**Toolkit:**

Integrating Patient-Reported Outcomes Assessments into Routine HIV Care

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# OVERVIEW

Introduction: What is a PRO?

A patient-reported measure or outcome (PRO) is defined as “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”1. PROs provide the patient perspective of the effects of disease and treatment including comprehensive assessment of symptoms such as mental health symptoms like depression/anxiety; well-being and satisfaction; health behaviors such as medication adherence; risk behaviors such as substance use and sexual risk behavior; as well as other social determinants of health and practical or safety information such as housing status and intimate partner violence.

Evolution of PROs in care

While historically PROs have had a much larger role in research than care, the use of PROs in clinical care has been increasing as a result of several key developments. These include the rapid progression of technological infrastructure leading to the expanded incorporation of touch-screen tablets, internet-based applications, and electronic health records (EHRs) in clinical care2. Furthermore, PROs are increasingly being demanded by regulators, payers, accreditors, professional organizations, and providers to measure and address PRO-related outcomes at the level of the patient, clinic, and healthcare system as well as provide population information2. Legislative demands to improve health care outcomes without increasing costs puts more emphasis on quality of care, value-based reimbursement and patient engagement and has led to PROs increasingly be identified as the most direct and relevant measure to demonstrate high-quality patient-centered care2. The most common reasons cited for implementing PROs in clinical care among stakeholders who have already implemented them included screening, monitoring, treatment evaluation and treatment planning; and quality improvement including that mandated by external agencies3. Other reasons cited in interviews of respondents from a range of health care settings where PROs had been implemented included shared-decision making between patients and providers, and less often for reasons related to satisfaction or reimbursement3.

Relevance of PROs to modern HIV care

Advances in antiretroviral therapy (ART) over the past decades have increased the life expectancy of people living with HIV (PLWH) and transformed HIV from a fatal disease to a chronic manageable condition4. The associated decline in mortality since ART has been introduced has led to increased emphasis on managing quality of life and comorbidities, including those associated with HIV and its treatment. Many of the symptoms, health behaviors, and life circumstances associated with living with HIV and these comorbidities are not directly observable and are more easily measured by direct patient report. Yet, many such variables are under-addressed and not measured well in clinical care: in HIV care, examples include antiretroviral medication adherence, substance use, sexual risk behavior, and depression5. Reasons for this have included social desirability bias, time constraints, limited communication skills to convey symptoms or feelings, or linguistic and/or cultural barriers6-9. PROs help address these barriers. On-site PRO collection prior to routine clinical care appointments, via hand-held computer tablets with real-time results available to providers during clinic visits, has improved provider ability to detect and address depression/suicidal ideation, inadequate antiretroviral (ART) adherence, and substance use in HIV care5,10. Integrating PROs into clinical care of patients with chronic conditions, such as cancer, rheumatoid arthritis, and HIV, have been shown to be acceptable to patients and providers and valuable in clinical care10-12; they have improved patient-provider communication13-17 and increased patient satisfaction with care16,18-20.

Evidence-based support for PROs in HIV Care

PROs have been found to be highly useful to providers and acceptable to patients. An in-depth dossier of evidence details this evidence here [add Dossier link] and supports the idea that implementing PROs in HIV care can:

1. Improve detection of health behaviors, symptoms, and mental health issues
2. Increase provider awareness and interventions to address depression, drug and alcohol use, intimate partner violence, and other domains in order to improve health outcomes
3. Improve patient-provider communication, by helping patients prioritize and raise concerns and helping providers identify and initiate areas of discussion that can be difficult to know are needed and/or difficult to initiate without the PROs (e.g., sexual risk behavior)
4. Improve delivery of care, e.g., allow providers to focus on the most relevant issues during the visit rather than identifying the issues, improving symptom management and other care and therefore reducing emergency department visits and hospitalizations. \*Note this is based on a compendium of studies in chronic disease populations: data regarding reducing hospitalizations is not based on PLWH.

Toolkit purpose

This Toolkit is designed to provide practical advice to support the introduction of clinical PRO assessments into routine HIV care. These insights draw from a range of sources, including practical experience integrating PROs into HIV clinical care at multiple sites, published literature, and primary interviews with stakeholders with experience integrating PROs into HIV clinical care. While some of the information in this Toolkit applies to all formats of PRO assessment, we focus on implementation of tablet-based patient self-administered PRO assessments in clinical care due to the clear advantages outlined in Chapter 3 [add Chapter 3 link]. Every HIV clinic is a little bit different so no one-size-fits all approach will allow PRO integration into every HIV clinic. Therefore, this toolkit was designed to help provide resources, tips, and learning to help implement PROs adapted as needed for individual clinics.

Chapter overview: steps toward implementation

Though the process of PRO implementation is iterative, the chapters of this Toolkit sequence tasks into a general chronologic order starting with planning and decision-making (Chapters 1-3), then implementation (Chapters 4-6), and finally ongoing collection, maintenance, evaluation and improvement (Chapter 7). Chapter 1 helps assess and improve a clinic’s readiness for PRO implementation. Chapter 2 offers a pathway for stakeholder engagement. Chapter 3 itemizes steps needed in order to build technical infrastructure for electronic data collection. Chapter 4 operationalizes important steps to create a PRO assessment that best suits the needs of an individual HIV clinic and its patients. Chapter 5 outlines the decisions and protocols to support integration and ongoing success. Chapter 6 offers insight into initial and ongoing staff training needs. Chapter 7 provides strategies for monitoring, evaluating and sustaining the success of integration of PROs into clinical HIV care.

How this Toolkit was developed

Evidence and practical tips found in this Toolkit are drawn from real-world PRO implementation experiences and data collected 1) within the PROgress study, a ViiV-funded project evaluating impact, effectiveness, and sustainability of PRO collection in routine clinical HIV care at Midway Specialty Care in Ft. Pierce, FL, and St. Michael’s Hospital in Toronto, ON; and 2) within the Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS), a network of 8 U.S. HIV clinics. As of early 2020, >85,000 clinical PRO assessments had been completed by >20,000 patients with HIV across CNICS sites as part of routine clinical care visits to improve care and facilitate research on health domains important to long-term outcomes among PLWH.

Language

There are a number of acronyms throughout this toolkit. They are defined in Appendix 1. We also define terms that may be unfamiliar or whose meaning differs by context in Appendix 2. For example, we use the term provider to refer to the physician, fellow, nurse practitioner, physician assistant or other clinician who is providing patient care. We realize in different contexts, terms such as provider have broader or narrower meaning and therefore include a glossary.

Resources

* Add citation for website including URL
* Add Dossier

# CHAPTER 1. ASSESSING AND IMPROVING READINESS TO IMPLEMENT PROs IN HIV CLINICAL CARE

Are PROs right for my clinic right now? If not, how do we get there?

The appropriateness and readiness of PRO integration in your clinic depends on many factors, including the patient population, needs and perceptions of clinic leadership and providers, logistics, technical capacity, and cost. The tool below is designed to help you assess and improve the feasibility of integrating PROs in your clinic within each of these dimensions, by helping envision how to overcome barriers.

Note: For the website version, the “yes”es are clickable check boxes, with “no” clickable as a link to bring up the text that follows after each “if no…”

**Patient population:**

* Does the majority of the clinic patient population possess literacy skills to read at the 6th grade level? Yes No
  + If “no”: PROs that are based on text only may be appropriate for only a subset of the population. An enhancement to text is use of a pre-recorded voice to help guide patients through a brief set of PROs. While this has advantages if reading levels are low, it adds a great deal of time/patient burden to the assessment and therefore should be considered only if needed or only for those patients who need it.
* Does the majority of the clinic patient population possess the cognitive and physical capacity to complete a brief PRO assessment? Yes No
* If “no”: self-administered PROs may be less appropriate for these patients, and time may be better spent eliciting verbal self-report or the report of caretakers. Clinic staff may need a consistent means of distinguishing these patients from those with the ability to self-administer PROs. Of note, the ability to complete a brief PRO assessment on a tablet has been found to be feasible in many patient populations including the elderly (particularly if no mouse or keyboard as in tablets)21,22. This is often much more feasible than expected.

