Pre-Implementation Guide and Questionnaire for PROs Delivered through the Epic PROMIS App

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To be used by pilot Epic site leaders at the following institutions:
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Draft

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Pre-Implementation Planning Guide

Introduction

The purpose of the pre-implementation process is to prepare each institution to roll out Epic PROMIS smoothly, with a minimum of surprises and disruption at the time patients and clinical staff actually begin using PROMIS. By gathering the answers to the questions in this document and doing the preliminary work to prepare on paper, each site leader at each institution will be able to create a smooth implementation when the time comes.

This document presents the issues that we'll explore during the pre-implementation phase of Epic PROMIS at each institution. This is a working document, and is intended to be completed by the site leader at each university (Liebovitz, Bian, Harris, and Kannampallil) or the person they designate. Therese and Annette are consultants to the site leaders. Working together, we can strategize, inform, discuss best practices, and help each other along the way.

Although we will 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 we capture all necessary information and that decisions are made that will customize the implementation for each institution. This conceptual diagram illustrates the general planning process, and also the necessity of revisiting and revising as we explore new territory at each stage of the process.

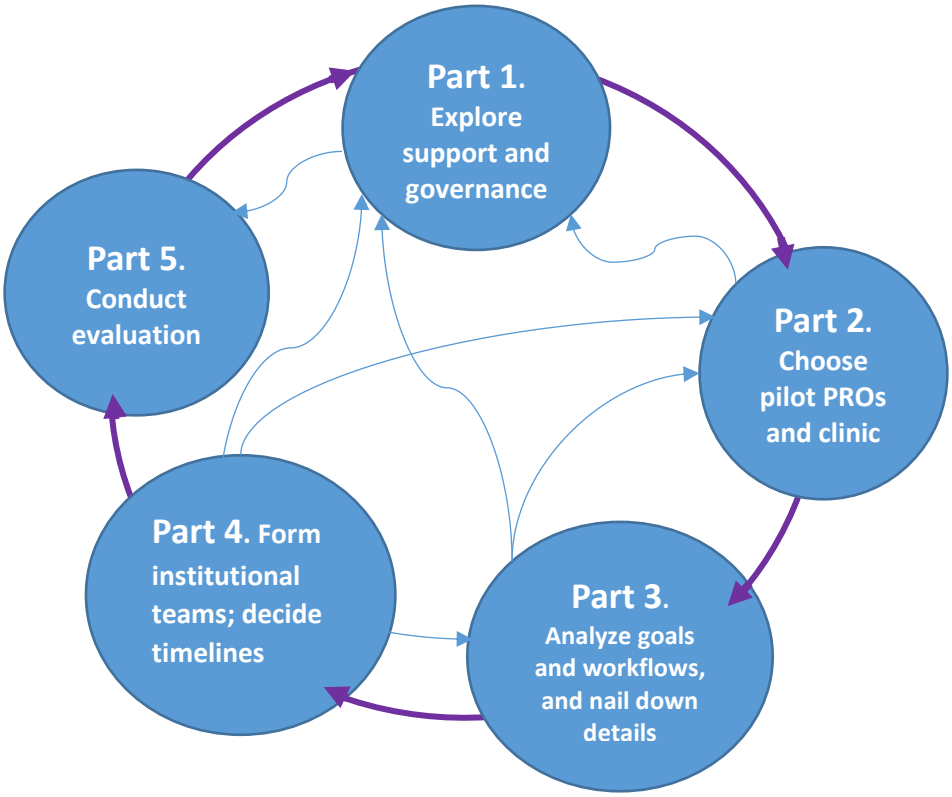

Figure 1: Implementation planning is simultaneously both sequential and non-linear.

This document is *not* intended to be read as a manuscript. As we work through these issues in our home institutions and gain insights, we can share those insights along the way. We will take time to reflect on our experience throughout the project, and in the final EASI-PRO grant year we hope to produce a manuscript about lessons learned.

