

HPTN 035
Enrollment
Decision-
Making:
Microbicide
Legacy Study

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Challenges in Conducting HIV Prevention Research

Logistic

- ✓ Target areas with high HIV incidence rates
- ✓ Meet accrual and retention targets
- ✓ Require high product adherence

Ethical

- ✓ Be transparent
- ✓ Eliminate coercion
- ✓ Promote community ownership

Requires community to understand research and researchers to understand the community!

Niketa Williams



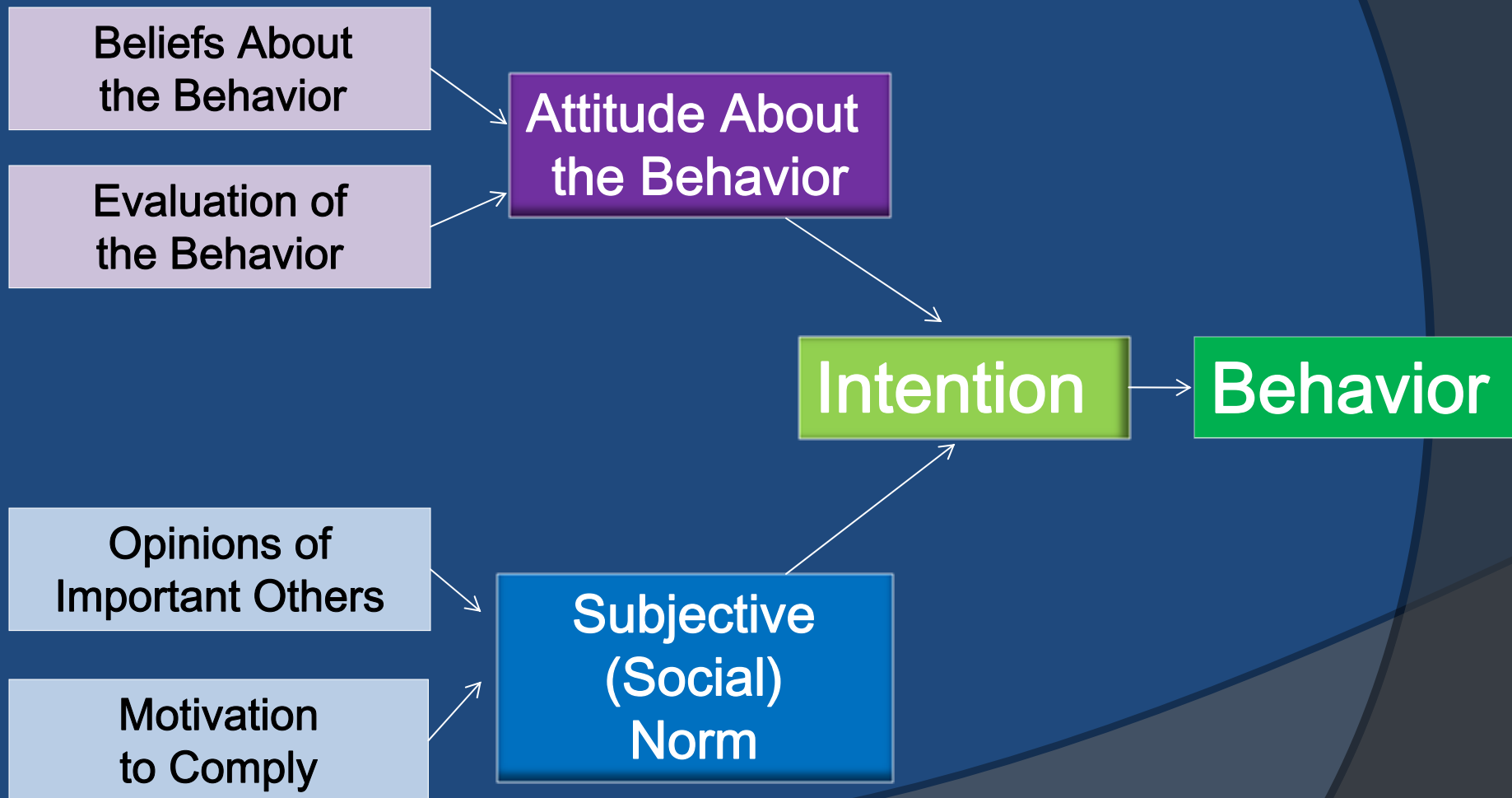
Hypothesis

- ❖ A potential participant's attitudes and understanding as well as their social context will influence their intention to enroll in a study