**Clinic leadership:**

* Is the clinic’s leadership likely to support the implementation of PROs? Yes No
  + If “no”: consider what is driving this perceived lack of support. What are the clinic leadership’s key goals and priorities, and what evidence regarding the use of PROs may align with them? Leadership typically supports PRO implementation for a variety of reasons including improving patient care, better assessing needs, and enabling better data collection for administrative tasks such as mandated reporting and quality assurance from external agencies (See Chapter 2, “Engage Stakeholders”). [Add Link to Chapter 2 here]
* Is there an individual or individuals on staff that can generate stakeholder interest in PRO collection and champion PROs as a priority? Stakeholder support or clinic champions have been shown to be useful for successful integration of PROs in clinical care.6 Yes No
  + If “no”: see Chapter 2, “Engage Stakeholders” which offers support for illustrating the benefits of PROs in clinical care. [Add Link to Chapter 2 here]
* Is there an individual or individuals on staff that can champion PRO data collection with respect to managing day-to-day operations? Yes No

If “no”: consider what steps would be needed to identify such an individual or allot time in an existing individual’s duties that would be accountable for the ongoing success of this operation. For example, this individual may supervise front desk staff, or may be a designated medical assistant.

**Providers:**

* Are clinic providers supportive of the use of PRO measures in clinical care? Yes No
  + If “no”: consider the basis for this. What are their perceptions of the value of PROs? What experiences form their basis for the lack of support? What are their concerns (see Chapter 2’s section, “Address Common Concerns”)? Have your providers had negative experiences with PROs? To what extent are these concerns still relevant in the context of brief tablet-based PRO collection? Provider concerns often focus on potential impact on clinic flow or visit length. Does focusing on specific domains that may be particularly relevant for improving care in a clinical setting but otherwise are assessed poorly such as substance use or intimate partner violence impact support? Does focusing on a brief assessment with plans to implement in such a way to minimize impact on flow minimize these concerns?
* Has their response to changes in prior clinic protocols been positive? Yes No
  + If “no”: identify what is driving this. To what extent may the evidence supporting the benefits of PROs in terms of improving clinical care ameliorate these concerns? [Add Link to Chapter 2 here]

**Logistics and flow:**

* Is there a plan as to how the clinic can allot time at the beginning of the visit for patients to take a PRO assessment without disrupting flow? Yes No
  + If “no”: do opportunities exist to collect information from patients while they are waiting for their provider? Do opportunities exist for patients to complete PROs prior to the appointment, off-site, using personal electronic devices? While this can lessen the impact on clinic flow, as a stand-alone approach it excludes patients who lack such devices. It may however be useful as a supplementary approach to within-clinic PRO collection to decrease impact on clinic flow. This may be a particularly useful approach in care settings with Telehealth visits, an increasingly common practice as a response to the COVID-19 pandemic. See Chapter 5, “Outline Workflow”. [Add Link to Chapter 5 here]
* Does the clinic have a plan to allot space on-site for patients to take a PRO assessment? Yes No
  + If “no”: can patients complete the PROs while they are waiting for their provider’s in the examination rooms? Do opportunities exist for patients to complete PROs prior to the appointment, off-site, using personal electronic devices? While this cannot replace in-person PROs, as many patients do not have the resources to complete PROs off-site, it may decrease the numbers of patients completing PROs in the clinic setting. See Chapter 5, “Outline Workflow”. [Add Link to Chapter 5 here]

**Technical capacity:**

* Does the clinic possess the technical capacity to support electronic data collection? Yes No
  + If “no” or “not sure”: see Chapter 3, “Building Technical Infrastructure”. [Add Link to Chapter 3 here]

**Cost:**

* Can my clinic afford the resources necessary, such as the staff time and electronic equipment (e.g., iPads or other tablets)? Yes No
  + If “no” or “not sure”, see the section detailing startup and recurring costs, below, bearing in mind that equipment costs change over time and are decreasing at the time of this writing.

Startup and recurring costs

Understanding the financial costs associated with implementing PROs is fundamental to long-term success. There are different types of costs to consider: initial start-up (or one-time capital costs), and recurring fixed costs.

Start-up costs bring a project to operational status (e.g., software development, purchase of office equipment, licenses, etc.). These costs incur at the beginning of the project or at a single point in time, and not as a year-to-year or month-to-month expense.

Table 1 contains some of the start-up costs to consider when developing a program budget.

|  |  |
| --- | --- |
| ***Table 1.* Examples of start-up or capital costs** | |
| Budget Category | Description |
| Personnel | * Dedicated staff to oversee the PRO process implementation (often existing clinic staff who manage this as part of their portfolio of duties)   + Coordinate the process   + Manage the PRO devices (e.g. tablets)   + Available to address any immediate issues raised by either patients or clinic staff * Part-time or short-term staff to help with IT program start-up (e.g., IT professional) |
| Office expenses | * Materials for new staff overseeing PRO adoption if staff are being added: additional chairs, tables/workstations * New space requirements: modification of existing space or rental of new space for new staff if staff are being added, or dedicated space for PRO completion by patients (in many settings patients complete the PROs in the examination room while waiting for their provider and new space is not necessary) |
| Equipment | * Hardware: computers for new staff; tablets for patients to complete the PROs in-clinic * Software: licenses for computers, software for PRO |
| Communication | * Network costs: additional phone or internet connectivity costs (less often an issue in the current era where almost all clinics have internet available |

Of note, many of the costs (e.g. internet) do not necessarily apply to many clinical settings as these resources are already available. Personnel are likely the most important component of costs in most clinics whether it is adding new staff or shuffling duties. IT costs can include platform development vs. integration of existing platforms (several are available as Shareware but still will require programming (see Chapter 3). [Add Link to Chapter 3 here]

Recurring costs occur on a regular basis, and typically fall within an annual budget period. 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) should be budgeted for each coming year. Again, many of these will not apply to many clinic settings however personnel considerations are key. Table 2 shows examples of recurring costs.

|  |  |
| --- | --- |
| ***Table 2.* Examples of recurring costs** | |
| Budget Category | Description |
| Personnel | * Staff to oversee the continued implementation of PROs e.g. connectivity issues, updating PRO devices, ongoing intermittent support * Can sometimes be implemented into duties of existing staff (e.g. front desk staff or medical assistants) depending on clinic flow |
| Office expenses | * Office supplies/space |
| Equipment | * Software: maintaining computer licenses |
| Communication | * Network costs: wi-fi, phone lines |
| PRO licenses | * Potential license fees permitting the use of certain PROs |

Of note, many of these costs do not apply in most clinical care settings (e.g. communication costs in most clinics do not apply as phone and internet resources already exist and do not include incremental additional costs when adding programs). Personnel likely is the most significant of cost in most clinical care settings even when some tasks are integrated into existing roles such as the front desk staff.

**Sample cost itemization tool**

Note: interactive version for website with columns where they can enter numbers. Will want to reformat this section to match website.

Below is an itemization of startup and maintenance costs for integrating and administering PROs. Enter costs in the left hand column to determine:

Fixed costs

* Device or devices (e.g. iPads or other tablets). You may wish to purchase more than one device in order to administer PROs to more than one patient at a time
* Printer, if PRO results are printed out (printer is not a cost if integrated into electronic health record (EHR) or presented to provider on screen at start of visit)

Recurring costs in 1 year

* WiFi access (monthly fee X 12 months)
* Paper, 1 page of PRO results per patient (no cost if electronic) multiplied by number of visits for which PROs are administered in a year
* Toner for printer. Number of cartridges needed depends on number of PROs administered. A standard cartridge prints 220 pages
* Salary associated with % FTE for staff member setting up and overseeing use of tablets. In the PROgress study, staff estimated a maximum of 4 minutes per patient for explanation of procedure, setup, collection of device, and delivery of paper–based results

One of the biggest issues that lead to delays and practical barriers including unplanned costs with PRO implementation involves integration with the EHR. Creating new platforms can be expensive and time consuming, integrating with EHRs is sometimes not feasible and the burden of the slow and/or complex EHR control processes have been noted as a hurdle3. This is even before taking into account the frequent changes in EHR products that are occurring across many healthcare settings.