In attempting to create a consolidated implementation guide, this document draws on a number of sources, particularly the *HealthMeasures* website produced as part of the EASI-PRO grant[1], a users' guide from the Patient Centered Outcomes Research Institute (PCORI)[2], a PROs implementation questionnaire now being used for new clinical implementations at Northwestern[3], and an implementation study from the University of Utah also produced as part of the EASI-PRO grant[4], an AMIA workshop on PRO implementation[5], a workflow methodology from a project participant (Nick Soulakis)[6], and other sources[7]. We have worked from *HealthMeasures* as a base, because it is most comprehensive, and added in information from other documents where useful and appropriate. In addition, we draw on the ideas in the textbook: *Managing Technological Change: Organizational Aspects of Health Informatics*.[8] Collectively, these documents cover most of the questions that must be answered in advance of implementation for PRO success. We will continue refining this list, and all comments and additions are welcome.

Assumptions

This document assumes the following:

- All institutions involved in this pre-implementation project are aiming to eventually adopt Epic PROMIS from the Epic App Orchard.
- The PROs in question are intended primarily for clinical use.
- All institutions plan to begin with a pilot implementation in order increase learning, examine experiences, and increase the chance of eventual success. The pilot implementation will involve only one (or perhaps two) clinics and a minimal number of PRO measures within each clinic.
- The EASI-PRO pre-implementation project is slated to run from approximately February through July, 2019.
- All information in this document 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.
- We as an EASI-PRO group are engaged in research as to how to implement Epic PROs successfully and efficiently and we will document our experience.

Getting Started

The most successful PRO implementations "facilitate the initiation of a collaboration between care providers, administration, and EHR teams."[9] It is therefore important to work with your institution to create a smooth implementation.

The very first, highest priority thing to do is to make sure that no one feels blindsided by the project and the intention to establish an instance of Epic PROMIS. 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.

Obtaining Information for a Successful Pilot

The balance of this document is composed of questions and considerations for a successful pilot project. This document functions as a guide to gathering the information needed to prepare for PROs, and will culminate in a pilot implementation protocol.

Each of the following sections contains a list of potential questions that will help assemble information relevant to that section. Question sections solicit both factual information and institutional decisions. Many questions include additional probes. Questions are not necessarily mutually exclusive. Some will resonate more than others, and 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 powers that be, 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 and distrust and even rejection among physicians, other clinicians, 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, senior administrators), the better and smoother the eventual Epic implementation will be. Essentially, we are doing the hard work of figuring things out up front. Implementation down the road will be much smoother as a result of this preparation.

We will discuss and plan the process for getting answers as we tackle each section together. As a project group, we'll also share and discuss the answers and the process of obtaining information throughout the project, keeping track of lessons learned.

Part I: Early Considerations: Institutional Support and Governance

One of the stongest recommendations in regard to PRO implementation is that institutional support is critical for success. [10] Likewise, PROs at an institutional scale require governance to avoid a haphazard implementation.

IMPORTANT NOTE: Although we place this section first, in order to emphasize the importance of institutional support and governance, we will tackle this section over the course of the project, rather than right at the beginning. Questions relating to institutional support and governance generally require stakeholder interviews, and we need not hold up the answers to other questions while we gather the information for this section.

Part I, Section 1: Institutional Support

PROs will inevitably bring about change, and you should have at least some degree of institutional backing, even if it is preliminary, to make sure that this effort may be able to be sustained, to grow, and to be considered beneficial across the organization. Note that at this stage, the institution may be pressing for implementation of PROs *or* this may be a demonstration project designed to understand the value of PROs and consider their future use. (Utilize Lorenzi, p. 79 table and text. Scales for insight and discussion. [11])

