

PRS Project Efficacy Criteria for Structural Evidence-Informed Interventions (S-EI)

Intervention Description

- Clear description of key aspects of the intervention

Quality of Study Design

For before/after studies

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

For two-group studies with a comparison arm that did not meet the evidence-based criterion on sample size

- Studies with a comparison arm that met all evidence-based criteria with the exception of sample size (i.e., $n \geq 40$ per arm), and have at least 25 participants per study arm will be considered as evidence-informed.

Quality of Study Implementation and Analysis

- Analysis must be based on pre-post changes or post-intervention levels
 - Note: For pre-post changes used in analysis, measures must be identical, including identical recall period
- Analysis based on an $\alpha = .05$ (or more stringent) and a 2-sided test

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:
 - Greater reduction (or lower increase) in HIV/STD incidence, risk behaviors or HIV-related stigma;
 - Greater increase in HIV protective behaviors (including Pre-exposure prophylaxis [PrEP] uptake and adherence);
 - Greater improvement in, or higher level of, a medication adherence-related behavioral or biologic outcome (including viral suppression); or
 - Greater improvement in linkage to, retention in, engagement or re-engagement in HIV medical care post intervention versus pre intervention
- A relevant outcome is defined as:
 - Sex risk behaviors (e.g., abstinence, mutual monogamy, number of sex partners, consistent condom use with anal/vaginal sex, condomless anal/vaginal sex, proportion of anal/vaginal sex acts protected, refusal to have unsafe sex) directly impacting HIV risk
 - Drug injection behaviors (e.g., frequency of injection drug use, needle sharing)
 - PrEP uptake and adherence

- Antiretroviral treatment (ART) or PrEP prescriptions (as outcomes of provider interventions only)
- HIV-related stigma
- HIV testing (e.g., utilization of HIV C&T services, repeat testing)
 - Note: HIV testing is a relevant outcome only if the study reports new HIV infections
- Medication adherence outcome measure that may include electronic data monitoring (e.g., MEMs caps), pill count, pharmacy refill, or self-reported adherence
- Biologic measure indicating HIV or STD (e.g., prevalence or incidence measures of hepatitis, HIV, or other STDs)
 - Note: Biologic measures of STD infections are relevant outcomes only as a proxy for HIV behavior
- HIV morbidity or AIDS mortality (includes biologic measures of HIV viral suppression or CD4 count)
- HIV medical care visit – measures of a 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
 - For *linkage to care*, a relevant outcome is the completed first HIV medical visit for newly diagnosed HIV-positive persons
 - For *retention in care*, a relevant outcome is having completed multiple HIV medical visits over a period of time
 - For *engagement in care*, a relevant outcome is having one completed HIV medical visit over a period of time**
 - For *re-engagement in care*, a relevant outcome is the completed HIV medical visit for persons who were lost to or inconsistent in care
 - Note: Completed HIV medical visits must be documented in medical records, administrative or agency records, or surveillance reports
 - Note: Self-reports of completed medical visits validated by medical records, administrative or agency records are also acceptable
- In summary, the effect must be:
 - Reported at the required follow-up
 - Based on the quality of the study design
 - Based on the study implementation and analysis

No Demonstrated Significant Negative Intervention Effects

- No negative and statistically significant ($p < .05$) pre-post intervention effect for any relevant outcome
 - A negative intervention effect is defined as:
 - Greater increase in HIV/STD incidence, risk behaviors or HIV-related stigma; greater decrease in HIV protective behaviors;
 - Greater reduction in, or lower level of, a medication adherence-related behavioral or biologic outcome; and/or
 - Lower level of linkage to, retention in, or re-engagement in HIV medical care in the intervention arm relative to the comparison arm or post intervention versus pre intervention

Additional Limitations to Evaluate

- No evidence that additional limitations resulted in considerable bias that reduces the confidence of the findings
 - Examples of limitations
 - Effects only found within potentially biased subset analyses
 - Too many post-hoc analyses
 - Inconsistent evidence between effects
 - For serial cross-sectional studies, statistically significant differences in demographic characteristics between “pre” and “post” samples that may introduce bias
 - Other notable biases threatening internal or external validity

**Currently, engagement in care is not a relevant outcome for the Linkage to, Retention in, and Re-engagement in Care (LRC) Review, but is a relevant outcome for the SI Review.

All criteria must be satisfied for an intervention to be considered as an effective Structural Evidence-Informed (S-EI).

