PRO Planning Guide

An Implementation Planning Guide for Patient-Reported Outcome Measures

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See PRO Planning Toolkit Overview (below) for a full list of authors
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Notice:

This document is one component of a four-member set of PRO implementation planning “decision tools” comprised of the following documents:

1. The PRO Planning Toolkit Overview explains this set of documents more fully and provides a full list of authors and acknowledgements. This document also provides brief instructions for using these planning tools. https://doi.org/10.18131/g3-ejp7-cb85

2. The PRO Planning Guide includes structured lists of specific questions that should be answered to implement PROs as well as resources to aid in decision making. https://doi.org/10.18131/g3-0shy-pn30

3. The Decision Log based on the PRO Planning Guide was created to serve as a record of planning decisions. https://doi.org/10.18131/g3-vy44-c949

4. The Implementation Plan Template functions as a model for a clinic implementation plan. https://doi.org/10.18131/g3-fev6-hc15

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Preface

The following PRO Planning Guide was developed with the specific aim of providing PRO implementation guidance to three large university medical institutions. All three institutions were new to patient-reported outcomes (PROs), and all were implementing the Epic PROMIS app. This guide, therefore, is heavily focused on very early, pilot clinic implementations and on the Patient-Reported Outcomes Measurement Information System (PROMIS). However, the information it contains is generalizable to institutions and hospital systems that already have PROs in operation and to institutions and hospital systems wishing to use non-PROMIS PROs.

This guide has a companion document called the Decision Log, which reformulates the questions in this guide into a spreadsheet that can be used as an interview guide and as a means of recording decisions made during the planning process. Establishing a separate decision log for each clinic implementing PROs is recommended. An Implementation Plan Template is also available for use in transforming the information recorded in the clinic’s decision log into a readable, sharable implementation plan. The PRO Planning Guide, a blank Decision Log, and the Implementation Plan Template as well as an explanatory guide for the toolkit are all available at https://digitalhub.northwestern.edu/collections/e71c88e3-3a0b-4b56-90ce-8ddc75a78e81.

Introduction

The purpose of this PRO pilot implementation planning process is to prepare institutions that are new to PROs to roll out a set of measures smoothly in a single clinic, with a minimum of surprises and disruption at the time patients and clinical staff actually begin using PRO measures. By gathering the answers to the questions in this guide and doing the preliminary preparation work on paper, each site leader at each institution will be able to create a smooth implementation when the time comes.

This guide presents issues to be explored during the early implementation planning phase of PRO measures at each pilot clinic. This is a working guide, and it is intended to be completed by a site leader or by the person he or she designates.

A Focus on Pilot Implementations

This PRO Planning Guide is limited in scope due to its focus on implementation of PROs within pilot clinics at university medical centers that do not have established PRO implementation protocols. If your institution or hospital system
already has standardized PRO implementation protocols or pre-set options from which clinics may choose, please consult those protocols for best practices. For additional discussion concerning this topic, please see the section “How Will the PRO-EHR System be Governed.”

Implementation processes in this document focus on individual clinics rather than on institutional or hospital system-wide implementation. In addition, this guide is heavily focused on PROMIS measures. It is important to bear in mind that as an institution progresses to a greater number of PRO installations across multiple clinics and across multiple institutions within a larger hospital system, it will need to consider the trade-off between the efficiency arising from creating standard measure repositories used across clinics versus the customizability from allowing clinics to request unique measures matched to their operations. Rather than tackling the entire potential PRO implementation lifecycle, this paper focuses on more basic challenges such as stakeholder buy-in, determination of populations and approach, training, evaluation, and workflow changes. In all cases, although this PRO pilot initiative was initiated in specific clinics, the process has been designed to be generalizable and adaptable to the needs of other clinics for future PRO implementation.

Planning is Simultaneously Sequential and Non-Linear

Although you will want to proceed systematically, it’s important to note that implementation is not a chronological list of steps to follow. It will be necessary to jump forward and to circle back between the various planning stages to ensure that you capture all necessary information and that decisions are made that will customize the implementation for each institution. The conceptual diagram shown in Figure 1 illustrates both the general planning process and the necessity of revisiting and revising as you explore new territory at each stage of the process.
This guide is not intended to be read as a manuscript. Throughout the process, we address the sociotechnical aspects of the implementation, and we incorporate the Human-Organization-Technology Fit (HOT-fit) sociotechnical framework. The HOT-fit framework examines the relationships between the technological, human, and organizational components of a health information system and emphasizes that implementation success depends on more than technological excellence. The technological dimension focuses on system, information, and service quality; the human component encompasses system use and user satisfaction; and the organizational component concentrates on structure and
environment. This implementation planning guide is also informed by the work, *Managing technological change: Organizational aspects of health informatics*, by Nancy Lorenzi.³

In attempting to create a consolidated implementation guide, we draw on a number of foundational sources:

