

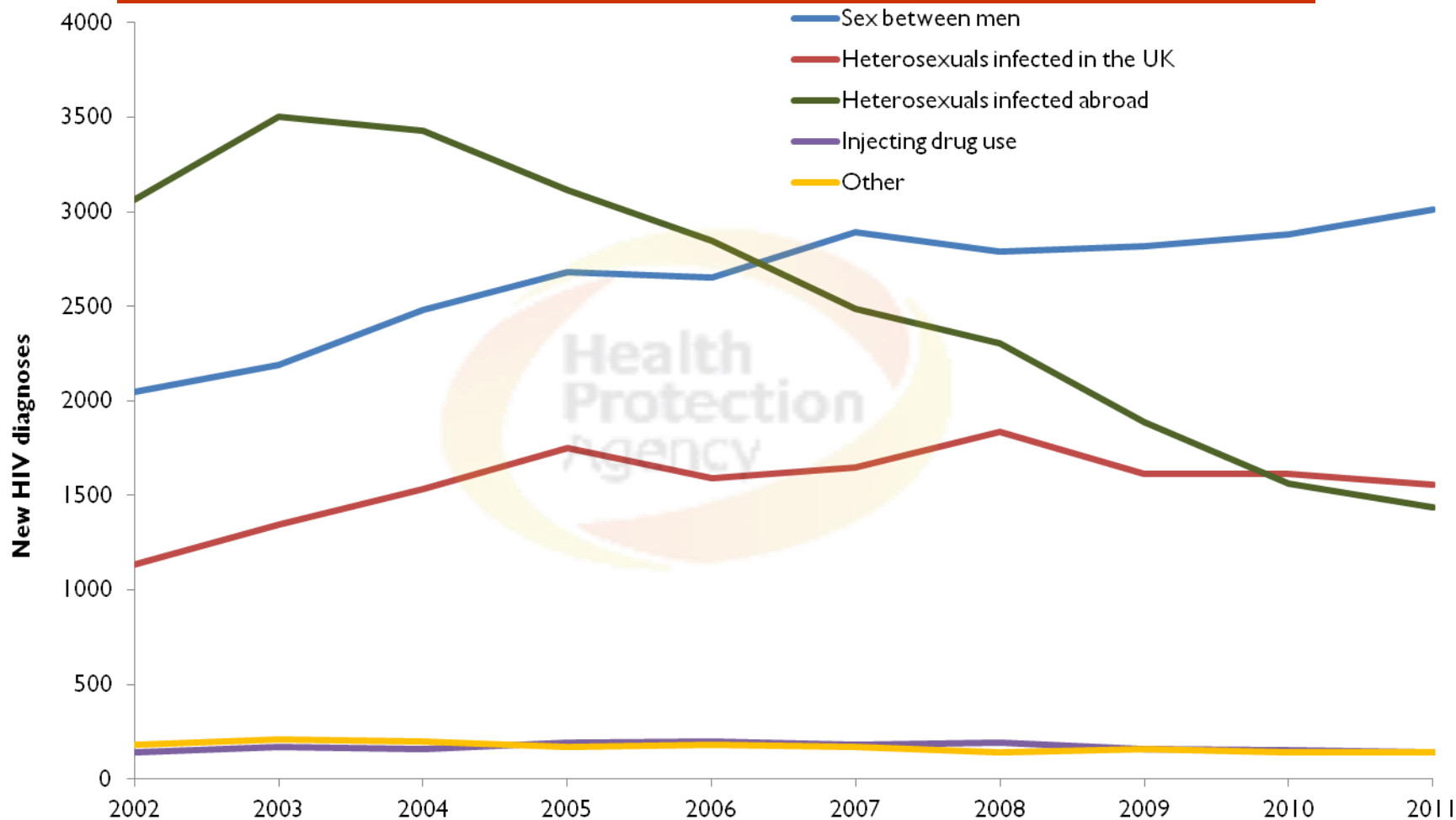
# ART and Transmission



Martin Fisher

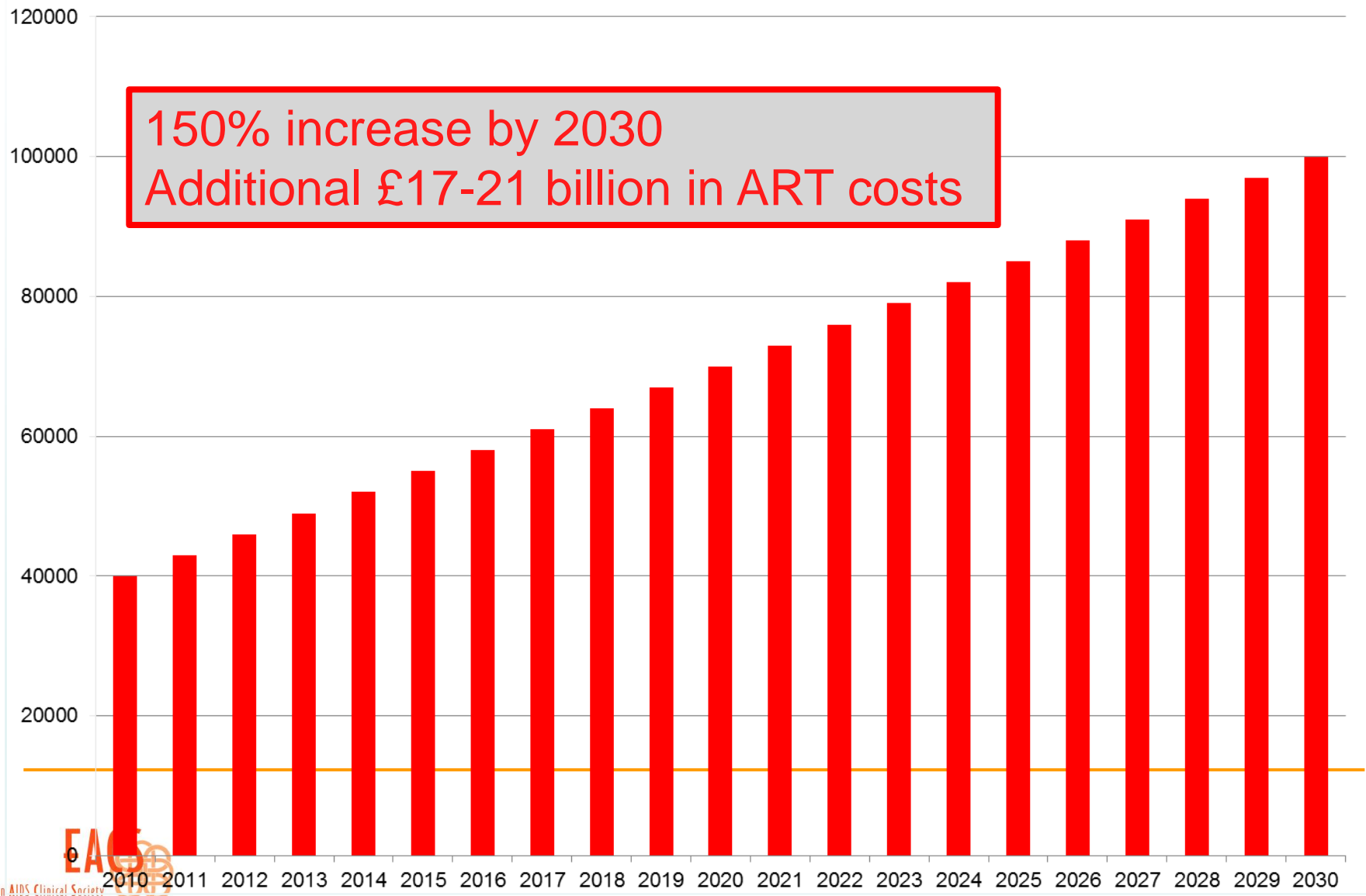
Brighton and Sussex University Hospitals, UK

# New HIV diagnoses by exposure group: United Kingdom, 2002 – 2011<sup>1</sup>



<sup>1</sup> Data adjusted for missing exposure group information

# Predicted increase in the number of MSM living with HIV in the UK



# Global HIV Epidemic

- 2011 figures:
  - 2.2 million adults newly infected with HIV
    - 2.5 million total new infections
- 5 new infections for every 2 individuals treated in Sub-saharan Africa

# Recent Prevention Trials

## Study

Treatment for prevention

HPTN 052

Tenofovir/Truvada for discordant couples

Partners PrEP

Truvada for heterosexuals

TDF-2

Medical male circumcision

Truvada for MSMs

iPrEx

Tenofovir vaginal (coital)

Caprisa 004

Prime boost Vaccine

Truvada for women

FEM PrEP

Tenofovir gel (daily)

for women

VOICE

## Effect size (95% CI)

**96% (73; 99)**

**73% (49; 85)**

**63% (22; 83)**

**54% (38; 66)**

**44% (15; 63)**

**39% (6; 60)**

**31% (1; 51)**

**0% (-69; 41)**

**0% (-49; 34)**

**Efficacy**

0% 10 20 30 40 50 60 70 80 90 100%

# Outline

- Review of rationale for ART and reducing transmission
- Review of key data
- Consideration of issues for implementation
- Outline ongoing research
- Outline key policy documents
  - **Pre-exposure prophylaxis**
    - Microbicides
  - Post-exposure prophylaxis
    - **ART as prevention**

- Post-exposure prophylaxis

# PEP

- Biological plausibility
  - “window of opportunity” in 72 hours
- Animal model studies
- Case-controlled study
  - 81% protection in health-care workers
- **No RCT**
- One published study for sexual exposure (PEPSE)....



# PEPSE

- **“Praca Onze” Study**
  - MSM in Rio, Brazil
  - Given PEP pack to start after risk exposure
  - N=200, follow-up 24 months
  - 10 seroconversions in “non-PEP users” (4.2%); 1 seroconversion in “PEP user” (0.6%);  $p < 0.05$
  - However...overall HIV incidence 2.9/100py compared to 3.1/100py expected;  $p > 0.97$
  - *“PEP did not appear to substantially affect HIV transmission”*

# PEP

- Guidelines continue to recommend
  - Occupational and sexual exposure
- Guidelines beginning to embrace viral load and ART status
  - e.g. UK guidelines no longer recommend PEPSE if viral load undetectable
- Variation in timing
  - e.g. EACS 48 hours, WHO and UK 72 hours
- Opportunities to improve tolerability
  - Truvada, raltegravir, maraviroc
- Opportunity for more-effective prevention strategies?....

*But...PEP is an essential part of PrEP....*

- Microbicides

# Microbicides

- Biological plausibility
- Effectiveness in animal models
- RCTs for vaginal application ....

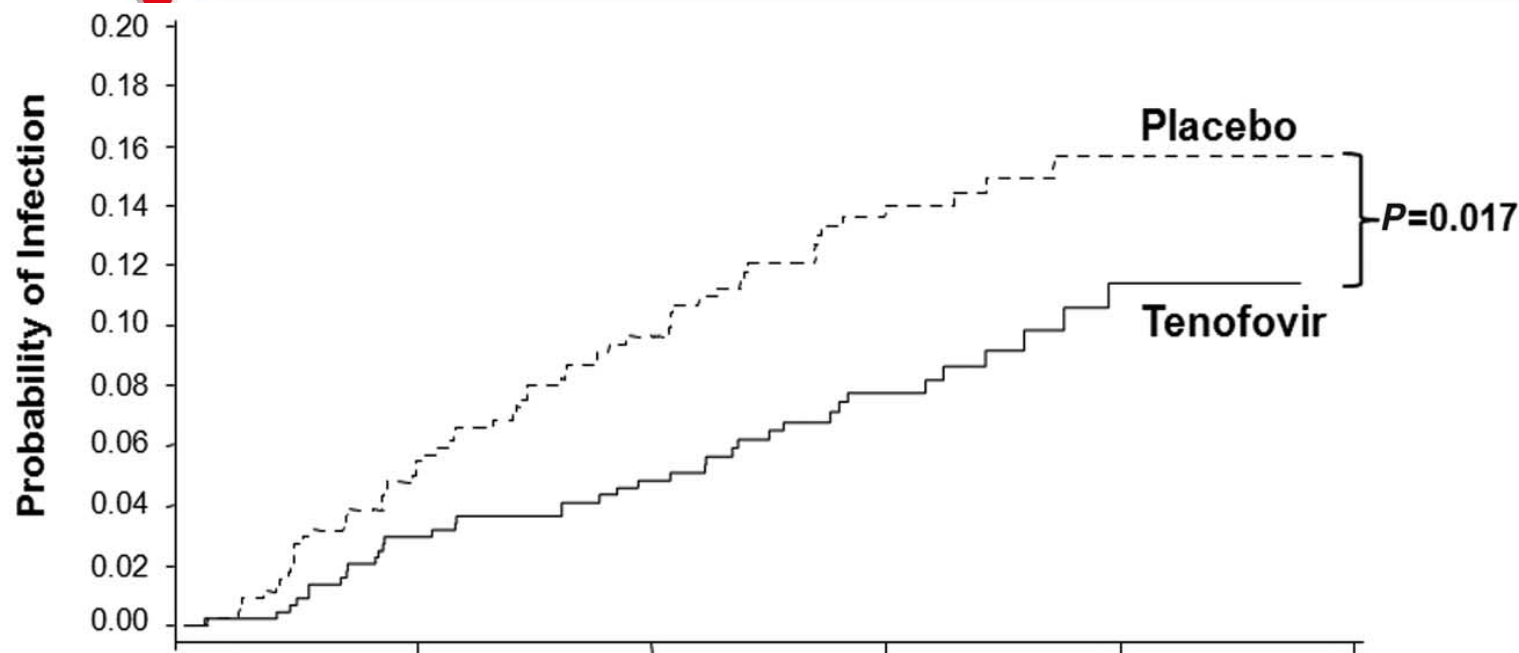


# CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA



CAPRISA IS A UNAIDS  
COLLABORATING CENTRE  
FOR HIV PREVENTION RESEARCH



Months of follow-up	6	12	18	24	30
Cumulative HIV endpoints	37	65	88	97	98
Cumulative women-years	432	833	1143	1305	1341
HIV incidence rates (Tenofovir vs Placebo)	6.0 vs 11.2	5.2 vs 10.5	5.3 vs 10.2	5.6 vs 10.2	5.6 vs 9.1
Effectiveness ( <i>P</i> -value)	47% (0.064)	50% (0.007)	47% (0.004)	40% (0.013)	39% (0.017)

Science  
July  
2011

# Microbicides

- But....
- November 2011: VOICE trial
  - Tenofovir vaginal gel arm discontinued
  - No efficacy compared to placebo
- Ongoing research:
  - Different modes of application (rings)
  - Different agents (e.g. dapivirine, maraviroc)
  - Other patient groups (MSM and rectal microbicides)

- Pre-exposure prophylaxis (PrEP)

# PrEP

- Biological plausibility
- Animal model studies
- RCTs....

