

# AVAC

Global Advocacy for HIV Prevention

## Giving Voice to Young Women: REACH Stakeholders Consultations

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MTN Annual Meeting



# Outline

- AVAC-MTN partnership
- The importance of GPP
- Regional REACH consultation
- Follow-up national REACH workshops
- Lessons learned & next steps

# MTN-AVAC Partnership

- Jan 2011: CHOICE Consultation
- Sep 2011: VOICE Update Stakeholder calls
- Oct 2011: MTN 017 Consultation
- Oct 2011: ASPIRE Consultation
- Jul/Aug 2014: Ring/ASPIRE Roadshows
- Oct 2015: Ring/ASPIRE Stakeholder Update
- Sep 2016: MTN 034 Consultation
- Feb 2017: MTN 034 Stakeholder Update Meetings

# Putting the GOOD in GPP

GPP guidelines developed to facilitate building of effective partnerships among all research stakeholders – just as other aspects of trial conduct are informed by guidelines



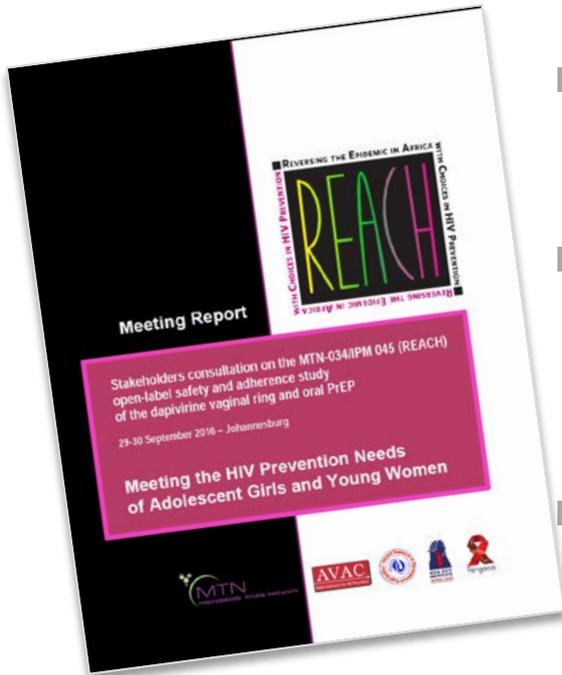
# Regional MTN 034 Consultation

- As part of the protocol development process, consultative meeting in Jo'burg 29-30 Sept 2016 with stakeholders from each trial site
  - 36 stakeholders, including 15 young women ages 16-25, 6 MTN researchers
- MTN co-hosted the meeting with AVAC in close partnership with:
  - Impact Research and Development Organization (Kenya)
  - Soul City Institute for Social Justice (South Africa)
  - Pangaea Zimbabwe AIDS Trust (Zimbabwe)
- Closed research literacy workshop for young women
- Group dinner and discussion
- All day meeting (and some dancing)





# Meeting Objectives



- Provide overview of what we know and don't know about oral PrEP and the dapivirine ring
- Solicit feedback on study design, potential concerns and challenges (e.g., legal and ethical) and ways to address these
- Consider how REACH fits into the broader HIV prevention landscape and identify communication challenges and/or opportunities
- Establish new ties and strengthen existing relationships between researchers and key stakeholders for continued engagement in each country

# Choice and Empowerment

- Overall support of the study
- Concept of choice is important and empowering
  - Neither the ring nor PrEP (or other methods) will be right for everyone
  - Young women: having choice is empowering and gives control
- Overcoming male partner control
  - Get their buy-in
  - It's time we placed our own health above our partner's desires

*Trying two products is good, I support it. REACH helps young women to have control over their health, not to depend on her sexual partner, and to be under less risk.*

*Using condoms is not so easy. If you try and negotiate, it's like you're saying you're not being faithful. [The ring and PrEP] would give me ownership. I don't have to tell my partner I'm using them.*

*If he says 'don't use it,' I won't. So, I think we should first deal with women – empower each other.*

# About the Products

- Those who'd never used the ring had notions that it would be difficult to use, comparing it to the female condom
- Former ASPIRE participants said they were unsure about the ring at first, but got more confident in using over time
- Stigma, side effects, pill size were seen as drawbacks
- Using PrEP requires commitment and perseverance



