

la PreP & les *Sex Workers*

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**COREVIHs IdF Ouest & Nord
21 Mai 2014**

Déclaration de liens d'intérêts , Gilles Pialoux

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intervenant ou invité dans un symposium d'un laboratoire
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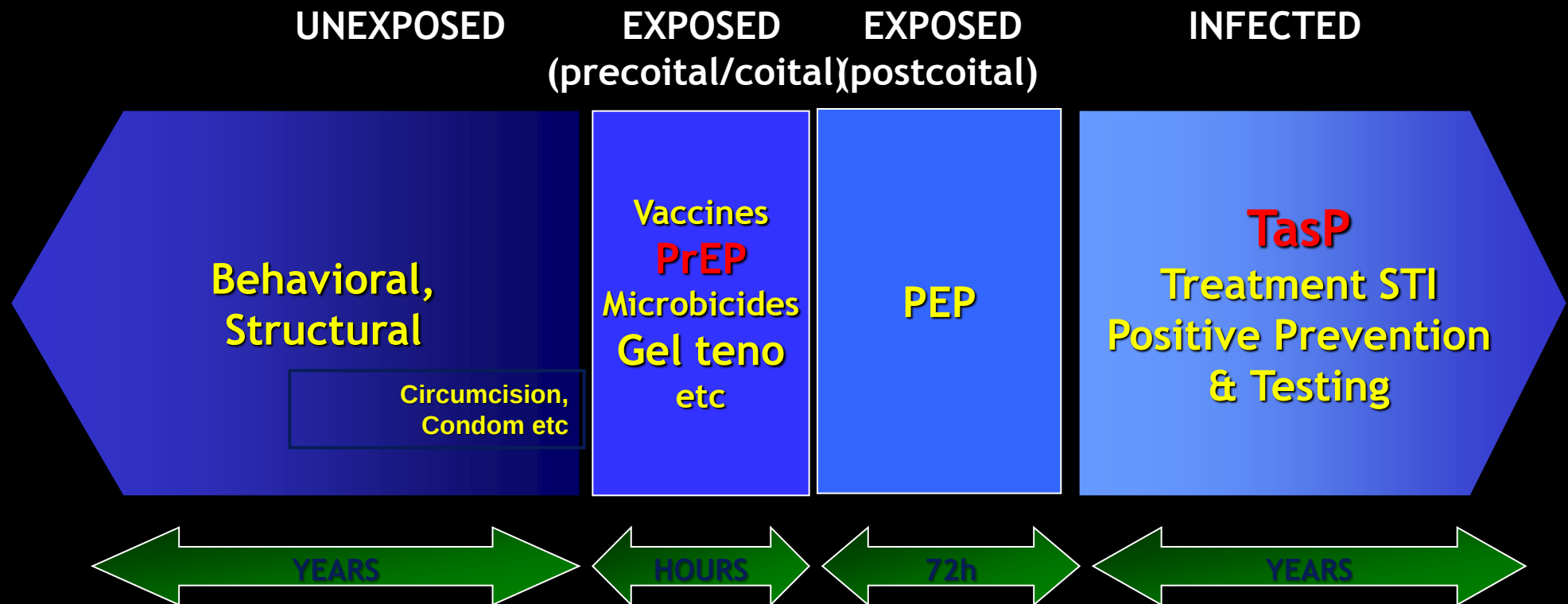
Parts sociales ou actions dans un laboratoire pharmaceutique : Aucune

Membre du COS de AIDES

Investigateur de ANRS-IPERGAY

**Cette présentation n'illustre pas les
habitudes de prescription de l'auteur ni
de son équipe mais fournit une vue des
éléments scientifiques sélectifs issus
de la bibliographie.**

ARV et opportunités de prévention sexuelle VIH



Male circumcision



Auvert B, PloS Med 2005
Gray R, Lancet 2007
Bailey R, Lancet 2007

Treatment of STIs



Grosskurth H, Lancet 2000

Male & female condoms



Structural / legal

HIV Counselling and Testing

Coates T, Lancet 2000



Behavioural Intervention



Treatment for prevention



Donnell D, Lancet 2010
Cohen M, NEJM 2011
www.aids2012.org

Microbicides Gel, anneaux, film..



Abdool Karim Q, Science 2010

Oral PreP



Grant R, NEJM 2010 (MSM)
Baeten J, NEJM 2012 (couples)
Thigpen, NEJM, 2012 (Heterosexuals)

Post Exposure prophylaxis (PEP)



Scheckter M, 2002

Kits de Prevention/RdR combinée







Gels V/R, film,
Anneau vaginal
microbicides



Comprimés
Injectables

PREP

CAN A PILL A DAY
PREVENT HIV?

Participation on this new and
HIV PREVENTION STUDY

at no cost to 30060 or
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Participants will be compensated for their time and transport.

 MOTHER CITY MEN'S HEALTH PROJECT
Time to Stand Up.

