

Welcome and State of the Network

Cape Town,
South Africa

27th September 2016

The HIV/AIDS Epidemic in 2016

- 17 million people were accessing antiretroviral therapy
- 36.7 million people globally were living with HIV
- 2.1 million people became newly infected with HIV
- 1.1 million people died from AIDS-related illnesses

The Cost of the Epidemic

- US\$ 19 billion was invested in the AIDS response in low- and middle-income countries
- Domestic resources constituted 57% of the total resources for HIV in low- and middle-income countries in 2015.
- Recent updated UNAIDS estimates indicate that US\$ 26.2 billion will be required for the AIDS response in 2020

Emerging Problems

- Ongoing challenges with adherence
- Emergence of antiretroviral resistance to first line tenofovir containing regimens
- In the US only 30% of people living with HIV have achieved viral suppression
 - CDC 2014
- The majority of new infections in the US are transmitted by people not in medical care
- HIV prevention remains a priority

HIV Prevention in 2016

- Clear evidence for PrEP effectiveness
 - Proud (UK) & IperGay (France) studies
- WHO recommends PrEP for all population groups at substantial risk of HIV infection
 - Populations with an HIV incidence of about 3 per 100 person-years or higher
- The dapivirine antiretroviral intravaginal ring demonstrated to be safe and effective for HIV prevention

PrEP Access Problems



The HIV Prevention Research Agenda

- Ongoing PrEP demonstration projects
- Open-label evaluation of the DPV intravaginal ring (DREAM and HOPE)
- Phase 1 evaluation of novel microbicide candidates and formulations
- Phase 2/3 evaluation of LA PrEP and bnAb
- Phase 3 evaluation of the ALVAC/gp120 with MF59 adjuvant HIV vaccine regimen

The HIV Prevention Score Card

	Clinical Trials		Implementation		
	Safety & Effectiveness	Cost	Medical Monitoring	Burden	Adherence
Oral PrEP	+++ / +++	\$\$	++	++	+++
LA PrEP	++ / ?	\$\$\$	+++	+++	++
Antibodies	++ / ?	\$\$\$\$	++++	++++	0
Vaccines	++ / +	\$\$	++	+	0
Microbicide gels	+++ / +	\$\$	++	++	+++
Intravaginal rings	+++ / ++	\$	+	+	++
Circumcision	+++ / +++	\$	0	0	0

MTN Activities in 2015/2016

Completed MTN Trials (1)

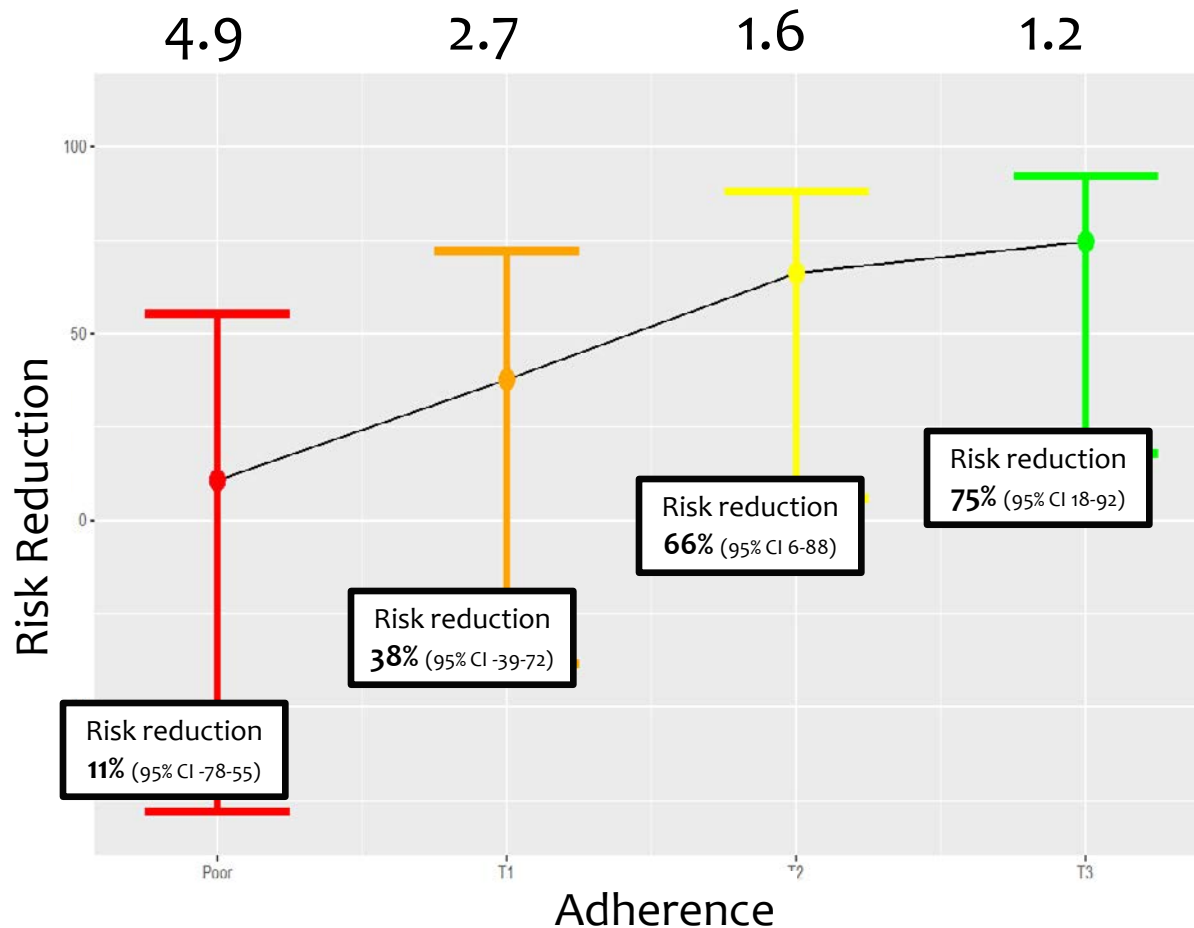
- MTN-017
 - Phase 2 rectal safety and acceptability study
- MTN-011 study
 - PK/PD coital study of TFV gel
- MTN-014 study
 - Rectal/vaginal safety and PK study of RGTFV gel
- MTN-020 (ASPIRE) study
 - Phase 3 evaluation of the DPV IVR

