



What's next with the dapivirine ring?

Lisa Rossi

Microbicide Trials Network

2018 AVAC Partners Forum

Johannesburg, South Africa – 14 February 2018

Our work is not done

- **We want to learn more about attitudes about and use of the ring**
 - MTN-032 – Assessment of adherence in ASPIRE and HOPE
- **We want to learn more about the ring in high-risk populations**
 - Adolescent girls and young women – REACH (MTN-034/IPM 041)
 - Pregnant and breastfeeding women – MTN-041, MTN-042, MTN-043
- **We want to evaluate the next generation of the dapivirine ring**
 - 3-month ring (MTN-036 / IPM 047)
 - Dual-purpose ring (MTN-030/ IPM 041, MTN-044)

Adolescent girls and young women



Why REACH?

We need to see that PrEP and the ring can work for and be made available to adolescent girls and young women ... *How?*

- By understanding how to help young women use these better
- By collecting more safety information on PrEP and the ring so that drug regulatory authorities can consider expanding approval for girls under 18

Reversing the Epidemic in Africa with Choices in HIV Prevention

REACH at a Glance

- Designed to answer these and other questions:
 - Are PrEP and the ring safe and acceptable in girls and young women?
 - Are they willing to use these products?
 - Which one do they prefer?
- Will enroll 300 girls and young women ages 16-21
- 5 trial sites in Kenya, Uganda, South Africa and Zimbabwe – to begin 2Q 2018



Pregnant and breastfeeding women



MTN-029/ IPM 039

- Conducted in 16 US women who were still able to produce milk but were no longer breastfeeding
- Women used the ring for 14 consecutive days
- Very small amount of drug found in breastmilk

Three studies now being planned to take place in Africa

Three studies being planned

4 sites – Malawi ,Uganda, South Africa, Zimbabwe

MTN-041

- To understand views about use of the ring and oral PrEP during pregnancy and breastfeeding among:
 - Women currently breastfeeding or pregnant
 - Male partners
 - Health providers, midwives, social service providers, local leaders
- Expected to start next month

MTN-042

- Will assess safety and PK of ring and PrEP in pregnant women in step-wise fashion – in early stages of development

MTN-043

- Will assess safety of ring in breastfeeding women

Next generation dapivirine rings



A ring used for 3 months

MTN-036 / IPM 047

- Phase I safety and PK study underway in the US of a ring containing 200 mg of dapivirine used 3 months
- Will enroll 36 women

Preventing both HIV and pregnancy

MTN-030 / IPM 041

- PK and safety of rings containing 200 mg dapivirine and a hormonal contraceptive - levonorgestrel - used for 14 days
- Enrolled 24 women at US sites
- Study completed – results most likely at HIVR4P

MTN-044

- Will look at 90-day use among 24 women in US
- Expected to start in 4-5 months?



Thank you