



Welcome & State of the Network

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MTN Regional Meeting, September 2019, Cape Town

Welcome to the 2019 MTN Regional Meeting



Opening Thoughts

- Some considerations: **options vs. choices.**
- What are our **challenges** as we await the regulatory opinions?
- **Where are we** today with our work?
- Reflecting on **who we are** and **what we do.**

Options vs Choices

- **Options** are the things and **choices** are our decision.
 - A condom is a prevention option
 - Using condoms is a choice (but often not a choice that women get to make)
- **Options** are fixed and **choices** aren't.
- ***Option** is a noun for a thing and **choice** is a noun for your decision.*

Choices



Pill



Vaginal ring



Injectable



Vaginal/rectal
inserts



Vaginal films



Vaccine

- People's preferences and needs are not all the same
 - What matters is what people will use and what can be delivered – safely, cheaply, easily
- People want **options** ... so they can make **choices** ... so they can be **free of HIV**

How do we misinterpret Options vs Choices?

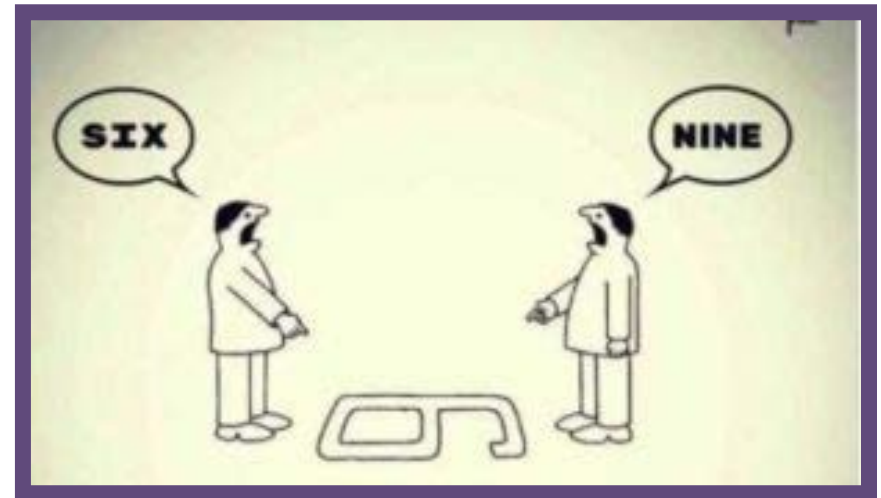
- When the Contraceptive Action Team was established, its objective was to diversify the number of contraceptive *options* at each site
- What was available across sites:
 1. Injectables
 2. Oral contraceptives
- With limited *options*, most (>70%) women chose *injectables*

How do we misinterpret Options vs Choices?

Two possible interpretations of predominant use of injectables:

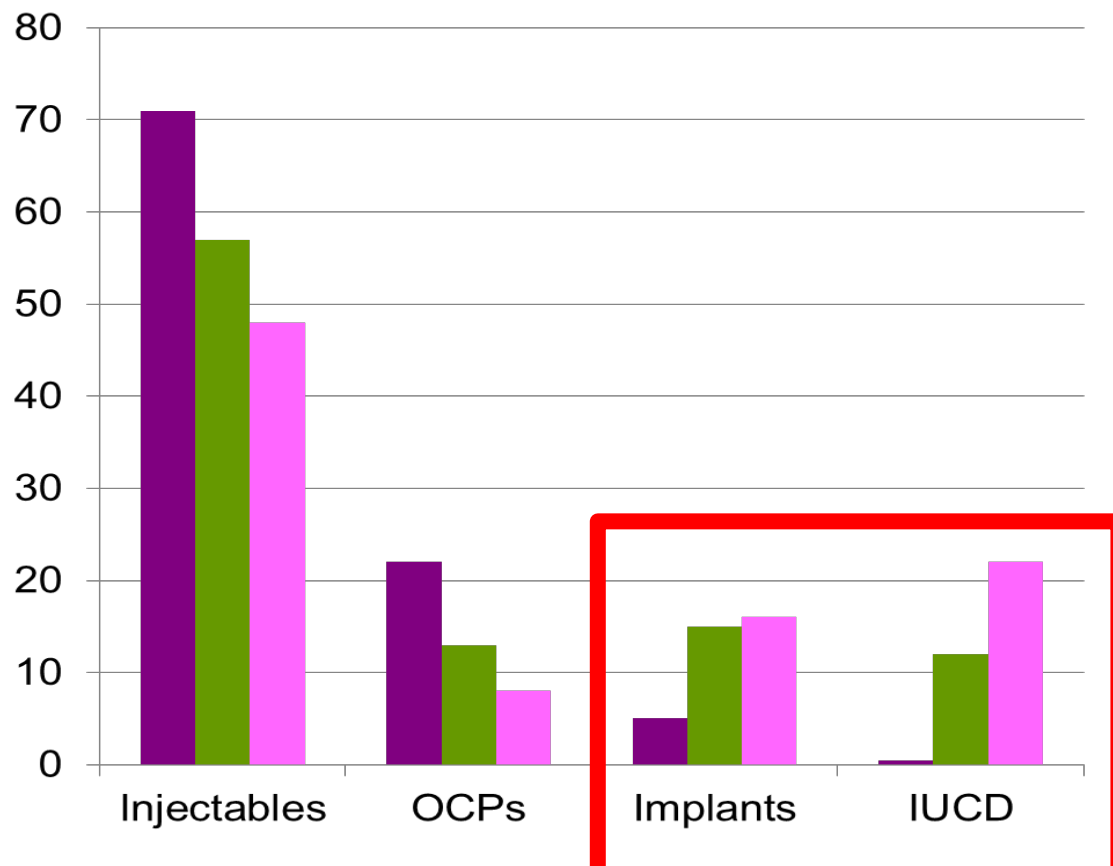
1. Women really love injectable contraceptives
2. Women did not have many options, so they chose injectables