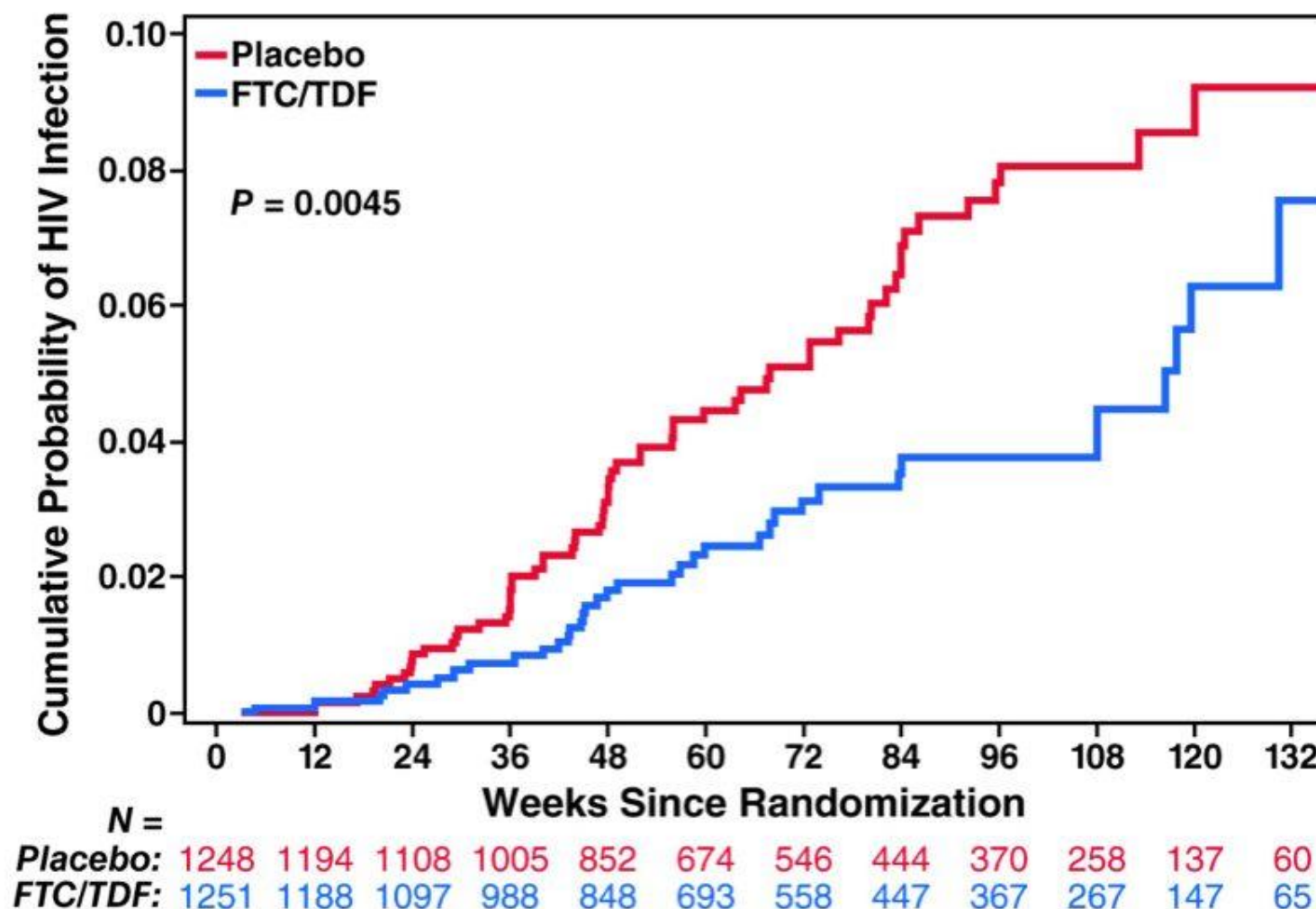




**Efficacy: 44%, 95 CI: 15 – 63%**

**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





PARTNERS PrEP STUDY

**Efficacy TDF: 67%, 95% CI: 44 – 81%**

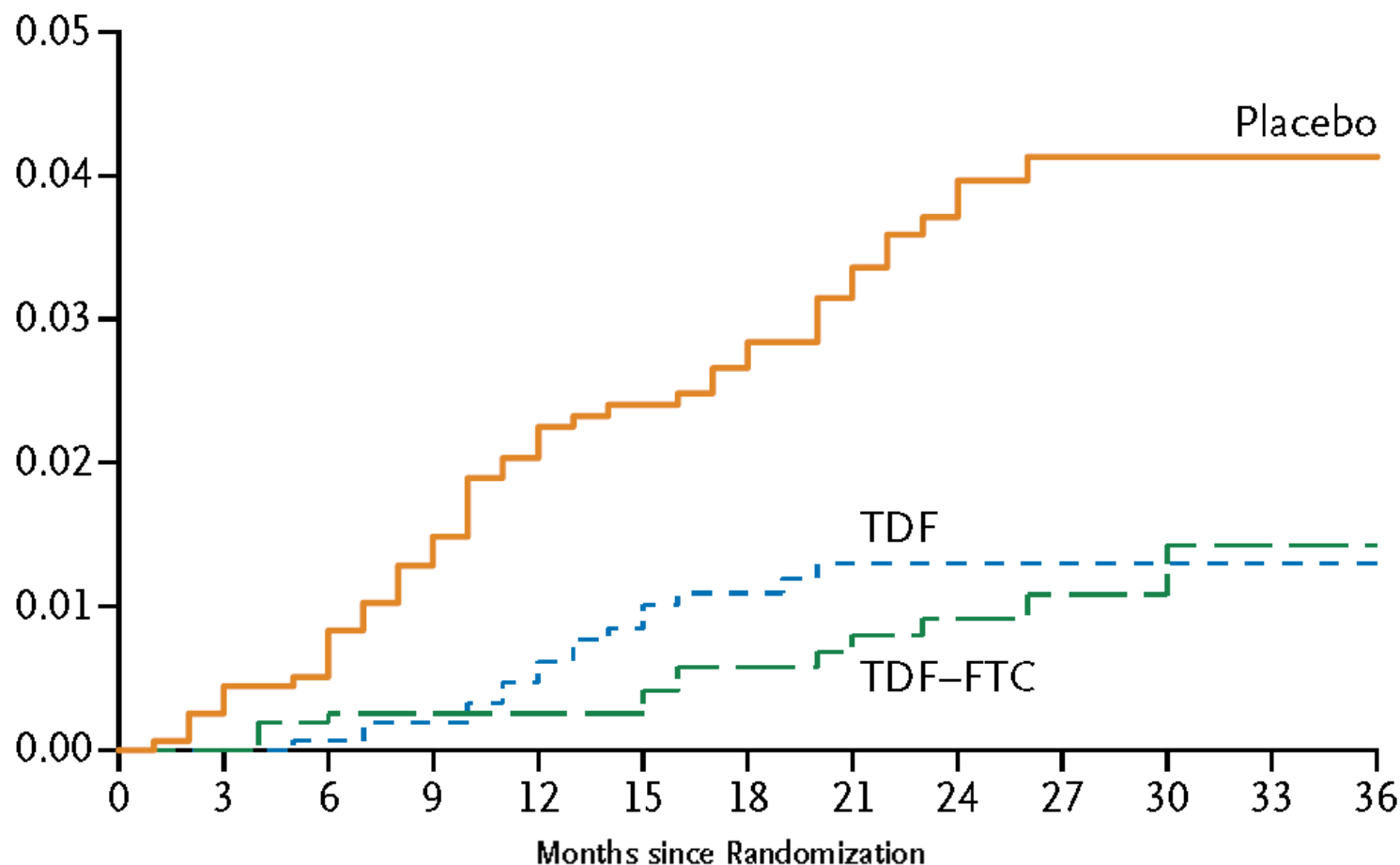
**FTC/TDF: 75%, 95% CI: 55 – 87%**

**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

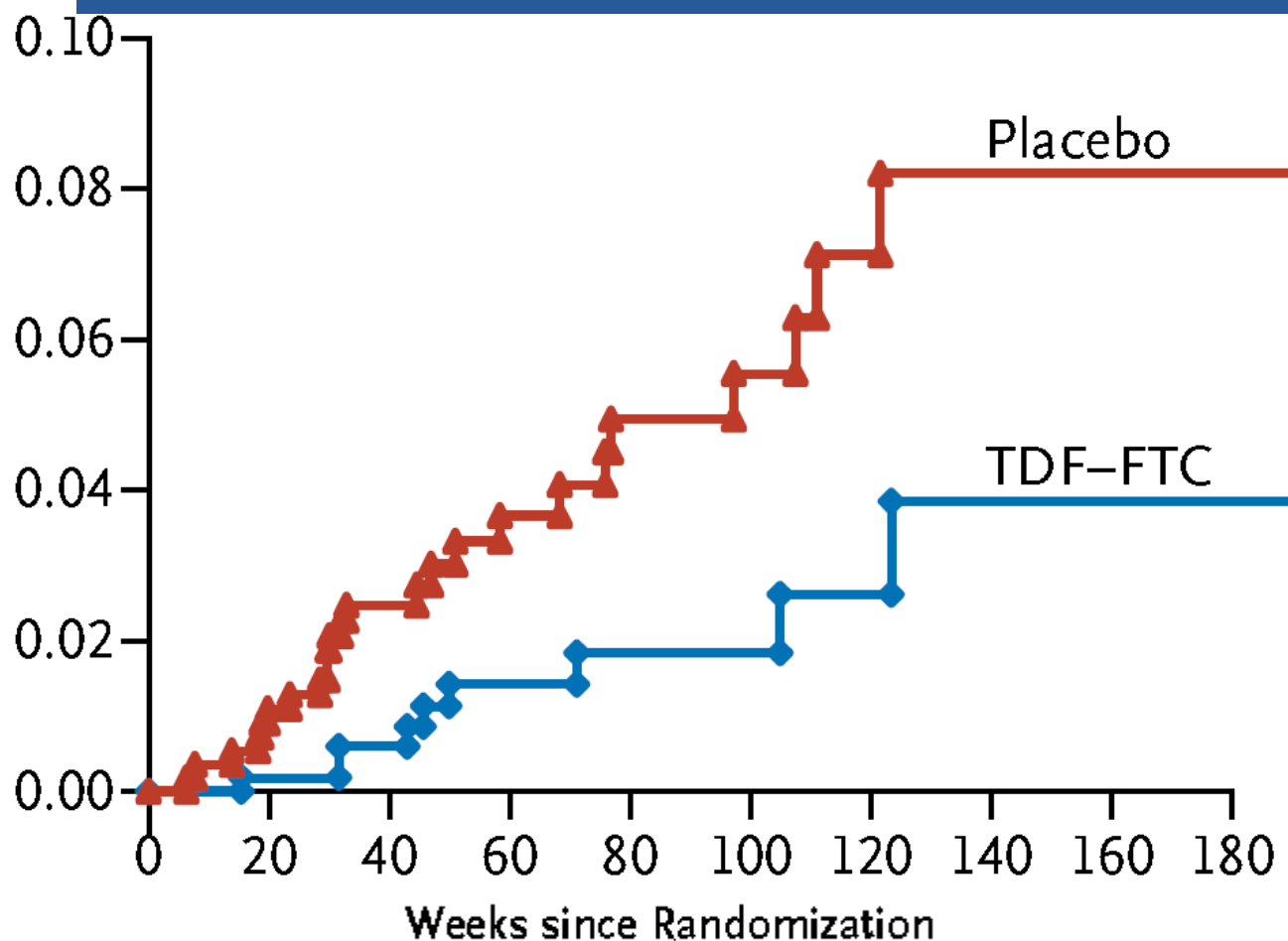


# TDF-2 Study

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

**Infections Numbers: 52 – 17 = 35 averted**

n = 1,219 heterosexual men and women;  
Botswana



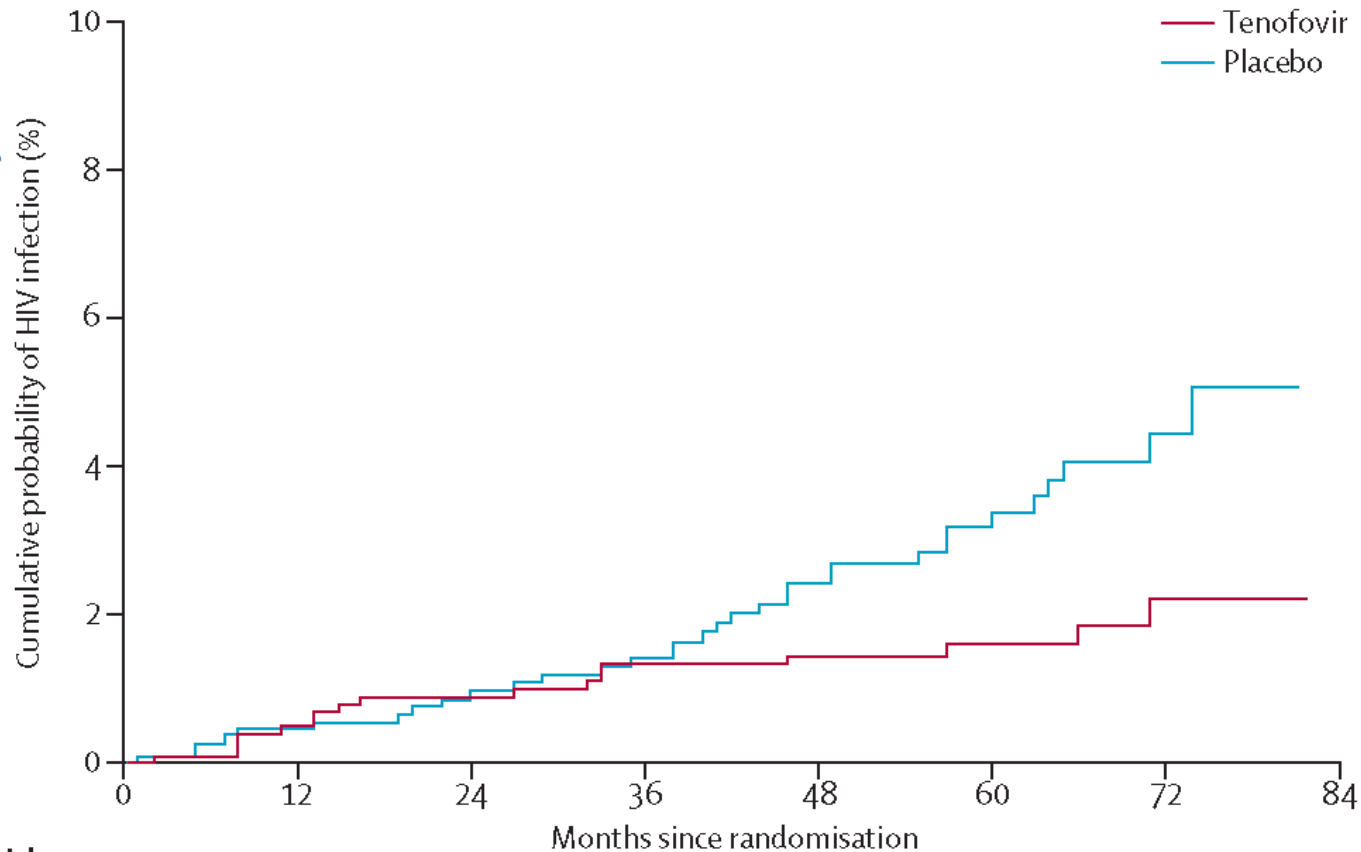


# Bangkok Tenofovir Study

## 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

# Oral TDF and FTC/TDF PrEP Study

**Effect Size**  
(95% CI)

**FTC/TDF for HIV  
discordant couples  
(Partners PrEP)**

