

Implementation Toolkit for the Integration of PROs within the Routine Care of People Living with HIV

EVA-21719 | September 24, 2018 | Version 2.1

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List of Abbreviations

Acronym	Definition
AACTG	Adult AIDS Clinical Trial Group
ABCD-SF	Assessment of Body Change Distress Questionnaire Short Form
AHRQ	Agency For Healthcare Research And Quality
ASSIST	Alcohol, Smoking, and Substance Involvement Screening Test
AUDIT-C	Alcohol Use Disorders Identification Test Consumption
CFAR	Center for Aids Research
CNICS	CFAR Network of Integrated Clinical Systems
CQI	continuous quality improvement
EHR	electronic health record
ePRO	electronic PRO
EQ-5D	EuroQol Group
FTE	Full Time Equivalent
HIV	human immunodeficiency virus
HRQL	health-related quality of life
ISOQOL	International Society for Quality of Life Research
IT	information technology
M&E	monitoring and evaluation
MOS	Medical Outcomes Study
NQF	National Quality Forum
PCORI	Patient-Centered Outcomes Research Institute
PDSA	Plan, Do, Study, Act
PHQ-9	Patient Health Questionnaire 9-item
PLHIV	people living with HIV
PRO	patient-reported outcome
PROM	patient-reported outcome measure
SMAQ	Simplified Medication Adherence Questionnaire
WKKF	W.K. Kellogg Foundation

Overview

Introduction

This Patient-Reported Outcome (PRO) Implementation Toolkit is designed to provide practical advice to support the introduction of PROs in a clinical setting that supports the management of people living with human immunodeficiency virus (PLHIV). These insights are drawn from a range of sources, including published literature and primary interviews with stakeholders who have experience with integrating PROs into HIV clinical care.

Much of the real world evidence and practical tips found in the Toolkit are drawn from conversations with staff from the Center for Aids Research (CFAR) Network of Integrated Clinical Systems (CNICS). CNICS is an electronic medical records-based network of HIV clinics. It provides a research infrastructure to support research on HIV clinical outcomes and comparative effectiveness trials. CNICS sites include routine collection of PROs electronically as part of their clinical care (see, for example, Crane et al. 2017; Fredericksen et al. 2012; Fredericksen et al. 2016).

What Are PROs, PROMs and How Can They Support Routine HIV Clinical Care?

A PRO is a subjective description by the patient of “*any report of the status of a patient’s health condition that comes directly from the patient without interpretation of the patient’s response by a clinician or anyone else*” (FDA 2009). PROs provide the patient perspective of the effects of disease and treatment on well-being, function, symptoms, satisfaction with (and preference for) treatments, risky behaviors (such as substance abuse), and other outcomes.

In the context of this document, PROs are generated and collected using standardized, validated questionnaires (Patient-reported outcome *measures* [PROMs], sometimes referred to as ‘instruments’); these are completed by the patients.

PROs are increasingly being used within HIV care to improve patient management. A complementary Evidence Review and Summary Report (Kleinman et al. 2018) to this document has been developed which outlines the value of clinically relevant PROs; this evidence is drawn from published literature across multiple therapy areas, including HIV.

In this review, the reader will find evidence suggesting that implementing PROs into routine clinical care:

1. Can be used to change patient health outcomes by:
 - Improving identification and monitoring of mental health issues, risky behaviors, and symptoms
 - Improving overall quality of life as measured by PROs
2. Can have an impact on patient-provider communication, thereby:
 - Providing information hitherto unknown to the provider

- Helping to focus the consultation
- 3. Are accepted by patients and providers as part of routine clinical care
 - Providers value the data they receive
 - Patients think that they are “easy to use”
 - Both patients and providers endorse continued use
- 4. Can impact on health services delivery in different ways
 - They do not adversely interfere with clinic flow
 - They do not increase the length of the consultation
 - They may cause increased referrals external to the clinic

What Is the Purpose of the Implementation Toolkit?

This toolkit has been designed to support PRO uptake in routine HIV care by highlighting key considerations for implementers; this includes implementation insights, example materials and testimonies from stakeholders who have first-hand experience with PRO implementation, covering key areas that need to be actioned or assessed. The objective is to facilitate easier and more effective PRO use where appropriate.

What Other Guides Are Available?

This toolkit was developed specifically for implementation of PROs in HIV routine care. Other more general guides exist, and provide somewhat different—though useful—information. These include the “Users Guide to Implementing Patient-Reported Outcomes Assessments in Clinical Practice” by the International Society for Quality of Life Research (ISOQOL) (Version 2, 2015), and the results of a workshop held by the Patient-Centered Outcomes Research Institute (PCORI) in 2013.

The ISOQOL guide focuses on the PROs, the types, timing of administration, score assessment and presentation and evaluation of use. The current document provides broader information on identification of stakeholders, finance, training, information technology (IT) issues, monitoring, and evaluation. The PCORI document summarizes a far-ranging workshop, and provides recommendations in areas of infrastructure/shared resources, as well as recommendations for methods and health systems.

What Steps Are Needed for PRO Implementation?

PRO implementation involves several stages of planning and execution, as well as follow-up and assessment. Each chapter in the toolkit considers a different step in the implementation process. The order in which the steps are followed depends on the needs of the individual clinic. The chapters available in this resource are outlined below:

- Chapter 1: Choosing PROs and Implementation Approaches to Meet Patient and Clinic Needs
 - The focus of this chapter is the appropriate selection of PROs based on clinic's needs and their HIV patient population; it includes links to available PROs and a discussion of the administration, scoring, and interpretation process
- Chapter 2: Obtaining Stakeholder Buy-in
 - The focus of this chapter is on identifying stakeholders who are critical to implementing PROs in an HIV clinic, the information stakeholders need to provide buy-in, and considerations for approaching stakeholders
- Chapter 3: Making the Business Case for PRO Implementation
 - This focus of this chapter is on building a compelling case to secure funding or endorsement of the program.
- Chapter 4: Building PRO Infrastructure
 - The focus of this chapter is on setting up the PROs to be administered electronically and the potential approaches connecting the electronic PRO (ePRO) system to the electronic health records as well as key considerations for IT
- Chapter 5: Integrating PROs into Clinic Care Settings
 - The focus of this chapter is the integration of the PRO system into the clinic flow including considerations of when and where to administer the PROs
- Chapter 6: Training Clinic Personnel
 - The focus of this chapter is on training the various staff on what they need to know about the PRO implementation and how they may engage with patients
- Chapter 7: Monitoring and Evaluation
 - The focus of this chapter is how to monitor, evaluate and update the PRO system used in a clinic

All chapters where possible include comments from stakeholders and practical tips from implementers.

References

Crane HM, Crane PK, Tufano JT, et al. HIV provider documentation and actions following patient reports of at-risk behaviors and conditions when identified by a web-based point-of-care assessment. *AIDS Behav.* 2017;21(11):3111-3121.

Food and Drug Administration. Guidance for industry on patient-reported outcome measures: use in medical product development to support labeling claims. *Fed Regist.* 2009;74(235):65132-65133.

Fredericksen R, Crane PK, Tufano J, et al. Integrating a web-based, patient-administered assessment into primary care for HIV-infected adults. *J AIDS HIV Res.* 2012;4(2):47-55.

Fredericksen RJ, Tufano J, Ralston J, et al. Provider perceptions of the value of same-day, electronic patient-reported measures for use in clinical HIV care. *AIDS Care*. 2016;28(11):1428-1433.

International Society for Quality of Life Research (prepared by Aaronson N, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). *Users Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version 2*. January 2015.

Kleinman I, Skalicky A, Short D, Crane H, Fredericksen R, Lober B. Implementing Patient-Reported Outcomes (PROs) Within HIV Routine Care: An Evidence Review and Summary. ViiV Healthcare Report; May 2018.