Completed MTN Trials (2)

- MTN-023
 - Phase 2a safety study of a DPV IVR in adolescent females in the US
- MTN-024
 - Phase 2a safety study of the DPV IVR in post menopausal women in the US
- MTN-027
 - Phase 1 safety and PK study of MK-2048/Vicriviroc (MK-4176)/MK 2048A IVR
- MTN-028
 - Phase 1 PK study of IVR containing Vicriviroc (MK-4176) and MK-2048

The ASPIRE Study

Incidence



Ongoing MTN Trials

- MTN-015 & MTN-016
- MTN-025 (HOPE Study)
 - A Phase 3B open-label follow-on trial to assess the continued safety of and adherence to a vaginal ring containing dapivirine in women
- MTN-029
 - Phase 1 PK study of the DPV IVR in lactating women
- MTN-032
 - Assessment of ASPIRE and HOPE adherence

Pending MTN Trials (1)

- MTN-026
 - Phase 1 rectal safety and PK study of DPV Gel
- MTN-031
 - A Phase 1, randomized, double-blind pharmacokinetic and safety study of dapivirine/levonorgestrel vaginal rings
- MTN-033
 - An open label randomized Phase 1 pharmacokinetic study of dapivirine gel administered rectally to HIV-1 seronegative adults
- MTN-034 (REACH)
 - A Phase 2a crossover trial evaluating the safety of and adherence to a vaginal matrix ring containing dapivirine and oral FTC/TDF in an adolescent female population

Pending MTN Trials (2)

- MTN-037
 - A Phase 1 rectal safety and pharmacokinetic study of PC-1005 (MIV-150/Zinc Acetate/Carrageenan Gel)
- MTN-038
 - A Phase 1 study of the 90 day tenofovir vaginal ring
- MTN-039
 - Safety and PK study of TDF and EVG administered rectally

Opportunities & Challenges

Opportunities for the MTN

- Building on the foundation of the ASPIRE trial
 - The HOPE study
 - DPV IVR safety studies in new populations
- Moving towards a three month DPV and tenofovir IVR
- Development of a combination contraceptive / antiretroviral IVR
- Moving rectal microbicides towards Phase 3
 - Evaluate new products
 - Take the best into a global Phase 2A study

Challenges for the MTN

- Building upon the ASPIRE and Ring data to demonstrate the value of the DPV IVR for HIV prevention
- We all need to be ambassadors for topical microbicides
 - Safety, acceptability, affordability, and scalability
 - Oral PrEP may not be the first choice for everyone
- Generating compelling data and rigorous trial designs to advance rectal microbicides into an effectiveness study
- Donor fatigue
 - Several large prevention studies are ongoing or planned and may limit funds for microbicide research

Farewells in 2016

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