***Practical tip:*** A plan regarding technical approaches (Chapter 3) is important before realistic costs estimates can be conducted. EHR-based approaches are not necessarily the most effective (due to many PLWH not being linked to patient portals), efficient, modifiable, or practical. However, this is a quickly moving area and will need to be assessed on a site-by-site basis (Chapter 3). [Add Link to Chapter 3 here]

Creating a business case for PRO implementation

Your organization may require the development of a formal business case for PRO implementation in order to assist in identifying short and long-term goals and associated budget requirements. Needs, solutions, approaches, risk assessments, and value analyses may be included in a business case. Table 3 shows an example of this format.

|  |  |
| --- | --- |
| ***Table 3.* 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, the Evidence Dossier [Add Link here], 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 section articulates what is to be accomplished both short- and long-term so the scope of the service is clear |
| Service overview | The proposed new service can be described in more detail, including:   * 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 (health topics) 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. Formation of a reference or steering group or updating of a community action board could be considered to support prioritization and 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 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 |

Resources

* Wallace Foundation – [Budget Builder](http://www.wallacefoundation.org/knowledge-center/resources-for-financial-management/pages/program-based-budget-template.aspx), [Resources for Financial Accounting](http://www.wallacefoundation.org/knowledge-center/resources-for-financial-management/pages/operations.aspx)
* Parkland Hospital – [Developing a Budget](https://www.parklandhospital.com/phhs/developing-a-budget.aspx)

# CHAPTER 2. ENGAGE STAKEHOLDERS

Identify stakeholders

Early stakeholder engagement facilitates successful PRO implementation and its sustained use. Stakeholders include clinic leadership, patients, providers, and staff, and may also include others, such as hospital administrators or researchers. Each brings unique perspective, concerns, and valuable input. The broad goal of improving care tends to engage stakeholder interest with very specific concrete examples such as identifying otherwise undetectable suicidal ideation, depression, or inadequate adherence to antiretroviral therapy being very relatable goals that almost all stakeholders can appreciate. Furthermore, these types of goals have a strong evidence base supporting their likely success.

Stakeholder goals may vary. Early discussions to understand both concerns and goals can be helpful for tailoring information and helping secure valuable support. For example, providers may be most motivated to adopt PROs to increase the appropriate diagnoses or identification of issues such as inadequate adherence; administrators meanwhile may also want to know if PROs can help satisfy external reporting requirements such as the percentage of clinic patients who complete a mental health instrument. Regardless of the stakeholder or motivation, engagement early in the process can identify and address benefits and concerns around PRO implementation (see section in this chapter, “Addressing Common Concerns”. [Add Link]

Prepare demonstration of value

A step to achieving buy-in from stakeholders is demonstrating value. Developing a value proposition for PROs is based on the review and analysis of the [benefits](https://en.wikipedia.org/wiki/Cost-benefit_analysis) and costs that PROs can deliver to providers, staff, patients, and administrators. Ideally, the value proposition would be short and easy to read or a brief presentation. Examples include brief presentations demonstrating evidence that supports the impact on care such as increased provider awareness of depression, substance use, and inadequate adherence23. [Add Link to slide set here] While clinical benefits such as increased provider awareness of risk behaviors likely are relevant for virtually all HIV clinics, additional benefits may be applicable for specific settings (e.g. reporting requirements or meeting annual depression screening requirements for specific state-based payees). Providers particularly have appreciated the value of the somewhat rare but important identification of PLWH reporting suicidal ideation24 as well as otherwise missed substance use25.

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 provide/patient interaction, more holistic use of clinical setting services [e.g., referrals], and improved health outcomes for patient).

***Practical tip:* Be able to provide a clear justification for PRO data collection as providers and staff are more likely to support PRO implementation if they understand the value3. Short practical examples are likely more compelling.**

Example 1. On average, ~30% of PLWH in the United States report depression at any one time, and this is associated with many poor outcomes such as mortality26. It is notable that even among PLWH with known depression there are substantial gaps in the depression treatment cascade with lack of follow up to see if treatments are effective27. We plan to integrate a brief clinical assessment of PROs including depression to identify the ~20% of our clinic with undiagnosed or undertreated depression to improve care for those PLWH.

Example 2. We have had two women in our clinic recently die as a result of intimate partner violence (IPV). The CDC has estimated that the rate of IPV among women with HIV is double the rate of those without HIV (~55%)28. We are also seeing increasing heroin overdoses. We would like to implement a brief clinical assessment of PROs in clinic to allow a standardized approach to screening for IPV, drug and alcohol use, depression and inadequate adherence to allow us to better identify those PLWH in our clinic who may benefit from additional interventions such as addressing IPV and ensuring Narcan for those using illicit opioids.

Meet with stakeholders

Meeting with diverse stakeholders as a group presents an opportunity to describe the purpose of PROs, alleviate concerns or misapprehensions, and to coalesce support for their known value in improving care and clinical outcomes.5 An adaptable sample presentation for this purpose is here. [Add Link here]

Beyond the presentation of static information, we recommend giving stakeholders the opportunity in this meeting to interact with PRO measures and their output in order to better understand the process and its potential. This step, in our experience, has been a key turning point in generating enthusiasm and helping stakeholders visualize integration into daily routine. An example of an electronically administered touch-screen PRO assessment for this purpose is here, [Add Link here] which your audience may self-administer on their own or other devices. Sample output, or the results generated for providers is here [Add Link here]. An interactive tool for determining average timing to completion for varied combinations of individual PRO measures is here. [Add Link here]

Figure 1 shows a sample agenda for an initial meeting with stakeholders.

***Figure 1:* Sample initial stakeholder meeting agenda**

Initial orientation to PROs:

* PROs-introduction, definition
* History/current status of PRO science
* Reasons to use PROs- clinical/research value, reduces social desirability bias
* Advantages computer-based, patient self-administration
* PROs: common measurable domains of HIV care
* iPad or other tablet demo of PROs: what patients see
* Delivery of results: what providers see
* Potential for electronic alerts in real time for intimate partner violence (IPV), suicidal ideation, other alerts
* Evidence detailing elements of successful implementation; reasons for prior failures
* Discussion: thoughts, concerns, potential for integration into clinic

Further discussion could include:

* Integrating PROs into clinic flow
* Integrating PROs into EHR
* Concerns, questions, identification of opportunities for using PROs to improve workflow/effectiveness with patients
* Opportunities for the use of aggregate PRO data

***Practical tip:*** Bring tablets and a demonstration version. Showing how straight forward it is for PLWH to complete, and how straight forward it is to get PLWH started with an assessment is crucial to alleviate staff concerns. Shorten the agenda as needed to ensure adequate time for the demonstration.

Provide overview of value

A comprehensive overview of the potential value of PROs is available in the form of an Evidence Dossier, as a companion document to this toolkit. [Add Link here]

Address common concerns

Stakeholders will likely have many valid concerns about introducing PROs into their practice. Below is a list of common initial stakeholder concerns regarding the implementation and ongoing use of PROs. Many of these concerns have proven addressable in the past integration efforts. Table 4 summarizes common concerns, followed by suggestions regarding how they can be effectively addressed.

|  |  |
| --- | --- |
| ***Table 4:* Common initial stakeholder concerns, and how to address them** | |
| **Common concern** | **How to address** |
| PROs create too much additional work for providers in terms of the need to document additional non-urgent issues. | * Evidence shows that while there is a modest increase in workload with respect to documentation, providers value the additional information that they believe may otherwise have been missed, such as suicidality, depression, ART non-adherence, substance use, and HIV transmission risk behavior10,29. * Additionally, there are ways in which PROs may reduce this burden. In the Review of Symptoms Index, for example, patients select the degree to which they are bothered by symptoms; the most bothersome ones can be prioritized/prominently displayed in a results report (see example here).[Add Link here] * Focusing on targeted domains (health topics) that measure key clinical domains that are highly actionable such as substance use can alleviate this concern. |
| Addressing PRO results adds too much time to the visit. | Evidence shows that providers perceived time expenditure as not having necessarily increased, but rather as having been prioritized differently29. |
| PROs take the focus of the visit away from the patient’s chief complaint and force providers to address issues that would not otherwise have been top-of-mind for the patient. | It is true that the additional information potentially provided by PRO results likely impacts discussions. Additional issues may get raised that would not have otherwise been identified. PROs can focus on highly actionable and clinically relevant domains that providers agree are important to address such as substance use. Alternatively, if a broader PRO assessment is addressed, providers can review results with patients and ask which concerns they are most interested in addressing today. The experience remains patient-driven, presuming the absence of more serious concerns found in the PROs (e.g., suicidality). |
| PROs are redundant. I have great rapport with my patients, and they are honest with me about their needs and behaviors already. | Evidence shows that patients are more honest in responding to questions on a computer tablet than answering questions in person, particularly on sensitive topics9,30-32. Social desirability bias among patients toward their providers may impede complete reporting even when there is good rapport. HIV care clinicians have expressed surprise at patients’ PRO responses, particularly on sensitive topics, among patients they assumed they knew well10. |
| Addressing an itemized list of symptoms and behaviors is at odds with my professional style, which prioritizes connecting with the patient as a human being rather than a list of problems to be solved. | PROs are not meant to replace communication with providers, but rather to enhance it. PROs have been shown to empower the patient to take inventory of their health and better prioritize their needs in preparation for their visit33,34. PROs can be viewed as a means of amplifying, organizing, and articulating the patient’s voice in care. They allow relevant issues to be identified so the provider can focus the discussion in a productive manner in those areas most likely to benefit the patient rather than spending most of the interaction gathering information about potential issues. |
| Patients will not tolerate a PRO assessment. | Evidence does not support this. Across several clinical settings and diverse populations of PLWH, tablet-based PRO assessments administered on site prior to the clinic visit have proven to be well-tolerated, with patients reporting high levels of satisfaction with the process.33-35 |
| PROs will negatively impact clinic flow. | Prior implementations suggest minimal impact on flow after the initial ramp-up if done well6. The impact of PROs on flow is modifiable, and there are many ways to reduce it. Suggestions include minimizing the length of PRO assessment to include only the most clinically important domains of care; varying the frequency with which specific measures are administered (e.g., annually for less mutable domains, such as gender identity); administering PROs only when patient has arrived sufficiently early (or if the provider is running late); remote PRO completion**.** [Add Link here] |
| PROs require too much staff time to administer. | The staff burden required depends on the format of PROs used. This toolkit is focuses on tablet-based collection as it requires less time, patients prefer it and complete it more efficiently, there is no scoring or data entry steps, and results are available to providers in real-time. If using tablet-based data collection, the labor involved consists of explanation to patients of the procedure, peripheral monitoring to determine when the patient is finished, and device stewardship and sanitization. Depending on the clinic flow, these responsibilities can be performed by a dedicated staff member, or integrated into front desk staff duties (incorporated into check-in procedures), or integrated into medical assistant duties (incorporated into rooming and completion of vital signs). By incorporating PROs into rooming or check-in procedures the amount of staff burden can be decreased but still exists. |