Chapter 1. Choosing a PRO Implementation Approach to Meet Patient and Clinic Needs

"I think at first just start small. One of the things that we had to do too is prioritize our surveys that we were putting on e-PRO because ... have a little bit of an order in which they get completed, Also understanding your workflow because you don't want patients to sit there for chapter 5

and complete 20 minutes' worth of survey, (if) the providers are ready to see them. So, you have to be conscious of how much you're asking the patient to do and what the impact will be like on their workflow. ... where does this fit...there's always cost ... understanding how this can benefit your patients, ... There's obviously training you need to think of and you will have to have turnover, so how are you going to train your new staff. And if there are problems with the equipment, what's the ..."

- *Implementer from a large US HIV clinic*

1.1 Identifying the Appropriate PROs for a Clinic?

"What do we want to know about our patients that would allow us to do a better job—to increase our knowledge and take action?"

- *Clinic Director, speaking about their implementation experience*

PROs are used in a range of patient settings and for different purposes, including patient management, service benchmarking and research. The focus of this toolkit is upon improving patient care. As such a key consideration of PRO implementation is how the information will be used to support an individual patient's management and to improve clinical decision making. An early step therefore is to assess how actionable any PRO findings are—i.e., when the information is elicited, what can be done as a consequence to improve care.

An early consideration is to consider the **areas of focus (domains)** that will be explored by PROs. This requires engaging clinical colleagues at the outset to determine what focus would help to improve patient health outcomes or the quality of care. Areas critical to HIV management may include PROs that assess medication adherence, alcohol/substance abuse, high-risk sexual behaviors, mental health, and stigma.

The choice of PROs will reflect factors unique to a clinic, including the demographics and characteristics of the patient population, their needs and what providers believe may be sub optimally reported (e.g., medication adherence, depression and substance use).

Once an area of focus is identified, consideration will then be given to the **specific PRO instrument** that may be adopted. There are many available that may be practical for adoption in HIV management.

The criteria in Table 1 include some of the issues to consider when selecting a PRO for use in the clinic:

Table 1. Considerations for Selecting PRO instruments

Key Factors
<ul style="list-style-type: none">● Does the PRO address the questions that are relevant and important for the clinic?● If results of the PRO indicate some action is needed, can this be done in the consultation or at follow-up appointments● Does the PRO provide data that is unavailable from objective assessments such as lab tests● Does the PRO represent a concept that is critical to HIV care (e.g. medication adherence)● Has the PRO been previously used in the HIV field<ul style="list-style-type: none">○ Are the PRO instructions easy to understand?○ Are the questions simply stated and use words/terms that patients can understand?○ Is the recall period relatively short○ Is the PRO itself short and to the point● Does the PRO give information about what a change in score means clinically?● Are there simple instructions on how to interpret the PRO results for a patient?● Do scores from healthy comparison population(s) exist?

1.2 Examples of PROMs Used to Support Decision-making in HIV Clinical Care

Table 2 below provides a selection of PROs that have been used in HIV patients in clinical care settings.

Practical Tip – Administer the PROs in order of importance, i.e. obtaining patient-reported information on adherence is more critical than quality of life.

Table 2. PROs Used with HIV Patients

PRO	Items and Domains	Website
Mental Health		
Patient Health Questionnaire 9-item (PHQ-9)	9 items Depression severity	http://www.cqaimh.org/pdf/tool_phq9.pdf
Substance Use		
Alcohol Use Disorders Identification Test Consumption (AUDIT-C)	3 items Alcohol use	https://www.integration.samhsa.gov/images/res/tool_auditcf
Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)	Approximately 8 questions with 10 parts per question for 7 questions Patients are asked items about injection drug use and drug/alcohol treatment	https://www.integration.samhsa.gov/clinical-practice/sbirt/ASIST.pdf
Adherence		
Adult AIDS Clinical Trial Group (AACTG) 4 Item Adherence measure	4 items Skipped taking pills within different timelines	https://doi.org/10.1080/09540120050042891
Antiretroviral Medication Adherence Rating Scale Item	1 items Antiretroviral medication adherence	
Antiretroviral Medication Adherence Visual Analogue Scale	1 item VAS Antiretroviral medication adherence	
Simplified Medication Adherence Questionnaire (SMAQ)	6 items Medication non-adherence	https://eprovide.mapi-trust.org/instruments/simplified-medication-adherence-questionnaire
Sexual Risk Behavior		
Sexual Risk Behavior Inventory	Sexual risk behavior across sex, sexual orientation, gender identity, partner HIV serovirus status and partner treatment status Approximately 12 items – skip patterns determine which items are completed by an individual	Fredericksen RJ, Mayer KH, Gibbons LE et al. Development and Content Validation of a Patient-Reported Sexual Risk Measure Use in Primary Care. Journal Gen Intern Med. 2018;May 29.
Quality of Life		
EuroQol Group (EQ-5D)	5 items Quality of life	https://euroqol.org/support/how-to-obtain-eq-5d/
Medical Outcomes Study (MOS) SF-12	12 items Health-related quality of life (HRQL)	https://campaign.optum.com/optum-outcomes.html
Other		
Assessment of Body Change Distress Questionnaire Short Form (ABCD-SF)	26 items Body image disturbance	
HIV Symptom Index Distress Module	Experience with treatments, perceived level of fatigue	https://medicine.yale.edu/intmed/vacs/groups/HIVSymptomIndexDistressMod.aspx

Note that these instruments are the ones used by the different CNICS sites

1.3 What Permissions Are Needed to Use a PRO?

While many PROs are available in the public domain, others require licenses (with potentially fees) or developer notification before being used. Table 2 above includes contact information for the developers of a few PROs currently used with PLHIV. Regardless of which PROs are selected for use, check with the developer for permission to use the instrument or any licensing fees. Not all PROs are free to use and requirements for use can change over time.

1.4 How Might the PROs Be Administered? Should a Patient be Guided Through the Questions?

PROs can be completed by a patient without support (self-administered) or the patient may be guided through the process by another person (interviewer-administered) who typically asks the questions. In the context of clinical implementation AND given that many of the topics in PROs used in HIV clinics focus on potentially embarrassing or stigmatizing questions, it may be that a self-administered process is preferred.

The rationale for selecting self-administered PROs o includes the following:

- Allows direct assessment from the patient
- Eliminates the need for an interviewer to be trained and on site, thus keeping costs down
- Ensures that the patient feels an element of privacy when responding to questions that may be potentially embarrassing or stigmatizing such as sexual behavior or mental health issues
(Lawrence et al. 2010)

Self-administered PROs are used by all the CNIC sites for the above reasons. Even in clinics with low literacy rates the majority of patients are still able to complete self-administered PROs.

Practical tip: One relatively common reason for a patient not being able to self complete a PRO process is that they may not bring their glasses – clinics may benefit from making a set of reading classes available.

Practical Tip: A staff member should check on the patient early in the process to make sure they are not having any difficulties with completing the PRO – i.e. does their body language indicate they are having difficulties

1.5 Mode of Administration – How are the PROs presented to the patient?

The mode of administration, or the method used to deliver the PRO instrument to the patient is another consideration. For example, PROs may be completed in paper or electronic format in a clinic.

An electronic mode of data capture is highly recommended for a clinical setting, since it is generally easier for the clinic staff and the patients, and can provide an option for immediate and accurate scoring and presentation of results.

In Table 3 some of the advantages/disadvantages of paper and electronic methods are considered.

Table 3. Advantages and Disadvantages of Paper vs Electronic Administration

Advantages of electronic administration; e.g., via iPad	Advantages of paper
Can be programmed to target specific PROs to select patients	Some patients may be more comfortable with paper questionnaires, if they are unfamiliar with electronic devices.
Data is entered directly by the patient	The process can be implemented more quickly and at less cost.
Can be programmed to require responses to each question, thus eliminating the risk of missing information.	
Potentially less intrusive than paper forms	
May be considered more private and secure once entered than paper	
Questions that are not relevant based upon a patient's previous answers can be automatically skipped and not shown; this decreases patient burden and optimizes the use of time.	
Post-launch adjustments can be made	
Real-time accurate summary results including interpretation guides can be automatically generated. Paper forms will require manual review, scoring and interpretation.	
Data storage allows simpler storage and recall of previous PRO results; paper forms may need to be scanned or data entered into a computer for storage, or for tracking results over time	

Below are some things to consider when programming an electronic mode of administration.

