used and its ability to meet the PRO system goals of the intervention
- General benefits:
  - User interface is designed for PROM administration, typically making the program more user friendly for collecting and reporting PROM data
  - Many systems may allow for transfer of PROM data into the EHR, and can pull information from the EHR to inform PRO assessment
  - Advanced and tailored reporting options are usually available
  - PROMs typically will be scored in real-time, and can generate alerts for potentially concerning scores (see Chapter 11, Responding to Issues)
  - Asynchronous collection of PROMs is possible
- General drawbacks:
  - Patients may not be accustomed to entering patient data into systems outside of the EHR patient portal. They may have less trust in non-EHR affiliated systems or be unaware that the PROM collection is linked to their care
  - The use of a stand-alone system may complicate data extraction for research purposes if it requires gathering and merging data from both the stand-alone system and the EHR
  - Additional costs are required to purchase and maintain an outside system
  - Configuration relies on a dedicated technical support team provided by the PRO system, rather than from the health system's EHR and information technology teams
  - Outside systems may raise data security concerns

Minimal integration
- Paper-based PROM collection can still be integrated into the EHR such as scanning completed PROM forms or entering PROM data into the EHR manually
- Benefits:
  - Paper-based approaches may be more user-friendly to certain patients or within certain clinical settings
  - Fewer upfront costs required
  - Less need for specialized training on how to use an electronic PRO system
- Drawbacks:
  - Higher chance of redundancy in PROM capture
  - Automatic PROM scoring and generation of PROM reports is not available
  - Generally relies more on manual processes and workflows, such as requiring staff to identify eligible patients and track PROM administration over time
  - Manual entry of PROM data by clinical team may add errors

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of integrating PROs into the EHR. For more detailed information please see the following sources:

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

- ePROs in Clinical Care Website

14 GOVERNING THE SYSTEM

KEY POINTS

- *Governance provides oversight for the development and management of a patient-reported outcome (PRO) system, including developing and enforcing standards and policies to guide decision-making about the PRO system*

- *Governance bodies can advise on the needs and structure of the PRO system, inform the selection of appropriate measures, and provide examples of good practice in using patient-reported outcome measures (PROMs) in care*

- *Governance can be centralized, decentralized, or a hybrid. Regardless, governing bodies should be composed of individuals with multidisciplinary perspectives*

OVERVIEW

Governing bodies provide strategic input on the structure and process of implementing and evaluating the PRO system. Governance is often overseen by a committee of individuals with multidisciplinary perspectives, who may or may not already be aligned with a role in existing organizational leadership. Governance groups should develop scopes of work and identify how they will make decisions regarding the PRO system. Additional activities in their domain include identifying current and future needs of the PRO system, disseminating good practices, and providing guidance on the selection of specific PROMs.

PRO system governance can be centralized, decentralized, or a hybrid. In centralized models, a core decision-making body holds most of the say in what PROMs are collected, how they are collected, how the data is used, and how the system generally operates. In decentralized groups, these decisions are deferred to the specific group who has interest in collecting and using PROMs. Hybrid approaches exist but can lead to confusion regarding who the ultimate decision-maker is.

A. What is the general purpose of a PRO system governance group?

- Provide oversight for the development and management of a PRO system
- Develop and enforce standards and policies to guide decision-making about the PRO system
- Ensure data security and consider ethical and legal issues

B. What activities should governance groups undertake?

Define a scope of work and decision-making process
- Establish a charter including a mission and scope of work
- Re-review charter with some regularity (e.g. annually) to determine whether it still meets the needs of the health system
- Identify how decisions will be made and transparently communicate this decision-making process within and outside the governance group
- Identify mechanisms for reporting decisions and results to health system leadership
- Create a process for managing and prioritizing PRO system implementation requests

Identify the current and future needs of the PRO system
- Align goals of the PRO system and health system
- Explore the need and value of PRO information across different groups (e.g. clinical, quality improvement, research)
- Use needs assessment methods such as interviews, focus groups, surveys, and observational studies to learn about the current environment and potential value of a PRO system
- Connect with clinical champions to explore desirable attributes for a PRO system