Include providers in PRO selection process and output design

Without clear relevance or usefulness to providers, PROs will be less useful and less likely to succeed long term in the clinic. Therefore, consider early engagement of providers to determine what PRO domains would be of most use to improve their ability to provide the best possible care for PLWH, and, by extension, patient outcomes. It is worth including providers in decisions regarding the reporting of PRO results: what form of presentation the reporting will take, including scoring and interpretation, organization of information, and aesthetics. This early engagement ensures inclusion of only the domains most relevant to providers and the needs of PLWH. In addition, proactive engagement in this process promotes buy-in and a sense of investment in the PROs as a clinically useful tool tailored toward your clinic’s specific needs. See the sections titled “Select PROs: domains and attributes to consider” and “Format Results” in Chapter 4, “Create PRO Assessment”.[Add Link here]

*Practical tip:* Concerns that PROs will lengthen visits is a very common provider concern before PRO implementation3. When presenting plans to implement PROs to stakeholders, it is very important to emphasize that data suggests this is not likely the outcome29. Demonstrate the actual time to complete the assessment during stake-holder discussions using tablets and a demonstration assessment.

*Practical tip:* Impact of PROs on clinical flow is an almost universal stakeholder concern3. Reassuring stakeholders with a clear plan to start slow and ramp up only as the kinks are worked out to minimize impact on clinical care is crucial. Examples of successful roll-out approaches that have been used to minimize impact on flow include starting on the slowest clinic days of the week, starting with one full-time provider who was a PRO advocate and happy to work with the team as roll-out began, and starting with a very targeted brief assessment.

Secure implementation champion

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. This person is tasked with advocating for the use of PROs, inspiring the range of stakeholders and increasing/maintaining commitment to maintain momentum of PRO adoption. The champion will remain close to the process as it 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. 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 focus on the sustainability of the PRO implementation.

# CHAPTER 3. TECHNICAL CHOICES AND INFRASTRUCTURE

Understanding PRO Choices

A successful PRO implementation should integrate both treatment- and patient-centered perspectives into one health information system, which should be crafted to optimize the patient experience, to enhance the provider’s clinical use of the data, to minimize any challenges to clinic flow and efficiency, and to maximize population health utility of the information. In this context, population health may include clinic-level, research, and public health uses of the data.

The first major step is confirming that all stakeholders share the intent to implement computerized collection of PRO data. While PROs may be collected by paper, the manual approach, while traditional, will likely be dismissed once a variety of factors are considered. The disadvantages of paper-based collection include increased clinic workload to administer PROs and enter responses, workload, decreased accuracy from required data entry, provider effort in summarizing data to realize clinical utility, and patient perceptions of both the utility and process of providing PRO responses. See Chapter 4 for more details regarding relative advantages and disadvantages. [Add link]

The second step is deciding which of four types of PRO systems to consider: (1) a commercial “standalone” PRO system that can be integrated with an EHR, (2) an EHR vendor’s “built-in” questionnaire tools, (3) a locally developed PRO system, or (4) a PRO system supplied as part of participation in a research or clinical network. All EHR and standalone PRO system vendors highlight their system’s ability to gather PRO questionnaire responses, provide those responses to providers, and ensure they become part of the medical record. However, it is important to examine each of these four options carefully to compare: the true cost of acquiring, integrating and supporting any particular product; the experience of the patient in accessing the system and recording their responses; the experience of the provider in accessing and using a clinically relevant summary of longitudinal patient data; and the “cost” (licensing, implementation, maintenance”) of persisting the data in the EHR – and if the data are persisted, whether that is done as a scanned image, an electronically transmitted summary form and/or discrete observations. How the data are stored impacts the ability to derive secondary value, beyond clinical utility, from population health applications.

Often IT organizations strongly favor using tools from their existing EHR vendor, in order to avoid a new vendor relationship and contract, simplify implementation of interfaces, avoid a new set of security considerations, to advance an agenda such as increasing patient use of a patient portal system, or simply to make use of existing vendor support mechanisms. However, the impact of a choice made only on these technical and operational considerations can significantly impact the experience of the patient and the value to the provider, which should be paramount to maximize data collection and use.

Once the four types of PRO systems have been considered, and an evaluation is determined the approach that best balances function and cost, has provider support, and is acceptable to any applicable IT governance process, than the particular pathway chose will then drive other technical needs (i.e., for software/operating system support, hardware platform, data storage attributes to support high data integrity, data center needs to ensure secure operation).

Identify Issues to Guide Choices

It may be helpful to organize the issues to be addressed according to the phases of gathering, using, storing, and reusing PRO data. These include: (1) the flow of information from the patient to the provider, (2) the use of the information by the provider, (3) storing the information to meet medico-legal requirements for medical record collection, retention and accounting of disclosures, and (4) reuse of the data for population health purposes.

Gathering information from the patient:

* In what settings will the patient use the system? Only in the clinic? At home, or in another location of their choosing?
  + What kind of support can be provided for in-clinic use?
  + In what locations can the patient use the system prior to their clinic visits?
  + What support is available for out of clinic use?
  + Can in-clinic use serve as a “backup” plan for patient’s unable to complete PROs outside the clinic, and if so, how does the communication occur to ensure that the patient can be prompted?
* Can the system deliver reminders to the patient to complete PROs, or to the staff that a PRO has not been completed prior to a visit?
  + What hardware will deliver those reminders and what constraints does that place?
* What devices will the patient use in clinic? Tablets or iPads are a common choice.
  + Can concerns about damage or loss of in-clinic devices be assuaged?
  + Are there valid concerns about device cleanliness?
  + How will defective or mis-configured devices be identified and repaired?
  + What level of duplicate devices are needed to ensure tolerance of faulty hardware?
* Can the patient use the device of their own choosing out of the clinic? Can they use that device in clinic?
  + - Can they use their phone?
    - Can they use a computer?
    - What security considerations are there if they are using a device that is not theirs?
* How do we validate the identity of the patient when initially enrolling them?
* How do we authenticate patients when they are using the system?
  + Is that done in person, for in-clinic use?
  + Do we sign them in with a patient-specific username/password and what kind of registration process do we use to support that?
  + How do we manage support for recovering passwords, or other login issues?
  + Does logging in present too much of a barrier to use and are there strategies such as one-time questionnaire links which can be used?
    - What are the institutional concerns around using one-time links?
    - How does it impact the data that can be shown to the patient?
    - How does it impact the value to the patient?
* What controls the patient’s periodic usage of the system.
  + Can the patient use the system electively, like a diary in their control, or only on a fixed schedule, as if it were an in-clinic questionnaire?
  + Can they edit/correct/revise their responses? How do they address errors?
  + Can the system deliver reminders to the patient to complete PROs, or to the staff that a PRO has not been completed prior to a visit?
  + What hardware will deliver those reminders and what constraints does that place?
* Do we need to implement a patient’s “right be forgotten” in a particular setting?
  + Does that conflict with the need to maintain records, or to make data available for population health uses?

