



Integration of Behavioral Science in the MTN

**Where We've Been and Where We're
Going**

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Outline

- **BRWG overview**
- **Data collection technologies**
- **Challenges in measuring acceptability**
- **Innovations in adherence measurement**
- **Other behavioral assessments in MTN trials**
- **Future agenda**



BRC/BRWG Mission: 2006

Mission:

To develop the vision, scientific agenda, and set priorities for behavioral research on microbicides within the Microbicide Trials Network

Scope of BRC & Accomplishments

2006 BRC behavioral research

- **Multiple disciplines**
 - **Epidemiology**
 - **Psychology**
 - **Sociology**
 - **Anthropology**
- **Utilize mix of methods: qualitative & quantitative**
- **Identify best approaches to measurement of adherence and acceptability**
- **Integrate behavioral assessments in every MTN protocol**

2011 BRWG behav. Res

- ✓ **Multiple disciplines**
 - ✗ **Epidemiology**
 - ✗ **Psychology**
 - ✗ **Sociology/Demography**
 - ✗ **Anthropology**
- ✓ **Method mix:**
 - ✓ **VOICE-C, ATN 062; 008; 001**
- ✓ **Method studies:**
 - ✓ **Pictorial ACASI (035b)**
Wisebag (003), biomarkers (001; 003)
- ✓ **Most protocols have behavioral components!**



NEW TECHNOLOGIES FOR BEHAVIORAL DATA COLLECTION

Pictorial ACASI on Handhelds: MTN 035b



Images change as participant selects more partners.
Number shown on screen & audio “reads” number.

Interactive Voice Response for Daily Adherence: 004/062

- CASI by telephone



- Callers respond to pre-recorded questions using keypad or by speaking into phone

Qualitative Interviews via Video

Teleconferences: ATN 062



Tell Juliana

If you are eligible to enroll in the microbicide study MTN 004, you will be automatically eligible to enroll in a second study.


Tell Juliana is a study of young women's opinions about microbicide use. If you enroll, this is what you'll be doing:

1. You'll meet *Juliana* via a web-cam live teleconference, and she will show you how to use a phone diary.
2. You will use a phone diary for 14 days and earn \$2 per call, up to \$80.
3. You will be able to send email-messages to *Juliana* telling her anything you want about your experiences using the microbicide.
4. On day 14 of the trial, you will have a private teleconference with *Juliana* to discuss your opinions in more detail. You will be paid \$25 for that interview.
5. On day 21 of the trial, you will have a final teleconference with *Juliana* about your experiences using the web and the phone diary during the trial. You will be paid an additional \$25 for completing the teleconference.







You can earn up to \$130 participating in this study

Get more information at <http://hivcenternyc.org/research/gender/telljuliana.htm>

ACASI with Product use calendar: 003

Repeat  Question


6 days ago (Tuesday), did you insert gel?

| Yesterday Sunday | 2 days ago Saturday | 3 days ago Friday | 4 days ago Thursday | 5 days ago Wednesday | 6 days ago Tuesday |
|---|---|---|--|---|---|
|  |  |  |  |  |  |
| <input type="checkbox"/> Yes | <input type="checkbox"/> Yes | <input type="checkbox"/> Yes | <input type="checkbox"/> Yes | <input type="checkbox"/> Yes | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No | <input type="checkbox"/> No | <input type="checkbox"/> No | <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Do not remember | <input type="checkbox"/> Do not remember | <input type="checkbox"/> Do not remember | <input type="checkbox"/> Do not remember | <input type="checkbox"/> Do not remember | <input type="checkbox"/> Do not remember |


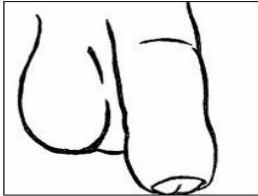
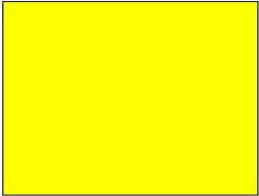
ACASI with pictures: 003

- *For known challenging questions:*

Q1b

Repeat  Question

Is your primary sex partner circumcised? By circumcised, we mean when the foreskin of the penis is removed or cut off.

