

# MTN-020 Qualitative Update

---

Liz Montgomery and Miriam Hartmann  
Women's Global Health Imperative  
RTI International  
San Francisco, CA, USA





# Agenda

---

1. Accrual Update
2. Overview of Themes to Date
3. Interesting Case Selection
  - Single IDIs
  - Serial IDIs

# Accrual Update

Site	SIDI1	SIDI2	SIDI3	Single IDI	FGD	Total # of IDIs / FGDs	Total # of Women Interviewed
DTHF	4	0	0	0	0	4	4
MRC (Isipingo)	4	0	0	4	0	8	8
MU-JHU	13	9	0	2	0	24	15
UZ-UCSF (Spilhaus)	12	12	0	6	0	30	18
UNC- Lilongwe	9	0	0	1	0	10	10
WRHI	10	1	0	2	0	13	12
<b>Total</b>	<b>52</b>	<b>22</b>	<b>0</b>	<b>15</b>	<b>0</b>	<b>89</b>	<b>67</b>

# Accrual Progress

	SIDI1	SIDI2	SIDI3	Single IDI	FGD**	Total # of Women Interviewed
<i>Target # / Site</i>	12-14	12-14	6-7*	≥3	2	~35
<i>Target # all sites</i>	72-84	72-84	72-84	18	12	~210
Total to date	52	22	0	15	0	67

\*Anticipate that not all women will take part in 3 SIDIs

\*\*Estimated 10 women per FGD



# **OVERVIEW OF SELECT THEMES**

# Motivations for Participation

---

I feel at risk  
for HIV and  
want to  
know my  
status

I value the  
health care  
benefits



# Ring Acceptability/Adherence

---

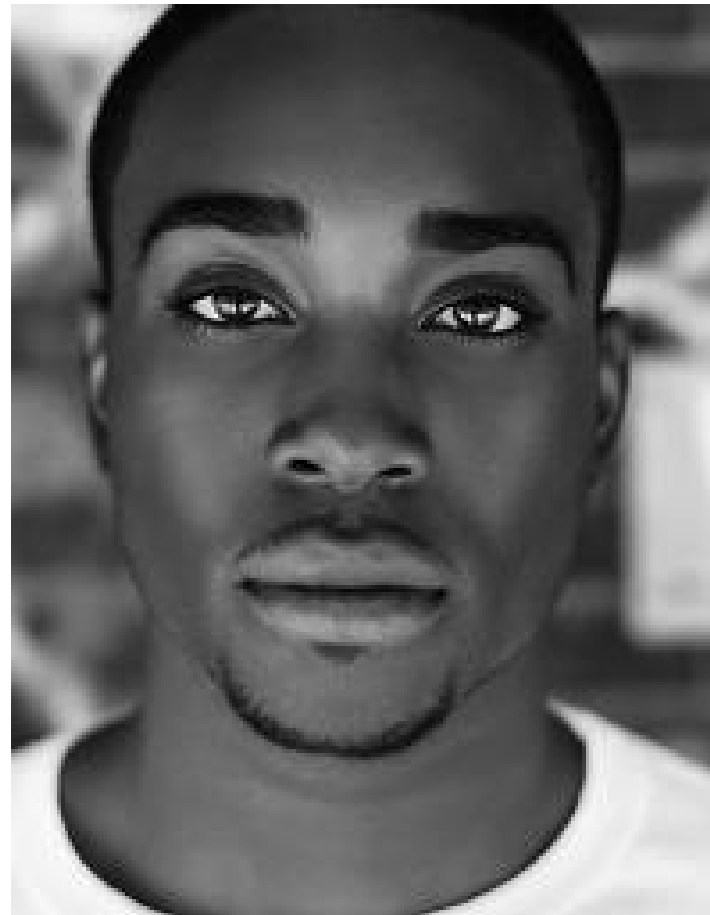


- ❑ Generally high reported adherence
- ❑ Discreteness facilitates use
- ❑ Non-adherence associated with negative influence from other participants and some side effects
- ❑ Expulsion associated with defecating
- ❑ Participant engagement activities reported to improve adherence

# Male Partners/Sex

---

- ❑ Promiscuity of partners motivates participation
- ❑ Differing opinions and levels of disclosure to partners
- ❑ Concerns
  - Partner will feel ring during sex
  - Associate ring use with infidelity
  - May cause harm to partner





# Rumors



DBC01078 [RF] © www.visualphotos.com

Did you hear that ASPIRE  
is Satanic?

No, but did you hear that the  
ring causes cancer?

# Understanding Study/Procedures

- ❑ Placebo concept still confusing to some
- ❑ Ring use inspections
  - Confusion over purpose and what is done
  - Belief that it demonstrates lack of trust





Single IDIs and Purposively Selected Serial IDIs

# **INTERESTING CASE SELECTION**

# Single IDI Cases

---

- 15 Single IDI cases
  - 14 sero-convertors
  - 1 termination due to partner



# Reported Adherence

---

- ❑ Few adherence problems reported
- ❑ One woman reported a single instance of ring expulsion while defecting with immediate re-insertion
- ❑ Only one woman reported removing ring prior to sex, attributed improper ring and condom use to her sero-conversion



# Responses to Product

---



- ❑ Initial belief that ring is protective/using active ring
- ❑ Retrospective comments on lack of side effects support belief that they were using placebo
- ❑ One participant believed she alternately received placebo and active ring during study

# Responses to Study

---

- ❑ Generally sad, but appreciative of the study
- ❑ At least one woman expressed disappointed that the ring did not protect her



# Interviewing Sero-Convertors

---

- Generally gone well, but some sensitivity
- Important for participant to be aware that the interviewer knows her HIV positive status.
  - Before Interview/Introduction: To inform participants about shared confidentiality regarding her HIV status.
  - During Interview: Introduce when discussing Acceptability and Adherence topic [before question 5 on IDI].

**“As I mentioned before we will be talking about your experience in ASPIRE and your HIV status...”**





# Questions on Single IDIs

---

- Have any sites had other early terminators (i.e. not sero-convertors) they've considered enrolling?
- Any additional issues encountered with conducting single IDIs?
- What other themes have emerged related to the study/ring use with this sample?



# 'Interesting' Serial IDI Cases

---

- 4 cases purposively selected to date
  - 2 interviewed at MU-JHU
  - 2 selected at MRC
- Example indicators of interesting cases
  - Disclosure of widespread or situational non-use (e.g. before sex)
  - Shift in overall attitude towards study
  - Demonstrates unique behavior (e.g. able to bring partner into clinic, different from peer group, etc.)



# Example Interesting Case

---

- Selected based on:
  - Self-reported perfect adherence.
  - After adherence workshops, reported not using product
  - Concerned about HIV risk because partner is promiscuous
  - Through workshop realized HIV risk and decided to use ring
- Upon being interviewed as a serial IDI case
  - SIDI1: she reported the ring coming out once while washing her vagina, but did not report widespread non-adherence
  - SIDI2: reported non-adherence prior to adherence workshops



# Final Topics for Discussion

---

- Site input:
  - Are we getting interesting, useful information?
  - Are there topics we should be exploring further/less?