 triangle project
Ukhaya kwakho, kwakho kwakho
Ukuzalwa kwakho, ukuzalwa kwakho

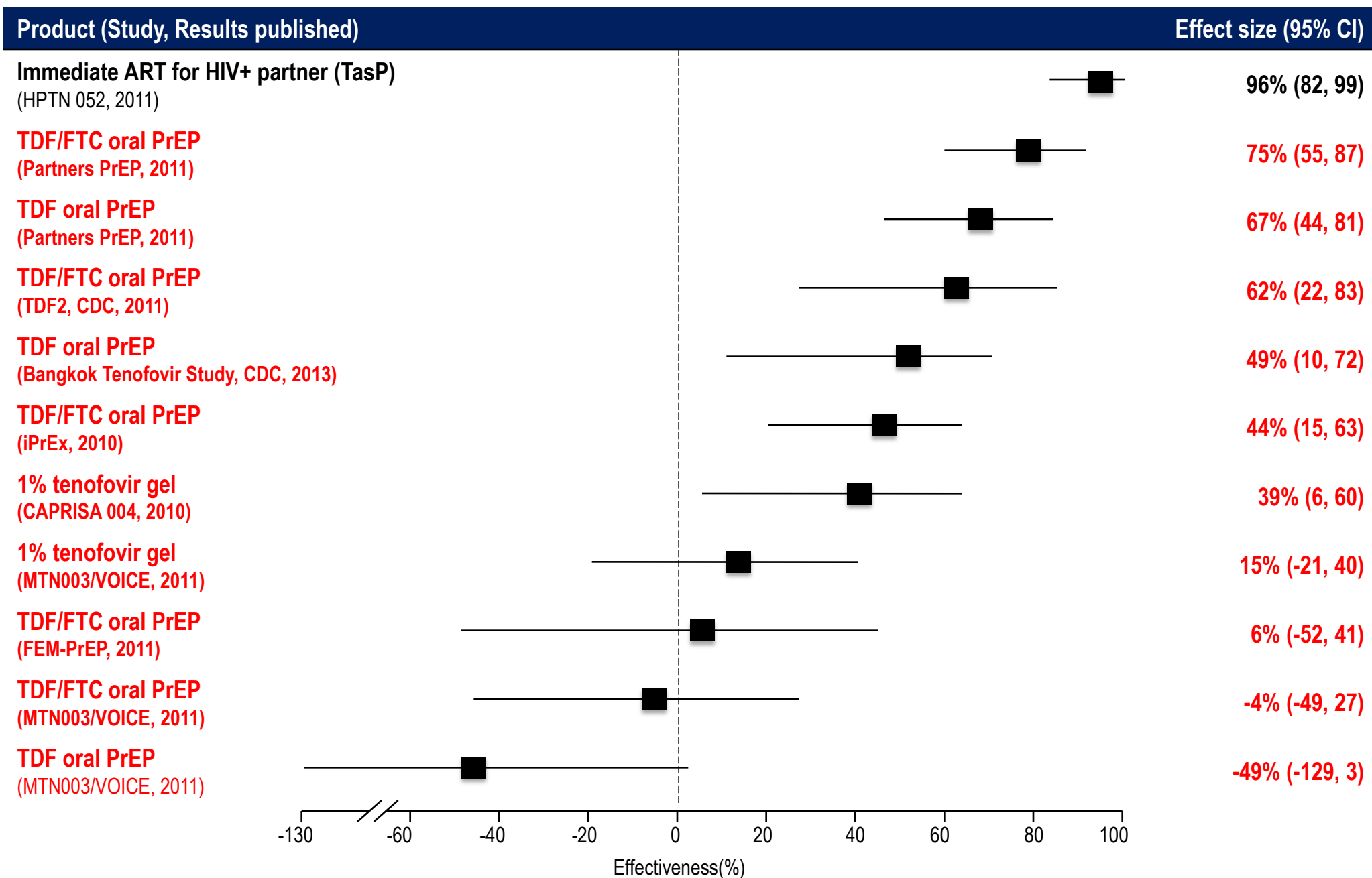
Potential types of PrEP

How are the antiretrovirals used?	• Oral pill • Topical gel (microbicide) • Rectal • Vaginal • Injection • Intravaginal ring, film ...
How often are the antiretrovirals used?	• Daily • Intermittently • Coitally (before/sex)
How many antiretrovirals are used?	• Single • Combination
What antiretrovirals are used?	• Over 25 available

Anneaux et films vaginaux



Tenofovir-based prevention results, as of June 2013



Mots Clés de la PreP

- Efficacité
- Combinée
- Desinhibition
- Observance
- Résistances
- Disponibilité

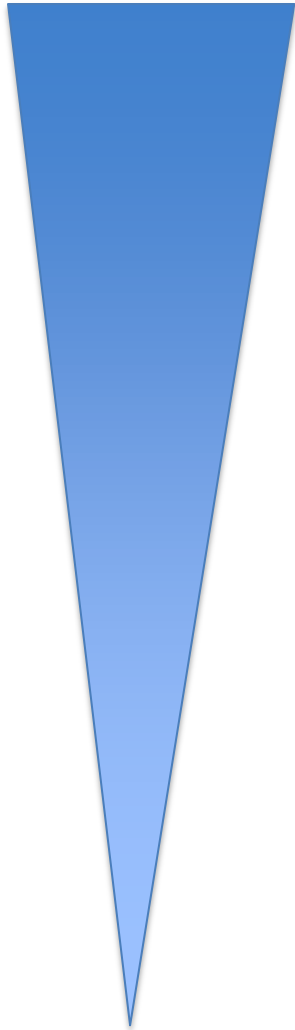
Table 1 Efficacy and adherence rates across PrEP trials

Study [reference]: countries	Population	n	Efficacy	Lower bound of 95% CI	Adherence ^a
Partners PrEP [8]: Kenya, Uganda	Heterosexual couples	4758	67% TDF; 75% TDF/FTC	44% TDF; 55% TDF/FTC	82%
TDF2 Study [9]: Botswana	Young men and women	1219	62% TDF/FTC	21.5%	80%
Bangkok TDF [12]: Thailand	IVDU	2413	49% TDF	9.6%	67%
iPrEx [7]: S. America, SA, Thailand, USA	MSM	2499	44% TDF/FTC	15%	51%
FEM-PrEP [10]: Kenya, SA, Tanzania	Young women	2120	6% TDF/FTC	-52%	37%
VOICE [11]: South Africa, Uganda, Zimbabwe	Young women	5029	-49% TDF; - 4% TDF/FTC	-130% TDF; -50% TDF/FTC	30%

Abbreviations: FTC, emtricitabine; IVDU, intravenous drug users; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; SA, South Africa; TDF, tenofovir disoproxil fumarate.

^aAdherence was assessed by the proportion of participants with drugs detectable in plasma and who remained free of infection in the active PrEP arms.

ADHERENCE



Partners PrEP

BK IDU

TDF2

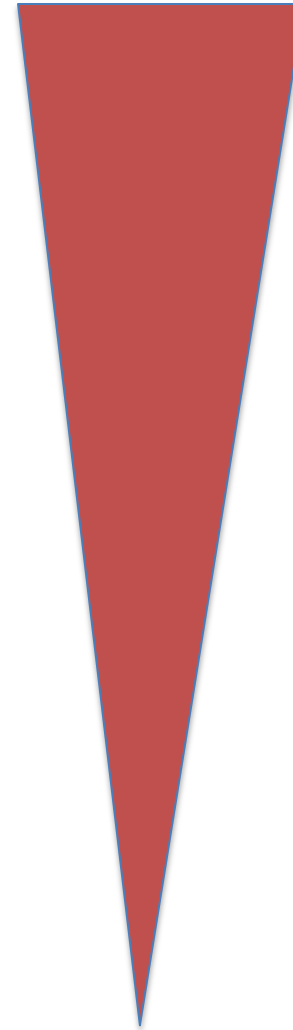
iPrEx

CAPRISA 004

FEMPREP

VOICE

EFFICACY

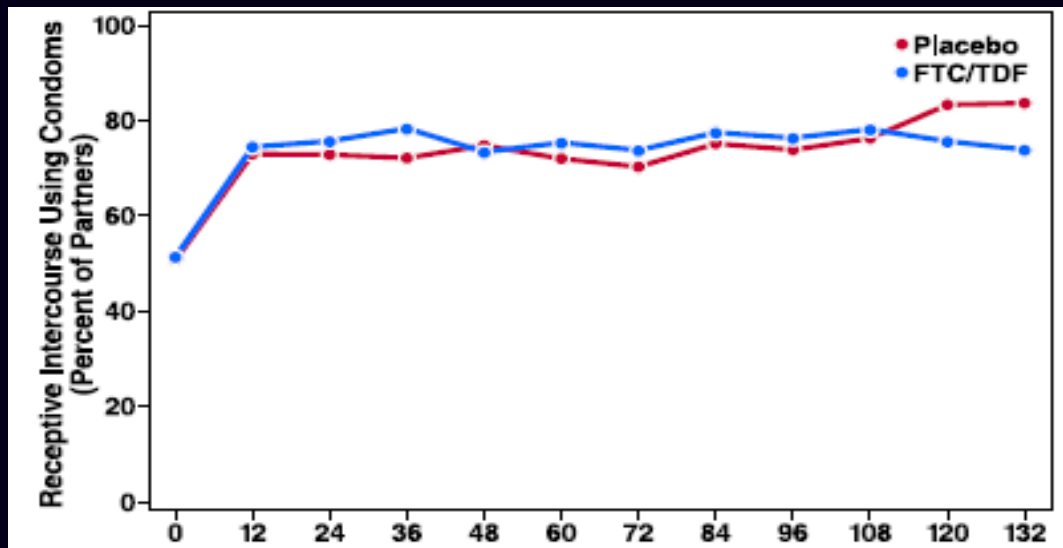
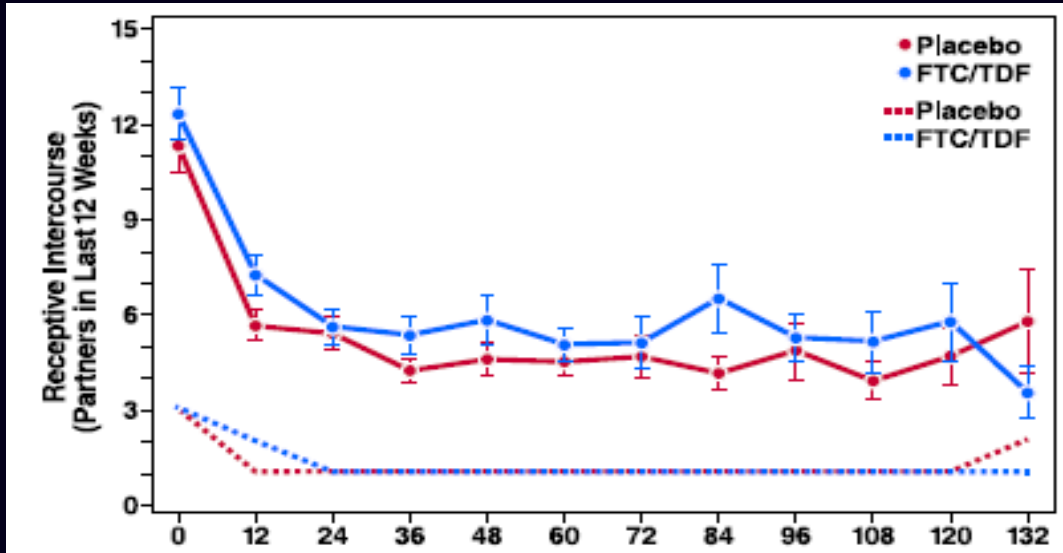


