



State of the Network

Ian McGowan & Sharon Hillier

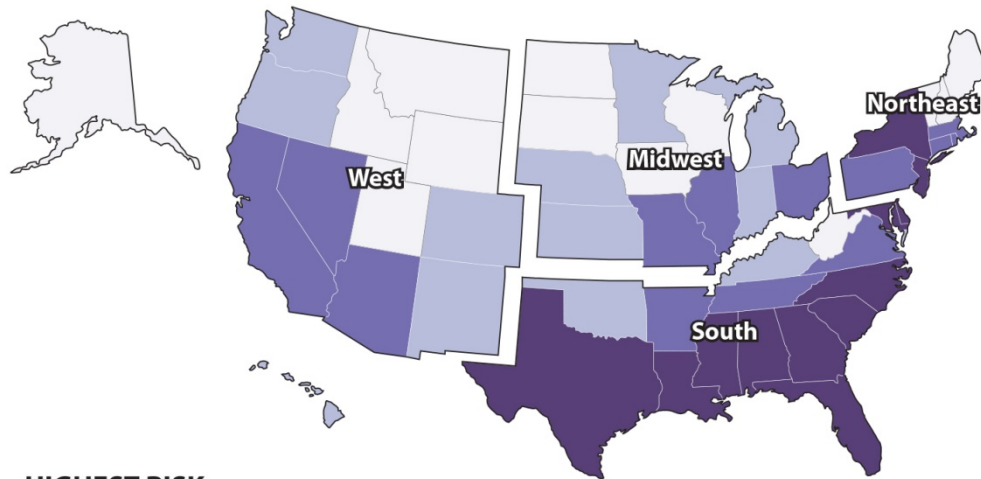
Annual Meeting

March 14th, 2016



HIV Infection in the US

Lifetime Risk of HIV Diagnosis by State



HIGHEST RISK

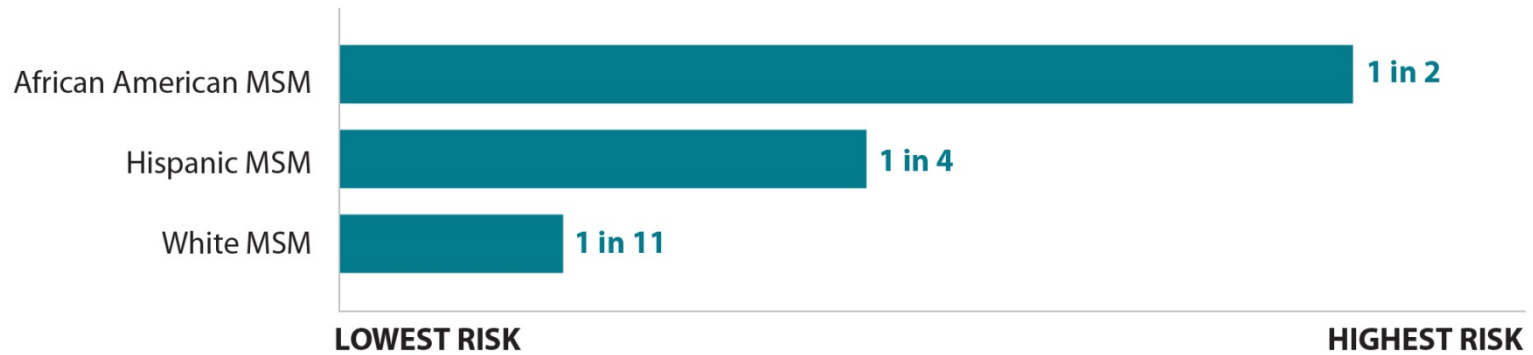
LOWEST RISK

State	One in "n"	State	One in "n"	State	One in "n"	State	One in "n"
District of Columbia	13	Nevada	98	Michigan	167	West Virginia	302
Maryland	49	Illinois	101	Oklahoma	168	Wisconsin	307
Georgia	51	California	102	Kentucky	173	Iowa	342
Florida	54	Tennessee	103	Indiana	183	Utah	366
Louisiana	56	Pennsylvania	115	Washington	185	Maine	373
New York	69	Virginia	115	Colorado	191	Alaska	384
Texas	81	Massachusetts	121	New Mexico	196	South Dakota	402
New Jersey	84	Arizona	138	Hawaii	202	New Hampshire	411
