

## PRS Criteria for Evidence-Informed Interventions (EIs) for Linkage to, Retention in, and Re-engagement in HIV Care (LRC)

### Quality-Study design

- Evaluates data before and after intervention implementation in studies without a comparison arm

### Quality-Study implementation and analysis

- For pre-post intervention changes, analysis based on a 2-sided test with a p value of  $< .05$

### Strength of Evidence

#### Demonstrated Significant Positive Intervention Effects

- Statistically significant ( $p < .05$ ) positive pre-post intervention effect for  $\geq 1$  relevant outcome measure
  - A positive intervention effect is defined as an improvement in linking to, retention in, or re-engagement in HIV medical care from pre to post intervention
  - A relevant outcome is defined as an actual/completed outpatient primary HIV medical care visit or HIV viral load and/ or CD4 counts when used as proxies
    - For *linkage to care*, a relevant outcome is the actual/completed first HIV medical visit for newly-diagnosed HIV-positive persons
    - For *retention in care*, a relevant outcome is having actual/completed multiple HIV medical visits over a period of time
    - For *re-engagement in care*, a relevant outcome is the actual/completed initial HIV medical visit for HIV-positive persons who have fallen out of, but have returned to, HIV care
  - HIV viral load is a relevant outcome if there is a statistically significant improvement in viral load levels in the post- intervention arm relative to the pre-intervention arm and there is at least one significant positive intervention effect for another relevant LRC outcome. Viral load levels must be measured using a lab report or medical chart abstraction.
  - A positive intervention effect must be documented in medical records, administrative or agency records, or surveillance reports
  - Self-reports of medical visits validated by medical records, administrative or agency records are also acceptable

#### No Demonstrated Negative Intervention Effects

- No statistically significant ( $p < .05$ ) negative pre-post intervention effect for any relevant outcome
  - A negative intervention effect is defined as a worsening in linkage to, retention in, or re-engagement in HIV medical care post intervention compared to the pre-intervention
- No other statistically significant harmful intervention effect that causes substantial concern

#### U.S. studies with a comparison arm that did not meet the evidence-based criterion on sample size

- U.S. studies with a comparison arm that did not meet the evidence-based criterion for sample size (i.e.,  $n \geq 40$  per arm), but have at least 25 participants per study arm will be considered as evidence-informed. These studies must also demonstrate at least one significant positive intervention effect on a relevant LRC outcome and no significant negative intervention effects.

**Additional Limitations to Evaluate:**

- No evidence that additional limitations resulted in considerable bias that reduces the confidence of the findings
  - Examples of limitations
    - Too many post-hoc analyses
    - Inconsistent evidence between effects
    - Inappropriate subset analyses
    - Not accounting for various reasons why participants were not included in the LRC outcome
    - For serial cross-sectional studies, there are statistically significant differences in demographic characteristics between “pre” and “post” samples that may introduce bias
    - Other notable biases threatening internal or external validity

**Additional Study Strengths**

All Evidence-informed studies that exhibit additional strengths will have those strengths noted on all summary documentation. These strengths include:

- Study design-related strengths:
  - For studies using serial cross-sectional designs in a clinic setting, having comparable clinic samples across different times
- Implementation-related strengths:
  - Outcomes occur within or exceed optimal follow-up assessment time points
    - Linkage or entry to care outcomes occur  $\leq 3$  months (follow up time point of at least 3 months)
    - Retention in care outcomes occur  $\geq 12$  months (follow up time point of at least 12 months)
    - Re-engagement outcomes that re-engage persons within 6 months of intervention initiation or retain persons re-engaged in care for 2 visits for at least 12 months after intervention initiation
  - Targeting persons who have been lost to care at least 12 months
    - Re-engagement studies that attempt to re-engage persons who have been lost to care 12 months or longer
  - Sample size
    - Linkage, retention, and re-engagement studies with baseline sample sizes equal to or above 100
- Impact-related strengths:
  - Post-intervention data or levels meet the National HIV/AIDS Strategy objectives
    - Percent of persons linked to HIV care post-intervention is at least 85%
    - Percent of persons retained in HIV care post-intervention is at least 80%
  - The study shows evidence of ART initiation from pre- to post-intervention<sup>1</sup>
    - Linkage, retention, and re-engagement studies that demonstrate a statistically significant positive change or at least a 10% increase in the percent of persons who initiate ART from pre- to post- intervention

<sup>1</sup>Although initiating ART is dependent on a health care professional, this element is an important step in the care continuum and demonstrates additional evidence of engagement in care.

**All criteria must be satisfied for an intervention to be considered as a LRC Evidence-Informed intervention (EI).**