**75% (55; 87)**

**TDF for HIV  
discordant couples  
(Partners PrEP)**

**67% (44; 81)**

**TDF for young  
heterosexuals  
(TDF-2)**

**63% (22; 83)**

**TDF/FTC for  
injecting drug users  
(Bangkok TDF)**

**49% (10; 72)**

**TDF for MSM and  
TW  
(iPrEx)**

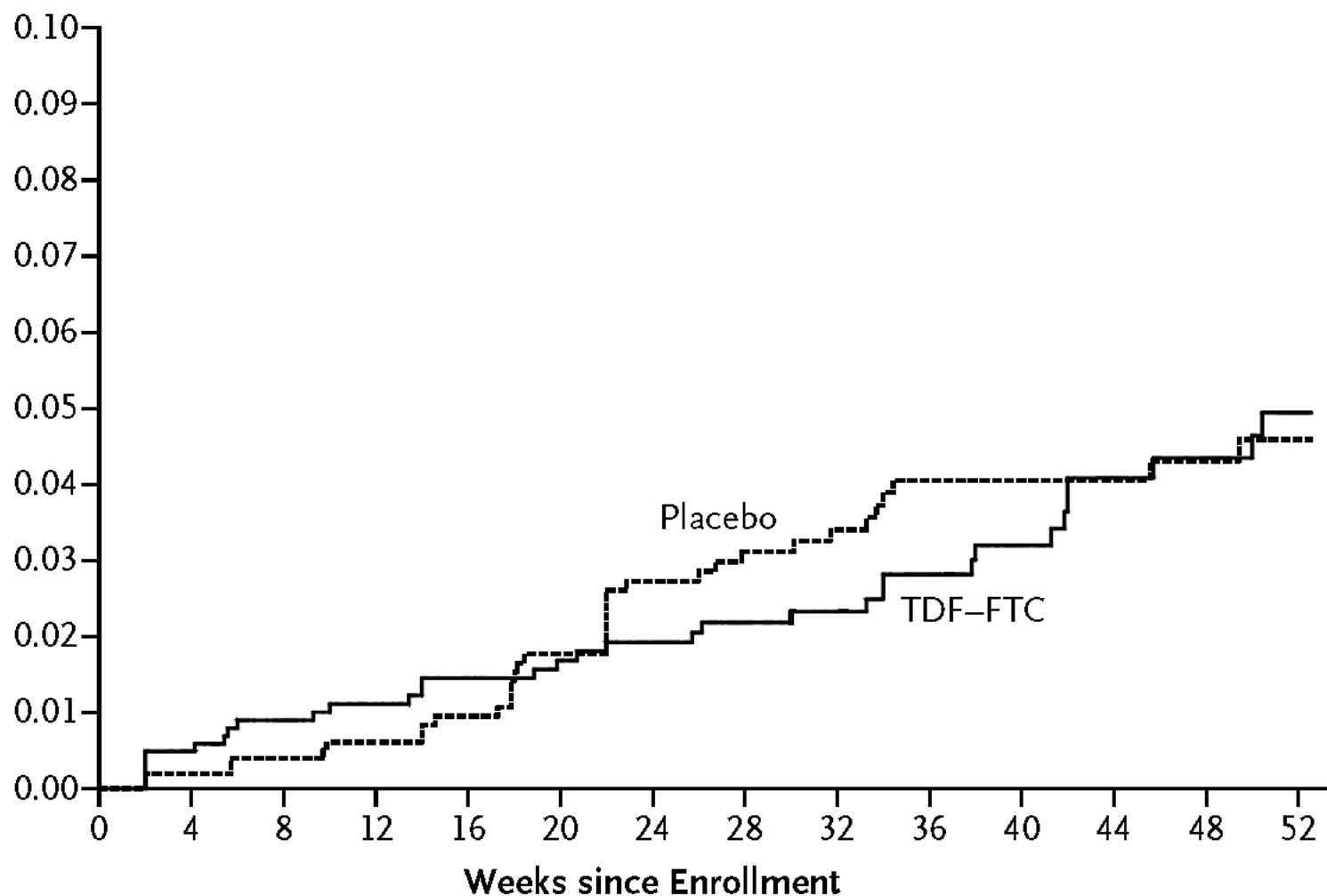
**44% (15; 63)**

**Efficacy**

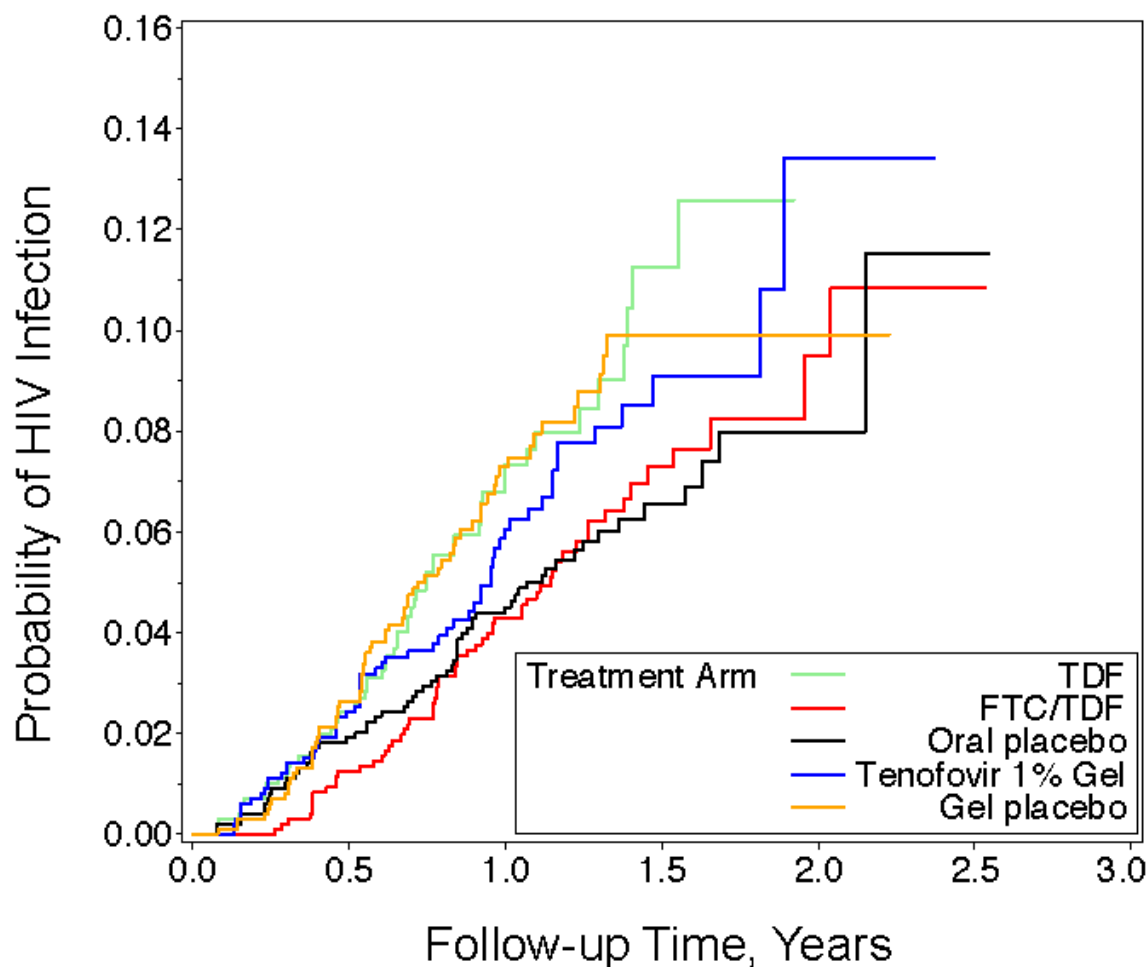
0 10 20 30 40 50 60 70 80 90 100%

# FEM-PrEP Efficacy: 6%, 95% CI: -52 – 41%

n = 2,120 women;  
Kenya, South Africa, Tanzania

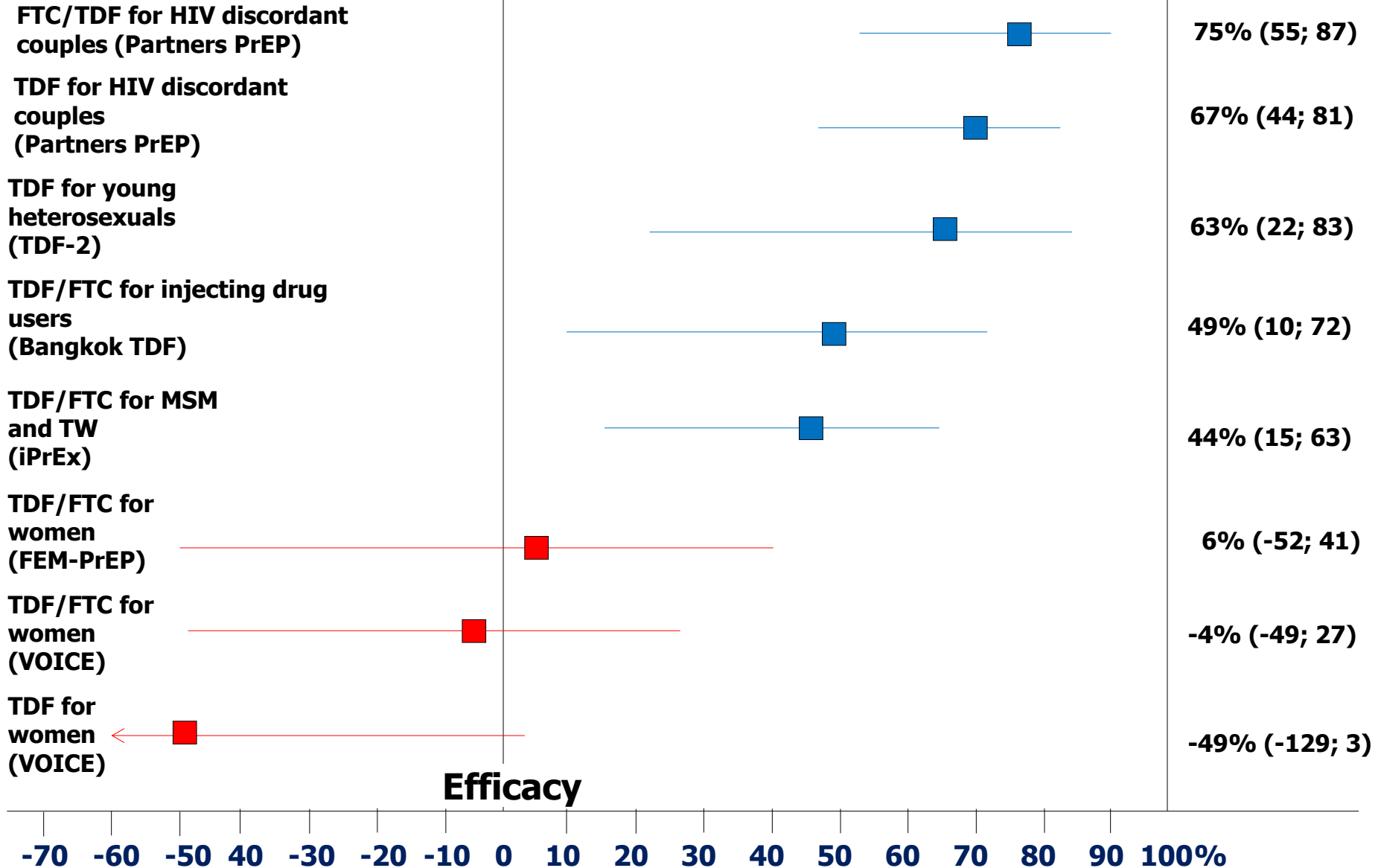


**Efficacy TDF: -49%, 95% CI: -130 – 3%**  
**FTC/TDF: -4%, 95% CI: -50 – 30%**  
 n = 3,019 women in oral PrEP or placebo,  
 South Africa, Uganda, Zimbabwe



# Oral TDF and FTC/TDF PrEP Study

**Effect Size  
(95% CI)**



Modified from: Abdool Karim SS. Lancet 2013; 381(9883):2060-2.



