



**ePROs** (Electronic Patient-Reported Outcomes)

# ePROs in Clinical Care

Guidelines and tools for  
health systems

/ **GOVERNANCE**

/ **INTEGRATION**

/ **REPORTING**





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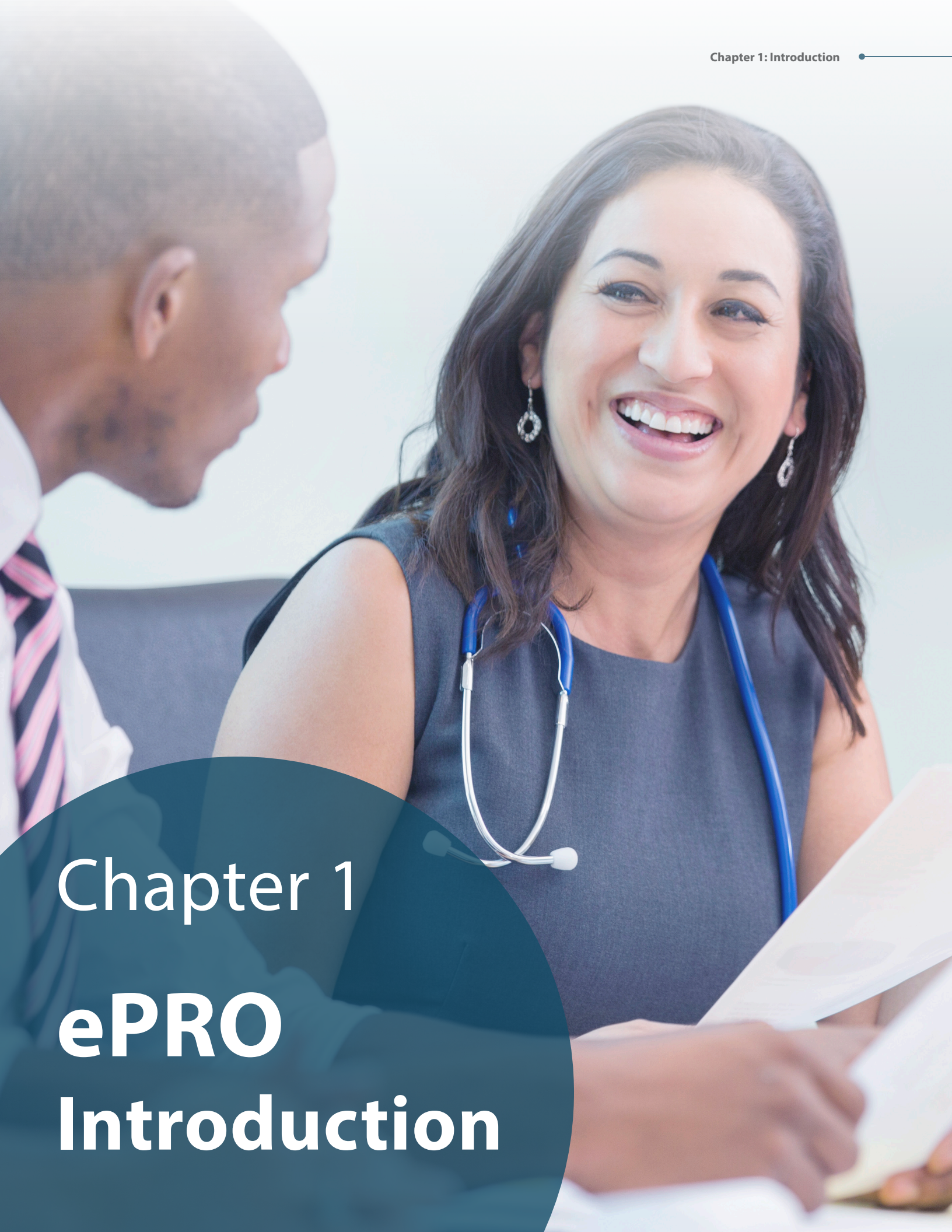
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# Chapter 1

# ePRO

# Introduction

## Chapter 1: Introduction

# Getting Started



### Learning Objectives

- The drivers of PROM and ePRO use in clinical care
- Common ways PROMs are used in clinical practice
- The methods behind the recommendations in this toolkit

The overall purpose of this toolkit is to help healthcare systems successfully govern and integrate electronic patient-reported outcomes (ePROs) into clinical care. The toolkit is designed to help healthcare systems with the many tasks surrounding ePRO implementation. This toolkit will help readers to:

- formulate strategies for user engagement in the governance of ePRO use across healthcare delivery systems
- identify important elements of ePRO tool design, data flow, and workflow to support ePRO use across health system stakeholders
- recognize potential pitfalls and strategies for integrating ePROs into clinical practice
- design ePRO reporting tools that meet the needs of health systems and end-users.

This toolkit has been developed based on our team's experience in the study and application of ePRO tools across multiple settings. The guidelines were developed iteratively and integrate evidence, findings from the literature, prospective data collection, and direct health system implementation experience, along with expert opinion from stakeholders who have a known interest or experience in ePRO implementation for clinical care. For a detailed description of the methods, please refer to the Background and Methods section below.

## Who should use this toolkit

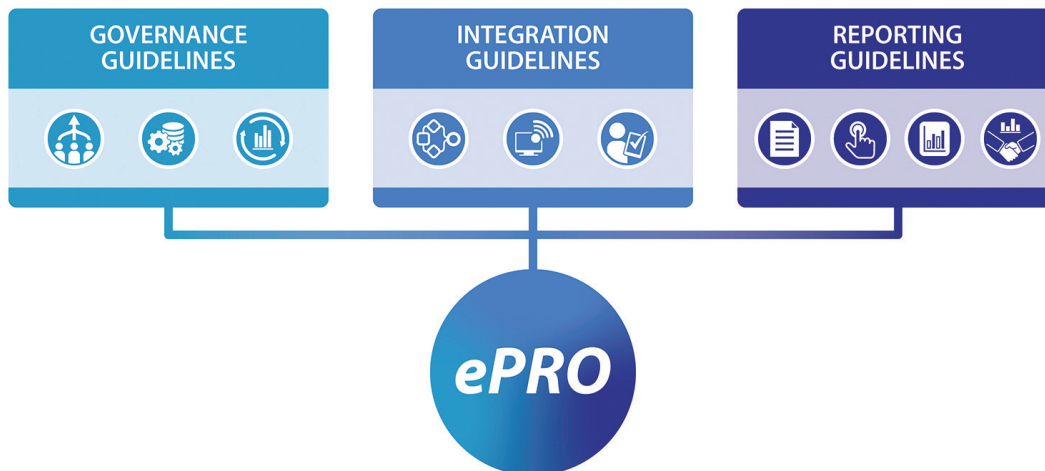
The target audience for this toolkit encompasses health system stakeholders who are considering initiating or expanding ePROs for care delivery across the health system. This may include administrators, governance committee members, clinicians and other care team members, information technology (IT) and informatics professionals, patient advocates, and software designers and developers. This toolkit may also be relevant for health system professionals involved in marketing, patient experience, and change management.

This toolkit is not targeted toward the actual development of new ePRO software or patient-reported outcome measures, or toward formal research on ePRO use, although there may be content relevant to readers interested in these topics.

## How to use this guide

While this toolkit reflects our experiences developing and applying ePRO tools across a large health system, we recognize that every healthcare system and site is different. Rather than provide a prescription for how to implement ePROs, we present what we have learned from experience as guidelines for other healthcare systems engaged in similar work. The guidelines are organized around three core topic areas: ePRO Governance, ePRO Integration, and ePRO Reporting (see **Figure 1A**).

**Figure 1A** Core content areas reflected in this toolkit



Chapters 2-4 will provide recommendations for ePRO Governance, Integration, and Reporting respectively, Chapter 5 (Future Directions and Resources) provides recommended resources and tools for further exploration. For users interested in understanding the big picture, we recommend reading through the toolkit in its entirety before beginning ePRO integration. Once the process has begun in earnest, users may wish to refer back to individual chapters. While we have organized the guidelines as progressive chapters, many aspects will need to be considered continuously or concurrently.

## A note on language

There are many topic-specific terms and acronyms throughout this toolkit. An **Abbreviation** list is available in Chapter 5 (Future Directions and Resources) to define acronyms or terms that may be unfamiliar. We recognize that parallel terms may exist for a common concept, such as the use of “electronic medical record” and “electronic health record,” and readers may have different preferences for terminology based on their background and fields. The focus of this toolkit is supporting ePRO implementation, and thus we use this term throughout when references PROs in the context of clinical care. Where warranted, we use the term PROMs when referencing measurement; however, we use this term sparingly to support ease of readability.

# Background and Methods

## What is a patient-reported outcome measure (PROM)?

Patient-reported outcome measures (PROMs) are questionnaires that allow patients to directly report their experience with disease symptoms or well-being, without modification by a healthcare team member. PROMs can provide clinically meaningful and patient-centered insight into screening, diagnosis, and response to treatment.

PROMs are particularly relevant when assessing health issues for which the patient is the best source of information. For example, a measure of forced air volume is necessary to diagnose certain lung conditions; however, this physiologic measure does not provide information about whether patients can perform the physical activities they enjoy (e.g., jogging).

PROMs are standardized assessments of patient experience with symptoms, often measured repeatedly over time, to evaluate the impact of treatments or progression of disease. PROMs are, therefore, developed through iterative psychometric and clinical content review and validated among target patient populations to evaluate their psychometric properties before use.

PROMs cover a variety of clinical domains, including physical function, mental and emotional health, social functioning, and health-related quality of life (HRQoL). This data can provide critical insight into the overall well-being of individuals and their response to treatment. It is also important to note that PROMs are distinct from other types of patient-reported health data (e.g., past medical conditions or family health history) or from patient-generated health data (e.g., tracking physical activity or number of hours slept per day).

## The growth of PROMs in healthcare delivery

Originally developed to support clinical research, PROMs provide teams with three primary advantages (*ISOQOL, 2015; Snyder et al, 2017; Wu et al, 2013*):

- better standardized assessments of patient symptom experiences
- remote monitoring and tracking of patient health status, minimizing the burden for in-person clinical evaluation
- assessment of patient-centered outcomes and quality of life.

As the breadth of validated PROM measures continues to expand, a variety of stakeholders—including patients, providers, healthcare administrators, population health teams, and payers—are increasingly interested in utilizing PROMs as part of routine clinical data gathered to inform care delivery. Beyond point of care use, federal and local policies are also incentivizing the use of PROMs to support value-based models of care delivery and quality monitoring (*Person and Family Engagement Strategy [CMS] nd; Promoting Interoperability Programs [CMS] nd; Patient-Reported Outcomes [NQF] nd; Freel et al, 2018; Basch, 2017*)

PROM data enables patients and providers to understand multiple dimensions of health and role functioning (*Lavallee et al, 2016*). Even further, advancements in health IT have driven the electronic capture of PROMs, or ePROs, in clinical care (see **Figure 1B**) with the goal of:

- improving the efficiency and quality of patient data
- improving care quality and delivery
- managing population health outcomes

With the continued rise of ePRO use in clinical care, there is a need for sharing best practices around how ePROs are governed, integrated into clinical care, and able to facilitate diverse reporting and decision-making needs (*Austin et al, 2019*).

**Figure 1B**

Drivers of ePRO use for clinical care by stakeholder group

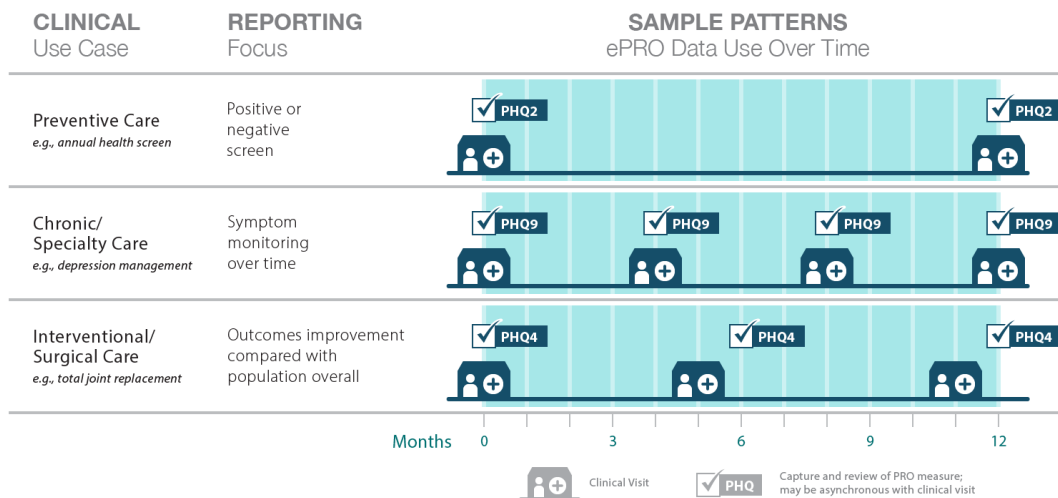


## Organizing ePRO measurement for care delivery

ePROs may support a multitude of patient-care goals, including screening and needs assessment, diagnosis, symptom monitoring, shared decision-making, and outcomes assessment (individual or population-level). The goals for ePRO use will be dependent on each healthcare setting's context, and there may be multiple goals to consider.

**Figure 1C** outlines three common use cases that characterize the patterns for ePRO use in preventive care, chronic/specialty care, and interventional/surgical care. These use cases provide a framework for the development of an ePRO measure selection strategy and associated governance structures within a health system. (Please refer to *Austin et al, 2020* for more detailed descriptions of common use cases for ePRO use in clinical care).

**Figure 1C** Common use cases for ePROs in clinical care



ePROs that are used in multiple settings across the healthcare system may need additional governance support and standardization to avoid duplication and the creation of an unnecessary burden for patients and care teams. Health systems may be well served by organizing ePROs into categories that reflect how they will be implemented across the system to meet goals for clinical care, specifically:

- **Generic measures:** These are measures that apply to any patient population, such as assessing quality of life or physical function. A generic ePRO may be implemented system-wide and will have multiple use cases (and therefore dependencies or constraints) for how it is used in clinical practice.
- **Condition-specific measures:** These measures apply to a specific patient population (i.e., one with a defined clinical condition), such as assessing symptoms for multiple sclerosis or low back pain. A condition-specific ePRO may be implemented in a narrower scope, for example, within a single clinic or department.

Lastly, it is important to note that health systems are increasingly leveraging ePRO data to support broader functions, such as population health, quality improvement, care quality assessments, contractual reporting, and research. The perspectives of patients, health system

administrators, and payers are therefore important to understand. While many of these perspectives will be reflected in this toolkit, our primary focus will be how ePROs are used to directly support patient care from the perspective of the health system.

A health system's selection of ePRO measures will depend on context for use and should continuously be informed by the growing body of evidence for how ePROs inform patient-centered care and care quality. While this guide does not directly recommend any specific ePRO measures, we do note topics for health systems to consider when thinking about their measure selection strategy across the enterprise.

## Innovation, technology, and continuous learning

As the use of ePROs in clinical practice has evolved, so has the technology available to support ePRO data collection and review. A variety of third-party apps, web-based platforms, and electronic health record (EHR) functionality have emerged, promoting new modalities for engaging users in ePRO data collection and review and identifying significant challenges related to workflow and interoperability. One example includes efforts by EPIC and Cerner, the two largest US-based EHR vendors, to work with the Patient-Reported Outcome Measurement Information System (PROMIS), which supports ePRO measurement across a range of important health domains. Increasingly, PROMIS measures are included in existing EHR questionnaire sets to support the expanded use of these measures in clinical care (see Chapter 5, Recommended Resources, “**Technical Implementation Guides**” for more information on EASI-PRO implementation) (*Patient-Reported Outcomes Measurement Information System [NIH] no date (nd)*; *Seamless integration of patient-reported outcome measures in electronic health records [EASIPRO] nd*).

The **Technical Primer for ePRO Integration** included in this chapter provides additional background on how health systems should think about integrating ePRO technologies into clinical settings. The integration of ePROs into clinical practice will illuminate many sociotechnical complexities, including the innovative use of technology, changes to workflow and patient-provider decision-making processes, and downstream impacts on healthcare policies and payment.

## Toolkit methods

This toolkit was developed through work funded by the Agency for Healthcare Research and Quality (AHRQ) as part of its Digital Healthcare Research Program. The toolkit builds on over 10 years of experience at the University of Washington (UW) implementing ePROs for research, clinical care, and quality improvement. In 2015, the UW Medicine system, our team's primary setting, launched a large-scale practice transformation initiative that prioritized better capture

and use of the patient voice in clinical care. This initiative provided an environment in which to observe and learn about the processes of integrating ePROs into clinical practice.

The activities and methods that led to the development of this toolkit were grounded in action research theory (*Austin et al, 2020*) and marked by iterative, participatory forms of data collection and knowledge generation, as described in **Table 1A**. The information and recommendations made in this toolkit are meant to blend both peer-reviewed and real world evidence, providing tangible lessons that can be applied in complex healthcare environments.

In addition to the references cited throughout the toolkit, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

**Table 1A** Description of project methods for design guideline development

Phase	Goal	Sample Activities
<b>Planning</b>	Understand current evidence; engage stakeholders in inquiry & problem identification	<ul style="list-style-type: none"> <li>• Ongoing analysis of peer-reviewed literature</li> <li>• Qualitative synthesis of PRO literature (2010-2015)</li> <li>• Community-building activities</li> <li>• Development of ePRO workshops and education</li> </ul>
<b>Acting</b>	Gain real world experience with ePRO governance, integration, and reporting practices	<ul style="list-style-type: none"> <li>• Participation and leadership on ePRO governance committees</li> <li>• Involvement in ePRO project design, workflow modeling, and implementation</li> </ul>
<b>Observing</b>	Gather qualitative and quantitative data to evaluate ePRO processes and outcomes	<ul style="list-style-type: none"> <li>• Participant observation</li> <li>• Interviews / Focus groups</li> <li>• ePRO implementation data (e.g., usage metrics, outcome data, etc.)</li> </ul>
<b>Reflecting</b>	Triangulate learnings across stakeholders and contexts	<ul style="list-style-type: none"> <li>• Stakeholder engagement activities</li> <li>• National conference presentations (e.g., <i>AcademyHealth</i>, <i>American Medical Informatics Association</i>, <i>International Society for Quality of Life Research</i>)</li> <li>• Coordination of educational workshops (local, national)</li> </ul>

## Project team

This project was led by a multidisciplinary research team of experts in user-centered design, biomedical informatics, systems engineering, health services research, and national guideline development for ePRO use in clinical practice. Core project team members include are listed in **Table 1B**.

**Table 1B** Core project team member roles and expertise

Core Team Member	Project Role	Related Areas of Expertise
<b>Danielle Lavallee,</b> PharmD, PhD	Co-Principal Investigator	<ul style="list-style-type: none"> <li>• Patient-reported outcomes</li> <li>• Health information systems (adoption and use)</li> <li>• Stakeholder engagement</li> </ul>
<b>Cynthia LeRouge,</b> MS, PhD	Co-Principal Investigator	<ul style="list-style-type: none"> <li>• User-centered design</li> <li>• Biomedical informatics</li> <li>• Health information systems (adoption and use)</li> </ul>
<b>Elizabeth Austin,</b> MPH	Co-Investigator	<ul style="list-style-type: none"> <li>• Patient-reported outcomes</li> <li>• Health information systems (adoption and use)</li> <li>• Implementation research</li> </ul>
<b>Andrea Hartzler,</b> PhD	Co-Investigator	<ul style="list-style-type: none"> <li>• User-centered design</li> <li>• Biomedical informatics</li> </ul>
<b>Joseph Heim,</b> PhD	Co-Investigator	<ul style="list-style-type: none"> <li>• Systems engineering</li> <li>• Health services research</li> </ul>
<b>William Lober,</b> MD	Co-Investigator	<ul style="list-style-type: none"> <li>• Biomedical informatics</li> <li>• Health services research</li> </ul>
<b>Jenney Lee,</b> MA	Project Staff	<ul style="list-style-type: none"> <li>• Qualitative research methods</li> </ul>
<b>Savitha Sangameswaran,</b> MS	Project Staff	<ul style="list-style-type: none"> <li>• Biomedical informatics</li> </ul>
<b>Courtney Segal,</b> PhD(c)	Project Staff	<ul style="list-style-type: none"> <li>• Health services research</li> <li>• Patient-reported outcomes</li> <li>• Implementation research</li> </ul>

# ePRO Stakeholders and Settings



## What will you learn?

- The variety of healthcare settings for ePRO implementation
- Which stakeholder groups are affected by ePRO implementation
- How stakeholders can be involved in the process
- How healthcare setting might impact stakeholder engagement

ePRO implementation seeks to capture and provide data that enhances the delivery of healthcare and provides a better understanding of healthcare outcomes.

To achieve this important goal, stakeholder engagement is critical. Stakeholders include individuals who use and benefit from the data generated, as well as those directly involved in implementation. Here we provide an overview of stakeholder engagement in the governance, design, and integration of ePROs in healthcare settings.

Within this overview, we consider the variety of settings in which ePROs may be implemented and the potential roles and perspectives held by stakeholders within those settings. This chapter is intended to provide an orientation for conducting stakeholder engagement in the context of ePRO implementation, articulate the importance of stakeholder engagement, and provide guidance on how to identify which stakeholders are relevant to the setting of use.

## Healthcare settings for ePRO implementation

Healthcare settings range from single-specialty community clinics to large health systems that may include multiple hospitals and affiliated clinics covering a wide breadth of specialties (*Burns & Pauly, 2018*). In addition, settings vary by whether they are affiliated with an academic institution; are an inpatient or outpatient facility; are an integrated health system; and are a non-profit, for-profit, or government organization. Other characteristics to consider may include the population(s) served, location of the facility (e.g., urban vs. rural), the intended use of ePROs, and whether and where ePRO data is to be contributed outside the healthcare setting (e.g., for quality measures).

It is critical to understand the makeup of the setting for the ePRO implementation because the characteristics of the setting affect how the implementation is conceived and carried out. Across settings, the range of internal resources available for developing an ePRO implementation will vary; once users have identified which resources are available internally, then it can be established how to access additional external resources. People, whether internal or external to a particular setting, are an especially important resource.

## Identifying stakeholders

A stakeholder is any individual or group with either a personal or a professional interest in the topic at hand (*AHRQ, 2011*). In the context of ePRO implementation, potential stakeholders include anyone who is interested in their development, will be involved in carrying them out, or will be affected by their application.

Related to this is the task of identifying stakeholders at different levels of the organization, from leadership to direct patient care, in order to design intervention strategies that support system-wide change (*Proctor et al, 2009*).

The range of potential stakeholders who should be considered part of an ePRO implementation are presented in **Figure 1D**. As the figure illustrates, individuals in some stakeholder groups will be directly affected by the clinical application of ePRO implementation through direct interaction with ePRO systems. For example, clinic staff may encounter altered workflows around the collection and reporting of ePROs, and clinicians and patients will interact with ePRO data as a new data source to inform shared decision-making and treatment monitoring. These stakeholders should be involved at each phase of the implementation process. However, a number of stakeholder groups are critical to the success of any implementation, and it is important to consider how and when to engage individuals across all groups.

**Figure 1D** Important stakeholders for ePRO implementation



## Involving stakeholders

Seeking a range of perspectives and expertise in each phase of the implementation process helps ensure that stakeholder needs are identified and addressed. See **Figure 1E** for more information on how stakeholders can play a role in ePROS governance, integration, and reporting.

**Figure 1E** Stakeholder role relationships



It is important to consider that certain stakeholders may be especially critical to the success of ePRO implementations. This is particularly true of individuals who will be directly involved in the clinical application of ePROs (e.g., patients and providers). A successful engagement strategy should aim to solicit involvement from a wide range of stakeholders with a variety of perspectives and expertise; this will ensure that those stakeholders who will be directly involved in the use of ePROs are engaged at each step of the process.

Many methodologies exist for planning and carrying out stakeholder engagement strategies. Chapter 5's **Tools and Resources** section provides additional material for Stakeholder Engagement that will guide users in developing a stakeholder engagement strategy that suits their particular needs and goals. More information about involving stakeholders in each phase of ePRO implementation can be found in the Governance, Integration, and Reporting chapters of this toolkit.

# Technical Primer for ePRO Integration

## Advances in the field of ePRO technology



### What will you learn?

- Ways that the ePRO field is advancing
- Common approaches to ePRO integration with health system technology
- How this guide will approach technology recommendations

Traditional efforts to collect PROMs have focused on paper administration. For example, a common workflow may involve a patient receiving a clipboard at check-in with a paper PROM to complete prior to the visit. As a modality for data collection, paper has several advantages and is often easy to integrate into an existing workflow.

Yet, paper-based approaches limit the scalability and sustainability of PROMs. Most notably, paper-based approaches limit the ability to visualize PROM data and the capacity to engage with patients outside the healthcare setting, such as for pre-visit planning or remote monitoring.

As a result, recent years have seen significant advancements in the technology available to support ePRO use in the healthcare setting. EHR vendors have improved patient portal functionality and data reporting tools in an effort to adapt to the needs of ePRO users. A multitude of third party apps and web-based platforms have emerged, often offering sophisticated functionality that is rooted in user-centered design.

SMART on FHIR and other API-based (application programming interface, used for exchanging data across technical platforms) functionalities have advanced the potential of technology platforms like EHRs and third party apps to integrate, share data, and operate in tandem during clinical workflow. These technologies present opportunities to advance not only ePRO data collection, but also the manner in which healthcare teams engage with patients about their health, thus facilitating greater inclusion of the patient voice in clinical decision-making. It is important to acknowledge, though, that these tools are continuing to evolve. While health systems may be moving toward ePRO administration, paper-based approaches will likely remain a necessary tool for clinical teams to ensure complete data collection.

Beyond technology used within the healthcare setting, there has also been an increase in the availability of consumer-driven and mobile health (mHealth) technologies that allow patients to track a variety of health symptoms and wellness activities. These tools can empower patients to take a more active role in the self-management of their health and may provide meaningful data to better inform healthcare teams about a patient's health status.

With the continued development of consumer-driven technologies, we can expect to see extensive change as health systems work to understand the role of these tools and how to better engage with patients.

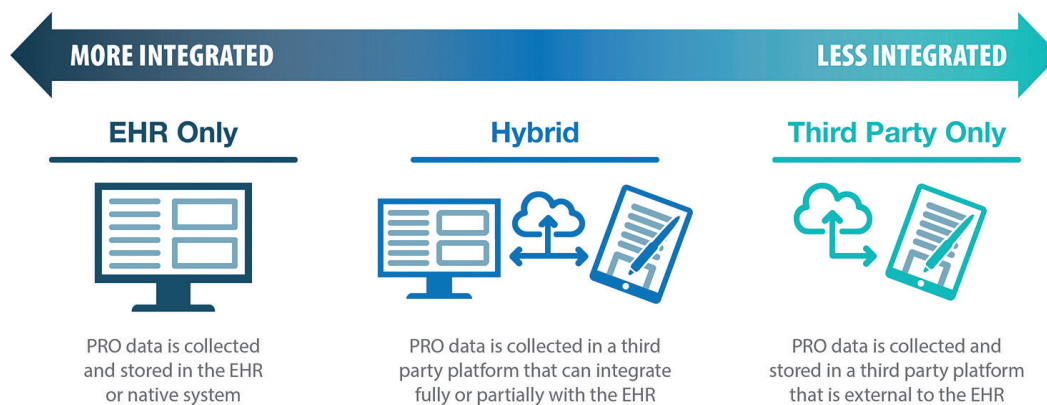
## ePRO integration approaches

There are many approaches to using technology for ePRO data collection and application, and there is often no 'one size fits all' solution (*Hsiao et al, 2019; Segal et al, 2013; Snyder et al, 2017*). Each health system will need to select the ePRO integration approach that best aligns with their goals, resources, and existing environment, and that approach may evolve over time. The goal of this toolkit is to provide information that can guide healthcare organizations in selecting the best strategy for their system.

However, at a high level, there are three fundamental approaches that can be considered: EHR only, third party only, and a hybrid of EHR and third party tools (see **Figure 1F**).

**Figure 1F**

Fundamental approaches to ePRO technical integration



- **In the EHR only model**, the EHR is the only tool used to facilitate ePRO data collection and reporting. This approach may allow for a more seamless experience for users, but EHR tools may have limitations in functionality or customizability.

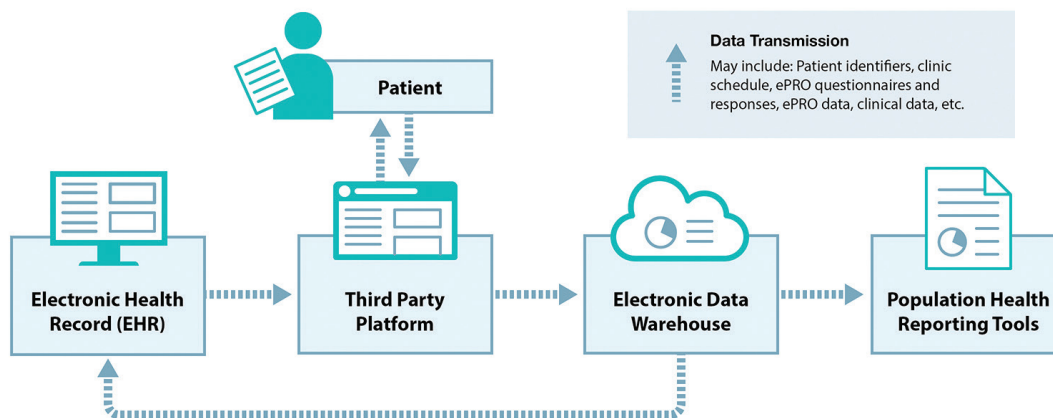
- **In the third party only approach,** ePRO data collection and reporting occur through an app or web platform that is external to the EHR. Third party apps may be more nimble to launch and customize; however, collecting data outside the EHR may potentially present barriers to uptake and workflow, particularly for ePRO reporting.
- **In the hybrid approach,** both the EHR and a third-party tool are used with some degree of integration. Full integration will allow data to flow back and forth between the tools, whereas for partial integration, data may only flow one way or may be limited in scope. This approach can capitalize on the flexibility of third-party tools while still maintaining a footprint in the EHR workflow and documentation; however, it may raise additional data security or interoperability challenges.

