Supplementary File S5

Clinical Decision Flowchart

Step-by-Step Visual Guide for LAI-PrEP Bridge Period Navigation

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Viruses Journal Supplementary Materials

Purpose of This Flowchart

This clinical decision flowchart provides systematic guidance for LAI-PrEP bridge period management at the point of prescription. It translates the evidence-based decision support algorithm into actionable clinical workflows, enabling clinicians to:

- Rapidly identify patients for same-day switching protocols
- Assess population-specific risks and barriers
- Stratify patients by predicted success rate
- Select appropriate evidence-based interventions
- Implement structured follow-up protocols

Critical Insight: Without systematic intervention, 47% of LAI-PrEP prescriptions do not result in injection initiation. This flowchart addresses that implementation gap.

1 Step 1: Oral PrEP Status Assessment

INITIAL TRIAGE QUESTION

Is the patient currently taking oral PrEP?
This is the single most important clinical decision point that determines bridge period pathway.

1.1 YES: Patient on Oral PrEP â† Expedited Pathway

Secondary Question: Recent HIV Test?

1.1.1 If YES (HIV test within 7 days):

* PRIORITY 1: Same-Day Switching Protocol

Predicted Success: 90%
Bridge Period: 0–3 days
Actions at Prescription Visit:

- ✓ Inject TODAY (preferred) or within 3 days maximum
- ✓ Submit insurance authorization same day
- ✓ Document switch in medical record
- ✓ Schedule next injection (2 or 6 months)
- ✓ Provide injection site care instructions

Evidence: OPERA cohort (n=302), Trio Health (n=146) demonstrated 85–90% success with same-day protocols.
Key Point: Do NOT make these patients wait. They are already engaged and adherent.

1.1.2 If NO (HIV test ¿7 days ago or never):

* PRIORITY 2: Rapid Transition Protocol

Predicted Success: 85–90%
Bridge Period: 7–14 days
Actions at Prescription Visit:

- ✓ Order STAT HIV testing (same day if possible)
- ✓ Submit insurance authorization TODAY (do not wait for test)
- ✓ Schedule injection for next week (tentative)
- ✓ Confirm injection once negative test result received
- ✓ Continue oral PrEP until injection
- ✓ Set text reminders for test and injection appointments

Goal: Minimize wait time to preserve oral PrEP adherence momentum.

1.2 NO: Patient NOT on Oral PrEP â† Standard Pathway

Proceed to **STEP 2: Population & Barrier Assessment**
This pathway requires systematic risk assessment and intervention planning.

2 Step 2: Population & Barrier Assessment

2.1 Population Identification

Identify patient's primary population (baseline success rate without barriers):

Population	Baseline Success	Evidence Source
MSM	55%	HPTN 083
Cisgender Women	45%	HPTN 084, PURPOSE-1
Transgender Women	50%	HPTN 083, PURPOSE-2
Adolescents (16–24)	35%	PURPOSE-1, oral PrEP
PWID	25%	Oral PrEP cascade
Pregnant/Lactating	45%	PURPOSE-1
General Population	53%	Real-world cohorts

2.2 Barrier Assessment Checklist

Check ALL barriers that apply. Each barrier reduces success rate by approximately 10 percentage points:

Structural Barriers:

☐ Transportation barriers (no reliable access to clinic)

☐ Childcare needs (cannot attend appointments without childcare)

☐ Housing instability (homeless or unstable housing)

☐ Insurance delays expected (prior authorization typically ¿2 weeks)

☐ Scheduling conflicts (work/school during clinic hours)

Interpersonal & Systemic Barriers:

☐ Medical mistrust (history of negative healthcare experiences)

☐ Privacy concerns (disclosure fears, confidentiality needs)

☐ Healthcare discrimination (experienced/anticipated discrimination)

☐ Competing priorities (other urgent health/life needs)

☐ Limited healthcare navigation experience (new to system)

Population-Specific Barriers:

☐ Legal/criminalization concerns (PWID, sex work, immigration)

☐ Lack of government identification

☐ Active substance use (interfering with appointment attendance)

2.3 Calculate Adjusted Success Rate

Calculation Formula

Adjusted Success Rate = Baseline Rate – (10% Ã— Number of Barriers)
Examples:

- MSM (55%) with 1 barrier (transportation) = 45% success
- Cisgender woman (45%) with 3 barriers (transport, childcare, mistrust) = 15% success
- PWID (25%) with 4 barriers = Cannot go below 0% (use 5–10% estimate)

Note: This is a simplified clinical calculation. The full algorithm uses multiplicative probability adjustments for greater precision.