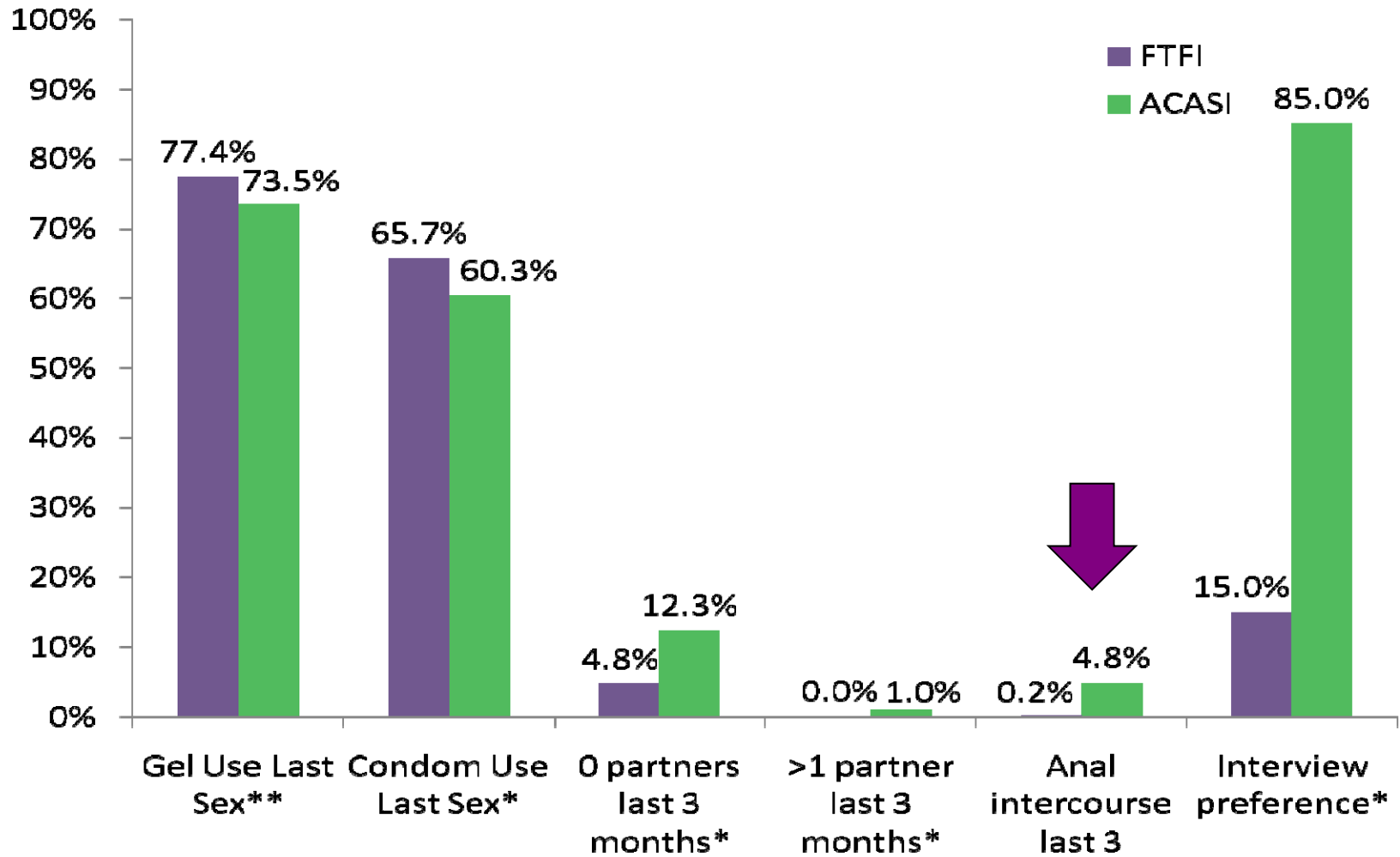
Circumcised Uncircumcised Do not know

Previous Next



**DO NEW TECHNOLOGIES
MAKE A DIFFERENCE?**

Differences in Reports from FTFI to ACASI in 035b



*p=0.06

**p<0.05



ATN-062 IVR Feedback

- **~1/3 of participants said that having to call the phone diary reminded them to use the gel**
 - “phone diary and the gel went hand in hand”
- **~1/3 said that using the gel reminded them to call**
- **Monetary compensation was key motivator for calling compliance**

Next.... *Newer* Technologies

- Adherence assessments of opening events via bags (and bottles)
 - Initially tested in CAPRISA 004
 - Wisebag pilot in development for 003
- Texting and/or telephone interviews (018?)
- Remote pill count by phone (018?)
- Self-report comparisons & integration with biomarkers





ACCEPTABILITY IS COMPLEX

Product Acceptability (MTN-004)

In her own words:

“It was uncomfortable. I didn't like the fact that it would leak. I didn't like how when I would take the applicator out, I would see yellow, greenish stuff on the applicator. ...It was just nasty, I didn't really want to see that. [...]

But for instance, if I didn't know who my partner was, [...]if it was just anybody or somebody that I just met or [...] who I'd only been dating for a little while, and I didn't want him to use a condom, but I wanted to be safe that he wasn't going to transmit anything to me, I would use it. (Female, vaginal gel use)”

Qualitative results: RMP2-MTN 006

Liking: *It was the fourth day that I started having problems. I started with some bladder problems, back problems (...) I felt like somebody was going to rip my uterus out (...) And then I had to go to the emergency room (...) we found out ... that there was no abnormalities (...) I might have had an allergic reaction to it. I wanted to keep going, but they suggested I stop.*

SCORE: 5