- The *HealthMeasures* website, featuring PROMIS patient-reported outcome measures, is the base for this guide.⁴
- We have also consolidated information from the *User’s Guide to Implementing Patient Reported Outcomes in Health Systems* produced by the Patient Centered Outcomes Research Institute (PCORI),⁵
- The *User’s Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice* produced by the International Society for Quality of Life Research (ISOQOL),⁶ and its companion guides.⁷,⁸
- “Patient reported outcomes - experiences with implementation in a University Health Care setting,” an implementation study from the University of Utah.⁹

This guide also contains information from the following sources, as well as others cited throughout the text: An AMIA workshop on PRO implementation,¹⁰ a collection and use framework,¹¹ the Consolidated Framework for Implementation Research (CFIR),¹² and advice based on participant expertise. In addition, we draw on the ideas in the textbook, *Managing Technological Change: Organizational Aspects of Health Informatics*.³

Collectively, these documents cover most of the questions that must be answered during implementation planning for PRO success. We will continue refining the questions to be answered in connection with PROs, and all comments and additions are welcome.

**Assumptions**

This guide assumes the following:

- The PROs in question are intended primarily for clinical use.
- All institutions plan to begin with a pilot implementation in order to increase learning, examine experiences, and increase the chance of eventual success.
- The pilot implementation at each institution will involve only one (or perhaps two) clinics.
- All information in this guide relates only to each institution’s *pilot*
implementation.

- If the pilot is successful, it may be followed by a phased rollout in other clinics within the institution and eventually within the hospital system.

## Getting Started

The most successful PRO implementations “facilitate the initiation of a collaboration between care providers, administration, and EHR teams.”\(^\text{13}\) It is therefore important to work with your institution to create a smooth implementation.

To get started, it is important to make sure that no one feels blindsided by the project and the intention to implement PRO measures. Senior management and hospital administrators should be informed at the highest levels about the intention to conduct this exploration and the desire to implement PROs in a single clinic (or possibly two). They should be on board from the beginning to avoid negative reactions to the project. Make sure everyone in a position of leadership at the University and at the hospital is aware of the project, the goals, the context, etc. This awareness building should happen early and often. Awareness building should continue at all levels so that everyone comes along together and no one wants to put on the brakes.

## How to Use this Guide

The balance of this guide is composed of questions that should be answered to gather the information needed to prepare for PROs. We recommend that you read through this guide for background and context. This guide has a companion document, called the *Decision Log*, which reformulates the questions below into a spreadsheet. After reading this guide, you may use the *Decision Log* as an interview guide and a means of recording decisions made during the planning process. It is recommended to establish a separate decision log for each clinic implementing PROs. In other words, if you are implementing PROs in two clinics within a single institution, create two individual decision logs, one for each clinic, because different clinics will customize PROs in different ways.

An *Implementation Plan Template* is also available for use in transforming the information recorded in the clinic’s decision log into a readable, sharable implementation plan.

The most up-to-date versions of the *PRO Planning Guide, Decision Log, and Implementation Plan Template* are all available at [https://digitalhub.northwestern.edu/collections/e71c88e3-3a0b-4b56-90ce-8ddc75a78e81](https://digitalhub.northwestern.edu/collections/e71c88e3-3a0b-4b56-90ce-8ddc75a78e81).
Obtaining Information for a Successful Pilot

Each of the following sections contains a list of potential questions that solicit both factual information and institutional decisions. Many questions include additional probes. Questions are not necessarily mutually exclusive. Some will resonate more than others. You may wish to consider some more deeply and jettison those that do not speak to you or your institution.

Although factual questions have right and wrong answers, other questions are meant to provoke thought and investigation. Many of these decisions won’t be easy and may entail varying amounts of behind-the-scenes work, such as convening committees, working with senior leadership, talking to clinicians and staff, and educating everyone along the way. By assiduously and thoroughly obtaining clear and complete answers to these questions, you’ll be able to handle the conversations and decisions in advance that will otherwise slow down your implementation and cause anxiety, distrust, and even rejection among physicians, other clinicians, and staff and administrative personnel.

The more thoroughly the institution answers these questions and the more people who are involved in the process of getting answers (committees, colleagues, and senior administrators), the better and smoother the eventual implementation will be.

Part I: Early Considerations: Institutional Support and Governance

One of the strongest recommendations in regard to PRO implementation is that institutional support is critical for success.9 Likewise, PROs at an institutional scale require governance to avoid a haphazard implementation. In addition, institutions belong to a larger hospital or medical system must take into account the needs and requirements of that system.

IMPORTANT NOTE: This section is placed first to emphasize the importance of institutional and system-wide support and governance. However, the implementation team will usually want to tackle this section over the course of the planning project, rather than right at the beginning. Questions relating to institutional and system-wide support and governance generally require interviews with senior leadership. The answers to clinic-level questions (below) can be gathered simultaneously with institutional and system information. Questions related to institutional support are placed at the end of the companion Decision Log.