Questions relating to institutional support

- Who are key stakeholders at the institutional level for this project?
- Are leaders at the highest levels aware of this pilot project?
- Does the Epic PROMIS *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 key stakeholders at the institutional level in regard to collection of PROs within the pilot clinic or within the institution on a larger scale?[12] In other words, why does the institution want to implement PROMIS, (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).[13]
- Closely related, how do senior leaders define "success" for this pilot? What is most important or least important to 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? (Utilize Lorenzi, p. 167-168. [14])
- What barriers do senior leaders foresee that might hamper the implementation of PROs at the institution?
- Are there any processes currently used, sanctioned, or promoted by your institution that will potentially come into conflict with your planned use of Epic PROMIS, in the pilot clinic? If so, have you held appropriate conversations to ensure that the institution is behind this pilot project and to resolve or skirt any conflicts? [15]
- Are there any regulatory or external requirements that would be fulfilled by utilizing

PROs? [16]

- Will PROs also be used for research now or in the future? [17]
- 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 level and at the clinic level. For example, at Northwestern—where PROs are used quite extensively and usage is growing—a steering committee exists which is headed by the Vice President and Vice Chair for Quality, among other individuals. A nurse clinical quality leader, working with other staff, acts as implementation specialist. An active and engaged committee can coordinate assessment content and assessment timelines and provide transparency about what 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 Epic PROMIS grows.[18] (Utilize Lorenzi, p. 118, table on p. 116. Analyzing the organization's readiness for change. [19])

Questions relating to governance and oversight

- Is there an oversight body related to EHR-embedded PROs within your organization?[20]
- 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 over-burdening patients. 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." [21]
- Closely related is this question to be considered under PRO selection, where it is repeated: 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? (see https://www.sciencedirect.com/science/article/pii/S1553725017304804?via%3Dihub for a discussion of issues related to system-wide integration). If you do not know the answer to this question or if it depends 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.
- 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? [22]

- How will you manage conflicts that may arise between team members or within the organization? (Relates to organizational culture.) (Utilize Lorenzi, Inventory Table 9.1 on p. 136; p. 141 different kinds of conflicts. [23])
- Question for future consideration: For this pilot, we will create a pilot project protocol which will serve as the project charter. Future projects, however, may benefit from written parameters. Who will create future project charters and on what schedule? [24]

Part II: Where to Start: Choosing Clinic(s) and PROs

In Part II, we start by selecting populations, patients, and PROs. This is necessarily a non-linear process. A challenge at present is that there is a limited selection of measures available in Epic PROMIS. Therefore, for this pilot at this time, it's best to start by examining the list of measures available to your institution within Epic, then choosing a clinic where these measures can add value. For example, a urology clinic would be an unsuitable pilot location because Epic does not yet have available any measures on urinary symptoms. We discuss selection of measures in far greater detail in the next section, and we will move back and forth between sections. Before continuing, skip to Section II.2 to examine available measures.

Part II, Section 1: Selecting Populations and Patients

For this 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 that care providers and patients can use. Use encourages continued completion.

Early, known, information:

- At present, UChicago plans to contact Orthopedics and plans to choose a single procedure to start with, such as ankle disorders.
- UIC will be working with Family Medicine. Since Family Medicine is broad, UIC might narrow this down to a single clinic or service line within Family Medicine.
- Florida will work with a clinic within Family Medicine, Internal Medicine, or Diabetes. Again, Florida might consider narrowing to a single clinic or service line.
- Wash U most likely plans to begin with the Pain Clinic and/or a pediatric specialty clinic.