# PrEP Studies: why different results?

- Statistical anomaly
- Gender difference
- Pharmacokinetics of genital tracts
- Serodiscordant versus casual partners
- Biological co-factors and higher risk for acquisition
- **Adherence**

# FEM-PrEP: Adherence Measurements

	Drug	Placebo
<i>Reported</i>		
Usually/always took study pill	95%	95%
<i>Reported</i>		
Easy/very easy to take pills	97%	96%
<i>Measured</i>		
Pills taken (based on number returned)	86%	89%
<i>Measured</i>		
Effective drug levels in blood near time of infection	26-40%	NA

# Dose Response Relationship between Adherence and PrEP

Study	Reported Efficacy	Adherence*	HIV Protection Estimate
FTC/TDF Partners PrEP	75%	81%	90%
TDF Partners PrEP	67%		86%
TDF2	63%	79%	78%
Bangkok TDF	49%	67%	70%
iPrEx	44%	51%	92%

\* Based on tenofovir blood levels in non-seroconverters

# Concerns about PrEP

- Which drug(s)?
- How often?
- Cost
- Toxicity
  - Decreased BMD seen in trials
- Healthcare utilisation
- Regular HIV testing
  - How often?
- Adherence
  - How much is enough?
- Resistance
- Who to target?
- “Stopping rules” as well as starting rules
- *Awareness*
- *Willingness*

***What will adherence be like if people know they are on active drug?***

# Intermittent PrEP

Fixed / Time-based dosing

Event-based dosing

Fixed dosing with event-based supplementation

Periodic PrEP

Patient preference: daily > event-based

But adherence patterns in trials....

50% MSM last AI “planned”; but.....

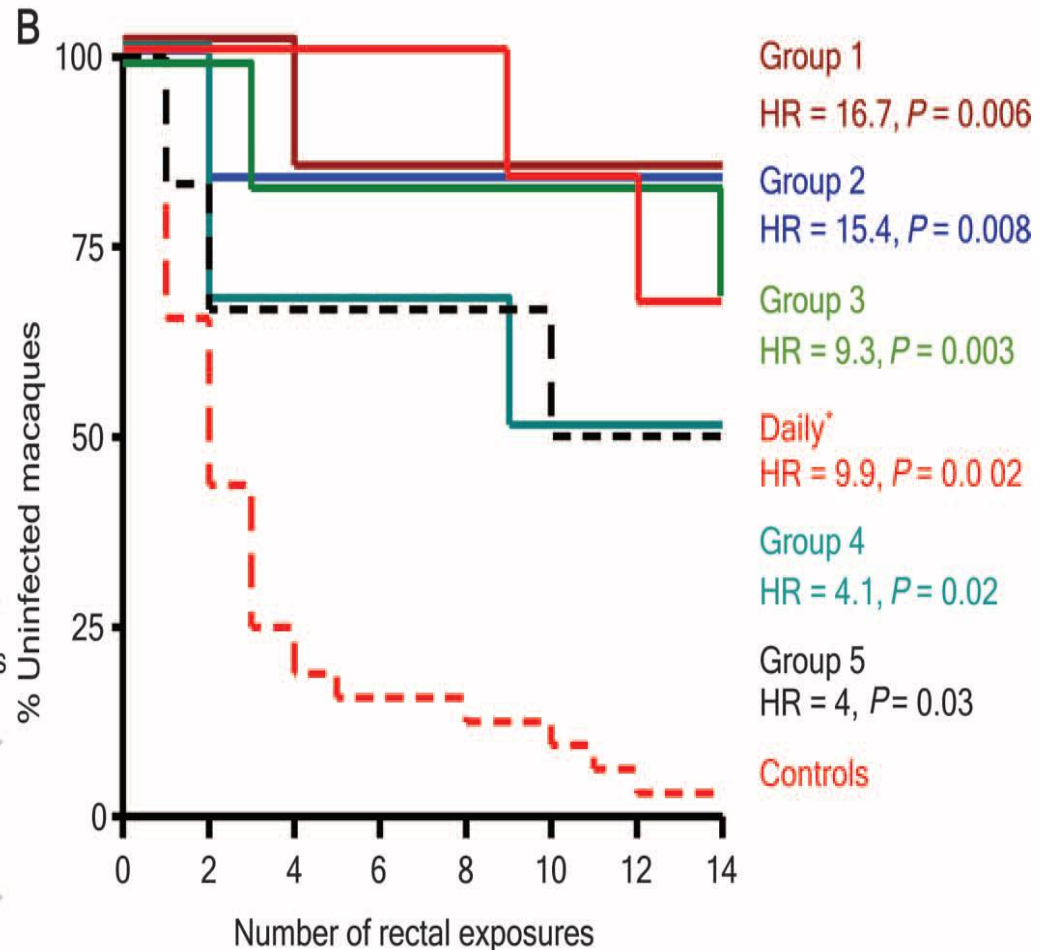
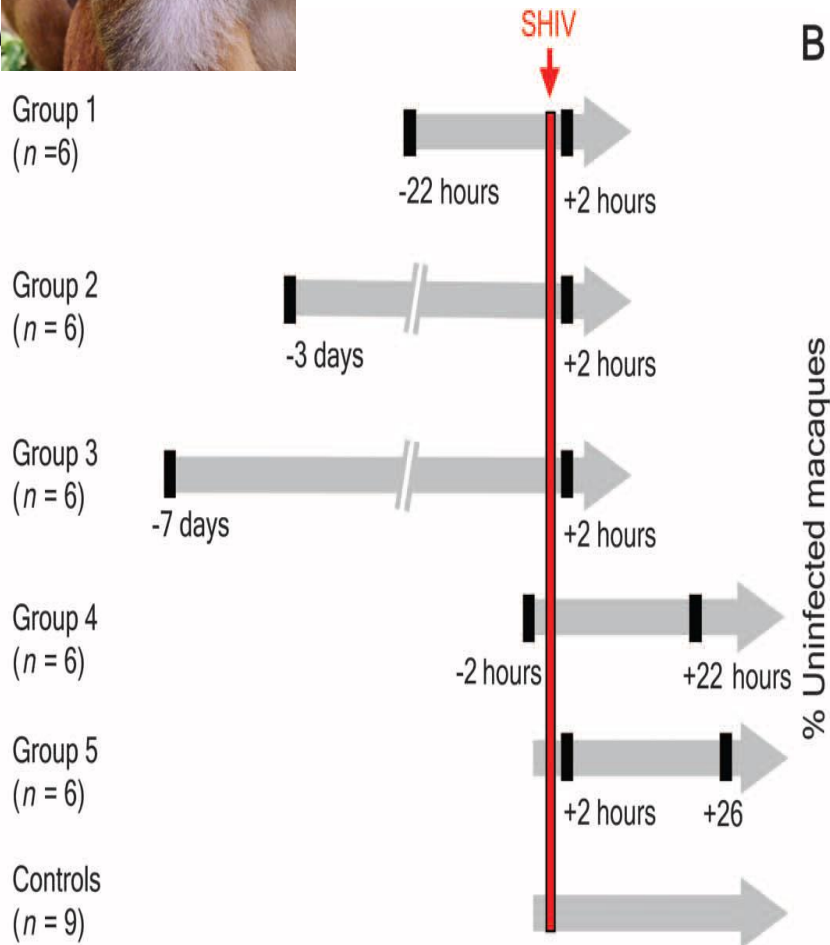
Concerns regarding pharmacokinetics

?need to achieve steady-state before intermittent dosing

*Buchbinder, CROI 2012 #68*



# Efficacy of iPrEP with TDF/FTC in the SHIV Macaque Model



# Key Ongoing Studies

- ANRS “IPER-GAY” (France)
  - RCT
  - PrEP versus placebo
  - Pericoital PrEP (TVD)
- PROUD (UK)
  - RCT
  - Immediate versus deferred
  - Recommended daily PrEP (TVD)



# FDA approve Truvada

## **FDA NEWS RELEASE**

**For Immediate Release:** July 16, 2012

**Media Inquiries:** Erica Jefferson, 301-796-4988,  
[erica.jefferson@fda.hhs.gov](mailto:erica.jefferson@fda.hhs.gov)

**Consumer Inquiries:** 888-INFO-FDA

### **FDA approves first drug for reducing the risk of sexually acquired HIV infection**

*Evidence-based approach enhances existing prevention strategies*

Today, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir disoproxil fumarate), the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners



*Centers for Disease Control and Prevention*

**MMWR**

Morbidity and Mortality Weekly Report

Weekly / Vol. 62 / No. 23

June 14, 2013

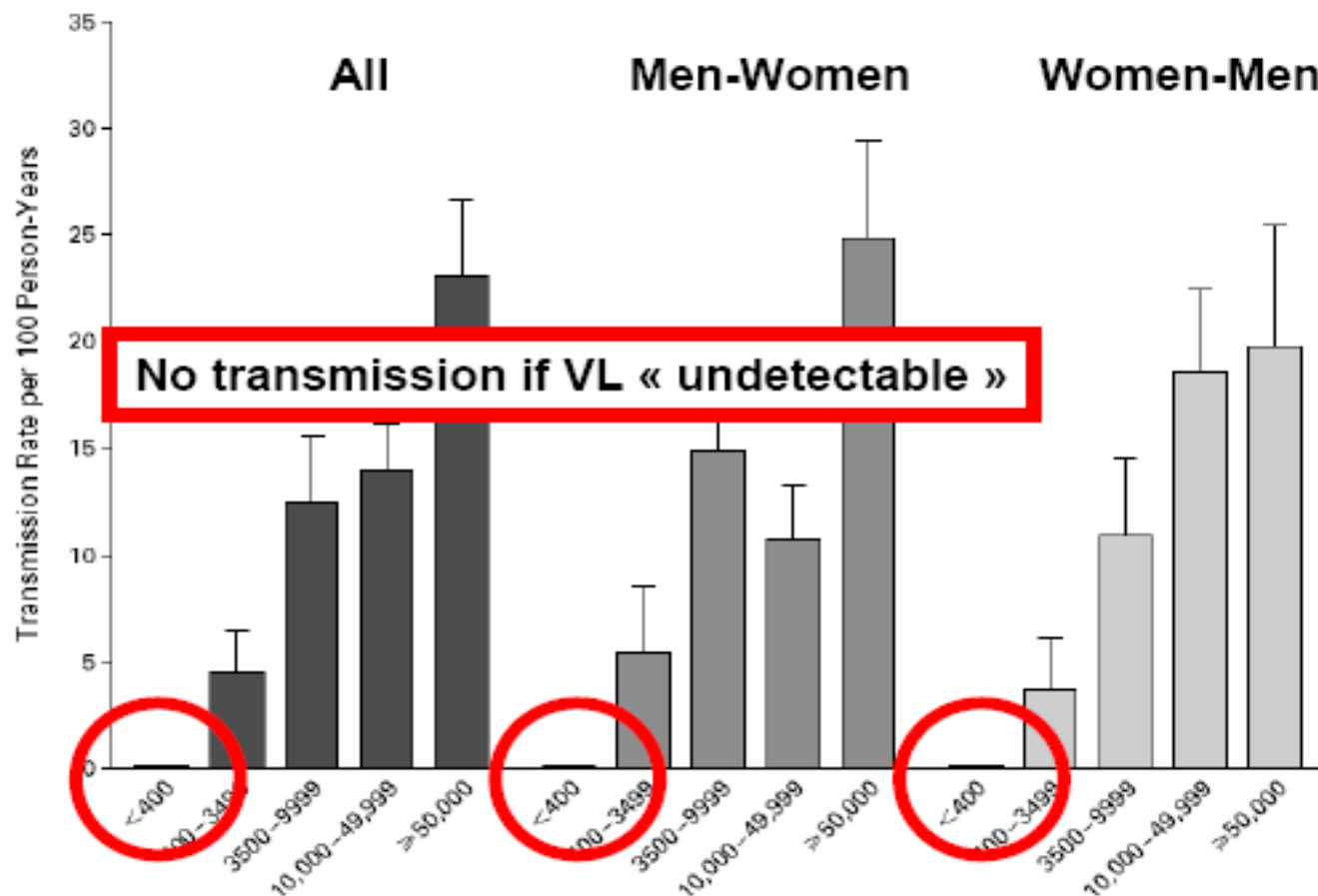
Morbidity and Mortality Weekly Report

## **Update to Interim Guidance for Preexposure Prophylaxis (PrEP) for the Prevention of HIV Infection: PrEP for Injecting Drug Users**

- Treatment as prevention (TasP)

# TasP

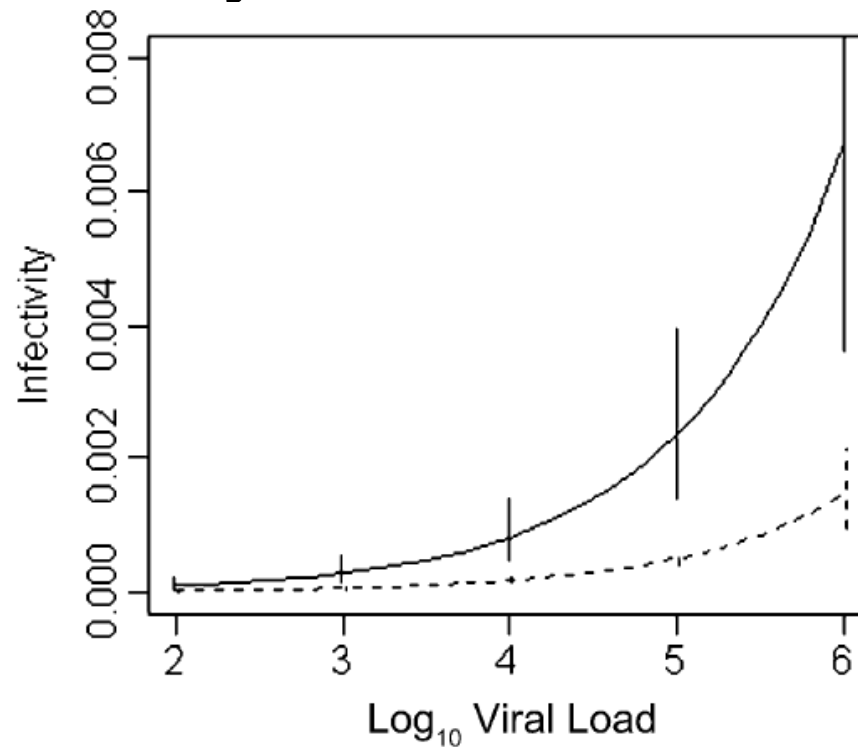
- Biological plausibility
- Observational studies
- “Ecological” studies
- Mathematical models
- RCT .....



