PRS Criteria for Evidence-Based Interventions (EBIs) for Linkage to, Retention in, and Re-engagement in HIV Care (LRC)

Quality of Study design

- Prospective or quasi-prospective study design
- Appropriate and concurrent comparison arm, or appropriate non-concurrent comparison arm that was implemented in a different clinic or agency within 12 months of the start of the intervention and was similar with respect to population and setting
- Random allocation of participants to study arms or if non-randomization, potential bias in allocation to intervention is minimized

Quality of Study implementation and analysis

- For *linkage to care* interventions, linkage to care occurred within or less than 6 months after the initiation of the intervention
- For *retention in care* interventions, retention in care occurred at least 6 months after the initiation of the intervention
- Comparison between intervention arm and an appropriate comparison arm
- Analysis of participants in study arms as originally allocated, or contaminated participants may be excluded if numbers are small, but participants may not be re-assigned for analytic purposes
- Analysis of participants may be based on intervention exposure, where participants exposed to < 50% of the entire intended intervention may be excluded
- Analysis must be based on between-group comparisons on post-intervention levels or on pre-post changes in measures
    - For pre-post changes used in analysis, measures must be identical, including identical recall period
- Analysis based on a 2-sided test with a p value < .05
- With nonrandomized assignment, either no statistical differences exist in baseline levels of the outcome measure, or baseline differences must be controlled for in the analysis. If moderately biased assignment or historical comparison was used, differences in baseline demographics also must be controlled for in the analysis
- Baseline sample of ≥ 40 participants (or charts) per study arm

Strength of Evidence

Demonstrated Significant Positive Intervention Effects

- Statistically significant ($p < .05$) positive intervention effect for ≥ 1 relevant outcome measure
    - A positive intervention effect is defined as an improvement in linking to, retention in, engagement in, or re-engagement in HIV medical care, or HIV viral suppression in the intervention arm relative to the comparison arm.

- A relevant outcome is defined as an actual/completed outpatient primary HIV medical care visit or HIV viral load and/ or CD4 count when used as proxies for a HIV medical care visit, or HIV viral suppression
  - 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 HIV diagnosis
    - For *retention in care*, a relevant outcome is having actual/completed multiple HIV medical visits over a period of time
    - For *engagement in care*, a relevant outcome is at least one 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 were out of care, but have returned to HIV care
- HIV viral suppression is a relevant outcome if there is a statistically significant improvement in viral suppression levels in the intervention arm relative to the comparison arm. HIV viral suppression must be measured using a lab report or medical chart abstraction.
- Effect at a required follow-up assessment time point and based on the analyses that meets all study implementation and analysis criteria

No Demonstrated Significant Negative Intervention Effects

- No statistically significant ($p < .05$) negative 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, or HIV viral suppression in the intervention arm relative to the comparison arm
- No other statistically significant harmful intervention effect that causes substantial concern
- For an intervention with a replication evaluation, no significant negative intervention effects in the replication study if the intervention was implemented in the exact same way as the original study and with the same or similar cohort/population

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
    - Not adjusting for cluster effects for studies that allocate individuals to a group-level intervention

- Not accounting for factors that may influence findings, but are not attributable to the intervention (e.g., historical events)
- Other notable biases threatening internal or external validity

All criteria must be satisfied for an intervention to be considered as an LRC Evidence-Based Intervention (EBI).