Objective

- ❖ To perform a qualitative analysis of participant motivations, attitudes, perceptions and experiences through conducting 31 semi-structured interviews of HPTN 035 enrollees following their completion of that study

Theory of Reasoned Action



Inclusion Criteria

- ❖ Successfully completed HPTN 035 follow-up and study exit visit
- ❖ Agreed to future contact for research
- ❖ Able and willing to provide Informed Consent
- ❖ Able to score 5/6 correct answers on Enrolment Comprehension Quiz

Methods

- ❖ Target group for recruitment generated from de-identified SCHARP Demographics forms
- ❖ 'Purposeful sample' for diverse group (age, ethnic group, language, partner status, income, education, number of children, etc.)
- ❖ Sensitised in person (at clinic) or via phone by Legacy translator using approved script
- ❖ Appointments set for 2-8 weeks post-HPTN 035 exit visit

Methods - 2

- ❖ Face-to-face 'semi-structured' interviews by PI
- ❖ ~ 2 hours for consent and interview
- ❖ Participant's preferred language; through an interpreter
- ❖ Audio recorded
- ❖ Translated/transcribed to English -Translator A
- ❖ Content verified/reviewed -Translator B
- ❖ Remunerated ~ \$7 for participation
- ❖ Approval by 3 Ethics Committees
- ❖ Grounded Theory analysis

Grounded Theory Analysis ²

STAGE	PURPOSE
Codes	Identify anchors that allow the <u>key points</u> of the data to be gathered
Concepts	Collections of codes of similar content that allows the <u>data to be grouped</u>
Categories	Broad groups of similar concepts that are <u>used to generate a theory</u>
Theory	A collection of explanations that explain the subject of the research

² Glaser B., Strauss A., 1967 The Discovery of Grounded Theory: Strategies for Qualitative Research: Chicago: Aldine

Analysis

- ❖ Transcripts - systematically analyzed and coded to understand underlying principles guiding attitudes and behaviors
- ❖ Key points ('codes') were grouped into ('concepts') which were organized into 'categories'
- ❖ Consensus for definitions was tested through independent coding by a second reviewer

Results:

Enrollment Decision-Making

Major Codes:

- A. Recruitment Influences
- B. Internal Decision-Making
- C. Influences Through Discussion with Others
- D. Expectations of Relationship with Study Staff

A - Recruitment Influences

Sub Codes:

- ❖ Staff Recruiters
- ❖ Peer / Family Recruiters
- ❖ Free Health Services

A - Recruitment Influences

❖ Staff Recruiters

“...there were some staff from here that...came to the community to sensitize people about the study and at first they gave us some yellow leaflets... and this is how I came to know there is a study...”

A - Recruitment Influences

❖ Peer / Family Recruiters

“I didn’t believe that they were saying the truth, that is what made me lose (throw away) that leaflet, but what made me come after two weeks is that I had a friend of mine who came here...and she encouraged me...”

“...I told my other friend, the one they got my contact phone number through, she is much older than me and she encouraged me to go ahead. She said that if it was not for her being over-age, she would have joined as well.”

A - Recruitment Influences

❖ Free Health Services

“They were simply encouraging us, because it was good for our health... from what I looked at how they were attracting people – they centered their information that you could get free medical care, whereby the project would pay for it, and then you could have medical examinations, which would be very expensive, if you did it for yourself.”

B - Internal Decision-Making

Sub Codes:

- ❖ Skepticism
- ❖ Learn Health Status
- ❖ Free Health Services
- ❖ Vested Interest
- ❖ Contribute to Research
- ❖ Potential Stigma
- ❖ Independent Process

B - Internal Decision-Making

❖ Skepticism

“When you tell other people about the study, most of them say that they [study staff] are Satanists. I felt lazy about telling other people about it, so I just kept quiet.”

“I told my sister that people are saying that those are Satanists and she said to me “how can I take you to the Satanists you are my relative?” She went on to say that I should not listen to or follow what people say in the community.”

B - Internal Decision -Making

❖ Learn Health Status

“I wanted to be examined and tested so that I know that I don’t have any disease, that’s what pleased me to join.”

