

A TOOLKIT TO SUPPORT THE IMPLEMENTATION OF PATIENT- REPORTED OUTCOME MEASURES IN ROUTINE HIV CARE

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There Is Increasing Recognition for HIV Care and Management to Look Beyond Viral Suppression in Terms of Patient Outcomes

PROs may include one or more dimensions of care

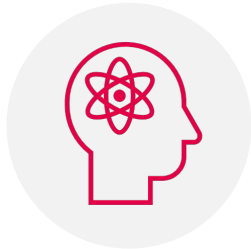
Being virologically suppressed **does NOT mean** PLHIV are enjoying a good HRQoL

.....

Many determinants of HRQoL are **difficult to directly identify** but are critical for optimal HIV care

.....

PROs may be especially relevant in HIV care because many issues are sensitive (eg, sexual risk behavior, alcohol/drug use)



Health behaviors
eg, adherence, substance use, sexual risk behavior



Overall HRQoL



Social well-being
eg, social support, stigma



Mental health
eg, depression, anxiety



Life circumstances
eg, housing, nutrition, intimate partner violence



Satisfaction with medication/ treatment/care



Physical symptoms

HRQoL, health-related quality of life; PLHIV, people living with HIV; PRO, patient-reported outcome.

In HIV Care, PROs May Improve Patient–Provider Communication and Detection of Otherwise Hidden Needs

PROs have the potential to improve several aspects of HIV care



Provider awareness and monitoring

- Facilitates understanding of personal or stigmatizing symptoms (eg, depression, suicidal ideation, substance use)
- Identifies HRQoL issues



Patient–provider communication

- Provides information previously unknown to the provider
- Promotes honest discussion of sensitive topics
- Focuses clinic visits and prioritizes needs/concerns



Health outcomes

- Addresses symptom control and outcomes for mental conditions (eg, depression)

HRQoL, health-related quality of life; PRO, patient-reported outcome.

Implementation of PROs in Routine HIV Care Is Challenging and Initiation May Seem Overwhelming

The **PROgress Project** developed evidence, insights, and resources to support implementation of PROs in routine HIV care

1

PROgress evidence review and summary report

Highlights the value of PROs in HIV and other disease states by summarizing published evidence and addressing key questions such as

- What difference can PROs make to provider–patient communication?
- How do patients value PROs?
- How do providers value PROs?
- How do PROs impact clinic flow?

2

PROgress study

Implementation science study of integration of PROs within 2 HIV outpatient clinics to demonstrate feasibility and fill evidence gaps

- Conducted in Fort Pierce, Florida, USA, and Toronto, Ontario, Canada

3

PROgress Implementation Toolkit

Highlights key stages and decision points of PRO implementation based on real-world PROgress Study experience and that of other sites

Compiled iteratively as PRO implementation steps were completed at the PROgress Study sites

PRO, patient-reported outcome.

<https://progresshivcare.org/>

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

- ✓ Chapter 1: Assessing and improving readiness to implement PROs in HIV clinical care
- ✓ Chapter 2: Engage stakeholders
- ✓ Chapter 3: Technical choices and infrastructure
- ✓ Chapter 4: Create PRO assessment
- ✓ Chapter 5: Outline workflow
- ✓ Chapter 6: Train clinic personnel
- ✓ Chapter 7: Monitor and evaluate
- ✓ Appendix: Online PRO timing tool
- ✓ Appendix: Sample stakeholder presentation

PRO, patient-reported outcome.

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The Toolkit includes information on

✓ 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?
 - Patient population
 - Clinic leadership
 - Provider support
 - Logistical and clinic flow considerations
 - Technical capacity
 - Start-up and running costs
- Creating a business case for PRO implementation

Example of creating a business case

Potential sections	Description
Executive summary	Brief description of overall plan including goals, milestones, summary of implementation
The case for investing in PRO elicitation in routine HIV care	<ul style="list-style-type: none"> • Outlines case for integrating PROs into care • See complementary report to this Toolkit, the Evidence Review and Summary (available at https://progressshivcare.org/#evidence), which outlines the value of clinically-relevant PROs to HIV care • Contrast current service provision with an enhanced service that includes PROs • Describe key elements, e.g. likely patient numbers, impact
Statement of goals and objectives	Includes long- and short-term goals
Service overview	Describe proposed integration in more detail, including: <ul style="list-style-type: none"> • How PROs will be gathered • How the PRO process will integrate into the current workflow (mapping the patient and information journey) • Which patients will be eligible • How roles within the service will adapt or evolve • Any new resources required, including personnel, facilities, program support requirements (e.g. IT) and hardware/software • What PRO domains (health topics) will be used
Project team	<ul style="list-style-type: none"> • Proposed project leadership, and any proposed roles for existing or new personnel required to ensure adoption • 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	Convey confidence in how the project will be managed and monitored
Financial analysis	Carefully estimated cost of investment required; 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

PRO, patient-reported outcome.