The capabilities of ePRO technologies vary widely, and certain technologies may better meet the needs of different care settings, users, or existing technology environments.

For example, the use of third-party platforms may allow each local practice within a health-care organization to easily tailor the ePRO content and cadence to their local workflows. For one healthcare organization, this may be seen as a benefit, as it minimizes the burden on the centralized IT resources needed to support, adjust, and maintain ePRO tools. To another organization, however, this approach may undermine efforts to standardize and maximize use of the native EHR.

When determining which approach to use, one of the most important considerations is how ePRO data will need to flow between platforms in order to support ePRO data review at the point of care and by other stakeholders. **Figure 1G** gives an example of data flow considerations for the collection, storage, and display of ePRO data when using a hybrid approach.

**Figure 1G** Example of data flow processes for hybrid approach to ePRO integration



In response to the growth of ePRO tools, agencies such as PCORI, Health Level 7 International (HL7), the Office of the National Coordinator (ONC), and AHRQ have partnered on several initiatives to facilitate the implementation of ePROs in clinical workflow.

The PCORI's Users' Guide to Incorporating Patient-Reported Outcomes into Electronic Health Records (*Snyder et al, 2017*) provides thoughtful framing questions to assist healthcare settings in assessing potential ePRO platforms. The HL7 PRO FHIR Implementation Guide (FHIR Overview [HL7 FHIR] nd) provides direction and technical specifications for the capture and exchange of ePRO data using FHIR standards. As part of this effort, HL7 and ONC established preliminary structured data standards that allow the same ePRO variable to be captured and shared across multiple platforms (EHRs, apps, etc.). Please see **Technical Implementation Guides** in Chapter 5's Tools and Resources section for more information.

In comparison with those guides, our toolkit will focus on key considerations for how technology will impact the use of ePROs in practice, including:

- the need for multiple data collection modalities
- customization of ePRO content or functionality for ePRO reporting
- alignment with clinical workflow
- the preferred location for data storage and reporting tools (i.e., within the EHR, data warehouse, or external tool)
- the healthcare organization's available resources and approach to technology management

As healthcare organizations begin to understand their current capabilities and evaluate potential technology platforms of choice, it will be critical to first consider the needs of users (e.g., patients, care teams) and then select the technology that best aligns with the desired care delivery experience.

## Changing how healthcare works with IT

The rise of EHRs and other health IT has led healthcare organizations to think differently about the role IT plays in supporting and advancing care delivery. Many healthcare teams are looking to expand the role of IT in improving workflow and care delivery design, which requires new expertise inclusive of such disciplines as clinical informatics and user-centered design.

In light of the recommendations from the Stakeholder and Settings section above, we encourage readers of this guide to think holistically about how IT and informatics professionals can support ePRO efforts and the roles they should play throughout the planning, design, deployment, and evaluation of ePRO tools.

## A note on how technology is discussed in this toolkit

The use of technology to support ePROs will be referenced throughout this toolkit.

- In the **Governance chapter**, Guidelines 1-5 will touch on how health systems can evaluate the technical capabilities of different ePRO technologies and determine the technology platform that will best align with user needs.
- In the **Integration chapter**, Guidelines 6-10 will describe the intersection and interdependencies between ePRO technology and clinical workflow.
- In the **Reporting chapter**, Guidelines 11-24 will provide detailed insight on how to leverage technology to support ePRO reporting.

It is important to acknowledge that technology changes rapidly and that each health setting will use technology differently. Therefore, the recommendations in this toolkit are meant to remain agnostic to any particular ePRO technology platform. When relevant, the toolkit may provide examples that refer to a specific technology approach; however, the goal of the toolkit is to provide readers with key learnings and tools that can guide their use of any ePRO technology.



## Chapter 2

# ePRO Governance

## Chapter 2: ePRO Governance

# Key Concepts and Background



### Learning Objectives

- Discuss ePRO implementation from a health system's perspective
- Define governance for ePROs at the health system level
- Discuss facilitators and barriers for governing ePROs



### Use this chapter if you are

- Leading system-wide ePRO implementation
- Creating oversight of ePROs and promoting governance around the use of IT tools
- Evaluating ePRO implementation and use in health systems



### Key Concepts



**Alignment**



**Infrastructure**



**Continuous Learning**

Health organizations often rely on governance strategies (see **Defining ePRO governance** box) to manage and formalize policies for the adoption and use of institutional resources. Establishing a structure for governing the electronic capture of patient-reported outcomes (ePROs) supports the needs of multiple stakeholders to design, implement, evaluate, and ultimately sustain ePRO measurement across the health system.

Some best practices exist for governance of information technology (IT) resources in health systems (AHIMA, 2017), as well as for the security and coordination of data infrastructure for single or multi-institutional medical research (McGraw & Leiter, 2013). However, little guidance is available to support the implementation of ePROs (as well as the implementation of broader digital patient-generated health data [PGHD]) across a health system.

### Defining ePRO governance

Governance is the strategic process and structure whereby responsibilities of ePRO implementations are conceptualized and carried out. Governance activities are commonly overseen by a decision-making committee, with the involvement of multi-disciplinary workgroups that participate in the development and pilot of new ePRO resources as needed.

The purpose of this chapter is to convey the priority governance principles and activities that health systems can adopt to effectively plan for and manage both the technical and human factors of ePRO implementation.

## Why ePRO governance?

An organization may decide to establish (or expand on existing) ePRO governance when there is an increasing demand for health IT resources across different stakeholder groups and clinical settings that would benefit from oversight and policies. Institutional resources (including health IT) require standards to scale efficiently across a health system, as the potential exists for redundancy and one-off projects when multiple needs for the same data exist. Governance introduces a platform to establish infrastructure standards, leverage implementation best practices, and engage stakeholders in decision-making processes.

## What does ePRO governance include?

Governance can follow different models (e.g., a single steering committee or multiple bodies) and serve different purposes in various contexts (e.g., selection of PROMs to develop into ePRO tools) (Biber et al, 2018; Gerhardt et al, 2018; Papuga et al, 2017). Thus, what a governance structure looks like and how it functions will vary across different organization types and settings. Governance structures, at the basic level, aim to provide oversight and supervision to support the management of ePRO implementations. As discussed in the guidelines that follow, at minimum, ePRO governance should include the following:

- multidisciplinary membership
- clarity on scope of work guided by standards and policies
- clarity on decision-making and oversight that fall within the governing body's remit including sponsorship by an organizational champion

## The governance guidelines: what to expect

The guidelines in this chapter are intended to support healthcare organizations develop or expand their enterprise ePRO initiatives. Governance must balance both the technical ramifications of ePRO implementations (i.e., how will IT support ePRO functionality) and the clinical consequences (i.e., how will ePROs support patient care). Therefore, the critical role of multi-disciplinary stakeholder engagement is echoed within each of the guidelines.

The first two guidelines describe the fundamental principles of goal setting and strategizing when planning for ePRO implementation, regardless of scale and purpose. The remaining three guidelines provide tangible strategies to develop and sustain governance, adhering to the principles presented in Guidelines 1 and 2 throughout the governance journey. Collectively, these guidelines are intended to be flexible in nature, acknowledging that there is no one-size-fits-all approach to governance and that health systems will be at different starting points. These guidelines offer a strategic resource to navigate core dimensions and establish effective governance throughout the ePRO implementation journey.

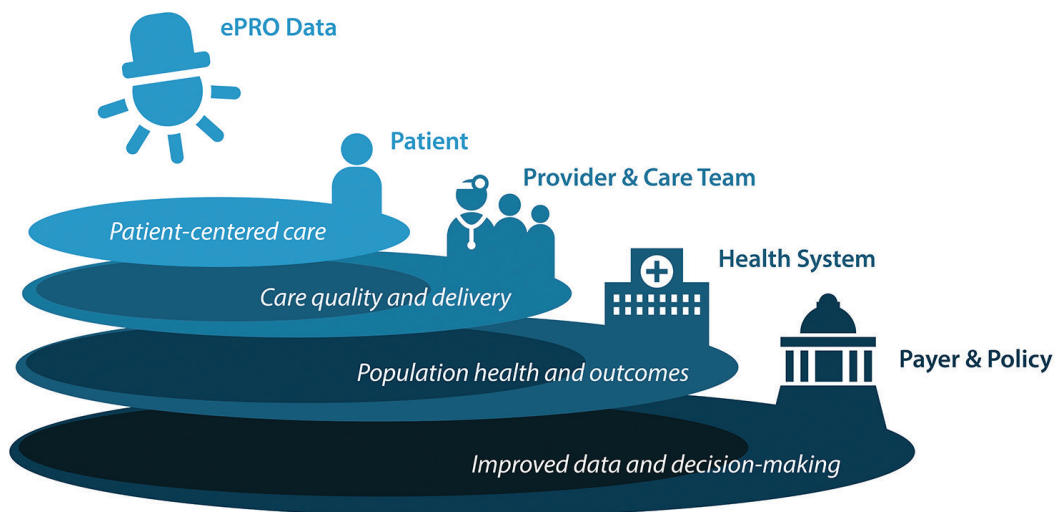
In addition to the references cited throughout the chapter, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

# ePRO Governance Guidelines

## Guideline 1. Align ePROs with health system goals

Central to ePRO initiatives is patient care. Yet the data derived for patient care may support other goals for clinical care, quality improvement, and contractual obligations. Finding opportunities to align the use of patient-reported outcome measures (PROMs) for enhancing patient care with overall health system goals (see [Figure 2A](#)) supports the efficient use of IT resources while taking into account the various competing drivers and constraints in a health system environment.

**Figure 2A** Health system goals for ePROs



At the core, ePROs should support patient care decisions, as well as illuminate other dimensions of care quality. For example, ePRO data for hip pain and function may provide the healthcare team insight on how a patient is progressing following a hip replacement. At the health system level, this same data may be reported to meet the needs of contractual obligations demonstrating performance achieved on patient-centered measures. In this context, the same measure aligns with both patient care and business operations for contractual reporting.

This priority-setting guideline aims to inform the initial stages of developing governance by identifying how to align the use of ePROs with different health system goals (for example, practice transformation or quality improvement). Key to this guideline is the involvement of stakeholders to prioritize the scope of resource and policy needs.

## STRATEGY A

### Clarify how ePROs will inform care delivery and align with health system goals

The time patients and their clinicians have together is often constrained and filled with competing priority issues. It will be difficult for clinical teams to adopt ePRO collection if the data is not relevant to the delivery of care for their patient populations or if it is unclear how ePRO scores can lead to direct and actionable benefits for patient care.

ePRO scores may be designed for different purposes (See [Table 2A](#)), including conducting a needs assessment, symptom monitoring, supporting shared-decision making, or analyzing population health initiatives. When possible, ePROs should suit a variety of stakeholder needs to economize organizational resources. Prior to navigating specific content needs, understanding common clinical goals of PROMs and the context of PROMs use serves to frame the goals of ePRO governance implementation strategies.

**Table 2A** Application of ePRO data in clinical settings

Healthcare Goal	Application of ePRO Data
<b>Needs assessment</b>	<ul style="list-style-type: none"> <li>Detect the presence and frequency of symptoms, functional impairments, and/or health risks</li> </ul>
<b>Shared decision-making</b>	<ul style="list-style-type: none"> <li>Discuss potential outcomes of a treatment or intervention based on an individual's own experiences and the experiences of similar patients</li> </ul>
<b>Symptom monitoring and management</b>	<ul style="list-style-type: none"> <li>Identify the need for new treatment or changes in treatment</li> </ul>
<b>Outcomes assessment</b>	<ul style="list-style-type: none"> <li>Determine the effectiveness of a treatment or intervention</li> </ul>
<b>Quality improvement</b>	<ul style="list-style-type: none"> <li>Evaluate quality of care among populations, conditions, and health care disciplines</li> </ul>

## STRATEGY B

### Identify stakeholders' current and future information needs for ePROs

Work conducted to understand different use cases for ePROs across the healthcare system allows for the identification of relevant ePROs to consider for adoption where cross-cutting use exists.

The initial phase in developing governance objectives and strategies entails identifying various stakeholder goals for ePRO use. The information needed to support these goals drives the selection of ePRO measures (see Guideline 3, below), configuration of data collection and reporting workflows (see Chapter 3. Integration), and presentation of results to end users (see Chapter 4. Reporting).

Direct engagement with health system stakeholders helps to define intended use of ePROs in clinical practice. A needs assessment seeks to learn about the current environment of PROM use and the desired future state for how data will inform decisions, often collating data from various sources. Consider both the types of methods that can be used to facilitate the needs assessment and the opportunities where more extensive engagement with individual stakeholders can provide insight into the nuances and complexities of using ePROs.

#### Needs assessment methods

- ✓ Interviews and focus groups to explore current and future state needs
- ✓ Surveys of information needs and gaps
- ✓ Observation of processes in practice
- ✓ Audit questionnaires already deployed in the EHR
- ✓ Review of protocol and policy documents

Clinical champions are a valuable resource to identify additional individuals or groups for participation, bringing diversity into the work of understanding end-user informational needs. The feedback gathered from champions and other stakeholders can generate 'wish lists' for specific ePROs or domains of information (e.g., depression, physical function, social function) that are important to capture. Feedback can also highlight the hurdles and technical barriers users may experience regarding successful use in practice.

This type of stakeholder input serves to advance an understanding of the settings and context of ePRO tool use, as well as any consequences—intended and unintended (e.g., burden on patients)—that may result from implementation across diverse care settings. In addition, direct engagement of stakeholders can help support buy-in for expanding the use of ePROs.

## Guideline 2. Align goals for ePRO use with IT infrastructure

Implementing ePROs can require complex functionality related to the deployment, collection, tracking, reporting, and documentation of PROMs.

Traditionally, efforts made by health systems to develop new digital tools (e.g., new electronic health record [EHR] functionality) begin with the process of gathering functional requirements that describe how the tool will be used in practice and the technical specifications necessary to support the desired functions and IT standards. As an important planning step, health systems benefit from clarifying their requirements for ePRO tools and how requirements can guide their overall strategy for ePRO projects and system maintenance.

Stakeholder input (see Chapter 1, ePRO Stakeholders and Settings section) can inform functional requirements to guide the selection and/or development of ePRO tools. Defining the functional requirements can illuminate limitations or barriers that need to be addressed for system-wide ePRO implementation.

### STRATEGY A

#### Identify ePRO functional requirements to support system-wide implementation

Each health system will need to consider technical specifications and approaches for ePROs, based on vendors used, current data infrastructure supported, and the health system's vision for how ePROs will be integrated across the system. See Chapter 3, Guideline 8 for examples of different IT approaches that could be utilized for each of the core ePRO functions. An important role for ePRO governance is helping to gather “ideal” requirements for ePROs before and during the planning phase. This supports efforts to:

- understand what the technical capability needs may be
- select implementation approaches that will support identified needs across the system
- align with resource availability

Needs assessment through stakeholder engagement (see Guideline 1) can determine preferences for the design and use of ePRO tools and develop an understanding of the capabilities and limitations of available technical approaches.

## STRATEGY B

### Specify the approach for using health IT infrastructure to support ePRO use

While health IT resources facilitate ePRO implementation, the fundamental strategy for how technology will support ePRO use may vary from one health system to another. Integration into clinical workflows may include:

- standalone applications or platforms
- PROM questionnaires incorporated in the EHR along with the patient's other health information
- a hybrid approach wherein external platforms and/or apps are used with programming to support integration into EHR workflows

#### Practice Consideration

The resources needed for ePROs may involve more than just the designated ePRO platform. Additional resources such as tablets or kiosks, strong Wi-Fi connections in waiting rooms, or even additional staff, may be needed for clinical teams to be successful.

The strategy selected (see Chapter 1, **Technical Primer for ePRO Integration** section) should be informed by health system leadership and take into account available IT resources, IT governance, and future changes in technological capabilities. Whenever possible, implementation teams should conduct feasibility testing and seek mentorship from external health systems using ePROs to support the identification of best practices.

## STRATEGY C

### Establish standards for how ePRO functionality is designed and used in practice

Health systems benefit from establishing IT standards and best practices for ePRO tool design and use (e.g., common data standards, centralized reporting tools). Once health systems have determined their system-wide approach to ePRO tools (i.e., EHR, third-party vendor, hybrid approach), there are a variety of more nuanced decisions to consider for each aspect of ePRO functionality. Over time, some key best practices may emerge that will benefit from formal dissemination (e.g., how to automate health risk screening tools in the primary care population).

Health systems may want to consider opportunities to recommend IT approaches to deploying ePROs that:

- most effectively meet the intended goals for functionality
- are the most sustainable to maintain across multiple PRO deployments
- if possible, conserve clinical, administrative, and technical resources and mitigate the burden on end-users

Establishing IT standards for ePROs may be one way to ensure learnings about best practices and recommendations are disseminated across the system. Spending time to identify sustainable project strategies and disseminating these best practices up front can greatly reduce the need for rework after ePRO tools are put into practice.

## Guideline 3. Establish an ePRO governance structure

A governance structure provides formalized oversight to ePRO implementation, including decisions related to selection, technical configuration, and application of ePROs within and across the healthcare system.

In addition, governance committees may promote stewardship of IT and data resources, support tracking and evaluation of ePRO use, and facilitate the dissemination of shared knowledge and lessons learned.

### Components of ePRO governance

- ✓ Aligns with health system needs
- ✓ Fits within the organizational committee structure
- ✓ Sponsored by organization executives (or leadership)
- ✓ Driven by organization mission
- ✓ Charged with a defined scope of work
- ✓ Includes interdisciplinary membership

## STRATEGY A

### Align ePRO governance with existing organizational and leadership structures

The need for ePRO governance emerges once it is determined that interest and need within the organization exist to address system-wide implementation. While no single model exists for ePRO governance, decision-making approaches are most effective when in alignment with the

organizational structure for existing committee work and initiatives. When possible, it is advisable to seek executive sponsorship for ePRO governance in order to stay aligned with health system priorities and to work within the context of other existing committees. Further, consider other committees that support patient engagement, IT infrastructure, and clinical operations where overlap may occur.

## STRATEGY B

### Identify interdisciplinary governance membership

Membership comprising diverse experience and expertise within the organization is an important attribute for representative and transparent governance. Membership should include individuals with direct experience implementing PROMs in clinical care as well as individuals utilizing the data for quality and contractual reporting.

Given the reliance on IT resources, developing a partnership with IT personnel and informaticists within an organization is important to support decisions regarding ePRO development and deployment. When considering membership, identify people who have the ability to move initiatives forward and take action on decisions made by the committee. [Table 2B](#) includes a list of roles and perspectives to consider for inclusion in the ePRO governance membership.

**Table 2B** Stakeholder representation to consider for ePRO governance

Stakeholder	Experience/Perspective	Role
<b>Clinical champion</b>	Committed to using ePROs for direct patient care. Experience implementing and using ePRO data in patient care.	<ul style="list-style-type: none"> <li>Supports messaging to others about the importance of ePRO data for patient care.</li> <li>Provides input on how ePRO data integrates into clinical care</li> <li>Supports the creation of policies and procedures to guide system implementation</li> <li>Provides insight on how ePRO data is tracked/ monitored over time to assess patient outcomes</li> </ul>
<b>Clinical staff</b>	Experience implementing and using ePRO data in patient care.	<ul style="list-style-type: none"> <li>Provides input on how ePRO data integrates into the clinical workflow</li> <li>Participates in creation of policies and procedures to guide system implementation</li> <li>Identifies training needs for staff</li> <li>Identifies resource needs for implementation, including training</li> <li>Provides insight about how ePRO data are tracked/ monitored over time to assess processes</li> </ul>

(Continued)

Stakeholder	Experience/Perspective	Role
<b>EHR architect</b>	Experience using IT infrastructure and data architecture to support healthcare delivery and business operations.	<ul style="list-style-type: none"> <li>Provides knowledge on EHR functionality regarding report and store abilities for ePRO data</li> <li>Provides knowledge on how non-EHR based platforms integrate with the EHR (i.e., interoperability)</li> <li>Provides inside knowledge on future developments or upgrades to existing capabilities</li> </ul>
<b>EHR analyst</b>	Experience pulling data from the EHR and/or other data warehouse(s) for clinical support and quality improvement.	<ul style="list-style-type: none"> <li>Provides knowledge on how data is queried for reporting, including strengths and limitations</li> <li>Informs the development of reporting for ePRO projects</li> </ul>
<b>Population health analyst</b>	Experience pulling data from the EHR and/or other data warehouse(s) for contractual or payment reporting.	<ul style="list-style-type: none"> <li>Provides insight about and knowledge of policies and expectations for external reporting</li> <li>Articulates required measures and time points needed to support business goals</li> </ul>
<b>Operations lead</b>	Experience providing high level management/direction-setting of key service lines, operational areas, or health system initiatives.	<ul style="list-style-type: none"> <li>Provides insight to and knowledge of policies and expectations for external reporting</li> <li>Understands workflows within clinic settings as well as competing demands for staff and initiatives</li> </ul>
<b>Healthcare informaticist</b>	Experience with design, development, adoption, and application of IT-based solutions to support healthcare service delivery, management, and planning.	<ul style="list-style-type: none"> <li>Provides insight on how technology and data analytics can be used to improve patient care plans</li> <li>Applies user-centered design principles to system design and reporting structures that leverage information management</li> </ul>
<b>PROM specialist</b> (e.g., psychometrician, researcher)	Experience with the development of PROMs, knowledgeable of measurement properties and principles.	<ul style="list-style-type: none"> <li>Supports the assessment/vetting of different measures for clinical care</li> <li>Provides expertise in assessing the strengths and weaknesses of PROMs</li> <li>Supports development of training on PROMs</li> </ul>

## STRATEGY C

### Define the scope of ePRO governance oversight, including the decision-making capacity

The overarching function of the ePRO governance committee is to provide oversight and training and to ensure continual improvement of the program. Defining the charge of the committee supports success. Steps to achieve this include:

- establishing a charter for the committee, inclusive of mission and scope of work, to clarify the goals of the governing body
- ensuring clarity in the charge of the group, as well as a mechanism for reporting results to health system leadership
- reviewing committee work and accomplishments regularly (e.g., annually) to inform continued direction

Establishing a value proposition and writing a governance charter can formalize decision-making activities (see template in Chapter 5, **Tools and Resources** section). How the committee functions over time, however, may evolve. In the early stages of ePRO implementation, ePRO governance may serve to conduct a needs assessment to plan for and create policy around PROM implementation.

As work and efforts mature, the ePROs governance may shift toward providing support to teams, offering training to providers and patients to support implementation, identifying opportunities to improve upon current efforts and initiatives, and supporting system-level reporting on ePRO data reflecting metrics of both processes and outcomes.

### Guideline 4. Identify governance activities that guide practice

Governance activities can be established that formalize procedures for planning and conducting ePRO implementation. These mechanisms can be in the form of documented policies, procedures, or templates that set the rules and expectations agreed upon by the governing body. If a formal governance body is established (see Guideline 3), the group can develop specific practices and requirements to facilitate the management and sustainability of ePRO implementation.

Good governance requires that processes and decision-making are transparent. Generating system-level guidance helps supports necessary standardization, reduce variability, and streamline

reproducible processes. These governance activities will inform individual site implementations addressed in Chapter 3, **Integration**.

## STRATEGY A

### Clarify expectations about the selection of relevant, evidence-based PROMs

A fundamental component of any ePRO implementation is the selection of relevant, evidence-based PROMs that support clinical goals for patient care (see Guideline 1). Governance can ensure adherence to this principle by providing guidance on measurement selection to end-users as well as creating a repository of endorsed ePROs available.

There are several considerations when selecting one or more PROMs for use in clinical practice, with well-known guidance available (see ISOQOL guidance in Chapter 5, **Tools and Resources** section). This includes, but is not limited to, the following:

- type of PROM to use (i.e., generic versus condition-specific measure, also clinical domain)
- psychometric properties (i.e., validity and reliability)
- available evidence of the specific PROM use in practice
- pragmatic issues related to administration (e.g., time for completion, resources for administration)

In the traditional research context, the selection of which PROMs to use is driven by theoretical frameworks that explain the relationships between measurable constructs within a specific clinical domain and the health phenomenon of interest. For health systems, the use of ePROs across settings and stakeholders may drive the adoption of common (or core) domains with a multitude of potential uses, rather than discrete uses within specific clinical domains.

Aggregating ePROs by core measurement domains (e.g., health-related quality of life, function, depression, pain, or substance use) allows for the identification of common areas of interest across diverse healthcare settings for which enterprise resources would be beneficial.

#### Practice Consideration

When possible, establish common or core domains of PROM instruments available as enterprise resources. Organize the core domains into a catalog of recommended ePROs.

## STRATEGY B

### Create a process for managing the intake and prioritization of ePRO implementation requests

Health systems should ensure there are adequate mechanisms to evaluate and prioritize ePRO IT projects. Health systems can assess their current process for IT project intake and prioritization (which we refer to as the project-intake phase) and consider adaptations to account for the nuances of ePRO measurement and design.

For example, some types of ePROs may require more support for testing and training than other IT projects. Project requests that lack clear clinical champions or established workflows are likely to be less successful (see Chapter 3, **Integration**). Additionally, evaluation at the IT project-intake stage can serve as a governance requirement to ensure that only ePRO implementations that strongly align with health system goals are approved or prioritized. One opportunity to standardize the process is to develop an ePRO project-intake form (see Chapter 5, **Tools and Resources** section).

## STRATEGY C

### Define key measures for success to support ePRO implementation and evaluation

The planning phase for any project is the rigorous period when project scope and tasks are outlined. Governance can provide expectations for the scope and approach to project management by introducing dimensions for evaluation.

Defining key evaluation metrics provides a framework for how to plan and execute ePRO integration in local settings (see Chapter 3, **Integration**). This also allows for consistent metrics across implementations and pilots for collective learning via the governing body. Clearly defined criteria for reporting project status (see [Table 2C](#)) can serve to escalate risks and issues to the levels required by the organization.

**Table 2C** Evaluation components of ePRO implementation to consider for ePRO governance

Design/Integration Component	Role
<b>Deploy/collect</b>	<ul style="list-style-type: none"> <li>• % of eligible patients who receive ePRO notification</li> <li>• % of eligible patients who submit ePRO notification</li> <li>• Usage rates for different ePRO modalities</li> <li>• Average check-in and/or waiting room time</li> </ul>
<b>Track</b>	<ul style="list-style-type: none"> <li>• % of missed ePROs (not complete by time of clinical visit with provider)</li> </ul>
<b>Review</b>	<ul style="list-style-type: none"> <li>• Time spent preparing ePRO data for contractual reporting</li> <li>• % of missing data (i.e., incomplete ePROs responses)</li> </ul>
<b>Document</b>	<ul style="list-style-type: none"> <li>• % of ePROs reflected appropriately in clinical documentation and decisions</li> </ul>
<b>IT resource utilization</b>	<ul style="list-style-type: none"> <li>• ePRO build project completion status (on time, on resource)</li> <li>• % of standard vs. custom builds or use of available functionality</li> <li>• Level of onsite support needed</li> <li>• Number of post-build change requests</li> </ul>

## Guideline 5. Disseminate best practices for use and management

Governing bodies can establish guidance and policies that facilitate standards in ePRO design, use, and management at the clinic level. Standardization of ePRO functionality supports efficient management of resources and the ability to establish timelines and workflows for conducting the projects. In turn, dissemination (or the targeted distribution of information and materials to a specific audience) serves to spread knowledge, lessons learned, and the associated best practices based on organization experience. This supports system-wide learning and advancement of ePRO implementation.

### STRATEGY A

#### Promote successful ePRO use in practice

Continuous learning within the health system results when ePRO implementations are evaluated and shared across the organization. Over time, best practices may emerge allowing future efforts to expand ePRO use. Clinical teams implementing ePROs should be encouraged to document their experiences with expected plans for reporting back outcomes from work conducted.

Processes followed, lessons learned, facilitators and barriers encountered, and outcomes evaluated during ePRO implementation will provide important insight to others considering similar endeavors.

Governing bodies can further support system learning by identifying or creating opportunities to share and discuss experiences. Opportunities may include the following:

- highlight ePRO implementation experiences through internal communications (e.g., intranet, newsletter spotlights)
- include ePRO team presentations during routine governance meetings
- create quarterly ePRO discussion forums (e.g., learning forums, workshops, lunch & learn sessions) to focus on new or ongoing initiatives to advance the capture of patient-reported and patient-generated health data in clinical practice
- include ePRO team presentations during system leadership meetings
- publish results of ePRO implementations in peer-reviewed publications

Promoting successful ePRO experiences not only builds institutional knowledge, it also supports continued culture change concerning the importance of including the patient voice in practice.

## STRATEGY B

### Create shared resources to inform future ePRO implementations and use

Clinical teams benefit from understanding what resources are already available and accessible. Existing PROMs available for use within the health system, particularly those built into IT systems (i.e., EHR, patient portals, etc.) should be accessible for reference by teams interested in expanding data capture to include patient-reported data. If available, workflow templates and training materials from previous implementations may also be repurposed or enhanced.

