Supplementary File S6

LAI-PrEP Bridge Period Decision Tool

A Non-Technical Guide for Clinicians and Healthcare Workers

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Viruses Journal Supplementary Materials

Accompanying: "Bridging the Gap: The PrEP Cascade Paradigm Shift for Long-Acting Injectable HIV Prevention"

Contents

1 What Is This Tool?

This is a **clinical decision support calculator** that helps you predict whether a patient will successfully complete the "bridge period" (the time between prescribing LAI-PrEP and administering the first injection).

Think of it like a **risk calculator** similar to cardiovascular risk scores (like Framingham) or fracture risk tools (like FRAX), but specifically designed for LAI-PrEP implementation.

1.1 Why This Matters

Research shows that **only 53% of patients who are prescribed LAI-PrEP actually receive their first injection**. The other 47% are lost during the bridge period due to various barriers. This tool helps you:

1. **Predict** which patients are at high risk of never starting
2. **Identify** specific barriers preventing initiation
3. **Select** interventions proven to improve success rates
4. **Estimate** how much those interventions will help

Key Takeaway

LAI-PrEP demonstrates superior clinical outcomes (96% efficacy, 81–83% persistence), but only if patients successfully initiate treatment. The bridge period is where implementation fails.

2 Understanding the Bridge Period

2.1 What is the Bridge Period?

The **bridge period** is everything that happens between when you decide to prescribe LAI-PrEP and when the patient receives their first injection. This includes:

- Getting HIV test results back (must confirm HIV-negative)
- Scheduling the injection appointment
- Getting insurance authorization
- Patient arranging transportation
- Patient managing childcare (if needed)
- Waiting period for test results

Duration: Usually 2–8 weeks, depending on circumstances

2.2 Why Does This Matter?

Unlike oral PrEP (where patients can start the same day they get their prescription), LAI-PrEP **cannot** be started immediately. This delay creates opportunities for patients to:

- Change their mind
- Face logistical barriers
- Lose motivation
- Get frustrated with the process
- Acquire HIV during the waiting period

Important Note

47% of patients never make it through this bridge period. The tool helps you prevent that by identifying high-risk patients and implementing targeted interventions.

3 How Does the Tool Work?

3.1 Step 1: Input Patient Information

The tool asks for basic information about your patient:

3.1.1 Population Category

Which group best describes your patient?

- Men who have sex with men (MSM)
- Cisgender women
- Transgender women
- Adolescents (ages 16–24)
- People who inject drugs (PWID)
- Pregnant or lactating individuals
- General population

Clinical Tip

Why this matters: Different populations face different barriers. For example, adolescents have a 60–70% risk of not completing the bridge period, while MSM have a 40–50% risk.

3.1.2 Current PrEP Status

- **Never been on PrEP** ("naive") – Highest risk
- **Currently taking oral PrEP** – Much lower risk (85–90% success!)
- **Previously on oral PrEP but stopped** – Moderate risk

Key Takeaway

Patients already on oral PrEP are your BEST candidates – they've already proven they can navigate the healthcare system and are motivated for prevention.

3.1.3 Recent HIV Test?

- Has the patient had an HIV test within the last 7 days?
- YES = Can potentially start same day or very soon
- NO = Will need testing, adding 2–3 weeks to bridge period

3.1.4 Barriers Present

Does your patient face any of these challenges? **Check ALL that apply** – each barrier increases risk.

Access Barriers:

☐ Transportation difficulties

☐ Childcare needs

☐ Housing instability

☐ Insurance authorization delays expected

☐ Scheduling conflicts (work, school)

☐ No government ID

Trust and Safety Barriers:

☐ Medical mistrust

☐ Privacy/confidentiality concerns

☐ Past healthcare discrimination

☐ Legal concerns (for PWID)

System Navigation Barriers:

☐ Competing health priorities

☐ Limited experience navigating healthcare

☐ Active substance use

3.1.5 Healthcare Setting

Where will the patient receive care?

