



Welcome & State of the Network

Sharon Hiller & Jared Baeten

MTN Annual Meeting, February 2019, Washington

Welcome

There is much to celebrate in HIV prevention in 2019

- global expansion of PrEP, ART, VMMC
- more research than ever into new prevention products (topical, systemic, vaccine) & how to deliver them
- new commitment in US to end HIV/AIDS by 2030

State of the Network



Funding Opportunity Title

HIV Prevention Clinical Trials Network Leadership and Operations Center (UM1 Clinical Trial Required)

Funding Opportunity Announcement (FOA) Number

RFA-AI-19-005



State of the global epidemic

36.9 million
people living with HIV
[31.1 million – 43.9 million]



1.8 million

people newly infected
[1.4 million – 2.4 million]



0.9 million

HIV-related deaths
[0.7 millions – 1.3 million]

Source: UNAIDS/WHO estimates

Great success in treatment but....

- The success in treatment has not been matched with equal success in **reducing new HIV infections**.
 - HIV prevention services are not being provided on an **adequate scale** and with **sufficient intensity** and are **not reaching the people who need them the most**.
 - **Women and girls continue to be disproportionately affected**.
 - Stigma and discrimination still have terrible consequences and impede our outreach to **men who have sex with men, sex workers and transgender people**

“There is a HIV prevention crisis.”

- Michel Sidibé UNAIDS Executive Director, 2018

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: choices that fit people's lives



Pill



Vaginal ring



Injectable



Vaginal/rectal inserts



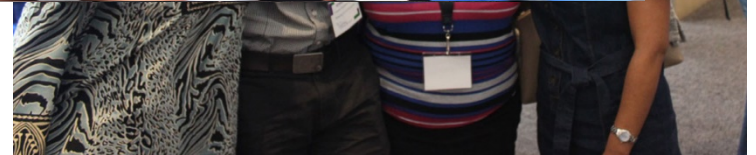
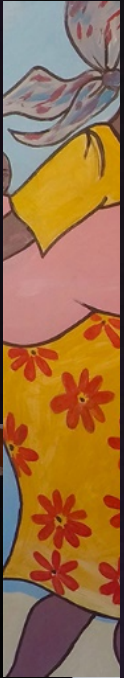
Vaginal films



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



We are doing a lot

Since we saw each other here last year, much has happened:

- EMA inspections in Cape Town, Kampala, and Washington & continued progress in EMA review of the dapivirine vaginal ring (w/ SAHPRA, FDA next)
- Completion of HOPE
- Launch of REACH !
- Poised to launch key, wrap-around studies of the ring in pregnancy and lactation
- Robust set of studies laying the groundwork for the rectal microbicide agenda

Dapivirine ring

HIV-1 incidence = 4.1 (95% CI 3.2-5.1)

MTN-020/ASPIRE placebo
EXPECTED

54% reduction
P=0.01

HIV-1 incidence = 1.9 (95% CI 1.0-3.4)

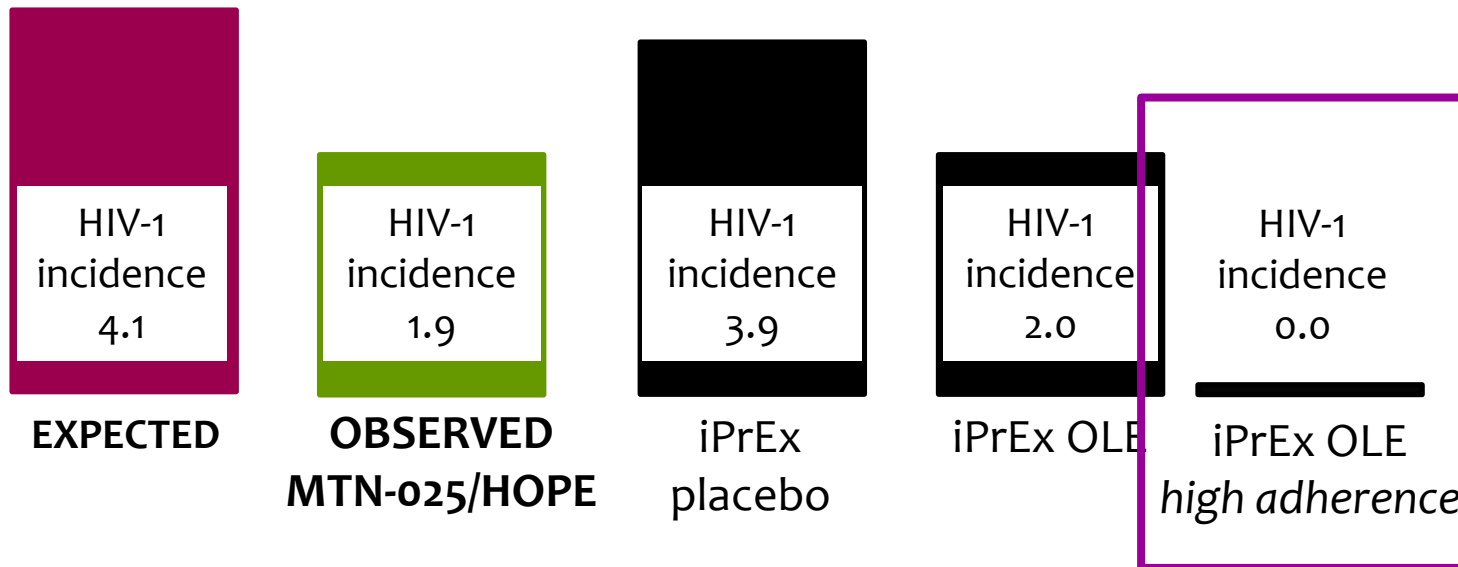
MTN-025/HOPE
OBSERVED

The dapivirine vaginal ring is poised to offer a new prevention option



HOPE and the Story of PrEP

- The HIV-1 incidence observed (CROI 2018, final #s pending) in MTN-025/HOPE compares favorably to that seen in prior open-label extension studies, for example iPrEx OLE:



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How Good is the Ring if You Use It?