Presenting information to the provider

* How can the information be presented to the provider?
  + Discrete values sent to an EHR and viewed through charting or table functions?
  + Customized, domain-specific longitudinal patient summary?
* How can the provider access those views of information?
  + While logged into the EHR, using EHR tools?
  + While logged into the EHR, viewing a static summary?
  + While logged into the EHR, using an application within the EHR to view the data interactively?
  + Similarly, the last two options may be options in a vendor system, locally developed system, or system provided as part of a research or clinical care network.
  + Are there visualization considerations that create opportunities to overlook or erroneously interpret information?
  + Especially if patients can use the system electively, are there vizualizations which efficiently present a large amount of information?
* Is viewing information closely linked to the providers documentation process?
  + Are there “macros” or summary information that can be imported into the documentation?

Storing information into the Medical Record

* Are the PRO data preserved as discrete observations in the EHR?
* Are they preserved in their entirety, or are only in the form of scores or alerts?
* Are they preserved as a visit-specific a longitudinal summary, imported or preserved in the EHR system and linked to a specific encounter?
* If not part of the EHR, are the data preserved in a system that meets reliability, security, assurance, and retention requirements under appropriate regulations?
* Are there other more general regulatory or policy considerations, such as privacy practices or security regulations, or Institutional Review Board guidance, with which the system has to comply?

Reuse of information for population health

* Are there individual level metrics of frequency and completeness of use? Is individual level data collected from patients and providers to monitor satisfaction and barriers to use?
* Are there clinic level indicators of use available to show broad patterns of use and monitored for changes that might represent systematic barriers or enablers to use?
* Are there clinical level metrics based on aggregate outcomes of clinical significance, so that PRO data may be used to monitor patient-reported impacts of changes in care patterns?
* Are adequate data being collected to satisfy any research or public health goals for secondary use of those data?
* Are the PRO data represented using standard formats and value sets, such that extracted data may have its structure and meaning consistent with that form other systems?

Consider System Features

Table 5 describes considerations for the PRO system features, adapted from an AHIMA publication in 2013, which reflect a similar set of concerns.

|  |  |
| --- | --- |
| ***Table 5.* Key considerations for defining PRO system characteristics data** | |
| **Key Consideration** | **Definition** |
| 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 | |

Consider Data Quality

System features may include creating a dashboard to enhance usage monitoring, improve data accessibility and monitor data 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), and through consideration of issues that discourage patients from starting or completing PRO sessions. **Figure 2** describes the characteristics that define data quality.

**Figure 2** describes the characteristics that define data quality.

***Figure 2.* The characteristics that define data quality**

A close up of a sign

Description automatically generated

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.

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

Resources

**Guidance on Infrastructure**

* Snyder C, and Wu, A.W., eds. Users’ Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.  
  Available at: <http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records>
* 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**

* ePROs in Clinical Care: Guidelines and tools for health systems. (<https://epros.becertain.org/>) 2020.
* Clinical Data Capture and Management Evaluation Checklist, [Oracle Data Sheet](http://www.oracle.com/us/industries/health-sciences/clinical-data-capture-ds-2656334.pdf).
* 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>

# CHAPTER 4. CREATE PRO ASSESSMENT

Determine mode of administration

PRO measures may be administered in electronic or paper format. While we briefly describe the advantages of each below, at this point for all but the briefest assessments being integrated on the most temporary basis, the tablet-based approaches have tremendous advantages.

**Advantages of paper administration**

* May be more familiar to patients with low computer literacy.
* Quick, lower-cost start-up.

**Advantages of tablet-based administration**

* Ability to automate skip patterns within assessment so that patients only receive relevant questions (e.g., no smoking frequency questions shown if indicates not currently smoking), reducing time burden. The ability to integrate skip patterns dramatically reduced patient burden and therefore impact on clinic flow. It may be one of the most important advantages of tablet-based collection.
* Patients prefer or perceive advantages to tablet-based to paper-based administration21,22
* Automated scoring within domains (e.g., PHQ-9). This reduces errors and also staff burden as no scoring by staff is required. It facilitates having scored results available to provider in real-time to enable clinical care impact.
* Ability to link PRO responses to real-time pager alerts to clinic staff for high-risk patients, such as when suicidal ideation is endorsed. Among clinics that are also doing research, can use same approach to automate pages for other reasons including study recruitment.
* Ability to administer in multiple languages yet easily interpret results.
* Generation of real-time, comprehensive summary of results, with potential to illustrate differences between time points using graphics.
* No physical space required for paper feedback form data storage.

Furthermore, depending on goals, additional benefits can include:

* Potential for remote administration such as for telehealth visits with real-time results delivered to clinic staff.
* Programming flexibility allows for patient-specific administration, such as showing specific PROs to select patients at select time intervals based on historic responses or risk factors.
* Ability to synchronize with audio accompaniment when needed for PLWH with lower literacy levels or those with poor vision.
* Easier to compile population-level data for analysis.
* Potential for information to populate EHR as discrete data.

While paper-based administration may be easy to implement quickly at a low cost, we strongly recommend tablet-based administration given advantages in reducing patient burden through algorithmic and skip-patterned administration, automated real-time alerts and scoring interpretation, and staff data entry burden, as well as patient preference. Given the burden on staff of scoring instruments such as the PHQ-9 when using paper-based collection, one study demonstrated that despite greater start-up costs, using a computerized approach was also less expensive in the long run for doing anything but the smallest number of assessments (cit). It is worth noting that this study was from an era before the prices in tablets have decreased so substantially and therefore is likely a significant underestimate of the savings.

In Figure 3, we offer considerations when selecting and programming a tablet-based mode of administration.

***Practical tip:*** *Adding audio options to tablet-based PRO collection are very helpful if working with a very low literacy population, but for many PLWH it will increase completion times substantially and therefore should be avoided when not needed to minimize impact on flow.*

***Practical tip:*** *While audio options in general should be avoiding, they can be helpful with particular populations to help address low literacy levels as well as other problems. For example, the three main Amharic dialects have different vocabulary and grammar making text-based options more challenging. Despite also having different pronunciations, adding an audio option appears to be an important tool to help with understanding for some Amharic speakers.*

***Figure 3.* Considerations for tablet-based PRO administration**

Location

* Remote vs. on-site completion, or a combination of both

Media (tablet, desktop, laptop, phone)

* Screen size for readability relative to proposed content
* Recommend use of touch-screen technology, rather than mouse/keyboard, to maximize accessibility to all PLWH

Language

* Many PRO measures have been validated in multiple languages

Patient experience

* Font size and graphics appropriate for varying vision quality
* Simplified language, e.g., to a 6th grade literacy level in a given language
* Ability for patients to revise their response
* Option to skip questions

Select PROs: domains and attributes to consider

*“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***

A key consideration when implementing PROs is how the information will support clinical decision-making and improve an individual patient’s care. What would be helpful to know about patients that cannot be easily or necessarily revealed through lab results or direct observation during the visit? What lines of inquiry might patients more comfortably and comprehensively answer in a computerized assessment, relative to face-to-face discussion? Most importantly, what PRO domains, or health topics, are directly actionable and eliciting and acting on the information would result in an improvement in care?

There are many domains of inquiry critical to HIV management and amenable to PRO assessments. Examples include depression/suicidal ideation, antiretroviral medication adherence, alcohol/substance use, and HIV/sexual transmitted infection transmission risk behaviors. In addition, PROs offer an opportunity to explore social and context-based domains, such as partner violence, housing, social support, HIV stigma, and health-related quality of life (HRQL). Figure 4 shows key factors needed for selecting PRO domains.

|  |
| --- |
| **Figure 4. Key Factors in selecting domains to include in a PRO assessment** |
| * Does the domain address topic(s) that are relevant and important for the patients, providers, and/or the clinic? * Does the domain address an area or provide data that is unavailable from objective assessments such as laboratory tests * Does the domain represent a concept that is critical to HIV care (e.g. medication adherence) * Has the PRO been previously used and validated for use among PLWH?   + 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? |
| * Is there information regarding what the scores of the PRO instrument means? Does a change in score provide clinically meaningful information? |
| * Are there simple instructions on how to interpret the PRO results for a patient? |

Once the desired PRO domains are identified, consider which PRO measure is most appropriate within each domain. To ensure consistent uptake and relevance, a PRO measure used in clinical care should be:

* Brief- the smallest number of items possible to provide the desired insight
* Validated- accurately measures what it says it will
* Easy for patients to understand (comprehensible to 6th grade literacy level)
* Easy to recall (e.g., shorter vs. longer recall periods, particularly for mundane behaviors)
* Interpretable by providers at a glance

Note that while many PROs are free of charge in the public domain, others require licenses and sometimes require fees or developer notification before use. In addition, requirements for use may change over time. Many high quality instruments are available that do not require a license for use and in most circumstances may be preferrable.