« Rakai » Study: Transmission risk as a function of viral load

Quinn et al. *N Engl J Med* 2000;342:921-9

# Infectivity and Viral Load



**Figure 1.** Per-act probability of transmission (infectivity) vs log<sub>10</sub> plasma HIV-1 RNA (copies/mL) from a model that includes plasma human immunodeficiency virus type 1 RNA and condom use only. Solid line is without reported condom use and dashed line is with reported condom use. Vertical lines represent 95% confidence intervals.

# Partners in prevention study

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Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis

---

Transmission rate (per 100 years)

Initiated ART

Not initiated ART

0.37 (95% CI 0.09–2.04)

2.24 (1.84–2.72)

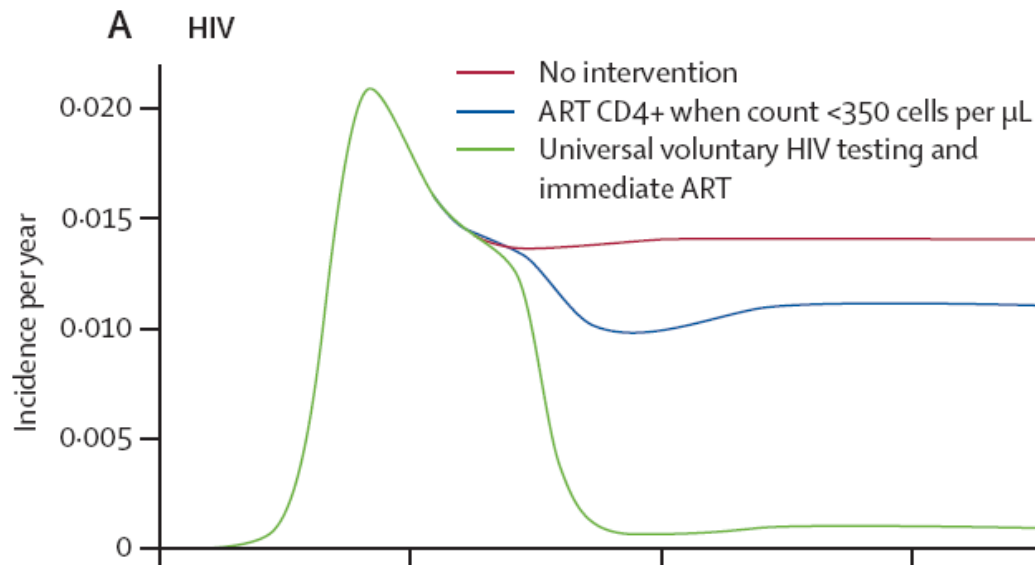
( $p=0.004$ )

**92% reduction in HIV transmission with ART**

# ART for Prevention: The WHO Model

- Annual testing by all >15 year old individuals
- All HIV+ individuals started on ART immediately
- 99% decrease in infectiousness
- High adherence with ART
- Low failure with first line ART

- 95% reduction in new HIV cases in 10 years
- HIV Incidence reduced from 15-20,000 to 1000 per million
- Prevalence decreases to less than 1% by 2050



# Models of ART and transmission

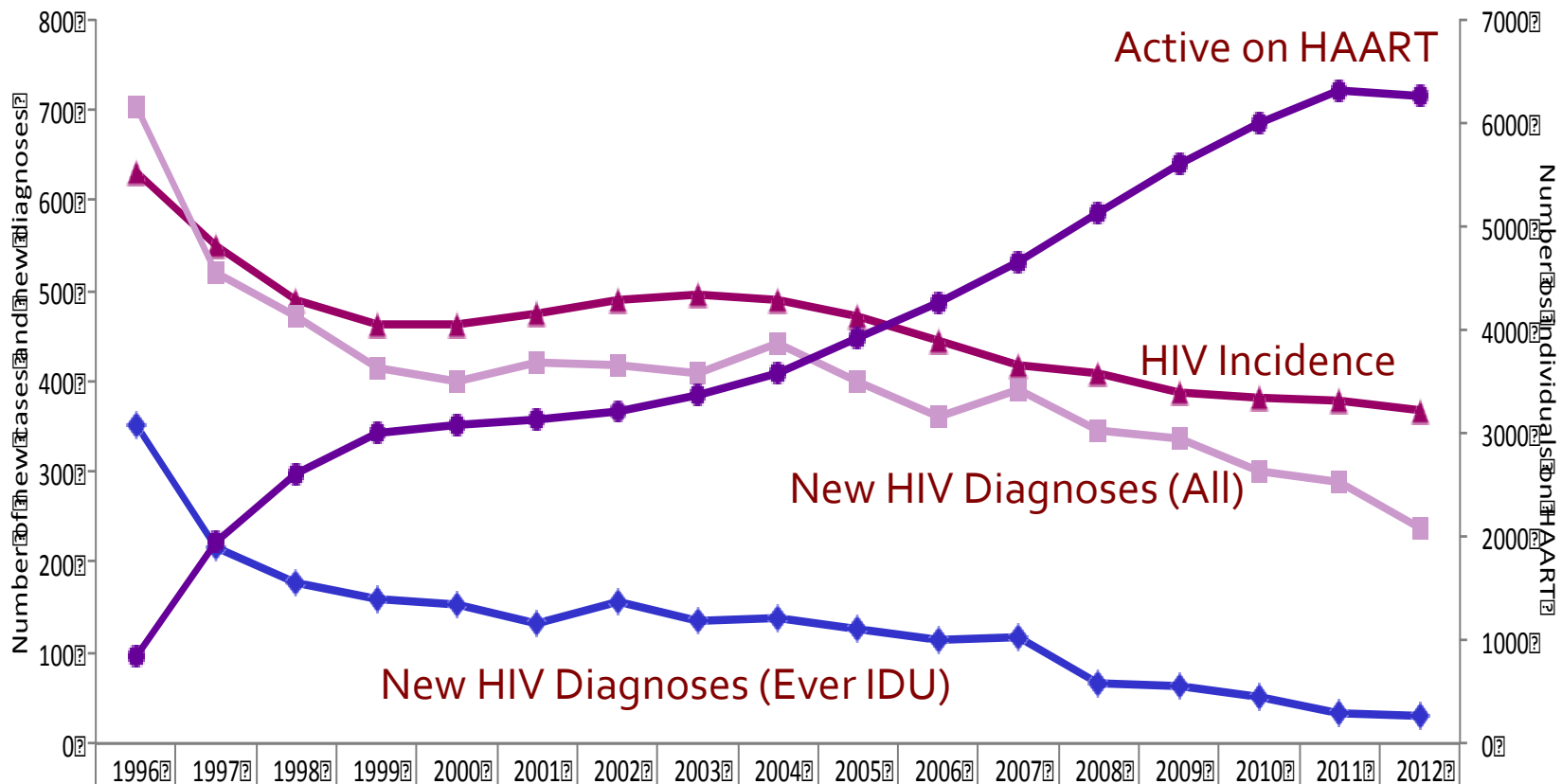
San Francisco	Katz, Am J Pub Health, 2002	Increase in risk behaviour in MSM will outweigh benefit of ART
Australia	Clements, JAIDS, 2004	ART benefits outweighed by increased risk in MSM
South Africa	Bertran, JAIDS, 2004	WHO guidelines: 12% reduction in incidence US guidelines: 72%
Amsterdam	Bezemer, AIDS, 2008	Benefits of ART outweighed by increased risk behaviour in MSM
British Columbia	Lima, JID, 2008	67% reduction in incidence if 100% treated at CD4 <350
Australia	Wilson, Lancet, 2008	ART rather than condoms may increase incidence 4 fold
WHO	Granich, Lancet, 2009	Annual testing and universal ART could reduce prevalence of HIV to <1%

***Variability: from elimination to escalation!***





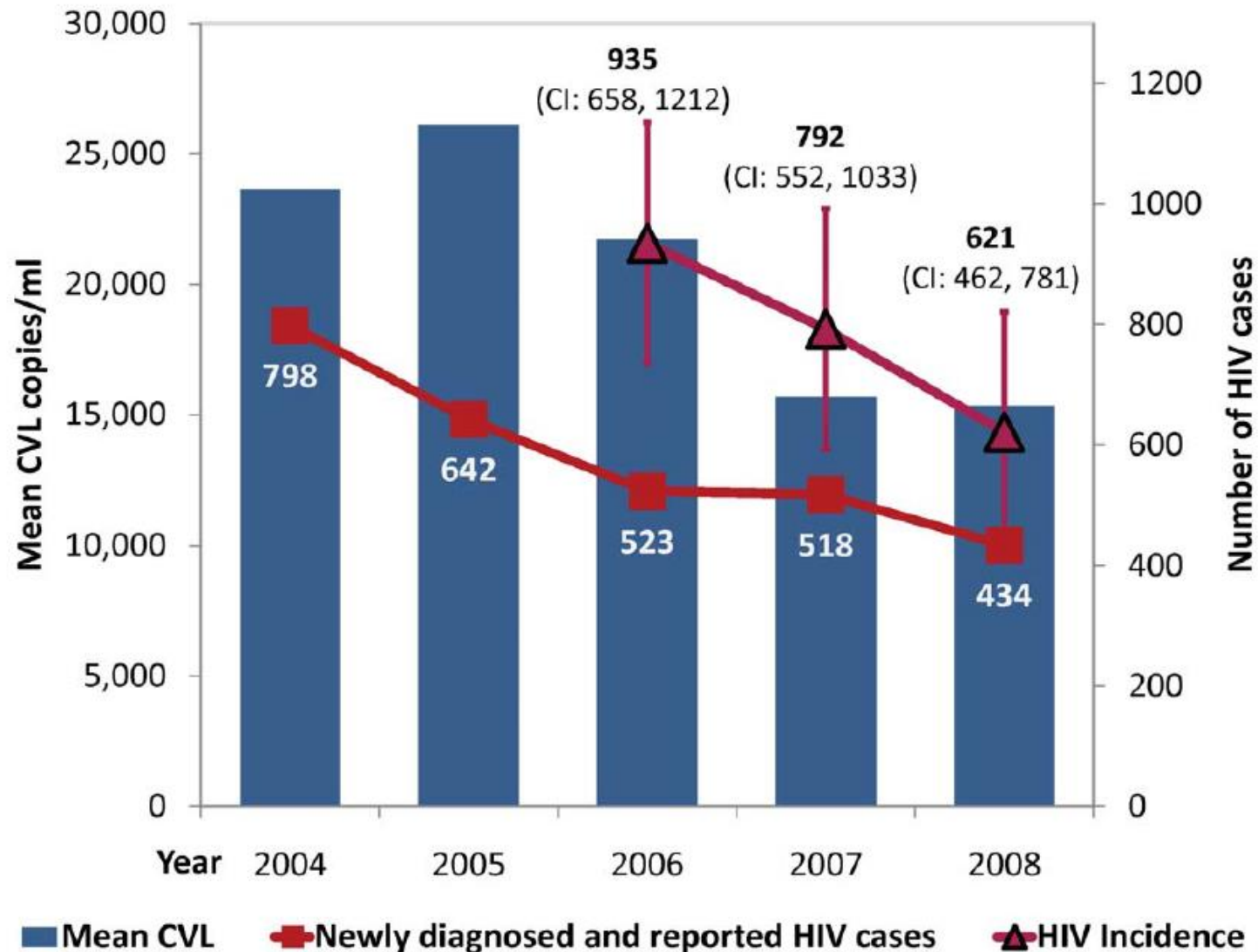
# HAART Use & New HIV Diagnoses for BC by year, 1996-2012



	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
HIV Incidence	632	551	490	461	461	476	489	495	490	472	446	418	408	387	382	380	368
New HIV Diagnoses	702	519	471	416	400	420	418	408	442	400	361	391	345	337	301	289	238
New HIV Diagnoses (Ever IDU)	352	215	177	159	152	132	156	136	137	125	115	118	65	64	52	34	29
Active on HAART	837	1960	2596	2994	3079	3120	3211	3356	3585	3913	4256	4654	5123	5595	5999	6298	6260
HIV Prevalence	7900	8228	8593	8933	9150	9408	9690	9936	10216	10398	10566	10790	11040	11280	11500	11700	11972

