

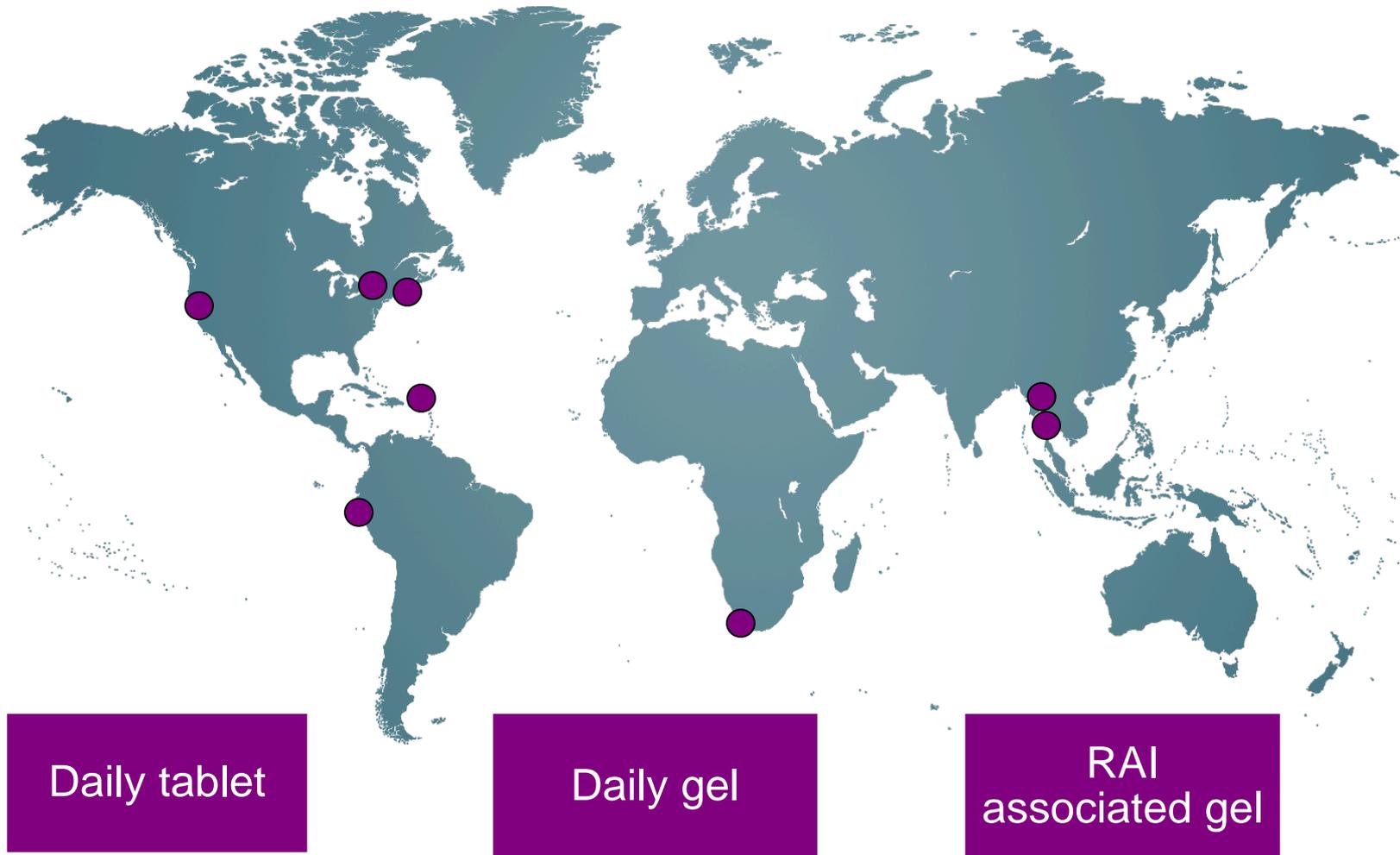
Revolutionizing our Counseling Approaches in HOPE

Lessons from MTN-017

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195 MSM and TGW



MTN-017....a study of firsts

- Phase II rectal microbicide study
- Biomedical HIV prevention study to implement a single counseling approach from the beginning
- To share results of pharmacokinetic testing with participants during their counseling sessions
- To integrate brief data convergence into the counseling session to improve accuracy of adherence measurement
- To record all counseling sessions (N=1,612)
- To assess fidelity to the counseling intervention during the study to address counselor drift (n= 416)