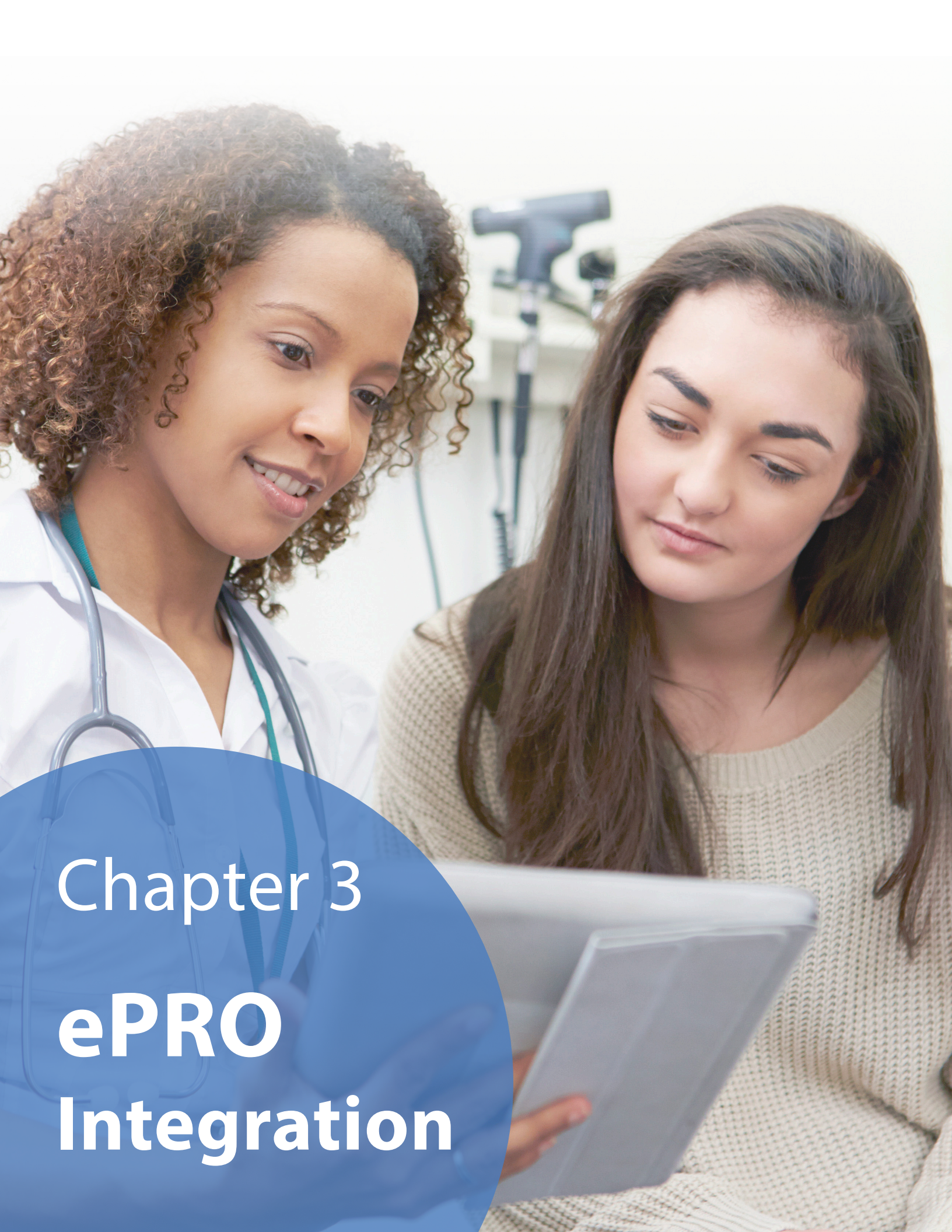
#### Practice Consideration

Create an ePRO asset inventory and/or a catalog of ePROs supported by the health system that are available for use by clinical teams via ePRO tools.

## STRATEGY C

### Establish a stakeholder feedback loop

Creating a feedback loop to stakeholders involved in ePRO implementation facilitates transparency and instills trust in the governance process, especially regarding how the input provided informs decisions and processes. Governance can provide opportunities for ongoing engagement, learning from others, and platforms to disseminate shared learnings or evidence generated from pilot studies. Synthesis of gathered feedback is best focused on the major functions that facilitate ePRO use and how these functions fit into the overall resources and processes.



# Chapter 3

## ePRO

### Integration

## Chapter 3: ePRO Integration

## Key Concepts and Background



### Learning Objectives

- Define common elements of ePRO workflow
- Understand key considerations for ePRO workflow design and integration into clinical practice
- Discuss potential pitfalls and supportive strategies for successful implementation of PROs across healthcare settings



### Use this chapter if you are

- Responsible for managing the implementation of ePROs within a clinical setting
- Involved in ePRO implementation within a clinical setting



### Key Concepts



**Workflow**



**Technology**



**Engagement**

As one moves from governance to the actual integration of ePROs into clinical practice, there are specific guidelines and steps to take to achieve integration. In this chapter, we focus on the unique considerations that we believe are important for successfully integrating electronic patient-reported outcomes (ePROs) into clinical care.

The guidelines in this chapter assume that organization-wide activities, such as ePRO governance and culture-building efforts, are already underway within your health system. For further information, refer to Chapter 2 on **Governance**.

Although this chapter will provide some basic introduction to the concepts of workflow design and modeling, change management, and implementation, for more in-depth information on these concepts, please refer to the **Tools and Resources** section (Chapter 5). The guidelines proposed in this chapter draw from current evidence and real-world learnings from implementing ePROs across diverse settings.

## The intersection of workflow and health information technology

Introducing the implementation of new technology into a healthcare setting is difficult and requires significant workflow planning and redesign to be successful. The amount of workflow redesign required will depend on the existing processes and the context where care is provided (i.e., the current state), including workflow, staffing, physical environment, and organizational culture.

For the purposes of this chapter, we define integration as the broad goal of incorporating ePROs into clinical care. An ePRO implementation can be considered the set of processes a team undertakes to integrate ePROs within a specific setting. Lastly, we define workflow as the repeatable patterns of activities that enable the use of ePROs in practice.

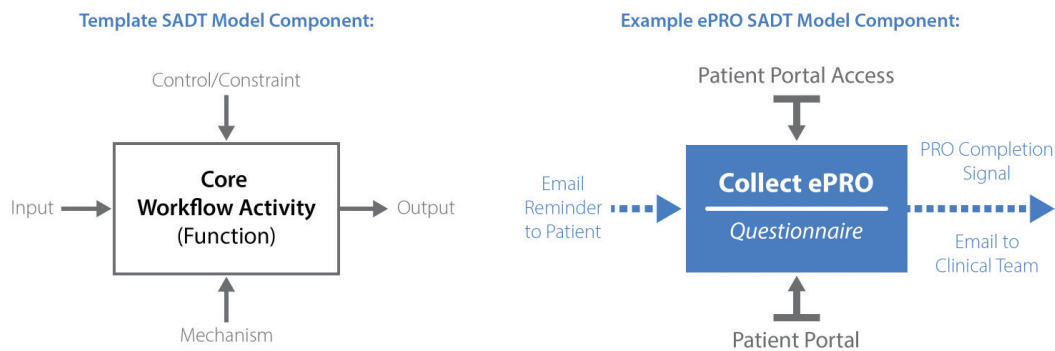
## Designing workflows to support scale

The ongoing work conducted in healthcare settings depends on complex systems of people, processes, facilities, and technology. Scaling new tools across healthcare environments can exacerbate complexity and highlight broader challenges around balancing customization with standardization. When integrating ePROs into clinical care, one must appreciate that the current web of patient care and management processes is a complex adaptive system that is constantly changing in response to the broader environment and actions of individuals within it. Viewing ePRO integration from a complex systems perspective is important for ensuring ePRO workflows and implementation processes have the flexibility to respond to this dynamic, emergent environment.

There are a number of approaches to designing and modeling workflows for health information technology (HIT) implementation, and this chapter will remain agnostic to any particular recommendation for how project teams should proceed. Instead, we have utilized Structured Analysis and Design Technique (SADT) to present the common components that translate across ePRO workflows in different clinical settings.

Briefly, SADT is one approach to workflow modeling based in systems engineering that examines commonalities across diverse workflows for the same process (Marca & McGowan, 1988; Multic et al, 2020; IEEE Computer Society, 1998). The strategy used to construct SADT models is hierarchical aggregation and decomposition. Aggregation is used to hide details and complexity; decomposition reveals lower-level component processes. In this way, you can examine the complete workflow at the level of detail most appropriate for the questions or designs to be addressed. **Figure 3A** shows the template for SADT modeling, which includes the core workflow activity (or function to be accomplished) and the associated inputs, outputs, controls, and mechanisms that influence how that step is completed. The benefit of SADT models is that they identify the common workflow components that must be in every implementation, creating a workflow blueprint that individual settings can then customize for their unique environment. For a health system, this can be particularly valuable, as the SADT model provides a template that can aid governance and leadership teams in comparing complex workflows across individual clinical sites.

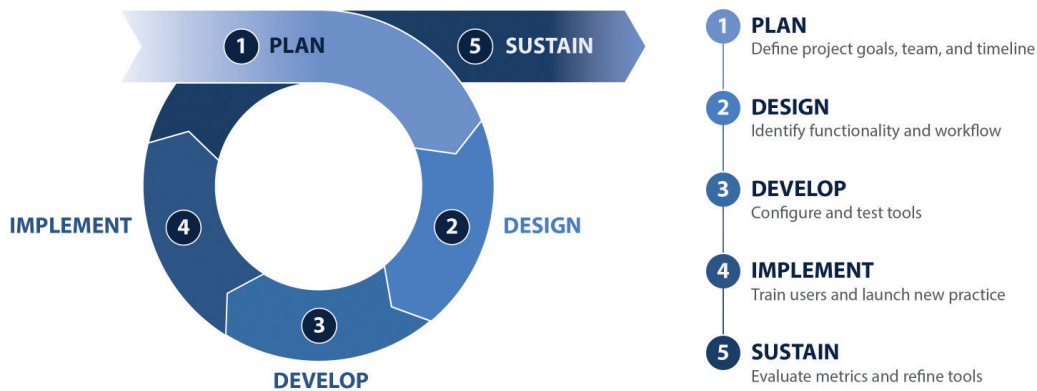
**Figure 3A** SADT model components



In this chapter's guidelines, we will present workflow recommendations that draw from an SADT model developed for ePRO implementation. Note that it is not necessary for readers to understand how to develop SADT models; the ePRO model we present can be used as a template to support the design and customization of workflows within your setting. If you are interested in learning more about the SADT modeling method, please refer to Workflow resources in the **Tools and Resources** section (Chapter 5).

## Managing implementation in practice

Every health IT project starts with a project implementation plan organized as a sequence of project phases or stages. Commonly accepted project implementation phases include plan, design, develop, implement, and sustain (see **Figure 3B**) (Canada Health Infoway, 2013). Your organization may define these phases differently, so we recommend you align with the current practice within your organization.

**Figure 3B** Common project implementation phases

As part of the implementation process, project teams should establish a detailed project plan, utilize evidence-based implementation methods whenever possible, and engage in change management throughout the implementation process.

It is also important to acknowledge that ePRO tool implementation should bring together a variety of different disciplines, including clinical, IT and informatics, health system administrators, staff, and patients. These stakeholders may not all use the same language for how they approach concepts around functionality, workflow, and care delivery experience, so project leaders may need to establish common understanding.

## Change management

When introducing ePROs to a clinical setting, the impact of the associated changes on the organization and the work and people involved must be considered. Change management is a necessary component of any HIT initiative. Any changes to existing processes in health systems necessarily entail a need to understand organizational culture and climate, resistance to change, and change management. The practice of change management (*Kotter & Cohen, 2002; Cohen, 2005*) focuses on:

- engaging the right people to lead change
- explicitly communicating the objectives of the changes
- adequately planning and organizing the sequences of activities involved
- mobilizing leadership to support the change process

## Evaluating implementation process and effectiveness

Managing the implementation process can often involve efforts to identify, diagnose, and address implementation barriers that influence user adoption of new practices. There are many evidence-based methods and tools that can guide implementation planning, facilitation, monitoring, and evaluation. Some examples from both healthcare practice and research include:

- **Lean Management**, a set of performance improvement tools that can guide teams in optimizing complex workflows to enhance system performance (*What is LEAN?* [Lean Enterprise Institute] nd)
- **IHI Model for Improvement**, which can guide teams in accelerating improvements via facilitating change on a small scale using Plan-Do-Study-Act cycles (*Improving Health and Healthcare Worldwide* [Institute for Healthcare Improvement] nd)
- **Proctor's Outcomes for Implementation Research Model**, which can provide a framework for aligning outcomes across implementation process, care delivery, and patient experience (Proctor et al, 2011)
- **Consolidated Framework for Implementation Research (CFIR) Framework**, which can guide identification of implementation factors that impact adoption and outcomes (Damschroder et al, 2009)
- **Non-adoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) Framework**, which can guide teams in diagnosing and addressing challenges with non-adoption, abandonment, and sustainability of new HIT interventions (Greenhalgh et al, 2017)

The approach your team takes will depend on the prior experience and culture of your organization and goals for ePRO use; however, we recommend leveraging existing evidence-based practice in implementation facilitation and evaluation whenever feasible.

Please visit the **Tools and Resources** section of Chapter 5 for more resources related to Change Management, Workflow, and Implementation and Evaluation.

## The integration guidelines: **what to expect**

This chapter provides direction and information on the design and implementation of ePRO tools used in clinical practice. These guidelines cover recommendations to support the nuances of ePRO implementation throughout the phases of implementation planning, design, execution, and sustainment.

The first guideline focuses on understanding how patient-reported outcome measure (PROM) data will be used at the point of care, recognizing that there are many different use cases and applications of PROMs to clinical decisions. The next three guidelines advise on workflow, technology, and user engagement strategies to support ePRO use in practice. The last guideline of the chapter provides recommendations to sustain ePRO use via continuous learning. It is essential to understand that:

- The sequence in which you undertake the outlined steps may shift, depending on your practice context (e.g., size, type, budgets, and deadlines).
- These guidelines are organized in a temporal sequence, but some of the activities may overlap or occur simultaneously.
- You may need to use these guidelines in concert with your health system's internal policies, procedures, and guides.
- This chapter will address some broad principles that will apply across different settings, acknowledging that nuances will exist for different environments.

In addition to the references cited throughout the chapter, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

# ePRO Integration Guidelines

## Guideline 6. Clarify how data will be accessed and support care

The first step to implementing ePROs is understanding how stakeholders will use data for clinical decisions and care delivery. This important first step of understanding how ePRO data will be accessed and used highlights key design, workflow, reporting, and/or resource needs that must accompany ePRO tools in order to make them actionable.

The selection of PROMs will likely be an iterative process that involves identifying the PROMs that best align with goals, testing the use of ePROs in practice, and ongoing evaluation of impacts on care delivery (*van der Wees et al, 2019*). In this guideline, we focus on three strategies that seek to clarify a) how ePROs should inform patient care, b) what resources clinical teams might need to respond to ePRO data, and c) how ePRO data will be used more broadly for health system delivery.

### STRATEGY A

#### Clarify how ePROs will inform patient care

Integrating ePRO data with clinical data can enhance clinical decision-making and patient-centered care. In Guideline 1 (Chapter 2, **Governance**), we focus on aligning ePROs with health system and stakeholder goals to determine the measurement strategy. In Guideline 6, our focus is on ensuring that clinical teams establish clear use cases for how ePRO data is used at the point of care.

**Figure 3C** provides an example of how a single data point, in this case a measure of depression symptoms (Patient Health Questionnaire), might be used to support clinical decisions in different contexts of care. Even though each scenario uses the same ePRO, the clinical purpose, reporting focus, and patterns of data collection vary significantly. At the beginning of any ePRO initiative, project teams should begin by defining the use case for clinical decision-making (e.g., preventive, chronic,

#### Practice Consideration

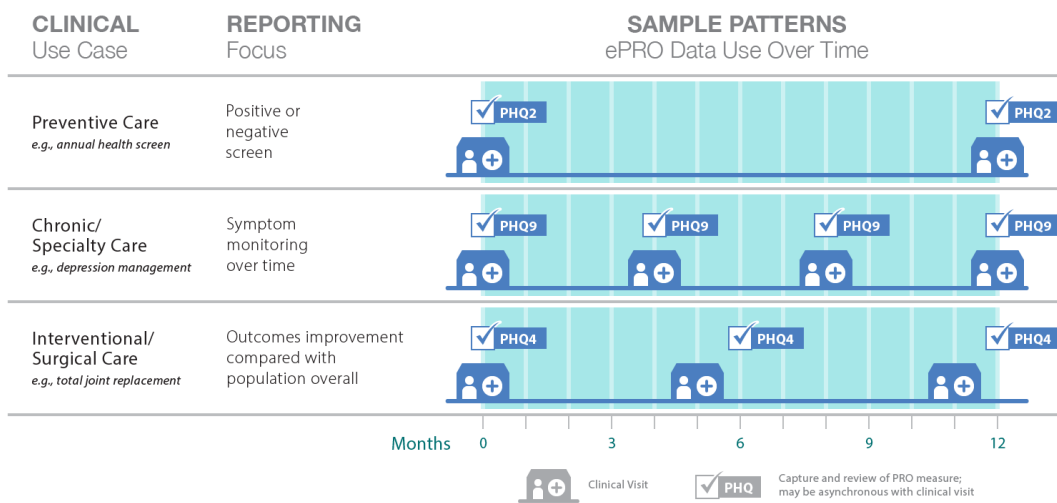
It is important to remember that ePROs may not benefit every patient or context of care. There may be situations where ePROs are not reliable or actionable, cause undue stress or anxiety for patients, or are not appropriate for certain types of clinical encounters. While ePROs often provide a net benefit for patients, care teams and health systems, project teams may need to provide training on how to manage exceptions.

interventional) and by clarifying the ePRO score thresholds (or, if appropriate, minimal clinically important difference, MCID) for clinical action or follow-up.

Of note, not all uses of ePROs will be accompanied by pre-defined thresholds for clinical action; however, it is valuable for project teams to establish guidance for how care teams should apply ePROs to care delivery and, when possible, align them with existing care pathways or clinical protocols. By starting with the ultimate goal of determining how ePROs should inform patient care, project teams can better understand the needs for ePRO workflow and reporting.

**Figure 3C**

Example ePRO clinical use cases across different contexts of care (Austin et al, 2019)



## STRATEGY B

### Identify resources needed to support clinical teams in responding to ePROs in practice

Determining the resources needed to support the clinical team for its specific use case for ePROs can help clarify the project scope and resources required for project implementation.

For example, consider the use case in [Figure 3C](#) of the PHQ-2 for preventive care. In Strategy A above, the project team may have identified that a PHQ-2 score of 3 or higher is considered abnormal.

Next, the project team should identify what the appropriate response should be from the clinical team, such as conducting a follow-up assessment during a clinical visit or referring the patient to a behavioral health specialist. In many cases, ensuring that clinical teams are able

to appropriately respond to ePRO data requires additional resources, such as training, clinical decision-support tools, patient education supports, or additional staff time. Performing this step during the implementation planning phase can help with identifying the true scope of the project.

It is also important to consider that ePRO data may cover a variety of clinical and social domains (e.g., quality of life, functional status, symptom severity, emotional health, or financial distress). As a result, responding to ePRO data may require the expertise of multiple team members, including clinical providers (primary and specialty), nursing staff, social workers, and administrative support staff. The workflow for ePRO response may, therefore, involve several layers of collaborative team review and decision-making.

#### Resources needed might include:

- ✓ Training
- ✓ Decision response resources
- ✓ Staffing
- ✓ Budget
- ✓ Technical, e.g., tablets/kiosks
- ✓ Physical, e.g., space

## STRATEGY C

### Understand health system needs for ePRO data beyond point-of-care decision-making

The first two recommended strategies have focused on how ePROs will inform clinical decision-making at the point of care. However, with any clinical implementation, there may be additional needs for ePRO data within the health system, including for population health, quality improvement, and billing.

For example, the capture of ePRO data including pain and function within an orthopedic practice may also support reporting for national quality initiatives. In order to ensure that ePRO tools are designed to meet the needs of all stakeholders, it is important for the full project team, in particular, the IT professionals responsible for the design of ePRO data storage architecture, to understand all of the goals for ePRO data use. Working with clinic leadership to identify broader needs for PRO data can support this strategy (see Chapter 2, **Governance**). [Table 3A](#) below provides a few examples of considerations for ePRO use beyond the point of care.

**Table 3A** ePRO use beyond the point of care

ePRO Use	Sample Use Case	Potential Consideration
<b>Billing &amp; contractual reporting</b>	ePROs provide documentation that allows for billing of a particular care visit type	<ul style="list-style-type: none"> <li>The need for ePRO scores to be reflected in visit documentation (e.g., progress note)</li> <li>The need for ePRO completion status to align with the appointment date used for billing</li> </ul>
<b>Quality improvement</b>	ePROs are used as part of a care pathway to standardize processes for depression medication changes	<ul style="list-style-type: none"> <li>The need to align ePRO tools with existing order sets or tools for care delivery</li> <li>The need for reporting tools that allow care teams to monitor compliance with care pathways</li> </ul>
<b>Population health</b>	ePROs are delivered through the patient portal to meet screening requirements for patients who do not have an upcoming appointment	<ul style="list-style-type: none"> <li>The need for bulk distribution of ePROs to tailored patient lists</li> <li>The need for a single documentation point of screening completion status within the record</li> </ul>

## Guideline 7: Design workflows for easy data capture

In order to maximize the impact of ePRO data and the objectives for how ePRO data should direct care, ePRO workflows should be designed with two primary goals in mind:

- complete ePRO data collection for all appropriate patients, and
- intentional review of ePRO data by clinical teams

Accomplishing this will depend on an in-depth understanding of clinical workflow and planning for potential implementation needs in real world contexts of care.

To this end, partnership between clinical teams and IT personnel supporting the technical build is critical. This helps ensure that the technical functionality of ePRO tools aligns with clinical workflows. Without this partnership, the integration of ePROs into clinical practice might falter. This guideline builds on Guideline 6 by supporting the technical integration once it is understood how ePRO data will inform care.

## STRATEGY A

### Describe how core ePRO workflow activities will intersect with existing clinical workflow

In the chapter Introduction, we introduced the concept of SADT modeling, which is an approach to characterize common or core activities that consistently occur across multiple, diverse workflow environments. For ePRO, there are five core activities that should occur in every workflow:

- **deploy** (delivering the ePRO questionnaire to the patient)
- **collect** (the patient's completion of the ePRO questionnaire)
- **track** (how clinical staff monitor the completion status of ePRO questionnaires)
- **review** (how clinical teams access and view ePRO scores)
- **document** (how ePRO scores are archived for future use or use by other stakeholders)

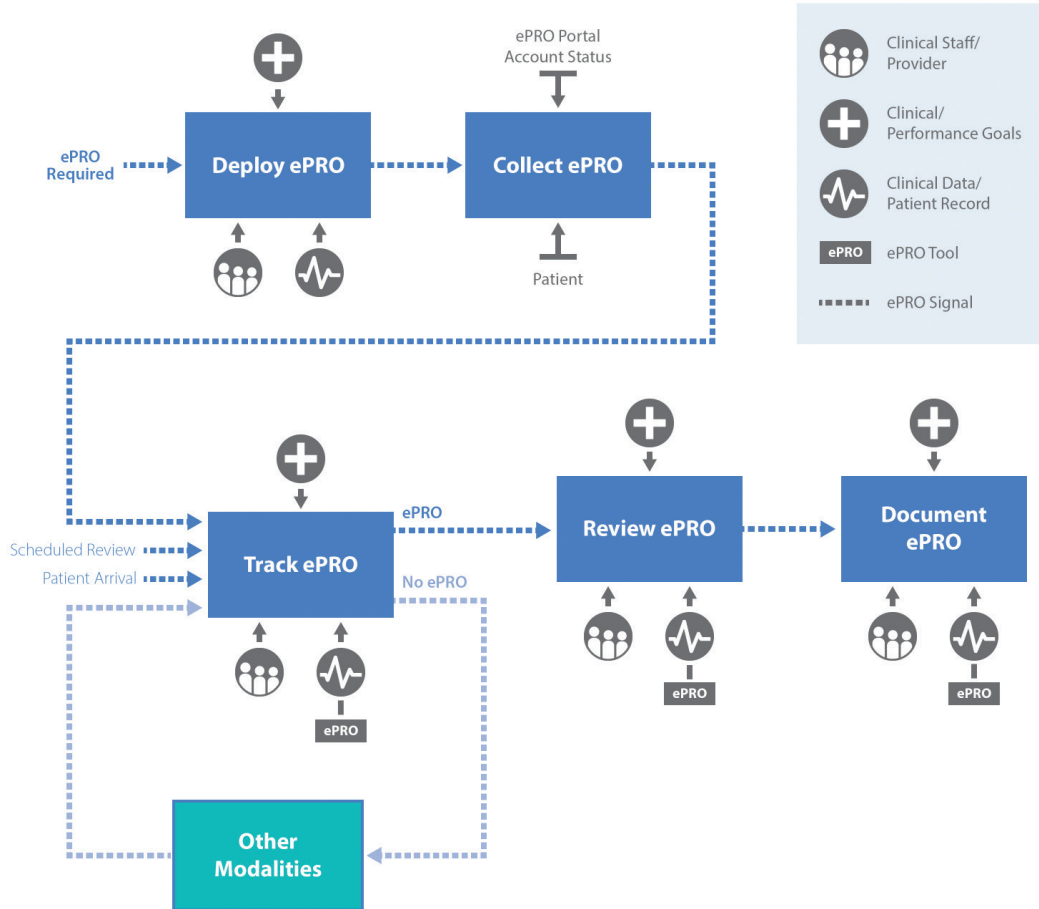
Each of these core ePRO activities may involve several sub-steps or micro workflows. For example, if we further expand the **collect** activity, it might include steps such as:

- patient receives notification of ePRO questionnaire to complete
- patient logs into patient portal, and
- patient completes questionnaire

While the workflow activities for **collect** and **review** may seem like the most relevant activities to consider, the activities of **deploy**, **track**, and **document** can often address the most critical linchpins for successful ePRO integration into clinical care.

**Figure 3D** outlines each ePRO core workflow activity. Of note, each step in the process should have a signal or output that triggers future steps in the workflow. For example, when a patient finishes the ePRO questionnaire (**collect**), this should produce a signal that aids the workflow for **tracking** ePRO responses (e.g., an automated alert to the clinical team).

**Figure 3D** Template for core activities in ePRO workflow



Utilizing the workflow diagram above as a template will help ensure that critical elements of ePRO workflows are considered and addressed. Once your ePRO workflow design is established, it is important to place that workflow within the context of existing care delivery processes. Each of the five core activities may need to be modified to better align with existing workflows, such as those for appointment forecasting, appointment check-in, or the clinical visit itself.

Much like any other implementation of new practices, we recommend engaging with clinical teams to understand their current state and to co-design workflow steps to achieve optimal workflow goals with minimal disruption to patient care.

### Approaches to consider

- ✓ Document existing workflows
- ✓ Identify updates to procedures necessary for ePRO integration along with resources needed
- ✓ Define protocols for how ePRO data will be communicated to appropriate care team members
- ✓ Identify impact of workflow on ancillary teams (e.g., scheduling, call centers, contact systems etc.)
- ✓ Engage with stakeholders (IT, clinic staff) to collect feedback and iterate as necessary

## STRATEGY B

### Assess and plan for potential barriers to ePRO use in clinical care

Workflow design often emphasizes the ideal state or best-case scenario. However, in order to ensure that data from patients is delivered to the healthcare team and is reviewed with the patient as needed, it is important to consider the ways that workflows might deviate or fail when put in the real world environment. Moreover, in busy healthcare settings, many challenging scenarios might arise that impact ePRO workflow.

Proactive work to identify possible workflow gaps and constraints during the design phase can help teams anticipate and manage barriers to ePRO use. This can minimize workflow disruptions, missing data, and missed ePRO reviews. [Table 3B](#) gives some examples of issues that may affect the different core activities of ePRO integration.

**Table 3B** ePRO workflow considerations and constraints

ePRO Core Activity	Potential Consideration
ePRO measure deployed	<ul style="list-style-type: none"> <li>• Clinical team member does not recognize ePRO is due</li> <li>• Clinical team member does not send ePRO measure to patient</li> <li>• ePRO measure is ordered, but another team member needs to authorize or finalize order to deploy</li> </ul>
ePRO data collected	<ul style="list-style-type: none"> <li>• Patient does not have access to portal or electronic tools where ePRO measure is located</li> </ul>

(Continued)

ePRO Core Activity	Potential Consideration
	<ul style="list-style-type: none"> <li>• Patient does not receive notification at all, or in time to complete ePRO prior to appointment</li> <li>• Patient cannot find ePRO measure within the portal or tool</li> <li>• Patient cannot, or does not, finalize and submit ePRO response</li> </ul>
ePRO response tracked	<ul style="list-style-type: none"> <li>• ePRO completion status is not flagged in clinical team views</li> <li>• ePRO results do not go to appropriate team member</li> <li>• ePRO response status cannot be seen until day of appointment</li> <li>• Clinical team cannot, or does not, remind patient to complete ePRO</li> <li>• ePRO results do not refresh in real time to support tracking</li> <li>• Staff does not update appointment documentation with forecasted ePRO needs</li> <li>• Multiple ePRO measures are sent, and staff cannot determine which ones are completed or still due</li> <li>• Clinical staff cannot, or do not, confirm ePRO measure completion at the time of appointment check-in</li> </ul>
ePRO score reviewed and documented	<ul style="list-style-type: none"> <li>• ePRO results are not available electronically in real time</li> <li>• ePRO has missing data and cannot calculate total score</li> <li>• PROM results are captured on paper but are not entered into EHR as discrete values for future follow-up</li> <li>• Provider is not aware that new ePRO results are available</li> <li>• Provider does not know how to locate ePRO reporting tools</li> <li>• ePRO reporting tools do not contain relevant clinical data</li> <li>• Provider is unsure of score interpretation and appropriate clinical response</li> <li>• ePRO responses are not validated or saved into the patient's record</li> </ul>

## STRATEGY C

### Evaluate the need for multiple data-capture modalities

To promote widespread use of ePRO data, it is critical to ensure that ePRO tools are easy for patients to complete and for clinicians to review. However, we recognize that due to a variety of factors such as resource availability (e.g., tablet computers available in a waiting room), healthcare setting characteristics and infrastructure (e.g., space constraints), patient characteristics (e.g., access to computers, language needs), or technological capabilities (e.g., access to patient portal), multiple data capture modalities may be warranted.