Part I, Section 1: Institutional Support

PROs will inevitably bring about change. Planners should have institutional backing, even if it is preliminary, to make sure that the PRO implementation effort
is able to be sustained, to grow, and to be considered beneficial across the organization. Note that at the early planning stage, the institution or hospital system could be pressing for implementation of PROs or this pilot may be a demonstration project designed to assess the value of PROs and consider their future use. (See also in reference: Lorenzi, p. 79 table and text. Scales for insight and discussion.³)

Questions relating to institutional support

- Who are senior leaders at the institutional level for this project?
- Are leaders at the highest levels aware of this pilot project?
- Does the pilot initiative have institutional support? Is the institution pressing for implementation of PROs, or is this a demonstration project designed to understand the value of PROs and consider their future use?
- What are the top priorities of senior leaders at the institutional level in regard to collection of PROs within the pilot clinic or within the institution on a larger scale?⁹ In other words, why does the institution want to implement PRO measures (assuming it does). What benefit(s) are anticipated from the use of PROs? Describe the primary aims for the institution’s use of direct-from-the-patient information (e.g., diagnosis, screening, monitoring a symptom/outcome to meet guidelines).
- Closely related, how do senior leaders define “success” for this pilot? What is the most important or least important factor in success? Do you feel clinicians and administrators are aligned in how they think about success for PRO implementation? What are the main areas of synergy? Where do you anticipate a divergence of opinion? (See also in reference: Lorenzi, p. 167-168.³)
- What barriers do senior leaders foresee that might hamper the implementation of PROs at the institution?¹²
- Are there any processes currently used, sanctioned, or promoted by your institution that will potentially come into conflict with your planned use of PROs in the pilot clinic? If so, have you held appropriate conversations to ensure that the institution is behind this pilot project and to resolve any conflicts?⁹
- Are there any regulatory or external requirements that would be fulfilled by utilizing PROs?
- Will PROs also be used for research now or in the future?
- Are there any ethical or legal issues that should be considered?

Part I, Section 2: How Will the PRO-EHR System be Governed?

Although one or two PRO measures used in a single clinic probably won’t require
a lot of governance, growth should be expected over time. As such, it is appropriate to consider up front how PROs will be governed, both at the institutional and system level and at the clinic level. For example, the institution may wish to establish a steering committee headed by a senior individual. An active and engaged committee can coordinate assessment content and assessment timelines and provide transparency about which clinics are participating or requesting to participate.

Assuming you have the green light from your institution, it may be appropriate to establish a governance structure for the fledgling PRO process, which can take the initiative forward and consider and make decisions regarding the inevitable questions that will arise over time as the use of PRO measures grows. (See also in reference: Lorenzi, p. 118, table on p. 116. Analyzing the organization’s readiness for change.)

Questions relating to governance and oversight

NOTE: If you do not know the answers to the following questions or if the answers depend on the outcome of this pilot, it’s not necessary to answer at this moment, but the issue should be borne in mind and relates closely to governance. (Other issues in connection with system-wide integration are also detailed in the extensive literature about PROs and bear consideration as the implementation moves beyond the pilot clinic to multiple clinics within an institution or hospital system.)

- Is there an oversight body related to EHR-embedded PROs within your organization?
- Are there guidelines or limits related to EHR-embedded PROs that must be followed? To quote from HealthMeasures, “Some organizations have a process for coordinating PRO assessments across the institution. This can reduce redundant assessments and patient over-burdening. For example, there may be limits on the number of PROs a patient can be asked to complete at one time or a restriction on what PROs can be used within an organization. Before you get too far in identifying what implementation you want, find out if your organization has an oversight committee and what guidelines exist for PRO assessments.”

Closely related is this question to be considered under PRO selection, where it is repeated: It is important to consider the future as you select measures. Especially as measures are adopted in more clinics, it is essential to consider the institutional or hospital system landscape in terms of measure selection and timing.

- Looking ahead, will your institution have a “core” measure or set of measures to be used in every clinical setting? Or will each setting choose
the measures most relevant to itself?

- Will the institution establish a frequency for core measures, and will that mesh with clinical PRO schedules?

- Will patients be expected to fill out measures from different clinics simultaneously?\(^5\)

- Will you create an executive steering committee or other governing body, if one does not now exist? Who will lead and who will serve on the executive steering committee or other governing body?\(^9\)

- How will you manage conflicts that may arise between team members or within the organization? This question relates to organizational culture. (See also in reference: Lorenzi, Inventory Table 9.1 on p. 136; p. 141. Different kinds of conflicts.\(^3\))

- Question for future consideration: For this pilot, we will create an implementation plan that will serve as the project charter. Who will create future implementation plans and on what schedule?
Part II: Where to Start: Choosing Clinic(s) and PROs

In Part II, we will select clinics, populations, patients, and PROs. This is necessarily a non-linear process. Some institutions may be limited in the selection of measures available for installation. Therefore, for this pilot, it’s best to start by examining the list of measures available to your institution, then choosing a clinic where these measures can add value. For example, a urology clinic would be an unsuitable pilot location if your installation does not yet have available any measures on urinary symptoms. We discuss selection of measures in far greater detail below, and we will move back and forth between sections.