Mississippi	85	Connecticut	139	Oregon	214	Wyoming	481
South Carolina	86	Rhode Island	143	Minnesota	216	Vermont	527
North Carolina	93	Ohio	150	Kansas	262	Idaho	547
Delaware	96	Missouri	155	Nebraska	264	Montana	578
Alabama	97	Arkansas	159			North Dakota	670

Source: Centers for Disease Control and Prevention

HIV Infection in US MSM

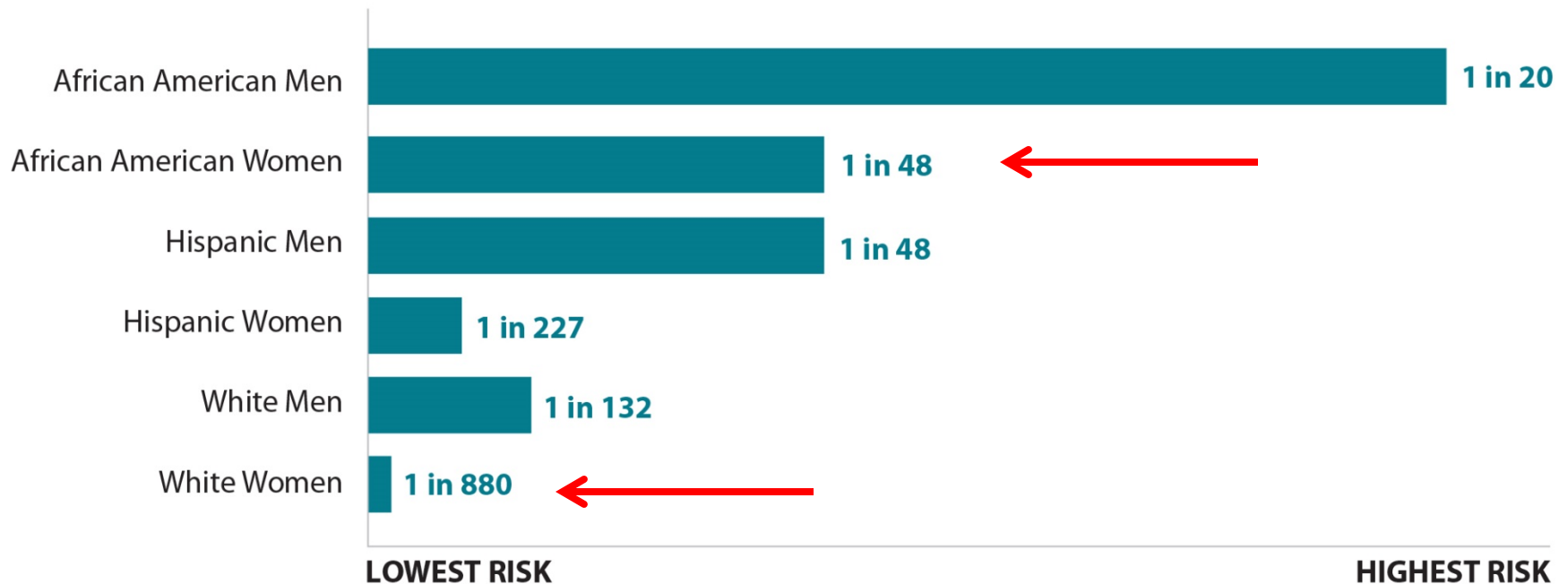
Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity



Source: Centers for Disease Control and Prevention

HIV Infection in US Women

Lifetime Risk of HIV Diagnosis by Race/Ethnicity



Source: Centers for Disease Control and Prevention

Global HIV Infection

Sub-Saharan Africa



In sub-Saharan Africa, there were an estimated 1.4 million new HIV infections in 2014. **A drop of 41% since 2000.**