Designing workflows that incorporate multiple modalities is critical to ensure widespread use of PROMs. Yet, multiple modalities will also introduce more complexity, as there will be multiple pathways that can facilitate the same workflow task. It may take more IT and staff investment to accommodate and support the variety of modalities. [Table 3C](#) highlights some of the advantages and considerations for different ePRO data collection modalities. Each ePRO implementation may use a combination of modalities, depending on the characteristics of their setting and resources available. We recommend designating “primary” versus “secondary” modalities to support streamlined workflows for clinical staff.

**Table 3C** Modality considerations for ePRO data collection

Modality	Advantages for ePRO Data Collection	Considerations for ePRO Data Collection
<b>Electronic</b> (computer, kiosk, web-based portal)	<ul style="list-style-type: none"> <li>Electronic data collection facilitates optimal data storage (discrete variables, development of datasets and registries)</li> <li>Electronic data collection facilitates real time scoring and allows for greater reporting capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Electronic data collection requires all users to have access to technology (computer, internet) at home or in clinic</li> <li>Electronic data collection may require more tracking effort on behalf of clinical teams</li> </ul>
<b>Mobile</b> (app, tablet, smartphone)	<ul style="list-style-type: none"> <li>Electronic data collection facilitates optimal data storage and reporting capabilities</li> <li>Mobile data collection may be most aligned with some users’ preferences</li> </ul>	<ul style="list-style-type: none"> <li>Mobile data collection requires users to have access to specific technology (smartphone or tablet), which may never be universal</li> <li>Mobile data collection may require extra steps (i.e., downloading app) and additional work to ensure patients are set up to use</li> <li>Mobile data collection may have formatting limitations for the display of certain PROs</li> </ul>
<b>Paper</b>	<ul style="list-style-type: none"> <li>Paper may be considered more customary or comfortable for users</li> <li>Paper completion (particularly in the healthcare setting) may be easiest to monitor/ track</li> <li>Paper may be necessary in the event that electronic systems are unavailable and may be a necessary back up.</li> </ul>	<ul style="list-style-type: none"> <li>Paper data collection can prohibit electronic data storage (i.e., if documents are only scanned versus actual data entry)</li> <li>Paper data collection prohibits electronic scoring and reporting, unless transcribed by staff</li> <li>Transcription errors and burden should be considered if staff data entry is used</li> </ul>
<b>In-person facilitation</b>	<ul style="list-style-type: none"> <li>In-person facilitation promotes data completeness</li> </ul>	<ul style="list-style-type: none"> <li>In-person facilitation may influence patient responses or freedom to share perspectives</li> <li>In-person facilitation is very resource intensive and impacts clinic flow and overall clinic visit time</li> </ul>

## Guideline 8: Leverage health IT to facilitate ePRO use

Once ePRO measures have been selected and the workflows designed, it is important to understand how health IT can support health system and project goals regarding how ePROs should integrate with care delivery. The use of IT to deploy PROMs offers an opportunity to provide efficiency in clinical workflow. Throughout the five core workflow activities mapped in Guideline 7 (i.e., deploy, collect, track, review, and document), clinical teams should dedicate time to identifying areas where IT can improve efficiency.

### STRATEGY A

#### Utilize best practices for the design of ePRO tools

Once you have identified the different ePRO core activities and implications for workflow, we recommend giving thought to the design of the ePRO tool. It is critical to think about many aspects of development, including the different users of the tool, their views within medical records, ways to leverage the existing IT functionalities of your health system, and the methods to identify and address user needs in ePRO tool design.

Utilize established best practices when designing the ePRO tool, particularly those that incorporate principles of user-centered design (see User-Centered Design in Chapter 5, **Tools and Resources**). Conducting usability or formative testing can provide invaluable feedback on the user experience with ePRO tools. Similarly, testing ePRO tools in multiple, diverse environments and across all user views (e.g., provider, clinical staff, patient) can highlight critical barriers to ePRO tool use in clinical workflow. Lastly, engaging in formal pilot testing prior to broader rollout of ePRO tools can identify key training and facilitation considerations that will support adoption and use.

#### Practice Consideration

Healthcare providers have limited time in which to review ePRO data in the course of patient care, and may have established workflows for how they currently use EHR screens to guide care activities. How ePRO data is presented and formatted can affect a provider's ability to use ePRO data for clinical decision-making. Refer to our guidelines in Chapter 4 for recommendations on ePRO reporting.

It is important to remember that the use of ePROs in practice is an emerging space; it may be helpful to get feedback from other health systems to identify models for ePRO tool design and workflow and lessons learned from the field. Consider reaching out to health systems that are using a similar technology platform as your system for their ePRO implementations to gain insights early in the planning and design project phases. **Table 3D** provides examples of different functionality approaches that could be considered to address different user needs.

**Table 3D** Examples of ePRO functionality approaches

ePRO Activity	Examples of Functionality Design
<b>ePRO measure deployed</b>	<ul style="list-style-type: none"> <li>By placing a manual, stand-alone order</li> <li>Through the inclusion in an order set for a particular disease-specific pathway</li> <li>Through automated deployment based on an algorithm that recognizes an upcoming clinic visit (i.e., visit type, patient diagnosis, date of last ePRO completion)</li> </ul>
<b>ePRO data collected</b>	<ul style="list-style-type: none"> <li>Through the patient portal, prior to visit</li> <li>Through the patient portal, in waiting room</li> <li>Through the EHR, during visit</li> <li>With skip logic and/or computer adaptive testing, or without</li> </ul>
<b>ePRO response tracked</b>	<ul style="list-style-type: none"> <li>ePRO completion is integrated into existing, passive reporting tools (i.e., front desk staff can confirm completion at time of check-in)</li> <li>ePRO completion is monitored through new, tailored reporting tools (i.e., those that can generate customizable lists to support follow-up)</li> <li>ePRO responses launch active alerts or push notifications (i.e., providers get notified of patient response in real-time)</li> </ul>
<b>ePRO score reviewed</b>	<ul style="list-style-type: none"> <li>Within a reporting tool specific to that ePRO and/or clinical condition</li> <li>Within a general reporting tool where all patient-generated health data and/or clinical data appear together</li> </ul>
<b>ePRO score documented</b>	<ul style="list-style-type: none"> <li>Within the workflow (i.e., flowsheets, progress notes) for that clinic visit</li> <li>Within a general registry where ePRO data is stored together</li> </ul>

## STRATEGY B

### Identify where health IT can improve the efficiency of ePRO workflow

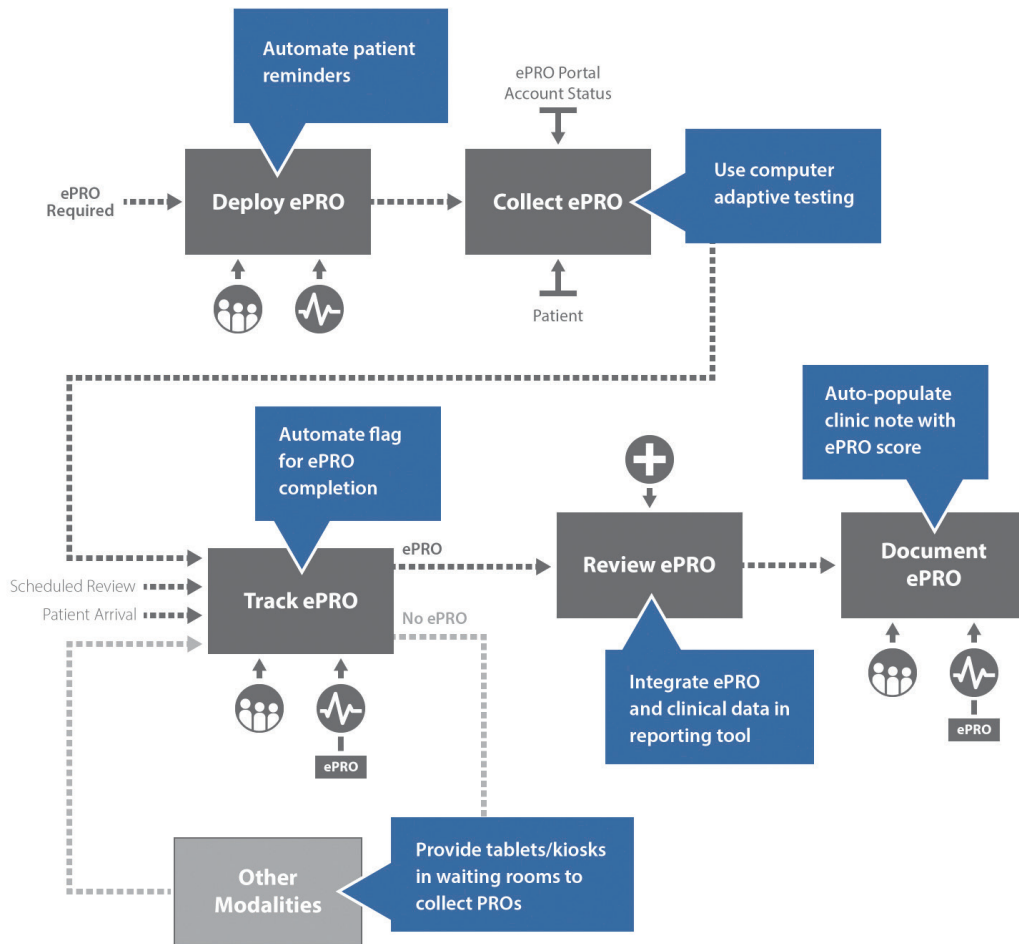
As implementation teams build ePRO tools, they should consider how to use health IT to enable more efficient capture and review of ePRO data.

**Figure 3E** highlights some potential IT-related functionalities that teams can consider to increase efficiency. Health IT can improve the efficiency of a workflow through functionality that

automates steps, curates information to support rapid review, nudges behavior (e.g., alerts or reminders), or allows for user customization. Project teams should work with their IT professionals to understand possible IT functionalities and implications for ePRO workflow.

**Figure 3E**

Clinical workflow considerations for health IT-enabled ePRO collection and reporting



## STRATEGY C

**Ensure health IT tools provide a seamless experience for patients and clinical teams**

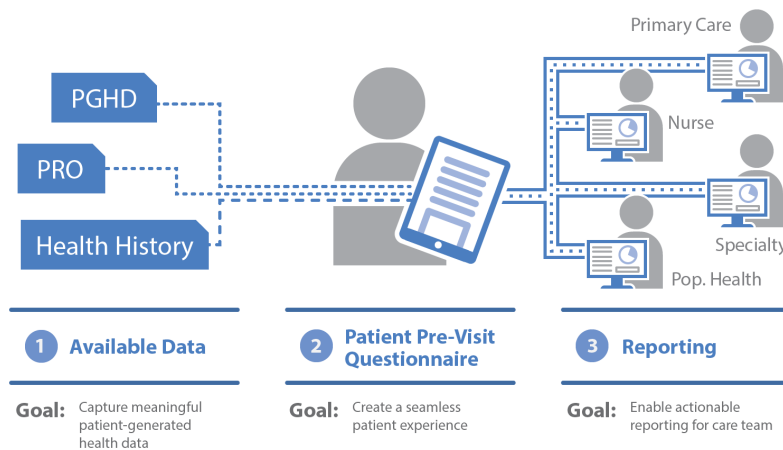
It is important to recognize that ePROs are one component of the whole care delivery experience. As project teams design ePRO tools and workflows that address stakeholder goals, teams will also need to consider how ePRO tools will interact with other health IT tools used during the care delivery process. For example, as shown in [Figure 3F](#), a patient might receive an ePRO prior to a visit, along with several other requests for information such as prior medical history, patient-reported data, or insurance information. Ideally, all of these requests should present as one “ask” to the patient. Similarly, a provider may need to review ePRO scores alongside multiple other types of clinical data for that visit.

### Practice Recommendations

- ✓ Assess complexities arising from additional IT tools, if available (e.g., scheduling systems, contact systems), on ePRO workflow
- ✓ Understand the timing and type of health IT systems patients interact with when accessing care
- ✓ Perform adequate testing of the ePRO tool prior to launch
- ✓ Test ePRO tools in multiple, diverse environments and across all user views (e.g., provider, clinical staff, patient)

If ePRO tools require additional logins, require patients or staff to access screens outside the normal workflow, or if ePRO tools generally have a different look and feel than the health IT tools already in use, patients and care teams may be less likely to use them. Lastly, project teams should thoroughly test how ePRO tools interact with other health IT tools in use to support care delivery. Utilizing learnings from the testing and pilot phases can help further clarify the experiences of patients and providers.

**Figure 3F** Data flow for patient-reported health data requests



## Guideline 9: Engage users in ePRO adoption and use

The use of ePROs in clinical practice may be new to both patients and care teams and is distinctive from other types of data they may be used to (i.e., past medical history). User engagement is critical to facilitate adoption and eventual use of ePROs. Effective and sustainable implementation of ePROs requires active participation by patients and all members of the care team.

Chapter 2 (**Governance**) highlighted the drivers and implications of stakeholder engagement in the design of ePRO tools. In Guideline 1, we focus on evaluating the information needs of stakeholders for ePRO collection and use. Here, we will focus particularly on training, education, and engagement of users for ePRO data collection and review.

### STRATEGY A

#### Identify strategies to actively engage patients in ePRO use

Engaging patients in ePRO use should start early in the implementation planning and design phases. Patients will need to understand the value of ePROs for their care in order to engage in ePRO collection and use.

##### Practice Recommendations

Patients will have different accessibility needs, including the potential need for literacy, audio, or visual supports, or language translation. Project teams should be proactive in identifying the resources available to support patients in ePRO completion, and integrating those recommendations into policies and procedures that support staff and other implementation team members. Project teams should also consider the appropriate role of caregivers (including parents or guardians) in assisting patients in ePRO measure completion and recognize that policies for caregiver/guardian support may vary based on different PROM clinical domains (e.g., general health vs. behavioral health) (*Web Content Accessibility Guidelines (WCAG) Overview [Web Accessibility Initiative] nd; About Section 508 Standards [US Access Board] nd*).

Consider the patient's own workflow (see [Table 3E](#)) to target junctures of engagement that are critical to the success of collecting and using ePROs in practice. When designing engagement strategies, it is important to consider that local clinics often have their own approaches for facilitating care processes (e.g., how to make an appointment, how to contact the clinical team, financial mechanisms, non-office hour procedures). Obtaining input on existing engagement activities from clinics and patients is critical. Involving patients, either from the clinical settings you are implementing in or from Patient & Family Advisory Councils, in the design and implementation of patient engagement strategies can greatly augment patient adoption of ePRO tools.

**Table 3E** Example ePRO engagement strategies for patients

Core Activity	Patient Experience	Sample Engagement Strategy
<b>Deploy</b>	Patient receives email notification	Tailor notification message to help patients understand context for ePRO measure
<b>Collect</b>	Patient completes ePRO questionnaire	Provide multiple formats for completing ePRO questionnaire
<b>Track</b>	Patient prepares for visit	Acknowledge patient for completing ePRO ahead of time
<b>Review</b>	Patient and provider review ePRO score	Show ePRO scores to patient during visit
<b>Document</b>	Patient accesses documentation of clinical visit	Give patients access to their past ePRO scores

## STRATEGY B

### Consider the multidimensional needs for ePRO training

Clinical team members of all roles need training in order to implement ePRO workflow steps and integrate ePRO data into care delivery. Training is often underappreciated and overlooked for various health IT systems, including ePROs, which may be deceptively labeled as intuitive. Excellent training for ePROs is not only about the transfer of necessary information for using the ePRO technology, but also about the mastery of interpreting ePRO reports and using the reports in the patient/provider communication process (especially in the context of shared decision-making).

It is important that training for clinical teams reflects each of the five core workflow activities (deploy, collect, track, review, document). Training should also consider multiple dimensions of knowledge needed by care team members, including the context and value of ePROs, ePRO project goals, technical knowledge (i.e., how to use ePRO functionality), and needed adaptations to current practice to accommodate ePRO integration.

Project teams should utilize training strategies that best address the needs of different clinical team member roles and are considerate of their availability to engage in training, which may be limited. This may include both informal (e.g., mentoring) and formal training (e.g., training video(s), job aid, lunch and learn). Project teams should also invest in evaluating training effectiveness, for example, by assessing team members' satisfaction with training, understanding of content, and performance resulting from training.

Of note, not all providers may have experience using ePRO data in practice, and the introduction of this new data source may raise provider concerns around the timeliness and appropriateness of their response to ePRO data. Provider engagement in ePRO data use should be a key component of the project team's training strategy. Project teams may want to pair provider training on ePRO use with additional training to support collaborative or shared decision-making, as well as training that embeds ePRO use within the broader context of care delivery (for example, aligning ePROs with an existing care pathway).

### Sample Learning Objectives for ePRO Training

At the end of ePRO training, clinical teams should be able to:

- ✓ Describe the **value** of ePROs for care delivery
- ✓ Define the **context** for ePRO use (e.g., which patients, what timepoints, what settings of care)
- ✓ Specify **goals** for successful ePRO use
- ✓ Understand how to use ePRO **functionality** (deploy, collect, track, review, document)
- ✓ Understand how to **integrate** ePROs into decision-making and/or the clinical encounter
- ✓ Identify **resources** to navigate barriers to ePRO use in real world practice
- ✓ **Adapt** current practice to accommodate ePRO integration

## Guideline 10: Encourage continuous learning throughout implementation

The field of ePRO use continues to mature, and like most health IT tools, intersect with many sociotechnical layers of healthcare delivery. The launch of an ePRO tool should be considered the start of a continuous effort to observe, evaluate, adapt, and improve all aspects of ePRO tool design and implementation.

We recommend engaging with the QI (quality improvement) resources in your healthcare organization or utilizing the QI methodology referenced in this chapter's Introduction throughout the entire integration process of implementation planning, launch, and ongoing monitoring. We also recommend establishing structures that facilitate and disseminate continuous learning across the organization around ePRO technology advancements, implementation best practices, and continued alignment with care transformation.

## STRATEGY A

### Engage in routine implementation monitoring to improve ePRO workflows and tools over time

As part of the implementation process, it is important to monitor and iteratively evaluate implementation progress. This may occur via activities such as real-time reporting and stakeholder feedback. The initial launch phase of an ePRO tool should maintain engagement of the full multidisciplinary project team, including dedicated time from IT and/or informatics team members, as well as time for iterative cycles of reflection and refinement of functionality or workflows (e.g., Plan-Do-Study-Act cycles).

Project teams should identify key implementation process and outcome metrics that can support ongoing assessment of implementation progress, including feasibility, fidelity, acceptability, sustainability, adoption, and cost. The selection of implementation process and outcome metrics should align with your health system's internal goals or initiatives (see Guideline 4, Strategy C), and can be guided by formal evaluation frameworks (see Chapter 3 Introduction). Project teams should also ensure that clinical champions and key staff roles have the ability to easily access and view data reports in real time throughout implementation.

#### Sample implementation monitoring metrics

- ✓ % of eligible patients who receive ePRO notification
- ✓ % of eligible patients who submit ePRO responses
- ✓ % of missing data (i.e., incomplete ePRO responses)
- ✓ % of ePRO responses appropriately documented by clinical team

While quantitative data will provide critical insight into implementation progress, feedback from users (patients, healthcare teams) through formal or informal routes (e.g., interviews, conversations, observing practice) can better contextualize issues with workflow or tool alignment and inform adaptations that improve ePRO use. Please visit [epros.becertain.org](https://epros.becertain.org) for a sample implementation monitoring template.

## STRATEGY B

### Identify site-level leadership to monitor changes to ePRO technology over time

In alignment with implementation and change management process, identifying a champion who can monitor changes can help sustain ePROs tool use over time. ePRO tools are often part of a larger technology ecosystem within a healthcare setting, and changes to other technologies can affect how well ePRO tools function over time. For example, changes to patient portal functionality could impact how patients access ePRO questionnaires. Changes to clinical order sets might affect how ePRO data is cataloged and stored within the electronic data warehouse. The maintenance of ePRO tools beyond their initial launch should reside with the clinical teams that use them most; that way, the status of ePRO tools is taken into account as broader changes are made to tools that impact care delivery. In parallel, though, there should be strong communication pathways between the clinical teams managing ePRO implementations and the PROs governance teams that can enable broader support for communication, standardization, and resource allocation as ePRO use scales beyond single settings.

Beyond maintenance of established ePRO tools, ePRO technology itself is advancing. As project teams design ePRO tools, they may encounter functionality needs that are out of scope or not fully developed. ePRO project teams, in partnership with PRO governance teams, as well as with teams that govern other aspects of health system technologies (patient portal, data and analytics, etc.), may develop a roadmap that documents future ePRO functionality needs and that ensures project teams are alerted to advances in ePRO technologies (e.g., the release of new functionality by the ePRO vendor).

## STRATEGY C

### Ensure learnings from ePRO implementation and use are communicated throughout the organization

Throughout implementation monitoring, project teams should report learnings back to PROs governance teams, healthcare leadership (administrative and clinical), and IT teams to support continuous learnings for future implementations, particularly around best practices for standardization of workflows and tools that can support health system efficiencies for ePRO use.

ePRO implementation efforts require support across different levels of the organization, from clinical and operational leadership to frontline staff to patient and family advocacy teams. Communicating lessons learned across these different levels serves to educate about work accomplished, challenges faced, and opportunities for future improvements. Broad communication also ensures that change does not occur in silos and that other teams across the organization learn from and build on prior experiences.

Surgical Site

- ☐ Cervical
- ☐ Lumbar

Patient Parameters

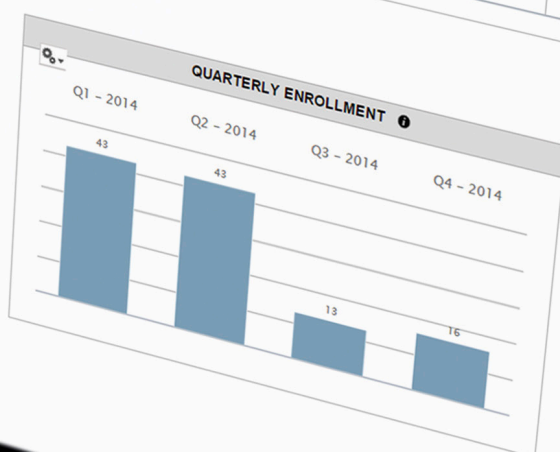
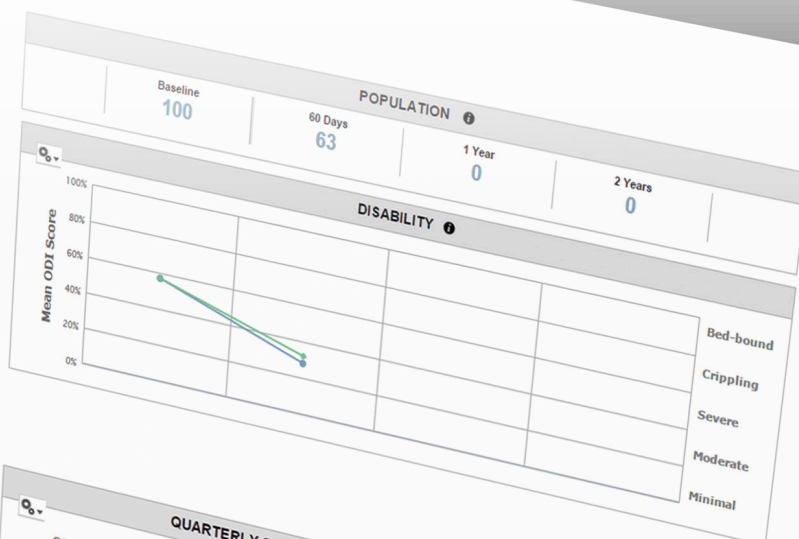
- ☒ Male
- ☒ Female
- ☒ Smoker
- ☒ Non-smoker
- ☒ Surgical
- ☒ Non-surgical
- ☒ Readmitted
- ☒ Not Readmitted
- ☒ Age Below 18
- ☒ Age 18 - 30
- ☒ Age 31 - 50
- ☒ Age 51 - 70
- ☒ Age Over 70

Submit

AT-A-GLANCE

DISABILITY

PAIN



# Chapter 4

## ePRO

## Reporting

## Chapter 4: ePRO Reporting

# Key Concepts and Background



### Learning Objectives

- Recognize that the concept of ePRO reporting includes both report design and report use.
- Explain the relevance of a user-centered design approach to reporting.
- Identify appropriate *content* elements for ePRO reports to help providers effectively assimilate ePRO into the care process.
- Identify appropriate *functions* for ePRO reporting systems to help providers effectively assimilate ePRO into the care process.
- Identify appropriate *presentation* elements for ePRO report interface design to help providers effectively assimilate ePRO into the care process.



### Use this chapter if you are

- Designing or redesigning ePRO reports
- Performing a root cause analysis of issues with the use or non-use of ePRO reports
- Intending to use ePRO reports in the delivery of care
- Generally interested in the design and use of digital reports in health care contexts



### Key Concepts



Data &  
Information



System Function  
& Interaction



Presentation



Using Reports

PRO measures are generally scored—whether manually or by an automated system—using a calculation based on validated algorithms. However, simply reporting the patient’s score to the provider is often not sufficient to fully support the patient care process (e.g., shared decision-making, ongoing condition monitoring).

This chapter provides an in-depth look at how ePRO reports can be constructed leveraging various types of ePRO content, automation, and visual presentation; this approach can increase the clinical usefulness of ePROs by examining the ways in which they can be transformed, appended, aggregated, and distilled. This chapter also recognizes that reporting consists of both report construction as well as meaningful, effective use.

## Need for guidelines

Robust literature exists to guide the design of reports and visualizations in other domains, but available models and guidelines do not adequately address considerations specific to the unique nature of electronic patient-reported outcome (ePRO) reporting in clinical practice. Stakeholder-informed guidelines regarding critical design considerations for ePRO reports and the use of these visualizations can support successful clinical integration of ePRO data. Such guidelines can assist both developers and implementation teams in key decisions regarding the content, visualizations, and functions associated with ePRO reports and their use across a healthcare system.

While a moderate degree of organizational customization may be needed for a system-wide deployment of ePROs in order to meet clinician expectations of utility and ease of use, some general considerations for ePRO reporting exist. The guidelines in this chapter provide these general considerations.

## ePRO reporting to providers

As the collection of ePROs increases across healthcare settings, so does the need to develop reports that incorporate effective mechanisms (e.g., visualizations) for bringing ePRO data to providers. Many providers perceive an ePRO system as a potentially valuable addition to augment their patient care process if it can meet their preferences for report design and if the ePRO workflow is streamlined.

Given the complex requirements for ePRO capture and use, ePRO systems must consider how to analyze and deliver actionable insights in the clinical context for a variety of audiences and purposes, including individual patient care and decision-making, clinical quality improvement, and population health.

This chapter takes the perspective of human-centered design of ePRO reports and their use, particularly use by front-line providers for clinical care purposes. The chapter includes design considerations for meeting requirements across diverse user groups of providers (e.g., different clinical specialties) and considerations for integrating ePRO data with electronic health record (EHR) data to provide meaningful reports that support the patient care process and quality of care. While we focus on providers as front-line users of ePROs adopted by health systems, we encourage readers to review the design guidelines with an eye towards what may be useful and applicable to their efforts regarding a human-centered approach to providing reports directly to patients.

## What is ePRO reporting?

ePRO reporting refers to the way in which PRO data is packaged electronically and used by providers. In an ePRO system, the patient enters the information into the system by providing answers to items from one or more PRO measures. In order to make this patient-entered data clinically actionable, it must then be reported to the patient's provider(s) in a clear and relevant way for providers to efficiently and accurately understand the reports.

But, the goals of ePRO reporting do not stop there. The ultimate goals of integrating ePRO reports into clinical care (i.e., into a patient encounter) involve enhancing existing knowledge and understanding with ePROs to move toward wisdom. Wisdom in the use of ePROs includes appropriate integration of ePROs into assessments of patient status, communications with patients in a shared decision-making process, and care coordination efforts.

**Figure 4A** Ideal ePRO reporting process (moving from data to wisdom)



Therefore, an ideal reporting process will progress from the collection of PRO data to wisdom gained from using ePRO reports effectively in decision-making and improving the care process, as outlined in **Figure 4A** and further described here:

- Data enters the system as patient scores of patient-submitted PRO measures.
- As data accrues, for example, by repeated collection of ePROs over time, a broader depth of information is available for interpretation. In an ePRO system, these steps may be accomplished through the system itself or entered into the system following manual collection of PRO measures from patients.
- The information can then be transformed and synthesized in various formats supported by the ePRO system in order to glean knowledge about patient condition. For example, a functional status measure collected over time following a procedure can be reported on a longitudinal graph that visually depicts each ePRO (see Guideline 12 for details about longitudinal information on ePRO reports). The graph can also be annotated with other salient data (e.g., patient comorbidities and medications) that adds further relevant clinical context to PRO information (see Guideline 14 to learn about adding contextual information to ePRO reports).
- Once the ePRO report is available for review, the provider can interpret the findings of the report (i.e., knowledge) that are most salient to patient care, thereby gaining intelligence.
- Finally, intelligence gained can be put to action in the care process as wisdom through application in medical decision-making and communication with the patient.

Enactment of this flow in patient encounters embodies the ePRO value proposition in the clinical care process.