(Elizabeth Brown)

Lessons from HOPE

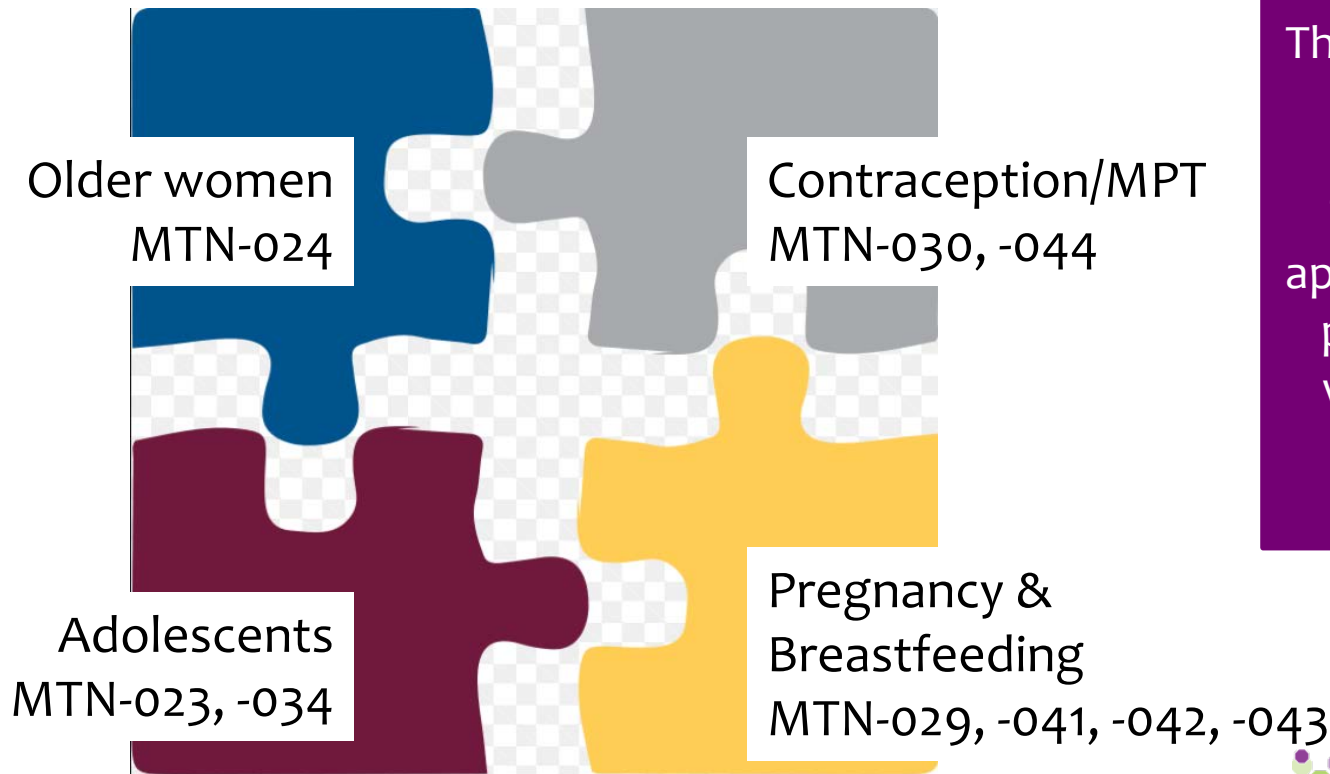
(Thes Palanee-Phillips & Nyaradzo Mgodzi)

HIV Prevention 2019

(Mitchell Warren)

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.

This comprehensive approach is essential for products to work for women in their lives.

Prevention in real life

- For women, prevention options have to work & be workable
 - in pregnancy & lactation
 - with & without contraception
 - younger & older



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PrEP in Pregnancy

(Jillian Pintye)

DELIVER and B-Protected

(Katie Bunge, Lisa Noguchi, Jen Balkus)

Optimizing Counseling Fidelity

(Iván Balán)

Prevention options for young people



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Prevention for Youth 2.0

(Lisa Hightow-Weidman)

Persistence and Autonomy

(Dominika Seidman)

REACH

(Lulu Nair & Kenneth Ngunjiri)

Science at the Cutting Edge



- We are potentially standing on the cusp of a new prevention product, w/ more on the way
 - Discrete, person-controlled, well-tolerated, desired
 - Supported by rigorously-done, collaborative, multinational work

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The Case for On-Demand Prevention

(Craig Hendrix)

DESIRE

(José Bauermeister)

How Do People Make Choices?

(Julie Downs)

Science that Advances HIV Prevention



Prevention going forward

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prevention strategy with a HIV prevention method.

Enjoy this meeting

- Meet someone new
- Enjoy the plenary sessions
- Come to the reception tonight
- Think about how we can change HIV prevention for this world

State of the Network



Welcome!



MTN

microbicide trials network