2000 2.3 million [2.2 million–2.4 million]
2014 1.4 million [1.2 million–1.5 million]



Eastern Europe and central Asia

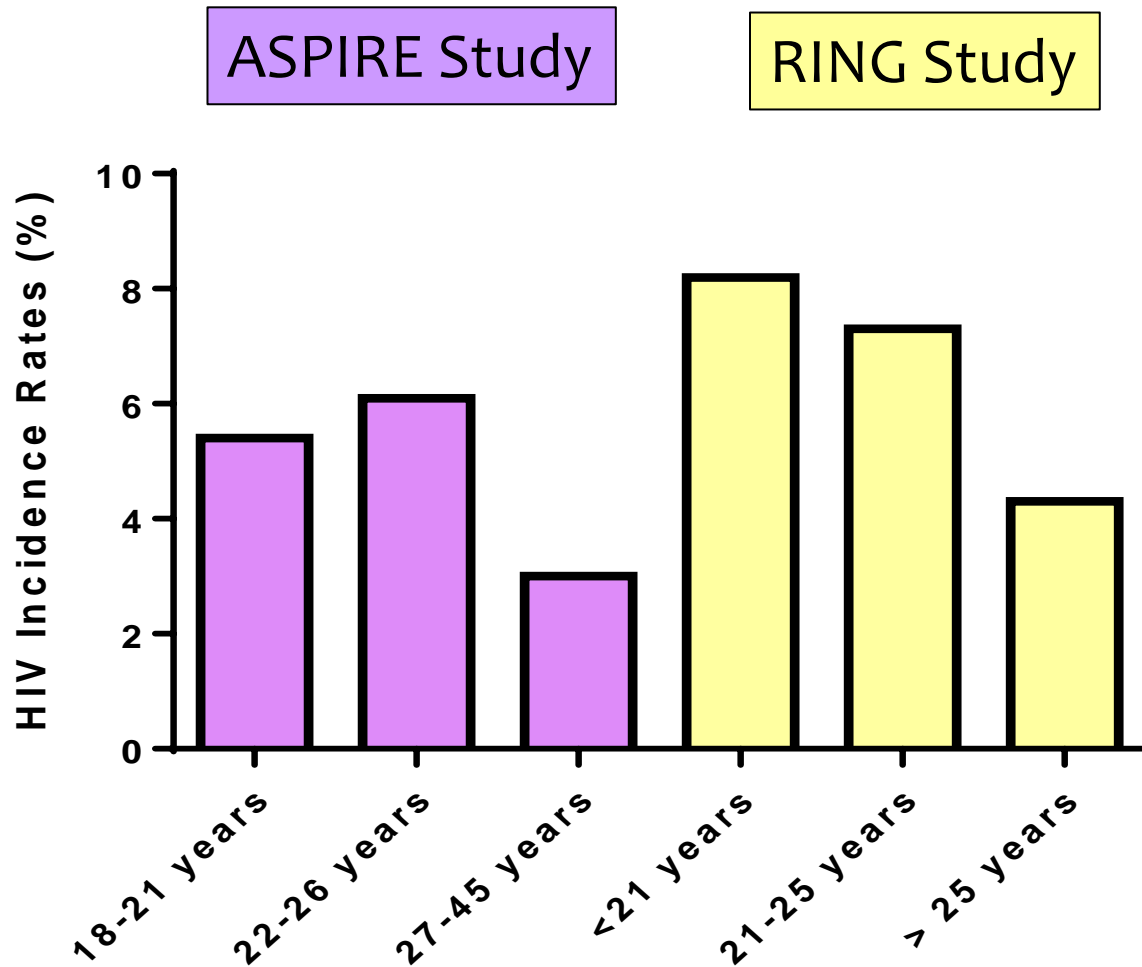


In eastern Europe and central Asia, **new infections rose by 30%** between 2000 and 2014.