- Use a large font size – making it easier for older adults to read
- Use radio buttons to ensure only one response per item
- Consider making different languages easily available (e.g., the user can choose between English and Spanish)
- Make it easy for patients to go back to questions and correct or change their answer
- Allow the ability to skip questions
- Note that many people prefer a touch screen rather than a mouse or keyboard, this is especially true for older patients
- Keep typing at a minimum

The electronic mode of administration is preferable to that of using paper and is highly recommended for implementation. Moving forward this toolkit assume an electronic mode of administration.

Several options exist for electronic administration and the advantages and disadvantages of each should be considered:

- Laptop
- Desktop computer
- Tablet – strongly recommended – rationale below.
- Handheld device
- Bring-your-own device or smartphone

Consider what might work best in the clinic and with the patient population. A stationary desktop or laptop computer has the advantage of being secure, and less likely to be dropped, lost, or stolen but relies on using a mouse or keyboard which may be difficult for some patients. A tablet or handheld device is portable, and permits PRO completion in multiple locations, like the waiting room or exam room and has the added advantage of using a touchscreen as well. Bring your own device or smartphone has the advantage of allowing the patient to use a familiar device but requires app development , the ability to either print hard copies or to link somehow to the electronic medical record and the patient must remember to bring it with them to the appointment Any of these choices will require an upfront financial commitment.

1.6 The Importance of PROMs with Clear Scoring and Interpretation Guidelines.

It's best to choose a PROM that has clear scoring and missing data guidelines. Clear scoring guidelines will help support providers to make decisions based upon the output. A completed PROM can have a range of different outputs of value. For example:

- total scores based upon all questions
- scores that are based on a discrete concepts or sections within a PROM
- Scores based upon a single-item.

Some PROMs require an algorithm that helps convert responses into scores that are easy to interpret and explain, such as a single number; some PROMs simply require answer scores totaling up.

The scores can then be compared against an interpretation grid. For example, a depression score of 24 from a depression severity questionnaire may suggest 'severe depression'; it is important to understand the sensitivity and specificity of the cut-offs.

It may also be valuable where a PROM instrument provides:

- Reference scores for 'similar' patient groups that allow providers to compare their patients with similar patients; e.g., those on the same type of medication.
- Reference scores for HIV patients, which then allow the provider to compare individual patient scores with the average of a larger population

- Reference scores for general population, which allows the provider to compare an individual patient score with a normative score
- Linking scores to clinical practice guidelines

The value in an approach that enables a comparison of the change in a patient's score over time should also be considered.

An example of interpretation guidance is presented in Table 4 for the PHQ-9 (Kroenke et al. 2001). The PHQ-9 captures the frequency of depressive symptoms experienced in the past two weeks by asking 9 questions. The response options to each question are "not at all (0)," "several days (1)," "more than half the days (2)," and "nearly every day (3)." The PHQ-9 has been used to make a tentative diagnosis of depression in at-risk populations, and it has been validated for use in primary care (Cameron et al. 2008). To score the PHQ-9, the totals for each question are summed to reach a total score (maximum 27).

Practical Tip – Keep score presentation simple, providers are busy and have limited time to review and interpret (see section 5.2 for an example)

Practical Tip – Show results of last three visits to provide a longitudinal snapshot to the provider

Table 4. Example of PHQ-9 Scoring

PHQ-9 Score	Provisional Diagnosis	Treatment Recommendations
5-9	Minimal symptoms*	Support, educate to call if worse, return in one month
10-14	Minor depression**	Support, watchful waiting
	Dysthymia	Antidepressant or psychotherapy
	Major depression, mild	Antidepressant or psychotherapy
15-19	Major depression, moderately severe	Antidepressant or psychotherapy
≥20	Major depression, severe	Antidepressant or psychotherapy (especially if not improved on monotherapy)

*If symptoms are present for more than two years, then probable chronic depression, which warrants antidepressant or psychotherapy (ask "in the past two years, have you felt depressed or sad most days, even if you felt okay sometimes?")

** If symptoms are present for more than one month or severe functional impairment, consider active treatment

PHQ-9 scoring resources provide an example of how PRO information can be translated into clinically useful information (http://www.cqaimh.org/pdf/tool_phq9.pdf).

1.7 Timing, Frequency, and Duration of PROs?

"We decided on a five-minute time limit so that we knew that we weren't giving patients 20 different questionnaires to complete when they only have a five-minute window to do the questions."

- Clinic Manager, speaking about implementation experience

After selecting domains and instruments of interest, consider the timing, frequency, and duration of administering the PRO to patients in the clinic. Not all PROs need to be administered at every visit. Base the choice on clinical relevance, and those most likely to change with an action or intervention.

An electronic PRO system has the advantage in that it could be programmed to set a time interval for each instrument, with the patient completing only what is due or appropriate for that day.

The clinic team should discuss the burden on the patient, as well as the clinic flow before implementing PROs and this can help shape PRO implementation.

Consider having the patient only complete PROs during a routine provider visit rather than at other visits, such as appointments for testosterone injections, a nutritionist. Do not administer PROs during acute or urgent care visits.

1.7.1 Start-up

Start the PRO implementation slowly. First implement one or two of the more benign PROs asking about symptoms rather than behaviors (which may be embarrassing or stigmatizing). This will help ensure patients are comfortable and identify any timing, equipment or other issues. Time the PROs to ensure that the full set takes no more than 5-15 minutes – may want to stop patients after 15 minutes if they appear to be struggling. Make sure that providers receive PRO data regardless of whether patients have completed or not.

Another approach to starting up could be to implement the PROs only with a few providers which would allow the identification of any issues in PRO summary delivery or provider interpretation.

1.8 Resource Materials

[ISOQOL User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice. V2:](#)
January 2015

[PROMIS](#) health measures

[REDCap Shared Library, REDCap data collection instruments](#)

1.9 References

Cameron IM, Crawford JR, Lawton K, et al. Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *Br J Gen Pract.* 2008;58(546):32-36.

Fredericksen RJ, Mayer KH, Gibbons LE et al. Development and Content Validation of a Patient-Reported Sexual Risk Measure for Use in Primary Care. *Journal of General Internal Medicine.* 2018; May 29

Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16(9):606-613.

Lawrence ST, Willig JH, Crane HM, Ye, J et al. Routine, self-administered, touch-screen computer – based suicidal ideation assessment linked to automated response team notification in an HIV primary care setting. *Clinical Infectious Diseases.* 2010;50:1165-1173.

Chapter 2. Obtaining Stakeholder Buy-in

2.1 Engaging Key Stakeholders Early in the Implementation Process

At a very early stage of considering PRO implementation, it is important to engage key stakeholders to ensure that the proposal can build momentum from initial scoping, through to implementation in a sustainable state. Failure to engage, alleviate concerns and secure endorsement can delay or ultimately derail the project. Such stakeholders may include (but are not limited to) patients, clinic staff, care providers, researchers, and hospital administrators. Use the broad goal of improving care to engage stakeholder interest. For example, most stakeholders will be interested in how PROs can be used to identify a suicidal or non-adherent patient.

In engaging stakeholders, it should be recognized that their goals may be considerably different. Early discussions to understand both concerns and hopes are important, and the tailoring information to meet these needs can help secure valuable support. For example, providers may be most motivated to adopt PROs to increase the appropriate diagnoses or identification of issues such as non-adherence; administrators meanwhile may want to know if PROs can help in justifying resource demands such as additional FTE capturing data to satisfy clinical requirements such as mental health assessments. Regardless of the stakeholder or motivation, engagement early in the process can negate lingering (and possibly false) objections being raised that can impede proposals.