Lima et al, in preparation, 2013

# San Francisco: “Ecological Study”

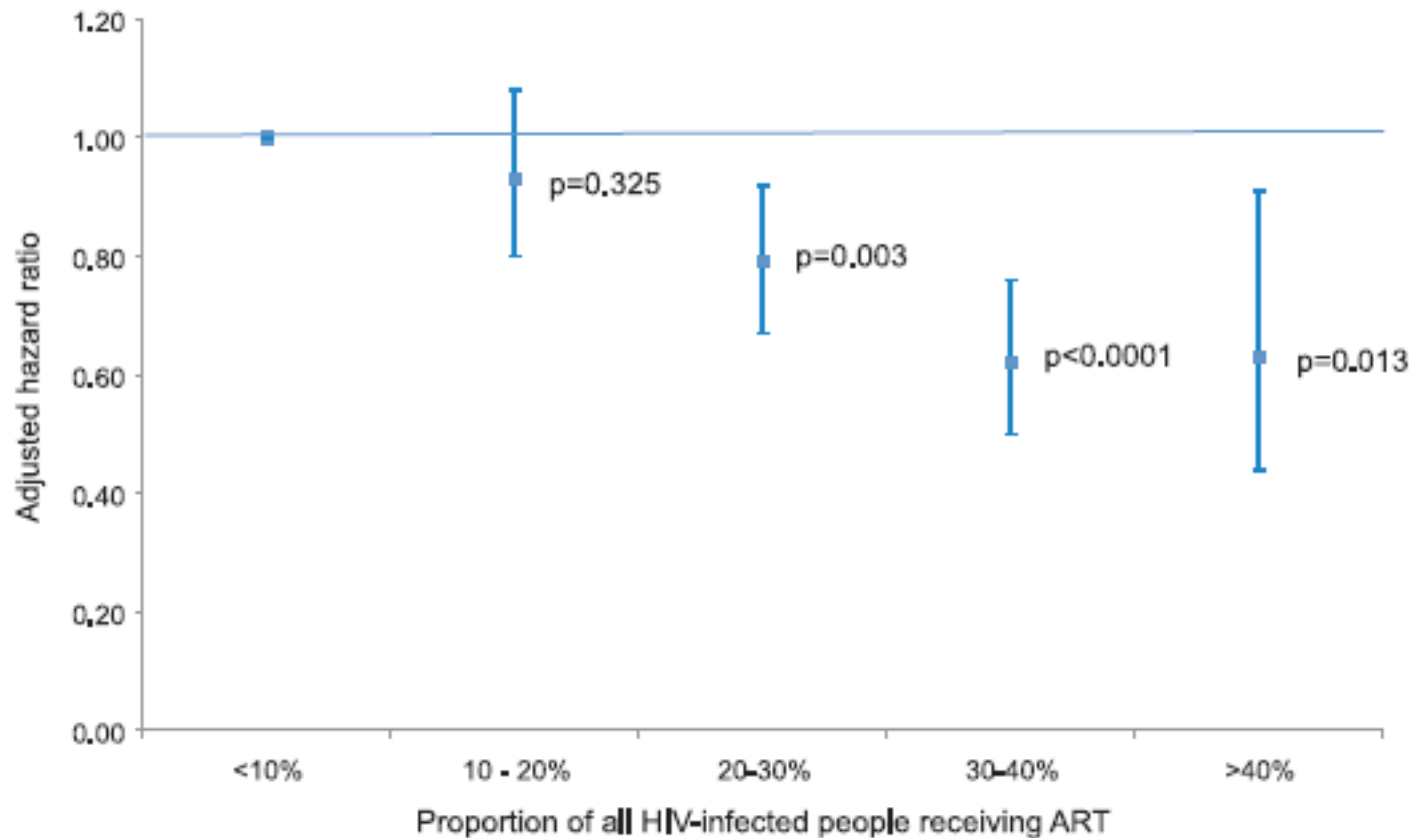


## **High Coverage of ART Associated with Decline in Risk of HIV Acquisition in Rural KwaZulu-Natal, South Africa**

Frank Tanser,<sup>1\*</sup> Till Bärnighausen,<sup>1,2</sup> Erofili Grapsa,<sup>1</sup> Jaffer Zaidi,<sup>1</sup> Marie-Louise Newell<sup>1,3</sup>

Science, February 2013

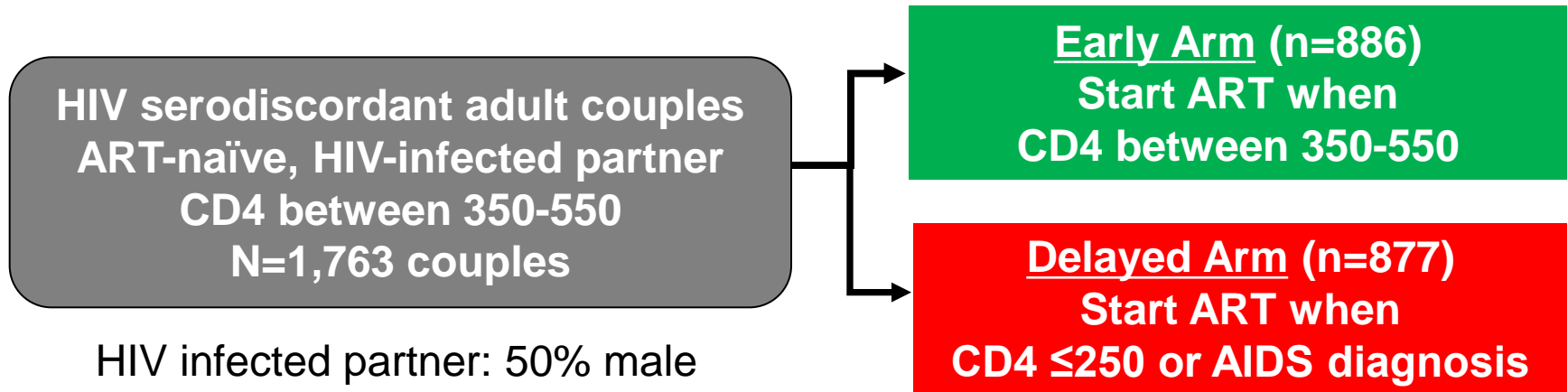
- Africa's largest population-based prospective cohort study
- 16,667 individuals uninfected at baseline
- Followed-up between 2004 and 2011
- HIV prevalence varied from <10% to >40%
  - Overall increase from 18 to 24%
- ART coverage increased during study period from <10% to 37%



An individual living in a community with high ART coverage (30-40%) was 38% less likely to acquire HIV than in a low coverage area (<10%)

# Prevention of HIV-1 Infection with Early Antiretroviral Therapy

Multicenter, international, randomized, NIH-funded Phase III study



## Primary Clinical Endpoint (in HIV-positive partner)

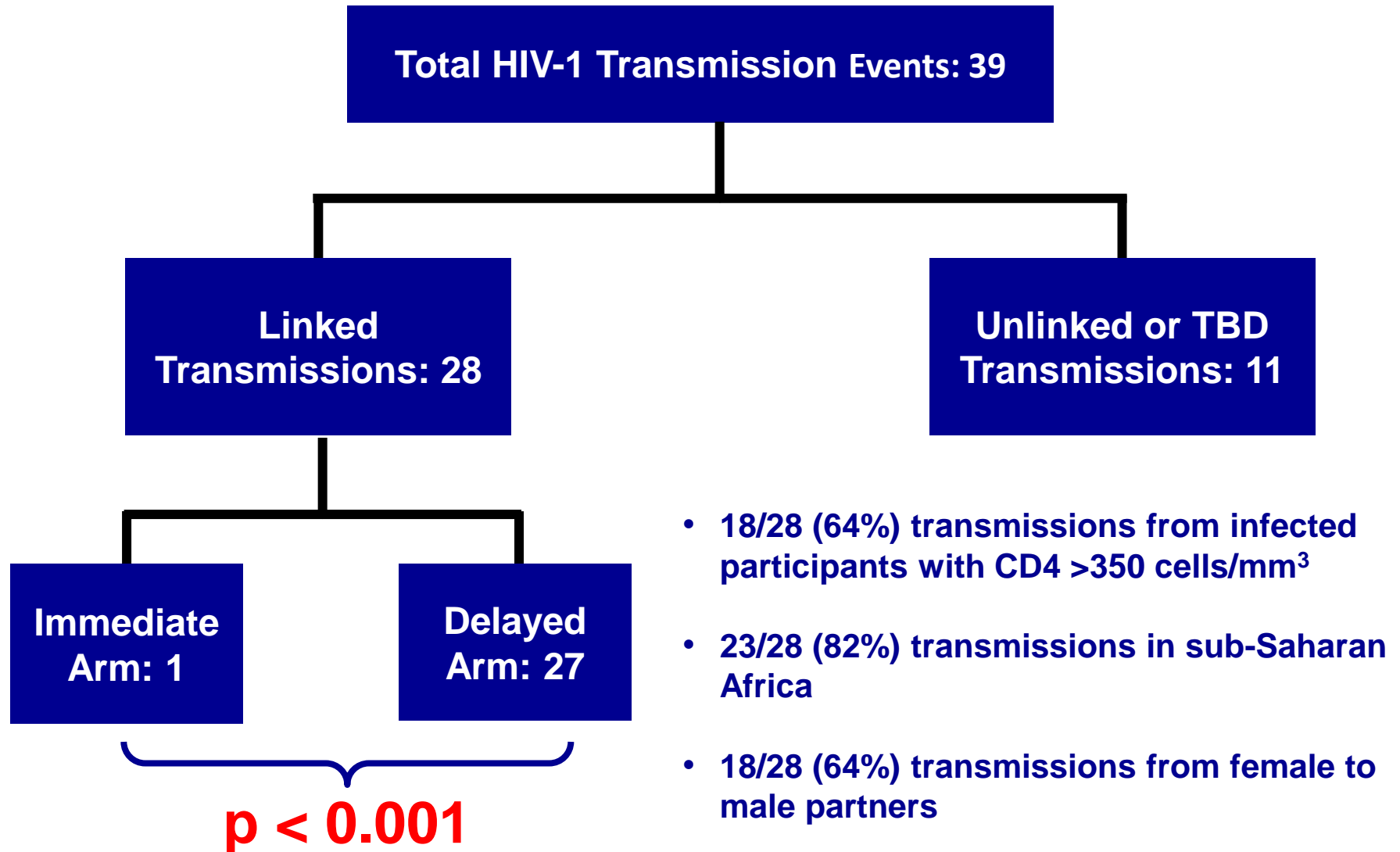
- Clinical Event: Pulmonary tuberculosis, severe bacterial infection, a World Health Organization stage 4 event, or death

## Primary Prevention Endpoint (in HIV-negative partner)

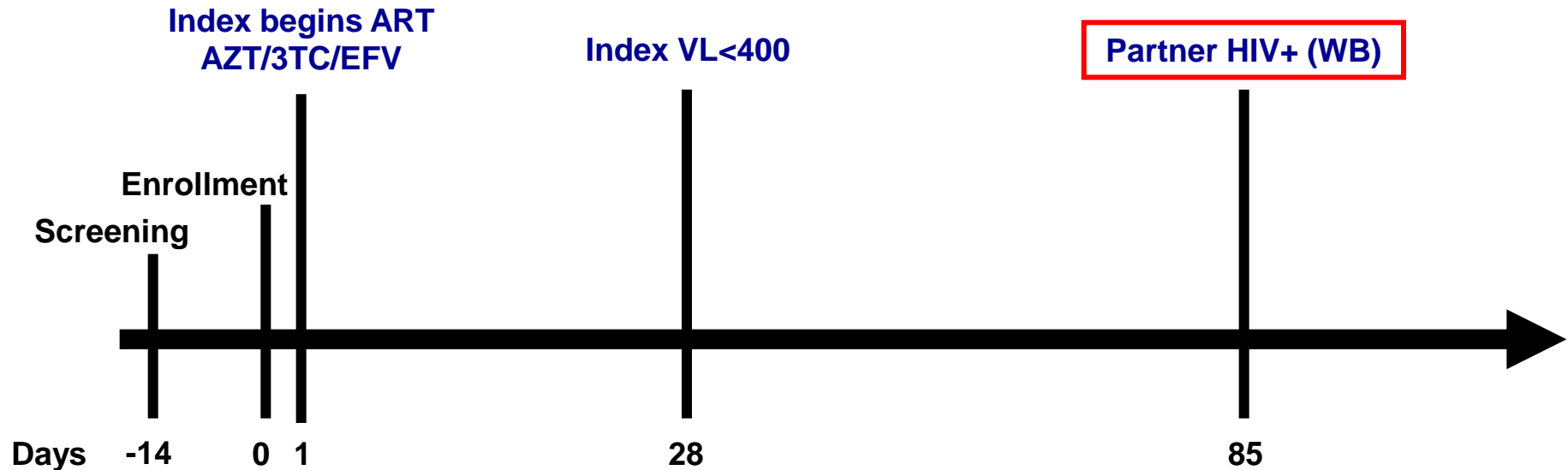
- Linked HIV transmission to HIV-1 negative partners

**DSMB recommended study be stopped early on 28<sup>th</sup> April 2011**

# HPTN 052: HIV-1 Transmission



# One Transmission Event on ART



Partner VL < 400  
Index VL = 87,202

Single Genome Analysis: 1-2 viruses transmitted

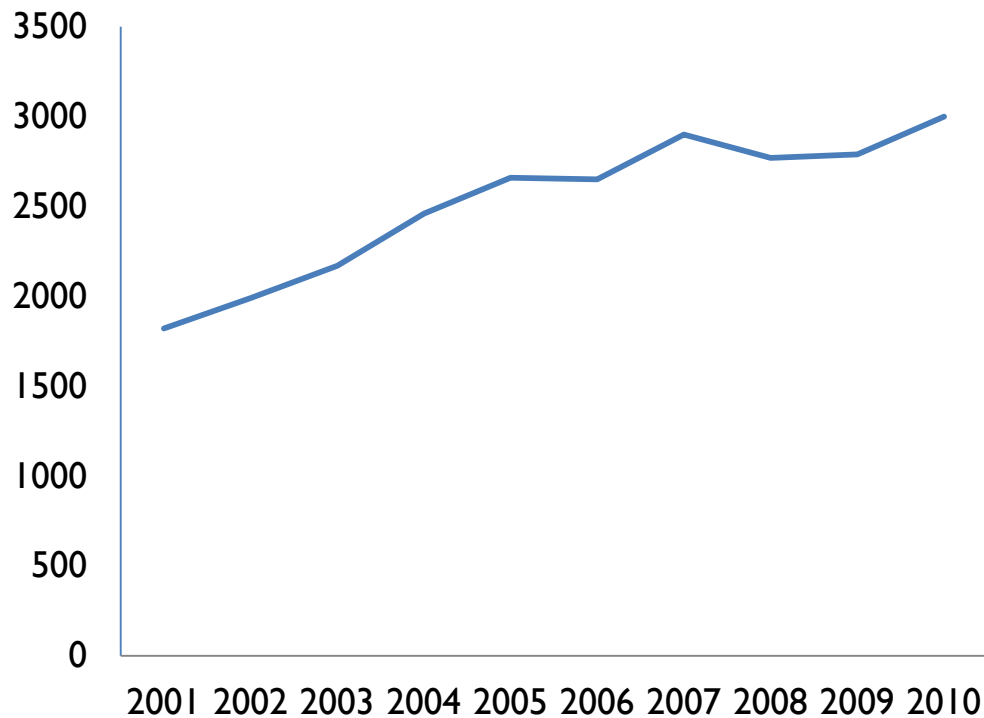
Analysis of Transmission: >50 days earlier (84 – 190 days)