2000 100 000 [90 000–120 000]
2014 140 000 [110 000–160 000]



HIV Incidence Rates in ASPIRE & RING Studies



The PrEP Landscape in 2016 (1)

- Oral PrEP
 - Optimization of Truvada delivery
 - Increasing availability
 - US, Canada, France, South Africa, Kenya, Israel
 - 2nd generation regimens being evaluated
 - Maraviroc combinations
 - Tenofovir alafenamide
 - New molecules
 - EFdA (Merck)



Planned, Ongoing and Completed PrEP Evaluation Studies (June 2015)



KEY Ongoing Planned Completed

For the latest on these studies, visit www.avac.org/prep/track-research.

Data from demonstration projects and open-label extension studies are beginning to come in. So far, the findings suggest that people want and will take daily oral PrEP correctly outside of a clinical trial setting. Expanded and faster rollout is key.

The PrEP Landscape in 2016 (2)

- Injectable PrEP
 - Rilpivirine & Cabotegravir
- Intravaginal rings
 - Phase 3
 - Dapivirine
 - Phase 1/2
 - Tenofovir
 - Tenofovir disoproxil fumarate
 - Vicriviroc + MK 2048
 - Dapivirine + Levonorgestrol

The PrEP Landscape in 2016 (3)

- Rectal microbicides
 - Phase 2
 - Reduced glycerin tenofovir gel
 - Phase 1
 - Maraviroc
 - Dapivirine
 - Griffithsin
 - MIV-150 / Carageenan / Zinc
- Implantable PrEP



MTN Highlights from the Past Year

The MTN Portfolio 2015 / 2016

Completed studies

MTN-017
MTN-020
MTN-024

Ongoing studies

MTN-015
MTN-016
MTN-023
MTN-027
MTN-028
MTN-029

Studies in development:

MTN-026
MTN-030
MTN-031
MTN-032
MTN-033
MTN-034
MTN-035
MTN-036
MTN-037

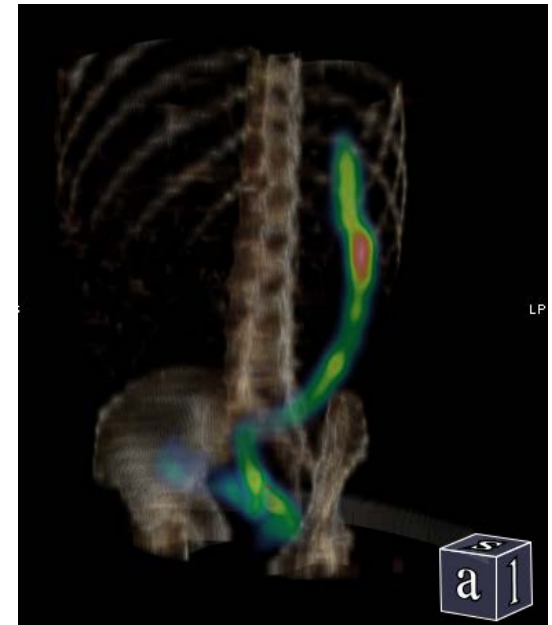
Intravaginal Ring Studies

- Dapivirine
 - MTN-020
 - MTN-023
 - MTN-025 (HOPE)
 - MTN-029
 - MTN-031
 - MTN-034
- Dapivirine / Levonorgestrel
 - MTN-030 / IPM 041
- Vicriviroc / MK-2048
 - MTN-027 & MTN-028
- Dapivirine 200 mg IVR
 - MTN-036 / IPM 047