Experiences from those who have implemented PROs across multiple clinics suggest that the approval routes and the key personnel to engage can be very variable; it cannot therefore be assumed that one route or tactic will necessarily work in another clinic

Practical Tip – It's critical to obtain buy-in from nursing and front desk management before implementing PROs

2.2 Securing a Champion of PRO Implementation

One effective strategy for building momentum around PRO implementation is to identify or cultivate a champion in the setting where PRO implementation will take place. A champion is tasked with advocating for the use of PROs, inspiring the range of stakeholders and increasing/maintaining commitment and maintain momentum of PRO adoption. The champion will remain close to the process as the evolves and will serve as a communication conduit for all parties, including eliciting arising concerns and issues, and communicating plans and successes in navigating these as the project evolves. This may typically be effectively disseminated from a position of clinical or administrative influence. The champion is often the clinic director – and a day to day champion such as PRO coordinator once implementation occurs. Champions provide leadership, guidance, and encouragement to stakeholders, and are focused on the sustainability of the PRO implementation.

2.3 How Can the Value of PROs Be Demonstrated?

An important step in achieving buy-in from stakeholders may be the development of a written “value proposition” for PRO implementation. Developing a value proposition for PROs is based on the review

and analysis of the benefits and costs that PROs can deliver to providers, staff, patients, and administrators. The value proposition must be short and easy to read for the busy stakeholder.

Table 5 below provides a flow to develop the value proposition.

Table 5. Steps to Identify Benefits of PROs in Clinical Care

Five stages of analysis and development:
1. Identify the stakeholders for whom PRO implementation delivers benefit or value.
2. Define the benefit, value, or impact for each stakeholder from the PRO implementation (i.e., positive, negative or neutral experiences). This stage includes gathering perspective and feedback to understand the needs of the stakeholder.
3. Demonstrate the benefit, value, or impact the PRO can have on stakeholders.
4. Present alternatives to PRO implementation. This step assures the stakeholders that all options have been considered.
5. Support the previous steps with evidence demonstrating the continued value of PRO implementation to the stakeholders.

Adapted from: Barnes et al. 2009

Practical Tip: Consider providing the value proposition in an oral presentation – allows for questions and discussion and improves buy-in from busy staff

In the case of PRO, adoption in the clinical setting, a value proposition should consider who the beneficiaries are (e.g., the patient, the provider) and what the advantage unique to the stakeholder might be (e.g., better quality patient data for diagnosis, and improved provider/patient interaction, more holistic use of clinical setting services [e.g., referrals], and improved health outcomes for patient).

In addition to developing a written value proposition for PRO implementation, informational events can be held to explain the purpose, value and timing of PRO implementation. Ongoing follow-up to garner stakeholder involvement or buy-in will be a necessary part of the PRO implementation to ensure momentum builds and any emerging concerns are addressed. The PRO champion can provide a pivotal role with this.

The subsequent chapters in this toolkit provide more information on how to get the PRO implementation started.

Practical Tip: Identify a staff member with practical experience using PROs and engage that person in both the value proposition and any in-person meetings

2.4 References

Barnes C, Blake H, Pinder D. *Creating & Delivering Your Value Proposition: Managing Customer Experience for Profit*. London, United Kingdom: Kogan Page Limited; 2009.

Chapter 3. Making the Business Case for PRO Implementation

3.1 Developing a Business Case

A business case is a formal statement of business goals, reasons they are attainable and the plans for reaching those goals. Business cases should be concise, no more than 15-20 pages at most. They may need to be updated as goals change.

3.1.1 What Does a Business Case Look Like for PRO Implementation?

While implementation of PROs in clinics is about improving patient care developing a formal business case assists in identifying short and long-term goals and associated budget requirements. Needs, solutions, approaches, risk assessments, and value analyses can all be part of a business case (Table 6).

Table 6. Example PRO Business Case Format

Potential Sections	Description
Executive Summary	This is a brief description of the overall plan including the goals, milestones and a summary of implementation.
The case for investing in PRO elicitation in routine HIV care	This section should succinctly outline the case for investment in PRO adoption. This can draw upon the complementary report to this toolkit (Kleinman et al. 2018) which outlines the value of clinically relevant PROs use; this evidence is drawn from published literature across multiple therapy areas, including HIV, and highlights how PROs can enhance care including increasing the detection of relevant diagnoses and risk behaviors, facilitate improved patient-provider communication and can be integrated within workflows without adverse effects. This can contrast current service provision against an enhanced service with PROs and how this will benefit. The overview may also describe key elements such as the likely patient numbers and impact of the service.
Statement of Goals and Objectives	This should clearly articulate exactly what is to be accomplished both short and long-term. This will be clear about the scope of the service.
Service overview	The proposed new service can be described in more detail, including: <ul style="list-style-type: none">● How PROs will be gathered● How the PRO process will integrate into the current workflow (mapping the patient and information journey)● Which patients will be eligible● How roles within the service will adapt or evolve.● Any new resources required, including personnel, facilities, program support requirements (e.g. IT) and hardware/software.● What PRO domains will be used
Project team	It is important to outline who is leading the project, and any proposed roles for existing or new personnel required to ensure adoption. This will include any champion role and any stakeholder reference group. Formation of a reference or steering group can ensure prioritization and focus to resolve issues and accountability for continued momentum in project progression.
Milestones and deliverables for implementation	Conveying confidence in how the project will be managed and monitored will be important to secure buy in.
Financial Analysis	There should be a clear and carefully estimated cost of what investment is required. This should include start-up and recurring costs.

Risk Management Plan	This section will details risks specific to the business plan. This may include process failures such as IT/wi-fi, staff turnover etc.
Measurable and Achievable Outcomes	Based on the goals section of the business, determine how success will be measured.

The resources provided below are online resources, guidances, and templates for budget development that could be used for PRO implementation. Before using any of these resources, it is important to check if approved budget guidance and templates are available from your organization.

3.2 Assessing the Financial Costs

“Because I think a lot of people start PRO programs, but then they end up not being sustainable because they need, for instance, full-time staffers to train and implement across all sites. Whereas in our example, I was needed, that was my full-time job and then once it was established it actually kind of just seamlessly embedded within our workflows and now the tablet is considered a part of the medical assistant’s duties.”

- Clinic Manager, implementing PROs at a large health facility

Understanding the financial costs associated with implementing PROs is fundamental to the project. There are different types of costs to consider: initial start-up (or one-time capital costs), and recurring fixed costs. A budget reflecting both types of costs should be created and reviewed by stakeholders and those responsible for proposing and funding the project.

3.2.1 Start-up or One-time Capital Costs

Start-up costs are needed to bring a project to operational status (e.g., software development, purchase of office equipment, licenses, etc.). These costs are typically incurred only at the beginning of the project or at a single point in time, in that they do not incur year-to-year or month-to-month expense.

Table 7 contains some of the start-up costs to consider when developing a program budget, but does not reflect all possible start-up costs for PRO implementation, as this will depend on individual clinic characteristics (e.g., integrated vs. standalone clinic).

Table 7. Examples of Start-up or Capital Costs

Budget Category	Description
Personnel ¹	<ul style="list-style-type: none"> Dedicated full-time or part-time staff to oversee the PRO process implementation <ul style="list-style-type: none"> Coordinate the process Manage the ePRO devices Available to address any immediate issues raised from both patient and clinic staff Part-time or short-term staff to help with IT program start-up (e.g., IT professional)
Office expenses	<ul style="list-style-type: none"> Materials for new staff overseeing PRO adoption: additional chairs, tables, bookshelves New space requirements: modification of existing space or rental of new space for new staff, or dedicated space for PRO completion by patients
Equipment	<ul style="list-style-type: none"> Hardware: computers for new staff; electronic devices for PRO Software: licenses for computers, software for ePRO
Communications	<ul style="list-style-type: none"> Network costs: additional phone or internet connectivity costs

¹ Personnel costs are often the majority of a budget and are the most important to fund adequately

3.2.2 Recurring Costs

Recurring costs occur on a regular basis, and typically fall within an annual budget period. The major portion of recurring costs is usually the addition of a single employee. Unlike one-time costs, recurring costs generally remain the same within the budget year (e.g., general administrative costs, rent, license renewal, etc.). However, normal price increases (e.g., rent increases, pay raises, or other cost-of-living increases) need to be budgeted for each coming year.