Table 6 lists PRO domains relevant to HIV care.

|  |  |
| --- | --- |
| ***Table 6.* Examples of PRO domains and measures relevant to HIV care** | |
| **Patient-reported….** | **Example of commonly used measures** |
| **Symptoms** | |
| Depression | PHQ-936,37 |
| Anxiety | PHQ-536,37 , GAD-738 |
| HIV-related symptoms (past 4 weeks) | HIV Symptom Index39 |
| **Behaviors** | |
| ART adherence (multiple recall periods) | Self-Rating Scale, 30-day visual analog scale, AACTG adherence instruments (7 day missed dose, last missed dose, weekend missed dose)40-42 |
| Nicotine use (lifetime, current)   * tobacco cigarettes * e-cigarettes * vaped nicotine | Bruneck study measure43, e-cigarette measure adapted from Bruneck (not published, available from CNICS) |
| Drug use (specific drug list should be modified to address those drugs used in individual clinics)   * cocaine/crack * methamphetamine * heroin * fentanyl * marijuana * illicit stimulants/opioids/sedatives * hallucinogens * inhalants | Modified ASSIST for drug use 44,45  Includes:   * Lifetime and current drug use likely relevant for every clinic   Could also consider including the items to assess:   * Mode of intake (marijuana, cocaine, meth, fentanyl, heroin only) * Impact of substance use * Drug overdoses * Narcan supply (opioid users only) * Needle sharing |
| Alcohol use | AUDIT/AUDIT-C for alcohol use46,47  (AUDIT-C alone, or AUDIT-C with full AUDIT for those with hazardous alcohol use scores on the AUDIT-C) |
| Sexually transmitted infection (STI) risk (past 3 months) | Sexual Risk Behavior Inventory48  Includes:   * # of partners * gender of partner * perceived partner HIV status * perceived partner ART/PrEP use * condom-less sex: oral, anal, vaginal (y/n) * % of time receiving partner for condom-less anal sex (MSM only) * concern for recent STI exposure |
| Physical activity (past month) | Lipid Research Clinics Questionnaire39 |
| **Substance use treatment history** | |
| Substance use treatment (past year for all substances, ever for alcohol) | Treatment Services Review (adapted)49 |
| **Identity** |  |
| Sexual orientation (current) | Not published, available from CNICS |
| Gender identity (current) | Not published, available from CNICS |
| **Basic Needs** | |
| Housing type and stability (past month) | Not published, available from CNICS |
| **Exposure to Violence** | |
| Intimate partner violence (past year) | Intimate Partner Violence 4-item measure (IPV-4)50  Includes:   * Physical violence * Sexual violence * Psychological violence |
| Childhood household violence (before age 18) | Adverse Childhood Experiences-International Questionnaire (ACE-IQ) (adapted)51 |
| **Social Dimension** | |
| Social support (current) | Multifactorial Assessment of Perceived Social Support-Short Form (MAPSS-SF)52 |
| HIV-related stigma (current) | HIV Stigma Mechanism Measure (adapted)53 |
| **Quality of Life** |  |
| Health-related quality of life (current) | EQ-5D54 |

“I think at first just start small. One of the things that we had to do too is prioritize our surveys… because you don’t want patients to sit there 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.

***- Implementer from a large US HIV clinic***

Identify scoring and interpretation needs

Too much detail: consider shortening this section

In order for providers to easily review and process PRO results, choose measures with clear scoring and missing data guidelines. PRO results may 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 PRO
* scores based upon a single-item

Some PROs require an algorithm that helps convert responses into scores that are easy to interpret and explain, such a as single number; some PROs 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 PRO measure 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 PLWH, 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 7 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).

|  |  |  |
| --- | --- | --- |
| ***Table 7.* Examples 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\*\*  Dysthymia  Major depression, mild | Support, watchful waiting  Antidepressant or psychotherapy  Antidepressant or psychotherapy |
| 15-19 | Depression, moderately severe | Antidepressant or psychotherapy |
| ≥20 | Major depression, severe | Antidepressant or psychotherapy (especially if not improved on monotherapy) |

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>).

Determine order of PRO measures in assessment

The chronological order in which PRO measures are placed in the assessment may have an impact on your patients’ response. We recommend beginning the assessment with a relatively benign domain, such as family history of chronic conditions, before building up to more sensitive topics such as sexual risk behavior, intimate partner violence, or substance use. Another consideration is that you may want to place the measures with the highest clinical relevance (e.g., suicidal ideation, ART adherence) earlier in the assessment in order to ensure that the patient completes the most critical information.

Determine frequency of administration overall and for each measure

After selecting domains and measures of interest, consider ways to minimize the patient time burden for completing PROs. This includes length of time for completion of assessment, the frequency with which patients will be offered PROs, and the frequency with which patients will be shown specific measures.

A tool for estimating the average length of time your PRO assessment will take to complete can be found here. [Add link]

To establish the desired frequency with which patients will be offered the PRO assessment, consider the intervals in which your clinic’s patients typically are seen for routine visits. You may wish to administer PROs no more frequently than every 3 months, every 6 months, or annually, depending on timing of visits and your patient population’s needs. Benefits of more frequent assessments is richer information but greater burden. However, too frequent just annoys patients.

*Practical tip:* Occasionally PLWH come to clinic very frequent (e.g. for wound care, IV antibiotics, other reasons). It is therefore important to set a PRO eligibility window so that PLWH who are clinic multiple times in the same week are not asked to complete them repeatedly. It will both annoy PLWH and impact clinical burden.

An electronic PRO platform can be programmed to show individual PRO measures at specific time intervals. Not all PROs may need to be administered at every visit. For example, gender identity and sexual orientation are less prone to change relative to other domains, and so might be asked only every two years. Other domains, such as family history of chronic conditions, only need to be asked once.

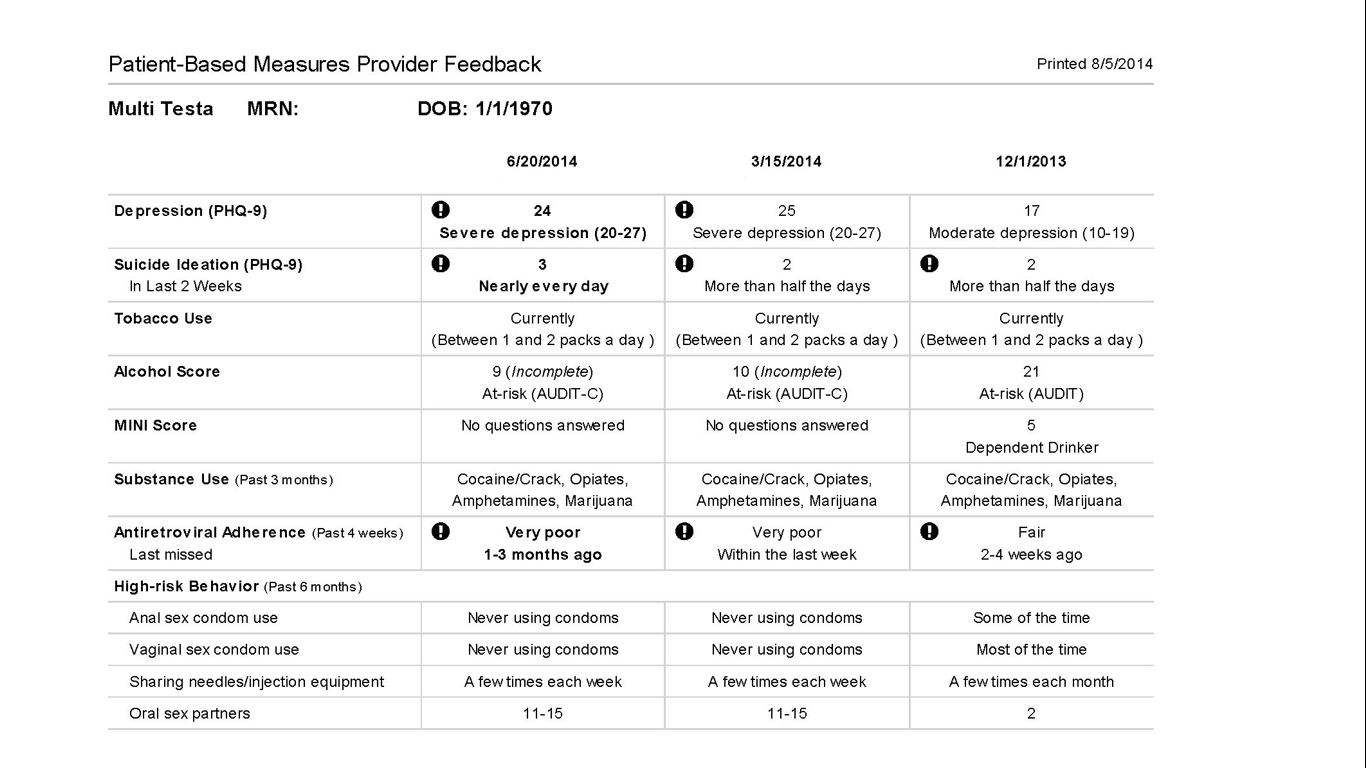
An electronic PRO platform can also be tailored to administer individual measures with varying frequencies, based on an individual patient’s previous responses. For example, for an older patient who previously indicated having never smoked in the PROs, it may not make sense to again ask about smoking habits on each subsequent visit; this question could be skipped in lieu of domains more relevant to that patient, and revisited less frequently (e.g., every 2 years). Conversely, patients who in previous PROs endorsed specific symptoms or risk behaviors, might be shown corresponding PRO measures more frequently. For example, it would be appropriate for a patient who six months ago indicated having experienced recent intimate partner violence to be administered this measure at every visit, while only annually for patients that have consistently denied its occurrence in previous PROs.