3 Step 3: Risk Categorization & Intervention Selection

Based on adjusted success rate, categorize patient and select interventions:

3.1 Low Risk: Adjusted Success ¿70%

Risk Level: Low
Predicted Success: 70–85%
Standard Protocols:

- Text/email reminders for appointments
- Expedited HIV testing (within 3–5 days)
- Standard insurance authorization process
- Patient education materials

Follow-up: Brief check-in call 1 week post-prescription

3.2 Moderate Risk: Adjusted Success 50–69%

Risk Level: Moderate
Predicted Success: 60–75% (with interventions)
Enhanced Protocols:

- **Assign patient navigator** (2–3 contacts during bridge period)
- Text/email/phone reminders
- Expedited/same-day HIV testing
- Address 1–2 key barriers with targeted interventions
- Insurance support (tracking, appeals if needed)

Barrier-Specific Interventions:

- Transportation â† Uber/Lyft vouchers, mileage reimbursement
- Scheduling â† Extended hours, weekend appointments
- Insurance â† Pre-authorization assistance, patient assistance programs

Follow-up: Navigator contact within 24–48 hours, then weekly

3.3 High Risk: Adjusted Success 30–49%

Risk Level: High
Predicted Success: 40–60% (with intensive interventions)
Intensive Interventions Required:

- **Navigator assignment** (MANDATORY – minimum 3 contacts)
- Accelerated HIV testing (same-day rapid test if possible)
- Transportation support (vouchers, rides, mileage)
- Barrier-specific intensive support:
  - Childcare vouchers or on-site childcare
  - Flexible scheduling (early/late/weekend)
  - Insurance advocacy and appeals
  - Peer navigation (if available)
- Close follow-up (every 2–3 days)
- Case conference if barriers persist

Multiple Intervention Modalities: Combine structural support (transportation, childcare) with interpersonal support (navigation, peer support)

3.4 Very High Risk: Adjusted Success ¡30%

Risk Level: Very High
Predicted Success: 20–40% (with maximum interventions)
Maximum Intensity Interventions:

- **Intensive navigation** (multiple contacts weekly)
- **Peer navigator** (if available, especially for PWID, transgender populations)
- **Harm reduction integration** (for PWID)
- **Mobile/outreach services** (bring services to patient)
- **Low-barrier protocols**:
  - No ID requirement
  - Flexible scheduling

  - Home visits if needed
  - Telehealth options
- Address ALL identified barriers simultaneously
- Daily contact first week, then every 2–3 days
- Case management beyond bridge period

Critical: These patients require healthcare system-level support, not just individual interventions. Consider alternative care delivery models.

4 Step 4: Evidence-Based Intervention Library

Select interventions based on specific barriers and population:

Intervention	Target Barriers/Populations	Effect
High-Impact Interventions (¿15% improvement)		
Same-day switching	Oral PrEP patients	+25%
Patient navigation	All barriers, all populations	+15%
Peer navigation	PWID, transgender, MSM	+18%
Harm reduction integration	PWID, substance use	+18%
Moderate-Impact Interventions (10–15%)		
Transportation support	Transportation barriers	+12%
Accelerated testing	HIV testing delays	+12%
Anti-discrimination protocols	Discrimination experiences	+12%
Low-barrier protocols	Multiple barriers, PWID	+12%
Childcare support	Childcare needs	+10%
Insurance support	Insurance delays	+10%
Prenatal integration	Pregnant/lactating	+10%
Medical mistrust intervention	Medical mistrust	+10%
Supportive Interventions (5–10%)		
Flexible scheduling	Scheduling conflicts	+6%
Text/email reminders	All patients	+8%
Confidentiality protections	Privacy concerns, adolescents	+8%
Pregnancy counseling	Pregnant/lactating	+8%
Mobile delivery	Housing instability, PWID	+8%
Cultural competency	Discrimination, mistrust	+7%
Telehealth options	Transportation, rural	+5%
Community partnerships	All populations	+5%
Extended clinic hours	Scheduling conflicts	+5%
Same-day appointments	Competing priorities	+5%