Table 8. Examples of Recurring Costs

Budget Category	Description
Personnel	<ul style="list-style-type: none">• Full-time or dedicated part-time staff to oversee the continued implementation of PROs e.g. connectivity issues, updating ePRO devices• Part-time staff to help with program start-up (e.g., IT professional) and ongoing intermittent support.
Office expenses	<ul style="list-style-type: none">• Office supplies; office space
Equipment	<ul style="list-style-type: none">• Software: maintaining computer licenses
Communications	<ul style="list-style-type: none">• Network costs: wi-fi, phone lines
PRO licenses	<ul style="list-style-type: none">• Potential license fees permitting the use of certain PROs
Evaluation	<ul style="list-style-type: none">• Staff time related to routine monitoring and period evaluations

3.2.3 Budget Development Resources

Wallace Foundation – [Budget Builder, Resources for Financial Accounting](#)

Parkland Hospital – [Developing a Budget](#)

3.3 References

Kleinman I, Skalicky A, Short D, Crane H, Fredericksen R, Lober B. Implementing Patient-Reported Outcomes (PROs) Within HIV Routine Care: An Evidence Review and Summary. ViiV Healthcare Report; May 2018.

Chapter 4. Building PRO Infrastructure

"Anytime you are doing anything with technology, there's always costs associated with that, are you going to use a tablet, an iPad, a stationary computer in your infrastructure. Your wireless can it handle more traffic, tracking of equipment?"

- Director of IT, implementing PROs at a large health facility

4.1 What Is Needed to Set Up an ePRO System?

A successful PRO system should integrate both treatment- and patient-centered perspectives into¹ one health information system. The first major step is deciding what vendor to work with. The second step is deciding whether to use a vendor's standalone system, vendor system with electronic health record (EHR) system integration, EHR vendor product, locally developed system, or system supplied as part of a network activity.

In some medical centers, it may be possible to integrate PRO systems into the clinic's EHR system, while in others, a standalone PRO system may be more feasible. This decision will then drive all other needs (i.e., software, hardware, data storage, data center needs).

There are a variety of ways to design a vendor system with EHR integration of the information flow, from patient-reported input on an electronic device to a PRO server integrated with the patient's EHR. The final product is the patient's PRO data reports, which could be available to providers in the form of a summary report.

- At the stage of **PRO input**, it is important to consider the type of device used, data entry checks or reminders, or IT support for troubleshooting issues with the PRO
- **PRO server and data storage** includes planning and designing the architecture of the PRO system to either be entirely disconnected to the EHR, exchange demographic, clinical, or patient reported outcomes, or be fully enclosed within the EHR and data storage system
- **EHR and data storage** includes the entirety of the patients' EHR, which may include the capacity to integrate with external PRO data systems or the ability to host PRO server and data storage within its own system
- At the stage of **discrete PRO data reports**, decision may include the capacity to produce real-time, question or item-level data, summary reports, or graphical displays

4.2 What Are Other Key Considerations for PRO Systems?

Other key technology considerations include system access, transmission, storage, and security. Table 9 describes considerations for the PRO system features.

Table 9. Key Considerations for Defining PRO System Characteristics Data

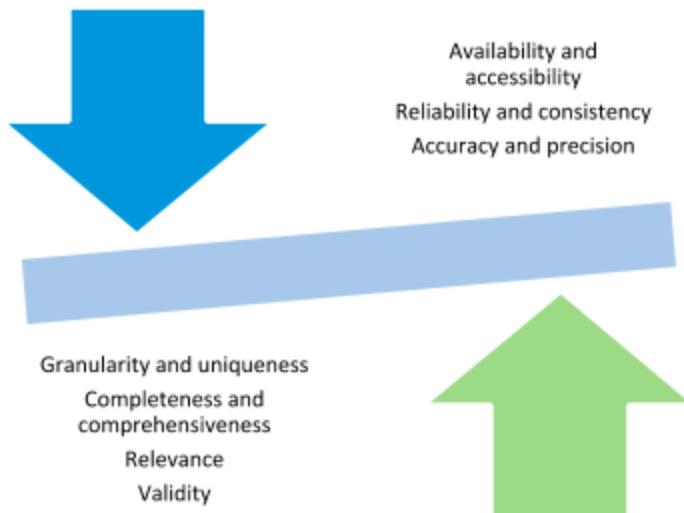
Key Consideration	Definitions
EHR infrastructure	Existence and type of EHR system. Important to consider because of both degrees of data integration and feature comparisons, between EHR vendor PRO tools, PRO tools that can be integrated with the existing EHR, and standalone PRO tools.

Data standards	Methods, protocols, terminologies, and specifications for the collection, exchange, storage, and retrieval of information associated with PROs
Dashboard design and alerting	Frequency and scheduling of alerts, the data displayed in the dashboard to monitor system performance and usage, the number of clicks or steps required to access information, whether there should be capabilities to temporarily mute or turn off certain features, and the types of icons and graphics that are recognized most easily.
Data accessibility	The data gathered by the PRO system must be accessible at both the individual and population levels, with quality, timeliness, and accuracy appropriate for each intended use.
Interoperability	The ability of different vendor systems and software applications to communicate, exchange data, and use the information that has been exchanged; interoperability is enabled by common data standards.
Adaptability of technology	Changes in the usage of PROs across different patient groups and/or different health domains; this capacity to adapt to new health system needs requires processes to be defined and documentation to be in place for local developers.
Adaptability of content	Consulting patients and providers, and using their input to determine how to collate data received; responds to the need to align PROs with patient/provider needs, or to translate the content into new languages.
Translatability	The capacity of PROs to function across different types of mobile devices and operating systems; ensuring hardware and system compatibility with technologies that are adaptable to a variety of needs will greatly facilitate the scaling up and sustainability of PRO systems in new settings.
Language	PROs must be delivered in a language or set of languages that is accessible by patients or family members reporting their outcomes, and the results must be delivered in a language that is accessible by providers or others who must understand and act on those results.
Workflows	PRO usage must fit with the workflows and activities that both patients and providers undertake. Those workflows may be a change from existing workflows, but planning for that change facilitates effective implementation.
Storage needs	PRO data used for clinical decision making must be considered part of the medical record and, whether stored within the EHR or apart from it, is subject to regulations and policies pertaining to data reliability, integrity and retention.
Data security and privacy	PRO systems and the storage of data from PROs must comply with applicable privacy and security regulations.

Adapted from: American Health Information Management Association 2013

System features may include creating an easy-to-navigate menu (i.e., dashboard) to enhance data accessibility and quality. Minimizing data errors within the PRO system is critically important. Errors or missing data can be reduced through automated data quality assurance measures that assess data for inconsistencies (e.g., validation rules built into the application). **Figure 1** describes the characteristics that define data quality.

Figure 1. The Characteristics that Define Data Quality



Adapted from: DAMA UK Working Group 2013

Accuracy and precision refer to the exactness of the data. Accuracy in healthcare is worth high levels of investment. The data must not contain errors, and must convey the correct information without being misleading. PRO answers that are considered valid or legitimate based on the survey's requirement are allowable. At the same time, it is important to realize that requiring a patient to answer a question does not guarantee accurate data, any more than requiring a health care provider to acknowledge an alert guarantees their thoughtful consideration of the underlying information. Patients should be given a pathway through the PRO process which encourages them to provide information useful to their care, and to understand the benefit of providing that information.

There must be a valid reason to collect the data to justify the time and effort required. PRO data collected that is not relevant can misrepresent a patient's health status and drive inaccurate clinical decision-making. Incomplete data collection can lead to incomplete understanding of patient health. Providers need the right level of access to the PRO data to adequately evaluate the data in a timely manner.

There must be a reliable mechanism that collects and stores the PRO data without inconsistency or variance. The level of data detail is important, since inaccurate decisions can occur if the data is not clearly presented. Simple raw data may have a different meaning than data that has been aggregated and summarized.

4.3 Additional Considerations

A PRO system that offers a wide range of software features can adapt to specific patient or provider needs without additional programming, and supports reporting and data visualization solutions.

