

MTN-003c / VOICE-C

Ancillary proposal

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VOICE-C Collaboration

- VOICE-C is the result of the close collaboration between the following MTN Working Groups:
 - Community Working Group (CWG)
 - Behavioral Research Working Group (BRWG)

Community Working Group (CWG)

- The goal of the MTN CWG is to conduct community preparedness and engagement activities to ensure successful conduct of microbicide studies and has the following aims



Community Working Group Aims

- To ensure community input into science generation and the research process of the MTN
- To build capacity for local communities to provide input into research at the site level
- To develop mechanisms for sharing experiences, lessons learned, and best practices for community involvement in MTN research



Behavioral Research Working Group

- Provide behavioral science support for the development of all of the MTN protocols
- Develop innovative techniques to capture critical behavioral data in clinical studies
- Develop the tools, including questionnaires, to capture behavioral data in MTN protocols



VOICE-C - The Big Picture

- Achieving high level of adherence in VOICE is KEY to being able to estimate the protective effect of the products against HIV
- We need to understand not just how much use (or non-use) there is in VOICE, but **WHY**
- VOICE-C aims to **qualitatively explore factors beyond the individual** that influence product use and non-use among VOICE participants

VOICE-C Study Population

Group 1	VOICE participants
Group 2	Male partners of VOICE participants
Group 3	Members of Community Advisory Boards (CABs)
Group 4	Key community stakeholders in the community surrounding VOICE-C sites



VOICE-C Study Design

- Exploratory sub study of VOICE using qualitative research methods, including focus group discussions (FGDs) and in-depth interview (IDI) at participating VOICE-C sites.
- **Descriptive component:** qualitative exploration of barriers and facilitators of product adherence
- **Strategic component:** issues identified through the descriptive component will be brought back to the VOICE protocol team, and a decision will be made about the modification or implementation of new adherence strategies across all VOICE sites

Primary Objectives

- To explore socio-cultural and contextual factors at the **household level** (i.e. relationship with partner, poverty) and at the **community level** (i.e., stigma against HIV, rumors about the trial) that participants identify as **influencing product use** (and non-use) in VOICE .
- To determine if factors identified by participants as influencing product use (and non-use) are different between the women who are randomized to the **vaginal product arm vs. oral product arm.**
- To elicit VOICE participants' perceptions of the **importance of adherence**, and its **barriers and facilitators** as identified by them.

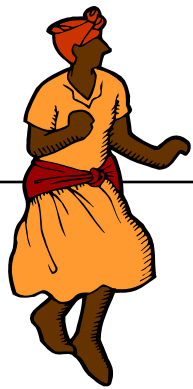
Secondary Objectives

Descriptive

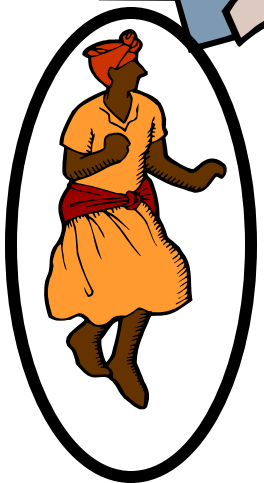
- To elicit **“external” perspectives** on the trial, its acceptance at the household level and in the community, and views on adherence-related issues among the following groups:
 - Male partners of study participants (Group 2)
 - CAB members (Group 3)
 - Key community stakeholders (Group 4)

Strategic

- To solicit the input of external stakeholders on **developing and implementing strategies** to improve product adherence in the trial.
- To collect **feedback on experience with these implemented strategies** through specific questions in the exit FGDs with VOICE participants and their male partners.



