Feedback: Then and Now

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Meeting the HIV Prevention Needs
of Adolescent Girls and Young Women
Zimbabwe Stakeholders Meeting on REACH
24 February 2017, Harare

About the meeting

- As part of the protocol development process, the MTN held a consultative meeting in Johannesburg 29-30 Sept 2016, to seek input about REACH from stakeholders from each of the trial site countries
  - The meeting was attended by 36 stakeholders, including 15 young women ages 16-25 , and 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

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AVAC Global Advocacy for HIV Prevention

Impact Research & Development Organization

SOUL CITY INSTITUTE FOR SOCIAL JUSTICE

Pangaea










Meeting objectives

- Provide overview of what we know and don't know about oral PrEP and the dapivirine ring, especially in adolescent girls and young women.
- 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.

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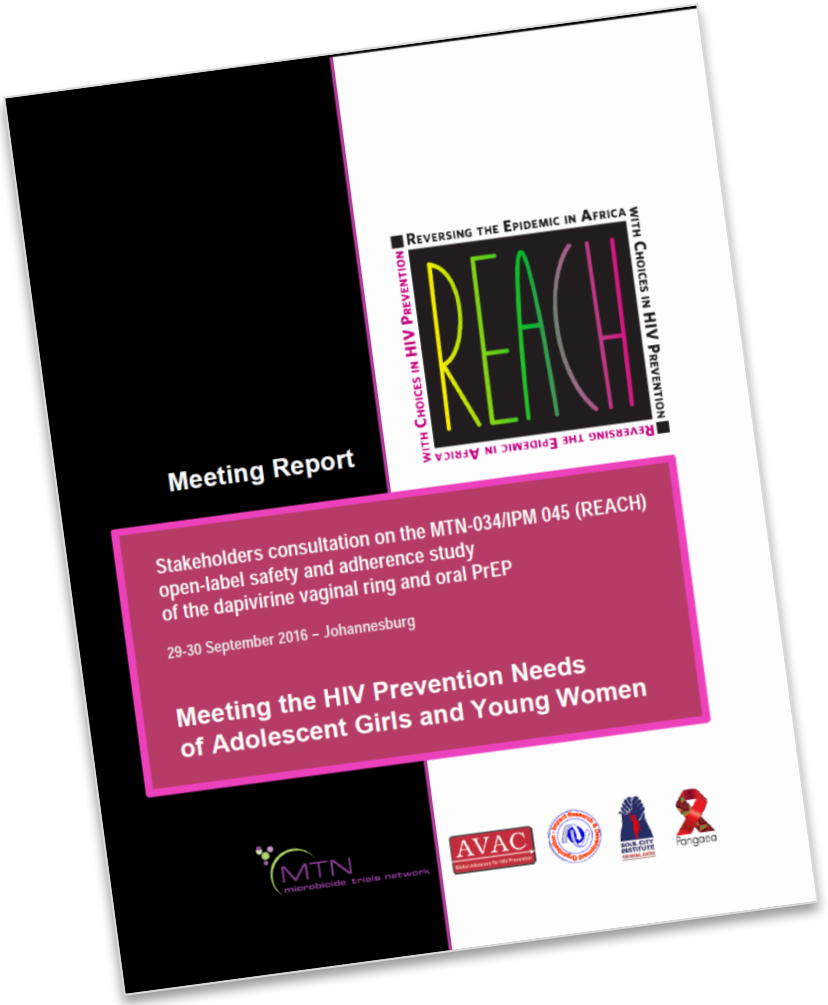
What did we hear??



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Choice and empowerment

- There was 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; gives them control of their health and lives
  - The products in REACH are themselves empowering
- 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: The ring

- 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.

When I first saw it, it was like, WOW!

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.

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About the products - PrEP

- Stigma, side effects, pill size were seen as drawbacks
- Using PrEP requires commitment and perseverance

I had side effects … the first few days – stomach aches, headaches, sleeping – and had to stop taking it because I had to study.

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

Once the body gets used to the pill it becomes easier. So, it depends on determination and if you feel it will benefit you.

The pill is too big and you must take it every day like a person who's HIV-positive.

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About adherence and product use

- The “adherence support menu” is a good idea

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…

- With the 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
  - A daily regimen is difficult and can get in the way
  - The size of the pills, side effects and stigma of ARVs will be challenges

Providing individual adherence results

- Individual adherence feedback would be very helpful – provided counselors are supportive and nonjudgmental
- With PrEP, could help overcome challenges and be motivating

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

Look, the pills are too large, and there are side effects when you start them. But if the nurse were to tell me the results and explain ways to take it well, that would be good.

It would be good to know if I'm protected. That would motivate me to take it every day.