Rectal Microbicide Studies

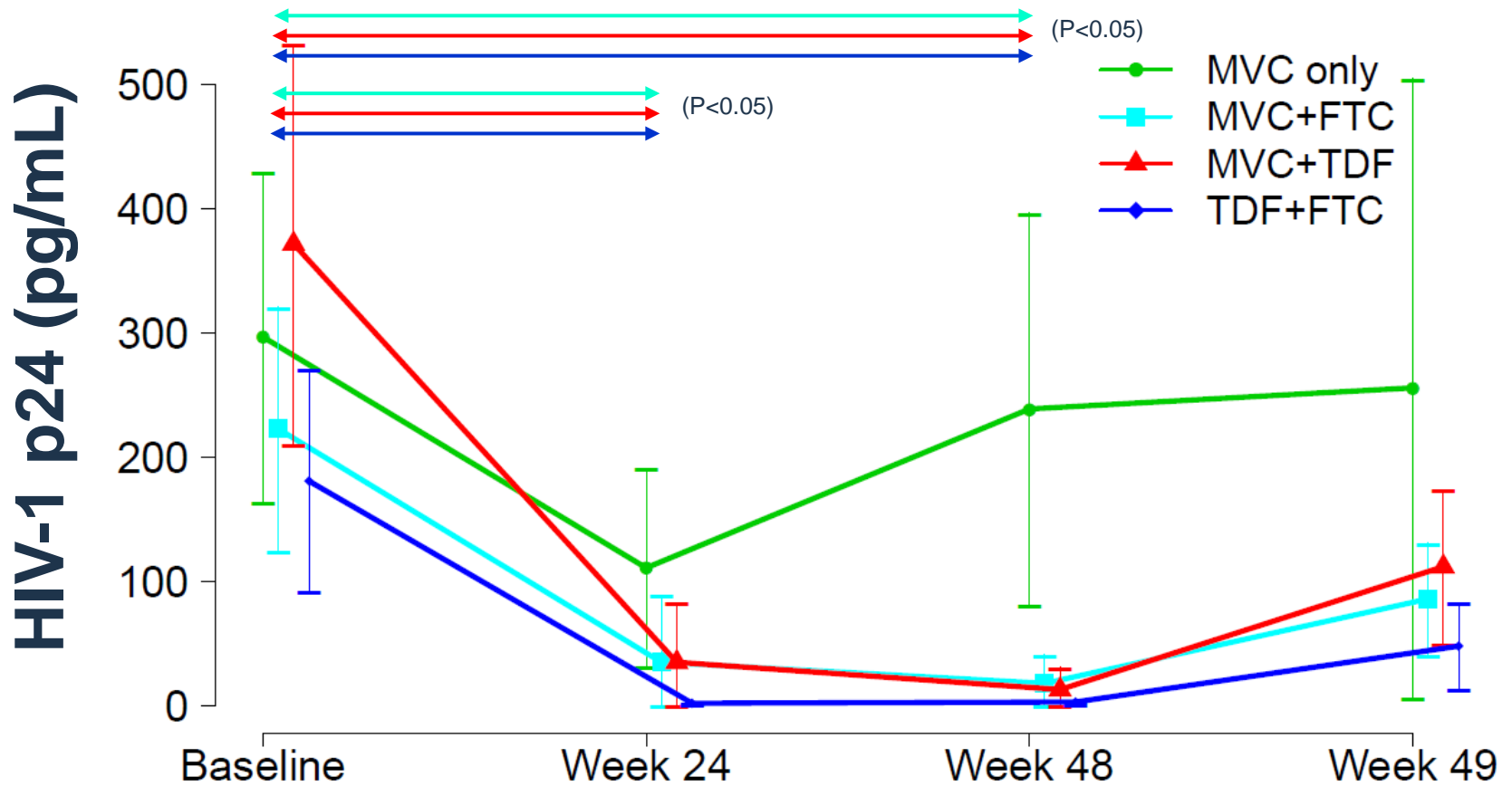
- Tenofovir gel
 - MTN-017
- Dapivirine gel
 - MTN-026
 - MTN-033
 - MTN-035



Network Collaboration

- HPTN-069 / ACTG 5305
- Phase 2 evaluation of maraviroc based PrEP regimens
- Approximately 400 men and 200 women enrolled in the study
- MTN contribution
 - CCR5 genotyping
 - Gut associated lymphoid tissue flow cytometry
 - Gut and cervicovaginal explant challenge