# HPTN 052



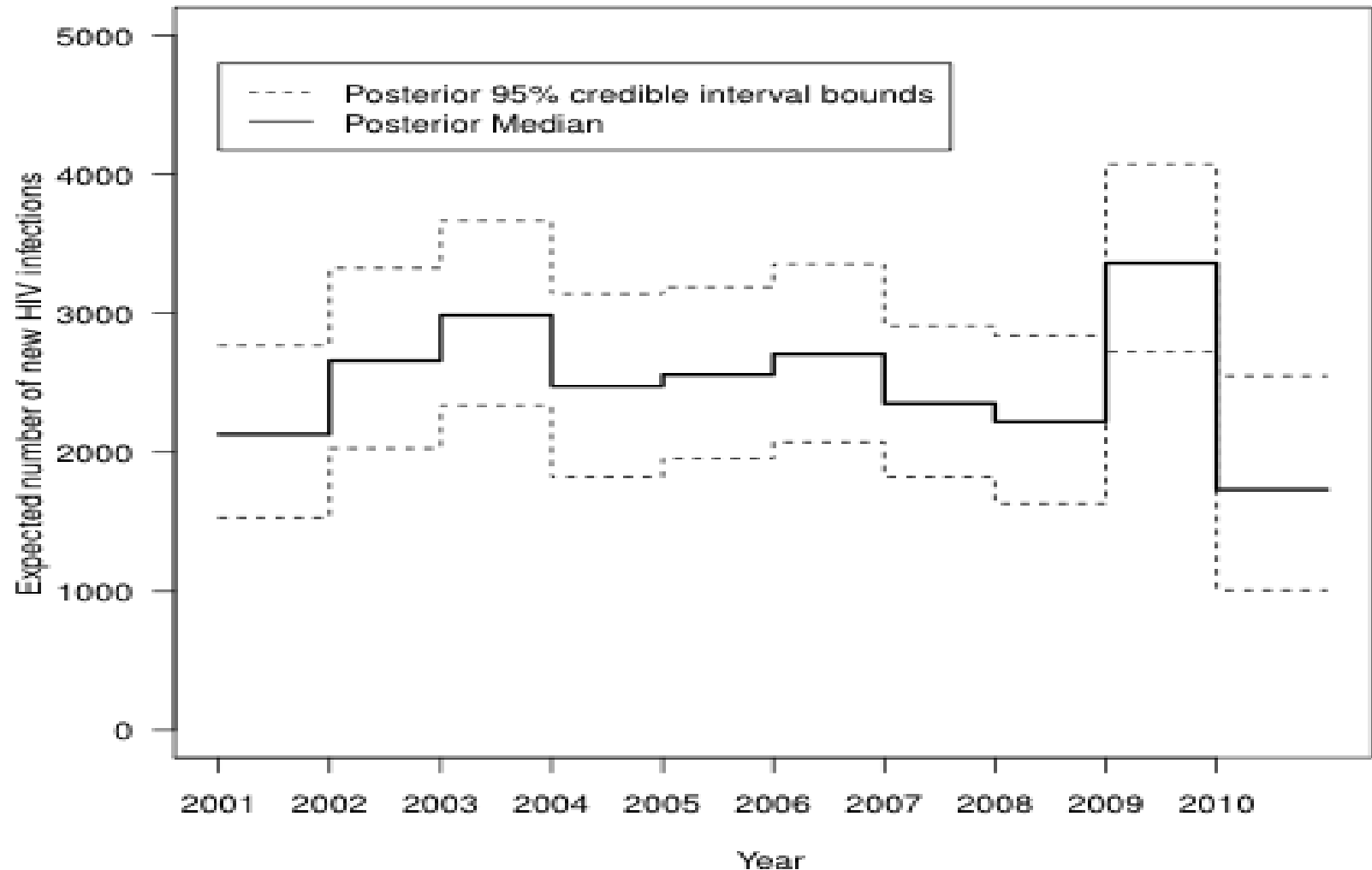


# HIV in MSM in UK



- Highest numbers ever
- >25% recently acquired
- >95% linkage to care
- >85% on ART
- >90% undetectable
- Improved testing policy
- Improved testing rates

# Annual HIV incidence in MSM, England & Wales: 2001-2010 (*Birrell et al.*)

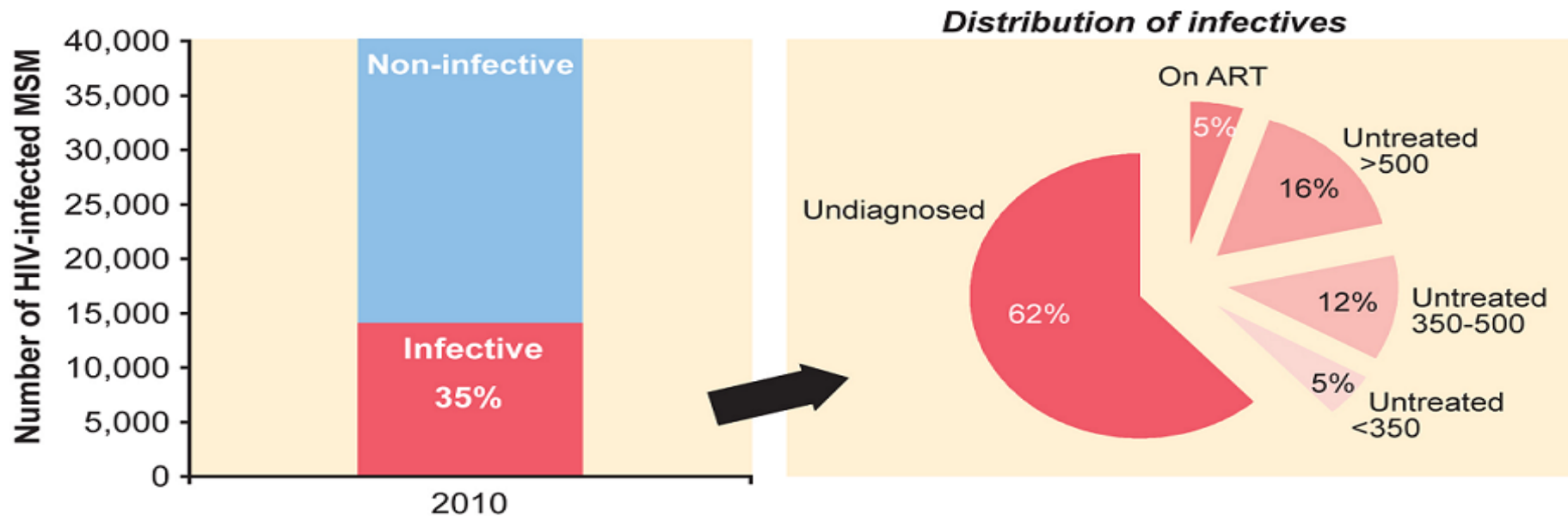


# Roll-out of ART for prevention

*“HPTN052 is a biological experiment in viral load reduction, not implementation research” (Fisher, K, iAPAC 2012)*

- Efficacy versus effectiveness
- Affordability versus cost effectiveness
- Feasibility
  - Need for high rates of HIV testing (models .90%)
  - Delivery, cost, sustainability of ART
- Acceptability
- Potential problems/challenges
  - Resistance, toxicity
- Ethics
  - <50% of those who need treatment on ART

# Distribution of infectives\* among HIV-infected MSM, UK: 2010, *Brown et al* (*HIV Medicine*, 2013, in press)



\* viral load >1500 copies/ml

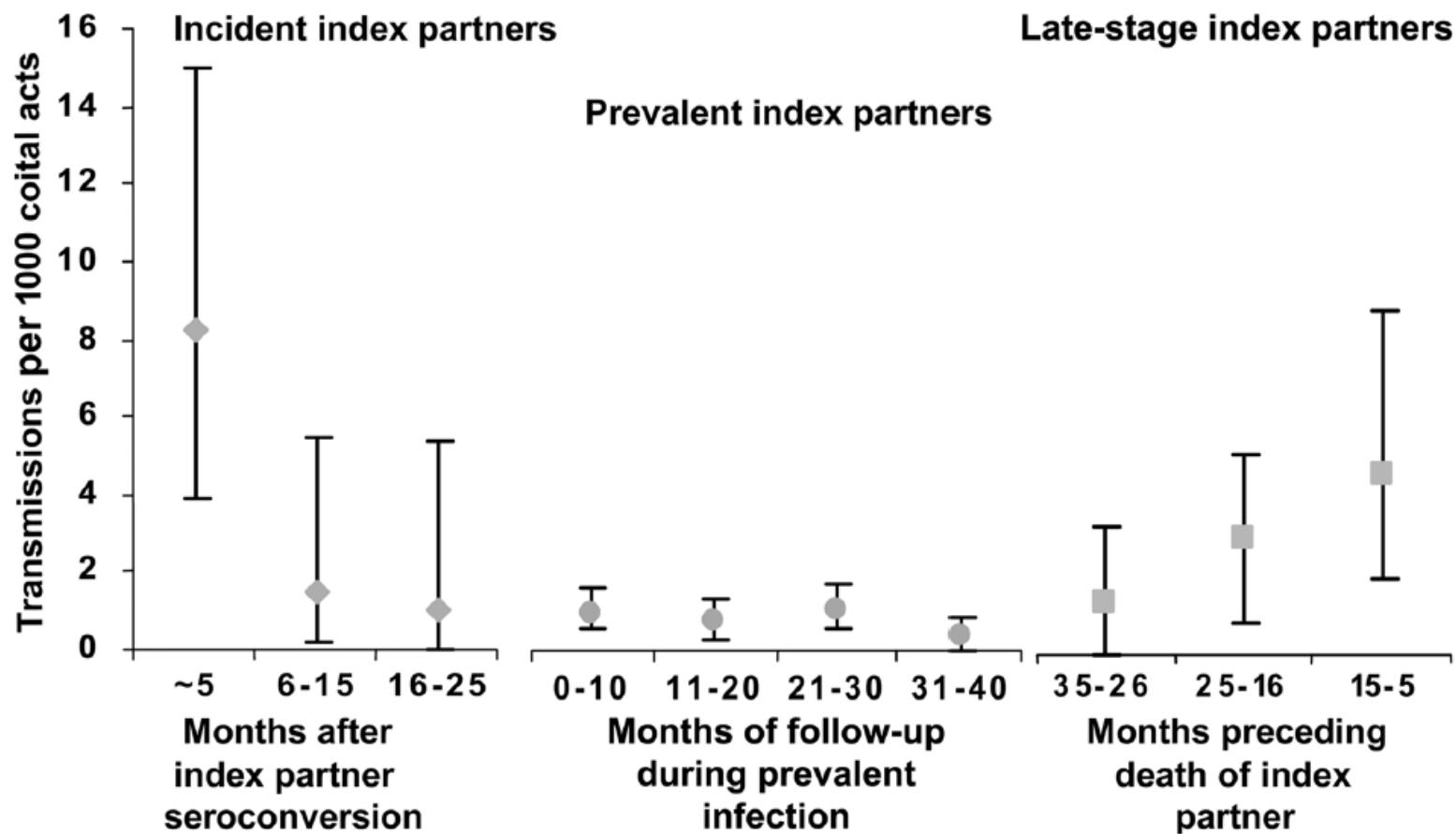
Extending ART to all MSM with CD4 counts <500 cells/mm<sup>3</sup> would reduce infectivity from an estimated 35% to 29% and, in combination with halving the undiagnosed, to 21%.

