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 ≥ 1 relevant outcome measure
    - A positive intervention effect is defined as an improvement in engaging 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 within 6 months
        - For *retention in care*, a relevant outcome is having actual/completed multiple HIV medical visits over a period of time, the minimum being 6 months
        - For *engagement in care,* a relevant outcome is an actual/completed HIV medical visit
        - 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 suppression is a relevant outcome if there is a statistically significant improvement in viral suppression 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 suppression 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, engagement 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 ≥ 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 may include:

- Study design:
    - For studies using serial cross-sectional designs in a clinic setting, having comparable clinic samples across different times
- Measurement and Sample:
    - Outcomes occur within or exceed optimal follow-up assessment time points
        - Engagement in or linkage to care outcomes occur ≤ 3 months (follow up time point of at least 3 months). Studies that engage or link persons with HIV ≤ 1 month will also be noted.
        - Retention in care outcomes occur ≥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, engagement, and re-engagement studies with baseline sample sizes equal to or above 100
- Impact:
    - 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[1]

- Linkage, retention, engagement, 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

[1]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).