



Barriers and Facilitators of Rectal Microbicide Use

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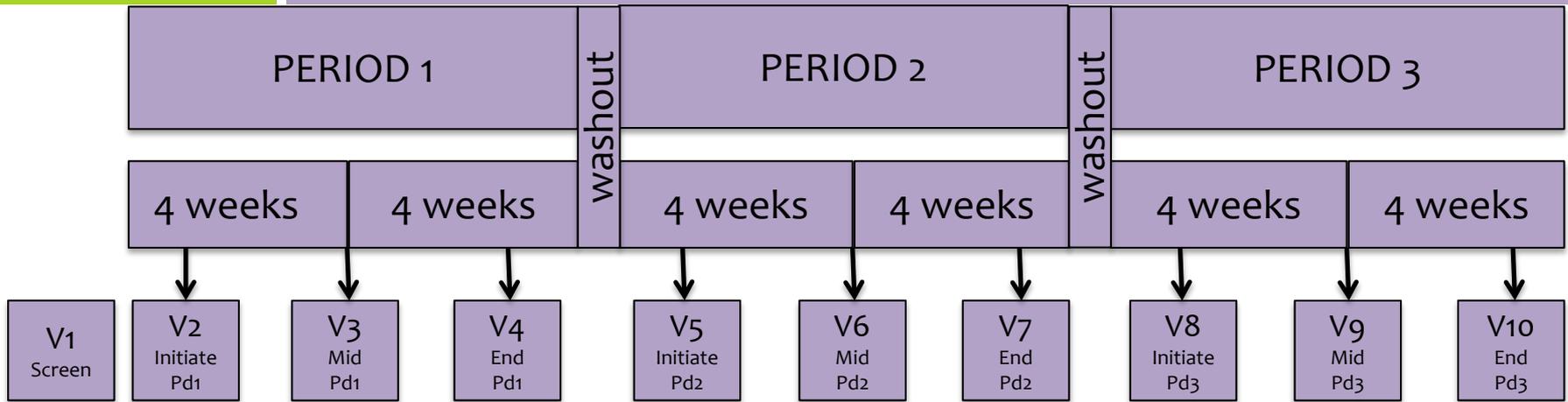
Background

- Adherence has been the Achilles' heel of HIV prevention trials
- Research to understand barriers and facilitators of microbicide use is critical
- Little research on barriers and facilitators of rectal microbicide gel use in the context of receptive anal intercourse

Barriers and Facilitators to Gel Use in MTN-017

- First phase 2 rectal microbicide gel trial
- MSM and transgender women used the gel in the context of receptive anal intercourse
- During adherence counseling sessions, participants discussed barriers and facilitators of gel use with sex

MTN-017: Study Design



Sequence	Period 1 (8 weeks)	Washout (~ 1 week)	Period 2 (8 weeks)	Washout (~ 1 week)	Period 3 (8 weeks)
1	Daily Oral		Daily Rectal		RAI Rectal
2	RAI Rectal		Daily Oral		Daily Rectal
3	Daily Rectal		RAI Rectal		Daily Oral
4	Daily Rectal		Daily Oral		RAI Rectal
5	Daily Oral		RAI Rectal		Daily Rectal
6	RAI Rectal		Daily Rectal		Daily Oral

MTN-017: Gel Use Instructions

At enrollment, participants were given applicators filled with gel and instructed to:

- insert one dose into the rectum within 12 hours before RAI and
- Insert a second dose into the rectum as soon as possible within 12 hours after having RAI or
- Insert a minimum of two doses within a 24 hour period each week if no RAI



SMS System

- At Initiate-Period visits, participants selected a convenient reminder time
- Received SMS daily at selected time requesting they report product use
- Compensation for reporting, with a bonus for reporting 6 days/week

Adherence Counseling

- Participant-centered adherence counseling was implemented at every study visit
- Counseling sessions were audio-recorded for fidelity monitoring and data analysis purposes