Questions relating to populations and patients

- What populations and patients are most suitable for collection and use of PRO data during the pilot implementation? [25]
- 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?" [26]
- 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?
- 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.)
- "Describe who you would like to complete a specific assessment. [27] Some example populations include:
    - Patients with an appointment with a specific clinician or in a specific clinic[28]

        - Patients with a specific procedure code[29]
        - Patients with a specific diagnostic code[30]
        - Patients with a specific order (e.g., pre-hip replacement surgery order set)"[31]
    - "Generate a description.[32] Examples:
        - All adult patients scheduled for an appointment with a medical oncologist in the Robert H. Lurie Comprehensive Cancer Center. This includes new and established patients.[33]
        - All adult patients who have order placed for a total hip replacement, total knee replacement, revision hip surgery, or revision knee surgery."[34]
    - Describe expected volume.[35]

Part II, Section 2: Selecting PRO Measure(s)

Measure selection is a thorny question, since 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. 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 information from Part I: Expected benefits. For example, the Northwestern Pain Clinic has started with a single measure: *the PROMIS Pain Interference Computer Adaptive Test*. In many cases, however, a single measure will be useless to the clinic in even a pilot implementation, so select the set of measures that will create value for the clinic.

Epic does not yet have all PROMIS measures available. As an example, David Leibowitz provided the following list of measures that are now available in Epic PROMIS. Your list may be different depending on what special updates your institution has purchased.

- Available starting in Epic 2018 and in Epic 2017 with special updates:
    - 64800-PROMIS CAT v2.0 - Upper Extremity Function
    - 64801-PROMIS CAT v2.0 - Ability to Participate Social Roles & Activities
    - 64802-PROMIS CAT v1.0 - Anxiety
    - 64803-PROMIS CAT v1.0 - Sleep Disturbance
    - 64804-PROMIS CAT v1.1 - Pain Interference
    - 64805-PROMIS CAT v2.0 - Physical Function
    - 64806-PROMIS CAT v1.0 - Depression
    - 64807-PROMIS CAT v1.0 - Fatigue
- Available starting in August 2018, in Epic 2018 with special updates E8408259 and E8408258, and in Epic 2017 with special updates E8330818 and E8330817:
    - 64808-PROMIS CAT v1.1 - Anger
    - 64809-PROMIS CAT v1.0 - Sleep-Related Impairment
    - 64810-PROMIS CAT V2.0 - Emotional Support
    - 64811-PROMIS CAT V2.0 - Social Isolation
    - 64823 - PROMIS PEDIATRIC CAT v2.0 - Pediatric Depressive Symptoms

- 64825 - PROMIS PEDIATRIC CAT v2.0 - Pediatric Mobility
- 64826 - PROMIS PEDIATRIC CAT v2.0 - Pediatric Pain Interference
- 64840 - PROMIS PARENT PROXY CAT v2.0 - Parent Proxy Depressive Symptoms
- 64842 - PROMIS PARENT PROXY CAT v2.0 - Parent Proxy Mobility
- 64843 - PROMIS PARENT PROXY CAT v2.0 - Parent Proxy Pain Interference
- 64845 - PROMIS PARENT PROXY CAT v2.0 - Parent Proxy Upper Extremity

All pilot measures chosen should, of course, be available in your installation of Epic. Work with your Epic team (see section below about team members) to find out exactly what measures are available to you, and choose from that list. Also ascertain that the measures have already been tested, and note any pre-set parameters and output.

Questions relating to measurement selection

- Which measures are available in your version of Epic? (A pilot clinic should be chosen based on available measures. Later, a wider set of measures may be available.)
- Which outcomes are important to measure for your given population?
- 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? (see https://www.sciencedirect.com/science/article/pii/S1553725017304804?via%3Dihub for a discussion of issues related to system-wide integration). If you do not know the answer to this question or if it depends 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.
- "What PROs do you want to use?" [36] Taking into account both availability and any institutional guidelines, which measure(s) should be selected for the pilot implementation?
    - 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
    - Second, read the very helpful guide to selecting measures on the *HealthMeasures* website: http://www.healthmeasures.net/images/applications/Guide_to_Selection_of_a_HealthMeasures_06_09_16.pdf[37]
        - 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 and we will work through these questions together as part of the project We will have some restrictions due to the limited number of measures available in Epic. For example, at present there isn't a disease-specific PRO available to use, so some of these questions relate to the future and are not applicable to this pilot. [38]