## A user-centered design approach to reporting

The provider is an important lead and primary ePRO report user in enacting the described ePRO reporting flow. Effective design for ePRO reporting considers report content and presentation along with the users' mental model (i.e., a person's thought process about how they may use the report in the real world), affecting their interaction with the electronic reports and situations of report use. A user-centered design (UCD) approach to designing ePRO reports to support effective human computer interaction acknowledges content, situation, and the users' mental model by:

- placing the user at the center of the design
- focusing on users and their tasks early in the design process

- measuring usability empirically
- supporting an iterative approach, whereby a product is designed, evaluated, and modified with real users repeatedly in quick successive iterations

Health systems that employ a UCD approach to ePRO reporting facilitate the likelihood of well-designed reports, engagement from providers in the implementation process, and successful adoption and use of ePROs. The methods used to inform our guidelines and the guidelines themselves reflect a user-centered focus on the provider using ePROs to serve and engage patients in the care process. For additional insight on introducing user-centered design best practices (including developing user personas) into ePRO reports, see Chapter 5 Tools and Resources related to UCD.

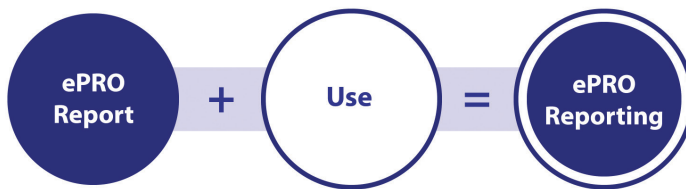
## Methods informing this section

As part of the larger ePRO action research effort described in the introduction to the design guidelines, this section was particularly informed by literature review (published literature on ePRO implementations) and in-depth interviews to arrive at insights regarding ePRO reporting. Twenty (20) in-depth interviews were conducted with providers (representing 11 medical and surgical specialties) at a large academic medical center with experience in using patient-reported outcome measures (PROMs). Drawing on a UCD approach, semi-structured interview guides explored the providers' design needs and preferences for ePRO reporting and the use of PRO data, as well as for issues related to reporting and visualizations identified through the literature review.

Our analysis of both the literature and the provider interviews identified recurring themes regarding issues and considerations critical to the usefulness and usability of ePRO tools by providers.

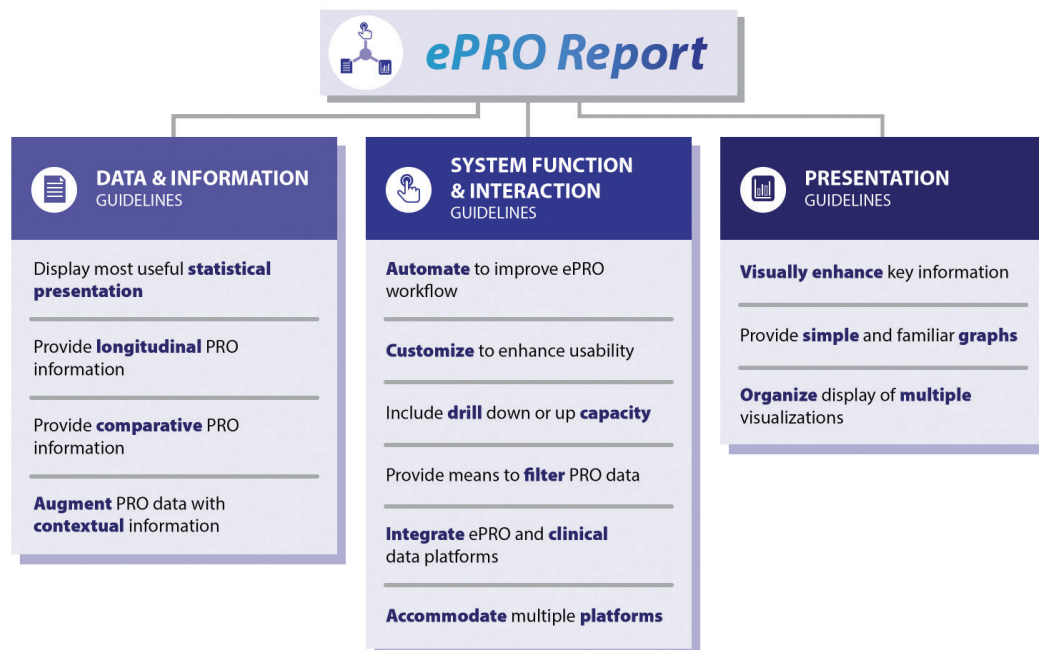
## The reporting guidelines: what to expect

Our analysis, as well as insights gathered from more generalized human-computer interaction and visualization domains, contributed to the development of a set of 14 guidelines that highlight key commonalities where standardization is possible for ePRO reporting, as well as situational nuances for which flexibility may be needed in the design of ePRO reports. As with much user-centered design work, these guidelines recognize that reporting is both a noun (report) and verb (use of the reports) as represented in [Figure 4B](#).

**Figure 4B** ePRO reporting: the noun and verb

Our analysis of the literature and interviews resulted in identification of 13 guidelines that span three key domains directly related to ePRO report design (**Figure 4C**). These are data and information (i.e., what type of data is provided), system functions and interactions (i.e., which capabilities are provided), and presentation (i.e., how data is visually represented). We provide a final guideline in this chapter related to ePRO report use that specifically focuses on effective access and interaction with the report in the context of a care encounter. Regarding the efforts needed to ready the provider and context to support appropriate and effective use of ePRO reports (e.g., training), we refer the reader to Chapter 3—Integration.

We provide multiple tables and graphs in this chapter to help the reader conceptualize the application of the ePRO Reporting Guidelines in ePRO reports. These graphs and tables convey the general nature of ePRO visualizations. The graphs and tables are not actual screen captures from ePRO reporting tools, nor do they represent actual PRO data.

**Figure 4C** ePRO report domains and guidelines

The following tools (found in Chapter 5, Tools and Resources) can help guide the application of the Reporting guidelines contained in this section. These tools can facilitate the discussion, direction and design of ePRO reports:

- ePRO functional requirements assessment for system design
- ePRO reporting design checklist

In addition to the references cited throughout the chapter, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

# ePRO Reporting Guidelines

## Guideline 11. Display most useful statistical presentation

PRO data is typically collected from patients in the form of a survey/questionnaire. Patient responses are usually a choice of pre-defined options made in response to an item (e.g., a question stem where someone responds to the level of agreement or experience, such as pain level) or a quantitative response to a question (e.g., how many times per week a symptom is experienced).

To provide meaning, these “raw” PRO survey responses must be summarized, organized, and analyzed to usefully derive information. The specific ePRO content (i.e., scores calculated through an algorithm that is specific to each PROM instrument) derived from raw data can be represented in various forms (e.g., raw score, standardized score). ePROs should be presented in an effective form that fits the context of use; otherwise, understanding and comprehension could be compromised.

### STRATEGY A

#### **Represent PRO data in ePRO reports in ways that enhance accurate interpretation and efficient comprehension for specific contexts of clinical care**

There are many ways to represent PRO data to appropriately reflect what is needed to support clinical use. In deciding how to represent PRO data in ePRO reports designed to support the clinical care process, designers should consider:

- the significance of the ePRO data to the clinical decision-making process within the domain of care
- the ways the ePRO report may be used within the care context
- what must be done to augment an understanding of the ePRO data (see Guidelines 14 and 21 in this chapter for additional information about supplementing ePRO data)

These considerations should guide the selection of the most appropriate forms to represent PRO data in ePRO reports.

**Table 4A** provides a list of options for representing PRO data along with considerations for aligning ePRO reports with clinical context and provider usability.

**Table 4A** Checklist for selecting how to represent PROM values

ePRO Representation Options	Key Considerations to Match Representations to the Clinical Context
<b>Individual item, subscore, and instrument score</b>	Does the clinical context call for... <ul style="list-style-type: none"> <li>The overall PROM score</li> <li>Domain scores (individual item scores aggregated to a subscore)</li> <li>Individual item scores</li> </ul>
<b>Unmanipulated score</b> (raw scores and weighted scores)	Does the clinical context call for... <ul style="list-style-type: none"> <li>Unmanipulated/raw PROM scores (generally, raw PROM scores are obtained by summing responses for items)</li> <li>Weighted scores (obtained by proportionally weighting individual items (or a domain/group of items) in the summation process)</li> </ul>
<b>Transformed, standardized, and norm-based score</b> (z-score standardization; t-score)	Does the clinical context call for... <ul style="list-style-type: none"> <li>Transformed scores, which are PROM scores obtained by converting the scoring range for the scale (e.g., z-scores). PROM scores may be transformed so that high scores define a favorable health state for all relevant scores.</li> <li>Norm-based scores, which are PROM scores that align the scale to normative values for a given population. Standardized and norm-based scores may allow the results of one PROM to be meaningfully compared with the results of other PROMs with differing raw scales.</li> </ul>
<b>Designated baseline</b>	Would it be useful to also include... <ul style="list-style-type: none"> <li>Baseline scores (to orient the provider in understanding patient progress)</li> </ul>
<b>Descriptive statistics</b>	Would it be useful to also include... <ul style="list-style-type: none"> <li>Mean</li> <li>Median</li> <li>Frequency</li> <li>Range</li> </ul>
<b>Quartiles</b>	Would it be useful to also include... <ul style="list-style-type: none"> <li>Quartiles to illustrate symptom intensity</li> </ul>
<b>Confidence intervals</b>	Would it be useful to also include... <ul style="list-style-type: none"> <li>Confidence intervals and p-values to discern significance</li> </ul>

(Continued)

ePRO Representation Options	Key Considerations to Match Representations to the Clinical Context
<b>Show differences in patient outcomes using unmanipulated (raw) scores or changes in score</b>	<p>Is it important to...</p> <ul style="list-style-type: none"> <li>• Show changes in PROM scores over time reported as raw scores</li> <li>• Show changes in PROM scores over time reported as the incremental change in score</li> </ul>

Some of the prevailing **challenges** for operationalizing the strategy are listed below, along with tactics to consider in addressing these challenges:

Challenges and Tactics Guideline 11	
Challenges	Tactics
<ul style="list-style-type: none"> <li>■ <b>Indicating scale direction</b> - PRO scales differ in whether a high score indicates a “favorable” health status.</li> <li>■ <b>“Good or bad” change</b> - How do we qualify change in score as positive or negative?</li> <li>■ <b>Provider Understanding</b> - Some providers may not be familiar with the PROs available and how they are scored.</li> <li>■ <b>Patient Understanding</b> - Raw numerical PRO scores may be difficult for patients to understand.</li> </ul>	<ul style="list-style-type: none"> <li>■ Provide additional means to contextualize PRO scores.</li> <li>■ Augment raw PRO scores with baseline or medically important difference benchmarks.</li> <li>■ Provide mouse-over (hover) text with additional information to explain PRO data.</li> <li>■ Provide simple, graphical representations.</li> </ul>

For additional insight on how to select and display ePRO statistics, see Chapter 5 Tools and Resources related to:

- sources for statistical representation of PRO scores
- data visualization

## Guideline 12. Provide longitudinal PRO information

In many cases, PRO data from a single point in time may not be sufficient to support patient-provider communication or decision-making. Monitoring PROs over time provides a broader view of a patient's health status that can facilitate timely intervention and inform future expectations as well as enhance follow-up care. Longitudinal visualizations of PROs provide a means to capture the progress of signs, symptoms, and outcomes in ePRO reports.

### STRATEGY A

#### Represent PRO data collected over time in longitudinal visualizations to improve its clinical usefulness

Longitudinal visualizations (e.g., graphs, tables) enable providers to view patient status as reported through ePROs, both as a specific point in time and as part of a trend. ePROs collected over time enable providers to trend PRO scores for a more holistic view of patient health. Longitudinal graphs and tables can be an effective means to illustrate patient trends and inform trajectory expectations. Longitudinal PRO data from one patient may also be valuable for comparing individual patient trends with trends from a reference population.

Representing longitudinal information can take many forms. [Figure 4D \(i-v\)](#) provides examples of how longitudinal information can be presented.

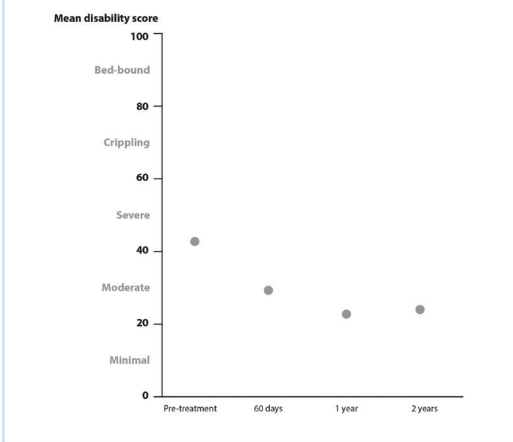


#### Quote from Provider Interviews

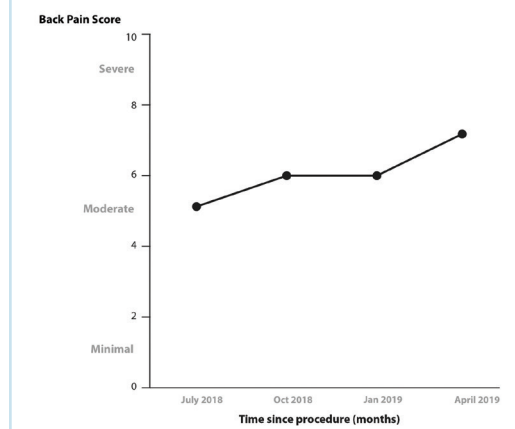
"It would be interesting for me to see [PRO data from] somebody from the time that I first started treating them...to really get an idea of how things are changing...if you've been seeing somebody for 10 years and their pain score has been the exact same the entire 10 years, to me, that gives you a lot of information about what to expect."

**Figure 4D (i-v)** Examples of presenting patient longitudinal trends

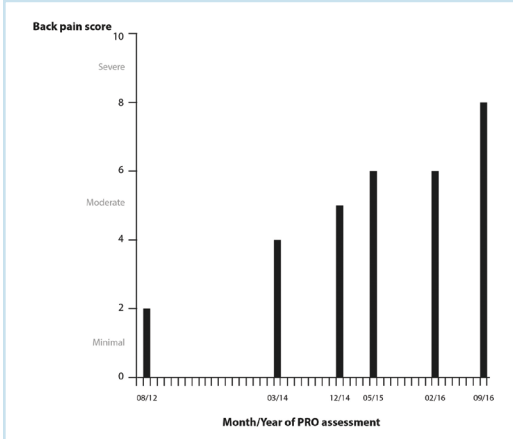
**(i). ePRO Longitudinal Points**



**(ii). ePRO Longitudinal Line Graph**



**(iii). ePRO Longitudinal Vertical Bar Graph**



**(iv). ePRO Longitudinal Table**

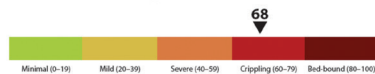
	Oct 2018	Jan 2019	April 2019
Pain			
Pain score	7	4	5
Pain score (mean)		5.5	5.3
Range		4–7	4–7

**(v). PRO Longitudinal Color Bar**

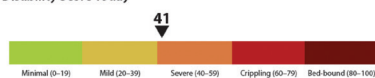
**Your results**

This report measures the level of pain you are experiencing at this time and will help you understand the degree to which your pain is affecting your ability to perform every day activities.

**Your Disability Score 60 Days Ago**



**Your Disability Score Today**



**Table 4B** lists factors to consider when providing PRO data longitudinally for provider use.

**Table 4B** Strategy considerations for providing PRO longitudinal data

Strategy Consideration	PRO Tips
<b>Time spans and intervals to display</b>	<ul style="list-style-type: none"> <li>May align with treatments, clinical benchmarks, or office visit schedules</li> <li>May vary by condition and clinical specialty</li> <li>Seem to provide easier orientation to the PRO timeline when axis labels use calendar dates rather than time from intervention</li> <li>Should be represented with proportional and consistent scaling to accurately reflect time between data points</li> </ul>
<b>Representing missing data</b>	<ul style="list-style-type: none"> <li>Can impact visual representations of trends and complicate interpretation. The impact may be mitigated when there is a clear, visual annotation regarding missing data.</li> </ul>
<b>Pre/post intervention status</b>	<ul style="list-style-type: none"> <li>Aids in clinical decision-making and helps providers communicate with patients about change in status over time</li> <li>Should clearly indicate whether the PRO was collected prior to or following an intervention</li> </ul>
<b>Trend lines</b>	<ul style="list-style-type: none"> <li>Show high level trends and generalities rather than precise representations of every change in patient status</li> <li>Can serve as a comparison to aid interpretation of individual patient scores</li> </ul>

Some of the prevailing **challenges** for operationalizing the strategy are listed below, along with tactics to consider in addressing these challenges:

#### Challenges and Tactics Guideline 12

Challenges	Tactics
<ul style="list-style-type: none"> <li><b>Partial Story</b> - Longitudinal displays may not tell the entire patient story.</li> <li><b>Trend line imprecision</b> - Connecting lines between measurement points may not provide a precise depiction of patient changes (especially when there are long intervals between measurement).</li> </ul>	<ul style="list-style-type: none"> <li>Provide access to additional contextual information (e.g., additional clinical data) to support patient-provider communication and decision-making.</li> <li>Use caution when interpreting the significance of trends and changes in scores over time.</li> </ul>

For additional insight on how to present longitudinal data on ePRO reports, see Chapter 5 Tools and Resources related to:

- statistical representation of PRO scores
- data visualization

## Guideline 13. Provide comparative PRO Information

Comparing PRO data from individual patients or groups of patients to reference groups (e.g., benchmark subpopulations or similar patients in a provider's practice) facilitates patient-provider communication regarding treatment progress, behavioral factors in intervention outcomes (e.g., the effect of smoking status), and the setting of expectations regarding interventions. Comparing a patient's individual PRO score with aggregate scores from similar patients, may be especially valued in some contexts.

### STRATEGY A

#### **Provide reports that compare individual patient data or patient group data with reference subpopulations to facilitate decision-making and inform patient care**

Providing ePRO reports that compare PRO scores (e.g., one patient or group of patients with a reference group of patients) facilitates understanding of patient status for clinical use of PROMs in patient care. ePRO reports can showcase various types of comparisons, as illustrated by **Figure 4E (i-v)**.

Comparison groups are matched by specified parameters, such as demographics or treatment type. Appropriate comparison groups for a patient or group of patients are dictated by the purpose of the comparison and the clinical context. Because defining a relevant group for comparison varies depending upon the clinical context, comparative ePRO reporting that offers options to filter data sets to arrive at appropriate comparisons may be most useful.

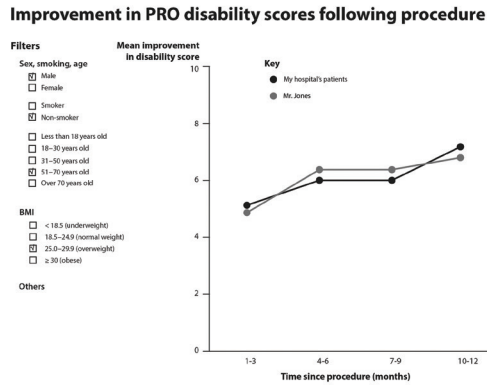


#### **Quote from Provider Interviews**

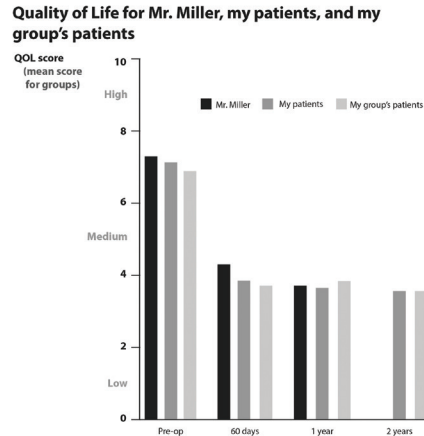
"If a patient is complaining of pain in a week or two after surgery and wondering, 'When is this going to end? How am I going to begin to feel better?' I think showing them on average other patients who have the same procedure, [who] recover at such and such time interval [would be helpful]."

**Figure 4E (i-v)** Types of comparisons in ePRO reporting

**(i). Line graph comparing one provider's patients with all other patients in a practice**



**(ii). Bar graph comparing one patient with all patients for one provider practice and with all patients in the practice group**



**(iii). Pictograph comparing one group of patients with another group of patients**

**Will you be helped by surgery?**

It is impossible to tell exactly what result you will get from surgery. However, doctors do know what happened to other people just like you.

People like you have a **50%** chance of having their symptoms helped by surgery.

A 50% chance means in the past, when doctors operated on 100 people like you, about 50 of them were helped by surgery.

Helped  
 Not helped



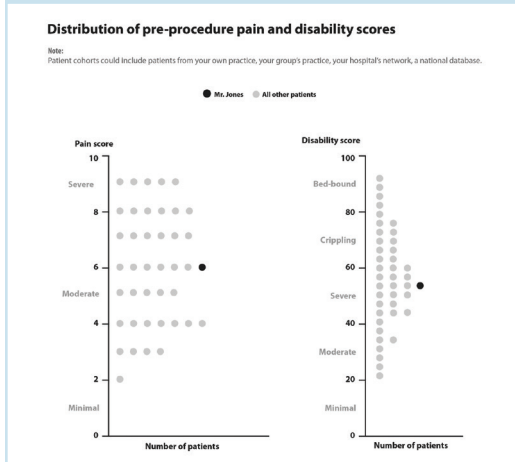
**(iv). Table comparing one patient with all other related patients in a hospital**

**Pre-operative level of pain and disability for Mr. Jones compared with my hospital's patients**

	Mr. Jones	My hospital's patients
<b>Leg Pain</b>		
Pain score	5	
Pain score (mean)		5.8
Range		2–9
<b>Back pain</b>		
Pain score	8	
Pain score (mean)		5.4
Range		1–9
<b>Disability</b>		
Pain score	52	
Pain score (mean)		51
Range		18–90

(Continued)

### (v). Scatter graph comparing an individual patient with all other patients in a practice



**Table 4C** lists factors to consider when designing ePRO comparative reports for provider use.

**Table 4C**

Strategy considerations for providing PRO comparative data

Strategy Consideration	PRO Tips
<b>Appropriate populations</b> (population, practice, provider)	Appropriate populations for comparison may include: <ul style="list-style-type: none"> <li>the general population (seeking general benchmark)</li> <li>patients within the same practice (particularly for comparing nuances in intervention practices) or</li> <li>the individual provider's patient panel (this patient compared with my average patient).</li> </ul>
<b>Identification of similar comparison groups</b> (diagnosis, intervention/treatment, symptoms)	Providers may define similar groups based on parameters including patient diagnosis, intervention/treatment, and/or symptoms).
<b>Importance of including patient characteristics</b>	Characteristics (e.g., demographics, socio-economic status, literacy) of the comparison group may be important in some circumstances, such as when comparing procedure complication rates.
<b>Accepted clinical benchmark exists</b>	When standardized expectations of outcomes exist for PROs, the standard outcome (e.g., blood pressure or A1C target) may be used as a comparator in lieu of or in addition to group comparisons to track patient progress.

Some of the more prevailing **challenges** regarding comparative content are listed below, along with tactics to consider in addressing these challenges:

Challenges and Tactics Guideline 13	
Challenges	Tactics
<ul style="list-style-type: none"> <li>■ <b>Selecting comparison groups</b> – It may be difficult to identify appropriate comparison groups.</li> </ul>	<ul style="list-style-type: none"> <li>■ Case mix or otherwise adjust comparison groups to derive appropriate comparison groups.</li> </ul>
<ul style="list-style-type: none"> <li>■ <b>Outliers</b> – Outlier data may skew comparison groups.</li> </ul>	<ul style="list-style-type: none"> <li>■ Provide the ability to select among comparison groups for various situational contexts.</li> </ul>
<ul style="list-style-type: none"> <li>■ <b>Appropriate comparisons can vary</b> – Even when common measures are used, the clinical context can mean different comparison groups are needed.</li> </ul>	<ul style="list-style-type: none"> <li>■ Determine whether the size of comparison groups/ patient population will require additional privacy measures.</li> </ul>
<ul style="list-style-type: none"> <li>■ <b>Comparing small populations/groups</b> – Small groups may necessitate greater data security to ensure patient privacy.</li> </ul>	<ul style="list-style-type: none"> <li>■ Consider including sample size, demographics, time of data collection, clinical setting, and benchmark information, to contextualize a comparison group.</li> </ul>
<ul style="list-style-type: none"> <li>■ <b>Contextual information</b> – Some comparisons may need additional information beyond PRO data for information to be clinically useful.</li> </ul>	

For additional insight on how to present comparative data, see Chapter 5 Tools and Resources related to:

- sources for statistical representation of PRO scores
- data visualization

## Guideline 14. Augment PRO data with contextual information

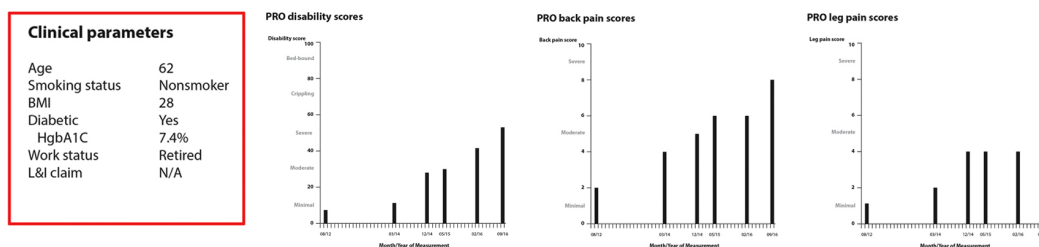
Augmenting PRO data with additional relevant information can add context and meaning to ePRO reports to enhance understanding and usefulness for patient monitoring and decision-making.

## STRATEGY A

### Include key augmenting information in ePRO reports to enhance understanding of patient context and meaning of PRO data

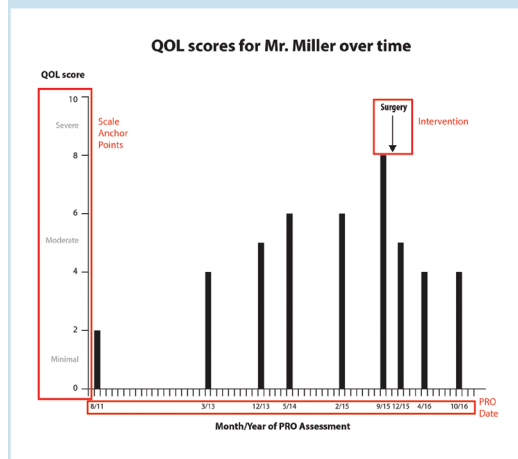
Various information sources (e.g., clinical data, practice guidelines) may be relevant and useful for augmenting PRO data to provide a holistic view of patient status. For example, annotating ePRO reports with clinical data (e.g., time of surgery) and demographic data can facilitate their usefulness, particularly in contexts involving an intervention (see [Figure 4F](#)). In addition to clinical data, there are many forms of contextual information (e.g., dates, qualitative score labels, timing of interventions, descriptive notes about patient scores) that may help contextualize PRO data presented in ePRO reports, as illustrated in [Figures 4G and 4H](#).

**Figure 4F** Clinical parameters (in red box) supplement PRO data presented in graphs



**Figure 4G – 4H**

**Figure 4G: Supplemental contextual information in red boxes**



**Figure 4H: Descriptive text — showing minimal clinically important difference**



The most relevant data to add will depend upon the clinical context, diagnosis, and other factors. **Table 4D** lists options to consider for supplementing reports with contextual information in various clinical contexts.

**Table 4D**

Strategy considerations for contextual information in a clinical context

Strategy Consideration	PRO Tips
<b>Minimal clinically important difference (MCID)</b>	MCIDs (as opposed to statistically significant differences) reflect changes in a clinical intervention that are meaningful for the patient (i.e., may result in a change in patient management). Indicating MCID with a visual cue (See <b>Figure 4F</b> ) can help providers discern meaningful changes in PRO scores.
<b>Logistical information</b>	Logistical information about the collection of the PRO score can help to facilitate accurate interpretation. Such information may include: <ul style="list-style-type: none"> <li>• Date of score</li> <li>• Date of intervention</li> <li>• Time before/since intervention</li> <li>• Annotation of baseline score</li> <li>• Reference values/text to anchor PRO score to context (e.g., severity level)</li> </ul>
<b>Scale interpretation cues</b>	Contextual information to help interpret PRO scales may include: <ul style="list-style-type: none"> <li>• A key or legend describing scoring method</li> <li>• Reference values/text to anchor PRO score to context (e.g., severity level – such as minimal, moderate, severe, crippling, bedridden)</li> <li>• Upper and lower normal range thresholds</li> </ul>
<b>Cues to designate improved versus worsening score</b>	An increase in score for certain PRO instruments represents a positive change, whereas on other instruments, an increase in score may represent a decline. Visual cues to provide clarity may include: <ul style="list-style-type: none"> <li>• Reference values</li> <li>• Clinical qualitative definitions (e.g., severe)</li> <li>• Color to distinguish between positive and negative score changes (see Guideline 21 regarding use of color)</li> </ul>
<b>Additional patient-provided data</b>	Patient-provided data that can aid in accurate interpretation may include: <ul style="list-style-type: none"> <li>• Photographs (series over time has been noted as particularly useful)</li> <li>• Qualitative statements that accompany a score allowing the patient to provide additional explanation of symptoms and activities</li> </ul>
<b>Clinical data</b>	Data from the patient's health record can support a more complete picture, enabling decision-making related to clinical program development and modification. Data may include:

(Continued)

Strategy Consideration	PRO Tips
	<ul style="list-style-type: none"> <li>• Intervention (e.g., medication prescribed, type of surgery)</li> <li>• Additional providers within the patient's care network</li> <li>• Discharge symptoms (e.g., temperature, pain level, wound drainage)</li> <li>• Clinical conditions (e.g., diagnostic code, chronic conditions)</li> <li>• Demographic details</li> <li>• Lifestyle information (e.g., smoking)</li> <li>• Hospital admit and discharge</li> <li>• Lab results</li> <li>• Medical event (e.g., stroke)</li> <li>• Range of motion assessments</li> <li>• Vital signs and biomarkers (e.g., body mass index, blood pressure level)</li> </ul>
<b>Response instructions</b>	<p>Possibilities for enhancing score representation include augmenting graphical information with guidance on how to respond to scores or changes in scores. For example, these might include indications that additional diagnostics or consultation with a specialty care provider may be helpful.</p>

Some of the more prevailing **challenges** regarding comparative content are listed below, along with tactics to consider to address these challenges:

Challenges and Tactics		Guideline 14
Challenges	Tactics	
<ul style="list-style-type: none"> <li>■ <b>Including MCID</b> – Not all PRO scores have MCIDs available, or existing MCIDs may be difficult to apply.</li> <li>■ <b>Customization requirements</b> – Some systems require customization to include information to augment PRO data.</li> <li>■ <b>Balancing quantity of augmenting information</b> – Too much information can contribute to “visual clutter.”</li> </ul>	<ul style="list-style-type: none"> <li>■ Consider whether MCID adds meaningful information for clinical decision making.</li> <li>■ Determine system capabilities for augmenting PRO data. Weigh process and costs to benefits of customization.</li> <li>■ Determine what additional information is key to the clinical process to avoid clutter.</li> </ul>	

For additional insight on how to augment PRO data with clinical data on ePRO reports, see Chapter 5 Tools and Resources related to:

- statistical representation of PRO scores
- data visualization

## Guideline 15. Automate to improve ePRO workflow

Automated functionality can increase efficiency, productivity, and quality of ePRO reports. Automated functions typically perform routine activities with less variability and are less subject to typographical error caused by manual data entry. Furthermore, the ability to auto-populate entry fields can provide an efficient means of data entry and clinical notetaking compared with manual input. As a result, automation that minimizes direct human computer interaction can make more efficient use of provider and support staff time while ensuring data quality and consistency in workflow.