Disseminate good practices for use and management of the PRO system
- Develop or identify specific practices and requirements for using the PRO system
- Identify standards for how the PRO system is designed and used in practice
- Consider whether there are common data standards, centralized reporting tools, or other standard data features which should be included in the PRO system
- Disseminate best practices as they emerge (e.g. automating health risk screening in primary care)
- Consider how to facilitate the PRO system's sustainability
- Define metrics that can be used to evaluate the success of the PRO intervention and its implementation

Provide guidance on the selection of specific PROMs
- Selection of relevant PROMs is essential to achieving the goals of the PRO system
- Governance can provide input on measure selection, and create repositories of 'endorsed' PROMs

C. Who can be included in PRO governance?

Members of an existing organizational leadership structure
- Decision-making is sometimes more effective when aligned with existing organization structures
- Sometimes these groups are better aware of existing priorities in the health system and can tailor recommendations to be mutually beneficial to both the health system and the PRO system

Multidisciplinary perspectives
- Diverse perspectives should be included in the PRO governance decision-making. These can include clinical champions, clinical staff, information technology experts, PROM specialists, informaticians, legal experts, project managers, data analysts, and patient representatives

D. What types of governance structures can be used?

Centralized
- Involves decision-making by a single person or specific group of people regarding all, or nearly all, aspects of the PRO system
- Promotes effective PRO implementation at a system level
- Decreases the likelihood that patients are subjected to redundant inquiries to complete PROMs across the healthcare system
- May make it more difficult to implement specialized or condition-specific PROMs, which may result in PROM data that is too general and not optimized to inform patient care
- Involves centralized processes that may be slow-moving and bureaucratic

Distributed
- Allows autonomous decisions about the implementation, oversight, and use of specific PROMs that fit the needs of specific individuals or groups (e.g. departments)
- Provides more flexibility and allows different individuals or groups to adapt content and approaches to fit their patients' clinical needs
- May be more burdensome as groups have increased management responsibilities versus a centralized model
- Can lead to patients being asked to provide redundant PROM data across settings
- May make collaborating and data-sharing more challenging
- May reduce ability to conduct quality improvement reporting or research

Hybrid
- A core central entity provides a set of rules for implementing and using PROM data, and provides some oversight, but allows for more customization and flexibility across groups
- Could be used in both centralized and decentralized institutional cultures
- Can lead to confusion and dispute regarding who is responsible for final decisions

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of governing the system. For more detailed information please see the following sources:

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

- ePROs in Clinical Care Website
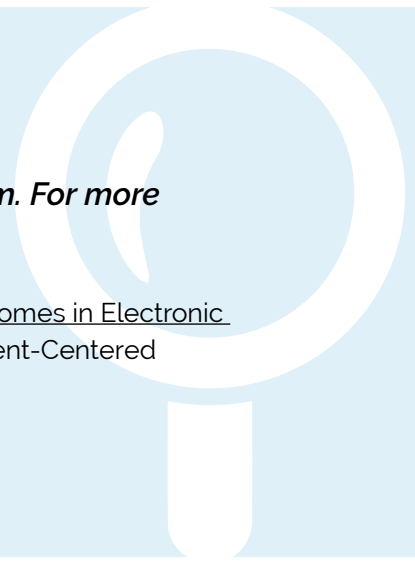
15 POOLING AND EXCHANGING DATA

KEY POINTS

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

- *Identifying an appropriate data model and associated meta-data is an important aspect of maximizing the utility of pooled patient-reported outcome (PRO) data, and there are numerous models to choose from*

OVERVIEW

Combining PRO data collected across different medical sites and different points can create robust datasets, allowing for more meaningful research questions to be answered. However, it is important to ensure that there is some degree of consistency across the aggregated data and how it is specified in the data model.

There are two overarching approaches to data architecture and curation. The first is through a centralized warehouse, which stores all the extracted data from many sites. The second is through a federated/distributed warehouse, wherein sites maintain their own data and respond to data analysis queries independently.

There are hundreds of available data models to choose from. Several factors must be considered when choosing a data model, including the granularity and specificity of the data and the clinical domains supported by the data model. Examples of popular data models include PCORnet, Consolidated Clinical Document Architecture (CCDA), and Shared Health Research Informatics Network (SHRINE).

