PrEP-Pro Study Protocol

Official Title

PrEP-Pro: Adapting a Multicomponent Intervention to Train and Support Providers to Promote PrEP for Adolescent Girls and Young Women in the Deep South

Institution

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Statement of Compliance

This study will be conducted in compliance with the protocol, Good Clinical Practice (GCP), and all applicable regulatory requirements, including NIH and UAB IRB regulations.

Protocol Summary

This study evaluates PrEP-Pro, a multicomponent training intervention designed to increase PrEP prescribing among Family Medicine (FM) residents providing care to adolescent girls and young women (AGYW) in Alabama. PrEP-Pro integrates provider education, sexual history-taking training, and peer-led support from PrEP Champions. The study will assess feasibility, acceptability, and preliminary effectiveness using a mixed-methods design across up to six FM residency sites.

Study Schema

Phase 1: Development and adaptation with Community and Scientific Advisory Boards' input.

Phase 2a: Pre-test at 2 sites with 2 PrEP Champions and 8–12 residents.

Phase 2b: Pilot test at up to 6 sites with 12 Champions and 72 residents over 6 months.

Data collection: Surveys, EMR review, Champion logs, and in-depth interviews.

Introduction / Background

Black adolescent girls and young women (AGYW) in the U.S. South are disproportionately affected by HIV, with rates nearly 9 times higher than White peers. Despite the proven efficacy of pre-exposure prophylaxis (PrEP), uptake among AGYW remains low. Barriers include provider knowledge gaps, lack of sexual history-taking, stigma, and competing clinical demands. Family Medicine (FM) residents are uniquely positioned to deliver preventive care, particularly in underserved areas. PrEP-Pro was developed to address these barriers by training FM residents in HIV prevention and supporting sustainable PrEP prescribing practices.

Additional protocol details are available:

Isehunwa O, Hill S, Menninger A, Hubner B, Krakower D, Long D, Pratt M, Clement M, Wagoner N, Lanzi R, Simpson T, Elopre L, Matthews L. A Multicomponent Intervention to Train and Support Family Medicine Providers to Promote Pre-exposure Prophylaxis (PrEP) for Adolescent Girls and Young Women in the Deep South: Protocol for the PrEP-Pro Study. JMIR Res Protoc 2023;12:e44908. URL: https://www.researchprotocols.org/2023/1/e44908. DOI: 10.2196/44908

Objectives and Endpoints

Primary Objective: To evaluate the feasibility and acceptability of PrEP-Pro among FM residents.

Secondary Objectives: To improve provider knowledge and skills in PrEP prescribing and sexual history-taking; to assess preliminary effectiveness on PrEP prescriptions and HIV/STI testing among AGYW.

Exploratory Objectives: To identify multilevel barriers and facilitators of PrEP implementation using COM-B (Capability, Opportunity, Motivation – Behavior) model and CFIR (Consolidated Framework for Implementation Research).

Specific Aims

HIV disproportionately impacts Black adolescent girls and young women (AGYW) in the Deep South. In Alabama, nearly half of PrEP-eligible adolescents are AGYW, yet none in a recent sample of 429 adolescents had been prescribed PrEP. Barriers include limited provider knowledge, infrequent sexual history-taking, and stigma. Family medicine (FM) residents represent a critical workforce to reduce disparities, but current training does not equip them with the skills or motivation to provide PrEP.

The PrEP-Pro intervention is a multicomponent training designed to improve PrEP prescribing for AGYW by equipping FM residents with knowledge, skills, and peer support. Guided by the COM-B model and CFIR, PrEP-Pro integrates:

1. Education on HIV epidemiology and PrEP.
2. Training in sexual history-taking.
3. Support from trained peer "PrEP Champions."

Our Specific Aims are:

Aim 1: Adapt PrEP-Pro training materials and tools with input from community and scientific advisory boards, FM residents, and AGYW.

Aim 2: Pre-test PrEP-Pro at two FM residency sites to assess feasibility and acceptability, and refine procedures.

Aim 3: Conduct a six-month pilot test of PrEP-Pro across up to six FM residency sites to evaluate acceptability, feasibility, and preliminary effectiveness. Identify determinants of implementation at the provider, clinic, and system levels through in-depth interviews and CFIR-guided analysis.

Impact:

PrEP-Pro has the potential to transform HIV prevention in the South by training a generation of FM providers to routinely offer PrEP to AGYW, directly addressing a major gap in HIV prevention.

Research Strategy

Innovation

- **Multicomponent intervention:** Combines education, skills training, and peer leadership in a single package.
- **Champion model:** Embeds "PrEP Champions" to sustain practice change, a proven implementation strategy adapted here for PrEP.
- **Implementation science framework:** Uses COM-B and CFIR to design, deliver, and evaluate the intervention.

- **Community-engaged design:** CABs of FM residents and AGYW co-develop content, ensuring contextual relevance.

Study Design and Procedures

A mixed-methods, multi-phase implementation science study:

- **Phase 1:** Development and adaptation of PrEP-Pro with CAB/SAB input and FM resident focus groups.
- **Phase 2a:** Pre-test at two residency training program sites (2 Champions, 8–12 residents).
- **Phase 2b:** Six-month pilot test at up to six sites (up to 12 Champions, 72 residents).