    - What are the goals and/or aims of the assessment?
    - 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?[39]
    - 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?
- Having chosen a measure or set of measures, familiarize yourself completely with the measure(s), reviewing a copy of the measure as it is to be displayed to a patient, and noting all questions and potential responses. [40]

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: Clinical Purpose, Barriers, and Evaluation

((Consider putting with PRO selection in previous section)) PROs should be used when the goals of clinical care will be enhanced by collecting data directly from patients in a systematic and validated manner. 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 clinical need and meaningful use of data[41]

- Describe the primary aims for use of PROs in this setting (e.g., diagnosis, screening, monitoring a symptom/outcome, to meet guidelines).[42]
- 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. [43]
- Will PROs also be used for research now or in the future? [44]
- 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?
- Are there any processes currently used, sanctioned, or promoted by your institution that will potentially come into conflict with your planned use of Epic PROMIS in the pilot clinic? If so, describe potential resolution. [45]
- Have all providers in this clinic committed to implementing PROs? Do you have buy-in from the clinical team for implementation of PROs?[46] If not, what are the implications of not having buy-in? Will PRO use be considered exploratory or optional?
- Are there any ethical or legal issues that should be considered?

Part III, Section 2: Workflow

Workflow is one of the most important keys to PRO success. Introduction of PROs—asking patients to answer questionnaires and asking clinicians to act on those answers—will change

clinical workflow. 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.

Dr. Nicholas Soulakis will work with us on this section of the project to fully understand the workflow of the clinic and therefore to identify which actors will be affected by the introduction of PROs and how new PRO processes may change current workflow. We will look for moments in the clinic workflow when patients can fill in their 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. (Utilize Lorenzi, p. 192 sticking points, staff satisfaction, patient issues . . . [47])

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.)
- 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? [48]
- What are moments of downtime or places in clinic workflow where patients might respond in clinic to PRO questionnaires, assuming not all patients complete questionnaires at home? (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 followup will be done?

Part III, Section 3: 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.

Questions relating to PRO delivery and location

- Method of intended 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?" [49] In an exam room?

  "List ways you will collect PROs" (examples: At home via MyChart, tablets in clinic, work stations in clinic, kiosks in clinic, on exam room computers [investigate: must lock out other EHR functions]) [50] [51]
- Where do you expect the patient is physically located when completing a PRO Assessment? [52]

- If measures will be sent via patient portal, what is the portal utilization rate? [53]
- What is the workflow for patients who have not completed their PROs prior to a visit? [54]
- 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? [55]

Part III, Section 4: Ordering, Triggers and Assessment Intervals

Although it is possible to set up ad hoc ordering for PROs (in which case certain additional questions apply, such as how long the assessment should remain available for the patient[56]), 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.

Questions relating to ordering, triggers, and assessment intervals

- "Describe when PROs should be made available to respondents. What triggers a PRO assessment?" [57]
    - Always prior to a specific type of appointment?
    - On a fixed schedule (e.g., 2 weeks, 1 month, 3 months after intervention)?" [58]
    - In conjunction with a specific procedure or diagnosis? If so, list ICD or CPT codes that should trigger administration. [59]
    - Using a combination of triggers, for example: Before the first appointment, then at 3, 6, and 12 months thereafter.
    - Should trigger apply to all new patients (in which case, define "new") or to all patients, both established and new?
    - Will patient demographics affect PRO ordering? For example, patient must be a certain age or a certain gender?
- Intended questionnaire timing:
    - "Explain timing for administration including: all points in a series if administered as a series, how many days in advance of a time point the questionnaire should be sent, how long the questionnaire should be available for a patient to answer, whether you want a lockout period when no questionnaires should be sent, and whether you would like reminder emails sent. If you want reminder emails, please also include the timing you would like for the reminder emails. Write reminder messages out in full." [60]
- "What triggers the schedule to start? (e.g., date of surgery, date of discharge from hospital)
    - 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
    - 2-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 5: 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. [61]