Part II, Section 1: Selecting Clinic(s), Populations, and Patients

For a pilot project, we recommend starting with a single clinic or possibly two different clinics that will allow more diversity of experience. It’s important not to tackle too much at once. It’s easier to expand after success than to cope with a pilot installation that is overly large and diverse.

Select PRO measures that provide information care providers and patients can use. Use and discussion by providers encourages continued completion.

Questions relating to choices of clinic(s), populations, and patients

NOTE: This section is based largely on the HealthMeasures document entitled “What You Need To Know Before Requesting Patient-Reported Outcomes in Your Electronic Health Record.” For additional information about this topic, see the User's Guide to Implementing Patient Reported Outcomes in Health Systems produced by the Patient Centered Outcomes Research Institute (PCORI) and the User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice produced by the International Society for Quality of Life Research (ISOQOL), and its companion guides.

- What populations and patients are most suitable for collection and use of PRO data during the pilot implementation? (See also: PCORI and ISOQOL)
- Which clinic will be the site of the pilot implementation? If a specific condition within a larger clinic will be the initial target, describe procedure or disease process.
- “What population of patients should complete the PRO(s) of interest?” (See also: ISOQOL)
- Are there any special considerations for the population of interest? For example, if the population includes pediatric patients, at what ages will parents have proxy roles? Will parents need to approve submissions?
Similarly, what about disabled patients or the cognitively impaired?\textsuperscript{13} (See also: ISOQOL.\textsuperscript{6})

- Exclusion criteria: Will any patients be excluded from the population of interest (e.g., patients flagged in Epic as requiring a translator, patients under 18 years old, etc.)\textsuperscript{13}

- “Describe who you would like to complete a specific assessment. Some example populations include:
  - Patients with an appointment with a specific clinician or in a specific clinic
  - Patients with a specific procedure code
  - Patients with a specific diagnostic code
  - Patients with a specific order (e.g., pre-hip replacement surgery order set)\textsuperscript{13}

- “Generate a description. Examples:
  - All adult patients scheduled for an appointment with a medical oncologist in the Comprehensive Cancer Center. This includes new and established patients.
  - All adult patients who have order placed for a total hip replacement, total knee replacement, revision hip surgery, or revision knee surgery.”\textsuperscript{13}

- Describe expected volume.\textsuperscript{13}

Part II, Section 2: Clinical Purpose and Barriers

While clinicians can ask individuals patients about their individual outcomes, PROs offer the advantage of collecting and understanding how patients are doing relative to a large group of similar patients. PROs generally do not replace clinical conversations, but they may enhance the clinical conversation and give clinicians information they would not otherwise be able to gather.

Questions relating to consideration of clinical need and meaningful use of data\textsuperscript{15}

- Describe the primary aims for use of PROs in this setting (e.g., diagnosis, screening, monitoring a symptom/outcome to meet guidelines).\textsuperscript{13}

- What benefit(s) are anticipated from the use of PROs? What do the physicians and the interdisciplinary team expect to accomplish due to the introduction of PROs? In other words, what are the clinical goals of having direct-from-the-patient information available?

- How do clinicians anticipate that care will change (if at all) as a result of having access to patient-reported information?

- Are there any regulatory or external requirements that would be fulfilled by
utilizing PROs? Note any deadlines.

- Will PROs also be used for research now or in the future?
- What will you measure to demonstrate the impact of PROs?
- Closely related to expected benefits, how will clinicians define “success” for this pilot? What factors are most important or least important to success?
- What barriers do clinicians foresee that may hamper the implementation of PROs in the clinic?¹⁶
- Are there any processes currently used, sanctioned, or promoted by your institution that will potentially come into conflict with your planned use of PRO measures in the pilot clinic? If so, describe potential resolution.¹⁶
- Have all providers in this clinic committed to implementing PROs? Do you have buy-in from the clinical team for implementation of PROs? If not, what are the implications of not having buy-in? Will PRO use be considered exploratory or optional?¹⁶
- Are there any ethical or legal issues that should be considered?¹⁶

Part II, Section 3: Selecting PRO Measure(s)

Measure selection is a thorny question because you'll want to choose the most beneficial and impactful measure for your installation. At their best, measures provide useful information that serves a strong clinical purpose, such as understanding patients’ experience when compared to a standardized population, understanding the patients’ state of health relative to a condition of interest, or providing a jumping off point for more effective clinical interviewing.⁵,⁶ Measures should be selected in light of the goals discussed in the sections above.

Ideally, one should start by figuring out what information is needed from PROs for a specific patient population, taking into account expected benefits. It is possible to start with just a single measure in a single clinic. In many cases, however, a single measure will not meet the needs of the clinic in even a pilot implementation, so select the set of measures that will create value for the clinic.

As with the rest of this guide, the assumption is that readers are selecting from PROMIS measures. However, even if you are contemplating measures that are not within the PROMIS family, the questions and advice below will help in making your choice.