Résistance dans les essais de PrEP

Essais	Infection post-inclusion		Résistance au TDF ou FTC	Infection active à l'inclusion		Résistance au TDF ou FTC
	Placebo	Traitement		Placebo	Traitement	
Bangkok TFV	33	15	0	2	0	0
CAPRISA 004	0	35	0	0	0	–
Fem-PrEP	35	33	1 placebo (M184V) 4 TDF-FTC (M184I/V)	4	1	0
iPrEX	64	36	0	8	2	1 placebo (M184V) 2 TDF-FTC (M184I/V)
Partners PrEP	51	27	0	6	8	1 TDF (K65R) 1 TDF-FTC (M184V)
TDFZ	24	9	1 placebo (K65R < 1 %)	2	1	1 TDF-FTC (K65R/M184V)
VOICE	128	173	1 TDF-FTC (M184V)	4	18	2 (M184I/V)
Total	7/663 (1 %) Bras de traitement seul : 5/328 (1,5 %)			8/56 (14 %) Bras de traitement seul : 7/30 (22 %)		

iPREX

Sexual Practices



- Sexual practices were similar in the two groups at all time points
- Number of partners with receptive anal intercourse decreased
- Percentage of partners using a condom increased
- More than 500 cases of syphilis in each arm !

ORIGINAL ARTICLE

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., Valdilea G. Veloso, M.D., Ph.D., Susan P. Buchbinder, M.D., Suwat Chariyalertsak, M.D., Dr.P.H., Mauro Schechter, M.D., Ph.D., Linda-Gail Bekker, M.B., Ch.B., Ph.D., Kenneth H. Mayer, M.D., Esper Georges Kallás, M.D., Ph.D., K. Rivet Amico, Ph.D., Kathleen Mulligan, Ph.D., Lane R. Bushman, B.Chem., Robert J. Hance, A.A., Carmela Ganoza, M.D., Patricia Defechereux, Ph.D., Brian Postle, B.S., Furong Wang, M.D., J. Jeff McConnell, M.A., Jia-Hua Zheng, Ph.D., Jeanny Lee, B.S., James F. Rooney, M.D., Howard S. Jaffe, M.D., Ana I. Martinez, R.Ph., David N. Burns, M.D., M.P.H., and David V. Glidden, Ph.D., for the iPrEx Study Team*

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<http://www.nejm.org/doi/full/10.1056/NEJMoa1011205>
http://www.nejm.org/doi/suppl/10.1056/NEJMoa1011205/suppl_file/nejmoa1011205

Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, Michael Martin, Pravan Suntharasamai, Udomsak Sangkum, Philip A. Mock, Manoj Leethochawalit, Sithisat Chiamwongpaet, Prophan Kitisin, Pitinan Natrujrote, Samyot Kittimunkong, Rutt Chuachoowong, Roman J. Gvetadze, Janet M. McNicholl, Lynn A. Paxton, Marcel E. Culin, Craig W. Hendrix, Suphak Vanichseni, for the Bangkok Tenofovir Study Group

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ESTABLISHED IN 1812

AUGUST 2, 2012

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Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women

J.M. Baeten, D. Donnell, P. Ndase, N.R. Mugo, J.D. Campbell, J. Wangisi, J.W. Tappero, E.A. Bukusi, C.R. Cohen, E. Katabira, A. Ronald, E. Tumwesigye, E. Were, K.H. Fife, J. Kiarie, C. Farquhar, G. John-Stewart, A. Kaka, J. Odoyo, A. Mucunguzi, E. Nakku-Joloba, R. Twesigye, K. Ngure, C. Apaka, H. Tamoooh, F. Gabona, A. Mujugira, D. Panteleeff, K.K. Thomas, L. Kidoguchi, M. Krows, J. Revall, S. Morrison, H. Haugen, M. Emmanuel-Ogier, L. Ondrejcek, R.W. Coombs, L. Frenkel, C. Hendrix, N.N. Bumpus, D. Bangsberg, J.E. Haberer, W.S. Stevens, J.R. Lingappa, and C. Celum, for the Partners PrEP Study Team*

ABSTRACT

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana

Michael C. Thigpen, M.D., Poloko M. Kebaabetswe, Ph.D., M.P.H., A.D., M.P.H., Dawn K. Smith, M.D., M.P.H., Mogogo M. Segolodi, M.Sc., Faith L. Henderson, M.P.H., H., Fatma A. Soud, Ph.D., Kata L. Chillag, Ph.D., B., Ch.B., Lovemore Ian Chirwa, M.B., Ch.B., M.Phil., Ch.B., Daniel Abebe, M.D., Evans Buliva, M.B., Ch.B., J., M.S.P.H., Sandra Johnson, M.A., Thom Sukalac, J., R.Ph., Clyde Hart, Ph.D., Jeffrey A. Johnson, Ph.D., J., Craig W. Hendrix, M.D., and John T. Brooks, M.D., for the TDF2 Study Group*

ABSTRACT



Efficacy: 44%, 95 CI: 15 – 63%

Infections Numbers: 64 – 36 = 28 averted

n = 2,499 men who have sex with men and transgender women;
Brazil, Ecuador, Peru, South Africa, Thailand, United States