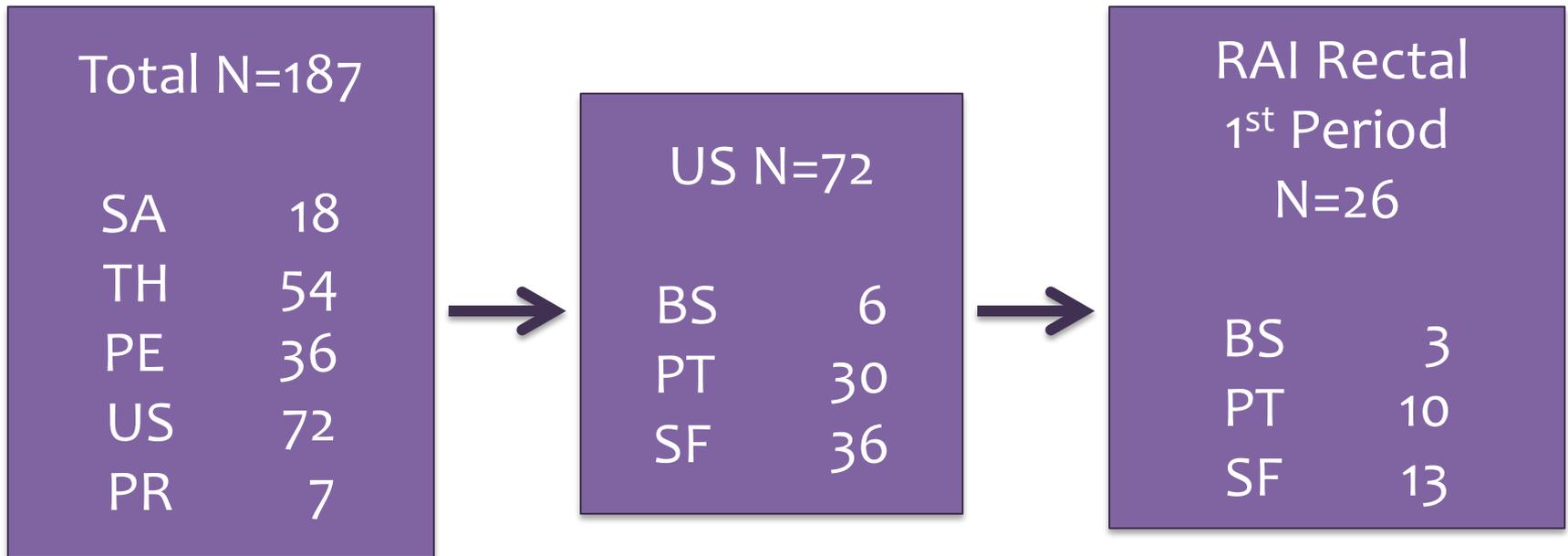
MTN-017: Adherence Findings

Adherence Level	Daily FTC/TDF Tablet (% ppts)	Daily TFV RG 1% Gel (% ppts)	RAI-associated TFV RG 1% Gel twice/week (% ppts)
≥ 80%	94%	83%	93%
100%	41%	29%	75%

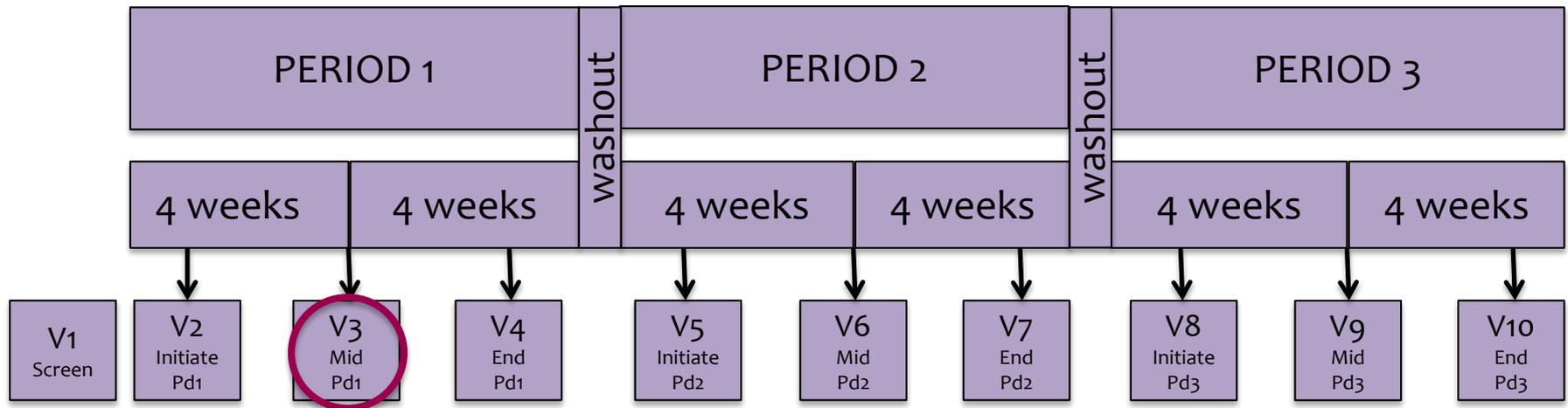
Timing of use during RAI Rectal regimen	% of RAI occasions	SD
Before and after	85%	28.6
Before	91%	22.6
After	90%	24.3
Before or after	95%	17.5

