Theories Used in BSS

Theory-driven research is a hallmark of BSS. BSS theories are conceptual frameworks that explain why people behave the way they do. They identify important drivers of human behavior such as an individual's knowledge, beliefs, motivations, intentions, goals, and skills.

BSS theories can strengthen clinical trials by:

- Enhancing the development of testable hypotheses about behaviors, such as sexual risk behavior, product adherence, and study retention.
- Focusing the content of behavioral assessment forms used in clinical trial research, thus reducing the number of topics and questions that are addressed.
- Informing adherence and sexual risk reduction counseling provided in trials, to help make them more effective.

Methods Used in BSS

Multiple behavioral and social research methods (mixed-methods) can help HIV biomedical clinical research meet multiple goals and address the diversity of populations involved. Each BSS discipline uses a set of research methods for scientific inquiry.

These research methods are generally categorized as:

- Quantitative methods - estimates the frequency or extent of human thoughts, feelings, or behavior; common methods include questionnaires and interviews.
- Qualitative methods - explains the drivers and processes behind human thoughts, feelings, and behavior; common methods include qualitative interviews or focus groups.

There are many different kinds of BSS research methods, some of which may be administered through technologies (e.g., computer surveys, electronic medication adherence monitors). The methods employed depend on the goals of the study and the social and cultural setting of the target population.

Take Home Messages

- BSS play a fundamental role in the implementation and impact of HIV biomedical clinical trials.
- Dedicated resources, such as budgets and staffing, are essential when integrating BSS into clinical research.
- BSS scientists should be included as vital members of protocol teams to ensure all aspects of the study use the best available science, are technically and ethically sound, and are culturally appropriate.
- Protocol teams should include expert BSS scientists from each country where the research will take place.
- Theories and methods from BSS should be utilized to frame and document social and behavior issues, such as participation, community engagement, gender dynamics, sexual and drug use, HIV-related stigma, risk perception and adherence.

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

Behavioral & Social Sciences in HIV Biomedical Clinical Research

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

The behavioral and social sciences (BSS) have made important contributions to HIV research since the beginning of the epidemic. This brochure describes how BSS can strengthen biomedical HIV clinical research, including clinical trials of HIV vaccines, non-vaccine prevention, therapeutics, and cure research.

About BSS

The BSS incorporate a number of scientific disciplines that study human behavior and social relations.

- Behavioral Sciences, such as psychology, neuropsychology, psychiatry, human development, and cognition; study decision processes and communication strategies within and between individuals within a social system.
- Social Sciences, such as anthropology, sociology, political science, economics, and geography; study social organizations, social structures and the physical environment as they shape individual and group experience and behavior.

The BSS employ theory-driven research and emphasize the importance of identifying and addressing behavioral and social aspects of disease prevention and health outcomes.

Role of BSS

BSS have many important roles to play in HIV biomedical research including:

- The value of knowing the research context – BSS provides theories and methods to anticipate, explore and rigorously document the diversity in HIV prevention trial dynamics, and to predict and prepare for its impact on study conduct and outcomes.
- The need to measure and support adherence – BSS provides strategies to improve adherence measurement and support in trials.
- The importance of addressing risk behavior – BSS provides approaches to strengthen risk behavior measurement and counseling in clinical trials.

Behavioral & Social Sciences Contributions to Strengthen HIV Biomedical Clinical Research

The most important way to integrate BSS into clinical trials is to include multidisciplinary behavioral and social scientists on the research concept and protocol teams from the earliest stages. Contributions of BSS at multiple junctures in the clinical trial life cycle include:

Preclinical / Acceptability

- Develop new biomedical prevention products
- Identify preferred characteristics of products among target groups of potential study participants
- Determine feasibility and acceptability of future use of new HIV products

Development

- Engage multidisciplinary expertise
- Impact trial participant sampling, recruitment, screening, and retention
- Contribute to the design of recruitment materials, informed consent documents, questionnaires, and interviews

↳ Preconcept ▶ Concept ▶ Protocol

Implementation

- Provide expertise to discern local practices, knowledge, and history that influence clinical trial conduct
- Guide efforts to conduct community engagement and staff training

↳ Startup ▶ Protocol

Completion

- Contribute to the analysis of quantitative and qualitative data
- Interpret and disseminate study results

↳ Analysis ▶ Dissemination