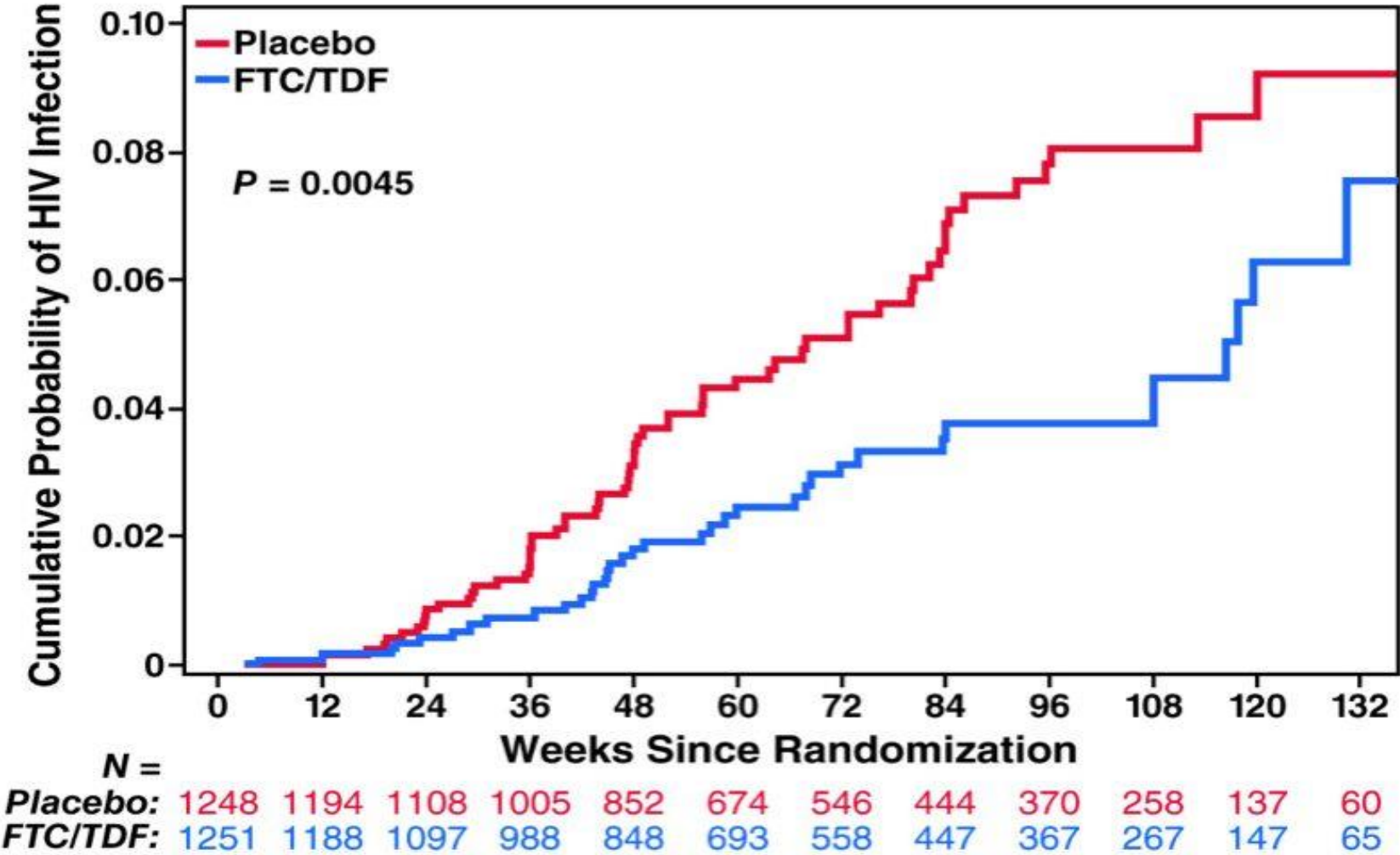


Table 1. Baseline Characteristics of the Subjects.*

Characteristic	FTC-TDF (N = 1251)	Placebo (N = 1248)	P Value
Age group — no. (%)			0.04
18–24 yr	591 (47)	662 (53)	
25–29 yr	274 (22)	241 (19)	
30–39 yr	249 (20)	224 (18)	
≥40 yr	137 (11)	121 (10)	
Sexual risk factors at screening			
No. of partners in past 12 wk	18±35	18±43	0.51
Unprotected receptive anal intercourse in past 12 wk — no. (%)	732 (59)	753 (60)	0.37
Unprotected anal intercourse with partner with positive or unknown HIV status in past 6 mo — no. (%)	992 (79)	1009 (81)	0.34
Transactional sex in past 6 mo — no. (%)	517 (41)	510 (41)	0.84
Known partner with HIV in past 6 mo — no. (%)	23 (2)	32 (3)	0.22
Sexually transmitted infections diagnosed at screening			
Syphilis seroreactivity — no./total no. (%)	164/1240 (13)	162/1239 (13)	0.95
Serum herpes simplex virus type 2 — no./total no. (%)	458/1241 (37)	430/1243 (35)	0.24
Urine leukocyte esterase positive — no. (%)	23 (2)	22 (2)	1.00
Hepatitis B virus status — no. (%)			0.11
Susceptible	827 (66)	803 (64)	
Immune because of natural infection	247 (20)	222 (18)	
Immune because of previous vaccination	149 (12)	190 (15)	
Current infection with hepatitis B virus	7 (1)	6 (<1)	
Indeterminate	21 (2)	27 (2)	

* Plus-minus values are means ±SD. Percentages may not total 100 because of rounding. FTC-TDF denotes emtricitabine and tenofovir disoproxil fumarate.

† Race or ethnic group was self-reported.