Gel Acceptability & Study Sub-sample

Country	% Liking Daily Gel	P-value	% Liking RAI Gel	P-value
South Africa	82	.002	73	.027
Thailand	85		91	
Peru	86		86	
US & PR	59		70	



Data Analysis



- Content analysis of counseling sessions
- Brief sections focused on barriers/facilitators of adherence

Adherence Counseling at Mid-Period Visit

STEP 1: Welcome participant and set structure for session

STEP 2: Review adherence data with participant

STEP 3: Explore what helped participant adhere to product use

STEP 4: Assess participant's thoughts on current adherence

STEP 5: Explore ways to improve adherence (if indicated)

STEP 6: Close the session

It's great that you were able to use the product over the past four weeks! What helped you use it on those occasions?

What are some of the obstacles that came up that kept you from using the product more regularly? What might you do to overcome this obstacle? What else?

Barriers to Gel Use with RAI



Barriers to Gel Use with RAI

Barrier	Total (N=26)	High Adherers* (N=20)	Low Adherers* (N=6)
Application Process Challenging	11	8	3
Physical Discomfort After Applying Gel	10	8	2
Difficulty with Product Dosing Regimen	10	8	2
Negative Effects of Gel on Sex	8	7	1
Disliking Applicator Design	7	5	2
Forgetting	7	5	2
Having to Anticipate Sex	5	3	2

*High Adherer ≥ 8 doses of gel per 4-week period; Low Adherer < 8 doses of gel per 4-week period

Application Process Challenging

"I just think it's kind of cumbersome and it's kind of a hassle. It [the gel] has to get in there somehow. You gotta get lubed up and bend over and it's not the easiest thing to remember to do it. To want to do it."

26-year-old man; San Francisco site; low adherence

Disliking Applicator Design

“It’s really blunt. If it was tapered or something it would be a little bit easier and I wouldn’t have to dread ... it’s one of those things where I’m like, ‘Oh god I gotta do it again.’ That’s how I feel about the product.”

33-year-old-man; San Francisco site; high adherence

“... I don't want to deal with customs in Rome asking about the applicators.”

57-year-old man; San Francisco site; high adherence

Physical Discomfort After Applying Gel

"Today I'm wearing an extra layer [of clothes]. I really feel for a woman who gets her monthly visit. [Addressing female counselor] You guys have pads for that thing. A man doesn't. And I don't know if a man would be interested in putting something on his bum to secure from that leakage."

30-year-old man; Pittsburgh site; high adherence

Having to Anticipate Sex

"If the 12-hour window were longer it would make things easier. Twelve hours is actually kind of a short time. I'm often out all day doing stuff and I might end up going out or meeting somebody that I hadn't planned on meeting 12 hours ago when I left my house. So that's a challenge."

30-year-old man; San Francisco site; low adherence

Negative Effects of Gel on Sex

“When you don't think you're gonna be having sex and then all of a sudden you're in a situation where you are gonna have sex it's kinda like, ‘Gee, can I go in the bathroom and insert this thing?’ That's a little – it can be a little awkward.”

64-year-old man; San Francisco site; high adherence

Difficulty with Product Dosage Regimen

“I pre-dose myself thinking that I'm going to have sex and then I don't have sex and I dosed myself afterward within 12 hours of the first one. And then what if I have sex the next day? Do you take one afterwards if it's been after 24 hours?”