Questions relating to handling results

EHR Display:

- How will PRO data be displayed in the EHR?
- Do providers want to review scores outside of clinical visits? [62]
- Who else needs to review the score (e.g., regulatory or population health teams), and will it be accessible for reporting? [63]
- Will other teams know that a recent score is available and the PRO measure does not need to be asked again? [64]
- How long should PRO results be retained? Should they eventually age out of the system? (May depend on Epic technical capabilities.) [65]

Special Notification Thresholds:

- "Are notifications about receipt of *all* PRO scores required?" [66]
    - 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?
- 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? [67]
    - List the values that you would like to flag as outside of normal limits for each of your PRO measures. [68]
    - If all PROs will not generate Inbasket messages, list the trigger values for Inbasket messages.[69]
- Do you want to send both regular alerts and special alerts, or only special alerts?
- Here is one example for illustration:
    - "PRO scores are available in the EHR after a patient completes an assessment. [70] 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." [71]
        - "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."

Part IV: Practical Matters

With clinic and PROs chosen, and workflow and implementation details determined, you'll now have a clearer picture of what 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 PROMIS pilot implementation.

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. [72]

A first step is assembling the Pre-Implementation team itself, which should contain sufficient manpower to complete the necessary research (including key stakeholder interviews) and to write the Implementation Protocol. If possible, site leaders may wish to recruit staff who can assist with necessary Pre-Implementation tasks.

The implementation itself will require multiple roles. For example, here is a sample work team from the Northwestern implementation questionnaire:

- Institution-level roles:
    - Executive Sponsor (VP)
    - Implementation coordinator at the institution level (This person receives new requests for PROs in clinics and helps determine eligibility, liaises with clinics, completes training, and tracks implementation over time.)
    - Institution-employed Epic IT person who will complete technical build.
- Clinic-level roles:
    - Physician Champion (must have one for each clinic that will adopt Epic PROs)
    - 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 physician champion or clinic manager)
    - Physicians and other providers (APNs, PAs, Nurses, Social Workers, MAs) who use Epic PROMIS 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? Using the Northwestern personnel outline as an example, note which roles you will fill at your institution. (In the next bullet, add a name to all roles.)
    - Project-level roles:
        - Site leader for pre-implementation project (e.g., Liebovitz, Bian, Harris, Kannampallil)

    - Additional staff to assist at each institution.
    - Consulting: (Anderson Northwestern, Nelson Northwestern, Soulakis Northwestern, Valenta UIC)
- Institution-level roles:
    - Persons to keep informed about the project as it progresses (high-level leaders at the institution and the hospital).
    - Executive Sponsor (VP) or equivalent position at your institution[73]
    - Implementation coordinator at the institution level (This person receives new requests for PROs in clinics and helps determine eligibility. This position may not be currently in existence.)[74]
    - Institution-employed Epic IT person (i.e., Who within the institution will implement PROs within Epic technically?) [75]
- Clinic-level roles:
    - Physician Champion (must have one for each clinic that will adopt Epic PROs) [76]
    - Operational Leader/clinic manager or equivalent position (must have one for each clinic that will adopt Epic PROs) [77]
    - Process Owner within the clinic (In other words, who is driving the PRO implementation at the clinic level? This might be a physician champion, an operational leader, etc. Another way of asking this question is, who will you talk to when you visit the clinic? For this pilot project, the answer might be that you *are* the process owner at the clinic level, but this should be made explicit and might change with future implementations.)[78]
    - Physicians and other providers (APNs, PAs, Nurses, Social Workers, MAs) who will use Epic PROMIS in the identified clinic[79]
    - Interested others, e.g., informaticists, measurement scientists, patient service representatives, evaluators, etc. [80]
- Who will fill the roles you have outlined? (Consider Responsibility Assignment Matrix.)