*It was easy to use ring and it was comfortable, I couldn't feel the ring. Even during my periods, it was no problem at all. During sex, I didn't have doubts about it.*

*The study team and doctor were supportive... and explained it was like brushing teeth ... We know we need to brush every day.*

“For me, I think I would be more comfortable with the ring as well because you don’t have to stress about having to swallow that—I mean even the size of PrEP for me, it’s not so cool. So I wouldn’t have to stress about swallowing the pill and I won’t even have to stress because sometimes you go to your boyfriend’s place without even planning it. Now I won’t have to stress to always have pills in my bag.”



Sinazo Peter, Johannesburg, Feb 2017 (age 25)

# About Adherence & Product Use

*I was a bit on and off when I started...but when I got information it was simple.*

*It is going to be a challenge to take the pill. Young women are out there, want to party, go to school...*

*When you hear the results, you feel embarrassed, because you had flushed the pills and said you took them.*

- “Adherence support menu” is good idea
- With ring, more support will be needed in the beginning, until confident inserting and removing and using during sex and periods
- With PrEP, sustained support will be needed: daily regimen, size of pills, side effects and stigma
- Individual adherence feedback would be very helpful – provided counselors are supportive and nonjudgmental
- With PrEP, could help overcome challenges and be motivating

# Sex, Parents and Consent

- Many of the young women liked that they would be able to make their own decisions about their health and wellbeing
- But there are risks: What if parents discovered study product at home? Assumptions of being HIV positive? Would need to lie about why they weren't coming home from school at usual time
- Should explore ways to involve parents in the study (one idea was to create a Parent CAB)
- If possible, participants should disclose to parents
- Not all young women will be able to or want tell a parent, so individual circumstances should be guide
- The kinds of measures could help prevent potential misunderstandings about the study and the risk of young women being stigmatized, chastised or harmed

# Youth-friendly & Community Support

- Make site a place we want to visit
  - Offer wifi, sports and entertainment
  - Link to drop-in centers and young women's support groups
- Include more youthful staff – young women will be more open with someone closer in age
- Hire counselors who won't be judgmental
- Target those likely to oppose the study and/or whose support was critical: parents generally, conservative religious organizations, peer groups, healthcare workers
- MTN urged to conduct additional stakeholders meetings

*Look at the type of counselors and service providers that communicate with the participant. Age difference matters.*

*A young participant cannot open up to an older counselor. If they ask – how many partners do you have, how many times did you sleep with them? I cannot say 10!*

# Reaching Young Women

- Involve youth before and throughout the study – youth CABs could help bridge gap between sites and young people in communities
- Consider ways to involve males to ensure they are aware of and understand the study
- Partner with NGOs that provide support – to help address social /structural factors that could undermine adherence
- Use both traditional and social media to reach potential participants and gain acceptance of peers
- Consider celebrity endorsements, such as Beyoncé and Bonang



# After the consultation...(from MTN)

- Feedback received validated study design & ensured inclusion of adherence results to participants at set time points
- MTN discussions with NIH about a parental waiver and informed consent
  - Informed consent and parental permission forms are now about 8 pages – down from the usual 15-16 page template!
  - Assent form (for under age 18) is just 4 pages
  - Cannot pursue a parental waiver - U.S. regulations do not permit for studies involving an Investigational New Drug (IND) (i.e. dapivirine ring)
- Protocol submitted to PSRC on 12 Dec. 2016, received approval 22 Dec., and NIH Regulatory Affairs approval 6 Feb 2017
- Sites received the final protocol (Version 1.0) 6 Feb. 2017 to begin preparations for submission to IRB/ECs, in-country regulatory and readying the site for study activation

# Follow-up Meetings

- Feb 23 & 24 2017: Zimbabwe Update meeting, Harare (AVAC, MTN & PZAT)
  - 38 stakeholders: young women, youth CAB, seasoned advocates, NGO reps, Review Boards and researchers.
  - Research literacy pre-workshop for young women followed by site visit
- Feb 28 2017: South Africa Update meeting, Johannesburg (AVAC, MTN & Soul City)
  - 37 stakeholders: young women, youth CAB, seasoned advocates, NGO reps
  - Workshop at Wits RHI, site visit, special session with CAT

# Objectives of Follow-up Meetings

- Provide update on study design and how feedback was incorporated
- Seek views on contraception requirements esp LARCs
- Identify key concerns and challenges for engaging adolescents in REACH and possible solutions to overcoming these
- Consider ongoing ways to provide feedback during the trial



# Thoughtful questions & feedback

“Can I put on my ring today, have sex, and experience protection the same way a person who has had it for two weeks does?”