<https://progressshivcare.org/>

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

✓ Chapter 2: Engage stakeholders

- Identify stakeholders
- Prepare demonstration of value
- Meet with stakeholders
- Provide an overview of the value of PROs
- Address common concerns
- Include providers in PRO selection process and output design
- Secure implementation champion

✓ Appendix: Sample stakeholder presentation

PRO, patient-reported outcome.

<https://progresshivcare.org/>



PRACTICAL TIP

Provide a clear justification for PRO data collection, as providers and staff are more likely to support PRO implementation if they understand the value.³ Short practical examples are more compelling.

Practical tips

Examples

Example 1: *Improve patient engagement in care via better detection of treatable problems.* On average, ~30% of PLHIV in the US report depression at any one time, and this is associated with many poor outcomes such as mortality.²⁶ It is notable that even among PLHIV with known depression, there are substantial gaps in the depression treatment cascade with lack of follow-up to see if treatments are effective.²⁷ We plan to integrate a brief clinical assessment of PROs including depression to identify the ~20% of our clinic with undiagnosed or undertreated



Sample stakeholder presentation

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

✓ **Chapter 3: Technical choices and infrastructure**

- Understanding PRO choices
- Identify issues to guide choices
 - Gathering information from the patient
 - Presenting information to the provider
 - Storing information into the medical record
 - Reuse of information for population health
- Consider system features
- Consider data quality
- Resources

PRO, patient-reported outcome.
<https://progresshivcare.org/>

Key considerations

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

Guidance on infrastructure

- Snyder C and Wu AW, 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 from: <http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records>. Accessed October 2020.

Resources

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

✓ Chapter 4: Create PRO assessment

- Determine mode of administration (paper vs tablet based)
- Select PROs: domains and attributes to consider
- Identify scoring and interpretation needs
- Determine order of PRO measures in assessment
- Determine frequency of administration for the full PRO assessment and for each measure
 - Individual PRO measures may not need to be administered at every visit (ie, gender identity)
- Format results
- Build your own PRO assessment
- Resources

✓ Appendix: Online PRO timing tool

PRO, patient-reported outcome. References for PRO measures are listed in the slide notes and can be found in the Toolkit.

<https://progresshivcare.org/>

FirstName LastName	MRN: 000000	DOB: 1/1/1900		
	9/29/2020	3/29/2020	9/29/2019	
Depression (PHQ-9)	15 Moderate depression (10-19)	10 Moderate depression (10-19)	2 No depression (0-4)	
Suicide Ideation (PHQ-9) In Last 2 Weeks	0 Not at all	0 Not at all	0 Not at all	
Concern for IPV (Past year)				
Felt trapped/controlled	Yes	No	No	
Fearful of harm	Yes	No	No	
Sexual violence	No	No	No	
Physical violence	No	No	No	
Substance Use				
Lifetime	Cocaine/crack, Crystal meth,	Cocaine/crack, Crystal meth,	Cocaine/crack, Crystal meth,	
Past 3 months				
Past 3 months injected				
Alcohol Score (AUDIT-C)				

Sample PRO summary report

Online time-budget tool

Interactive time estimate tool : Estimate Tool (Display)