5 Step 5: Special Population Protocols

5.1 PWID Fast Track

People Who Inject Drugs: Alternative Care Model Required

Critical Insight: Traditional clinic-based care results in ¡10% success for PWID. An alternative approach is essential.
Required Elements:

- **MUST** partner with syringe services program (SSP) or harm reduction program
- Bring ALL services to the patient (co-locate at SSP site)
- Use peer navigators with lived experience
- Low-barrier protocols:
  - No government ID required
  - No abstinence requirements
  - Flexible appointment times
  - No-show tolerant (immediate rescheduling)
- Rapid HIV testing at SSP site (same-day results)
- Mobile delivery if SSP partnership unavailable
- Integrate with medication-assisted treatment (MAT)
- Address housing and food insecurity simultaneously

Expected Outcome: 30–40% success (compared to ¡10% in traditional clinic)
Evidence: Harm reduction PrEP literature, oral PrEP PWID cascade studies

5.2 Adolescent Fast Track

Adolescents (16–24): Youth-Specific Approach

Key Barriers: Transportation dependence, privacy concerns, limited healthcare navigation experience
Required Elements:

- Youth-specific navigator (ESSENTIAL – trained in adolescent development)
- Transportation without parental involvement (vouchers, youth-friendly transit)
- Confidential scheduling and communication
- School-friendly appointment times (after school, early morning, weekends)
- Bundle appointments (test + inject same day when possible)
- Text-based communication (preferred by adolescents)
- Privacy protections (manage insurance EOBs, parental notifications)
- Brief, focused visits (adolescent attention span)

Expected Outcome: 35–50% success with navigation (vs. ¡20% without)
Evidence: PURPOSE-1 adolescent cohort, oral PrEP adolescent cascade

5.3 Oral PrEP Patients: Your Easiest Win

Current Oral PrEP Users: Highest Success Opportunity

Critical Message: These are your highest-success patients. Do NOT let them fall through cracks.
Streamlined Protocol:

- Recent HIV test (within 7 days)? â† INJECT TODAY
- No recent test? â† Order test, inject within 7 days maximum
- Same-day insurance authorization (do not delay)
- Minimal wait time (preserve adherence momentum)
- Build on existing provider relationship
- Continue oral PrEP until injection (if needed)

Expected Outcome: 85–90% success
Key Point: Every day of delay increases risk of oral PrEP discontinuation and loss to follow-up.

6 Step 6: Implementation & Follow-Up Timeline

6.1 Day 0: Prescription Visit

Essential Actions at Prescription:

☐ Complete barrier assessment (use checklist in Step 2)

☐ Calculate adjusted success rate and risk category

☐ Select interventions based on this flowchart

☐ Order HIV testing (expedited/STAT)

☐ Submit insurance authorization SAME DAY (critical!)

☐ Assign patient navigator if moderate to very high risk

☐ Provide transportation voucher if barrier identified

☐ Schedule tentative injection appointment

☐ Set up text/email reminders

☐ Give patient clear timeline and expectations

☐ Provide patient handout (Supplementary File S2)

☐ Document barriers and intervention plan in medical record

Time Investment: 15–20 minutes for comprehensive assessment

6.2 Day 1: Next Business Day

Navigator Actions:

☐ Contact patient (phone or text)

☐ Confirm understanding and motivation

☐ Address any new barriers that have emerged

☐ Confirm all appointment times

☐ Check insurance authorization status

☐ Problem-solve any concerns

6.3 Days 2–7: Testing Phase

Critical Period:

☐ HIV testing completed (ideally within 3–5 days)

☐ Results reviewed same day or next business day

☐ Navigator provides results and confirms injection appointment

☐ Text reminders sent (48 hours and 24 hours before injection)

☐ Insurance authorization confirmed or escalated if denied

☐ Address any barriers to injection appointment

High-Risk Patients: Contact every 2–3 days during this period

6.4 Days 7–28: Injection Window

TARGET: FIRST INJECTION

Injection Visit:

☐ Administer first injection

☐ Patient education on injection-site reactions (common, self-limited)

☐ Provide contact information for questions/concerns

☐ Schedule next injection appointment (2 months for cabotegravir, 6 months for lenacapavir)

☐ Hand off to retention/persistence program

☐ Document outcome in tracking system

☐ Celebrate success with patient!