PARTNERS PrEP STUDY

Efficacy TDF: 67%, 95% CI: 44 – 81%

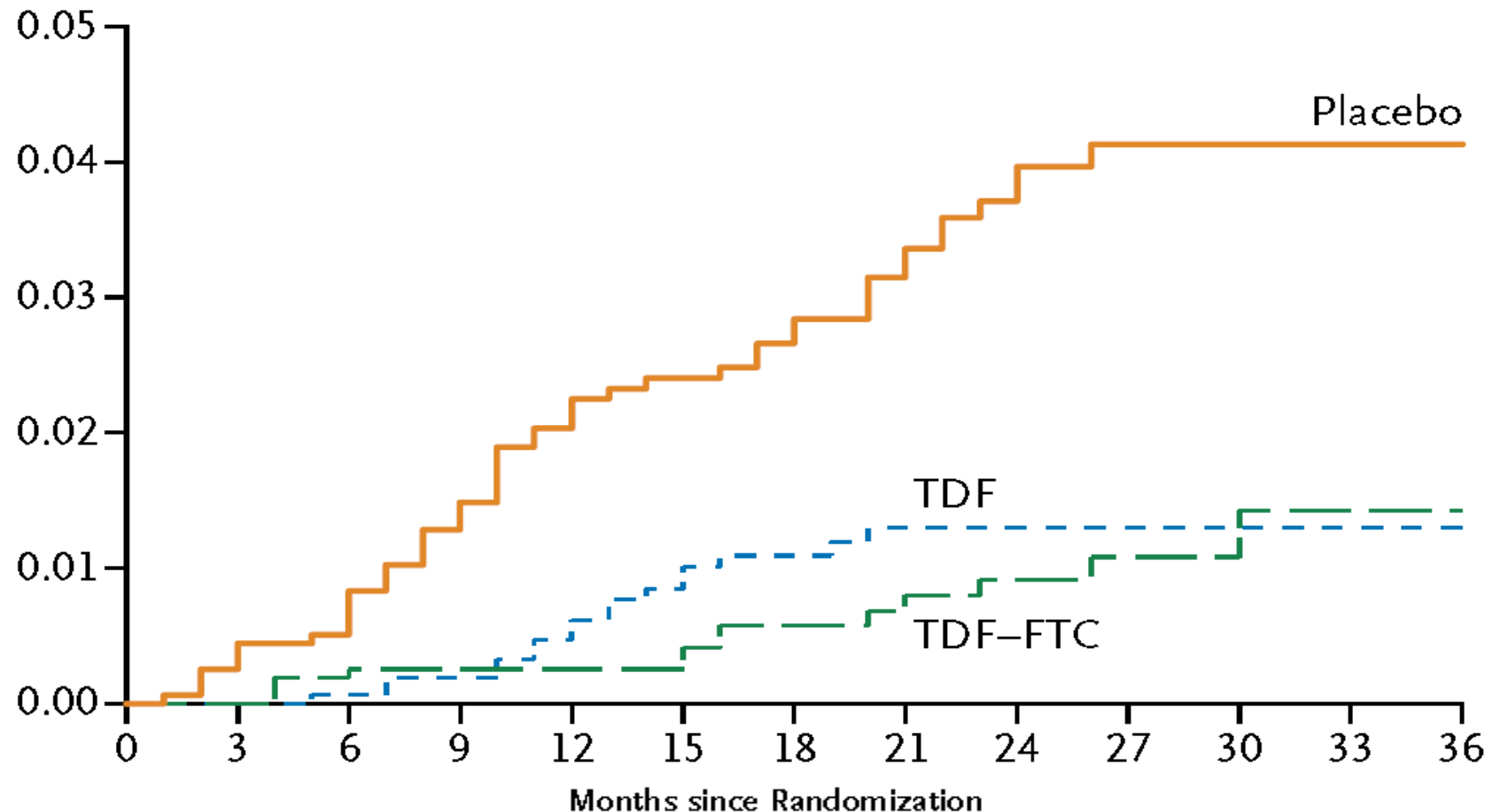
FTC/TDF: 75%, 95% CI: 55 – 87%

Infections Numbers

TDF: 52 – 17 = 35 averted*

TDF-FTC: 52 – 13 = 39 averted*

n = 4,747 heterosexual men and women with HIV infected partners;
Kenya, Uganda



* Each intervention when compared to placebo

Baeten JM, Donnell D, Ndase P, et al. N Eng J Med 2012; 367(5):399-410

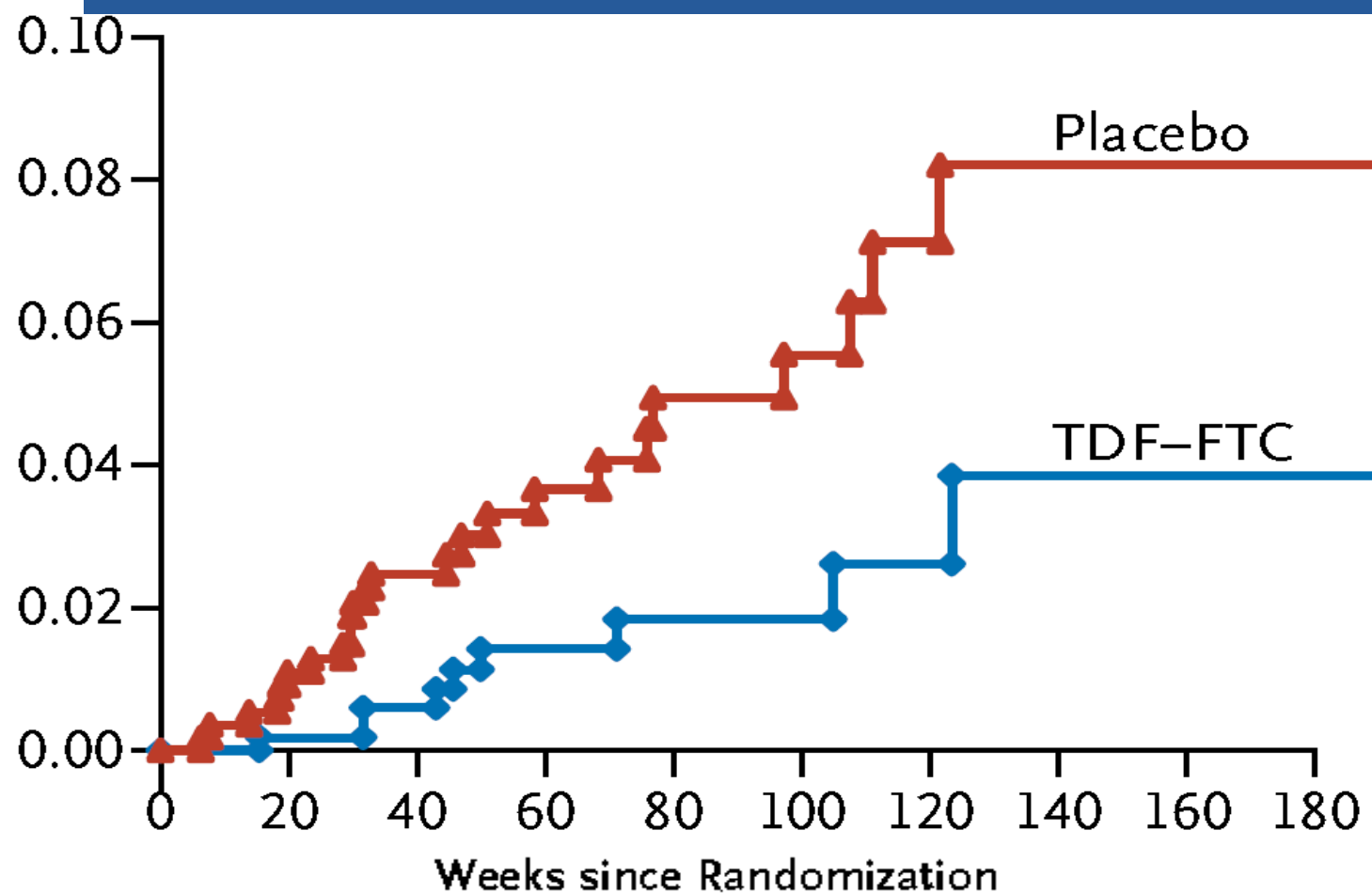


TDF-2 Study

Efficacy: 62%, 95% CI: 22 - 83%

Infections Numbers: $52 - 17 = 35$ averted

n = 1,219 heterosexual men and women;
Botswana

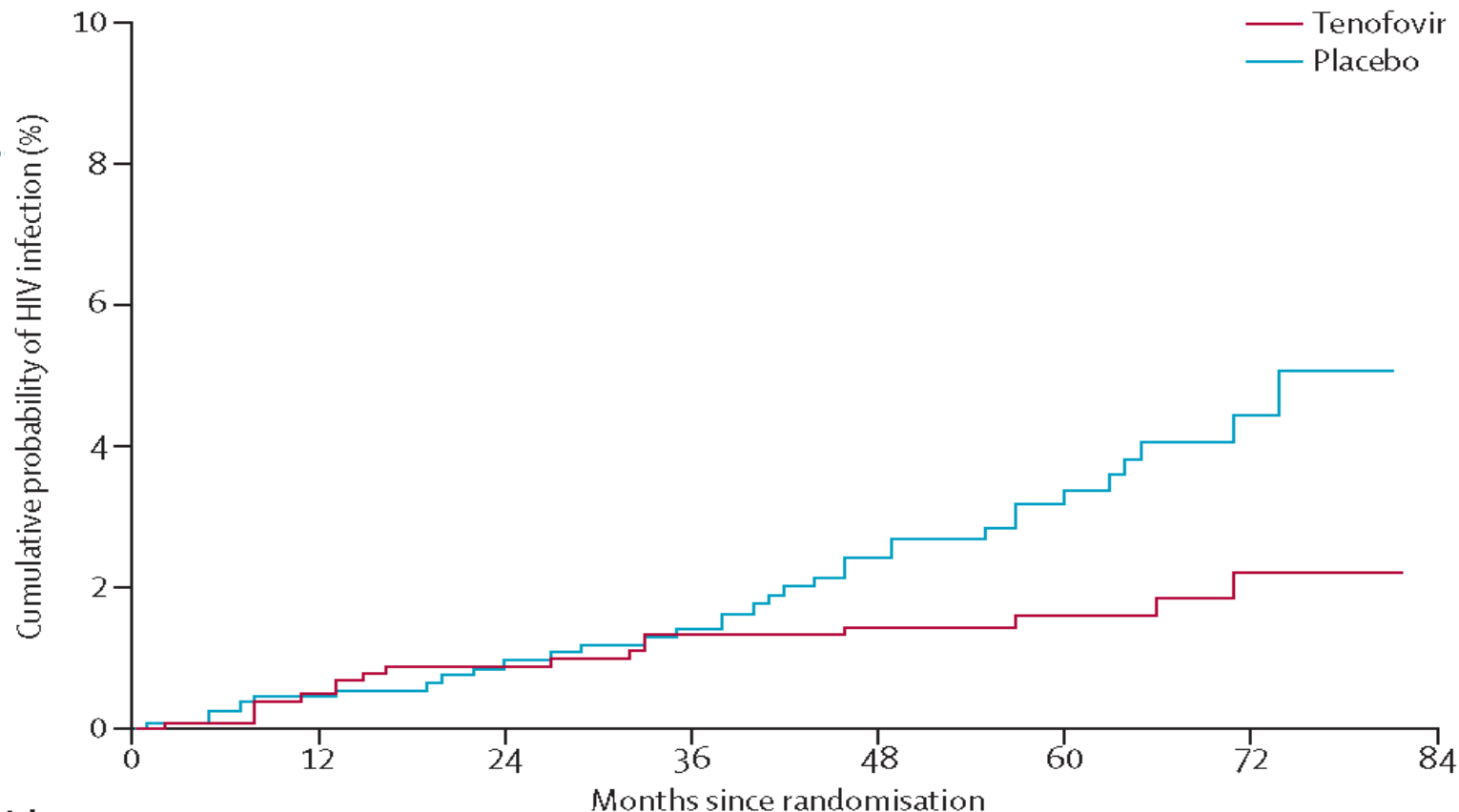




Bangkok Tenofovir Study

Efficacy 49%, 95% CI: 10 – 72%

Infections Numbers: $33 - 17 = 16$ averted
 $n = 2,413$ men and women who inject drugs;
Thailand



Number at risk

Tenofovir	1204	1007	933	857	736	521	241
Placebo	1207	1029	948	844	722	500	234

Nombre de femmes dans les essais PreP

ESSAIS	FEMMES	HOMMES	Total
iPrEx	0 (1 % TRANS HF)	2499	2499
TDF2	548	671	1219
Partners PrEP	2283	2475	4758
BK IDU	499	1924	2413

Total Femmes : 3330 Total Hommes: 7566 Total : 10 896

HIV Pre-Exposure Prophylaxis Interest among Female Sex Workers in Guangxi, China

Li Ye^{1,9}, Suosu Wei^{2,9}, Yunfeng Zou¹, Xiaobo Yang¹, Abu S. Abdullah^{1,3}, Xiaoni Zhong⁴, Yuhua Ruan⁵, Xinqin Lin⁶, Mingqiang Li⁷, Deren Wu⁸, Junjun Jiang¹, Peiyan Xie¹, Jiegang Huang¹, Bingyu Liang¹, Bo Zhou¹, Jinming Su¹, Hao Liang^{1*}, Ailong Huang^{4*}

1 Guangxi Key Laboratory of AIDS Prevention and Treatment, School of Public Health, Guangxi Medical University, Nanning, Guangxi, China, **2** The People's Hospital of Guangxi Zhuang Autonomous Region, Nanning, Guangxi, China, **3** Department of Medicine, Boston Medical Center, Boston University