Training

- Materials
 - Counseling Manual
- Received 1.5 days of onsite training
- Completed 2 practice sessions with colleague
 - 1 of two sessions needed to meet pre-established fidelity criteria
- Fidelity Criteria
 - Session tasks: 1 (poor) to 7 (high) [M ≥ 5 to pass]
 - Client-centeredness: 1 (low) to 5 (high) [M ≥ 4 to pass]
- Review first 10 sessions of each counselor, then 1 of 5 sessions; then 1 of 10 sessions
- Monthly coaching calls

	PRACTICE					STUDY VISIT									
	1	2	3	4	5	1	2	3	4	5	6	7	8	9	10
1	✓	✓				✓	✓	✓	✓	●	●	●	●	●	✓
2	✓	✓				●	✓	✓	✓	✓	✓	✓	✓	✓	✓
3	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4	✓	✓				—	—	—	—	—	—	—	—	—	—
5	●	●	●	●	✓	—	—	—	—	—	—	—	—	—	—
6	✓	●				—	—	—	—	—	—	—	—	—	—
7	●	✓				✓	●	✓	●	✓	✓	✓	✓	✓	✓
8	●	●	●	✓		●	●	✓	●	●	●	●	●	●	●
9	●	●	✓			✓	✓	✓	✓	✓	✓	●	✓	✓	●
10	✓	●				●	●	●	✓	●	✓	✓	●	●	●
11	✓	✓				—	—	—	—	—	—	—	—	—	—
12	✓	✓				✓	✓	✓	●	✓	✓	✓	✓	●	✓
13	✓	✓				✓	●	●	●	✓	✓	✓	●	●	●
14	✓	✓				✓	✓	✓	✓	✓	✓	✓	●	✓	✓
15	✓	✓				●	✓	✓	✓	✓	✓	✓	✓	✓	✓
16	●	✓				●	●	✓	✓	●	●	✓	✓	✓	●
17	✓	✓				✓	✓	✓	—	—	—	—	—	—	—
18	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	●	—
19	●	✓				✓	●	●	✓	✓	✓	✓	✓	●	✓
20	✓	●				✓	✓	✓	●	✓	✓	✓	✓	✓	✓
21	✓	✓				✓	✓	✓	✓	●	✓	✓	—	—	—
22	✓	✓				✓	✓	✓	✓	●	✓	●	●	●	●
23	✓	●				✓	✓	●	●	●	✓	●	●	●	●
24	✓	✓				●	✓	✓	●	✓	●	●	✓	●	✓
25	✓	✓				●	✓	●	●	●	✓	●	●	●	●

- 25 counselors trained, post-training
 - 58% met criteria in both sessions
 - 27% in one session
 - 15% in neither session.

- 18 counselors who completed ten visits
 - 44% met criteria on ≥80% of sessions
 - 50% met criteria on ≤50% of sessions
 - Fidelity ratings fluctuated over time

- Of the 199 study sessions reviewed
 - 64% met fidelity criteria.
 - Of sessions that did not meet criteria,
 - 19% did not meet task criterion
 - 28% did not meet client centeredness criterion
 - 53% did not meet either criteria

- Low task component ratings were mostly attributable to skipping tasks, not to conducting them poorly.



Key findings

- Recording of counseling sessions was feasible
- Fidelity monitoring critical to understanding obstacles to delivering the counseling intervention with fidelity
 - Variable learning following training
 - Insufficient use of manual
 - Drift in fidelity over time
- Counselors welcome coaching sessions

- Adherence to study products was high
- Within a non-judgmental interaction, participants openly discussed challenges to using the study products



Out of ASPIRE, there is HOPE

Options in HIV Prevention

A Participant-Centered Counseling Approach



Options in HIV Prevention

- Goal
 - Help participants chose a preferred method of HIV prevention and adhere to their desired plan
 - To facilitate a more open discussion of decisions regarding product use; including product discontinuation

- Fully client-centered
 - Motivational Interviewing-lite approach
 - Shown to improve health behavior change outcomes
 - An MI/Client-centered adherence intervention is NOT revolutionary--ensuring that it is implemented IS!