Community



family



individual

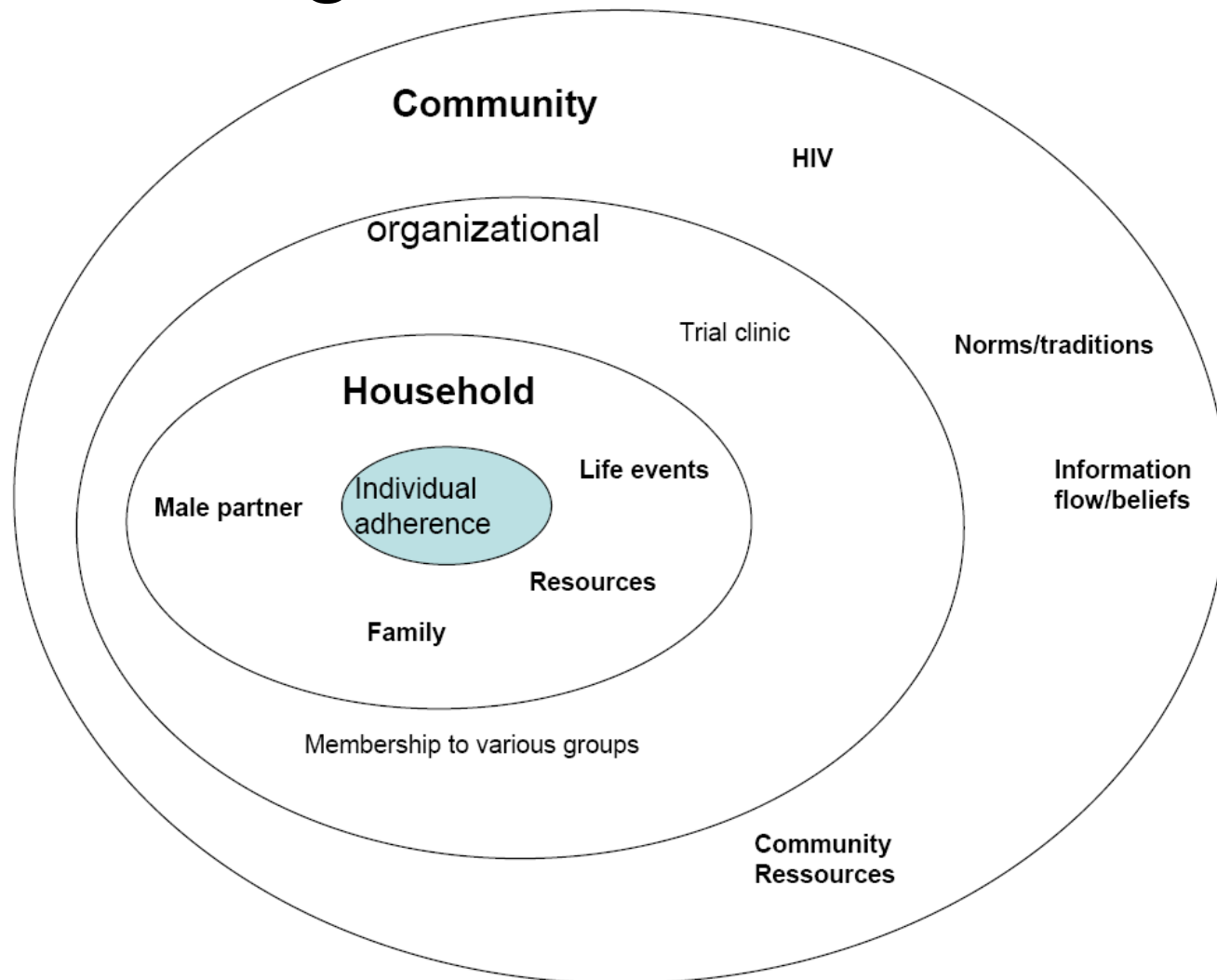


Groups/organizations



Partner

Socio-Ecological Model of Factors Affecting Adherence in VOICE



Qualitative Methods

- Quantitative methods (survey questionnaires):
 - Best to measure a behavior (product use): how much, how often and characteristics of who is adherent

- Qualitative methods:
 - Seek to understand WHY people practice certain behaviors (use or non-use of product)
 - Provides information on how people experience the topic of interest (i.e. being adherent) in their own words
 - Help identify intangible factors (i.e. norms, gender roles, religion, culture) affecting product use
 - Can describe variation and explain relationships between phenomena (i.e. work may be associated with non-use, because erratic schedule prevents taking products at the same time each day)

Sample Size and Study Procedures

At each VOICE-C participating site (N=approximately 270)

- VOICE participants- randomly selected N~ 140
 - Exit FGD (8 FGD; 4 per arm ~100 ♀)
 - Monthly IDI (1♀/arm/month during accrual=36 ♀)

- Male partners-systematically selected N~65
 - Exit FGD (4 FGD; 2 per arm ~50 ♂)
 - Quarterly IDI (1♂/ arm/quarter during accrual = 14)

- CAB- purposively selected N~15
 - Biannual FGD (5 groups with same 15 members)

- Key Community Stakeholders- purposively selected N~50
 - Biannual FGD (5 groups with 10 different participants each time)

Timeline for VOICE-C Data Collection

	Study Accrual Period						Follow-up Period					mo35	
	start	mo3	mo6	mo9	mo12	mo15	mo18	mo21	mo24	mo27	mo30		mo33
Group 1: VOICE ppts													
IDIs		XXX*	XXX	XXX	XXX	XXX	XXX						
Exit FGDs									X	X	X	X	
Group 2: Male partners													
IDIs		X*	X	X	X	X	X						
Exit FGDs									X	X	X	X	
Group 3: CAB members													
FGDs	X		X		X		X		X				
Group 4: Community Stakeholders													
FGDs	X		X		X		X		X				

*"X" refers to one data collection round. "XXX" refers to three monthly IDIs in that quarterly interval.

Socio-behavioral & Community Activities in other PrEP studies

- FEM-PrEP:
 - Site preparedness (community mapping; IDI & FGDs with community members and stakeholders)
 - IDIs during trial implementation
 - IDIs and FGDs with community stakeholders
 - Quarterly IDIs with 5% of participants
 - Intervention planning protocol (preparation of post trial activities)
 - Community engagement activities (building partnerships with CABs, and other civil society stakeholders; ethics training)



□ PrEP Botswana trial (CDC)

- Community monitoring survey to assess rumor/perceptions and awareness of trial (ongoing)
- IDI with community members knowledgeable about the trial and with HIV+ patients
- Qualitative substudy with trial participants (in development)



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