Role of Risk Assessment

The major goals of risk assessment are to:

- Screen research participants for trial eligibility
- Estimate study participants' potential HIV exposure and changes in exposure across study sub-groups over time; and,
- Characterize the context and causes of HIV risk factors in populations under study.

Depending on the phase of biomedical clinical research, risk assessment may be carried out to determine the a) eligibility of low-risk individuals for Phase 1 and 2 trials; b) eligibility of high-risk individuals for Phase 3 trials; and c) patterns of risk change among individuals in Phase 1, 2, and 3 trials.

Optimizing Risk Assessment Data Collection

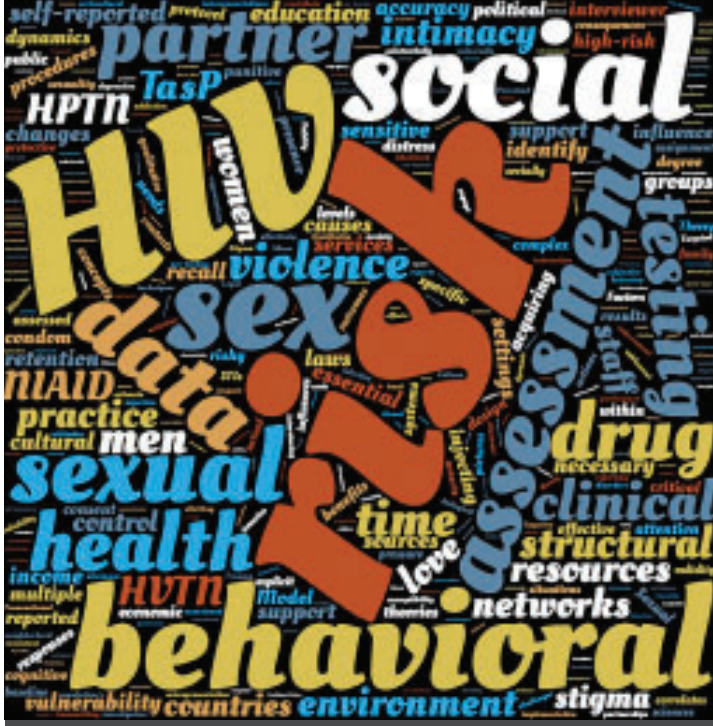
It is important to maximize the accuracy of risk assessment in HIV clinical trials. Since the proximal behaviors that convey HIV risk are private and cannot be observed directly, measuring HIV risk relies heavily on self-reported behavior. Approaches that may help maximize the reliability and validity of self-reported risk assessments include:

- Conduct formative research on survey question wording and format to ensure understanding by respondents, particularly when used in new settings and populations;
- Use previously validated instruments;
- Provide memory and recall aids, such as timelines;
- Ensure that site staff who collect data from participants are distinct from site staff who deliver counseling to participants; and,
- Administer risk behavior assessments through computer surveys rather than face-to-face data collection to reduce social desirability concerns and improve data quality.

Take Home Messages

- Risk assessment is a critical component of clinical trials of new HIV prevention and treatment technologies, and is relevant to trials testing cure strategies as well
- Both individual and contextual sources of risk should be included in risk assessment procedures.
- There are diverse methods for eliciting, defining, and quantifying behavioral and social risks. Each method has advantages and disadvantages that must be considered in the broader context for the appropriate use/inclusion of the concept.
- It is essential to invest in the interview and observational methods that provide the best estimates of risk behavior, its causes and correlates.
- Behavioral risk and its social context are so fundamental to trial success and interpretation that they should figure in the overall study design, site selection, recruitment, protocol design and fine tuning of these concepts and methods.

For questions or comments, please email the NIAID NIMH Behavioral and Social Sciences Project Team at NIAIDNIMHBSSPT@mail.nih.gov.



Risk Assessment in HIV Biomedical Clinical Research

https://daidslearningportal.niaid.nih.gov/local/pages/?id=8

About Risk

Many biomedical HIV research studies and clinical trials have a substantial focus or component on HIV infection risk. Risk is typically defined as the probability that an individual will acquire HIV infection over time.

Proximal factors known to create or enhance risk of HIV exposure and acquisition include:

- Condomless sex with a partner whose HIV status is unknown or serodiscordant in the absence of biomedical prevention (e.g. Pre-exposure prophylaxis [PrEP], treatment as prevention [TasP])
- Injecting drug use with shared equipment in the absence of biomedical prevention

These HIV transmission risk behaviors may be further influenced or affected by a wide range of factors operating at multiple levels.

Risk Assessment

In HIV biomedical research, risk assessment characterizes and documents the types and frequencies of risk factors that increase (or decrease) the likelihood of HIV exposure and acquisition for a given individual or population.

Assessing risk involves the use of different tools that, over time, have been shown to reliably generate data which are then subjected to appropriate analytic methods. The result is a measure of the risk (harm or benefit) of HIV exposure or acquisition associated with the measured factors. Examples include:

Data Collection Tools

- Questionnaires/Surveys (e.g. face-to-face, computer surveys, focus groups)
- Clinical assays (e.g. mucosal, hair, blood)
- Medical history (e.g. STIs)

Types of Data - clinical, epidemiological, and behavioral

Analytic Methods - qualitative and quantitative

Multilevel Influences on HIV Risk

Conceptual frameworks and methods are evolving to address biomedical, behavioral, and structural aspects of HIV risk. Proximal risk factors are those that directly affect a person's HIV risk, divided into individual, partner, and structural level factors (detailed in the figure below). Additionally, it is important to investigate potential influences on the proximal risk factors. These influencers may also occur at multiple levels.

To learn more about the full scope of influencers, or for more information on the integration of Behavioral and Social Sciences (BSS) in HIV clinical research, please visit the NIH website at: daidslearningportal.niaid.nih.gov/BSShome.