Explant Infection



Publications

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women

J.M. Baeten, T. Palanee-Phillips, E.R. Brown, K. Schwartz, L.E. Soto-Torres, V. Govender, N.M. Mgodhi, F. Matovu Kiweewa, G. Nair, F. Mhlanga, S. Siva, L.-G. Bekker, N. Jeenarain, Z. Gaffoor, F. Martinson, B. Makanani, A. Pather, L. Naidoo, M. Husnik, B.A. Richardson, U.M. Parikh, J.W. Mellors, M.A. Marzinke, C.W. Hendrix, A. van der Straten, G. Ramjee, Z.M. Chirenje, C. Nakabiito, T.E. Taha, J. Jones, A. Mayo, R. Scheckter, J. Berthiaume, E. Livant, C. Jacobson, P. Ndase, R. White, K. Patterson, D. Germuga, B. Galaska, K. Bunge, D. Singh, D.W. Szydlo, E.T. Montgomery, B.S. Mensch, K. Torjesen, C.I. Grossman, N. Chakhtoura, A. Nel, Z. Rosenberg, I. McGowan, and S. Hillier, for the MTN-020-ASPIRE Study Team*

Publications

The screenshot shows a web browser window with the URL www.mtnstopshiv.org/node/7196. The page features the MTN (Microbicide Trials Network) logo and a navigation menu with links for HOME, ABOUT, SITES, STUDIES, NEWS ROOM, NETWORK, MEETINGS & TRAVEL, PEOPLE, and RESOURCES. The main content area is titled "MTN Publications" and is updated as of February 9, 2016. It lists several research articles with their authors, titles, and publication details. A sidebar on the right titled "Resources" contains a list of links to various documents and materials.

MTN Publications
(Updated February 9, 2016)

van der Straten A, Brown ER, Marrasso JM, Chirenje MZ, Liu K, Gomez K, Marzinke MA, Piper JM, Hendrix CW, MTN-003 VOICE Protocol Team for the Microbicide Trials Network. [Divergent adherence estimates with pharmacokinetic and behavioural measures in the MTN-003 \(VOICE\) study](#). J Int AIDS Soc 2016 Feb 4;19(1):20642.

van der Straten A, Panther L, Laborde N, Hoesley CJ, Cheng H, Husnik MJ, Horn S, Nel A, Soto-Torres L, Chen BA. [Adherence and acceptability of a multidrug vaginal ring for HIV prevention in a phase I study in the United States](#). AIDS Behav 2016 Feb 2 [Epub ahead of print]

Danby CS, Cosentino LA, Rabe LK, Priest CL, Damare KC, Macio IS, Meyn LA, Wiesenfeld HC, Hillier SL. [Patterns of extragenital Chlamydia and Gonorrhoea in women and men who have sex with men reporting a history of receptive anal intercourse](#). Sex Transm Dis 2016;43(2):105-9.

Herold BC, Chen BA, Salata RA, Marzinke MA, Kelly CW, Dezzutti CS, McGowan I, Galaska B, Levy L, Piper JM, et al. [Impact of Sex on the Pharmacokinetics and Pharmacodynamics of 1% Tenofvir Gel](#). Clin Infect Dis 2016 Feb 1;62(3):375-82.

Dai JY, Hendrix CW, Richardson BA, Kelly C, Marzinke M, Chirenje ZM, Marrasso JM, Brown ER. [Pharmacological Measures of Adherence and Risk of HIV Acquisition in the VOICE Study](#). J Infect Dis 2016 Feb 1;213(3):335-342. PMID:PMC4704663

Balkus JE, Brown ER, Hillier SL, Coletti A, Ramjee G, Mgodini N, Makanani B, Reid C, Martinson F, Soto-Torres L, Abdool Karim SS, Chirenje ZM. [Oral and injectable contraceptive use and HIV acquisition risk among women in 4 African countries: a secondary analysis of data from a microbicide trial](#). Contraception 2016 Jan;93(1):25-31. PMID:PMC4688130