“I have a concern on policies not aligned with each other, for example, termination of pregnancy in South Africa where a 12 year old can ask for that service but cannot be in the REACH study.”

“I was in ASPIRE for 2 years. When I started using the ring for the first time, it was inserted at the clinic. The day I went home with the ring, I thought my marriage would be doomed. I was surprised that we had sex and nothing happened. It did not feel any different from the sexual experiences I had with my husband before.”

“How about disabled young women? How are we involving them in these programmes? They need PrEP as much as we do”

“What happens to us after the study? Will you give us the products or just leave us?”

“When the ring and PrEP was talked about, I did not hear mention of sex workers and it seemed the study was not for them, yet I thought sex workers are most at risk. Why were they not targeted and involved?”

# Parents: can't live with them or without them

"There is need for parents to change their mind sets and begin to acknowledge that young people are engaging in sex. As a parent, I may be educated and empowered but honestly speaking, if my daughter leaves her bag unattended, I will go through it to check for any signs of misbehaviour! It will take time for parents to really appreciate this PrEP and ring issue"

"How about when I am at home with my parents? Even if I am an empowered woman, I am not comfortable with my parents finding out that I am on PrEP"

"I really feel that our parents were supposed to be at this meeting with us. Anything about our parents, without our parents is against our parents"

"Imagine my mother telling my pastor that my daughter has a ring inside her! It will cause problems because before you know it, my pastor will tell my mother that this is a form of satanism. I really think that it is necessary to include religious leaders in consultations on PrEP"

As a CAB member in my community, I asked parents who sit on the board in our last meeting, whether they would support their children's participation in the PrEP study. They all refused and told me that if they agreed, it meant that they are encouraging young people to have sex. I am worried"

# Packaging and Privacy

“Can we use pill boxes that have pretty colours? They are discrete because they have no labels”

“I am a student in a tertiary institution. Many people visit me in my room, even boys. When they see that bottle, they will think I am HIV positive”

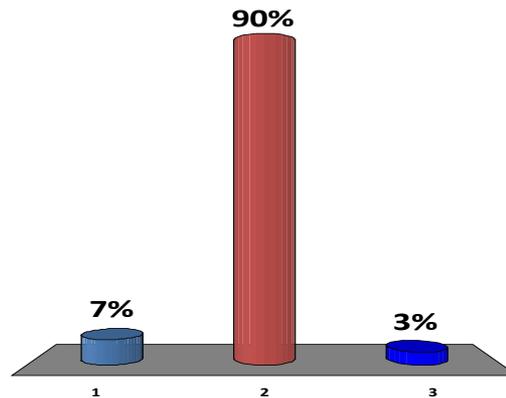
“I complained about PrEP to my service provider because I was not happy with the size of the bottle. He simply emptied them into a plastic bag and handed them to me. Was that ok?”

The fact that we have to go to the site is problematic because of stigma. I think there should be some ways where we can get the tablets and all without going to the site. The moment my parents hear I was at site, there's are you sleeping around or what”.

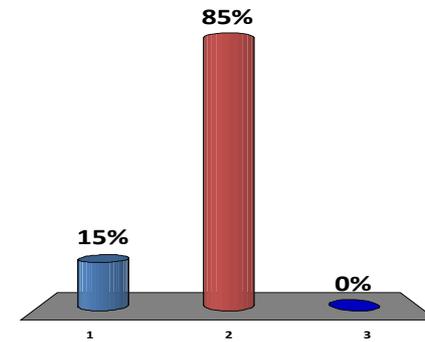
# Discussion on Contraception (1)