### STRATEGY A

#### Automate ePRO reporting functions to improve efficiencies in user workflow

Automating functions of ePRO reports, such as selecting, populating, calculating, and reminding, can improve usability and reduce the workflow burdens associated with the use of ePRO reports. There are several ways to automate functionality to improve data flow and user workflow, such as:

- auto-populating fields based on patient EHR data or other previously collected data (e.g., intervention type/date)
- auto-calculating PRO scores, sub scores, and associated statistics
- automating the archiving of PRO scores accommodate future retrieval
- automating patient reminders for PRO collection
- automating patient messages and directives (e.g., care instructions based on PRO scores)
- automating orders by supplying smart sets of ePROs to be delivered to the patient that adapt to the specific provider or patient situation (e.g., conditional automation)

Identification and the use of defaults to introduce efficiency through auto-population can create challenges, since defaults are infrequently overwritten (i.e., manually replacing default data). This can be a problem when exceptions to the default exist (e.g., updated patient data) and failure to overwrite can result in inaccurate information. Some reasons why defaults may not be overwritten include:

- conditions mandating overwriting the default are not apparent to the user
- user assumption that defaults are always correct, fear of changing defaults, or paying attention only to fields where direct input is required



### Quotes from Provider Interviews

“Some sort of pre-processing that could happen with it so that it’s teed up a little bit better for the provider to say, yeah, your blood pressure numbers are still elevated, therefore I’m going to change this medication...and again the more electronic that you can make it the better... I can definitely imagine ways to make it slicker with less involvement of the providers from actively having to manage it.”

“It [the ePRO system] knows what I’m going to be looking for, it’s presenting those key things...it’s a step ahead of me in terms of clinical decision-making. It’s got the right timeframe and it’s showing me that I’ve gone three months and I’ve never done a PHQ9 before.”

## Guideline 16. Customize to enhance usability

Providing ePRO report functions that allow some degree of customization to a provider’s practice creates a user experience that connects providers and patients with the PRO information they need more quickly than relying on generalized reports that are not customizable to the provider’s needs. Thus, customization can enhance the utilization and impact of ePROs in the clinical context.

## STRATEGY A

### **Offer functionality that allows providers to customize ePRO reports to meet their needs and preferences for incorporating PRO data into their practice**

Because not all features of an ePRO report are desired or needed in each context of use, tailoring content to context ensures that reports present relevant information without unnecessary visual clutter, thereby increasing report utility. Allowing users to dynamically tailor ePRO reports to their own needs, rather than relying on default settings that may not fit every user, also reduces the cognitive load associated with interpreting PRO data.

Clinical context factors to consider in customization options might include the health concerns addressed by the PRO assessment, the clinical domain, the clinical setting, patient characteristics, and provider preferences. Even within one provider's practice, the desired PROs and ePRO report presentation may not be static but subject to the conditions they treat and their purpose for viewing the PROs. Because of this, flexibility to select options to tailor the report to the context is an important aspect of customizing ePRO reports. The following are means to enhance ePRO reporting through customization:

- tailoring dashboard views (e.g., the ability to switch to tab or storyboard view; see Guideline 23 for more detail)
- aligning to the provider's preferred visualization type (e.g., bar chart or line graph)
- allowing the addition of visit notes or clinical markers to PRO tables and graphics
- subordinating or hiding ePRO reporting content that is not directly relevant to the context
- zooming in/out to view shorter or longer periods of time
- altering the time intervals displayed

It is important to note that there is a limit to the extent of flexibility that is feasible to accommodate the permutations of ePRO report options (i.e., balancing standardization and customization). A prevalent challenge to providing customized options is the potential IT cost and resources required to introduce tailoring features into ePRO systems that do not intrinsically provide situational customization options.



### Quote from Provider Interviews

“What actually would be helpful is that you could toggle the amount of time that you’re looking at so your X axis could vary so you could have every score you’ve ever had going back to when I originally diagnosed you...versus let’s look at the last year versus let’s look at the last six months. Being able to zoom in and out as you needed to.”

For additional insight on how to augment PRO data with clinical data on ePRO reports, see Chapter 5 Tools and Resources related to:

- UCD (user-centered design)
- data visualization

## Guideline 17. Include drill down and up capacity

Users may desire varying levels of detail regarding PRO data. For example, one provider may want to assess sub-scores or individual item-level responses to PRO measures by drilling down from an overall score. Another provider may wish to examine PRO scores among a group of patients by drilling up to population-level scores across the same PRO measure. To support flexible means for users to analyze PRO data across and within PRO instruments and thereby enhance understanding, functionality is needed to decompose (drill down) and aggregate (drill up) various PRO scores.



### Quote from Provider Interviews

“I would most commonly like to see them all at once and then I will zoom into the ones that I care about.”

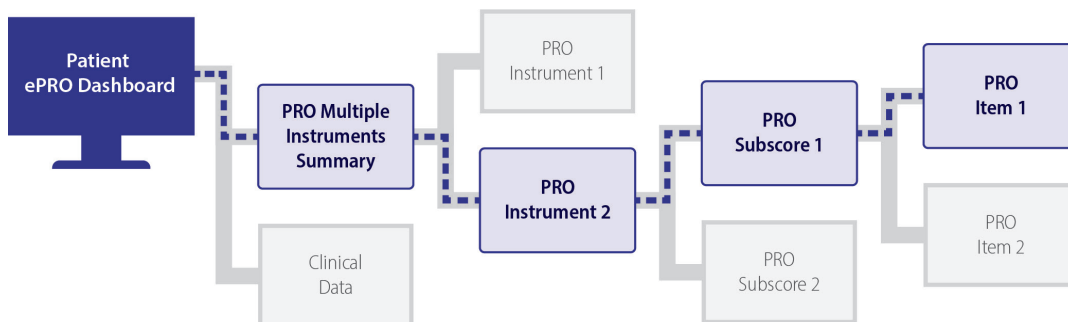
## STRATEGY A

### Provide drill down capabilities that allow users to zoom in to increasing levels of information granularity within ePRO reports

Generally, PRO instruments comprise multiple questions. In reporting PRO data, different levels of response detail are needed for various clinical situations and to present a complete picture. Sometimes the final score associated with an algorithm based on these questions (e.g., sum or mean of all question responses) is what is most clinically relevant, but there are occasions when more granular information may be useful. To make ePRO reports more valuable for clinical decision-making, reporting tools should include a means to drill down as well as drill up among the various levels of PRO data (e.g., allow providers to view various levels of PRO data detail including aggregated PRO scores, domain scores, subscale scores, and individual item scores).

Providing functionality that allows the user to navigate among levels of information offers the means to drill down from a summary page of PRO scores to a particular score of interest, and then to drill all the way down to individual items on a PRO instrument (as illustrated in [Figure 4I](#)). Drill down options for a PRO should be evident by visual cues embedded in the report (e.g., hover text indicating that drill down is available).

**Figure 4I** Flow of potential drill down levels beginning with dashboard



## STRATEGY B

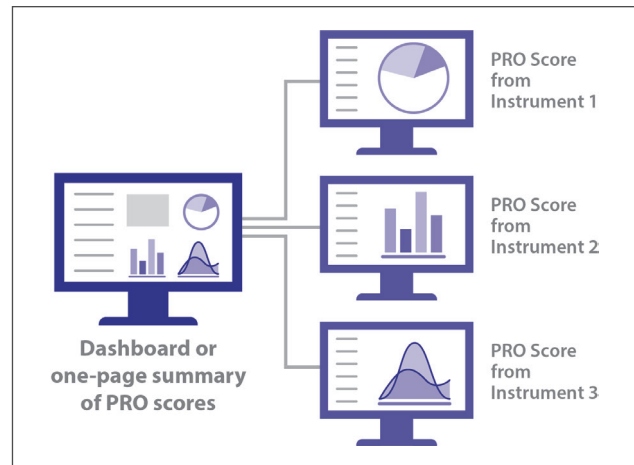
### Provide drill up (aggregating) capabilities that allow users to zoom out for a more comprehensive view of PRO data

Drilling up PRO scores by including PRO data from multiple assessment instruments on a single screen (e.g., multiple graphics on a dashboard) can also improve the clinical usefulness of PRO data. Various PRO assessments that can be aggregated on a dashboard may relate to one or more clinical domains.

**Figure 4J** depicts this type of aggregation.

**Figure 4J**

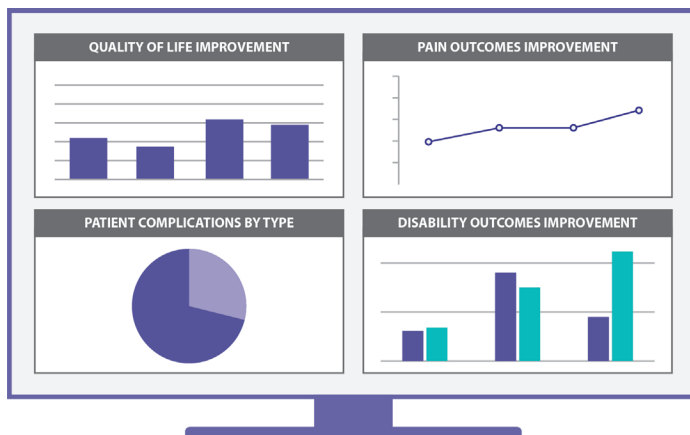
Flow of moving from aggregating multiple PROs on one dashboard/screen to individual PRO graphs



A dashboard can be used as a means to aggregate by serving as a summary page composed of various means of representing PRO scores (e.g., table or graphic) as well as scores from various instruments; this is similar to an aggregation of lab values in other contexts. **Figure 4K** depicts a dashboard that shows various types of graphics for individual PRO scores. Dashboards may provide a thumbnail visualization that can be selected to see larger/more expansive views of individual graphs.

**Figure 4K**

Various types of graphics on one dashboard



## Guideline 18. Provide means to filter ePRO data

ePRO reporting should provide data filtering functionality that allows users to view specific subsets of PRO data and exclude other data in a specific ePRO report. Data filtering functionality accommodates choosing a smaller part of the ePRO data set and using that subset for viewing or analysis. The resulting report (referred to as a view) is generally (but not always) temporary, meaning the data is kept, but the report image is temporary. The goal is to support ways to extract only what is relevant to the purpose at hand while delivering an engaging user interface.

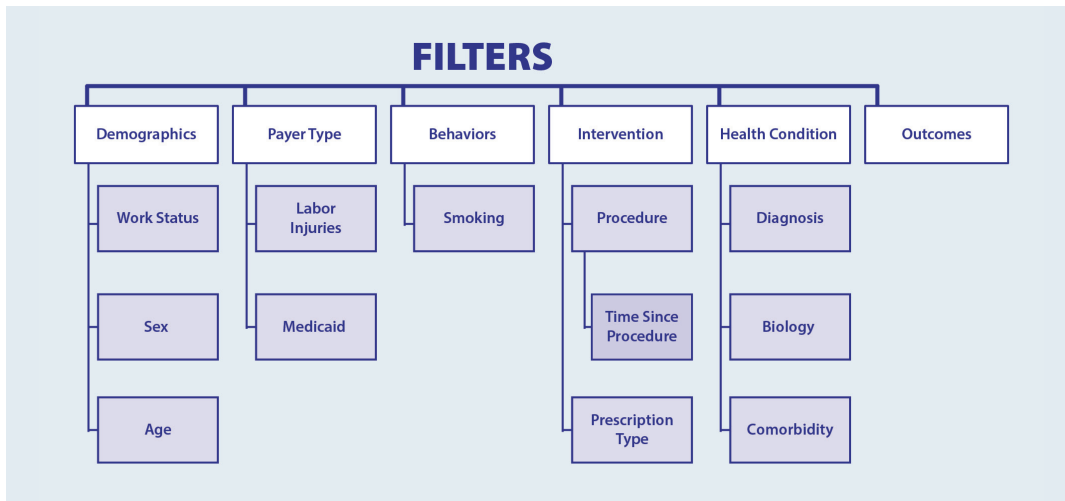
### STRATEGY A

#### **Provide ePRO data filtering as a form of data analytics to return report views showing subsets of data that support subgroup analysis**

As a data analytic technique, filtering functionality facilitates patient comparisons (for detailed information on comparative PRO data see Guideline 13), decision support in consideration of PRO data, and sometimes setting the stage for predictive analytics. For example, when working in a clinical context, filtering ePRO data for outcomes based upon patient characteristics (e.g., age, comorbidities, smoking status) may bring insight into decisions about whether to initiate an intervention. **Figure 4L** illustrates some examples of filters identified through provider interviews and literature to produce various types of ePRO reports.

One of the challenges when filtering ePRO data to make comparisons among subpopulations is to resist the tendency to jump to predictive conclusions and causality when sufficient data does not exist. While patient characteristics (see examples in **Figures 4L**) can be identified and used for filtering to identify ePRO subpopulation data and compare filtered data sets, true predictive analytics are not always possible. The data in the ePRO system may not meet the data set size required for some statistical analyses for predictive analytics. For filtered comparison, the subpopulation size included in the filtered report should be disclosed on the ePRO report in order to avoid the danger of making associations that may not be statistically supported. Discussions among clinical and data science communities should inform recommendations about the size of data sets required to provide desired analytics to prevent inappropriate interpretations of data.

**Figure 4L** Filter option examples

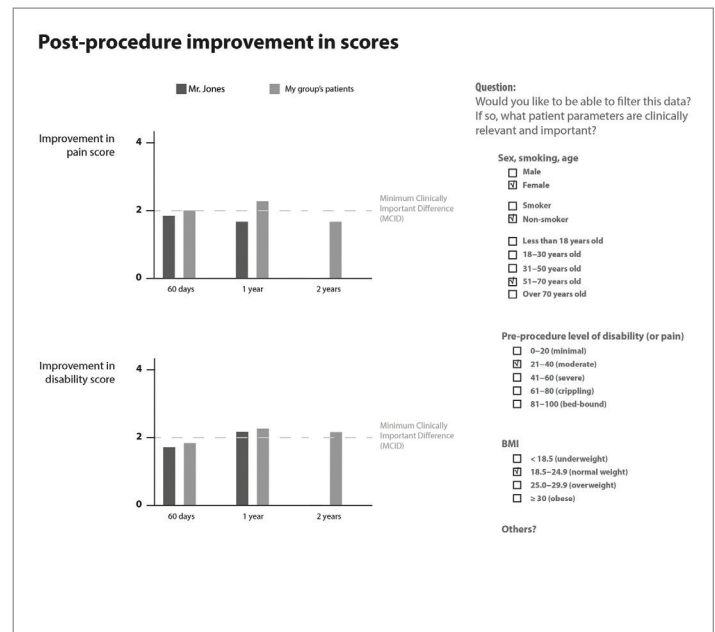


Another **challenge** for providing filtering functionality in a quick, efficient way (e.g., shown as selections from a pick list of patient demographics and characteristics on ePRO reporting systems) is determining what patient characteristics or demographics to offer as filter option(s). Relevant filter options are frequently driven by specialty and practice contexts.

Designers should balance the size of the pick list of filtering characteristic choices (i.e., the parameters available for selection) with the need to conserve both screen real estate and the effort required on the user's part in selecting filter parameters. **Figure 4M** provides an example of an ePRO report with a pick list of filter options. To rightsize the number of filtering options, consult with users and other stakeholders regarding what to include (and what filtering defaults to provide) for various ePRO reports.

It is of note that filtering data is only one aspect of data analytics. Aggregating various types of PRO data and coupling PRO data with other data sources (e.g., social determinants of health and EHR elements) can be used more extensively to support analytics and predictions that inform individual patient and population health.

**Figure 4M** Filtering options to the right of resulting graphs



## Guideline 19. Integrate PRO and clinical data platforms

Integrating ePRO and clinical data platforms (e.g., patient data stored in the EHR) can support the patient care process by centralizing important and relevant information for patient care in a single location to support ease of access. This can be achieved by embedding ePRO reports within the EHR system (e.g., ePRO report access from a tab within the EHR) or presenting clinical data pulled from an EHR as part of an ePRO report.

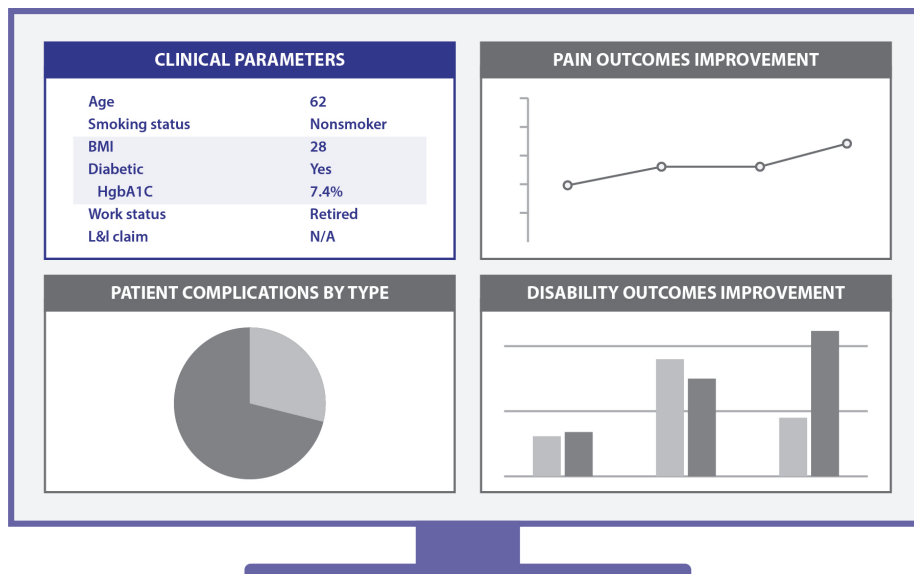
Integration of multiple forms of patient data can facilitate a holistic picture of patient health to assist decisions and communication related to individual patient care. The holistic picture afforded by integration can facilitate better service, increased robustness, and increased flexibility in using PRO data. **Figure 4N** provides an example of a dashboard that integrates PRO and clinical data to support a holistic perspective.



### Quote from Provider Interviews

“I think [clinical data] is useful information to get. It provides an important context for some of our patients.”

**Figure 4N** Dashboard integrating PRO and clinical data



Ideally, the clinical and PRO databases are constructed in a way that provides a functional pathway for compiling or otherwise integrating the data, but this is not always the case. The

feasibility of integrating PRO reports and EHR data varies by platform used. A feasible functional pathway is needed to accommodate pulling data from the respective sources for both of the following strategies.

## STRATEGY A

### Include EHR data in the ePRO report

Pulling clinical data from other systems (or system modules) into ePRO reports can help to contextualize PRO responses with clinical activities and results (e.g., length of stay, procedure-oriented complications, comorbidity). See Guideline 14 for more information about supplementing PRO data. Overall, ePRO data visualizations are complemented and contextualized by this information. Presentation and functional means to integrate clinical data within the ePRO report include:

- providing clinical data next to a graphical PRO representation
- showing clinical data in an ePRO report annotation
- providing the additional clinical information via a drop-down arrow (i.e., click to see more details)
- integrating PRO and clinical data in a dashboard
- creating a storyboard of the patient's journey of their health condition as a home page with clinical and PRO highlights. A storyboard is a visual sequence for displaying a story (e.g., a health journey) that can stimulate thought about each step of the patient's journey and focus attention on key components. This would allow providers to characterize the patient in terms of demographics, condition, treatment and response, and overall progress.

In addition, clinical data may be used as parameters for filtering PRO data to include only relevant subsets of information in requested reports, particularly for comparative PRO reports (see Guideline 18 regarding PRO filters and Guideline 13 for comparative ePRO reports).

One of the prevailing challenges in executing this strategy is determining what clinical and PRO data is most useful to coexist in a limited screen space. There is value in providing data from both sources in one view—it limits the need for providers to toggle between two screens to access needed information (e.g., by overlaying clinical and PRO data in a single ePRO report). However, this value may be undercut if the volume of data displayed becomes a hindrance to comprehension. A balance is needed regarding the amount of clinical data provided with PROs to avoid information overload and visual clutter.



### Quotes from Provider Interviews

“I look back and I say, ‘what was it that we changed that caused this to happen’ and I have to go digging to try and figure out what it was. If there was a way of saying there was an intervention and actually saying what that intervention was, and it was something that actually the system put into the tool for me so that I didn’t have to make that annotation that would be nice.”

“I think it helps whenever clinicians don’t have to go to two different programs or applications. If it’s right there with the rest of the labs or vital signs, it’s a lot easier to click on it, as opposed to opening it on a new application and remembering to do so.”

## STRATEGY B

### Embed ePRO reports within the EHR

Seamlessly embedding ePRO reports into the EHR can help to support a general clinical culture that recognizes the value of ePROs and ultimately integrates ePROs into standard clinical workflows. An organization that wants to integrate ePROs into existing clinical workflows may include ePRO reports, for example on an EHR flow sheet alongside EHR data. This presentation may include the use of clinical decision support queues related to ePRO scores (**Figure 40**).

**Figure 40** Flow sheet in EHR-related to PRO

For Clinic Staff	
Treat as below based on PHQ score and Depression Treatment Algorithm	
<b>0–9 (No to Mild):</b>	No action required
<b>10–14 (Moderate):</b>	Consider/address ALL of the following
	<ul style="list-style-type: none"> <li>Educate about depression, behavioral and treatment approach options</li> <li>Refer/recommend adding counseling</li> <li>Start, titrate, or adjust medication</li> <li>In EMR arrange for follow-up visit in 12 weeks</li> </ul>

(Continued)

≥ 15 (Severe):	Address ALL of the following
	<ul style="list-style-type: none"> <li>Educate about depression and treatment recommendations</li> <li>Start, titrate, or adjust medication</li> <li>Refer for psychiatric evaluation and medication review</li> <li>In EMR arrange for follow-up visit in 4 weeks</li> <li>Advise patient they will receive follow-up call in 2 weeks from Depression Care Program</li> </ul>

Some of the prevailing **challenges** for operationalizing these strategies are listed below, along with tactics to consider in addressing these challenges:

Challenges and Tactics Guideline 19	
Challenges	Tactics
<ul style="list-style-type: none"> <li><b>Cost</b> – Integrating ePRO with the EHR can be time consuming and costly.</li> <li><b>Technical capacity</b> – Not all EHR's have PRO modules or can easily integrate PRO data from outside systems.</li> <li><b>Free text difficulty</b> – Text fields are more difficult to integrate into ePRO reports than numeric or categorical data.</li> </ul>	<ul style="list-style-type: none"> <li>Review your EHR's capacity to integrate.</li> <li>Calculate if the IT time and resources available align with the benefits of integration.</li> <li>Provide a means for scanning or manually inputting the most important PRO data in the EHR.</li> <li>Use drop-down lists, where appropriate, in PRO and EHR systems rather than free text fields.</li> </ul>

## Guideline 20. Accommodate multiple platforms

To make ePROs more accessible to providers, ePRO reporting tools should be designed to accommodate the multiple computing platforms providers use for patient care. In addition to computing platforms, printed reports are needed in exceptional circumstances in which computing platforms are not available or where print is most optimal to support patient-provider communications.

## STRATEGY A

### Design ePRO reports for multiple computing platforms, including desktop and laptop computers, tablets, smartphones, and print to accommodate various clinical contexts and user preferences

Accessing patient data from different devices and computing platforms is common. Providers increasingly use smartphones and tablets in addition to traditional means (desktop computers and print) to improve the convenience and efficiency of clinical workflows. A busy provider may use tablet-based views to review patient data, while bedside charting often entails a desktop format. In addition, providers may use multiple devices (e.g., desktop or laptop computers) as they move from one patient location to another. Further, it is not uncommon that a provider references a paper-based report as part of the communication process with a patient to allow the patient to take the report with them after an exam. Therefore, ePRO reporting tools should accommodate multiple output platforms.

**Table 4E** illustrates considerations for common platforms that provide ePRO reports for provider use that might impact ePRO report layout, features, and security measures.

**Table 4E** Common platforms used in patient care

Platform	Considerations
<b>Print</b>	<p>Print can provide a convenient means to share PROs with a patient during or at the conclusion of a patient visit. Print may also serve as a backup means of receiving PRO surveys from patients who do not have access to or do not prefer electronic ePRO reports.</p> <p>A recognized challenge is the difficulty in transferring some visual cues (e.g., color, interactivity) from ePRO reporting to print while maintaining comparable effectiveness; meaning is sometimes lost. Another challenge is that print is not easily transferred into the EHR.</p>
<b>Desktop or laptop computer</b>	<p>While other platforms may offer providers easy access to PROs outside the clinic, desktop and laptop computers may be the best means of providing access to providers while they are working in the clinic or at the patient bedside.</p>
<b>Smartphone</b>	<p>Providing ePROs on a smartphone may be useful to providers who want to do a quick evaluation of the patient situation when other platforms are not convenient.</p> <p>However, the small screen of most smartphones presents a challenge, as some aspects of a visualization can be difficult to distinguish.</p>

(Continued)

Platform	Considerations
<b>Tablet computer</b>	<p>Our sources referenced the promise of this platform, but they did not report current widespread direct provider use for ePRO reporting. Projected increased use of tablets could combine aspects of desktop and smartphone utility.</p> <p>However, at present, tablets do seem to indirectly benefit providers in a clinical context by offering a means for patients to complete ePRO surveys in clinic while waiting to be seen. In addition, as ePRO reports become more directly available to patients, they may bring their own tablet devices into the clinical setting to share reports with providers.</p>

## Guideline 21. Visually enhance key information

Healthcare visits are often brief, making efficient review and synthesis of PRO data key. Visual cues can alert a provider to important aspects of a report. Appropriately executed, these enhancements increase an ePRO report's effectiveness.

### STRATEGY A

#### Prioritize key PRO information by using various visual elements (effects) to reduce cognitive load

Using visual cues (e.g., bolding, symbols, and color) can direct a provider's attention to important, urgent, or other primary PRO information. Visual cues may be used within ePRO reports to draw attention to:

- scores outside of a target range
- severity of scores
- scores requiring attention and potential clinical action
- a significant change in scores

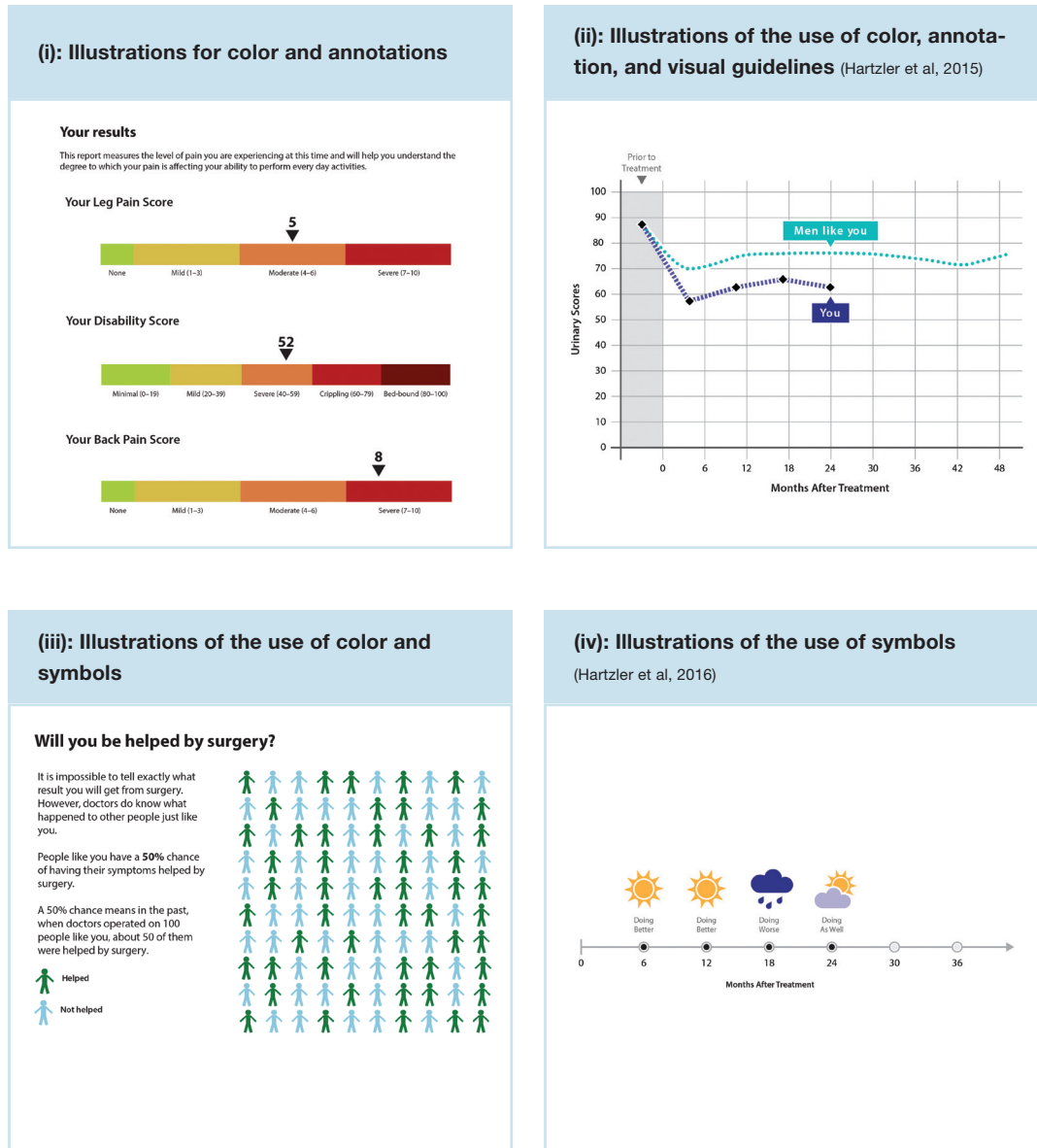
Enterprise systems (i.e., software applications designed to work broadly, not just in individual settings) should promote visual cue standardization to facilitate common understanding across the health organization. However, some exceptions may be necessary at the individual health unit level (e.g., the healthcare setting) to accommodate specific contextual nuances. Some strategies for applying visual cues to showcase key information are described in [Table 4F](#).

