PRS Efficacy Criteria for Pre-Exposure Prophylaxis (PrEP) Evidence-Informed Interventions (EIs)

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 (e.g., pre/post, historical comparison)

For two-group studies with a comparison arm

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

Quality of Study Implementation and Analysis

- Analysis must be based on pre-post changes
    - Note: Measures must be identical, including identical recall period
- Analysis based on a p value of < 0.05 and a 2-sided test

Strength of Evidence

Demonstrated Significant Positive Intervention Effects

- Statistically significant ($p < 0.05$) positive intervention effect for ≥ 1 relevant outcome measure
    - A positive intervention effect is defined as an improvement in PrEP-related behavioral or biologic outcomes from pre- to post-intervention
    - Relevant PrEP-related behavioral or biological outcomes are defined as and include:

<u>PrEP Patient-Level</u>

- Screening for PrEP eligibility and referring to PrEP services: assessed HIV risk behavior to identify a participant as an eligible PrEP candidate and referred those who were eligible to PrEP services (e.g., scheduled the first PrEP services appointment)
- Linkage to PrEP care: a participant completed healthcare visit that includes being prescribed PrEP
- PrEP initiation/uptake: initiation of PrEP among PrEP-naïve participants or those who were not PrEP users as defined by study authors via self-report or medical or pharmacy records (e.g., filled a prescription for PrEP, started taking PrEP)
- PrEP use: on PrEP (including lifetime, current use) based on self-report or medical or pharmacy records
- PrEP medication adherence or persistence: taking PrEP on a regularly agreed to schedule (e.g., daily dose, on demand) measured by electronic data monitoring (e.g., Medication Event Monitoring System [MEMS] caps), pill count, pharmacy refill, self-reported adherence, or medical record
- PrEP drug levels: based on assays that assess PrEP drug or drug metabolite levels in plasma, urine, hair, or dried blood spots
- Retention in PrEP care: completed PrEP medical visit(s) over a period of time (e.g., attended one visit every 3 months for at least 6 months) that is self-reported or documented in medical records

- HIV incidence: HIV infections that are self-reported or documented in medical records

PrEP Healthcare Provider- or System-Level

- PrEP prescribing behavior: self-reported by provider or documented in medical or pharmacy records
- PrEP utilization among health care systems and communities: number of people on PrEP assessed at the healthcare system or community level

No Demonstrated Significant Negative Intervention Effects

- No negative and statistically significant ($p < 0.05$) pre- to post- intervention effects for any PrEP-relevant outcome
  - A negative intervention effect is defined as the post-intervention effect showing:
    - Greater reduction in, or lower level of, PrEP initiation/uptake, PrEP use, PrEP medication adherence or persistence or PrEP drug levels
    - Lower level of screening for PrEP and referring to PrEP services, linkage to PrEP care, retention in PrEP care
    - Greater increase in HIV incidence
    - Lower proportion of PrEP prescribing behavior
    - Lower proportion of people on PrEP assessed at the healthcare system or community level

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

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