A. What are the different architectural approaches?

Centralized data warehouse
- Centralized data warehouses store all the data extracted from many different sites that use a given system
- Centralized data warehouses are typically maintained by a coordinating center that ensures that the data are entered into the warehouse and available for use
- Centralized data storage facilitates better data analysis as it allows statisticians to understand which data were collected, which are missing, and to conduct quality checks
- All sites contributing to the centralized warehouse must address legal, regulatory, and proprietary data sharing issues
- Contributing sites need to agree on a standard data interchange format

Federated/distributed data warehouse
- In federated/distributed data warehouses, data are kept in a locally maintained data warehouse at each site
- Data analysis queries can be submitted to the local sites, which run the analysis and respond with summary data
- There are fewer organizational concerns about sharing potentially identifiable patient data, as the local site has control of the data and only reports aggregated results
- Although data is held locally, this approach still requires different sites to agree on mapping of local types and potential values of data to the standard values and formats
- Record linkage to data is more difficult
- It may be difficult or impossible to replicate analyses, since they are conducted at the local level

B. What are the considerations for choosing a common data model?

- Pooled PRO data have little value if there is not a consistent data model and meta-data
- Considerations when selecting or creating a common data model include:
  - Granularity of data and whether person-level analyses are supported
  - De-identification and other limitations of data sets, including bins or categories of data rather than specific values (e.g. age range rather than date of birth)
  - Data specificity (e.g. how de-identification was handled with respect to dates)
  - Clinical domain(s) in the data model
  - Governance of the data model
  - Model use of standard interoperability references

C. What are some examples of data models to choose from?

- There are hundreds of data models to consider
- Here are examples of several popular options
  - PCORnet: Developed by the Patient-Centered Outcomes Research Institute (PCORI). Describes meaning of each data item, and in some instances the context of the collected data
  - Consolidated Clinical Document Architecture (CCDA): A general-purpose XML-based clinical data interchange format. It is commonly available in electronic health records that are certified by the Office of the National Coordinator – Authorized Testing and Certification Body. It is often used to move data from one system to another when the two systems have different internal data models
  - i2b2 – Shared Health Research Informatics Network (SHRINE): An open-source, XML-based network that allows groups to link their aggregated counts of patients meeting selected inclusion and exclusion criteria for demographics and other variables
  - Project-specific ad hoc data models: As opposed to choosing from an existing data model, a new data model can be created that includes only the data required for a specific project

RELEVANT PRIMARY RESOURCES

The information presented here is an overview of pooling and exchanging data. For more detailed information please see the following sources:

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

16 CONSIDERING THE ETHICAL AND LEGAL ISSUES

KEY POINTS

- *Equitable and inclusive patient-reported outcome (PRO) system development and implementation is vital to ensuring the utility of PRO measures (PROMs) for diverse patient populations*

- *PRO data has the potential to be used for multiple purposes. Having appropriate disclosures and consents in place are essential to ensure that this data can be ethically used*

- *Liability concerns, especially regarding how providers respond to PROM alerts, should be considered when designing PRO systems*

OVERVIEW

The routine collection of PROs, particularly when they are well-documented and integrated into electronic health records, presents opportunities to use the data for multiple purposes and to be accessed by an increasing number of people. As a result, the best ways to disclose PRO activities, consent patients, and minimize sources of liability need to be considered.

When collecting PROMs from patients for use in clinical care, health systems can provide no disclosure at all about the purpose of PROM data collection, though this approach limits the ability to store and re-use this data and may not be compliant with existing regulations. Alternatively, patients can be provided with general or specific disclosure information. These disclosures may also be accompanied by opportunities to opt-in or opt-out of completing PROMs and/or including them in other databases. When considering data re-use or data use for multiple purposes, patients can be offered no consent at all, provided with a general disclosure about data re-use, or asked to formally consent to have their data re-used.

Liability considerations regarding the use of PROMs should be reviewed by legal experts, including those with experience in data privacy and security, research regulations, reportable events, and informed consent. Concerns regarding how providers respond to PROM alerts are among the most complicated to address.