**Table 4F** Strategy considerations for applying visual cues

Strategy Consideration	ePRO tips
<b>Color — hue and value</b>	<p>Color is used to indicate the severity of PRO scores, to designate significant changes in score (via change in color), to provide a visual alert, or to indicate a patient's status in relation to the PRO assessment.</p> <p>The use of color should be judicious and attuned to potential challenges:</p> <ul style="list-style-type: none"> <li>• Traffic light colors (green, yellow, red) have been used with PROs to designate severity. While these color hues are familiar to most American audiences, other cultures may apply different meanings to them.</li> <li>• People with color vision impairment may have difficulty interpreting color, which limits the utility of color as a meaningful visual signal for certain users.</li> <li>• Color cues may become confusing or meaningless to the user when overused as an indicator to serve multiple purposes on the same ePRO report (e.g., using color to designate score severity, timing of PRO collection, improving versus worsening score, and hierarchy indicators on one screen).</li> </ul>
<b>Bolding</b>	<p>Bolding is most often used in ePRO reporting to enhance key text-based information that is part of an explanation; it may also be used for alerts or to set off ePRO report titles and subtitles.</p>
<b>Size of text or pictures</b>	<p>Larger text and pictures or graphs generally draw attention and signify more important information on ePRO reports and dashboards.</p>
<b>Annotation</b>	<p>Annotations are most often used in ePRO reporting to provide qualitative terms or explanations that complement quantitative data and are used to facilitate understanding and provide alerts.</p>
<b>Arrows</b>	<p>Arrows generally point to key elements of the PRO data. The number of arrows used should be minimized.</p>
<b>Shapes and symbols</b>	<p>Various shapes and symbols may be used to differentiate information, such as pre- and post-intervention PRO scores. Caution is needed to avoid the challenge of providing too many varying shapes and to ensure shape representation does not result in screen clutter and confusion.</p>
<b>In-text hovers</b>	<p>Explanations may be useful when providers are unfamiliar with certain aspects of a PRO or need reminders (e.g., how PRO scores are calculated, what are PRO benchmark scores). While useful to access when needed, this type of information is subordinate to direct PRO score information on ePRO reports. In-text hovers provide a means to subordinate these explanations, making them available only when a user places a cursor over a key word so that the explanation does not consume prime screen space.</p>

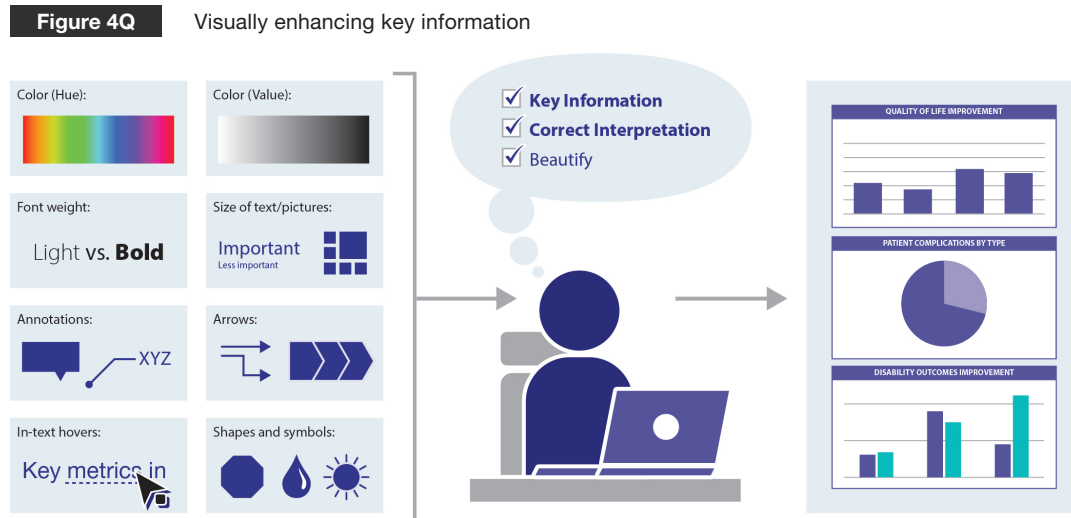
**Figure 4P (i-iv)** demonstrates that multiple forms of visual enhancement may be used in ePRO reports.

**Figure 4P** ePRO visual enhancements



The general challenge with introducing multiple visual enhancements in one report is to use the enhancements as complementary elements and avoid cluttering the screen in ways that create either visual or interpretive overload. **Figure 4Q** depicts the following goals to consider in making visual enhancement choices: Ensure that key information is clearly recognizable, may be easily

interpreted, and is appealing (i.e., beautification). Of these, in a choice situation, aspects of beautification may be best to forego, if there is a danger that key information may not easily be found or understood as a result of additional visual enhancements.



For additional insight on how to visually enhance key information on ePRO reports, see Chapter 5 Tools and Resources related to:

- data visualization
- UCD (user-centered design)

## Guideline 22. Provide simple and familiar graphs

Providing ePRO graphics in formats that are generally familiar to the public (e.g., a line graph) can help providers quickly understand and integrate the information being presented during a patient encounter, thereby improving the clinical usefulness of PRO data.

### STRATEGY A

**Promote general understanding and quick interpretation of ePRO reports by using simple, familiar graphs**

Providers generally have limited time to digest PRO information before meeting with patients and are primarily looking for trends and general comparisons in their review of ePRO reports for clinical care. Providing simple, commonly recognized graphs increases both the accessibility and efficient uptake of information presented to providers, which supports the clinical use of ePROs in busy healthcare delivery settings. In addition, in the spirit of patient engagement, when providers share ePRO graphics with a patient during a patient encounter, they need graphic formats that patients can easily understand.

It is crucial for designers to recognize the dynamics of the clinical use of PROs (time constraints, purpose, and patient sharing) and the need to balance simplicity with detail. Graphic choices generally should be simple (easy to interpret) yet presented in a way that enables users to discern trends and relative comparisons. As a result, line graphs and bar graphs are often an appropriate choice for displaying longitudinal and comparative PRO data (Table 4G). If patient engagement is a core driver of the use of ePRO graphics, pictographs (Table 4G) may be appropriate for graphics of PRO data being shared with patients.

Pie charts are another common type of graph; however, they come with some cautions when it comes to ePRO report application. While pie charts (Table 4G) may effectively show comparison in the case of a very limited number of properties, they lose their practical effectiveness as more comparators are added and additional screen space is needed to showcase the size and color of the contrasting wedges. For example, a pie chart may be an acceptable way to visually depict the proportion of people who experience a common side effect when starting a new medication. It becomes more challenging when we attempt to add details such as age, sex, or race to the pie chart to inform the provider about the patient and/or sub-population status or situation.


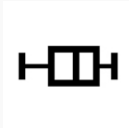

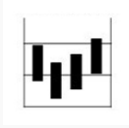
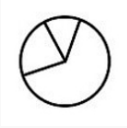


Caution is needed with simple, common graph types. For example, connecting PRO scores at points of time on a graph to form trending graph lines has intrinsic imprecision, particularly when patient status varies widely between the collection points. Furthermore, while trends and general comparisons may be detected with these graphics, they do not provide the level of precision and statistical detail supported by more complex graphics, such as a box plots. One must balance these cautions with the nature of the use of the graphs. While providers may prefer complex representations for research purposes to show distribution or provide statistical precision, it may take too much time to decipher more complex representations and statistical data during clinical encounters. Table 4G highlights graph types that may be more appropriate for precise analytical purposes.



#### Quote from Provider Interviews

“I think it has to be something that people have seen before and are able to interpret.”

**Table 4G** Example graph types for reporting PRO data

Graph Types (i)–(iv)	Graph Types (v)–(vii)
<p>Graph types (i)–(iv) (<b>line graph, bar graph, pie chart, and pictograph</b>) are generally considered easy to understand for the purposes of PRO clinical application to support patient encounters.</p>	<p>Graph types (v)–(vii) (<b>box plot, floating column graph, dot plot/matrix</b>) are generally considered to be suitable for more precise PRO analytical purposes.</p>
<p><b>(i) Line graph</b></p>  <p>Typically used for longitudinal PRO information; may be used for comparative PRO information with the addition of multiple lines</p>	<p><b>(v) Box plot</b></p>  <p>Typically used to show the distribution of data points.</p>
<p><b>(ii) Bar graph</b></p>  <p>May be used for either comparative or longitudinal PRO information</p>	<p><b>(vi) Floating column graph</b></p>  <p>Typically used for comparative PRO information</p>
<p><b>(iii) Pie chart</b></p>  <p>May be used for comparative PRO information</p>	<p><b>(vii) Dot plot/matrix</b></p>  <p>May be used for comparative or longitudinal PRO information</p>
<p><b>(iv) Pictograph</b></p>  <p>May be used for presenting comparative information</p>	

Some of the prevailing **challenges** for operationalizing these strategies are listed below, along with tactics to consider in addressing these challenges:

Challenges and Tactics Guideline 22	
Challenges	Tactics
<ul style="list-style-type: none"> <li>■ <b>Scale of X and Y axes</b> – The scale used to represent time (X axis) and PRO Score (Y axis) is critical to interpretation.</li> <li>■ <b>Choice among simple</b> – What if multiple graphs are “right” choices?</li> <li>■ <b>Missing data points</b> – Data is not always consistently reported by patients, which can lead to missing data points.</li> </ul>	<ul style="list-style-type: none"> <li>■ Carefully consider what time and PRO score scales support the clinical context.</li> <li>■ Provide graph type (e.g., bar or line) presentation options.</li> <li>■ Represent missing data points on visualizations (may be easier on a bar graph than line graph).</li> </ul>

For additional insight on providing appropriate graph and table visualizations on ePRO reports, see Chapter 5 Tools and Resources related to:

- data visualization
- statistical representation of PRO scores

## Guideline 23. Organize display of multiple visualizations

Displays that provide a visually centralized and aggregated view of multiple indicators of health status offer a collective perspective of data visualization not readily attained by viewing a series of independent, unconnected visualizations. In many clinical settings, providers can benefit from centralized access to multiple ePRO and clinical data graphs and tables, which may even be displayed simultaneously (e.g., dashboards). For example, following spine surgery, a surgeon may wish to see how changes in both pain and physical function have trended over time on one screen, as both are important outcomes related to the procedure. Providing centralized and organized access to the collection of relevant ePRO (and clinical data) visualizations can increase the use and efficiency of ePRO reporting.

## STRATEGY A

### Provide organizing structures that support a centralized display of the collection of ePRO (and clinical) visualizations relevant to a clinical context

To centralize the display of multiple types of ePRO and clinical visualizations, designers need to offer organizing structures. There are several possible ways to organize the centralization of multiple visualizations for ease of access and efficiency. Among these are tabs, menus, showing two or more graphs on one window, overlays of multiple PROs on a single graph, and dashboards (see [Figure 4R \(i-iv\)](#) for examples).

**Figure 4R** Organizing structure for presenting multiple ePROs



Nuances and tradeoffs exist for each of these types of organizing structures. For example, while presenting each ePRO report independently on one tab or menu option can help avoid information overload and screen clutter, toggling among tab or menu options also makes it more difficult to quickly digest the patient situation holistically. ePRO dashboards and overlays provide single-screen pictures supporting a more holistic perspective, but they need to be carefully designed to avoid overwhelming and confusing providers with too much information or clutter.

Thus, an overall challenge to using tools that organize the presentation of multiple ePRO reports (e.g., dashboards and overlaying multiple PROs on one graph) is to balance the amount and granularity of PRO information to be collectively presented on one screen, so that cognitive overload and confusion are minimized. Below are possible tactics that designers may want to consider in addressing the overall challenge of balancing, specifically when designing dashboards and overlaying multiple PROs on one graph.

#### Challenges and Tactics Guideline 23 — Dashboard



##### Challenges

- Balance the amount and granularity of PRO information to be collectively presented on one screen.



##### Tactics

- Minimize the number of tables and graphs on one dashboard.
- Include only key PRO information (i.e., recent PRO scores, PRO trends for key indicators, key demographics).
- Limit clinical information to only the most relevant items to complementing PRO information (subject to context, this may include recent diagnostic testing and admit/discharge dates).
- Showcase outlier information.
- Align time scales on all graphs and tables to facilitate rapid understanding.

#### Challenges and Tactics Guideline 23 — Overlay PROs on Graph



##### Challenges

- Balance the amount and granularity of PRO information to be collectively presented on one screen.



##### Tactics

- Limit the number of PROs presented on one visual (e.g., lines on a line graph) to two to three overlaid scores.
- Provide options to turn off or on the presentation of PROs on one graph (e.g., various lines on a line graph).

For additional insight on creating dashboards that include ePRO visualizations, see Chapter 5  
Tools and Resources related to:

- dashboard development

## Guideline 24. Model clinical use of ePRO reports

The value proposition of introducing ePROs to the clinical care process is contingent on not only the knowledge gained from well-designed ePRO reports, but also on the effective use of the reports to bring increased intelligence and wisdom into the care process. Reporting is the result of report design and use depicted in **Figure 4S** (further discussed at the beginning of this chapter). Unfortunately, not all organizations or even patient encounters will achieve the full potential of intelligent use of ePROs to increase wisdom in healthcare decision-making and care processes that may be gained. Indeed, the successful use of even the most well-designed ePRO reports is dependent on the characteristics and capacities of individual healthcare organizations and ePRO users.

**Figure 4S** Ideal ePRO Reporting Process (moving from data to wisdom)



Health systems are well advised to model strategies for ePRO report use to facilitate moving successfully from PRO data collection to ePRO report development to using the reports to improve patient care and shared decision-making efforts (i.e., to move from data to wisdom). Specifically, modeling successful use of ePRO reports can help avoid unintended consequences associated with the introduction of ePROs into the care process as well as enhance the potential positive impact of ePROs. Keys to this guideline and the concept of modeling include:

- the involvement of stakeholders to inform “use quality” (i.e., meaningful use) of ePROs within each health system and clinical specialty context
- a user centered perspective of ePRO use

## STRATEGY A

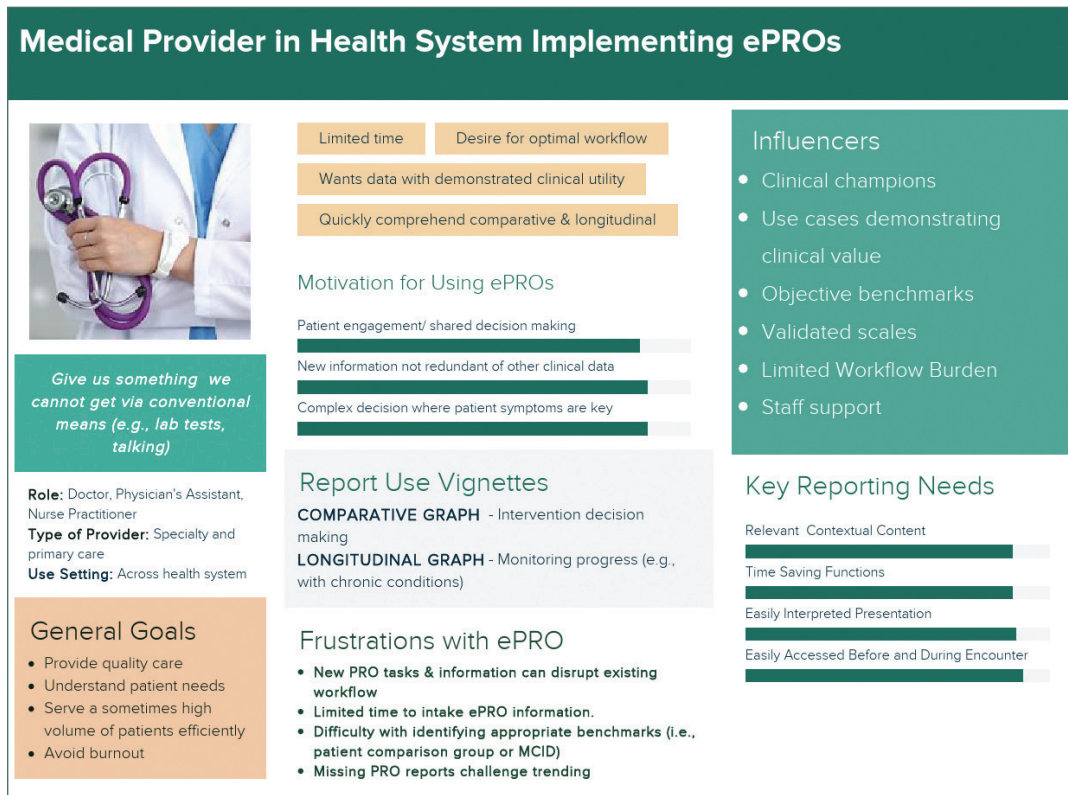
### Apply user-centered design techniques to model user, context, and workflow

A UCD approach attends to understanding user tasks and process (both current state and future state) and modeling the effective use of an ePRO report. Within the realm of UCD, understanding providers’ mental models (i.e., concepts of ePRO use) is integral to many aspects of developing an effective ePRO report and successful use process. Understanding the provider can help to motivate change, promote compliance, and/or recognize opportune moments where automation can assist.

UCD techniques, such as user personas, are structured ways of typifying a group of users in text and pictorial formats (i.e., conceptually modeling the end users). User personas go well beyond demographics, as they attempt to capture the user’s mental model, comprising their expectations, prior experience, and anticipated behavior. These models attempt to understand the intended users of technology—not just their demographics, but also how they think, feel, and behave, particularly in relation to a new or evolving technology.

**Figure 4T** presents the persona of a super-typical medical provider in a health system implementing ePROs evolved from our research. Among other things, the persona represented in Figure 4T highlights the providers’ general commitment to patient care as well as the challenges of introducing ePRO reporting into clinical practice, such as constraints on time and imperfect or non-existent measures or benchmarks in some domains. The persona also illustrates some of the motivations for using ePROs that may be shared and leveraged with providers, as appropriate, as well as potential influencers to motivate adoption (e.g., a clinical champion).

**Figure 4T** Super-typical medical provider persona, literature-based



Health systems can adapt the user persona presented in **Figure 4T** to their context as they consider ePRO reporting change management, report design, process modeling, and training. It would be beneficial for health systems to similarly model patients as users of ePRO systems to facilitate process and report design.

## STRATEGY B

### Showcase models of successful ePRO report use discovered in practice

Case studies that model successful ePRO report use can reveal best practices that provide guidance and further inspiration regarding how providers (particularly those new to ePROs) may successfully integrate the use of ePRO reports into their clinical encounter process. Stories and insights from peers and opportunities to shadow providers who regularly and successfully integrate ePRO reports into their workflow may also facilitate trust that the use of ePRO reports can make a difference in practice and provide value.

Quality use of ePROs may be enhanced if those involved with ePRO system design and implementation identify existing success stories within their health system (e.g., through the ePRO catalog process discussed in Governance Guideline 5 ) or in similar external practices very early in the process of adopting ePROs. ePRO teams can then facilitate structured opportunities, such as webinars and presentations, as well as informal networking to elicit and broadcast model practices and leverage the influence and enthusiasm of clinical champions. **Table 4H** provides some models for the use of ePROs identified through provider interviews that designers can share and look for in their own organizations.

**Table 4H** Models of ePRO Report Use

Model of ePRO Report Use	As described by providers:
<b>Pre-visit planning</b>	"Before I go in [to see the patient, I pull the ePRO report] to kind of tailor my discussion of what I'm going to talk about."
<b>Visual supplement to conversation</b>	"I'll sometimes pull that [ePRO report] up and say, well, I see this is what you said this time. This is what your total was last time. You know, that's an improvement or this is, you know, still an issue."
<b>Means to communicate forecasted trajectory</b>	"To forecast for them, this is where you can expect to be a year. This is on average where people are already a year following spine surgery. This is, you know, the likelihood that you achieve success pre-operatively."
<b>Promote interaction</b>	"Some patients asked me more about their prognosis and longevity than would have otherwise."
<b>Clinical decision/course of care</b>	"I think it might inform me ... it shows that patients who have had lumpectomies are faring worse in terms of their well-being than patients having mastectomy reconstruction. That might lead me to counsel people differently when they're choosing between those two options."
<b>Tailor focus of patient communication</b>	"...when I go in to chat with them, rather than me asking them a lot of questions, a lot of it's on the questionnaire. So, I could look at the questionnaire, and I can say, hey, I noticed this. This something that you've not brought up with [me] in the past. Let's chat about it."
<b>Patient counseling tool</b>	"I counsel patients that, looking in outcomes data, the people that smoke see improvements but not to the same degree as people who don't smoke. And so, I use that in my practice now for why you should stop smoking or why I won't do the surgery until you stop smoking... It's based on research in using those PROs to say, these are high-risk groups."

While the general value proposition for accessing ePRO reports is a net benefit, certain clinical situations may not justify sharing an ePRO report with the patient as part of the patient-provider communication process. One possible example is when discussion of the ePRO report may exacerbate patient stress or concern over health progress or status. For further discussion of exception situations where ePROs may not add desired levels of value, see the Integration section, Guideline 9 (Engage users in ePRO adoption and use).

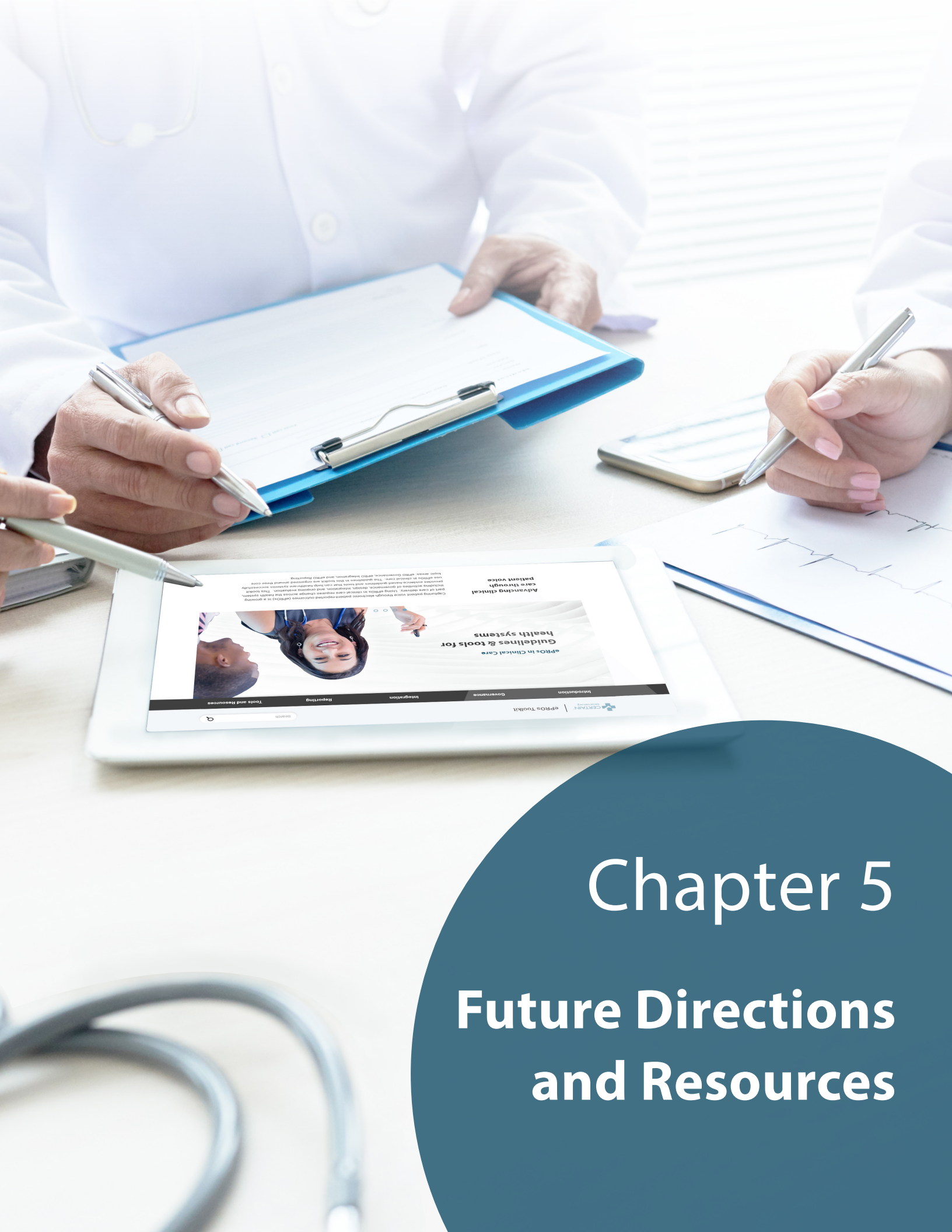


#### Quote from Provider Interviews

“Now if you don’t achieve success postoperatively, I’m not going to pull it [the ePRO report] back up and say, well you’re unfortunately not in a group that achieved success.”

For additional insight on introducing user-centered design best practices (including developing user personas) into ePRO reports, see Chapter 5 Tools and Resources related to:

- UCD (user-centered design)



# Chapter 5

## Future Directions and Resources

## Chapter 5: Future Directions and Resources

# Future Directions in ePRO Use

This toolkit comprises lessons learned from our own efforts to implement PROs within a large academic health system, lessons gleaned from the literature, and insights gathered through discussions with others involved in similar initiatives in healthcare systems across the United States. Over the course of this project, the landscape for capturing and utilizing ePRO data has continued to evolve.

Notably, the increased interest in capturing ePROs within different clinical settings has spurred discussions for how health systems can better coordinate efforts within and across the organization. We anticipate continued efforts among health systems to leverage technology-driven strategies for patient engagement. As a result, this will remain a fluid space for learning. Experience with ePROs, as well as with other forms of patient-generated health data, will produce new evidence for the advancement of patient-centered care. To support future directions, we highlight areas where practice-based learnings are needed to advance the use of ePROs and patient-centered technologies in clinical care.

**Table 5A** Challenges and recommendations for future ePRO work

Area	Challenges Facing ePRO Implementations	Future Directions
<b>Governance and leadership</b>	ePROs require multiple levels of health system governance. Supporting ePRO implementation through structured initiatives guided by multidisciplinary teams is important, but governance models are not well understood.	<ul style="list-style-type: none"> <li>Identify which governance models are most effective for different settings/systems</li> <li>Evaluate the impact of systemwide ePRO implementation on care quality metrics</li> <li>Evaluate how ePRO implementation supports contractual/quality reporting initiatives</li> </ul>
<b>Workflow and human factors</b>	Expanding the ability to collect data from patients outside of the clinical visit requires redesign of workflows to ensure patient care is safe, efficient, and high quality. Attention to how new workflows contribute to the efficiency of healthcare teams is also important.	<ul style="list-style-type: none"> <li>Identify workflow design standards that can support ePRO use across the health system</li> <li>Create guidance for involving patients and care partners in ePRO workflow co-design and implementation</li> </ul>

(Continued)

Area	Challenges Facing ePRO Implementations	Future Directions
		<ul style="list-style-type: none"> <li>• Explore how heterogeneity of user goals (diagnosis, severity, treatment plan, cadence of PROs) may impact design of workflows and tools</li> <li>• Understand how the capture of data outside of clinical care impacts the workforce with regard to burnout and workload</li> </ul>
<b>Technology evolution</b>	A “best of breed” ePRO technology does not exist. Challenges facing interoperability persist, further stifling advancement in ePRO and PGHD capture and use.	<ul style="list-style-type: none"> <li>• Expand use cases for how APIs and other tools can bridge gaps in EHR functionality for ePRO implementation</li> <li>• Design ePRO reporting tools to encompass implementation monitoring and evaluation needs at the clinic level</li> <li>• Design ePRO reporting tools to encompass implementation monitoring and evaluation needs at the health system level</li> </ul>
<b>Data-driven care and data science</b>	Clinicians and patients must know how to apply ePRO data to clinical practice and decision-making. Evidence on how PGHD improves care continues to evolve.	<ul style="list-style-type: none"> <li>• Create training resources for providers and patients to support score and visualization interpretation across clinical use cases</li> <li>• Generate real world evidence on how PROMs and PGHD may be used to inform decision-making</li> <li>• Consider the use of ePROs in leveraging predictive analytics to support population health, quality improvement, and process improvement</li> </ul>
<b>Citizen science and engagement</b>	Achieving patient-centered care through ePROs will require meaningful patient engagement. Health systems are not well poised to support patients acting in a partnership role.	<ul style="list-style-type: none"> <li>• Advance capacity for health systems to involve patient and community members in co-design of ePRO systems</li> <li>• Learn from citizen science culture and methodology to recognize innovative ways people leverage PGHD for healthcare</li> </ul>

## Conclusion

It is expected that the use and expansion of technology to drive improvements in the quality and efficiency of care will persist. This includes advancements in how patient-reported and patient-generated health data are captured and used to advanced collaborative and patient-centered care. Future endeavors will benefit from building a community of practice, inclusive of patients and community members, to advance research and knowledge translation around effective strategies. In this manner, as healthcare transforms, the patient voice will remain central to the journey.