4.4 Resources

Guidance on Infrastructure

PCORI Patient-Reported Outcomes (PRO) Infrastructure Workshop “Integrating PROs into EHRs” Atlanta, November 19-20, 2013, Draft – October 15, 2014

Coons SJ, Eremenco S, Lundy JJ, O’Donohoe P, O’Gorman H, Malizia W. Capturing Patient-Reported Outcome (PRO) Data Electronically: The Past, Present, and Promise of ePRO Measurement in Clinical Trials. *The Patient.* 2015;8(4):301-309. doi:10.1007/s40271-014-0090-z.

Other Helpful Information or Examples

Clinical Data Capture and Management Evaluation Checklist, [Oracle Data Sheet](#).

Review of Data Accessibility Methods In Healthcare (PDF Download Available). Available from:
https://www.researchgate.net/publication/280722426 REVIEW_OF_DATA_ACCESSIBILITY_METHODS_IN_HEALTHCARE [accessed Feb 12 2018].

The MAPS toolkit: mHealth assessment and planning for scale. World Health Organization (2015).United Nations Foundation. UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. Johns Hopkins University.

REDCap is a secure web application for building and managing online surveys and databases
<http://projectredcap.org>

4.5 References

American Health Information Management Association. Data Standards, Data Quality, and Interoperability. 2013 update. Available at: <http://library.ahima.org/doc?oid=107104#.WpmBX2rwapq>. Access date: February 27, 2018.

DAMA UK Working Group. The six primary dimensions for data quality assessment: defining data quality dimensions. October 2013. Available at:
https://www.whitepapers.em360tech.com/wp-content/files_mf/1407250286DAMAUKDQDimensionsWhitePaperR37.pdf. Access date: February 27, 2018.

Chapter 5. Integrating PROs into Clinic Care Settings

5.1 How Will the PROMs Be Integrated into the Clinic Flow?

An assessment of the clinic flow is needed to determine the appropriate place to administer the PRO—as well as the appropriate point in the clinic visit. A typical clinic flow might include the following stops for the patient, although mapping the process carefully to consider the best place to integrate is a valuable exercise:

The key question is where do **your** patients spend most of their waiting time as that will vary depending on individual clinic set-up

- Patient check-in
- Spending time in the waiting room
- Being taken to an exam room by a medical assistant
- Getting vitals taken
- Waiting in exam room
- Seeing doctor
- Labs
- Patient checks out

In this example, there are several timepoints in this where PROs might be administered, although suitability will be dependent upon wider factors such as the clinic layout, type of device used to administer the PROM, the degree of confidentiality and privacy afforded by the location etc. PROMs completed in clinic, are generally best completed in a quiet space, where patients can have privacy to focus. Since waiting times vary, clinics may need to build in a window for PRO completion – for example asking patients to arrive 10-15 minutes early for an appointment

Testimonials from stakeholders within clinics who have adopted PROs into routine care may provide useful insights on best approaches.

“.... did not want this to be an impediment to care in the clinic ... so she’s been very careful that the research coordinators are off to the side, they don’t get in the middle of the flow of the clinic. The paper with the PRO outcomes on it, the document kind of magically appears in the door before you get to go see patients. It’s really done very well and there’s no impact on flow at all.”

- MD and Clinic Director

“.... our patients don’t wait long before their visits, ...they are only going to be out there for a few minutes and they wouldn’t really be able to complete the survey, so we opted to do it in the exam room, give the patient more time, more privacy and then they also had access to a medical assistant who might be able to answer the questions better than say a front desk staffer who’s not really trained clinically.”

- IT director

"... the first thing was to really understand the workload of your clinic and then I ended up finding what I called pockets of clinic wait time. The way our clinic works is we have a lot of mid-level providers, like PA's and nurse practitioners and we also have fellows. So, there's a waiting period in the waiting room, then people get put into a room and they will wait for their first provider to see them. Then there's a wait period until the second provider goes to see them. And then there's a wait period in our lab until they get their labs drawn. So, you see that's four clinic wait periods and on average the total wait time of some of those periods in our clinic is probably around 45 minutes to an hour. I think on a bad day, there's days when it's sooner, but on average I think it's at least 30 minutes.... (PROs) are between 12 and 15 minutes."

- MD and Clinic Director

"So, a lot of the initial start-up time ... is looking at and examining our clinical workflows and really figuring out where is the best point of contact for administering our e-PROs. For instance, when we piloted ... we first tested whether or not it would work to ... give our tablet device to patients out in the waiting room or whether it would work in clinical exam rooms. We tested both methods to see what would work. We also looked at timing, so we created an interface that had 11 algorithms behind it, so that it wasn't just administering the same instruments every time. So, we created a prioritization of which were the most important instruments to administer and have it fit within a five-minute time limit so that we knew that we weren't giving patients 20 different questionnaires to give when they only had about that five-minute window."

- ePRO Project Manager

Practical Tip: If a patient is late for an appointment don't ask them to complete the PROs as it could interfere with clinic flow

Practical Tip: When thinking about the PRO process, make sure it fits around the clinic flow and don't make the clinic fit into PRO implementation

Practical Tip: Consider what other tasks the patient must do before the appointment – completing insurance or socio-demographic information etc. Keep the PROs short and simple to complete

Practical Tip: Remember the output must be ready for the consultation

Below is a list of questions that can be helpful to ask to clarify the appropriate method for PRO implementation in a clinic setting:

- Consider each staff in the clinic—what role will each of them play (e.g., provider, front desk, medical assistant, other staff)?
- Who will ensure the patient completes the intended PROMs during the visit?
- Who will provide instructions to the patient?
- How easy is it for the patient to complete the PROM?
- Where will the patient complete the PROM?
- What will the patient do with the PRO device when he/she has finished?
- What will happen with the patient's PRO information during the visit?
- How will the PRO data be delivered seamlessly to the provider?
- What results will be shown to the patient?

- Who will talk to the patient about the PRO results?

For providers and staff there is a question of whether the necessary staff are in the clinic to support the patient flow as they complete PROs (i.e., physicians, nurses, medical assistants and other clinical staff).

And at the clinic level, implementation of PROs needs to have sufficient rooms, and assumes no computer or scheduling problems.

5.2 How and When Are the Results of the PROs Presented to Providers?

"I think that that's one of the keys, if they are going to implement a system like this, it's important for the provider to have the data before they see the patient walk into the exam room. Because if it comes in after the fact then it's harder for the provider to actually act on that."

- Clinic Manager, speaking about implementation experience

The decision to have real-time PRO data available for a scheduled clinic visit, or to review data post-visit, depends largely on the ability of the PRO system to support the collection and scoring of data, and for the provider to interpret the results in a timely manner. CNICS preference is to have the data available at the time of the visit because that provides the most clinical value. Providing the data to patients or providers without simple interpretation will not be effective for a clinic appointment. Ideally the results should also be formatted in a way that supports sharing or communication to the patient.

Table 10 provides an example of a dummy report from a real PRO summary sheet in a large clinic.

Table 10. Examples of PRO Results Presentation

Patient-Based Measures Provider Feedback		Printed 8/5/2014		
Multi Testa	MRN:	DOB: 1/1/1970		
		6/20/2014	3/15/2014	12/1/2013
Depression (PHQ-9)	1 24 Severe depression (20-27)	1 25 Severe depression (20-27)	17 Moderate depression (10-19)	
Suicide Ideation (PHQ-9) In Last 2 Weeks	1 3 Nearly every day	1 2 More than half the days	1 2 More than half the days	
Tobacco Use	Currently (Between 1 and 2 packs a day)	Currently (Between 1 and 2 packs a day)	Currently (Between 1 and 2 packs a day)	
Alcohol Score	9 (Incomplete) At-risk (AUDIT-C)	10 (Incomplete) At-risk (AUDIT-C)	21 At-risk (AUDIT)	
MINI Score	No questions answered	No questions answered	5 Dependent Drinker	
Substance Use (Past 3 months)	Cocaine/Crack, Opiates, Amphetamines, Marijuana	Cocaine/Crack, Opiates, Amphetamines, Marijuana	Cocaine/Crack, Opiates, Amphetamines, Marijuana	
Antiretroviral Adherence (Past 4 weeks) Last missed	1 Very poor 1-3 months ago	1 Very poor Within the last week	1 Fair 2-4 weeks ago	
High-risk Behavior (Past 6 months)				
Anal sex condom use	Never using condoms	Never using condoms	Some of the time	
Vaginal sex condom use	Never using condoms	Never using condoms	Most of the time	
Sharing needles/injection equipment	A few times each week	A few times each week	A few times each month	
Oral sex partners	11-15	11-15	2	

5.3 How Is the PRO System Explained to Patients?

"... we give (the patient) a score and the interpretation on a paper print out. We also give a print out to the provider, the provider then scans it into the EMR, so that's how it gets put in."

