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 < 0.05

Strength of Evidence

Demonstrated Significant Positive Intervention Effects

- Statistically significant ($p < 0.05$) positive pre- to 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, or viral suppression 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
        - Completed HIV medical visits must be documented in medical records, administrative or agency records, or surveillance reports
        - Self-reports of completed medical visits validated by medical records, administrative or agency records are also acceptable:
            - For *linkage to care*, a relevant outcome is the actual/completed first HIV medical visit for persons with a new or recent diagnosis of HIV within 1 month
            - 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 persons who are HIV positive and were out of care, but have returned to, HIV care
    - ART initiation is a relevant outcome if there is an improvement in ART initiation from pre- to post-intervention
        - Lab reports, agency records, medical chart abstraction are acceptable
        - Self-report without validation is acceptable
    - HIV viral suppression is a relevant outcome if there is an improvement in viral suppression from pre-to post-intervention
        - Viral suppression levels must be measured using a lab report or medical chart abstraction

No Demonstrated Negative Intervention Effects

- No statistically significant ($p < 0.05$) 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, ART initiation, or viral suppression 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

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