33-year-old man; San Francisco site; high adherence

Forgetting

"Sex was always at night. It was usually the next morning when I got up, I would use it. It is post-intercourse and I think it just is like, 'Oh, I don't need to do that right now.' There is no sense of urgency except for the 12-hour timeframe. That would make it easy to miss."

57-year-old man; San Francisco site; high adherence

Facilitators of Gel Use with RAI



Facilitators of Gel Use with RAI

Facilitator	Total (N=26)	High Adherers (N=20)	Low Adherers (N=6)
Incorporating Gel Use into Routines	11	8	3
Using Gel in Anticipation of Sex	10	8	2
Taking Gel When Going Out	8	5	3
SMS Reminders	8	6	2
Ease of Gel Use	8	8	0
Commitment to Study	7	6	1
Having Gel Accessible at Home	6	5	1

Ease of Gel Use

“It didn't hurt and it wasn't a discomfort. It was very easy to open and apply. Ripping it open, the good lube, everything worked well”

30-year-old man; Pittsburgh site; high adherence

“I think it's even simpler than the stress of condom use... gel use happens prior, so the climax is not interrupted. So that's even better.”

38-year-old transgender woman; San Francisco site; high adherence

Incorporating Gel Use into Routines

"In all four cases I knew I was going to have sex because I had a date. So I knew that in the process of getting ready for the date, I was douching. And therefore it was easy after I douched. It was easy to automatically go on and use the applicator."

57-year-old man; San Francisco site; high adherence

"The second time I did it, I did it with the partner. He actually did it before and after. He did it for me...It was kind of erotic, in a sense."

39-year-old man; San Francisco site; low adherence

Using Gel in Anticipation of Sex

“It was really helpful to know that it was fine to use it even if I wasn’t entirely sure that I would have, I guess to like to say, applicable sex... So now I don’t have to get to the moment of negotiating with somebody and just be like, ‘And just a moment. I just have to go do the gel.’ So that’s useful. It’s like... the biggest tool [that you can have sex] after 12 hours.”

26-year-old man; Boston site; high adherence

Taking Gel When Going Out

“I have them in my computer bag, the overnight bag. Cause that's one less thing you have to remember ‘Oh, gotta go to the medicine cabinet. I'm gonna be gone for 3 days, better take 6 of these...’”

64-year-old man; San Francisco site; high adherence

Having Gel Accessible at Home

"I mean, I had it - keeping it close, right next to my bed and, I mean, if I did use it I would usually take out the other packet so that I would probably see it and remember it the next morning."

26-year-old man; Boston site; high adherence

SMS Reminders

“I get the text and that serves as a reminder.”

32-year-old man; Pittsburgh site; high adherence

“There was one time where I had sex later on, but I had to wake up early for work. And it was in between that time frame and it [the SMS] helped me remember - it actually kept me in check with the study.”

47-year-old man; San Francisco site; high adherence

Commitment to the Study

"The product doesn't make me happy, but I committed to it and I'm committed to the work and the people so - it's successful...I committed to it and when I commit to something I commit."

46-year-old man; Boston site; high adherence

Summary

- All participants reported barriers and facilitators
- Barriers to some were facilitators to others
 - Challenging application process vs. ease of gel use
 - Bulky, conspicuous applicator vs. portable, easy-to-use applicator
 - Hard to anticipate sex vs. happy could use gel far in advance of sex

Summary

- Barriers centered on
 - Problems with application
 - Discomforts perceived as related to gel use
 - Trouble remembering to use the gel
- Facilitators included
 - Techniques to aid with reminding oneself
 - Incorporating gel into routines

Conclusions

Future Studies

- Findings on barriers and facilitators can be used in future adherence counseling sessions for rectal gel studies
- Automated reminder systems are helpful

Product Development

- The simpler the regimen, the better
- Addressing barriers could increase marketability
- Different lifestyles and sexual routines necessitate an array of choices for HIV prevention

Acknowledgements

MTN-017 Participants
MTN-017 Study Team
HIV Center Team
Funders & Sponsors





Thank you!

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