*Same information,
different interpretations*



More Options/Different Choices

When at least 4 contraceptive *options* were available at each site, women *chose* differently



Increase in LARCs to 40% in ASPIRE from near 0% in VOICE

In HIV Prevention

More Options/ Different Choices

- In HOPE, women had the *option* to join/not join the study **and** to accept/not accept the ring
- In OPTIONS counseling women could *choose* or *not choose* the ring
 - This was a new concept.
- For the first time, we are just now beginning to really evaluate **choice** in MTN-034 (REACH)

Try each option, then choose

6 months
once a month



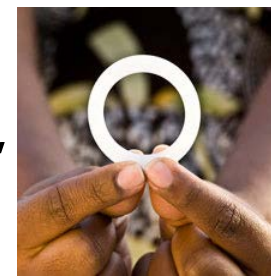
6 months
once a day



→ 6 months



or



→ 6 months



once a day
6 months



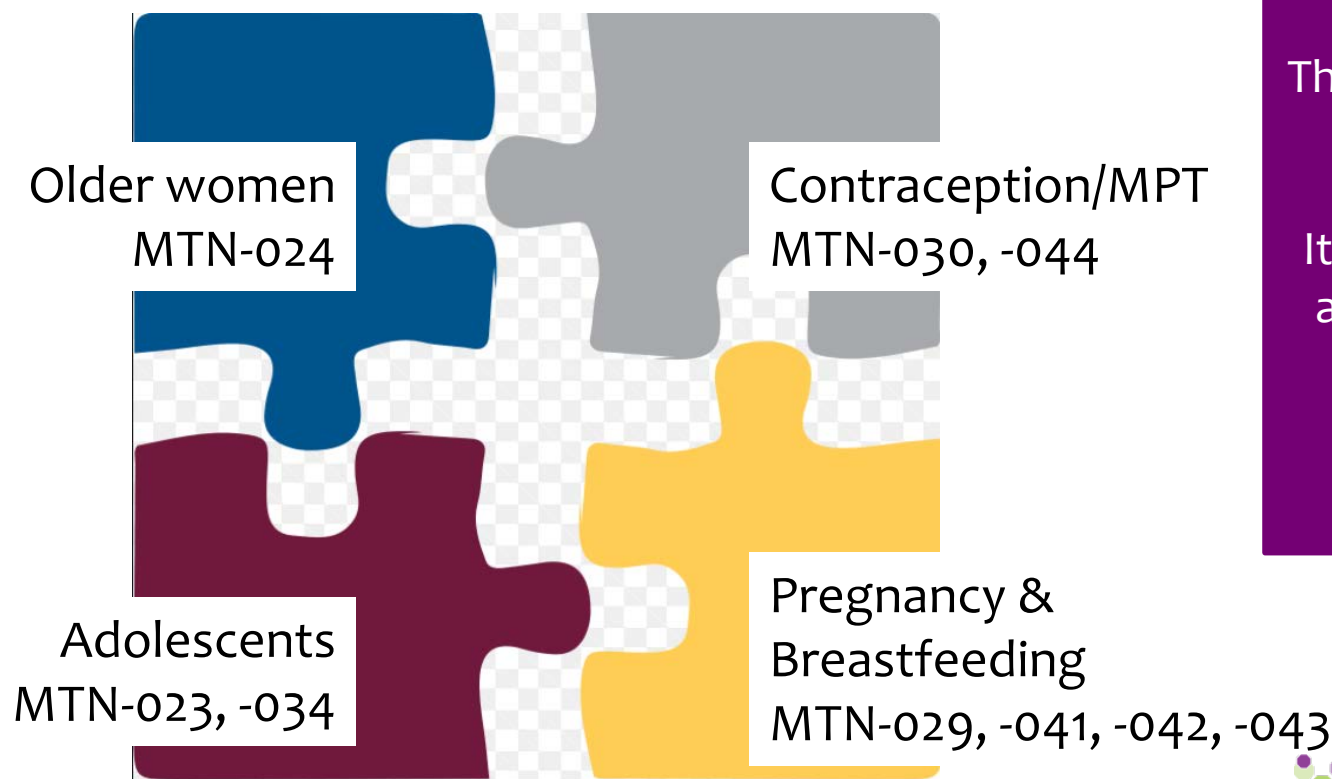
once a month
6 months

In addition to choice, we are learning more about safety

- We will learn more about the ring
 - in young African women in REACH (MTN-034)
 - For women who are pregnant in Deliver (MTN-042)
 - For women who are breastfeeding in B-Protected (MTN-043)

Pieces of the puzzle for dapivirine ring

Phase III, IIIb MTN-020, -025



Other safety MTN-012, -013, -036

This has taken years and years of dedication.

It is still only early days and we have so much more to do!

Challenges:

what is the status of ring approval?

- The dapivirine ring regulatory approval process continues to move forward
 - Under review at the EMA
 - S African submission regulatory submission ahead
 - FDA submission planned in the next months
- Remember: *The dapivirine ring substantially reduces HIV risk when used*
- While vaccine, antibodies and injectable cabotegravir studies continue in men and women, the regulatory approval of these products if proven to be successful are years away so we still need the ring!

Where are we with our work?

So much has happened this year!:

- Completion of HOPE and reporting of the results at IAS in Mexico City
- Launch of REACH – about 33% enrolled and good adherence to study products
- Poised to launch key, wrap-around studies of the ring in pregnancy (MTN-042) and lactation (MTN-043)