Goal Timeline:

- Oral PrEP patients: 0–14 days
- New patients, low risk: 14–21 days
- New patients, moderate/high risk: 21–28 days

6.5 If Patient Misses Appointment

SAME-DAY RESPONSE REQUIRED

Immediate Actions (Day of Miss):

- Call patient immediately
- Identify barrier that caused missed appointment
- Problem-solve barrier with patient
- Reschedule for ASAP (within 3 days if possible)
- Offer additional support (transportation, flexible timing, etc.)

If Cannot Reach:

- Send text message
- Try alternate contact method (email, secondary phone)
- Attempt contact daily for 3 days minimum

- Consider home visit or outreach for very high-risk patients
- Do NOT give up after one attempt

Key Message: Missing one appointment is NOT failure. Most patients who miss can still be successfully transitioned with rapid outreach and problem-solving.

7 Clinical Pearls

Top 10 Implementation Insights

1. The #1 Thing: Identify oral PrEP patients and transition them FAST. This is your easiest win and highest success rate.
2. The #2 Thing: Assign a navigator for anyone with 3+ barriers or very high-risk populations. Navigation is the single most effective intervention.
3. The #3 Thing: Submit insurance authorization THE SAME DAY as prescription. Do not wait for HIV test results. Delays here cause 10–15% attrition.
4. What NOT to Do: Prescribe and hope. Without proactive intervention, 47% will not initiate. Passive approaches fail.
5. PWID Specific: Traditional clinic-based care will fail for PWID. You MUST use harm reduction approach with SSP integration. There is no successful traditional alternative.
6. Timeline Matters: Every extra day increases attrition risk. Aim for ¡14 days for oral PrEP transitions, ¡28 days for new patients.
7. Barrier Assessment is Non-Negotiable: You cannot select appropriate interventions without knowing barriers. Budget 5 minutes for systematic assessment.
8. Multiple Barriers Require Multiple Interventions: Patients with 3+ barriers need 2–3 interventions simultaneously. Single interventions are insufficient.
9. Don't Reinvent the Wheel: Use evidence-based interventions from the library (Step 4). Effectiveness is proven; customize implementation to your setting.
10. Track Outcomes: Monitor bridge period success rates by population and intervention. Use data to improve your local protocols continuously.

8 Evidence Base

This flowchart is based on:

- **Clinical Trials**: HPTN 083 (n=4,566 MSM/transgender women), HPTN 084 (n=3,224 cisgender women), PURPOSE trials (n=10,761 across multiple populations)
- **Real-World Implementation**: CAN Community Health Network (n=302), OPERA cohort, Trio Health, SPAN clinics
- **Barrier Literature**: PrEP cascade studies, implementation science, structural barrier research
- **Intervention Evidence**: Systematic reviews and meta-analyses of navigation (k=23 RCTs), harm reduction integration, peer support
- **Computational Validation**: Decision support algorithm validated at UNAIDS scale (21.2 million patients), 100% unit test pass rate

Usage Instructions

For Clinicians:

- Print this flowchart and keep in LAI-PrEP prescription area
- Use at EVERY LAI-PrEP prescription to systematically assess and intervene
- Document selected interventions in medical record
- Share with nursing staff and navigators for care coordination

For Clinic Administrators:

- Train all prescribers on flowchart use
- Ensure navigation resources available for moderate/high-risk patients
- Track bridge period outcomes by population and risk level
- Use data to refine local protocols and resource allocation

For Researchers:

- Test flowchart effectiveness in prospective implementation studies
- Validate risk stratification accuracy in diverse settings
- Evaluate cost-effectiveness of tiered intervention approach
- Document adaptations needed for specific contexts

Use this flowchart at every LAI-PrEP prescription to systematically identify risks and implement evidence-based interventions.

Based on: Demidont, A.C.; Backus, K.V. Bridging the Gap: Computational Validation of Clinical Decision Support Algorithm for Long-Acting Injectable PrEP Bridge Period Navigation. Viruses 2025.