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

Brief specific disclosure
- All patients in the healthcare system are informed that PROMs will be collected and used in specifics ways (e.g. it will be used by their clinical care team to understand their health)
- Health systems can only use the PROM information for the informed purpose, unless it is also included in the consent that they can be used for other purposes without re-consent
- This option may be more respectful of individual decision-making, and is likely to be more consistent with many types of data uses

Robust specific disclosure with opt-in
- Patients are informed that PROMs will be collected and used in specific ways and are provided with information consistent with the Common Rule and other human research regulations regarding informed consent
- Individuals must indicate their willingness to participate and have their data used for explicit purposes
- Having this consent may increase the amount of time to complete the survey
- This option may be the most respectful of individual's abilities to make decisions about how their data is used

C. What consent options can be considered when using PROM data for multiple purposes?

No consent for data re-use
- Data would be re-used without additional notification/authorization
- This approach is easy to integrate into the system, but limits opportunities for data re-use given that patients have not consented for re-use

General disclosures about data re-use
- Patients would be informed that the system uses PRO data stored in electronic health records for multiple uses
- Patients may lack a full understanding of this re-use
- Some may choose to opt-out due to lack of specificity about re-use

Specific disclosure and authorization (opt-in) for data re-use
- Patients would be informed about specific activities associated with the re-use of their data, including any possible risk/benefits, and asked to consent to this re-use
- Patients would have a greater understanding of the purpose of data re-use, but this option may be more difficult to integrate into clinical settings

D. What are some liability considerations related to the use of PROMs?

- Liability considerations should be reviewed by legal experts, including those with experience in data privacy and security, research regulations, reportable events, and informed consent
- As applies to all issues of consent, appropriate procedures are required to obtain consent from patients who are unable to provide consent for themselves due to cognitive limitations or other reasons, and to obtain assent from minors old enough to provide it
- Liability concerns regarding responses to PROM alert systems are particularly complicated. Questions in this area to consider for potential liability include:
    - Is there a point at which a provider is obligated to respond to an alert?
    - How imminent and likely is the potential harm from the alert?
    - Is the provider or system positioned to respond to an alert?
    - What constitutes a reasonable response to an alert? Does this vary situationally?
    - How can responses to the alert be best documented?

RELEVANT PRIMARY RESOURCES

The information presented here is an overview for considering ethical and legal issues. For more detailed information please see the following sources:

- Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

A1

APPENDIX 1:
ADVISORY COMMITTEE

Nicola Anderson, PhD, MSc

Dr. Nicola Anderson is a Research Fellow and Lead Research Nurse, working in the field of clinical research since 2003. After completing a law degree (University of Cambridge, 1992) and then training as a Nurse, she completed an MSc in Healthcare Law and Ethics. Based at the Centre for Patient Reported Outcomes Research (CPROR) at the University of Birmingham in the UK, her PhD explored the use and implementation of Patient Reported Outcome Measures (PROMs) in the management of patients with end stage kidney disease requiring treatment with haemodialysis and her research currently focuses on the exploration of how PROMs might support person-driven integrated care across health and social care settings. Nicola works concurrently as Lead Research Nurse for Research Education at University Hospitals Birmingham NHS Foundation Trust.

Judy Baumhauer, MD

Dr. Baumhauer is a tenured Professor and serves as the Senior Associate Dean for Academic Affairs at the University of Rochester School of Medicine and Dentistry. She is a clinically active orthopaedic surgeon and the Director of the Clinical Health Informatics Core for the UR Healthcare System. Dr. Baumhauer is the past president of the ABOS, AOFAS, EOA and PROMIS Health Organization. Her research focuses on patient reported outcomes (PROs) in clinical decision-making. She has studied how collecting and sharing PROs affect patient engagement, patient satisfaction and clinical efficiency.

Michael Brundage, MD, MSc

Michael Brundage, MD MSC FRCP(C) is a Professor of Oncology and of Public Health Sciences at Queen's University in Canada. His research focuses on patient-reported outcomes both in clinical practice and in clinical trials, and on quality of cancer care. He has enjoyed the privilege of working with many organizations including the International Society for Quality of Life Research, the Canadian Cancer Trials Group, and Cancer Quality Council of Ontario. He is the Past-President of the Canadian Association of Radiation Oncology, and former director of Cancer Care and Epidemiology at Queen's. He is co-PI for the PROTEUS Consortium (with the PI Dr. Claire Snyder) which promotes resources to improve the quality of PROs in clinical practice and clinical trials internationally.