Setting and Sites

- Cahaba Family Medicine Residency Program
- Montgomery Family Medicine Residency Program
- UAB Huntsville Family Medicine Residency Program
- Additional sites as identified

Sites serve diverse patient populations with ≥20% Black patients.

Participants

Eligibility Criteria:

- Licensed FM resident (MD or DO).
- Provides care to AGYW in Alabama.
- Practices at clinic with ≥20% Black patient population.
- Willing and able to provide informed consent.

Sample Size:

- Pre-test: 2 Champions, 8–12 residents.
- Pilot: Up to 12 Champions, ~72 residents.

Intervention: PrEP-Pro

Core Components:

1. **Provider Education:** HIV epidemiology, PrEP indications/efficacy, prescribing practices.
2. **Sexual History Training:** Role-play, scripts, and tools for adolescent-focused sexual history-taking.
3. **PrEP Champions:** Peer residents trained more extensively (~4 hours, 3 sessions) to deliver training, provide ongoing support, and sustain intervention at their sites.

Materials:

- Training PowerPoints, reference "Badge Buddies," sexual history screening tool, PrEP prescribing guides, and patient-facing handouts.
- Online resource manual (Google Site) with curriculum, troubleshooting guides, and supplemental resources.

Study Procedures

Phase 2a: Pre-test

1. **Recruitment:** Up to 2 PrEP Champions and 12 residents. Partner program directors nominate potential Champions; those interested contact the study team to complete consent.

   Residents invited to participate through training with their residency site. Those interested in participating in the study self-consented and completed the enrollment baseline survey.

2. **Training PrEP Champions:**
   - Three sessions (total ~4 hours).
   - Content: HIV epidemiology, PrEP prescribing, sexual history-taking, role-play.
   - Delivery training: how to teach peers using standard slides and cases.
3. **Resident Training:** Champions deliver two 1-hour sessions to peers over 1 month.
4. **Data Collection:**
   - **Pre/post surveys:** demographics, PrEP knowledge/attitudes, AIM/IAM/FIM, EPAS.
   - **Champion logs:** time spent, resident contacts, support provided.
   - **IDIs:** up to 9 participants (Champions + residents) provide feedback.
   - **EMR review:** de-identified data on PrEP prescriptions, HIV/STI tests (3 months pre- and post-intervention).
5. **Refinement:** Content, tools, and procedures adjusted based on pre-test results.

Phase 2b: Pilot Test

1. **Recruitment:** Up to 12 PrEP Champions and 72 residents. Partner program directors nominate potential Champions; those interested contact the study team to complete consent.

   Residents invited to participate through training with their residency site. Those interested in participating in the study self-consented and completed the enrollment baseline survey.

1. **Training:**
   - Champions trained (same as pre-test).
   - Champions deliver two 1-hour sessions to peers.
   - Fidelity monitored via session observation and audio recording; feedback provided.
2. **Ongoing Support:**

- Champions meet biweekly with site administrators/social workers to troubleshoot insurance and workflow issues.
- Champions log PrEP-related activities and resident contacts.
- Peer Champions connected across sites for shared learning.

3. **Data Collection:**
    - **Surveys:** at baseline, 3 months, and 6 months.
    - **Champion logs.**
    - **IDIs:** with Champions, residents, AGYW patients, and stakeholders (~50 total).
    - **EMR review:** 6 months pre- and post-intervention, capturing PrEP prescriptions and HIV/STI testing.

Outcomes

Primary Outcomes:

- Acceptability (AIM, IAM, EPAS).
- Feasibility (FIM, training completion rates, Champion engagement).

Secondary Outcomes:

- Provider PrEP knowledge, attitudes, and willingness to prescribe.
- Frequency of sexual history-taking.
- PrEP prescriptions to AGYW.
- HIV/STI testing for AGYW encounters.

3.7 Data Analysis

- **Quantitative:**
    - Descriptive statistics for acceptability/feasibility.
    - Pre/post changes in prescribing/testing assessed using Wilcoxon signed-rank, McNemar's test, logistic regression, and Poisson regression.
    - Adjustments for provider demographics and site-level factors.
- **Qualitative:**
    - Thematic analysis of IDIs guided by COM-B and CFIR.
    - Triangulation across surveys, EMR, and interview data.

3.8 Timeline

- **Year 1:** Intervention adaptation, CAB/SAB input, FGDs.
- **Year 2:** Pre-test (2 sites), refinement.

- **Year 3:** Pilot test (up to 6 sites), data collection, analysis.

Human Subjects and Oversight

- **Risk:** Minimal (educational training, surveys, interviews), primarily related to potential discomfort discussing sexual health topics.
- **Benefits:** Participants gain knowledge and skills in HIV prevention; potential improvements in patient care for AGYW.
- **Consent:** Written for residents/Champions; separate consent for interviews.
- **Privacy:** EMR data aggregated and de-identified.
- **Compensation:** $50/hour for Champions' additional duties; $50 for IDI participants.
- **Monitoring:** PI and site investigators review training fidelity, data completeness, and adverse events (none anticipated).

Dissemination Plan

- Findings shared with CAB, SAB, and residency partners.
- Results presented at state, regional, and national conferences.
- Peer-reviewed manuscripts submitted to *JMIR*, *JAIDS*, and *Journal of Adolescent Health*.
- Findings inform NIH proposal for hybrid effectiveness-implementation trial.