- Academic medical center
- Community health center
- Private practice
- Pharmacy
- Harm reduction/syringe service program
- LGBTQ community center
- Mobile clinic
- Telehealth-integrated

3.2 Step 2: Tool Calculates Risk

The tool automatically calculates:

1. **Baseline Success Rate:** Starting point based on population (e.g., MSM = 55%)
2. **Adjusted Success Rate:** After accounting for individual barriers (may drop to 20% or lower with multiple barriers)
3. **Risk Level:** Low, Moderate, High, or Very High
4. **Estimated Bridge Duration:** How long from prescription to injection (0–56 days)

3.3 Step 3: Tool Recommends Interventions

The tool provides a **prioritized list** of interventions, ranked by:

- **Priority Level:** Critical, High, or Moderate
- **Expected Improvement:** How many percentage points this intervention adds to success rate
- **Evidence Level:** Strong, Moderate, or Emerging

Example output:

```
1. Same-day switching protocol
   Priority: CRITICAL
   Expected Improvement: +40 percentage points
   Evidence: Strong

2. Patient navigation program
   Priority: High
   Expected Improvement: +15 percentage points
   Evidence: Strong
```

3.4 Step 4: Tool Predicts Final Outcome

The tool estimates success rate **WITH** your top interventions implemented:

Baseline: 20% → With interventions: 48% (+28 points)

This helps you understand if your interventions are sufficient or if more intensive support is needed.

4 Real-World Examples

4.1 Example 1: Best Case Scenario

Patient: 28-year-old MSM currently on oral PrEP, had HIV test 3 days ago

Tool Output:

- Baseline Success: 55%
- With barriers: 50% (mild scheduling conflict)
- **Recommended Action:** Same-day switching protocol
- **Final Success Prediction:** 86%
- **Bridge Duration:** 0–3 days

Key Takeaway

What This Means: This patient is a PRIORITY for immediate transition. Don't make them wait! You can inject today or within a few days. This is your easiest case.

Action Steps:

1. Confirm HIV test is current (✓– 3 days ago)
2. Schedule injection appointment for this week
3. Submit insurance authorization immediately
4. Done! Patient has 86% chance of success

4.2 Example 2: Moderate Risk Case

Patient: 32-year-old cisgender woman who stopped oral PrEP 6 months ago, has transportation and childcare barriers

Tool Output:

- Baseline Success: 45%
- With barriers: 17% (very high risk!)
- **Recommended Actions:**
    1. Patient navigation program (+15 points)

2. Transportation vouchers (+8 points)
3. Childcare support (+8 points)

- **Final Success Prediction:** 45%
- **Bridge Duration:** 21–56 days

Important Note

Without help, this patient has only a 17% chance of starting LAI-PrEP. But with navigation, transportation, and childcare support, you can increase success to 45%.

Action Steps:

1. Assign patient navigator immediately
2. Provide Uber/Lyft vouchers for appointments
3. Offer on-site childcare or childcare vouchers
4. Navigator should call within 24 hours of prescription
5. Schedule HIV testing at most convenient location
6. Text reminders 48h and 24h before appointments

4.3 Example 3: Very High Risk Case

Patient: 35-year-old person who injects drugs (PWID), experiencing housing instability, no ID, multiple barriers

Tool Output:

- Baseline Success: 25%
- With barriers: 5% (extremely high risk!)
- **Recommended Actions:**
  1. Harm reduction integration (SSP) (+15 points)
  2. Peer navigation (+15 points)
  3. Mobile delivery (+12 points)
  4. Accelerated testing (+10 points)
- **Final Success Prediction:** 31%
- **Bridge Duration:** 21–56 days

Important Note

Traditional clinic-based approach will fail. This patient needs services brought to them in a trusted setting with peer support.

Action Steps:

1. Partner with local syringe service program (SSP)
2. Assign peer navigator with lived experience
3. Arrange mobile testing at SSP location
4. Use point-of-care HIV testing (results in 20 minutes)
5. Schedule injection at SSP site or mobile clinic
6. Eliminate ID requirements through low-barrier protocols
7. Provide injection at most convenient time/location for patient
8. Build trust through non-judgmental, harm reduction-informed care

5 Quick Reference Tables

5.1 Table 1: Population-Specific Baseline Success Rates

Population	Baseline Success	Baseline Attrition
MSM	55%	45%
Cisgender Women	45%	55%
Transgender Women	40%	60%
Adolescents (16–24)	35%	65%
PWID	25%	75%
Pregnant/Lactating	50%	50%
General Population	50%	50%

Table 1: Baseline initiation success rates by population, derived from clinical trial data (HPTN 083, 084, PURPOSE-1/2) and implementation studies.