School of Medicine, Boston, Massachusetts, United States of America, **4** School of Public Health, Chongqing Medical University, Chongqing, China, **5** State Key Laboratory for Infectious Disease Prevention and Control, Chinese Center for Disease Control and Prevention, Beijing, China, **6** Nanning Center for Disease Control and Prevention, Nanning, Guangxi, China, **7** Liuzhou Center for Disease Control and Prevention, Liuzhou, Guangxi, China, **8** Beihai Center for Disease Control and Prevention, Beihai, Guangxi, China

Table 2. Willingness to accept PrEP or participate in a clinical trial (N, %).

	Total	Having heard of PrEP	Willing	Unwilling
Willingness to accept PrEP	405	61 (15.1)	348 (85.9)	57 (14.1)
Willingness to participate in a clinical trial	348	52 (14.9)	189 (54.3)	159 (45.7)

Table 3. Reasons for refusing PrEP or participating in a clinical trial.

Reasons	Reasons for refusing PrEP (N, %)	Reasons for refusing a clinical trial (N, %)
Total	57 (100)	159 (100)
Concern about side effects	51 (89.5)	130 (81.8)
Self-perceived no HIV risk from commercial sexual behaviours	29 (50.9)	44 (27.7)
Not necessary or not effective	21 (36.8)	68 (42.8)
Concern about objections from family	18 (31.6)	33 (20.7)
Concern about discrimination by others	10 (17.5)	18 (11.3)

STUDY PROTOCOL

Open Access

Evaluating the effectiveness of personal resilience and enrichment programme (PREP) for HIV prevention among female sex workers: a randomised controlled trial

Winnie Wing-Yan Yuen^{1*}, William Chi-Wai Wong¹, Catherine So-Kum Tang², Eleanor Holroyd³, Agnes Fung-Yee Tiwari⁴, Daniel Yee-Tak Fong⁴ and Weng Yee Chin¹

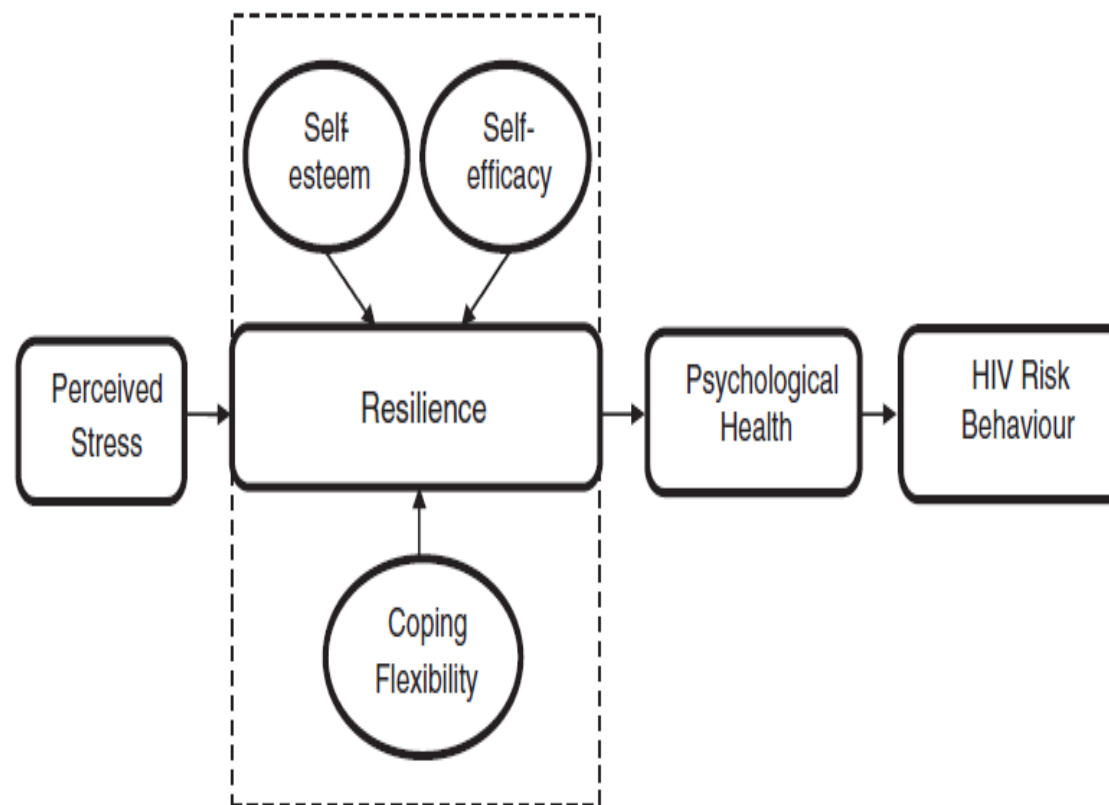


Figure 1 Proposed model of individual resources in predicting HIV risk behaviours.