Likelihood of use: *I can see me using it maybe once a week or twice a week, but seven days in a row would be a little bit too much (...) Because I don't have sex seven days in a row (...)*

SCORE: 10

* Likert scale 1-10

Qualitative Findings: MTN 001

- Product preferences and barriers to use differed among women; clear interest in both products.
- Gel perceived to improve sex by many women at Ugandan and South African sites:
 - “Since I started using it, the love with my husband increased...because he thinks I love him so much, yet it’s the gel.” –Ugandan participant.
- Pills seen more convenient and discreet than gel in US

Product Acceptability in MTN-001

| | Vaginal Gel | Oral Tablets | Dual |
|---|-------------|--------------|------|
| Future product use likely if proven effective | | | |
| All sites† | 83 | 93 | 82 |
| African sites | 100 | 100 | 99 |
| United States sites | 64 | 87 | 65 |

† p=0.002 (conditional logistic regression, controlling for period and sequence)

Geographic differences in reporting future willingness to use products.

FTFI interview affect?



Lessons Learned: Acceptability

- **Geographic differences need further study**
 - Puerto Rico vs. U.S. (MTN-004/ATN-062): better acceptability in Puerto Rico
 - Africa vs. U.S. (MTN-001) – More gel preference in Africa; US women prefer pills

- **The risk environment may be as important as gel characteristics**
 - Women may “forgive” characteristics if a product is effective or they perceive themselves at high risk



Next Steps for Acceptability Assessment

- **Standard set of questions across protocols**
- **Focus on characteristics**
- **Culturally tailored questions**
- **What is NOT liked**



ADHERENCE MEASUREMENT

Gel Adherence: 035

- Reported gel use (in three groups): 81%
- Similar gel adherence rates across groups

| BufferGel | PRO 2000 | Placebo | No Gel |
|------------------|-----------------|----------------|---------------|
| 81.5% | 80.6% | 81.4% | NA |