## South Africa

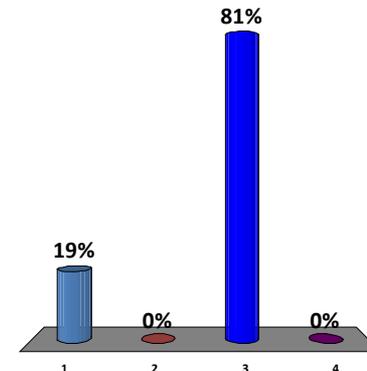
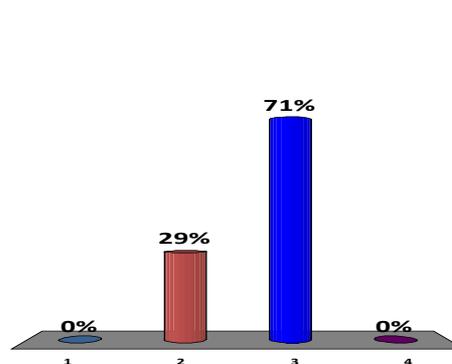
In REACH, investigators should:



## Zimbabwe



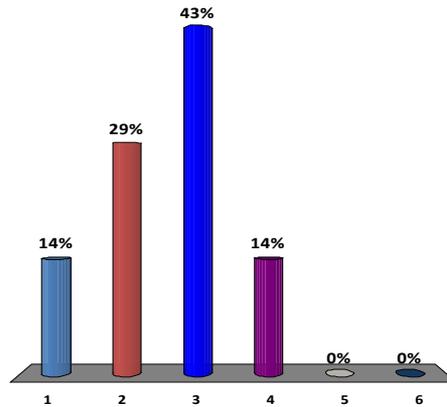
What, in your opinion, is the most important aspect of contraceptive counselling?



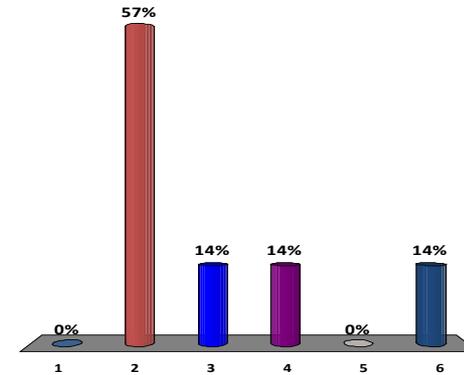
# Discussion on Contraception (2)

## South Africa

What do you think their biggest fear is concerning the implant?

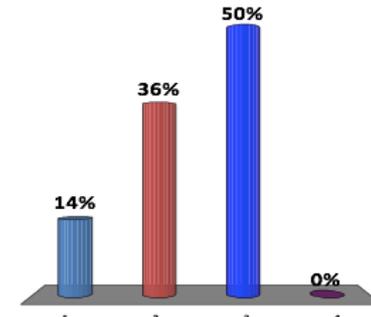
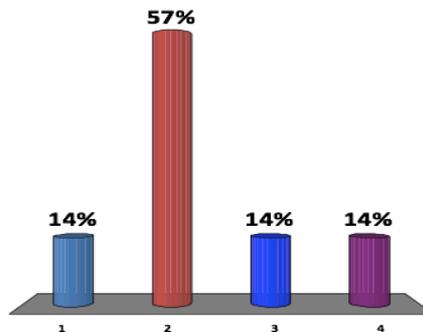


## Zimbabwe



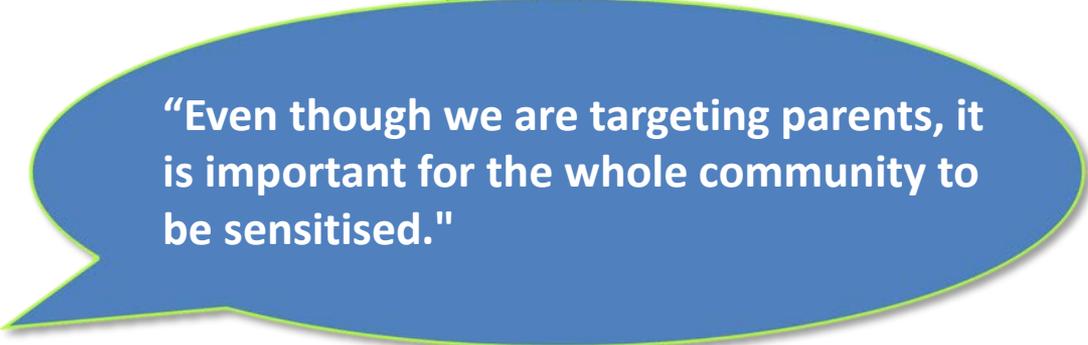
Suppose you went to your nearest family planning clinic and requested an IUCD. What do you anticipate the response would be?