Acceptability of vaginal microbicides among female sex workers and their intimate male partners in two Mexico-U.S. border cities: a mixed methods analysis

Angela M. Robertson^a, Jennifer L. Syvertsen^a, Gustavo Martinez^b, M. Gudelia Rangel^c, Lawrence A. Palinkas^d, Jamila K. Stockman^a, Monica D. Ulibarri^e, and Steffanie A. Strathdee^{a,*}

^aDivision of Global Public Health, Department of Medicine, University of California at San Diego, La Jolla, CA, USA

^bSalud y Desarrollo Comunitario de Ciudad Juárez A.C. (SADEC) and Federación Mexicana de Asociaciones Privadas (FEMAP), Chihuahua, México

^cEl Colegio de La Frontera Norte, Carretera Escénica Tijuana-Ensenada, Tijuana, Baja California, México

^dSchool of Social Work, University of Southern California, Los Angeles, CA, USA

^eDepartment of Psychiatry, University of California at San Diego, La Jolla, CA, USA

Table 1

Characteristics associated with female sex workers’ and intimate male partners’ concerns of male partners’ anger^a regarding microbicide use in Tijuana and Ciudad Juárez, Mexico (n=370).

	Concerned about male partners’ anger ^a (n=59, 17%)	Not concerned about male partners’ anger ^a (n=311, 83%)	Overall (n=370, 100%)	Concerned about male partner’s anger: marginal effect (robust standard error) ^b	
				Women (n=185)	Men (n=185)
Socio-Demographics					
Female gender (vs. male)	37 (63%)	148 (48%)	815 (50%)	--	--
Study site is Tijuana (vs. Ciudad Juárez)	54 (92%)	104 (33%)	158 (43%)	0.34 *** (0.04)	0.27 *** (0.06)
Median age in years (IQR ^c)	37 (29–44)	35 (30–42)	36 (30–42)	0.00 (0.00)	0.00 (0.00)
Median educational attainment in years (IQR)	7 (6–9)	6 (6–9)	6 (6–9)	0.00 (0.01)	0.01 (0.01)
Income ≥2500 pesos per month (>USD \$200)	39 (66%)	201 (65%)	240 (65%)	0.01 (0.06)	0.00 (0.05)
Median Rosenberg self-esteem score (IQR)	13 (12–14)	14 (12–14)	14 (12–14)	−0.05 *** (0.01)	0.01 (0.02)
Relationship Factors					
Median relationship duration in years (IQR) ^d	3 (2–5)	3 (2–6)	3 (2–6)	0.00 (0.01)	0.00 (0.01)
Median trust of partner on 10-point scale (IQR)	8 (7–10)	8 (8–10)	8 (8–10)	−0.02 (0.02)	−0.01 (0.01)
Median relationship satisfaction on 20-point scale (IQR)	15 (10–15)	15 (14–15)	15 (13–15)	−0.03 ** (0.01)	0.01 (0.02)
Male financial dependence on FSW’s income ^d	24 (41%)	88 (28%)	112 (30%)	0.11 * (0.06)	0.03 (0.05)
Any psychological aggression, past year ^d	46 (78%)	232 (75%)	278 (75%)	0.01 (0.07)	0.05 (0.06)
Any physical assault, past year ^d	30 (51%)	138 (44%)	168 (45%)	0.03 (0.06)	0.04 (0.05)
Any sexual coercion, past year ^d	13 (22%)	43 (14%)	56 (15%)	0.06 (0.08)	0.09 * (0.06)
Any injury, past year ^d	22 (37%)	64 (22%)	86 (23%)	0.07 (0.07)	0.14 *** (0.05)
Sexual Behaviours					
Sexually satisfied with steady partner (vs. not satisfied)	44 (75%)	284 (91%)	328 (89%)	−0.18 ** (0.07)	−0.15 ** (0.07)
Male partner had any outside sex partners (past 6 months; men only)	14 (64%)	52 (32%)	66 (36%)	0.19 *** (0.05)	0.13 *** (0.05)
Had any ‘steady’ concurrent sex partners (including regular clients; past year)	18 (31%)	42 (14%)	60 (16%)	0.15 ** (0.06)	0.07 (0.09)
FSW often/always uses condoms with clients (vs. rarely/never; past month; FSWs only)	17 (77%)	99 (84%)	116 (83%)	−0.06 (0.08)	0.63 *** (0.16)

Safety and Adherence to Intermittent Pre-Exposure Prophylaxis (PrEP) for HIV-1 in African Men Who Have Sex with Men and Female Sex Workers

Gaudensia Mutua¹, Eduard Sanders^{2,3}, Peter Mugo², Omu Anzala¹, Jessica E. Haberer⁴, David Bangsberg⁴, Burc Barin⁵, James F. Rooney⁶, David Mark⁷, Paramesh Chetty⁸, Patricia Fast⁷, Frances H. Priddy^{7*}

1 Kenya AIDS Vaccine Initiative, University of Nairobi, Nairobi, Kenya, **2** Kenya Medical Research Institute, Kilifi, Kenya, **3** Nuffield Department of Medicine, University of Oxford, Headington, United Kingdom, **4** Massachusetts General Hospital Center for Global Health, Boston, Massachusetts, United States of America, **5** The EMMES Corporation, Rockville, Maryland, United States of America, **6** Gilead, Foster City, California, United States of America, **7** International AIDS Vaccine Initiative, New York, New York, United States of America, **8** International AIDS Vaccine Initiative, Johannesburg, South Africa

Methods/Principal Findings: MSM and FSW were randomized to daily oral FTC/TDF or placebo, or intermittent (Monday Friday and within 2 hours after sex, not to exceed one dose per day) oral FTC/TDF or placebo in a 2:1:2:1 ratio; volunteers were followed monthly for 4 months. Adherence was assessed with the medication event monitoring system (MEMS). Sexual activity data were collected via daily text message (SMS) queries and timeline followback interviews with a one month recall period. Sixty-seven men and 5 women were randomized into the study. Safety was similar among all groups. Median MEMS adherence rates were 83% [IQR: 63–92] for daily dosing and 55% [IQR:28–78] for fixed intermittent dosing ($p=0.003$), while adherence to any post-coital doses was 26% [IQR:14–50]. SMS response rates were low, which may have impaired measurement of post-coital dosing adherence. Acceptability of PrEP was high, regardless of dosing regimen.

Table 3. PrEP adherence rates for daily and intermittent groups.