Format results

Output generated from PROs must be easy to interpret at-a-glance in a busy clinic setting. Ideally the results should also be formatted in a way that supports sharing or communication to the patient.

Figure 5 shows a sample PRO summary report (based on a fictional patient) illustrating a means for displaying PRO results across multiple time points. In this example, time points are retrospective moving from left to right, with alerts indicated by bold exclamation points to get the provider’s attention. A review of symptoms administered to the patient is summarized by placing the most bothersome symptoms in a text box. The use of color and shading may also promote readability.

***Figure 5.* Patient-reported outcomes provider feedback**



Build your own PRO assessment

After considering the PROs you would ideally like to administer to your patient population, as well as the frequency with which you would ideally administer individual measures, we strongly recommend calculating the potential time burden in advance of implementation. Below is an interactive tool to help calculate the anticipated average time burden to completion for several commonly used PRO measures. Multiple selections calculate a total anticipated average time. This tool may help demonstrate to stakeholders the number and nature of PROs that could be potentially queried, and the anticipated time burden and impact on clinic flow. [Add Tool Link Here]

Resources

* International Society for Quality of Life Research (prepared by Chan E ET, Haywood K, Mikles S, Newton L). Companion guide to implementing patient reported outcomes assessment in clinical practice. <https://www.isoqol.org/wp-content/uploads/2019/09/ISOQOL-Companion-Guide-FINAL.pdf>. Published 2018. Accessed July 2020.

# CHAPTER 5. OUTLINE WORKFLOW

Once you have decided on the mode of administration, which domains of care to measure, which measures to use, the average length of the assessment, and the format of PRO reporting, you are ready to begin visualizing the specifics of integrating PROs into your clinic’s workflow.

Select workflow: when, where, and how to administer PROs

There are three key ways to integrate PROs into your clinic’s workflow. Each has advantages and disadvantages, described below.

**Remotely, prior to appointment.**

In this option, PLWH are asked to complete a PRO assessment on their own time and on their own devices before the appointment begins. Results are either uploaded to an EHR, or printed out before the appointment by clinic staff and delivered to the provider and relevant staff.

ADVANTAGES:

* Minimal impact on clinic flow.
* Patient controls timing and location of response.

DISADVANTAGES:

* Difficult to respond to emergencies in real time, such as suicidal ideation or intimate partner violence (e.g., if endorsed after business hours).
* Excludes patients that do not have access to electronic devices.

**On-site at the beginning of an appointment.**

In this option, PLWH complete the PRO assessment upon check-in for a clinic appointment. For many clinics, PLWH wait long enough on average to complete a brief assessment before their provider appointment. Other clinics with limited wait times may need to schedule the appointment time 15 minutes earlier to allow enough time to complete the assessment. Front desk staff, or a medical assistant sets up the assessment on a touch-screen tablet. This is often done in conjunction with measuring vital sings.

ADVANTAGES:

* Up-to-the minute information on patient health status.
* Ability to respond quickly to emergencies, on-site and in real-time.
* Creates agenda for how time may be best spent during appointment.
* Includes everyone regardless of whether they have devices.

DISADVANTAGES:

* PRO completion is dependent on patient punctuality or provider delay, in order to avoid disruption of clinic flow.

**A combination of both approaches.**

In this option, PLWH are asked to complete a PRO assessment on their own time and on their own devices before the appointment. Some PLWH do not have access or will not complete the PROs remotely. Those who do not complete the PROs remotely are then asked to do it when they come to clinic.

Advantages include all of the above advantages. In addition, by having some of the PROs completed in advance, it decreases clinic flow burden. Finally, it provides options in the current era where a larger proportion of clinic patients are being seen via telehealth in response to the COVID-19 pandemic.

Define staff roles and centralize responsibility

Consider each staff member in the clinic and what role will each of them play (e.g., provider, front desk, medical assistant, other staff) in administering, tracking, and responding to PROs. A designated staff member is needed in order to ensure the steps of PRO administration are followed through for each patient. While we recommend that this responsibility falls upon a single individual that champions the collection of this data overall, other individuals, such as medical assistants, may be designated to act as “point people” for PRO collection on a day-to-day basis.

You will want to designate in advance:

* Who schedules patients for PROs, if these are to occur on-site prior to appointment
* Who maintains list of patients that should not be offered PROs, in order to avoid scheduling them
* Who introduces PROs to the patient and sets them up with the associated device
* Who decides at point of care whether it is appropriate to administer PROs to a particular patient based on timing (e.g., late arrival, provider running behind, etc.)
* Who monitors level of completion of PROs, offers help if needed, and collects tablet
* Who coordinates clinic response if suicidality or other risk behaviors are endorsed
* Who delivers results, if paper-based delivery
* Who sanitizes tablet in between patients
* Who discusses results with patients

Create protocol: when NOT to administer PROs

We recommend setting clear protocols regarding whether to ask patients to complete PROs, taking patient-based and flow-related factors into account.

**Patient-based factors**

We do not recommend administering PROs during acute or urgent care visits, as in those cases the priority is to address their acute issue; these patients are more likely to be too ill or in distress to tolerate an assessment. Similarly, PLWH with known low literacy levels, limited command of available languages, impaired cognitive functioning, impaired physical functioning that impedes answering questions, and patients historically easily agitated by questionnaires, should not be asked to self-administer PROs.

**Flow-related factors**

Flow-related factors should also be taken into consideration when deciding whether to administer PROs to a particular patient. Is the patient late? If so, is there enough time for the patient to complete the assessment? How busy is the clinic day? Is there sufficient private space and time for the patient to comfortably and confidentially self-administer the assessment without delaying other patients and providers? If providers are running late, is there an opportunity to administer PROs during waiting periods to help occupy time? For example, if a patient is late for their appointment, yet the provider is ready to see the patient and has a full schedule, it may be wiser to forego PROs for that particular patient on that day in the interest of not impeding clinic flow.

Set a standard for introducing PROs to patients

Consistent, accurate language is critical when introducing PROs to patients. We recommend that this messaging include the following attributes:

* Use a term patients will understand when referring to PROs, such as “personal health assessment” or “health questionnaire”; avoid terms like “survey”, which connotes population or data
* Very brief overview of the nature of PRO content (e.g., “symptoms and health behaviors”)
* Conveyance that the information is important to care team
* Gives care team a more complete picture of overall health
* Estimated time to completion
* Provider/care team will review the results
* Answering questions is optional

A sample script is below:

”Hi, I’m <name>. Your provider <name> is interested in finding out a little bit more about how you’re doing before your appointment starts.

This questionnaire gives us a better idea of your general health, like your health behaviors and any symptoms you might have. It takes about <x> minutes to complete. All questions are optional. Are you willing to do this today? (if yes) Great. Let us know if you get stuck and need help.”

Define emergency and high-risk protocols

PRO results may identify a life-threatening health issue, such as current suicidal ideation or intimate partner violence, requiring the use of emergency protocols. PROs can be configured to trigger pager alerts in real time when these or other symptoms are endorsed.

Consider which staff should receive alert for these circumstances, and how staff will respond to alerts in a timely fashion.