Melanie Calvert, PhD

Professor Melanie Calvert, PhD, is Professor of Outcomes Methodology at the University of Birmingham UK. Professor Calvert is Director of Birmingham Health Partners Centre for Regulatory Science and Innovation and Centre for Patient Reported Outcomes Research. She leads PROs research within National Institute for Health and Care Research (NIHR) infrastructure, is a member of the National Research Ethics Advisory Panel and a NIHR Senior Investigator. With international collaborators she led development of international PRO guidance, including the SPIRIT-PRO extension, CONSORT-PRO extension, PRO Ethics Guidelines and is a member of the SISAQOL-IMI initiative and PROTEUS Consortium. Recent work includes publications on inclusive and equitable PRO data collection, use of PROs in AI studies and real-world evidence generation. Her work has informed clinical guidelines, NICE, FDA and EMA guidance and Government policy.

Norah Crossnohere, PhD

Norah L Crossnohere is a patient-centered outcome researcher and Assistant Professor of Internal Medicine at The Ohio State University College of Medicine. She is passionate about measuring what matters most to patients and their loved ones. Dr. Crossnohere's research areas include advancing methods for measuring patient and caregiver preferences and experiences and engaging patients to inform medical decision making.

Rebecca Esparza

Rebecca Esparza is a two-time cancer survivor from Corpus Christi, Texas. She is a 22-year survivor of germ cell ovarian cancer and a 15-year survivor of papillary thyroid cancer. Since her remission from ovarian cancer in 2002, she has dedicated her life to cancer advocacy issues, working with a variety of cancer advocacy organizations. Rebecca has represented cancer patients on Capitol Hill over 40 times since 2003, encouraging her elected officials to make cancer issues a national priority.

Christopher Gibbons, PhD

Chris Gibbons is an Associate Professor and Chief of Section of Patient Centered Analytics at the MD Anderson Center. He conducts research to improve the lives of cancer patients by combining patient-reported data with psychometrics, user-centered design, machine learning and big data.

Dr. Gibbons' work focuses on both assessing the impact of interventions which seek to improve processes and outcomes of care using patient-reported assessment measures as well as more fundamental research to develop new assessment methods and modalities to enhance patient care. The latter involves the application of computer adaptive testing, tailored feedback, and machine learning algorithms to improve the accuracy, feasibility, and effectiveness of patient-reported assessments to improve clinical research and care.

Sandi Gulbransen

Sandi Gulbransen is the Chief Quality Officer for University of Utah Health. Sandi currently leads system-wide efforts focused on delivering high value clinical care to our patients and community. She and her teams provide strategy and support to align value work with national quality programs and benchmarks. Throughout her career, Sandi has applied engineering principles to design and implementation of process improvements leading to reliable, consistent and sustained improvements in outcomes, efficiency and productivity. Sandi holds a Master of Science in Biomedical Informatics from University of Utah School of Medicine, a Bachelor of Science in Industrial Engineering from University of Houston.
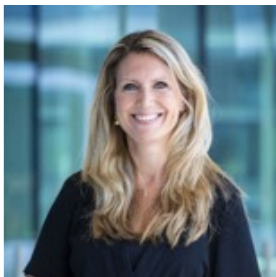
Lotte Haverman, PhD

Dr. Lotte Haverman is a psychologist by training and currently holds a position as head of 'pediatric psychology & PROMs' research group, Emma Children's Hospital. In 2007, she founded the KLIK PROM portal, implemented in over 40 hospitals in the Netherlands. To integrate implementation science in clinical care, she initiated the PROM expertise, which she leads as a director. She secured several grants to support research regarding PROM implementation with focus on patient participation and recently on health inequity. She is engaged in different international collaborations to advance PROM use in healthcare.
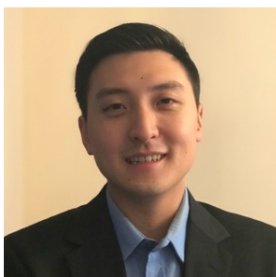
Yuchen Li, MD

Dr. Yuchen Li is a medical oncology resident at Juravinski Cancer Centre, Hamilton, Canada. He received his medical degree and completed internal medicine residency training at University of Toronto. Additionally, he is completing a Master of Public Health at Johns Hopkins Bloomberg School of Public Health. He has research interests in lung cancer and in quality improvement and healthcare policy initiatives.