- PRO Manager, speaking about implementation experience

The PRO system should be incorporated into the clinic routine so that patients become accustomed to it.

At the onset there should be a formal introduction for the patient, which should include explaining the reason for completing a PROM. The importance of completing the PROs at specified visits should be emphasized with the patients, specifically noting that this will provide them with an opportunity to help guide the agenda for their visit and identify problems important for their welfare. Patients should be told that their provider will receive the results of the PROs. PRO results will help the provider and the patient identify and address critical problems thus making the most of the visit.

PROs are done as a part of care so most Institutional Review Boards have found that no additional consent forms are needed.

A staff member should be available for hands-on training and support where necessary for patients the first time a PRO is being completed, so that they feel comfortable completing questionnaires on an electronic device. This may provide simple instruction such as navigating between questions on an iPad.

Example elements of a script for introducing a patient to PROMs in routine care:

"Hi, I'm <name>, we are using a new patient questionnaire in the clinic. We would like you to fill out the questionnaire on this tablet. The questionnaire asks about your general health, how you are feeling, and questions that will help your provider support you today. Please answer as many questions as possible. Please let me know if you get stuck and need help. It should only take a few minutes of your time."

5.4 What Is Needed if an Issue is Identified by the PRO

Below is an example from a CNICS clinic manager

Example outcome planning: Depression and Suicidality Action Steps

"We have escalation procedures for patients answering depression screen over a certain threshold of how frequently (they) are thinking of committing suicide. The PRO system will send an [electronic] page to the clinic psychologist and the clinic social worker (They will follow) a protocol that's been created for the clinic and...an assessment for safety. That assessment has three potential outcomes:

1. *We've got to get this person to the emergency department right now, there's clear and present danger here.*
2. *There is moderate danger, we've spoken to family, we've spoken to the support system and we will see (the patient) in clinic later this week; and*
3. *[everything] is it okay, we think that regular psychology and/or psychiatry visits will continue to be enough for this client."*

- Clinic Manager, speaking about implementation experience

For PRO results that indicate a potential health issue, decision aids such as a suicide or mental health protocol should be available. These will be dependent upon the PROM mix adopted by the clinic but

scenario planning is recommended. Consider who needs to know the information and how that information will be provided in a timely fashion.

- What needs to be put in place –e.g., an automatic notification to a social worker or mental health provider for suicide ideation;
- Automatic notification to a case manager for substance abuse or adherence issues

Examples of PROs with interpretation guidance are provided in the resources section (5.7).

Practical Tip: The PRO summary review sheet can use exclamation points and color to alert providers to issues

5.5 Piloting PROM Implementation

A pilot test of the entire PRO system should be conducted before it is ready to be completely implemented in the clinic setting. Readiness for a pilot test assumes the PROs have been selected and programmed, and that the clinic staff have all been trained.

Among the areas to be tested by the pilot may be:

- How are patients responding to the PRO process? Is the process clearly articulating and preparing patients? Are they able to navigate and complete the questions? Is sufficient support available for patients? Are anticipated completion times matching actual completion?
- Are the staff comfortable with the process?
- Is the flow integrating smoothly into care?
- Is the programming working – are summary scores being produced and delivered to the providers as expected?
- Are the providers able to interpret the PRO results and convey the results to patients?
- Is there any effect on clinic work flow that needs to be addressed before widespread implementation?

Where necessary, changes can be implemented and pilot-tested until the complete system is ready for rollout.

Case study – Graduated Approach to Implementation

"... we did a graduated approach ... we definitely had a lot of reluctant providers,... I think having the gradual approach was good because it got other people interested, ... once you're on this system you no longer have to hand out specific PRO health questionnaires, like the PHQ9 for depression to the patient, collect that and then enter that in. All of it would happen automatically through our PRO system. So, that actually increased buy-in.. and had a lot of people interested and eager to join the program."

- ePRO Manager

5.6 Planning for Full Integration into Clinical Care?

In the start-up phase, a full-time staff member such as an ePRO manager might be required to oversee implementation. However, once the PRO system has been tested and issues or challenges have been addressed, it is time to find sustainable staffing and funding for the PRO system. The PRO system needs to have a champion who oversees and/or manages any ongoing implementation/feedback. Necessary tasks to support the PRO system should be fully embedded within the clinic workflow to be part of standardized care and the medical record.

Multiple stakeholders, from senior leadership to medical directors, as well as the day-to-day users of the PRO system (like medical assistants), need to be involved in decision-making to ensure there is continual improvement of the system. Finding inter-departmental synergies for the PRO system will guarantee the sustainability of the PRO system.

Ongoing system monitoring, training, and education will ensure that the PRO implementation continues to improve and adapt to changing patient and clinic needs.

5.7 Resources

PCORI Patient-Reported Outcomes (PRO) Infrastructure Workshop “[Integrating PROs into EHRs](#)” Atlanta, November 19-20, 2013, Draft – October 15, 2014

The Ottawa Hospital, Patient Decision Aids <https://decisionaid.ohri.ca/azlist.html>

Mayo Clinic, Center for Innovation, [Depression Decision Aid, “What you should know”](#)

Dartmouth-Hitchcock, [Decision Support Toolkit for Primary Care](#)

National Learning Consortium, [Shared Decision Making, Fact Sheet](#)

Agency for Healthcare Research and Quality, [The Share Approach](#)

Chapter 6. Training Clinic Personnel

This chapter provides guidance on developing training for different staff members on the implementation of PROs into routine HIV care. Without adequate staff training, PRO implementation can become more difficult—e.g., staff unsure of what to do or how to interact with the patient, interruptions in the clinic flow. Training also serves to reinforce buy-in to the process and understanding of the value that this can bring by improving the effectiveness of the intervention.

6.1 Initial Training Needs

Training appropriate staff members on PRO implementation is critical to smooth functioning in the clinic. A range of materials for each role will need to be developed. It is envisaged that a general overview of the process and the value will be relevant to all involved; specific training elements relevant to the execution of individual roles will also need to be developed according to the flow adopted by the clinic.

The following are a non-exhaustive list of training topics that are relevant to PRO integration. These may not be relevant to all roles.

- Background, purpose, and value of the PRO system.
- How PROs are integrated into the workflow and the expectations for each role in the process.
- Which patients will complete the PROs and how this is determined and managed?
- How to introduce the PRO process to patients who are unfamiliar or require a reminder.
- Where and when patients are expected to complete the PROs, and how long this is expected to take?
- An awareness and understanding of the PROs adopted by the clinic:
 - Context and content of the instrument
 - Scoring and output of the instrument
 - Interpretation of results
- Familiarity with the IT system, the question flow and navigation requirements.
- Awareness of relevant clinical protocols and actions potentially triggered by the results.

Each clinic will have a different approach to facilitating communication regarding the implementation of PROs. Approach to communication can depend on the clinic staffing model – whether the same providers are there every day or whether, as in an academic setting, there are numerous providers working ½ day per week. Approaches to communication can include e-mail roll-out and updates, staff meetings, section in orientation manual for the clinic, specifically convened meetings for trainings. The choice depends on how the clinic is staffed and the usual methods used for communication.

PRO output given to providers should be easy enough to interpret that no specialized training is needed.

For certain roles there may be a benefit in training together and a sharing of approaches to improve the system. For example, physicians may have approaches to using and explaining the outputs that would support their peers; similarly, individuals who may explain the process to a patient may benefit from combined training and sharing of styles and experiences.