It is also possible to set alerts for other high-risk circumstances or behaviors, such as lack of housing, poor ART adherence, or STI transmission risk, which may be useful to other clinic staff such as case managers, health educators, or on-site pharmacists.

Pilot

Once the workflow protocols are in place, and clinic staff trained (see Chapter 6, Train Clinic Staff), [Add Link] we strongly recommend conducting a pilot test of the PROs and their operationalization within clinic workflow prior to launching PROs with actual patients. Walk through the patient experience from start to finish. Among the areas to test in this phase:

* Wifi connectivity. Test the assessment in all room areas in which patients will be administered PROs to ensure adequate internet connection.
* Responsiveness of touch-screen device.
* Ease of navigating content.
* Success of paging protocols when urgent issues are endorsed.
* Ease of generating results and delivery to provider.
* Ease of provider interpretation of results.
* Anticipated patient experience. Are they being moved around during this process for other purposes, such as collection of vitals? How easy or difficult is it to follow up with the patient? Is it clear to the PRO “point person” when the patient has finished or if they need help?
* Real vs. anticipated time burden.

Launch

We recommend a gradual approach, such as implementing PROs with a limited number of providers and their patients to start, to allow for troubleshooting before a wider scale launch. Check in with patients in this early phase regarding their experience of the process and solicit their insights for how to improve it. Check in with staff at all levels at least twice each day (e.g., once after the morning shift and once at the end of the afternoon shift), including front desk staff, medical assistants, and providers to assess and troubleshoot impact on flow, and make adjustments as needed.

***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***

Resources

* [ISOQOL User’s Guide](http://www.isoqol.org/UserFiles/2015UsersGuide-Version2.pdf) to Implementing Patient-Reported Outcomes Assessment in Clinical Practice. V2: January 2015
* [PROMIS](http://www.healthmeasures.net/explore-measurement-systems/promis) health measures
* [REDCap Shared Library, REDCap data collection instruments](https://redcap.vanderbilt.edu/consortium/library/search.php)
* PCORI Patient-Reported Outcomes (PRO) Infrastructure Workshop “[Integrating PROs into EHRs](https://www.pcori.org/sites/default/files/PCORI-PRO-Infrastructure-Workshop%20Report-111913.pdf)” 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”](http://centerforinnovation.mayo.edu/files/2016/01/depression-decision-aid-1.pdf)
* Dartmouth-Hitchcock, [Decision Support Toolkit for Primary Care](http://med.dartmouth-hitchcock.org/csdm_toolkits/primary_care_toolkit.html)
* National Learning Consortium, [Shared Decision Making, Fact Sheet](https://www.healthit.gov/sites/default/files/nlc_shared_decision_making_fact_sheet.pdf)
* Agency for Healthcare Research and Quality, [The Share Approach](about:blank)

# CHAPTER 6. TRAIN CLINIC PERSONNEL

Initial training

Training appropriate staff members on the integration of PROs is critical to its smooth integration into clinical care. 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.

Figure 6 shows a sample training agenda covering the topics necessary to equip staff and providers to begin administering PROs. This may be broken up into more than one training, such as one for orienting to PROs in general, and another detailing or developing protocols; or, for training different levels of staff. In our experience, initial trainings that include all staff types work well, particularly for smaller clinics. The training becomes a dynamic and iterative process in which staff members in different roles collaboratively think through how patients administered PROs will move through their visit, refining protocols in the process.

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 in the clinic only part time. 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.

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.

Ongoing training

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

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

***Practical Tip:*** Having staff complete a demonstration PRO assessment on the table can quickly demonstrate how easy it is and greatly decrease hurdles

***Practical Tip:*** While formal refresher sessions are one option to provide ongoing training and maintain enthusiasm, we have found that annual brief presentations of key findings (e.g. % of PLWH reporting depression, methamphetamine use, etc.) to the entire staff (as part of quarterly staff and provider joint meetings) has resulted in ownership and ongoing support not just from the providers but also from other staff members.

***Figure 6.* Sample training agenda**

Clinic staff training (all levels, group meeting)

PROs: purpose and general orientation

* PROs-introduction, definition
* Value of PROs- known clinical/research value, reduces social desirability bias, prioritizes needs
* PRO domains- examples
* iPad demo of PROs: what patients see
* Results: what providers see
* Silent group activity: all staff members self-administer PRO assessment on separate devices (if possible), as if at risk for all categories
  + Discussion of PRO assessment/experience of answering PROs
  + Discussion regarding improving, adding, or modifying content

Integration of PROs into clinic

* How PROs will fit into clinic flow: overview
  + Who follows up with patients at each step during their visit
  + How patient will move through the appointment post-PRO integration
  + Discussion of concerns, solicit feedback, refine protocol
* How to schedule PROs (if applicable)
* How to introduce PROs to patients
* Protocol for late patients or patients that are too ill/impaired to complete PROs
* Protocol for emergency (suicide/IPV) and other alerts
* Results: scoring and interpretation
* Results: delivery protocol
* Communication protocols between staff regarding PROs
* Care and storage of tablets
* Using the PRO platform: scheduling, patient lookup, data sets, etc.

Resources

* Eye for Pharma: Using ePRO for the First Time: [Lessons Learned](https://social.eyeforpharma.com/commercial/using-electronic-patient-reported-outcomes-epro-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.

# CHAPTER 7. MONITOR AND EVALUATE

*”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***

The implementation of any new process should be accompanied by a monitoring and evaluation (M&E) process to measure success and identify areas for improvement. This section provides a simple overview of some important considerations.

Identify indicators of success

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 8):

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

|  |  |
| --- | --- |
| ***Table 8.* 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/starting/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 9.

|  |  |
| --- | --- |
| ***Table 9.* Examples of SMART process and SMART performance indicators** | |
| **SMART Process Indicators** | **SMART Performance Indicators** |
| **PRO completion rates**: Over a six-month period, PRO 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. |

Determine process and timing

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 as priorities change.

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.

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 8 includes two examples of CQI specific to PRO implementation.

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

***Figure 8.* 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.

* Changes in total appointment length
* Number of patients completing PROs
* Patient satisfaction with care
* Provider perception of usefulness of PROs
* Time providers spend reviewing and integrating the PRO into the care process
* Changes in visit 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.

***Practical tip:***

Formal M&E plans are important in many settings to ensure ongoing success of programs and our often conducted annually. In our clinics, we have been particularly pleased with a more straightforward but ongoing approach that involves tracking completion rates. This measure is quick to generate, and easily trackable on a monthly basis. While it is a very simple measure as nursing/front desk/medical assistant and other staff turn over, priorities can drift and it quickly demonstrates that there is a need for retraining and reminders regarding the importance of the PROs.

A second streamlined approach to M&E that has proven both extremely valuable and also very efficient is examining reasons for those who did not complete the PROs. Was it because they forgot their glasses (we now keep several pairs of non-prescription reading glasses available). Was it because the demographic characteristics of the clinic have changed? We now offer the PRO assessment in Amharic at two of our clinics. Selecting several days every 6 months and evaluating the reasons why PLWH seen in clinic do not complete the PROs on those days has proven to be an extremely efficient practical and useful approach to ongoing M&E.

Resources

* Minnesota Department of Health - [SMART Goals Guidance](http://www.health.state.mn.us/divs/opi/qi/toolbox/objectives.html#examples)
* CDC Tools -[SWOT Analysis Tool](http://www.cdc.gov/phin/communities/resourcekit/docs/Evaluate_SWOT_Analysis_Tool.doc) , [SMART Objectives](https://www.cdc.gov/phcommunities/docs/evaluate_smart_objectives_template.doc) Template
* Agency for Health Research and Quality (AHRQ) - [Quality Measures: PROs for Quality Improvement of Clinical Practice](https://www.qualitymeasures.ahrq.gov/expert/expert-commentary/36851/quality-measures-patientreported-outcomes-for-quality-improvement-of-clinical-practice)
* National Quality Forum (NQF) - [Patient-Reported Outcomes in Performance Measurement](https://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx)
* The Commonwealth Fund - [Using PROs to Improve Health Care Quality](http://www.commonwealthfund.org/publications/newsletters/quality-matters/2011/december-january-2012/in-focus)
* W.K. Kellogg Foundation (WKKF) – [Step-by-Step Guide to Evaluation](https://www.wkkf.org/resource-directory/resource/2010/w-k-kellogg-foundation-evaluation-handbook)

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# APPENDIX 1. List of Abbreviations

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| --- | --- |
| **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 |

# APPENDIX 2. Glossary