Carolyn Petersen, MS, MBI, FAMIA

Carolyn Petersen is Assistant Professor of Biomedical Informatics at Mayo Clinic. She has masters degrees in biomedical informatics and in exercise and movement science, and is an American College of Sports Medicine-certified exercise physiologist. Ms. Petersen is a past co-chair of the ONC Health Information Technology Advisory Committee, a former consumer representative on FDA medical device advisory panels, and a former member of PCORI's Advisory Panel on Healthcare Delivery and Disparities. She is a member of the American Medical Informatics Association's Ethics Committee, a pastchair of AMIA's Ethical, Legal, and Social Issues Working Group, and a cancer survivor.

Ameeta Retzer

Ameeta Retzar is a research fellow at the Centre for Patient Reported Outcomes Research and the National Institute for Health and Care Research Applied Research Collaboration West Midlands. Ameeta's research interests include the equitable application and administration of patient-reported outcomes in clinical trial and routine practice.

Claire Snyder, PhD

Claire Snyder, PhD, is Professor of Medicine, Oncology, and Health Policy & Management at the Johns Hopkins Schools of Medicine and Public Health. She is Director of the Johns Hopkins Program for Building Lifestyle, Outcomes, and Care Services Research in Cancer (BLOCS). Dr. Snyder's research focuses on the quality of cancer care. Along with Dr. Michael Brundage, Dr. Snyder leads the PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders). She is a past president of the International Society for Quality of Life Research. Previously, Dr. Snyder worked at the U.S. National Cancer Institute and edited *Outcomes Assessment in Cancer: Measures, Methods, and Applications* (Cambridge University Press).

Angela Stover, PhD

Dr. Angela Stover is an Assistant Professor in the Department of Health Policy and Management at UNC Chapel Hill. Her research on PROs has spanned 20 years, including developing PROs and helping clinics implement PROs. Dr. Stover is one of the original developers of six of the NIH PROMIS scales. She is also trained in implementation science.

Elissa Thorner, MSPH

Elissa Thorner was a two-time breast cancer survivor by the age of 25 who became an advocate for patients living with cancer speaking out about their barriers and challenges including survivorship care, patient/caregiver/provider communication, improvements in quality and outcomes of care, and technology as a communication tool. She has an undergraduate degree from Georgetown University in Women's Health and a graduate degree from the Johns Hopkins School of Public Health in Health Education and Communication. Ms. Thorner previously oversaw breast cancer communication, education, and survivorship at the Johns Hopkins Kimmel Cancer Center where she co-directed the Young Women with Breast Cancer Program and now works as a healthcare consultant in cancer care.

Garrett Ursin

Garrett Ursin is a Software Developer at Epic. He specializes in PROM implementation, as well as visualizations of PROs for clinicians and patients.

Galina Velikova, MD

Professor Galina Velikova is an academic Medical Oncologist at the University of Leeds and Leeds Teaching Hospitals, UK with over 20 years' experience of patient-centred research using electronic Patient-Reported Outcome Measures and in leading collaborative research. She is on the Steering Committee for NHS England's national quality-of-life metric project for cancer survivors and is past Chair and elected board member of the European Organisation for Research and Treatment of Cancer Quality of Life Group; past President of the International Society for Quality of Life Research and is Chair of the National Cancer Research Institute Living with and Beyond Cancer Group.

Elliott Sparkman Walker

Elliott Sparkman Walker is The PROTEUS Consortium's communications consultant. She is a Director at SCP, a socially responsible communications and public relations agency that provides full-service communications and strategic planning services to nonprofit organizations, foundations, and government agencies. Her practice includes messaging, communications, and digital strategy and execution; writing and materials development; website management; and video production. A former journalist, Elliott was a longtime producer for NBC News TODAY, covering national politics and news. She has a B.A. in Music from Harvard College.

A2   APPENDIX 2: ADDITIONAL RELEVANT RESOURCES

The PROTEUS-Practice Guide draws primarily from the foundational resources noted in each chapter. For further reading, here is a selection of other relevant references.

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A Resource from the

PROTEUS

CONSORTIUM

The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice:
A Synthesis of Resources.

Prepared by Crossnohere N, Brundage M, Snyder C, and the Advisory Group, 2023.
Available at: www.TheProteusConsortium.org.