- Preparing to launch MTN-035 (Desire) in Malawi and Blantyre
- Preparing to launch MPT study (MTN-045) in Kampala and Zimbabwe

Lots on Many Plates!



The Work On Our Plates

- MTN-015 & 016: final reporting of HOPE outcomes to IPM/EMA/FDA/SAPHRA
- MTN-017: Clinical Study Report (in development)
- MTN-020: Trial Master File and regulatory inspection support
- MTN-023: Completion of publications (CSR completed)
- MTN-025 (HOPE): CSR and TMF
- MTN-026 and 033: Data analysis, publication and CSRs (DAIDS IND)
- MTN-034 (REACH): Approximately 33% enrolled.
- MTN-035: Enrolling.
- MTN-036: Data analysis and publication
- MTN-037: Data analysis, publication
- MTN-038: Data analysis, publication
- MTN-039: Pending activation
- MTN-041: Data analysis and publication
- MTN-042: Pending activation
- MTN-043: Pending activation
- MTN-044: Data analysis, publication
- MTN-045: Pending activation

Fast, Flexible, Efficient, Laser-Focused on Our Mission

September 2019

November 2020



Enrollment complete April/May 2020. Follow-up into 2021

Complete enrollment early 2020, complete study Q3 2020



MTN-039 to launch in the US and complete in Q3



First and 2nd cohort enrolled by Nov 2020; pass off to HPTN?



Enroll 200 mother-infant pairs by end of 2020

MTN-045 to complete in Uganda and Zimbabwe

Who we are: filling gaps



- New infections far outpace goals
- Needs are especially unmet for women, persons of color, trans, youth

Who we are: relentless science



Who we are: relentless science



Who we are: choices that fit people's lives



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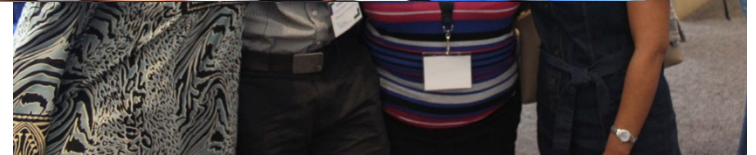
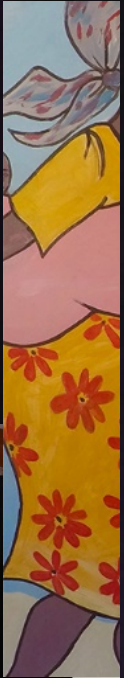
Vaginal films



Vaccine

- People's preferences and needs are not all the same
 - What matters is that people will use and what can be delivered – safely, cheaply, easily
 - No magic bullets – just real deals

Who we are: people





Who we are: people & their lives



Science & People to Advance HIV Prevention



State of the Network



Welcome!