IMPORTANT NOTE: Your EHR vendor may support only a subset of measures. For example, if you are using the Epic PROMIS app, Epic does not yet have all PROMIS measures available. Work with your EHR team (see Part IV, Section 1 below about team members) to find out exactly which measures are available to
you, and choose from that list.

**Questions relating to measurement selection**

- As presented previously in governance: It is important to consider the future as you select measures. Especially as measures are adopted in more clinics, it is essential to consider the institutional landscape in terms of measure selection and timing.9,14
  
  o Looking ahead, will your institution have a “core” measure or set of measures to be used in every clinical setting that could be compared across all of its clinics? Or will each setting choose the measures most relevant to itself? Note that these are not mutually exclusive, since the institution could establish core measures and clinics could also choose clinic-specific measures.

  o Will the institution establish a frequency for core measures, and will that mesh with clinical PRO schedules? Will patients be expected to fill out measures from different clinics simultaneously?

If you do not know the answer to these questions or if the answers depend on the outcome of this pilot, it is not necessary to answer at this moment, but the issue should be borne in mind.

- “What PROs do you want to use?”13 Taking into account both availability and any institutional or system-wide guidelines, which measure(s) should be selected for the pilot implementation?

  o Review the following guide from the developers’ of PROMIS and watch the video:
    
    http://www.healthmeasures.net/index.php?option=com_content&view=category&layout=blog&id=103&Itemid=877

  o Second, read the very helpful guide to selecting measures on the HealthMeasures website:
    

    - The HealthMeasures measure selection guide asks a number of questions you should consider in choosing a health measure. Each of these is explained in detail in the HealthMeasures document.

    - What are the goals and/or aims of the assessment?
      (Note: As an additional helpful reference, Franklin and colleagues identify four primary PRO uses that create value for senior leaders, including “1) individual patient care decisions, 2) quality improvement, 3)
value-based payment, and 4) population health and research,” and suggest that teams establish the value that PROs will provide prior to implementing PRO-collection strategies.11)

- Which outcomes are important to measure for your given population?
- Do you want to measure global or specific outcomes?
- Are the patient-centered outcomes primary, secondary, or exploratory endpoints?
- Is the PRO for screening, monitoring, intervention, or a combination?
- How old is your target population?
- Do you want to measure disease/condition-specific outcomes or universal (not disease/condition-specific) outcomes?
- Do you want fixed length outcome measures or dynamic (computer adaptive test, CAT) measures?
- How reliable, precise, and brief does the measure need to be?
- Is the measure appropriate for your target population?16

- Assuming that you are using PROMIS, review the available PROMIS measures in light of the answers to your questions, and choose the measure(s) you will use:
  - [https://www.healthmeasures.net/search-view-measures](https://www.healthmeasures.net/search-view-measures)
- Having chosen a measure or set of measures, familiarize yourself completely with the measure(s), reviewing a copy of each measure as it is to be displayed to a patient and noting all questions and potential responses.13
Part III: Detailed Implementation Considerations for Pilot

With the fundamentals of which measures and clinics you will choose figured out, you can delve into the details of goals of care, workflow, triggers, and handling results.

Part III, Section 1: Workflow

Introduction of PROs—asking patients to answer questionnaires and asking clinicians to act on those answers—will change clinical workflow. Smooth workflow is one of the most important keys to PRO success. Before tackling change, it’s important to understand the workflow in the target clinic as fully as possible. A clear understanding of the present workflow will help the implementation team locate moments when patients are waiting and utilize this downtime to advantage as a time when patients can answer PRO questionnaires if they didn’t complete them already at home. With preparatory workflow analysis, clinic staff can review and anticipate workflow changes rather than being caught off guard by new processes. (See also in reference: Lorenzi, p. 192. Sticking points, staff satisfaction, patient issues.3)

Questions relating to workflow analysis

- Do you anticipate any workflow-related barriers to implementation? Are there any problems to solve proactively? (Consider clinicians and staff in the chosen clinic as well as the time structure and load within the clinic itself.)6
- Ordering assessments and following up on results: How do you anticipate that physician practice will be changed by PROs, both temporally and in terms of clinical interaction? Is at least a core group of physicians on board with investing the time and change in practice required for PROs?9,6
- What are moments of downtime or places in clinic workflow where patients might respond in clinic to PRO questionnaires, assuming not all patients will complete questionnaires at home?5 (Note that most institutions have found that patients do not always complete questionnaires at home.)
- Who will follow up on an incomplete assessment, when, and how, assuming follow up will be done?