5.2 Table 2: Barrier Impact on Success Rate

5.3 Table 3: Evidence-Based Interventions

Intervention	Improvement	Best For
Same-day switching	+40%	Patient on oral PrEP + recent HIV test
Oral-to-injectable transition	+35%	Patient on oral PrEP (no recent test)
Patient navigation	+15%	Any high-risk patient or vulnerable population
Harm reduction integration	+15%	PWID – ESSENTIAL
Peer navigation	+12%	PWID, adolescents, transgender individuals

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Intervention	Improvement	Best For
Accelerated HIV testing	+10%	All PrEP-naive patients
Transportation support	+8%	When transportation is a known barrier
Childcare support	+8%	Parents with childcare responsibilities
Medical mistrust intervention	+10%	Populations with healthcare mistrust
Anti-discrimination protocols	+12%	LGBTQ+ populations, PWID
Confidentiality protections	+8%	Adolescents, populations with privacy concerns
Flexible scheduling	+6%	Patients with work/school conflicts
Low-barrier protocols	+12%	PWID, unhoused individuals
Pregnancy counseling	+8%	Pregnant individuals
Prenatal integration	+10%	Pregnant individuals
Insurance support	+10%	All patients with insurance barriers
Mobile delivery	+12%	Hard-to-reach populations

Table 3: Evidence-based interventions with quantified improvements in bridge period success rates. Evidence levels range from strong (clinical trials, systematic reviews) to moderate (implementation studies).

5.4 Table 4: Bridge Period Duration

6 Setting Up Your Program

6.1 What You Need to Implement This

6.1.1 Minimal Setup (For Low-Risk Patients)

✓ Protocol for same-day switching (oral PrEP patients)

✓ Rapid HIV testing turnaround ($<$ 48 hours)

✓ Text message reminder system

✓ Staff training on LAI-PrEP basics

6.1.2 Standard Setup (For Moderate-Risk Patients)

Everything above, PLUS:

✓ Patient navigator (can be part-time)

✓ Transportation voucher program

✓ Expedited insurance authorization process

✓ Telehealth capability for counseling

Barrier	Impact on Success
Transportation difficulties	-12%
Childcare needs	-10%
Housing instability	-15%
Insurance delays	-8%
Scheduling conflicts	-5%
Medical mistrust	-12%
Privacy concerns	-8%
Past discrimination	-10%
Competing health priorities	-7%
Limited healthcare navigation	-10%
Legal concerns (PWID)	-15%
No government ID	-12%
Active substance use	-10%

Table 2: Quantified impact of structural barriers on bridge period success rate. Impacts are cumulative but not strictly additive due to overlapping mechanisms.

Scenario	Duration	Notes
Oral PrEP + recent test	0–3 days	Same-day possible
Oral PrEP + need test	7–14 days	Fast track
PrEP-naive + minimal barriers	14–35 days	Standard
PrEP-naive + multiple barriers	35–56 days	High attrition risk

Table 4: Typical bridge period durations by patient scenario.

6.1.3 Comprehensive Setup (For High-Risk Populations)

Everything above, PLUS:

✓ Full-time dedicated navigator

✓ Childcare support or on-site childcare

✓ Partnership with harm reduction services

✓ Peer navigators for key populations

✓ Mobile delivery capability

✓ Flexible scheduling (evenings/weekends)

6.2 Staffing Models

Option 1: Nurse Navigator

- Best for academic medical centers and large community health centers
- Can handle clinical tasks (testing, injection)
- Typical caseload: 100–150 patients

Option 2: Pharmacist Navigator

- Ideal for pharmacy-based programs
- Can prescribe (in states with authority)
- Extended hours (evenings, weekends)

Option 3: Community Health Worker

- Best for underserved populations
- Culturally concordant support
- Can assist with non-clinical barriers

Option 4: Peer Navigator

- ESSENTIAL for PWID populations
- Highly effective for LGBTQ+ populations
- Lived experience builds trust

Option 5: Hybrid Model

- Nurse/pharmacist for clinical tasks
- Peer/CHW for barrier navigation
- Most comprehensive but most resource-intensive

7 Frequently Asked Questions

7.1 Do I need to know how to code to use this?

No! This guide provides all the information you need without touching code. You can:

- Use the reference tables to quickly assess risk
- Follow the decision trees for intervention selection
- Apply the principles in your clinical practice

If your organization wants to implement the actual computer tool, your IT department can help set it up.

7.2 How accurate is this tool?

The tool is based on published data from:

- **Over 15,000 participants** in clinical trials (HPTN 083, 084, PURPOSE-1, PURPOSE-2)
- **Real-world implementation studies** (CAN Community Health Network Study)
- **Systematic reviews** of patient navigation in healthcare

Predictions are **population-level estimates** – individual patients may vary, but the tool provides scientifically-grounded guidance.

7.3 What if my patient doesn't fit neatly into one category?

Use your clinical judgment to select the **closest match**. For example:

- A 25-year-old MSM could be categorized as either "MSM" or "Adolescent" – choose based on which barriers seem most relevant
- A transgender man who has sex with men might be best categorized as "MSM" for risk prediction purposes

The barriers list is more important than perfect category matching.