Client-centered mindset

“People possess substantial expertise and wisdom about themselves and tend to develop in a positive direction, given the proper conditions of support.”

(Miller & Moyers, 2006)

- **Collaborative**
- **Respectful of autonomy**
- **Evocative**
- **Empathic**

Discussing Residual Drug Levels

Non Client-Centered

During the study we will share with you the drug levels left in the ring. Drug levels let us know how much the Ring was used. This information, however, will not affect your participation in the study.

Client-Centered

During the study we will share with you the drug levels left in the ring. Drug levels let us know how much medication was released into your system and more importantly, give us an idea of the level of protection from HIV that you may be receiving from the Ring. What do you think about that? How might this be helpful to you?



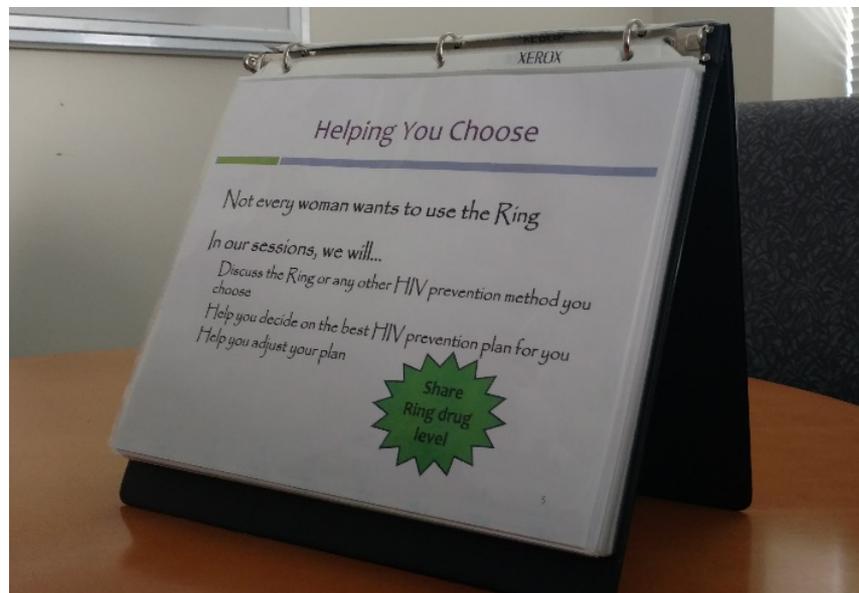
Overview of COACH Program

Counselling to Optimize Adherence, Choice, and Honest Reporting

- Components
 - Training/Counseling Materials
 - In-person training
 - Recording of sessions
 - Review/Rating of sessions
 - Monthly coaching calls

Maximizing Learning of *Options*

- Manual
- Flipchart
 - Guides the session
 - MI consistent language
- In-person training
 - 2 days
- Demonstration Videos
- Higher bar for certification
 - 3 “passing” mock sessions
 - 87% of sessions to date met criteria
 - 59% (10/17) of counselors certified with first 3 mock sessions



Maximizing Consistency

- Fidelity rating and Feedback forms
 - Rated in NY by a team of native speakers of study languages
 - First 3 sessions, then 1 of 10, then 1 of 20
 - Sent to counselor

7. Explore Ring use with participant (If participant is not going to use Ring, go to #8)

- Explores why ppt decided to use Ring
- Uses ppt's prior experience with Ring and self-knowledge to inform a plan for Ring use
- Explores potential obstacles with ppt
- Works with ppt to plan how to overcome obstacles (If necessary)

Notes:

1 2 3 4 5 NA

- Coaching
 - Monthly coaching calls (always available for consultation)
 - Motivate and sustain counselors' behavior change



What IS revolutionary....

- The infrastructure being implemented in HOPE to help counselors support participant's product use
- The support from HOPE and MTN leadership for the counseling component of a biomedical HIV prevention trial
- The empowering conversations that HOPE counselors will have with participants about using the Ring or the HIV prevention method of their choice and remaining HIV negative
- HOPEFULLY: Level of adherence and open communication in relation to using the Ring



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Thank you.