Part III, Section 2: PRO Delivery and Location

Decide where patients will be when they fill out PRO questionnaires and what staff will direct patients and set up machines if PROs are to be completed on-site.5
Questions relating to PRO delivery and location

- List the ways you will collect PROs, based on your intended method of PRO delivery: “Organizations have different approaches to where and how PROs are completed. For example:
  - Patient completes assessment at home on a computer via mobile device
  - Patient completes an assessment in a specific clinic on a tablet? At a kiosk?” In an exam room?”¹³

- Where do you expect the patient to be physically located when completing a PRO Assessment?¹³

- If measures will be sent via patient portal, what is the portal utilization rate?⁹

- In detail, what is the workflow for patients who have not completed their PROs prior to a visit?⁹

- If patient is expected to complete the PRO onsite or has that option, who will set up the PRO for the patient and when will the patient be allowed time to complete the PRO questionnaire(s)? How will the person who will start the PRO for the patient know that s/he should take this action?⁹

Part III, Section 3: Ordering, Triggers, and Assessment Intervals

Although it is possible to set up ad hoc ordering for PROs,¹³ it is best not to encourage ad hoc ordering for a pilot, since everything will be new and clinicians will be unfamiliar with the process. Instead, for the pilot, we recommend deciding on triggers that will automatically generate a PRO request to the patient.

NOTE: This section is based largely on the HealthMeasures document entitled “What You Need To Know Before Requesting Patient-Reported Outcomes in Your Electronic Health Record.”¹³ For additional information about this topic, see the User’s Guide to Implementing Patient Reported Outcomes in Health Systems produced by the Patient Centered Outcomes Research Institute (PCORI)⁶ and the User’s Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice produced by the International Society for Quality of Life Research (ISOQOL),⁶ and its companion guides.⁷,⁸

Questions relating to ordering, triggers, and assessment intervals

- “Describe when PROs should be made available to respondents. What triggers a PRO assessment?”
  - Always prior to a specific type of appointment?
  - On a fixed schedule (e.g., 2 weeks, 1 month, 3 months after intervention)?”
o In conjunction with a specific procedure or diagnosis? If so, list ICD or CPT codes that should trigger administration.

o Using a combination of triggers? For example: before the first appointment, then at 3, 6, and 12 months thereafter.

o Should trigger apply to all new patients (in which case, define “new”) or to all patients, both established and new?

o Will patient demographics affect PRO ordering? For example, must patient be a certain age or a certain gender?

• Intended questionnaire timing:

  o State timing for administration of PROs in detail. If you wish to administer PROs as a series, state all points in the series. Note how many days in advance the questionnaire should be sent and how many days the questionnaire should be available. If you would like reminder emails, include timing and associated reminder email text written out in full. If you want a lockout period when no questionnaires should be sent, please note.

  • “What triggers the schedule to start? (e.g., date of surgery, date of discharge from hospital)

  o Recurrent (e.g., every 6 months) Is there any event that changes the schedule? What is the “availability window” around each assessment? For example: assessment available 7 days before and 2 days after a specific type of appointment

  o Two-week post-surgery assessment is available starting 12 days after surgery and is closed 17 days after surgery

  • Will patients have the ability to completely opt out of receiving PROs? If so, who will collect opt-out requests and how will that information be transmitted/implemented in the system?

Part III, Section 4: Handling Results

After again reviewing your responses regarding clinical need and meaningful use of data, consider how clinicians will be notified about the existence of PRO data and how PRO data will be acted upon.

Questions relating to handling results

  EHR Display:

  • How will PRO data be displayed in the EHR? (NOTE: If you are using a vendor app, such as Epic, the vendor will determine the display.)

  • Do providers want to review scores outside of clinical visits?

  • Who else needs to review the score (e.g., regulatory or population health
teams), and will it be accessible for reporting?\textsuperscript{10}

- Will other teams know that a recent score is available and the PRO measure does not need to be administered again?\textsuperscript{10}

Special Notification Thresholds:

- "Are notifications about receipt of \textit{all} PRO scores required?"
  - What notification? To whom? Generate a detailed description and include notification text for each notification to be sent.
  - Do you want to use Inbasket messages for notifications?\textsuperscript{13}

- Should scores above or below a certain threshold be treated differently or generate special alerts? In other words, is there a specific score or score threshold for a measure that should generate a notification to a clinician, providing a message letting him or her know that a PRO result is available?
  - List the values you would like to flag as outside of normal limits for each of your PRO measures.
  - If all PROs will not generate Inbasket messages, list the trigger values for Inbasket messages.\textsuperscript{13}

- Do you want to send both regular alerts and special alerts, or only special alerts?\textsuperscript{13}

- Are there scores that should trigger particular actions on the part of clinicians or others?\textsuperscript{13}

- What action should be taken in cases where such scores are received?
  - Here is one example for illustration: "PRO scores are available in the EHR after a patient completes an assessment. Sometimes, there may be an interest in pushing a notification about a specific score to a provider. For example, this is sometimes seen with scores indicating severe depressive symptomatology.
    - Scores above 80 on measure Z indicate severe depressive symptoms. The social work team within our clinic should be notified of the score indicating severe depressive symptoms. The social work team has a protocol in place for addressing patients' depressive symptoms."\textsuperscript{13}
Part IV: Practical Matters

Numerous practical matters must be resolved in order to successfully implement Epic PROs. Part IV attempts to gather answers to many of the most practical questions surrounding a PRO pilot implementation.