Assessed by self-report in FTFI

Gel and Condom Use by Clinic- 035

(last act per woman based computation)

| | n | % Gel use | % Gel use without CD | % Condom use (n) |
|----------|-----|-----------|----------------------|------------------|
| Blantyre | 321 | 83 | 19 | 73 (429) |
| Lilongwe | 439 | 75 | 25 | 66 (582) |
| Durban | 522 | 79 | 17 | 77 (697) |
| Hlabisa | 256 | 79 | 16 | 76 (337) |
| Philly | 147 | 77 | 14 | 75 (198) |
| Lusaka | 237 | 83 | 27 | 70 (317) |
| Chituwiz | 193 | 94 | 22 | 81 (257) |
| Harare | 169 | 91 | 17 | 83 (222) |

But....Adherence is overreported

- CAP 004
- IPrEX
- What is associated with adherence? Is acceptability associated with adherence? In process by 035 team....*stay tuned...*

Partner Type Affects Gel Adherence

| | AOR | 95% Wald CI | |
|---|------|-------------|------|
| Ongoing Partner vs New Partner | 2.51 | 1.62 | 3.88 |
| <i>Controlled for site, age, schooling, number of sex acts – only Chitungwiza, Zimbabwe had significantly higher gel use than the reference site Philadelphia</i> | | | |

Last QFU - women who had a change in partnership status & acquired a new partner in 035 reported less gel use



Adherence Measurement in 001

- High levels of self-reported adherence across all product regimens: 94% of daily doses taken.

- PK (TFV concentration) as an adherence measure suggests significant over-reporting....
 - 35% to 65% non-adherence estimated using PK dosing data (Hendrix, 2011 CROI presentation).



Adherence measurement: Next steps

- Less emphasis on frequency of product use by self-report**
- Focus on non-use**
- Problems/barriers to use**
- Context of use/ non-use (e.g. partners)**
- Change in counseling (VASP) affect on self-reports**



BEHAVIOR ISN'T JUST ADHERENCE

Other Behaviors Assessed in MTN Trials

- ❑ Substance Use – 009
- ❑ Exposure to ARVs in childbirth – 009
- ❑ Sharing and selling of products – 001, 003
- ❑ Sex during menstruation – 005
- ❑ Partner effects – 035, 001, 003
- ❑ Partners, Community perceptions – 003c
- ❑ Depression among seroconverters -015
- ❑ Disclosure of HIV status among seroconverters- 015
- ❑ Vaginal hygiene – 003, 005



New Focus in Upcoming Trials

- PRODUCT CHOICE!!! (018)**
- Partial efficacy assessment and effect on use (018 proposed)**
- Behavioral disinhibition – (003 proposed)**
- New populations (pregnant/lactating women, MSM, adolescents)**



BRWG Lessons Learned

- ❑ New data collection technologies decrease over-reporting of adherence to gel use – but overreporting persists;**
- ❑ New technologies do increase reporting of other “sensitive” behaviors such as anal intercourse and sexual frequency**
- ❑ Partner factors can affect gel use**
- ❑ Acceptability measurement needs further refinement**
- ❑ Patterns of adherence and acceptability differ by cultural context and geographic area**



Final Thoughts: Where BRWG is Going

- Although self-reports of adherence may be improved with use of new technologies; other types of data are required...biomarkers**
- Behavioral data in microbicide trials can help understand adherence**
- The relationship between acceptability and adherence is nuanced – people may use what they don't like**
- Ancillary studies allow development of new tools and measures**
- What has been learned in microbicide trials contributes to behavioral science in general**



Who is the BRWG....

Core:

- Alex Carballo-Dieguez
- Julianne Etima
- Pamina Gorbach
- Barbara Mensch
- Ariane van der Straten

Other members:

- Alexandra Minnis
- Elizabeth Montgomery
- Andrew Forsyth/ Diane Rausch
- Kristine Torjesen
- Ian McGowan