B - Internal Decision-Making

❖ Free Health Services

“What interested me was that they said that there is a study and when you are sick as a participant and you want to go to the hospital, you come here and we will take you to the hospital and for me I became happy.”

B - Internal Decision-Making

❖ Vested Interest

“For me to join the 035 study, they were telling us that they will be trying the microbicides to try if that will cure (prevent) HIV so that is how I came to join up with this study so that we can find out if it will help us women.”

B - Internal Decision-Making

❖ Contribute to Research

“On my own, I just volunteered... even Fansidar they researched on people they did not know if it was going to cure malaria. It is just the same with the gel they are researching on us people ...we volunteered that they test on our bodies so that they see if the gel can be effective in protecting HIV. We just volunteered that they examine and test on our bodies.”

B - Internal Decision-Making

❖ Potential Stigma

“During our conversations with women in the community, they would always discourage you from joining, but for this study...since the day when I heard about it, I said this time around I will join because by not joining, that is how we women lack knowledge in many things.”

B - Internal Decision-Making

❖ Independent Process

“For me,... I would have been coming despite him refusing me because of what I have been told about the study. When he leaves in the morning for work, I also start off to come here, there was no way he would have stopped me.”

“...but if my husband was going to refuse me coming, I would have continued to come privately because I know that women are the most vulnerable. Like now I am here with the child whilst he is at work. He has gone to work for sure,... but I cannot know where he passes through when he knocks off...”

C - Influences Through Discussion With Others

Sub Codes:

- ❖ Selective Disclosure
- ❖ Medical Screening
- ❖ Recruitment of Others

C- Influences Through Discussion With Others

❖ Selective Disclosure

“I can only say that at first I did not tell anyone. I only told my husband and again because of people’s speculations, no one knew except my husband.”

C - Influences Through Discussion With Others

❖ Medical Screening

I started by asking [my husband] if he would be willing that I get tested...I said you know that there are a lot of diseases now so I want us to be in good health...I explained further on what would happen to me...that they will examine my vagina, draw blood for HIV test and urine for pregnancy test...my husband asked me if I was going to manage to have all those tests, I said yes."

C - Influences Through Discussion With Others

❖ Recruitment of Others

“I told one of my friends...that there is a study at Kamwala Clinic about gel which can prevent one from contracting HIV, but they also don't really know if it is effective ...they are still researching. She asked me if she could come and join, then I said 'yes you can go'...She then came and joined and she is exiting the study this month”.

D - Expectations of Relationship with Study Staff

Sub Codes:

- ❖ Research Distrust
- ❖ Poor Expected Relationships

D - Expectations of Relationship with Study Staff

❖ Research Distrust

“I don’t have any [researcher distrust], because I know that they are looking for a cure ...until they find the cure they will go researching till the cure is found.”

D - Expectations of Relationship with Study Staff

❖ Poor Expected Relationships with Study Staff

“I thought that they [the study staff] would be shouting at me but no, when I came they would greet me, and when I by-pass them, they would greet me themselves and be very cheerful.”

Limitations

❖ Biases

- ❖ Social desirability reporting

- ❖ Selection bias

 - ❖ Small sample size

 - ❖ Only enrolled participants were queried as to their opinions regarding enrollment

- ❖ Intentions regarding enrollment may not carry to other aspects of study e.g. adherence

Conclusions

- ❖ Attitudes about enrollment frequently revolved around enhanced health care services and its access, as opposed to study goals
- ❖ Negative social norms did not prevent enrollment of these participants, but may be significant in preventing other women from enrollment
- ❖ Positive social norms often originated from current or previous study participants

Lessons Learned

- ❖ Sensitisation of the community is critical to create a positive social norm based on correct study information
- ❖ Future efforts for microbicide study recruitment may benefit from using “peer” networks for education and recruitment
- ❖ Important that potential participants understand the study so decision to enroll is based on study goals rather than on ‘additional’ medical services

Way Forward for VOICE

- ❖ Qualitative sub-study of eligible women screening for VOICE comparing those who choose not to enroll to those who choose to enroll
- ❖ Look at personal, clinic, and protocol-dependent factors influencing decision to enroll
- ❖ Validity study to compare the generalizability of results during VOICE to a more general population potentially eligible for PrEP

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Thank you for your attention!

Any Questions?