# Tools & Resources

## Overview

In the following section, we have provided a selection of tools and resources that can supplement the content presented in this toolkit.

First, we have provided a set of questions that can be used to assess the reader's understanding of the key concepts presented throughout the toolkit ("**Check your understanding**"). These questions may be useful for an individual reader, a project team, or for ePRO-related training activities.

Second, we have provided an annotated list of external resources that have been referenced throughout the toolkit ("**Recommended Resources**"). This list includes a combination of peer-reviewed journal articles, external guides, and informational websites that readers can use for further exploration of the concepts and methods presented in this toolkit.

Last, we have provided a brief overview of the additional content that is available on the web version of this toolkit, including interactive tools to support the implementation of guidelines ("**Interactive Tools**").

The reference list for the toolkit may also be useful for recommendations for additional reading and current evidence from the field. We encourage readers to utilize the resources that best meet their needs.

## Check your understanding — Questions

The following questions may be a useful tool for individual readers or for teams working through the toolkit content. The correct question answers are provided in the next section.

### 1. Which of the following defines a patient-reported outcome (PRO)?

- ☐ a A patient's self-reported ability to perform the roles, tasks, or activities that are important to them given their current health status.
- ☐ b A clinician's interpretation of a patient's ability to conduct daily activities.
- ☐ c A patient's assessment of a research finding.
- ☐ d A clinician's interpretation of patient function based on radiographs collected prior to knee replacement surgery.

### 2. Which of the following is true about PRO data?

- ☐ a The primary purpose of collecting PRO data is to improve patient satisfaction scores.
- ☐ b PRO data can replace routine clinical labs used for diagnosis of chronic health conditions.
- ☐ c The development of new mobile platforms for tracking health and wellbeing is a noted barrier to PRO measurement.
- ☐ d Routine capture of patient symptoms via PROs can help facilitate discussions about the progression of a disease or a patient's response to treatments.

### 3. Which of the following can support health system efforts to understand stakeholder needs for PRO data?

- ☐ a Exploring how Smart on FHIR is being used in the health system.
- ☐ b Conducting a needs assessment to capture the current state of PRO use and information requirements for expanding future PRO use.
- ☐ c Reviewing the literature to see how research teams use PRO data in drug trials.
- ☐ d Integrating the PRO measures that are easiest to build.

- 4. Which of the following is true when structuring governance for how ePROs are used across a health system?**
- ☐ a Governance supports the health system's need to manage competing demands for clinical, IT, and administrative resources across different areas of clinical care.
  - ☐ b PRO governance should directly manage all technical configuration and application of ePROs within and across the healthcare system.
  - ☐ c PRO governance committees should be standalone structures that do not interact with existing leadership structures, so as to maintain autonomy over PROs work.
  - ☐ d Governance structures should be composed solely of members of health system leadership, such as medical directors, to drive culture change.
- 5. A headache clinic is interested in using PROs to track their patients' experiences with headache symptoms over time. Most of their patients are seen over a number of years throughout treatment and work with their providers to adjust different medications and lifestyle practices to help control and manage their headache symptoms. Which of the following best describes how PRO data supports care delivery in this context?**
- ☐ a PRO data is not granular enough for informing patient-level decisions.
  - ☐ b PRO data supports chronic management of headaches by understanding how headache symptoms change over time and the effectiveness of different treatment strategies.
  - ☐ c PRO data only serves to document symptoms for billing purposes.
  - ☐ d PRO data captures patient satisfaction with how the provider communicates treatment plans.
- 6. What are three critical areas of consideration when designing ePRO reports:**
- ☐ a Data and information, system functionality, and presentation.
  - ☐ b Location of patient, patient's age, and patient's diagnosis.
  - ☐ c Time of use, location of use, and PRO measure used.
  - ☐ d Number of providers in the practice, whether practice is single- or multi-specialty, and location of practice.

**7. Automating functions of an ePRO tool is beneficial because:**

- ☐ a Automation can make treatment decisions without the involvement of clinical teams.
- ☐ b Automation will decrease the cost of developing the ePRO tool.
- ☐ c Automation frequently results in improved efficiency, productivity, and data quality.
- ☐ d Automation always ensures complete data accuracy with zero risk of error.

**8. What type of graphical display can illustrate PRO data longitudinally for chronic care management for an individual patient?**

- ☐ a A display that only shows PRO data for a single time point (i.e., “today’s data”).
- ☐ b A display that shows trends in PRO data over time.
- ☐ c A display that compares PRO data for two populations at a specific time point (i.e., cross-sectional).
- ☐ d A display that compares aggregate PRO data for clinics and healthcare settings across a region (i.e., quality reporting).

**9. Which of the following is an example of how to visually enhance key information on ePRO reports?**

- ☐ a Using shapes to indicate the patient’s sex and age.
- ☐ b Overlaying multiple PRO scores on a single graph.
- ☐ c Using in-text hovers to provide information about other patients who responded to the same PRO measure.
- ☐ d Using color to indicate severity or significant changes in PRO scores.

**10. Which of the following correctly describes the key activities involved in an ePRO workflow?**

- ☐ a Send, complete, analyze
- ☐ b Collect, report, follow-up
- ☐ c Deploy, collect, track, review, document
- ☐ d Assign, collect, discuss, report out

**11. A rehab clinic has recently decided to implement an electronic survey to capture PROs related to pain level. The goal of their implementation is for patients to answer the PRO measure and report on their pain level for every visit so that their pain can be tracked over time. In preparing for their implementation launch, which of the following is an important consideration to ensure the rehab clinic gets complete PRO data capture for all patients at each visit?**

- ☐ a The need for multiple data collection modalities, such as having paper forms available.
- ☐ b How often they will need to report PRO data to support population health monitoring.
- ☐ c The clinical team's current process for reviewing lab results.
- ☐ d The provider workflow for visit documentation (e.g., progress notes, after-visit summaries).

**12. ePRO and clinical (electronic health record) data can be integrated to enhance patient care in which of the following ways?**

- ☐ a Incorporate ePRO reports into screens used in clinical workflow.
- ☐ b Use clinical parameters to filter ePRO responses appearing on an ePRO report that compares a patient with a group of similar patients.
- ☐ c Annotate clinical data on a longitudinal trend report of a patient's status.
- ☐ d All of the above.

**13. Membership comprising diverse experience and expertise within the organization is an important attribute for ePRO governance.**

- ☐ a True
- ☐ b False

## Check your understanding — Answers

### 1. Which of the following defines a patient-reported outcome (PRO)?

**Correct answer** **a**

A patient's self-reported ability to perform the roles, tasks, or activities that are important to them given their current health status.

**Rationale**

PROs capture the patient's voice and perspective about their experience with health status and disease symptoms, without any modification from clinical team members.

### 2. Which of the following is true about PRO data?

**Correct answer** **d**

Routine capture of patient symptoms via PROs can help facilitate discussions about the progression of a disease or a patient's response to treatments.

**Rationale**

PROs can provide contextualizing information about patients' experience with health and illness that can enhance clinical conversations and decision-making, especially when combined with other clinical data.

### 3. Which of the following can support health system efforts to understand stakeholder needs for PRO data?

**Correct answer** **b**

Conducting a needs assessment to capture the current state of PRO use and information requirements for expanding future PRO use.

**Rationale**

Planning a needs assessment starts with identifying and engaging the variety of stakeholders who will use PRO data both directly and indirectly. The scope of the needs assessment should reflect the various uses of PROs across different settings, which can include clinical decision-making, administrative quality improvement, incorporation into population health, and research activities.

**4. Which of the following is true when structuring governance for how ePROs are used across a health system?**

**Correct answer** **a**

Governance supports the health system's need to manage competing demands for clinical, IT, and administrative resources across different areas of clinical care.

**Rationale**

The increasing interest in using PROs for clinical care is one example where governance can support implementation efforts while keeping an eye toward needs and priorities of the system. This includes efficient stewardship of IT resources, evaluating efficiency and effectiveness, and ensuring the dissemination of shared knowledge and lessons learned.

**5. A headache clinic is interested in using PROs to track their patients' experiences with headache symptoms over time. Most of their patients are seen over a number of years throughout treatment and work with their providers to adjust different medications and lifestyle practices to help control and manage their headache symptoms. Which of the following best describes how PRO data supports care delivery in this context?**

**Correct answer** **b**

PRO data supports chronic management of headaches by understanding how headache symptoms change over time and the effectiveness of different treatment strategies.

**Rationale**

This use case represents how PROs can be used to support the management of chronic conditions. In this use case, the timeline for tracking the condition may be ongoing without a specified end date, and PROs may be used to help track the effect of small changes to treatment regimens and symptom monitoring overall.

**6. What are three critical areas of consideration when designing ePRO reports:**

**Correct answer** **a**

Data and information, system functionality, and presentation

**Rationale**

The three critical areas to consider when designing ePRO reports are what content will be included (i.e., data and information), what capabilities the system will provide (i.e., system function and interactions), and how the reports will look (i.e., presentation).

**7. Automating functions of an ePRO tool is beneficial because:**

**Correct answer** **c**

Automation frequently results in improved efficiency, productivity, and data quality

**Rationale**

Automated functions can perform tasks with less variability than relying on manual entry; this can improve data quality and also allow for more efficient and productive use of clinician and support staff time.

**8. What type of graphical display can illustrate PRO data longitudinally for chronic care management for an individual patient?**

**Correct answer** **b**

A display that shows trends in PRO data over time

**Rationale**

Displaying trends over time can allow PRO data to support the tracking of chronic condition symptoms and treatment adjustments.

**9. Which of the following is an example of how to visually enhance key information on ePRO reports?**

**Correct answer** **d**

Using color to indicate severity or significant changes in PRO scores

**Rationale**

Severity and significant change in PRO scores are key pieces of information that impact clinical care; using color to highlight this information can direct clinicians' attention to these important elements of an ePRO report.

**10. Which of the following correctly describes the key activities involved in ePRO workflow?**

**Correct answer** **c**

Deploy, collect, track, review, document

**Rationale**

All ePRO workflows contain five key activities or step: deploy (how the ePRO is sent to a patient), collect (how the patient enters their responses), track (how clinical teams track the completion status of ePROs), review (how clinical teams review ePRO reporting tools and apply to practice), and document (how ePRO data is stored for future use).

11. A rehab clinic has recently decided to implement an electronic survey to capture PROs related to pain level. The goal of their implementation is for patients to answer the PRO measure and report on their pain level for every visit so that their pain can be tracked over time. In preparing for their implementation launch, which of the following is an important consideration to ensure the rehab clinic gets complete PRO data capture for all patients at each visit?

Correct answer **a**

The need for multiple data collection modalities, such as having paper forms available.

Rationale

It is important to recognize that not all patients may be able to complete PROs electronically. Some patients may need the support of interpreters or assistive devices, and some clinics may not be equipped with kiosks or tablets in the waiting room. Implementation teams should plan for workarounds to ensure that data can be collected through multiple formats and still support clinical decision-making.

12. ePRO and clinical (electronic health record) data can be integrated to enhance patient care in which of the following ways?

Correct answer **d**

All of the above

Rationale

Integrating clinical data into ePRO reports can add value to clinical interpretation and decision-making.

13. Membership comprising diverse experience and expertise within the organization is an important attribute for ePRO governance.

Correct answer **a**

True

Rationale

An important aspect of governance is membership; ensuring diverse experience and expertise of stakeholders is critical when establishing governance structures for the use of ePROs.

## Recommended Resources

Items on the following list of Recommended Resources are presented in the general order in which they appear throughout the toolkit.

In addition to the references cited throughout the toolkit, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

### 1. ISOQOL User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice

#### Description

Before implementing any intervention or workflow into clinical practice, it is critical to clarify the goals and approach and to assess the resources available. This guide, developed by ISOQOL, provides different options for how to select PROM measures, as well as guidance on data collection and reporting for clinical practice. The purpose of this user's guide is to help clinicians who are interested in using PROMs in their clinical practice as a tool in patient management. A companion resource summarizes use cases gathered through stakeholder interviews into the dimensions outlined in the main user's guide.

#### Related to

Governance

#### Resources

- 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. <https://www.isoqol.org/wp-content/uploads/2019/09/2015UsersGuide-Version2.pdf>
- International Society for Quality of Life Research (prepared by Chan E, Edwards T, Haywood K, Mikles S, Newton L). Companion Guide to Implementing Patient Reported Outcomes Assessment in Clinical Practice, Version: February 2018. <https://www.isoqol.org/wp-content/uploads/2019/09/ISOQOL-Companion-Guide-FINAL.pdf>

### 2. PCORI User's Guide to Integrating PROs in EHRs

#### Description

ePROs can be reported and used in the context of a patient's other health data (e.g., laboratory reports, imaging studies, clinic notes) to promote patient-centered care. This guide provides recommendations for integrating ePROs into electronic health records, thus enabling use of PRO data for multiple clinical, research, and administrative applications, and thereby promoting patient-centered care. A multidisciplinary workgroup led by the Patient-Centered Outcomes Research Institute (PCORI) developed this guide, which builds on the ISOQOL user's guide.

(Continued)

**Related to**Governance,  
Integration**Resources**

- 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. <https://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records>

**3. ePRO Use Cases****Description**

The ability to scale PROs across healthcare systems has been limited by knowledge gaps around how to manage the diversity of PRO uses and leverage health information technology. This paper reports learnings and practice insights from UW Medicine's practice transformation efforts to incorporate the patient voice into multiple areas of care. This paper explores three PRO use cases (preventive care, chronic care management, and intervention assessment).

**Related to**Governance,  
Integration**Resources**

- Austin E, LeRouge C, Hartzler AL, Segal C, Lavalley DC. Capturing the patient voice: implementing patient-reported outcomes across the health system. *Qual Life Res.* 2020; 29:347-355. doi: 10.1007/s11136-019-02320-8. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Capturing+the+patient+voice%3A+implementing+patient-reported+outcomes+across+the+health+system&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Capturing+the+patient+voice%3A+implementing+patient-reported+outcomes+across+the+health+system&btnG=)

**4. Stakeholder Engagement****Description**

Seeking a range of perspectives and expertise in each phase of the ePRO implementation process helps ensure that stakeholder needs are identified and addressed. Many methodologies exist for planning and carrying out stakeholder engagement strategies. These resources provide information on stakeholder engagement, along with tools to build a stakeholder engagement plan.

**Related to**Stakeholders,  
Governance,  
Reporting,  
Integration**Resources**

- Institute for Patient- and Family-Centered Care - A Toolbox for Creating Sustainable Partnerships with Patients and Families in Research. <http://ipfcc.org/bestpractices/sustainable-partnerships/index.html>
- AHRQ Learning Modules: Engaging Stakeholders in the Effective Health Care Program. <https://effectivehealthcare.ahrq.gov/products/stakeholders-engagement-others/slides-2011-1>

## 5. Workflow

### Description

Introducing the integration of new technology into a healthcare setting is difficult and requires significant workflow planning and redesign to be successful. These resources provide basic information on workflow concepts, experiences of other organizations involved in health IT implementations, and practical tools for workflow assessment.

### Related to

Integration

### Resources

- HIMSS Toolkit - Workflow Redesign in Support of the Use of Information Technology within Healthcare. [https://s3.amazonaws.com/rdcms-himss/files/production/public/HIMSSorg/Content/files/workflow\\_redesign\\_030910.pdf](https://s3.amazonaws.com/rdcms-himss/files/production/public/HIMSSorg/Content/files/workflow_redesign_030910.pdf)
- AHRQ Workflow Assessment for Health IT Toolkit. <https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit>
- SADT: Marca, D., & McGowan, Clement L. (1988). SADT: Structured analysis and design technique. New York: McGraw-Hill. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=SADT%3A+Structured+analysis+and+design+technique.&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=SADT%3A+Structured+analysis+and+design+technique.&btnG=)

## 6. Technical ePRO Guides

### Description

There are many approaches to using technology for ePRO data collection and application. Once your health system decides on an approach, these resources can provide further information on technical specifications and considerations for technical integration within electronic health records or other technical platforms.

### Related to

Integration,  
Governance

### Resources

- Electronic Health Record Access to Seamless Integration of Patient-Reported Outcomes (EASIPRO). <http://EASI-PRO.org>
- Patient Reported Outcomes FHIR Implementation Guide. <http://hl7.org/fhir/us/patient-reported-outcomes/2018Sep/index.html>

## 7. Implementation and Evaluation Resources

### Description

Implementation is complex, and various models exist that support the applied implementation process, as well as formal evaluation. Relevant to ePROs are learning health system models that support real-world, complex interventions. The following resources are commonly used in healthcare delivery and research and may be dependent on preferences.

### Related to

Integration,  
Governance

### Resources

- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., & Hensley, M. (2011). Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and policy in mental health*, 38(2), 65–76. doi:10.1007/s10488-010-0319-7 [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Outcomes+for+implementation+research%3A+conceptual+distinctions%2C+measurement+challenges%2C+and+research+agenda.+Administration+and+policy+in+mental+health&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Outcomes+for+implementation+research%3A+conceptual+distinctions%2C+measurement+challenges%2C+and+research+agenda.+Administration+and+policy+in+mental+health&btnG=)
- Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A. Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, 4: 50. doi: 10.1186/1748-5908-4-50.
- Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R., & Shaw, S. (2017). Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. *Journal of medical Internet research*, 19(11), e367. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Beyond+adoption%3A+a+new+-framework+for+theorizing+and+evaluating+nonadoption%2C+abandonment%2C+and+challenges+to+the+scale-up%2C+spread%2C+and+sustainability+of+%E2%80%A6&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Beyond+adoption%3A+a+new+-framework+for+theorizing+and+evaluating+nonadoption%2C+abandonment%2C+and+challenges+to+the+scale-up%2C+spread%2C+and+sustainability+of+%E2%80%A6&btnG=)
- Cusack CM, Byrne C, Hook JM, McGowan J, Poon EG, Zafar A. Health Information Technology Evaluation Toolkit: 2009 Update (Prepared for the AHRQ National Resource Center for Health Information Technology under Contract No. 290-04-0016.) AHRQ Publication No. 09-0083-EF. Rockville, MD: Agency for Healthcare Research and Quality. June 2009. <https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/health-it-evaluation-toolkit-and-evaluation-measures-quick-reference>

## 8. Change Management

### Description

Change management is a necessary component of any HIT initiative. Change management theory applies a critical view to existing processes in health systems to understand organizational culture and climate and resistance to change. These resources describe the core concepts of change management, as well as tools and templates to help manage change.

### Related to

Integration

### Resources

- Canada Health Infoway - A Framework and Toolkit for Managing eHealth Change: People and Processes. <https://www.infoway-inforoute.ca/en/resource-centre/toolkits/change-management>
- The Heart of Change, John P. Kotter and Dan S. Cohen, Harvard Business School Press, Boston, 2002. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=i.%09The+Heart+of+Change%2C+John+P.+Kotter+and+Dan+S.+Cohen&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=i.%09The+Heart+of+Change%2C+John+P.+Kotter+and+Dan+S.+Cohen&btnG=)
- Lorenzi, N., & Riley, Robert T. (1995). Organizational aspects of health informatics: Managing technological change (Computers in health care (New York, N.Y.)). New York: Springer-Verlag. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Organizational+aspects+of+health+informatics%3A+Managing+technological+change+&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Organizational+aspects+of+health+informatics%3A+Managing+technological+change+&btnG=)

## 9. User-centered design

### Description

Underlying a user-centered design toolkit is advocacy for a user-centered design approach. These resources describe the concepts and importance of a user-centered design approach to the design of artifacts; methods and tools used to execute this approach are also included.

### Related to

Reporting

### Resources

- Still, B., & Crane, K. (2017). Fundamentals of user-centered design: A practical approach. CRC Press. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Fundamentals+of+user-centered+design%3A+A+practical+approach&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Fundamentals+of+user-centered+design%3A+A+practical+approach&btnG=)
- Mulder, S., & Yaar, Z. (2006). The user is always right: A practical guide to creating and using personas for the web. New Riders. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=The+user+is+always+right%3A+A+practical+guide+to+creating+and+using+personas+for+the+web&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=The+user+is+always+right%3A+A+practical+guide+to+creating+and+using+personas+for+the+web&btnG=)
- Tool used to create persona in Design Guideline 24. <https://xtensio.com/user-persona/>

## 10. Dashboard Design

### Description

Multiple ePRO visualizations (i.e., tables and graphs) can be presented on one screen via dashboards. These resources describe dashboard concepts, as well as best practices and methods in designing dashboards.

### Related to

Reporting

### Resources

- Few, S. (2013). Information Dashboard Design: Displaying data for at-a-glance monitoring (Vol. 81). Burlingame, CA: Analytics Press.
- LeRouge, C., Hasselquist, M.B., Kellogg, L., Austin, E., Fey, B.C., Hartzler, A.L., Flum, D.R., and Lavalley, D. (2017). Using heuristic evaluation to enhance the visual display of a provider dashboard for patient-reported outcomes. *AcademyHealth eGEMs (Generating Evidence & Methods to improve patient outcomes)*: 5(2), article 6. DOI:10.13063/2327- 9214.1283. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Using+heuristic+evaluation+to+enhance+the+visual+display+of+a+provider+dashboard+for+patient-reported+outcomes&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Using+heuristic+evaluation+to+enhance+the+visual+display+of+a+provider+dashboard+for+patient-reported+outcomes&btnG=)
- Dowding, D., Randell, R., Gardner, P., et al. (2015). Dashboards for improving patient care: review of the literature. *International Journal of Medical Informatics*, 84(2), 87-100. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Dashboards+for+improving+patient+care%3A+review+of+the+literature&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Dashboards+for+improving+patient+care%3A+review+of+the+literature&btnG=)

## 11. Data Visualization

### Description

Data visuals are included on most ePRO reports. These resources describe the data visualization concepts and theories, as well as best practices and methods in designing dashboards.

### Related to

Reporting

### Resources

- Kirk, A. (2019). Data visualisation: A handbook for data driven design. Second Edition (Revised Edition) edition, Sage. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Data+visualisation%3A+A+handbook+for+-data+driven+design&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Data+visualisation%3A+A+handbook+for+-data+driven+design&btnG=)
- Cairo, A. (2012). The functional art: An introduction to information graphics and visualization. New Riders. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=The+functional+art%3A+An+introduction+to+information+graphics+and+visualization.&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=The+functional+art%3A+An+introduction+to+information+graphics+and+visualization.&btnG=)
- Grossman, L. V., Feiner, S. K., Mitchell, E. G., & Creber, R. M. M. (2018). Leveraging patient-reported outcomes using data visualization. *Applied clinical informatics*, 9(03), 565-575. doi:10.1055/s-0038-1667041. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Leveraging+patient-reported+outcomes+using+-data+visualization.+Applied+clinical+informatics&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Leveraging+patient-reported+outcomes+using+-data+visualization.+Applied+clinical+informatics&btnG=)

(Continued)

- Arcia, A., Woollen, J., & Bakken, S. (2018). A systematic method for exploring data attributes in preparation for designing tailored infographics of patient reported outcomes. *eGEMs (Generating Evidence & Methods to improve patient outcomes)*, 6(1), 2. doi:10.5334/egems.190. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=A+systematic+method+for+exploring+data+attributes+in+preparation+for+designing+tailored+infographics+of+patient+reported+outcomes&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=A+systematic+method+for+exploring+data+attributes+in+preparation+for+designing+tailored+infographics+of+patient+reported+outcomes&btnG=)
- Lor, M., Koleck, T. A., & Bakken, S. (2019). Information visualizations of symptom information for patients and providers: a systematic review. *Journal of the American Medical Informatics Association*, 26(2), 162-171. doi:10.1093/jamia/ocy152. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Information+visualizations+of+symptom+information+for+patients+and+providers%3A+&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Information+visualizations+of+symptom+information+for+patients+and+providers%3A+&btnG=)

## 12. Statistical Representation of PRO scores

### Description

Quantitative PROMs are ultimately presented as scores and other forms of statistics on ePRO reports. These resources review key considerations in statistical representation of PROMs.

### Related to

Reporting

### Resources

- Davidson, M., & Keating, J. (2014). Patient-reported outcome measures (PROMs): how should I interpret reports of measurement properties? A practical guide for clinicians and researchers who are not biostatisticians. *Br J Sports Med*, 48(9), 792-796. [https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C48&q=Patient-reported+outcome+measures+%28PROMs%29%3A+how+should+I+interpret+reports+of+measurement+properties%3F+A+practical+guide+for+clinicians+and+researchers+who+are+not+biostatisticians&btnG=](https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Patient-reported+outcome+measures+%28PROMs%29%3A+how+should+I+interpret+reports+of+measurement+properties%3F+A+practical+guide+for+clinicians+and+researchers+who+are+not+biostatisticians&btnG=)
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## Interactive Tools

The content presented in this toolkit is also available online, at [epros.becertain.org](https://epros.becertain.org). The web version of this toolkit includes expanded content around the guidelines, as well as a collection of interactive tools that can support the use of these guidelines in practice. These tools include adaptable templates, worksheets, and checklists that can be tailored to the needs of individual project teams. For the full list of available tools, please visit [epros.becertain.org](https://epros.becertain.org); however, some examples of the interactive tools available include:

Tool Name	Related to	How It Could Be Used
<b>Stakeholder engagement planning tool</b>	Governance	This tool can be used to guide assessment of stakeholder perceptions and needs related to ePRO use across a healthcare organization.
<b>ePRO governance sample charter</b>	Governance	This template includes questions and considerations that can guide health systems in establishing ePRO governance teams and activities.
<b>ePRO functional requirements assessment for system design</b>	Governance	This tool provides a list of common ePRO functional requirements that may be considered in an assessment of technical capabilities.
<b>ePRO project intake checklist</b>	Integration	This checklist includes questions and considerations that can guide a project team in assessing the scope of a new ePRO project.
<b>ePRO sample implementation monitoring plan</b>	Integration	This tool provides a list of potential metrics and data definitions that can guide various phases of ePRO implementation monitoring and outcomes assessment.
<b>ePRO reporting functional requirements guide</b>	Reporting	This checklist contains key functional requirements to consider for ePRO reporting tools.
<b>ePRO reporting design checklist</b>	Reporting	This checklist contains key design considerations (content and presentation) to gather from each clinic/site regarding ePRO report needs and preferences.

We invite you to visit [epros.becertain.org](https://epros.becertain.org) to explore the additional content and resources available.

## Abbreviations

The following list includes terms that are frequently used throughout the toolkit.

Abbreviations		
<b>AHRQ</b>	Agency for Healthcare Research and Quality	<a href="http://www.ahrq.gov">www.ahrq.gov</a>
<b>AHIMA</b>	American Health Information Management Association	<a href="http://www.ahima.org">www.ahima.org</a>
<b>AMIA</b>	American Medical Informatics Association	<a href="http://www.amia.org">www.amia.org</a>
<b>API</b>	application programming interface	APIs enable information systems to communicate and transfer data among each other.
<b>EHR</b>	electronic health record	An electronic health record (EHR) is an electronic version of a patient's paper chart.
<b>ePRO</b>	electronic patient-reported outcome	Patient-reported outcome measures that are collected electronically.
<b>FHIR</b>	Fast Healthcare Interoperability Resources	A standard for exchanging healthcare information electronically, published by HL7.
<b>HL7</b>	Health Level Seven International	<a href="http://www.hl7.org">www.hl7.org</a>
<b>HRQoL</b>	health-related quality of life	Health-related quality of life (HRQoL) is an individual's or a group's perceived physical and mental health over time.
<b>ISOQOL</b>	International Society for Quality of Life Research	<a href="http://www.isoqol.org">www.isoqol.org</a>
<b>MCID</b>	minimal clinically important difference	Minimal clinically important differences are patient-derived scores that reflect changes in a clinical intervention that are meaningful for the patient.
<b>ONC</b>	Office of the National Coordinator	<a href="http://www.healthit.gov">www.healthit.gov</a>

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Abbreviations		
<b>PGHD</b>	patient-generated health data	Patient-generated health data (PGHD) is health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.
<b>PHQ-9</b>	Patient Health Questionnaire – 9	The PHQ-9 is a nine item questionnaire to assess the presence and severity of depressive symptoms.
<b>PROMIS</b>	Patient-Reported Outcomes Measurement Information System	Patient-reported outcomes measurement information system is a set of person-centered PROMs that support ePRO measurement across a range of important health domains including physical, mental, and social health. See <a href="https://healthmeasures.net/PROMIS">HealthMeasures.net/PROMIS</a> to learn more.
<b>PROMs</b>	Patient-Reported Outcome Measures	Patient-reported outcome measures (PROMs) are questionnaires that allow patients to directly report their experience with disease symptoms or well-being, without modification by a healthcare team member. PROMs can provide clinically meaningful and patient-centered insight into screening, diagnosis, and response to treatment.
<b>SADT</b>	structured analysis and design technique	SADT is an approach to workflow modeling based in systems engineering that describes systems as a hierarchy of functions.
<b>SMART</b>	Substitutable Medical Application and Reusable Technology	A standard for data access security.
<b>UCD</b>	user-centered design	User-centered design (UCD) is a method for technology design that focuses on the user experience throughout the design process.

## References

In addition to the references cited throughout the toolkit, we have provided an additional Supplemental Bibliography of resources that informed this work and may be useful to readers. Please visit the web version of this toolkit at [epros.becertain.org](https://epros.becertain.org) to access the Supplemental Bibliography.

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