		Active	Placebo	Overall
DAILY ADHERENCE RATE	Overall unadjusted	82% [62–89]	84% [63–96]	83% [63–92]
Median [IQR]				
	Adjusted*	92% [79–101]	93% [84–96]	92% [82–99]
INTERMITTENT ADHERENCE RATE	Overall unadjusted	72% [62–80]	68% [63–76]	68% [63–78]
Median [IQR]				
	Fixed doses	56% [31–88]	34% [19–72]	55% [28–78]
	Post-coital doses	32% [13–50]	19% [14–45]	26% [14–50]
	Post-coital doses – (MEMS events and self report sexual events)	27% [13–60]	16% [8–37]	23% [13–50]
	Post-coital doses within 2 hrs** (self report and sexual events per SMS)	115% [57–175]	100% [61–174]	105% [57–175]
	Post-coital doses within 2 hr (self report doses and sexual events)	100% [100–100]	100% [67–100]	100% [96–100]

*Adjusted accounts for extra openings and extra pills taken out.

**Days on which sexual event reported per SMS.

doi:10.1371/journal.pone.0033103.t003



**Et encore
la PreP en marche...**

Microbicides and PrEP

Where We Have Been and Where We Are Going



Ian McGowan MD PhD FRCP
Magee-Womens Research Institute
University of Pittsburgh



Intermittent PrEP Trials

- HPTN-066
 - Directly observed therapy
- HPTN-067
 - MSM (N = 180, Bangkok, Thailand)
 - WSM (N = 180 Cape Town, South Africa)
- **IPERGAY !**
 - MSM (1900)
 - France & Canada
 - Pericoital dosing



ANRS - IPERGAY

Phase pilote en cours

**Traitement antirétroviral “à la demande”
en prophylaxie pré-exposition de l’infection par le VIH
chez les hommes ayant des rapports sexuels avec des
hommes en France (Saint-Louis & Tenon (APHP) et Lyon)**



Essai randomisé en

- HSH à haut r
- ≥ 2 rapports
les 6 mois

- Dans les deu
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- Critère de ju
- Sérologie VII
- Deux comp
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**HELP
WANTED**

Next-PrEP (HPTN-069)

- Phase 2 study in at risk MSM in the US
- One year follow-up
- Four arms with 100 participants per arm
 - Maraviroc + FTC (P) + TDF (P)
 - Maraviroc + FTC + TDF (P)
 - Maraviroc + FTC (P) + TDF
 - Maraviroc (P) + FTC + TDF
- PK/PD subset in 60 participants



Intravaginal Rings

- Phase 1/2 development ongoing
- Dapivirine ± maraviroc
 - MTN-013
- Phase 3 starting Q3 2012
 - MTN-020
 - IPM-027
- Multipurpose technology
 - Antiretroviral + contraceptive



Ongoing Microbicide Trials

AVAC, July 2012

TRIAL NAME	PHASE	START DATE	LOCATIONS	SPONSOR / FUNDER	POPULATION	CANDIDATE(S)	STATUS / EXPECTED COMPLETION
FACTS 001	III	October 2011	South Africa	BMGF, CONRAD, South Africa DST, South Africa National DOH, USAID	2900 Women, Heterosexual	1% tenofovir gel	Ongoing / May 2014
CAPRISA 008	III	August 2012	South Africa	CAPRISA, MAC AIDS Fund, South African DST, USAID through CONRAD	700 Women	1% tenofovir gel	Ongoing / February 2015
IPM 027 (The Ring Study)	III	March 2012	Malawi, Rwanda, South Africa	IPM	1650 Women	4-week vaginal dapivirine ring	Ongoing / August 2015
MTN 003 (VOICE)	IIb	September 2009	Malawi, South Africa, Uganda, Zimbabwe	CONRAD, Gilead, MTN, NIAID, NICHD, NIMH	5000 Women, Heterosexual	1% tenofovir gel, Daily oral TDF/FTC, Oral TDF	Ongoing / March 2013
IPM 015	I/II	April 2010	Kenya, Malawi, South Africa, Tanzania	IPM	280 Women	4-week vaginal dapivirine ring	Ongoing / March 2012
IPM 014A	I/II	November 2009	Kenya, Malawi, Rwanda, South Africa, Tanzania	IPM	280 Women	Once-daily dapivirine vaginal gel	Ongoing / May 2012
IPM 014B	I/II	September 2009	South Africa	IPM	100 Women	Once-daily dapivirine vaginal gel	Ongoing / June 2012
IPM 020	I/II	July 2009	United States	IPM	128 Women	Once-daily dapivirine vaginal gel	Ongoing / June 2012
MTN 005	I/II	May 2011	India, United States	MTN, NIAID, NIMH, Population Council	252 Women	Placebo vaginal ring	Ongoing / May 2013
MTN 008	I	April 2011	United States	CONRAD, MTN, NIAID, NICHD	105 Women	1% tenofovir gel	Ongoing / April 2013
Project Gel	I	October 2010	United States	CONRAD, NICHD, NIMH	240 MSM	1% tenofovir rectal gel, HEC placebo rectal gel	Ongoing / December 2012
CONRAD 120	I	June 2012	United States	CONRAD	36 Women	1% tenofovir vaginal ring	Ongoing / December 2012
CONRAD 118	I	June 2012	United States	CONRAD	54 Women	1% tenofovir gel, Antifungal cream, Antimicrobial gel, Contraceptive ring	Ongoing / June 2013
CONRAD 117	I	June 2012	United States	CONRAD	48 Women	TFV/FTC fast dissolve vaginal tablet, TFV-only fast dissolve vaginal tablet	Ongoing / June 2013
CONRAD 114	I	March 2012	Dominican Republic, United States	CONRAD	72 Women	1% tenofovir gel, Depo-provera, Oral contraceptive	Ongoing / March 2013
IPM 026/MTN 013	I	November 2011	United States	IPM, MTN, NIAID, NIMH	48 Women	4-week vaginal dapivirine ring, 4-week vaginal dapivirine-maraviroc ring, 4-week vaginal maraviroc ring	Ongoing / April 2013
Sex Workers Study	Other	February 2010	India	NIH, Population Council, USAID, Y.R. Gaitonde Centre for AIDS Research and Education (YRG CARE)	267 Women	HEC placebo vaginal gel	Ongoing / February 2012
MTN 003C	Other	June 2010	South Africa	MTN, NIAID, NIMH	275 Women, Men	N/A	Ongoing / January 2013
MTN 003B	Other	November 2009	Uganda, Zimbabwe	Gilead, MTN, NIAID	518 Women	Daily oral TDF/FTC, Oral TDF	Ongoing / January 2013
MTN 016 (EMBRACE)	Other	October 2010	South Africa, Uganda, United States, Zimbabwe	MTN, NIH, CONRAD	800 Women	N/A	Ongoing / May 2013
MTN 015	Other	August 2008	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIAID	500 Women	N/A	Ongoing / May 2013



Rectal Microbicides

- Phase 1 safety, acceptability, PK/PD studies completed
 - RMP-01 (UC781)
 - RMP-02/MTN-006 (Tenofovir)
 - MTN-007 (Tenofovir)
- Phase 2 study to start in Q3 2012
 - MTN-017
- Rectal specific combination products in development
 - Tenofovir/maraviroc



MEN & WOMEN DEMAND RECTAL MICROBICIDES

Intra-Muscular Antiretrovirals

- Rilpivirine (NNRTI)
- Licensed for treatment of HIV
- IM nanosuspension
 - TMC278 LA
- Potential for 1-3 month delivery
- Phase 1 clinical trials in progress
 - Single dose PK/PD (London)
 - Multiple dose PK/PD (Pittsburgh)



Quel meilleur Kit pour les SW ?



**Preservatif + Prep
PreP gel , IM, cp ?
TasP + PreP ?**