Sex, parents and consent

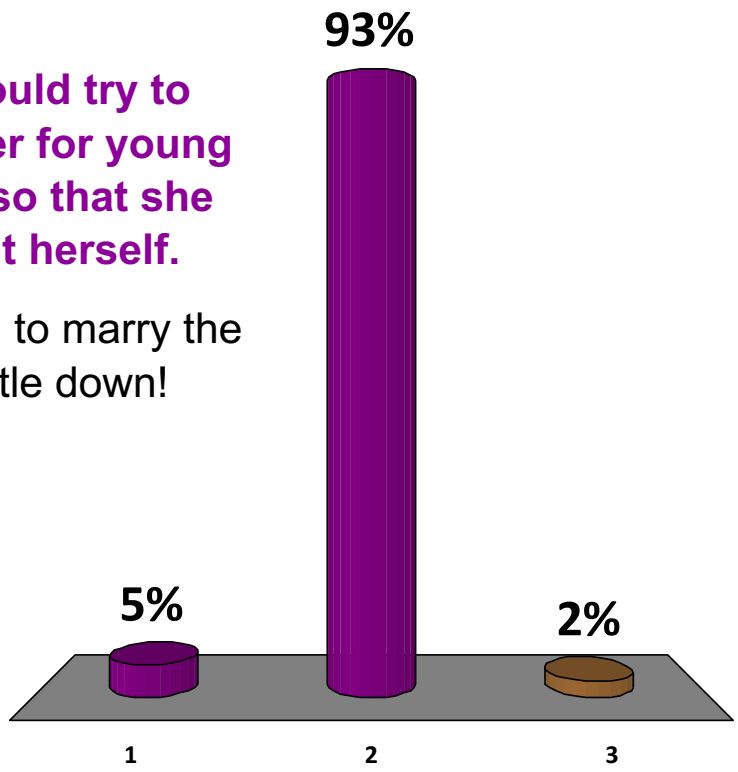
- Must have experienced sex to qualify for the study, but if under age 18, must also have a parent's permission to enroll
  - Will be difficult for most girls to admit they are having sex
  - Cultural and societal beliefs are non-accepting of premarital sex
  - This means girls who are motivated to join the study – and who are at high HIV risk – may not be able to
- Clinical trials can sometimes receive a waiver from the IRB/EC if there is obvious benefit
  - Parental consent not required; adolescent can enroll on her own
  - HPTN 082 - a PrEP study involving girls ages 16-25 - received a parental waiver

Stakeholders strongly supported us seeking a parental waiver

Scenario 1: Support for parental waiver

Nonku is a 17-year-old living in Cape Town, South Africa. She is living with her mother but she already has a 9-month-old baby. She currently has a boyfriend who she has been with for 1 year. She wants to enroll in REACH but she says that she does not want to talk about it with her mother yet. She is under 18 so under South African law she cannot participate in a clinical trial without parental consent.

1. Nonku should not be allowed in the study unless she brings her mother into the site.
2. **The clinical site should try to get a parental waiver for young women like Nonku so that she can provide consent herself.**
3. Nonku should be told to marry the baby's father and settle down!



Views on parental waiver…

- Many of the young women liked that they would be able to make their own decisions about their health and wellbeing
- But there were risks
  - What if parents discovered study product at home?
  - Assumptions of being HIV postive
  - Would need to lie about why they weren't coming home from school at the usual time
- How should the study protect young women from potential harm?

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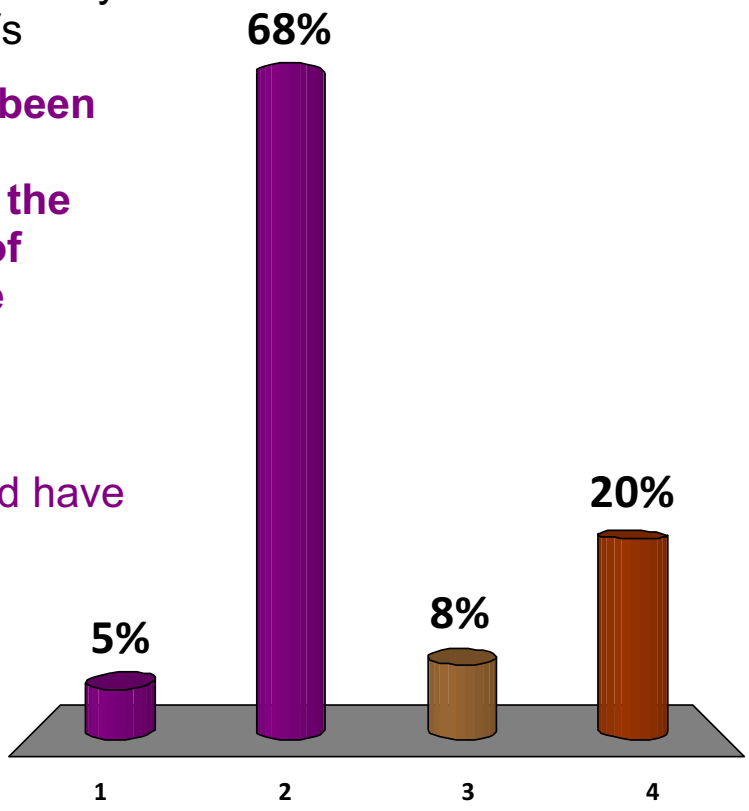
Scenario 2: Need for community sensitization

Leila is 18 has joined the REACH study and her mother does not know about her study participation. Leila's mother is very religious and does not agree with Leila's decision to be sexually active. Leila's mother finds her study product and accuses her in front of the entire family of being HIV positive. She is beaten and has to go to the hospital.