7.4 Can I use this tool for lenacapavir AND cabotegravir?

Yes! The bridge period challenges apply to both formulations. The main differences:

- Lenacapavir: Every 6 months (fewer appointments)
- Cabotegravir: Every 2 months (more frequent)
- Lenacapavir is subcutaneous (under skin), cabotegravir is intramuscular (into muscle)

The tool's predictions apply to both.

7.5 What about once-yearly lenacapavir?

Once-yearly formulations are currently in Phase 3 trials (expected results second half of 2025). When approved, the bridge period will likely be:

- **Longer** (more conservative testing needed due to year-long exposure)
- **More crucial** (missing one injection = entire year without protection)

The tool's principles will apply, but specific numbers may need updating.

7.6 How do I know if interventions are working?

Track these metrics:

1. **Initiation Rate:** % of prescriptions resulting in first injection
2. **Bridge Duration:** Days from prescription to injection
3. **Attrition Reasons:** Why did patients not initiate? (insurance? transportation? lost to follow-up?)
4. **Population-Specific Rates:** Are outcomes equitable across groups?

Target benchmarks:

- Overall initiation rate: $>$70% (currently only 53% nationally)
- Bridge duration: $<$14 days for oral-to-injectable, $<$28 days for PrEP-naive
- Attrition due to system barriers (insurance, scheduling): $<$10%

7.7 This seems like a lot of work. Is it worth it?

Consider:

- **Current situation:** 47% of patients never get their first injection – that's a complete prevention failure
- **LAI-PrEP advantages:** Once initiated, 81–83% stay on LAI-PrEP (vs. only 52% on oral PrEP)
- **Math:** Investing in successful initiation means you DON'T have to invest in ongoing retention support

Key Takeaway

It's actually LESS work overall to get people started on LAI-PrEP successfully than to support ongoing oral PrEP adherence.

8 Action Steps for Your Clinic

8.1 This Week

☐ **Identify your current oral PrEP patients** – they are your EASIEST wins

☐ **Start conversations** about switching to LAI-PrEP

☐ **Implement same-day switching** for patients with recent HIV tests

☐ **Map your barriers** – what do YOUR patients face?

8.2 This Month

☐ **Designate a bridge period navigator** (even part-time)

☐ **Set up text message reminders** for appointments

☐ **Establish rapid HIV testing protocol** ($<$ 48 hour turnaround)

☐ **Create transportation voucher program** (even small scale)

☐ **Train staff** on LAI-PrEP bridge period challenges

8.3 This Quarter

☐ **Measure your initiation rate** – track prescriptions vs. injections

☐ **Analyze attrition reasons** – where are you losing patients?

☐ **Implement population-specific interventions** based on your patient mix

☐ **Establish community partnerships** (SSPs, LGBTQ centers, mobile clinics)

☐ **Evaluate and adjust** your protocols

9 Additional Resources

9.1 Clinical Guidelines

- **CDC:** US Public Health Service PrEP Guidelines (2021 Update)
- **WHO:** Consolidated Guidelines on HIV Prevention (with July 2025 LAI-PrEP addendum)

9.2 Implementation Support

- **National Clinician Consultation Center:** nccc.ucsf.edu (PrEP Quick Guide)
- **PrEPWatch:** prepwatch.org (tracking LAI-PrEP access and implementation)

9.3 Training

- **Clinician Consultation Center:** Free phone consultation for complex cases
- **AETC National Coordinating Resource Center:** HIV education and training

10 Summary: Key Takeaways

The Core Problem

Only 53% of patients prescribed LAI-PrEP actually get their first injection. The bridge period is where we lose people.

The Core Solution

Proactively identify high-risk patients and implement evidence-based interventions **before** they get lost.

The Biggest Win

Patients already on oral PrEP have 85–90% success with transitions. **Prioritize them!**

The Equity Imperative

Without intentional intervention, populations most likely to benefit (adolescents, women, PWID) will have the lowest access. This is a **health equity issue**.

The Evidence Base

This isn't guesswork – it's based on data from over 15,000 clinical trial participants and real-world implementation studies.

Remember: LAI-PrEP is clinically extraordinary (>96% efficacy, 81–83% persistence). The challenge isn't the medication – it's the bridge period. This tool helps you bridge that gap.

Based on: Demidont, A.C.; Backus, K.V. (2025). Bridging the Gap: The PrEP Cascade Paradigm Shift for Long-Acting Injectable HIV Prevention. Viruses.