Duby Z, Hartmann M, Montgomery ET, Colvin CJ, Mensch B, van der Straten A. [Sexual](#)

Resources

- Acknowledgment of Support Language and Guidance
- Ancillary Study and Data Request Forms
- Audio Files
- Clinical Site Monitoring
- Conference Abstract Submission Timelines
- Financial Disclosure Policies and Tables
- HIV/AIDS Network Coordination (HANC)
- Image Galleries
- MTN Publications
- Manual of Operational Procedures
- Policies/Procedures
- Protocol Deviation Policy
- Safety and Reporting
- Staff Training
- Video Galleries

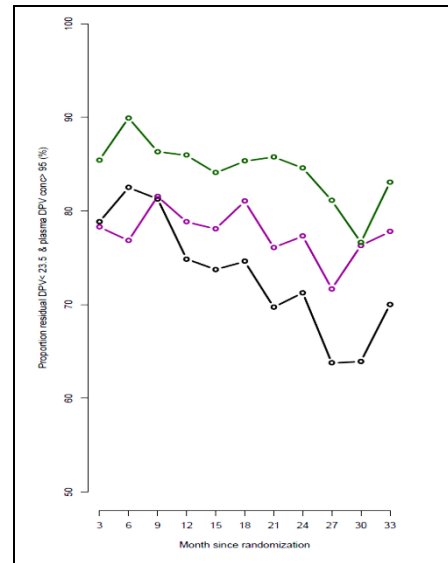


Challenges for the Year Ahead

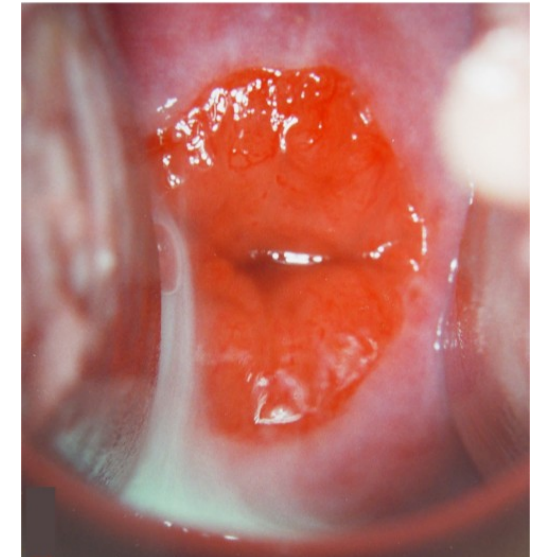


Understanding Suboptimal PrEP Efficacy in Young Women

- Differential non-adherence?
- Biological vulnerability?
- Compartmental pharmacokinetics?
- Sexual behavior?
 - STIs?
 - Anal sex?



Dapivirine
Plasma and
Ring PK by age



Cervical
Ectropion

Rectal Microbicides

- Are rectal microbicides needed with increased access to PrEP?
- Can we develop products that do not require an applicator?
- Which product (s) should be advanced into Phase 3 effectiveness studies?
- What would these studies look like?

\$\$ Managing The MTN Pipeline \$\$

- MTN-025 (HOPE): DPV IVR Phase 3B
- MTN-026: DPV gel rectal Phase 1
- MTN-030 (IPM 041): DPV ± LNG IVR
- MTN-031 (IPM 043): DPV IVR ± incentives
- MTN-033 (IPM 044): Rectal DPV ± applicator
- MTN-034 (IPM 045): DPV versus Truvada
- MTN-035: Oral Truvada + rectal DPV gel
- MTN-036 (IPM 047): 200 mg DPV IVR
- MTN-037: MIV-150/Carageenan/Zinc rectal Phase 1

For This Week

- Hear about the latest developments in HIV prevention research during the plenaries
 - News from CROI: Rings and beyond
 - Pipeline products
 - Rectal microbicides: Recent news & future plans
 - Lessons from contraception
- Participate in study specific meetings
- Don't forget to come to the Poster reception this evening!

It Takes a Village....





Thank You

Acknowledgements

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