1. The pills and rings should have been provided in different packaging so they did not look like ARVs
2. **There should have been more community sensitization about the study with people of Leila's parents' age**
3. Nothing could have prevented this.
4. Leila's parents should have been included in the consent discussion.



If and how to involve parents?

- Should explore ways to involve parents in the study
- If possible, participants should disclose to parents that they are in the study
- Not all young women will be able to or want tell a parent, so individual circumstances should be the guide.
  - In such cases, participants would be urged to disclose to another trusted adult
- One idea was to create a Parent CAB
- The kinds of measures could help prevent potential misunderstandings about the study and the risk of young women being stigmatized, chastised or harmed.

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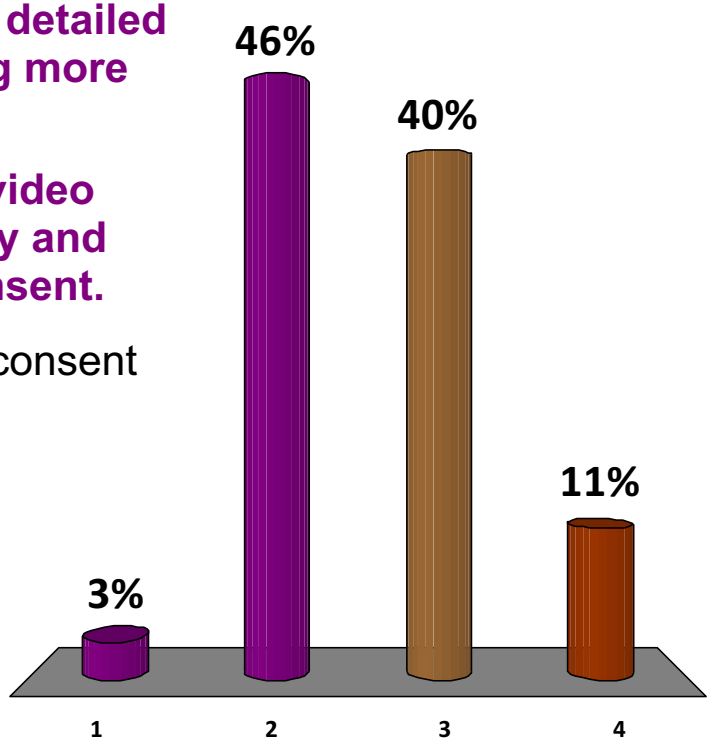
Views on the Informed Consent Process: Simplify and Shorten!!

Pretty is an 18 year old woman from Kisumu who comes to the clinic because she had heard about PrEP in the community and she wants to know more. She is interested in the study when it is described to her, but when she is provided with the consent form she is alarmed because it is 12 pages long and lists many risks with using PrEP, including bone loss and kidney damage. She is also worried about "fat changes"

1. These products are safe, so we don't really need to talk about risks.
2. **We should provide a much simpler 2-3 page consent and provide a more detailed brochure containing more information.**
3. **We should make a video presenting the study and then ask for the consent.**
4. We should keep the consent the way it is.



Make it youth-friendly

- Make the site a place they would want to go
  - 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

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!

Target communications for community support

- Communications and community engagement should aim to create a supportive environment for the study.
  - MTN urged to conduct additional stakeholders meetings
- Target those likely to oppose the study and/or whose support was critical:
  - parents generally
  - conservative religious organizations
  - peer groups
  - healthcare workers
  - males

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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

Then what happened?

After the consultation…

- Feedback received validated the study design and ensured inclusion of key aspects, such as provision of adherence results to participants at set time points
- MTN had many discussions with NIH about a parental waiver and the lengthy informed consent process
  - 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) – an experimental product that has not been approved.
  - While Truvada is approved for PrEP in some countries the dapivirine ring is not a licensed product

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Moved quickly to NIH approval

- Stakeholders meeting took place 29-30 Sept. 2016
- Protocol submitted to Prevention Sciences Research Committee (PSRC) on 12 Dec. 2016, with lengthy cover-letter explaining rationale
- Received PSRC approval 22 Dec. 2016, DAIDS Medical Officer sign-off on 4 Jan. 2017 and NIH Regulatory Affairs approval 6 Feb 2017 – very fast
  - No revisions were requested and no review needed
- 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

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Questions and Discussion