Social-Behavioral Science Core (SBSC) in IMPAAACT

K Rivet Amico, Nicole Montañez

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Social Behavioral Sciences

What is Behavioral and Social Sciences Research? (National Institutes of Health)

“Behavioral” …refers to what people do, as well as what drives them to do things, and it involves psychological processes like emotion.

“Social” …reflects how individuals interact with each other: in small groups, families, and communities, as well as within populations and in society.
Social Behavioral Sciences

What is the role of SBS in HIV Networks?

In addition to supporting protocols, procedures and implementation approaches that align with best practice... the benefits of integrating of SBS RESEARCH into biomedical trials have been recognized for decades

SBS offers insights into the factors (thoughts, feelings, beliefs, motivations, relationships, experiences) underlying the human behaviors that influence clinical trial outcomes

"You know, maybe we under-invested in research on human behavior," Collins said. "I never imagined a year ago, when those vaccines were just proving to be fantastically safe and effective, that we would still have 60 million people who had not taken advantage of them because of misinformation and disinformation that somehow dominated all of the ways in which people were getting their answers." – Francis Collins News Hour
Social Behavioral Sciences Research

Behavioral Social Sciences Research (BSSR)

Basic BSSR:
Understanding priority populations and risk settings

Elemental BSSR:
IMPAACT 2016 – Elemental Study- Evaluating a Group-Based Intervention to Improve MH and ART adherence

Integrative BSSR:
Contributing to the effective implementation of combination and multilevel strategies

Dube, Auerbach. Stirratt, Gaist 2019
Typology of SBS in Clinical Research (Corneli et al. AIDS and Beh 2019)

Prior to trial
Optimize fit in and responsiveness to community
Optimize aspects of study and procedures

How should the study be presented to community?
How could the study support adherence?
What will participants think about procedures?
Typology of SBS in Clinical Research (Corneli et al AIDS and Beh 2019)

Collection and use of social behavioral data
- Closely integrated within the study objectives and outcomes (embedded)
- To investigate a separate but related SB hypothesis (parallel)

Does risk perception influence outcome?
Do experiences on study influence uptake?
Are outcomes moderated by social/structural factors?
What is the treatment decision making process?
Prevalence and impact of IPV or ACE?
Validity of methods/measures?

Several IMPAACT Studies include Acceptability and Feasibility 2020, 2024, 2035
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<table>
<thead>
<tr>
<th>Year</th>
<th>Study Description</th>
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<tbody>
<tr>
<td>2017</td>
<td>Embedded Mixed Methods Acceptability and Feasibility</td>
</tr>
<tr>
<td>2036</td>
<td>Embedded Mixed Methods Acceptability and Feasibility</td>
</tr>
<tr>
<td>2009</td>
<td>Embedded Adherence and Social Determinants and Mixed Methods</td>
</tr>
<tr>
<td>2010</td>
<td>Embedded Multiple Measures of Adherence and Correlates Quantitative</td>
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Typology of SBS in Clinical Research (Corneli et al AIDS and Beh 2019)

Planned, added as amendment, or independent work
- Investigation/exploration of SB factors after the conclusion of the trial/collection of final outcomes

Do social harms persist after trial end?  
Do people have delayed benefits from participating in an influential study?  
Is product uptake different for those who participated in product efficacy trials?
Observations and Recommendations

- Review of studies enrolling and in development over the past 5 years within the IMPAACT Network

Progress and Strengths

- consistently include measures of product adherence, and treatment acceptability/feasibility
- are beginning to use more sophisticated approaches to understanding experiences with specific treatments
- increasing interest in patient centered outcomes
- greater recognition of implementation science
- increasing expertise in SBS

Areas for Growth

- promote standardized formative work
- harmonize SB measures
- Identify a bank of patient centered outcomes measures for use in all protocols
  - beliefs, attitudes, preferences, context
SBS Core
## Social Behavioral Science Core

<table>
<thead>
<tr>
<th>Year</th>
<th>AWG</th>
<th>SBSC</th>
<th>V2.0</th>
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<tbody>
<tr>
<td>2015</td>
<td>Established the Adherence Working Group</td>
<td>Standing committee mix of within and outside of IMPAACT network Experts in SBS</td>
<td>Nested core members within scientific committees</td>
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<td></td>
<td>Open group</td>
<td>Monthly and ad hoc</td>
<td>Collaboration in the development of studies</td>
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<tr>
<td></td>
<td>Monthly discussions focused on measurement and support of adherence</td>
<td>Review Concepts, Proposals and Protocols</td>
<td>Review of concepts in concert with other groups in the multidisciplinary protocol review group (MPRG)</td>
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</tbody>
</table>
SBSC

Operations Within the IMPAACT NETWORK

AD HOC SUPPORT
Provide recommendations for optimizing SBS in concepts/proposals

COMMITTEE SUPPORT
SBSC member embedded within committees

REVIEW PROTOCOLS
Provide high level review of protocols
Recommendations for measures/approach

EXPAND
SBS within/across network through workshops and webinars

MOBILIZE
Bring together network members doing or planning SBS work

CHARACTERIZE
Catalog SBS across protocols
Measures
Support/Procedures

INNOVATE
Identify potential gaps and strengths across network
Recommendations

SBSC Consultant and in Network
Experts
DAIDS
FHI360
SBSC

Operations Within the IMPAACT NETWORK

Tuberculosis: Jessica Haberer and Nicole Montañez
Complications and Comorbidities: Kenneth Ngure and Jennifer Libous
Treatment: Rivet Amico
Cure: Rachel Kidman
SBSC

- Recommendations for measures of SBS factors
- Best practices for adherence measurement and support?
- **Contact:** Nicole Montañez, Jennifer Libous, Rivet Amico

AD HOC SUPPORT
Provide recommendations for optimizing SBS in concepts/proposals
- As part of multidisciplinary protocol review group (MPRG) investigators receive comments from the SBSC
- Two independent reviewers using standardized form
- Full core team discussion
- Consolidated feedback and recommendations provided
Webinars, panel discussions and workshops are planned for quarter 3 to expand network-wide SBS knowledge and SBSR skills.

Sites have been queried on:
- Interest and expertise in SBS
- Topics of highest relevance
SBSC

• SBS expertise is present in CRSs, scientific committees, and protocol teams
• We are working to identify and invite senior and emerging SB scientists to share experiences (webinars, panel discussions, topic specific meetings)

• Mapping areas of SBS expertise within IMPAACT can facilitate ongoing and innovative work
CHARACTERIZE AND INNOVATE

Our ongoing work cataloging SBS in IMPAACT studies identified SB factors measured with some consistency (adherence, acceptability, context [food security, housing stability])

INNOVATIONS

- Harmonize certain SB and context measures → Cross protocol/study evaluations
- Study clinical trial implementation
- Use collected data from studies to evaluate the validity of measures to build evidence informed measurement strategies

SBSC
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CHARACTERIZE
Catalog SBS across protocols
Measures
Support/Procedures.

INNOVATE
Identify potential gaps and strengths across network Recommendations
As we enter a new structure, we look forward to continued growth of SBS in the IMPAACT NETWORK

SBSC member embedded within committees

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Acknowledgments

SBSC members: Rivet Amico, Jessica Haberer, Rachel Kidman, Kenneth Ngure, Jennifer Libous, Nicole Montañez, Ellen Townley, Tafadzwa Kasambira

impaact.sbscore@fstrf.org

THANK YOU!

We appreciate the ongoing support of the Network, protocol teams, scientific committees, and clinical research site team members. We look forward to a productive year together.