IMPORTANT NOTE: We include team selection as part of Part IV but in reality, team selection is usually an early action because the clinician champion is a key player in making many clinical decisions relating to PRO selection and function.

Part IV, Section 1: Work Team for Implementation

Prior to implementation, it pays to assemble a great team that can ensure that the implementation is as smooth as possible.

A first step is assembling the implementation planning team itself, which should contain sufficient manpower to complete the necessary research (including interviews with senior leaders) and to write the implementation plan.

The implementation itself will require multiple roles. For example, here are potential roles on a work team:\textsuperscript{15}

- **Institution-level roles:**
  - Executive Sponsor (VP)
  - Implementation coordinator at the institution level. (Although unlikely to exist during pilot implementation, an implementation coordinator may eventually be necessary to receive new requests for PROs in clinics and help determine eligibility, and to liaise with clinics, complete training, and track implementation over time.)
  - Institution-employed Epic IT person who will complete technical build

- **Clinic-level roles:**
  - Clinician champion (must have one for each clinic that will adopt Epic PROs)
  - Division Chair/Chief or other departmental leader (a clinician champion and an engaged departmental chair or chief working together help to engage the providers in PRO use)
  - Operational Leader/Clinic Manager or equivalent position (must have one for each clinic that will adopt Epic PROs)
  - Process Owner within the clinic (usually this is the clinician champion or clinic manager)
  - Physicians and other providers (APNs, PAs, Nurses, Social Workers, MAs) who use PRO measures in the identified clinic
  - Interested others (e.g., informaticists, measurement scientists, patient
service personnel, evaluators, etc.)

Questions relating to work team

- Who will act as “champion” for the pilot implementation?
- What are the roles you will seek to fill at your institution and/or system?

Project-level roles:
  o Site leader for implementation planning project
  o Additional staff to assist at each institution
  o Consulting and advice

Institution-level and system-level roles:
  o Persons to keep informed about the project as it progresses (high-level leaders at the institution and the hospital)
  o Executive Sponsor (VP) or equivalent position at your institution or within your system
  o Implementation coordinator at the institution level (This person receives new requests for PROs in clinics and helps determine eligibility. This position may not currently exist.)
  o Institution-employed Epic IT person (i.e., who within the institution will implement PROs within Epic technically?)

Clinic-level roles:
  o Clinician champion (must have one for each clinic that will adopt Epic PROs)
  o Division Chair/Chief or other departmental leader
  o Operational Leader/Clinic Manager or equivalent position (must have one for each clinic that will adopt Epic PROs)
  o Process Owner within the clinic. (In other words, who is driving the PRO implementation at the clinic level? This might be a clinician champion, an operational leader, etc. Another way of asking this question is, who will you talk to when you visit the clinic?)
  o Physicians and other providers (APNs, PAs, Nurses, Social Workers, MAs) who will use PRO measures in the identified clinic
  o Interested others (e.g., informaticists, measurement scientists, patient service representatives, evaluators, etc.)

- Who will fill the roles you have outlined?
Part IV, Section 2: Technical and Financial Considerations

Many technical, financial, and practical issues must be resolved when PROs are first implemented at an institution. It will be necessary to team up with technical personnel to ensure that implementations are technologically sound. Particularly, sites that plan to provide tablets for patients to use in order to answer questionnaires in the clinic or waiting room will need to ensure that tablets are set up and function properly over time. Technical support for all aspects of the implementation will be vital to success and should be arranged in advance.

Questions relating to technical and financial considerations

Cost

- What is the cost of any licensing fees, and who will pay the license fee?
- Do you have resources or funding to finance implementation or will your institution finance the technical work required to implement electronic PRO measures?

Technical implementation

- What is the name and department of the technical person who will work with you to construct and activate PRO measures at your institution? For example, who will install PROs initially as they are implemented, and who will be available to add PROs as they are wanted or become available?
- Who will run an end-to-end system test and when?
- Who will perform necessary in-clinic technical tasks for smooth implementation, such as creating an implementation checklist for clinics, ordering tablets on time, and ensuring a smooth physical rollout? (See Part IV, Section 3, Timing.)
- Who will liaise with the technical team to convey information and configure the clinic (and new clinics as they come online over time)?
- If tablets will be available in the clinic for filling out PROs, how will the tablet devices be chosen, configured, and paid for? By whom and on what schedule? Who will configure tablets or kiosks and support them when problems arise? Who will create an asset management model with an established product life cycle for tablets and create a “gold image” for the tablet, perhaps with the use of a Mobile Device Manager? How will tablets be stored, cleaned, and charged?
- Who will set up an IT trouble ticket support system? How will trouble tickets be submitted and resolved?
- Who will provide go-live support for any connectivity issues? Who will be on hand during go-live to answer PRO questions and offer other technical support?
Testing and quality assurance

Testing is important both for data integrity and patient safety. Testing can be performed by a vendor supplying a pre-built application. PRO measures that are custom-built within the local EHR should be tested in advance by the implementation team.