Include	Domain	Average completion time
<input checked="" type="checkbox"/>	HIV Symptom index ¹	0:00:53
<input checked="" type="checkbox"/>	Depression (PHQ-9) ^{2,3}	0:00:52
<input checked="" type="checkbox"/>	Anxiety (PHQ-5) ^{2,3}	0:00:26
<input checked="" type="checkbox"/>	Tobacco Use ⁴	0:00:36
<input type="checkbox"/>	Alcohol Use (AUDIT-C) ^{5,6}	0:00:34
<input type="checkbox"/>	Substance Use (ASSIST) ^{7,8}	0:01:27
<input checked="" type="checkbox"/>	Drug Treatment/past year (1 item) ⁹	0:00:09
<input checked="" type="checkbox"/>	Adherence (SRS) ¹⁰⁻¹²	0:00:08
<input checked="" type="checkbox"/>	Sexual Risk Behavior (SRBI) ¹³	0:00:51
<input checked="" type="checkbox"/>	Intimate Partner Violence (IPV-4) ¹⁴	0:00:26
<input checked="" type="checkbox"/>	Social Support (MAPSS-SF) ¹⁵	0:00:15
<input checked="" type="checkbox"/>	Quality of Life (EQ-5D) ¹⁶	0:00:52
<input checked="" type="checkbox"/>	Housing Status ¹⁷	0:00:41
<input type="checkbox"/>	Physical Activity ¹⁸	0:01:17
<input type="checkbox"/>	Gender Identity (1 item) ¹⁹	0:00:06
<input checked="" type="checkbox"/>	Sexual Orientation (1 item) ¹⁹	0:00:12
Estimated Time Needed to Adminster:		0:06:21

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

✓ Chapter 5: Outline workflow

- Select workflow: when, where, and how to administer PROs
- Define staff roles and centralize responsibility
- Create protocol: when not to administer PROs
 - Patient-based factors
 - Flow-related factors
- How to introduce PROs to patients
- Define emergency and high-risk protocols
- Pilot
- Launch tips
- Resources

PRO, patient-reported outcome.

<https://progresshivcare.org/>

Sample script



“ 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.🙏🙏

“ ... 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

Testimonials from case managers

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The Toolkit includes information on

✓ Chapter 6: Train clinic personnel

- Initial training
- Ongoing training
- Resources

Sample training agenda

Clinic staff training (all levels, group meeting)
PROs: purpose and general orientation
<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> - Discussion of PRO assessment/experience of answering PROs - Discussion regarding improving, adding, or modifying content
Integration of PROs into clinic
<ul style="list-style-type: none"> • How PROs will fit into clinic flow: overview <ul style="list-style-type: none"> - 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.

PRO, patient-reported outcome.

<https://progresshivcare.org/>

The Toolkit Provides Practical Advice to Support the Introduction of PRO Assessments Into Routine HIV Care

The Toolkit includes information on

✓ **Chapter 7: Monitor and evaluate**

- Identify indicators of success
- Determine process and timing
- Implement a process of continuous quality improvement
- Resources

Example process indicators

Examples of process indicators based on PRO data
Percentage of patients refusing/starting/completing the PRO process
Number of screenings for improvement in symptoms
Number of screenings to identify adverse events

Examples of performance indicators based on PRO data
Percentage of patients with depression who receive antidepressant medications or receive a referral
Number of patients who indicate suicidal ideation who are provided with an intervention, including a formal risk assessment
Patient satisfaction scores

Example performance indicators

“It helped in our setting to assign one domain to an HIV doctor and an HIV nurse. Once per month during an hour, a certain outcome indicator and related process indicators are being discussed during the weekly clinical HIV meeting. Not just one champion but making everybody partly responsible.”

HIV care physician steering committee member

Testimonials from HIV physicians

PRO, patient-reported outcome.
<https://progressshivcare.org/>

How Can You Access the Toolkit?

PROgress Project
<https://progresshivcare.org/>

PROgress Implementation Toolkit
<https://progresshivcare.org/toolkit.html>

Conclusions

- Implementing PROs provides a great opportunity for clinics to improve clinical care for PLHIV, yet PRO implementation can be perceived as a difficult and overwhelming step
- The PROgress Implementation Toolkit provides a practical resource to support the integration of PROs within routine HIV care
- This Toolkit is a novel resource that can be useful for different types of clinics and offers flexibility to adapt implementation processes

PLHIV, people living with HIV; PRO, patient-reported outcome.

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Why the Toolkit and PROgress Study Evidence Review and Summary Report Were Developed

“How quickly did you start to see the benefits of PROs at Saint Michael’s [Hospital in Toronto, Canada]?”

Response from Jean Bacon

- Executive Director of Ontario HIV Treatment Network
- PROgress Study Steering Committee member



How quickly did you start to see the benefits of PROs at Saint Michael’s?

PRO, patient-reported outcome. Find the full-length video here: [Improving quality of life through Implementation Science: PROgress – YouTube](https://progresshivcare.org/).
<https://progresshivcare.org/>