Part IV, Section 2: Technical and Financial Considerations

Epic PROs are new for all four institutions, so many technical, financial, and practical considerations are unresolved. 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

Costs

- What is the cost of the Epic PRO license fee, 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 bring up Epic PROMIS? [81]

Technical implementation

- What is the name and department of the Epic technical person who will work with you to construct and activate Epic PROMIS at your institution? [82] 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 within Epic? [83]
- Who will run an end-to-end system test and when? [84]
- 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.)
- Who will liaise with the technical team to convey information and configure the clinic (and new clinics as they come online over time? [85]
- 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? [86]
- Who will set up IT trouble ticket support system? How will trouble tickets be submitted and resolved? [87]
- 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?

Training

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

Ongoing support

- Who will support the application on an ongoing basis, both technically and administratively? [88]

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? [89] Note that our overall EASI-PRO pre-implementation project conducted as part of the EASI-PRO grant is planned to run approximately from January through June, 2019. However, each institution has a different schedule for its actual Epic implementation, and of course the physical implementation of the pilot project cannot begin before Epic PROs are available at your institution. Your Epic team (discussed above) can help answer questions about when Epic will be ready for use at your institution.

Questions relating to timing

- When will Epic PROs be installed and ready for use at your institution?
- When will the pilot implementation roll out at your institution? [90]

- What are dates for ordering necessary equipment?[91]
- How long will the implementation be considered a "pilot" implementation?[92]
- What is the planned formative evaluation schedule?[93]
- 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: Evaluation

Because this iteration of Epic PROs will be implemented as a pilot project, it is intended to end in an 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. A customized socio-technical formative evaluation tool is under development in connection with the EASI-PRO project, and Epic PROMIS pilots are welcome to utilize this tool. Other evaluation protocols may also be used. Headline metrics are being developed as part of the EASI-PRO projects. Institutions may choose to use this set of metrics as a starting point for their own analytics.

Evaluation relates closely to governance, since those governing the system will receive the evaluation results and determine next steps. This stage thus returns us to Part I of PRO implementation.

Part V, Section 1: Qualitative Socio-Technical Evaluation

Qualitative socio-technical evaluation can provide deep information about the psychosocial surround of the implementation. A good socio-technical 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 socio-technical evaluation

- Revisit your goals and your definition of success, as examined in Part I, expected benefits. Goals and expectations should guide evaluation.
- How will the pilot implementation be evaluated? (I.e., what tool will be used to evaluate the overall success of the implementation?)
- If there are failures, what did we learn? What caused the failure and how could it have been prevented? Can problems be corrected? How will what we learned in clinic 1 change our implementation in clinic 2? In other word, what will we change as a result of our learning? How will results be communicated to the governance process and who will take action to make changes?
- Did the pilot project meet key stakeholders' priorities?
- If the project is deemed a "success," what are the likely next steps?

Part V, Section 2: Metrics and Analytics

Metrics (usage statistics) project 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. [94]
- Getting the data: Who is tasked with pulling, assembling and formatting usage metrics

and from what resource on what timeframe? [95]

- 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. This section is optional. Note that institutions who wish to interact with patients may need to obtain IRB approval; the pre-implementation project as submitted to the Northwestern IRB does *not* assume patient interaction.

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). [96]

Conclusion

Having answered the questions above as thoroughly as possible, it is now time to transfer this information to a pilot implementation protocol stating who, what, when, and with what methods you will implement the pilot. The pilot protocol 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.

One project goal is to create a better guide, since no doubt there are things we missed and lessons to learn. Please provide feedback throughout the process about improvements that can and should be made to this guide, and also about lessons learned. We plan to write up our results.

Appendix: Technical Configuration Guide

Contains instructions for technical configuration of Epic PROMIS application within the EHR.

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