Protocol: Community Readiness Assessment for LEN Adoption Using the EPIS Framework

1. Background and Rationale

Lenacapavir (LEN), a long-acting injectable antiretroviral administered every six months, offers a promising alternative to daily oral ART with potential to improve adherence and reduce stigma. However, successful implementation required multilevel readiness, spanning individuals, healthcare providers, health systems, and sociocultural contexts.

A Community Readiness Assessment (CRA) is essential to:

- Identify barriers and facilitators to LEN uptake
- Tailor implementation strategies to the local context
- Align stakeholders prior to rollout

2. Study Objectives

Primary Objective

Assess community and health system readiness to implement LEN among adolescents and young adults (AYA) in suband key stakeholders in selected communities, using validated quantitative readiness scores and qualitative contextual analysis.

Secondary Objectives

- Evaluate knowledge, perceptions, and acceptability of LEN
- Identify structural, cultural, and health system barriers
- Assess provider preparedness and training needs
- Generate context-specific implementation strategies aligned with EPIS phases

3. Conceptual Framework: EPIS

The assessment will be structured using the EPIS (Exploration, Preparation, Implementation, Sustainment) framework (Aarons et al., 2011) which guides implementation across four phases:

Exploration

- Assess need for LEN and contextual fit
- Identify stakeholders and community dynamics

Preparation

- Evaluate capacity, resources, and training needs
- Determine acceptability and feasibility

Implementation

- Identify anticipated barriers/facilitators during rollout
- Assess service delivery workflows

Sustainment

- Evaluate long-term feasibility, financing, and policy alignment

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Table 1: EPIS Table

EPIS Phase	Simple question to ask	Community Readiness Assessment
Exploration	Should we do this here?	Identify community needs (e.g. injection preferences, clinic access), awareness, perceptions (e.g., if LEN fits local realities) and willingness among AYA and communities
Preparation	Are we ready to start?	Assess provider capacity, infrastructure,supply chain, and training gaps
Implementation	How do we make it work?	Identify anticipated barriers and co-develop solutions before rollout (e.g., (missed visits, workflow issues)
Sustainment	How do we keep it going?	Evaluate long-term feasibility, and program acceptability, and health system integration

4. Study Design

- **Design:** Mixed-methods cross-sectional study
- **Setting:** Primary Health Centers (PHCs) and ART clinics across urban, peri-urban, and rural communities
- **Potential Population:**
    - Adolescents and young adults
    - Healthcare providers (doctors, nurses, CHEWs)
    - Community leaders (religious, traditional, peer educators)
    - Policymakers and program managers

5. Sampling Strategy

Site Selection

- Stratified purposive sampling across:
    - Primary healthcare centers (PHCs)

Participant Sampling

- Adolescents and young adults: ~30–50 per site (survey + focus group discussions (FGDs))
- Providers: 10–15 per site key informant interviews (KIIs)

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6. Data Collection Methods

Quantitative Component

6.1 AYA Assessment Questionnaire

- Awareness and knowledge of LEN
- Willingness to switch to injectable ART
- Perceived benefits and concerns
- Stigma and privacy concerns
- Access barriers (distance, cost, clinic wait times)
- Sociodemographic characteristics
- Adherence history

6.2 Health Facility Assessment Questionnaire

- Staffing levels and workload
- Cold chain/storage capacity
- Injection delivery infrastructure
- Supply chain reliability
- Existing ART workflows

6.3 Community Assessment Questionnaire

- Knowledge of LEN
- Leadership/gatekeeper support
- Community attitudes
- Community resources and infrastructure (e.g., transportation access, proximity to health facilities, community health worker availability)

Scoring

- Adapted community readiness model scale (1–9):
    - 1–3: Low readiness (awareness stage)
    - 4–6: Moderate readiness (preparation stage)
    - 7–9: High readiness (initiation/sustainment stage)

Qualitative Component

6.4 Focus Group Discussions (FGDs)

- AYA (segmented by age, sex, and ART adherence status)
- Community/religious leaders

6.5 Key Informant Interviews (KIIs)

- Providers, policymakers, community leaders

Domains:

- Cultural beliefs about injections vs. oral medications
- Trust in health systems
- Gender dynamics and decision-making
- Stigma and confidentiality concerns
- Perceived feasibility of clinic visits for injections

7. Data Analysis Plan

Quantitative

- Descriptive statistics (means, proportions)
- Multivariable regression for predictors of willingness/intent
- Comparative analysis across regions/groups

Qualitative

- Framework-guided thematic analysis using EPIS constructs as a deductive coding structure (e.g., NVivo or ATLAS.ti)
- Coding framework aligned with:
    - Inner context (facility-level)
    - Outer context (policy, sociocultural)

8. Ethical Considerations

- Ethical approval from IRBs and collaborating institutions
- Informed consent from all participants
- Confidentiality and anonymization
- Sensitivity to stigma and HIV disclosure risks
- Data security and storage protocols
- Participant reimbursement policy
- Plan for returning findings to communities

9. Expected Outputs

- Community readiness profiles by site
- Identification of high- and low-readiness communities
- Context specific implementation strategy documents
- Policy Brief for health authorities
- Peer review manuscript

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10. Timeline

Months	EPIS Phase	Key Activities
Months 1-3	Exploration	- Ethical approvals - Stakeholder & community engagement
Months 3-4	Exploration	- Conduct surveys, FGDs, KIIs - Health facility assessments
Months 5-6	Preparation	- Complete data collection - Begin data cleaning and preliminary analysis
Months 7-8	Preparation	- Full data analysis (quantitative + qualitative) - Develop readiness scores
Months 9-10	Co-design	- Stakeholder workshops - Co-design and refine implementation strategies
Months 11-12	Sustainment	- Finalize strategy documents - Policy engagement - Dissemination (reports, briefs)

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Abbreviation Guide

ART
Antiretroviral Therapy is a combination of medications to suppress HIV, preserve the immune system, and prevent transmission.

AYA
Adolescents and young adults

CHW or CHEW
Community Health Worker or Community Health Extension Worker

CRA
Community Readiness Assessment

EPIS Framework
Exploration, Preparation, Implementation, Sustainment Framework

- EPIS Framework website
- Dissemination and Implementation Models in Health webtool- EPIS
- PubMed: Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework

FGD
Focus group discussions

IRB
The Institutional Review Board process is a regulatory and ethical review required for any research involving human subjects.

KII
key informant interviews

LEN
Lenacapavir is a prescription medicine approved for multidrug-resistant HIV and more recently approved as pre-exposure prophylaxis (PrEP) to reduce the risk of HIV in adults and adolescents. For the purposes of the INSPIRE Designathon, we are referring to the twice-yearly injectable for PrEP.

PHC
Primary Health Center