1. No. You are too young for contraception
2. No. You are too young for an IUCD
3. Sure!
4. Are you certain? Insertion will be painful.



# Involving Parents and Guardians

- Engage parents in study sensitisation meetings
- Information sheets which young people can present to their parents prior to their enrolment on the study
- Engage church leaders through dialogues
- Empower young women to articulate their needs to participate in the study, at home
- Creating linkages between health service providers and parents e.g. through DREAMS study



**"Even though we are targeting parents, it is important for the whole community to be sensitised."**

# Talk Contraception & Address Myths

- For high school students: use existing materials and training teachers on contraception
- For out of school youths: edutainment and making use of peer educators
- For youths in tertiary institutions: drama and arts
- For parents: WhatsApp groups

**“When using social media to disseminate information on contraception, caution must be applied, because there is a risk of personal information being leaked e.g. through shared screen shots of messages or emails”**

# Strategies for Engaging Youth

- Community buy in: community dialogues and consultation meetings
- Youth advisory board to review communication materials including the study protocols
- Opinion leaders or arts ambassadors to champion participation of young women in REACH
- Continuous consultation of young people
- Collaborating with youth orgs to address other social & economic problems young people face
- Youth friendly, e.g. making Wi-Fi available

# It's Not Just About Age...



“We really need those 50 year old doctors to be young at heart, because it may not be possible to get a 19 year old doctor. But it is wonderful to interact with a service provider who adapts to our needs and language as young people”

# Lessons Learned

- Ongoing engagement and mentoring – and never just a single meeting
- And not just about products
- Working with local partners with equal footing imperative to building ownership, trust and respect
- Fewer PPTs; more interactive exercises and lead time for discussions
- Take lots of photos and have fun energizers
- Have a formal dinner or reception so everyone can dress up & socialize
- Listen and take comments seriously
- Provide easy factsheets
- Critical to have young people there from various backgrounds
- Pre-meeting research literacy workshop & mentoring facilitates engagement
- Feedback: For the next consultations, *“you don’t have to come from the US. We can have local researchers”*

# Next Steps & Recommendations

- AVAC committed to work with MTN on Kenya follow-up workshop and ongoing engagement in all countries for this study
- Jointly developed concept for ongoing engagement and mentoring of meeting participants – at their request
- Build on this model for future consultations – within MTN and, ideally, across all px trial networks – ensuring that comments and suggestions are carefully considered in advance of protocol development and on an ongoing basis
- Recommendation: consider a young woman to be part of the protocol committee, ensure she has mentoring to engage

# The last word...



Anelisa Madalene,  
Johannesburg, Feb  
2017 (age 18)

“I love the fact that our researchers are so friendly. They aren’t telling us what we should be doing. We are telling them what they should be doing. Because now we are given a platform where we have to be ourselves. We have to complain – I don’t like this, I like. And as young people we know we are, we are so much... we are so complicated. Yeah, I’ll put it like that. And the fact that whatever we are saying is taken note and the feedback is so lovely, it’s really motivating and I’d love every young person to hear whatever we have to say. I would love for them to be a part of this because this is going to help us, this is for our future. Not only us but the next generation, this is going to continue. And it’s only going to start only when we know what we want.”

# Acknowledgements

- First and foremost, the young women who participated in these sessions – giving their time, energy and honest feedback, teaching us all so much, and, most of all, how to listen
- MTN – and their funders NIAID, NICHD & NIMH
- Bill & Melinda Gate Foundation
- USAID through their support of AVAC through the Coalition to Accelerate & Support Prevention Research (CASPR) and the previous Microbicides Access and Introduction Stakeholder Group
- Impact Research & Development Organization
- Pangaea Zimbabwe AIDS Trust
- Soul City