Where possible it may be that best practice clinic approaches can be documented or recorded for both ongoing review by staff members and for supporting the development of new team members. Such examples have included PRO coordinator scripts and video recordings of a physician conducting a mock consultation to demonstrate effective introduction and use of the PROM outputs.

Practical Tip: Use alternative methods of communication such as e-mail if in-person meetings are impractical or as a follow-up for those who can't attend

Practical Tip: Have a staff member assume the personality of a patient and complete the PROs to enhance understanding of the process and the difficulty patients may have

Practical Tip: If the clinic has an orientation manual for new hires, include a short paragraph about the PRO process

6.2 Ongoing Training

Consideration should be given to providing refresher training or process checks as time goes on to ensure that the process is operating optimally. Options may include observation by another staff member or a formal refresher session.

6.3 Useful Resources

Eye for Pharma: Using ePRO for the First Time: [Lessons Learned](#)

Schick-Makaroff K, Molzahn A. Strategies to use tablet computers for collection of electronic patient-reported outcomes. *Health and Quality of Life Outcomes*. 2015;13:2.
[doi:10.1186/s12955-014-0205-1](https://doi.org/10.1186/s12955-014-0205-1).

Chapter 7. Monitoring and Evaluation

The implementation of any new process should be accompanied by a monitoring and evaluation (M&E) plan to establish if this is successful and if improvements can be made. This section provides a simple overview of some important considerations.

Any M&E should be tailored to the aims and objectives of the individual program. It can serve to help the program grow and evolve to best meet the needs of stakeholders.

7.1 Identify Relevant Indicators to Help Assess the Program's Success

"Even though there is no correlation between patient satisfaction and quality of care, we all have to keep our patients satisfied. So, if patients feel like they are being heard and if their visits go better and if they get to voice their issues more completely by using a PRO, then chances are they are going to feel better about the visit. Then patient satisfaction scores will likely rise and those are also important to administrators and people who are vying for healthcare contracts. Patient satisfaction gets posted on the web and is tied to reimbursement."

- Physician /Medical Director, speaking about implementation experience

Clear and concise indicators are the basis of any effective M&E system. Two types of indicators are important to consider when assessing a PRO program (Table 11):

- Process indicators, which provide information about the scope and execution of the process.
- Performance indicators, which include program outcome information such as the effectiveness of service delivery.

Table 11. Examples of Indicators Based on PRO Data

Examples of process indicators based on PRO data	Examples of performance indicators based on PRO data
Percentage of patients refusing/startling/completing the PRO process.	Percentage of patients with depression who receive antidepressant medications
Number of screenings for improvement in symptoms	Number of patients who indicate suicidal ideation who are provided with an intervention.
Number of screenings to identify adverse events	Patient satisfaction scores

One simple method of reviewing any indicators to use in the M&E process is to use the SMART criteria (see below). Consider each of these points when developing new indicators or revising old ones.

- **Specific:** The indicator should accurately describe what is intended to be measured, and should not include multiple measurements in one indicator.
- **Measurable:** The indicator produces consistent results if obtained and tracked under the same conditions.
- **Attainable:** Collecting data for the indicator should be simple, straightforward, and cost-effective.
- **Relevant:** The indicator should be closely connected with each respective PRO outcome.
- **Time-bound:** The indicator should include a specific timeframe.

Examples of indicators developed using the SMART **indicators** are shown below in Table 12.

Table 12. Examples of SMART Process and SMART Performance Indicators

SMART Process Indicators	SMART Performance Indicators
ePRO completion rates: Over a six-month period, ePRO completion by at least 50 % of patients scheduled for routine clinic visit	Patient-provider communication: Over a six-month period, more than 70% of patients scoring moderate-to- severe depression on PHQ-9 will have discussion about depression symptoms with their provider documented in their medical record.
	Mental health service referrals: Over a six month period, more than 70% of patients scoring moderate-to-severe depressive symptoms on the PHQ-9 will receive immediate referral by their provider to the mental health services.

7.2 Determine the Frequency and Process of Monitoring and Evaluation

An M&E plan should be designed to measure progress over a program's life span. However, year-to-year M&E strategies are common, based on funding cycles or other factors.

Within annual cycles, data collection should occur at least once between the start and end of the program year. Frequency of collecting data is mostly dependent on the program's cost and length—i.e., longer programs, or those with more funding, can typically collect comprehensive data more frequently than shorter programs or those with less funding.

Data collection methods should be carefully considered to minimize the risk of bias arising from the method chosen. Ideally, an individual with research experience should have oversight of the proposed approach.

7.3 Implement a Process of Continuous Quality Improvement

Continuous quality improvement (CQI) is the process of improving the program on a continuing basis. It can be described as an ongoing cycle of collecting data and using it to make decisions to gradually improve program processes (US DHHS 2017). It therefore becomes key that a well-developed M&E plan precedes CQI action and decision-making. Several suggestions on proactively collecting feedback are below as are two examples of CQI.

- Keep lines of feedback in place
- Be ready to make changes in PRO implementation as clinic processes change and evolve
- Continue to have staff act as patients to ensure that flow and ease of use are in good shape

Figure 2 includes two examples of CQI specific to PRO implementation.

Figure 2. Examples of CQI

Example 1: A clinic identifies several barriers to the screening using the PHQ-9: insufficient time with patients, lack of privacy and space to discuss, patient discomfort in discussing and lack of social work resources. Through the CQI plan the clinic pilots an intervention with several providers using both process and performance measures. The pilot intervention focuses on, delivering feedback in exam room, setting guidelines on which patients need intervention (i.e. those with PHQ-9 scores in moderate-to-severe range), providing scripted messages for providers to share with patients, and patient information on what their PHQ-9 score means.

Example 2: A clinic seeks to encourage and improve medication adherence amongst its patient population. Patients visiting the clinic fill out the Adult AIDS Clinical Trial Group instrument for medication adherence on tablet computers before seeing a provider. Through the CQI plan the clinic pilots an intervention where providers review and discuss the medication adherence results with the patient during the clinic visit and review and address barriers to adherence.

Other variables that could be observed over time for any changes include

- Changes in total appointment length
- Number of patients completing PROs
- Patient satisfaction with care
- Time providers spend reviewing and integrating the PRO into the care process
- Changes in consultation length
- Time spent by staff supporting PRO implementation - ongoing
- Costs and resource use

CQI frameworks can help clinics implement and measure change at their facilities. One such framework is the Plan, Do, Study, Act (PDSA) cycle, which is a cyclical process for developing and implementing change:

- “Plan” means to collect and analyze data and develop solutions to improve the program.
- “Do” means to implement one of the proposed solutions.
- “Study” means to measure any changes as the result of the proposed solution that was implemented, and
- “Act” means to adopt the solution of standard practice, or start over.

CQI is designed to be executed quickly—and thereby reduce the time needed to test solutions through evaluation—so stakeholders can see results more quickly (Hunter et al. 2015).

The CQI process aims to bring multiple stakeholders together. The integration of stakeholders ensures the appropriate expertise to gather and analyze program outcomes meaningfully, and to then suggest, implement, and evaluate any quality improvement efforts at the program and organizational level.

7.4 Resources

Minnesota Department of Health - [SMART Goals Guidance](#)

CDC Tools -[SWOT Analysis Tool](#) , [SMART Objectives Template](#)

Agency for Health Research and Quality (AHRQ) - [Quality Measures: PROs for Quality Improvement of Clinical Practice](#)

National Quality Forum (NQF) - [Patient-Reported Outcomes in Performance Measurement](#)

The Commonwealth Fund - [Using PROs to Improve Health Care Quality](#)

W.K. Kellogg Foundation (WKKF) – [Step-by-Step Guide to Evaluation](#)

7.5 References

Hunter S, Ebener P, Chinman M, Ober A, Huang Y. *Promoting Success. A Getting to Outcomes Guide to Implementing Continuous Quality Improvement for Community Service Organizations.* Santa Monica, CA: Rand Corporation; 2015.

US Department of Health and Human Services. Administration for Children and Families. Children's Bureau. (n.d.) Continuous Quality Improvement. 2017. Available at: <https://www.childwelfare.gov/topics/management/reform/soc/communicate/>. Access date: February 27, 2018.

