

Using Social Science Research to Overcome Challenges Communicating HTE

FDA and JHU-CERSI: Assessing and Communicating
Heterogeneity of Treatment Effects (HTE) for Patient
Subpopulations: Challenges and Opportunities

November 28, 2018

Paula Rausch, PhD, RN
FDA/CDER/OCOMM

Associate Director, Research and Risk Communications

- No conflicts of interest to report
- This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

How can social science research be used to help overcome some of the challenges of communicating HTE?



What is Social and Behavioral Science Research?

(NIH OBSSR, ND)

- Behavioral and social sciences research is a large, multifaceted field, encompassing a wide array of disciplines.
- Focuses on understanding of behavioral or social processes, or on the use of these processes to predict or influence health outcomes or risk factors.
- “Behavioral” refers to:
 - overt actions
 - underlying psychological processes such as cognition, emotion, temperament, and motivation
 - biobehavioral interactions.
- The term “social” encompasses:
 - Socio cultural/economic/demographic status
 - biosocial interactions
 - Various levels of social context from small groups to complex cultural systems & societal influences.
- Uses various methodological approaches.
- Basic and applied research.
- Several key cross-cutting themes characterize social and behavioral sciences research, including:
 - The search for general principles of behavioral and social functioning;
 - Emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status.

Social and Behavioral Science Methods

Qualitative	Quantitative
Literature reviews	Primary surveys: Questionnaires <ul style="list-style-type: none">• Web-based (computer and cell phone)• Direct mail• Email
Environmental scans/“gray” literature	Primary surveys: Interviews <ul style="list-style-type: none">• In person• Telephone• Virtual/remote
Social media research	Secondary analysis of previously gathered survey data
Focus groups <ul style="list-style-type: none">• In person• Virtual/remote	Experimental studies
Interviews <ul style="list-style-type: none">• In person• Telephone• Virtual/remote	
Workshops & other guided listening sessions	
Direct observation	



Knowledge, understanding, learning, recall

Message effects

Self-efficacy/crisis efficacy

Emotions

Risk perceptions, including risk severity and susceptibility

Decision-making

Experiences

Opinions/attitudes

Actions/behavioral Intentions

Formatting

Some General Outcomes of Interest

Social Media Research

- Aggregates social data from millions of social and online sites without practical limitations.
- Qualitative and quantitative data can be collected on which thematic, spatial, and temporal analyses can be conducted.
 - gain insight on attitudes, opinions, thoughts and behaviors on certain topics
 - Identify emerging topics & trends
 - Obtain real-time overview of people's reactions during a specific event (e.g., valsartan recall) or over time
 - Identify potential influencers & opinion makers across key platforms
- Provides an opportunity to quickly collect a wide diversity of information produced by a large and heterogeneous group of people from geographically diverse areas.
- Data collectable over varying periods of time (including longitudinally).
- Allows SM researchers to build a broader, more-detailed and potentially more authentic picture of a topic or issue.
- Focuses on people's perspectives and meanings, in their own expressive language.
- Conversations occur in virtual social settings where users/posters choose to gather.
- Often allows more honesty and openness than might be possible in other forms of research.

An exploratory research method that involves using tools and techniques to extract and analyze unstructured data from conversations and discussions occurring on social media channels and the Internet that can enhance understanding of the social context surrounding topics/issues.



Thank You

Paula.Rausch@FDA.HHS.gov

301-796-3121