- If using a vendor-supplied application (such as the Epic PROMIS app), who will verify with the vendor that testing has been completed and the application is certified for quality?
- In the case of a custom-built EHR-integrated PRO application, which advanced analytical team will examine patient PRO measure scores generated by the EHR to verify data quality? Such testing may include examining data patterns (gaps in branching logic, unusual answers, skipped questions) from early pilot patient submissions and checking those against the scoring as tabulated directly (Excel, SQ, etc.) by the analyst from the published PRO instrument.

PRO data access and analysis

Access to individual PRO results on a patient-by-patient basis is covered in Part III, Section 4: “Handling Results.” This section addresses access to and analysis of aggregate data and recognizes that analysts may need special training or focused exposure to PRO data in the EHR’s data repository or data warehouse.

- Do those parties charged with retrieval and reporting of aggregate data have the requisite access and training to both obtain and analyze PRO data, or is supplemental training needed?
- What is the schedule for aggregate data availability? If access to aggregate data or the need for special training will cause a delay in the availability of data to reporting or data export consumers, what plan is in place for communicating this delay prior to pilot start?

NOTE: For questions relating to usage statistics and analytics (e.g., rates of completion), please see Part V, Section 2: “Metrics and Analytics.”

Training

- How will users be trained and engaged?
- Who will create training materials?
- Who will perform training?
- Who will be trained (e.g., MAs, nurses, physicians, social workers)?

Ongoing support

- Who will support the application on an ongoing basis, both technically and
Part IV, Section 3: Timing

Finally, with a clear picture in mind of what implementation will entail, what is the pilot project timeline at your institution? Your EHR team (discussed above) can help answer questions about when PROs will be ready for use at your institution.

Questions relating to timing

- When will PROs be installed and ready for use at your institution?
- When will the pilot implementation roll out at your institution?
- What are dates for ordering necessary equipment?
- How long will the implementation be considered a “pilot” implementation?
- What is the planned formative evaluation schedule?
- Are there current plans to begin another pilot or a more general rollout, assuming general success of the pilot implementation? When and on what schedule, if known?
Part V: Plan Evaluation

Evaluation can take the form of qualitative evaluation and/or examination of metrics. A formative evaluation is recommended early on after implementation in order to quickly detect and correct any problems. Evaluation relates closely to governance because those governing the system will receive the evaluation results and determine next steps.

Part V, Section 1: Qualitative Sociotechnical Evaluation

Qualitative sociotechnical evaluation can provide deep information about the psychosocial surround of the implementation. A good sociotechnical fit is critical to long-term project success. Qualitative analysis can help answer the question of whether and how the clinic, clinicians, and patients are benefitting from PROs.

Questions relating to qualitative sociotechnical evaluation

- Revisit your goals and your definition of success. Goals and expectations should guide evaluation.
- How will the pilot implementation be evaluated (i.e., what evaluation questions will be used to evaluate the overall success of the implementation)?
- If there were failures, what was learned? What caused the failures and how could they have been prevented? Can problems be corrected? How will lessons learned in the pilot clinic(s) change implementation in future clinics? How will results be communicated to the governance process, and who will take action to make changes?
- Did the pilot project meet senior leaders’ priorities?
- If the project is deemed a “success,” what are the likely next steps?

Part V, Section 2: Metrics and Analytics

Metrics (usage statistics) provide key information to help understand how much is being done and how numerically successful the implementation is.

Questions relating to metrics and analytics

- List the usage outcome measures/metrics to be used in evaluation. (See also: ISOQOL.⁶)
- Getting the data: Who is tasked with pulling, assembling, and formatting usage metrics and from what resource on what timeframe?⁹ (See also: ISOQOL.⁶)
- Using the data: Who will examine the metrics, on what schedule, and how will such metrics be used?
Part V, Section 3: Patient Feedback

At times, institutions wish to solicit feedback from patients or provide patients with information about how PROs are being used and their benefits.

Questions relating to patient feedback

- If you plan to solicit patient feedback OR provide information to patients in connection with this pilot project, describe your patient feedback strategy (note any plans to incorporate patient feedback into PRO design).

Conclusion

Answers to the questions in this guide should be recorded on the companion Decision Log (available at https://doi.org/10.18131/g3-vy44-c949). Information collected on a clinic’s decision log can then be transferred to a pilot implementation plan stating who, what, when, and with what methods you will implement the pilot. See https://doi.org/10.18131/g3-fev6-hc15 for an Implementation Plan Template. The pilot plan is your instruction manual for a real-life implementation. It ensures that you are ready with answers and decisions when questions arise, avoiding unnecessary delays and helping everything go smoothly.
References


13. HealthMeasures. What you need to know before requesting PROs in your EHR.  


15. Acknowledgment: Section draws on an unpublished implementation questionnaire from Northwestern Medicine.