# Increased HIV Incidence in Men Who Have Sex with Men Despite High Levels of ART-Induced Viral Suppression: Analysis of an Extensively Documented Epidemic

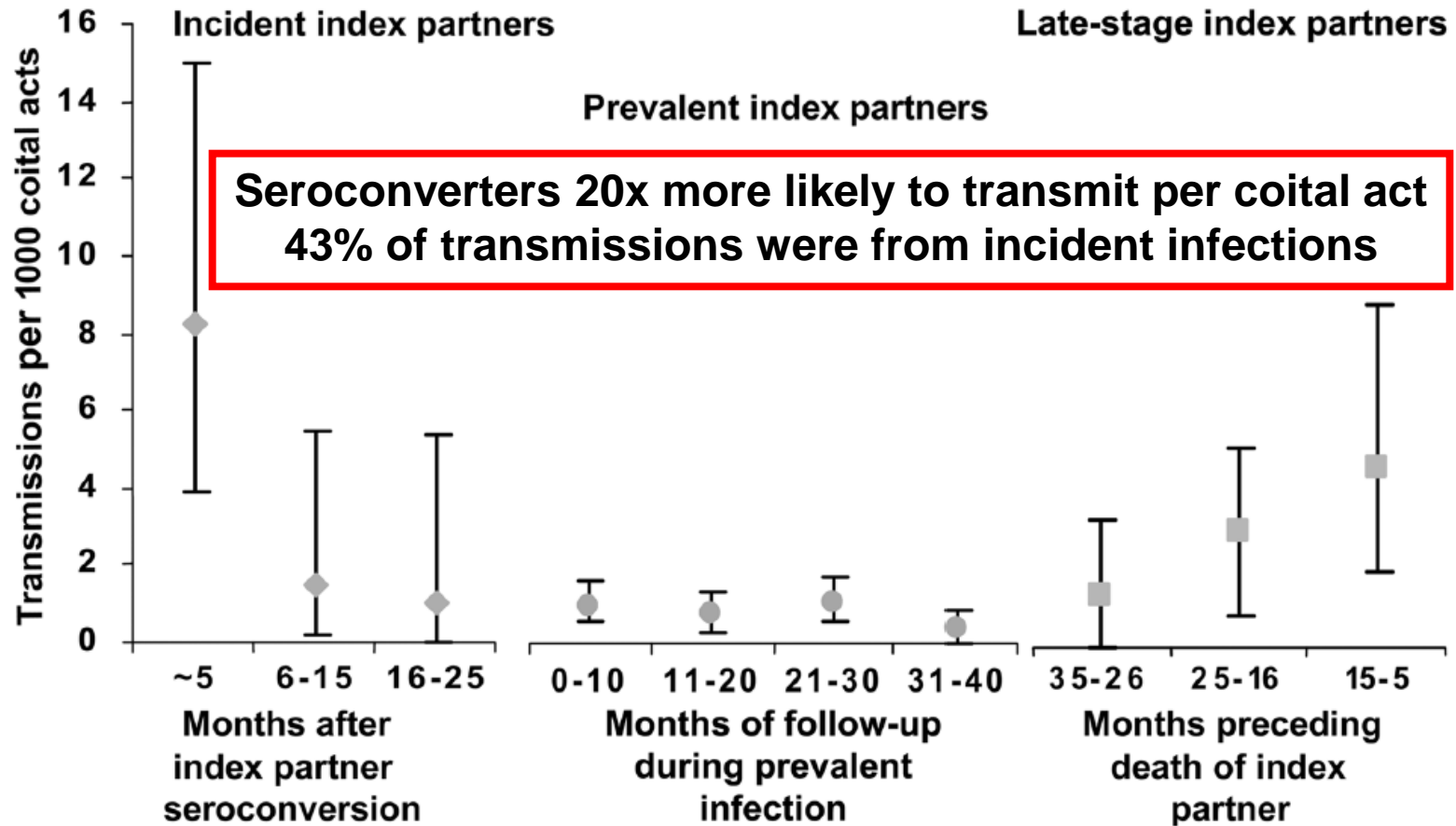
Andrew N. Phillips<sup>1\*</sup>, Valentina Cambiano<sup>1</sup>, Fumiyo Nakagawa<sup>1</sup>, Alison E. Brown<sup>2</sup>, Fiona Lampe<sup>1</sup>, Alison Rodger<sup>1</sup>, Alec Miners<sup>3</sup>, Jonathan Elford<sup>4</sup>, Graham Hart<sup>1</sup>, Anne M. Johnson<sup>1</sup>, Jens Lundgren<sup>5</sup>, Valerie C. Delpech<sup>2</sup>

- Source of new infections:
  - 7% diagnosed, ART experienced
  - 10% undiagnosed, ART naïve
  - 34% undiagnosed in established infection
  - **49% undiagnosed in PHI**

# HIV Disease Stage and Transmission (Rakai, Uganda)



# HIV Disease Stage and Transmission (Rakai, Uganda)



# HPTN 052: HIV-1 Transmission

**Total HIV-1 Transmission Events: 39**

**Linked  
Transmissions: 28**

**Unlinked or TBD  
Transmissions: 11**

**Immediate  
Arm: 1**

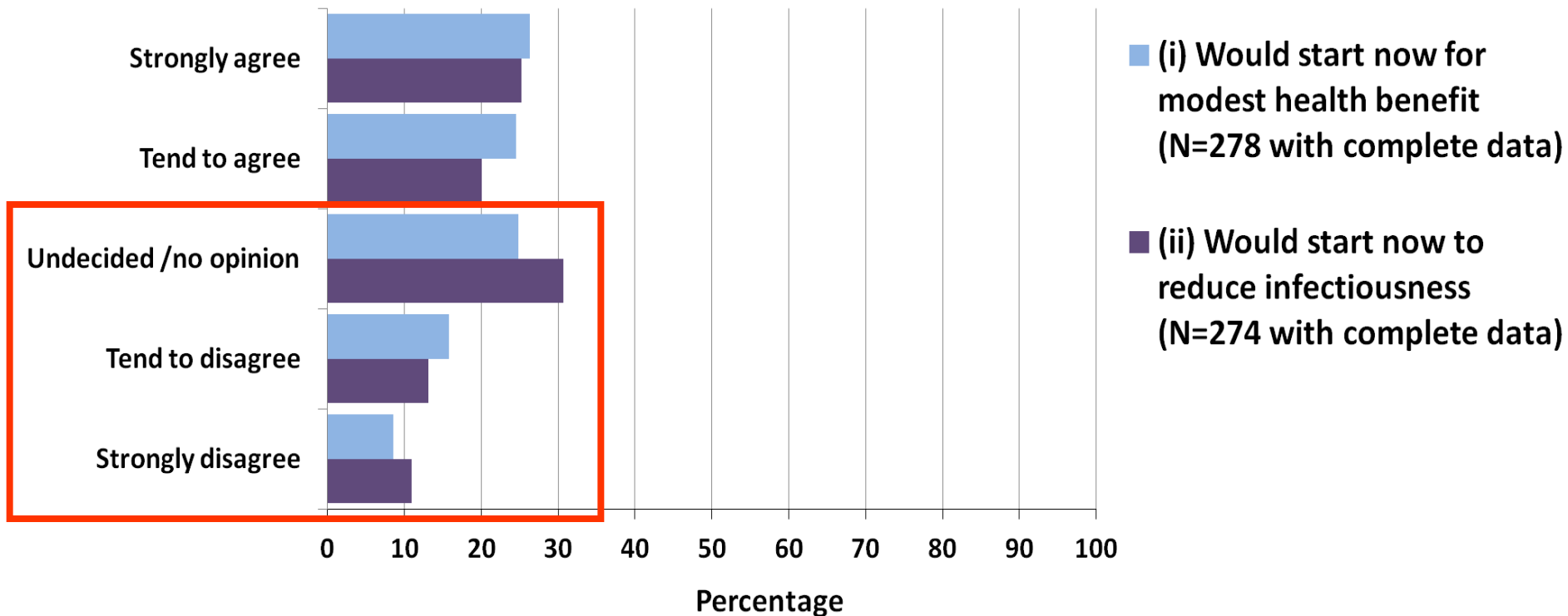
**Delayed  
Arm: 27**

**$p < 0.001$**

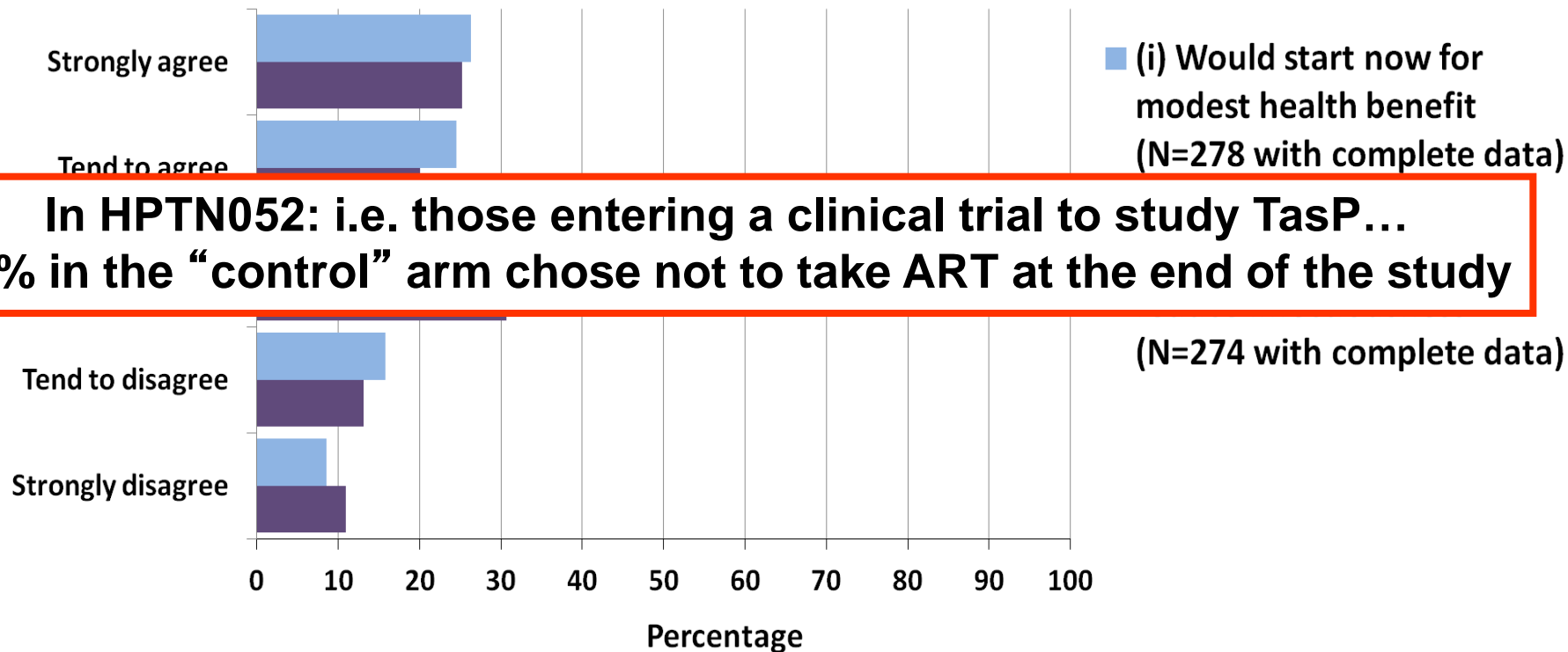
- 18/28 (64%) transmissions from infected participants with CD4 >350 cells/mm<sup>3</sup>
- 23/28 (82%) transmissions in sub-Saharan Africa
- 18/28 (64%) transmissions from female to male partners



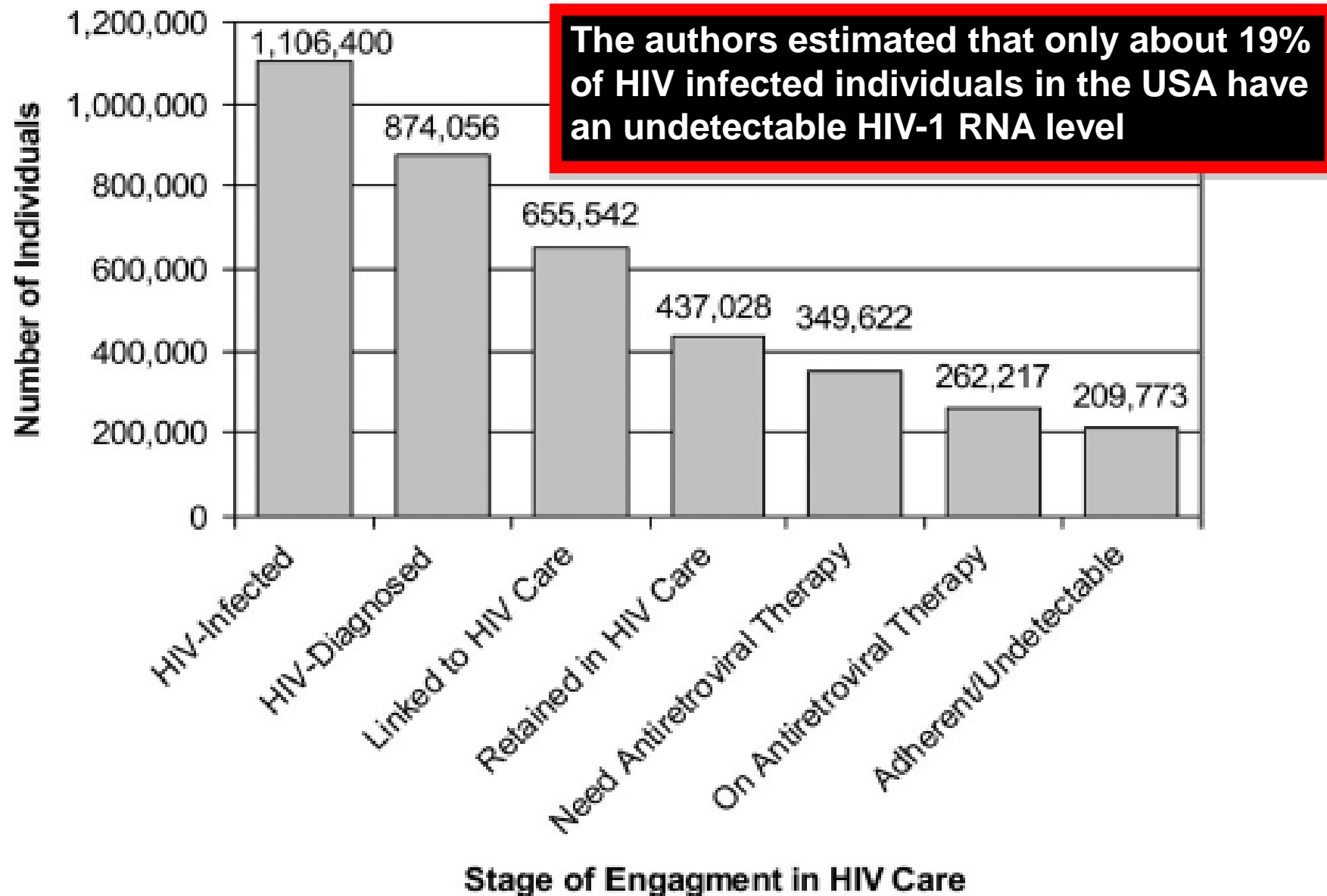
# Attitudes to early ART among 286 ART naïve individuals with CD4 $\geq 350/\text{mm}^3$



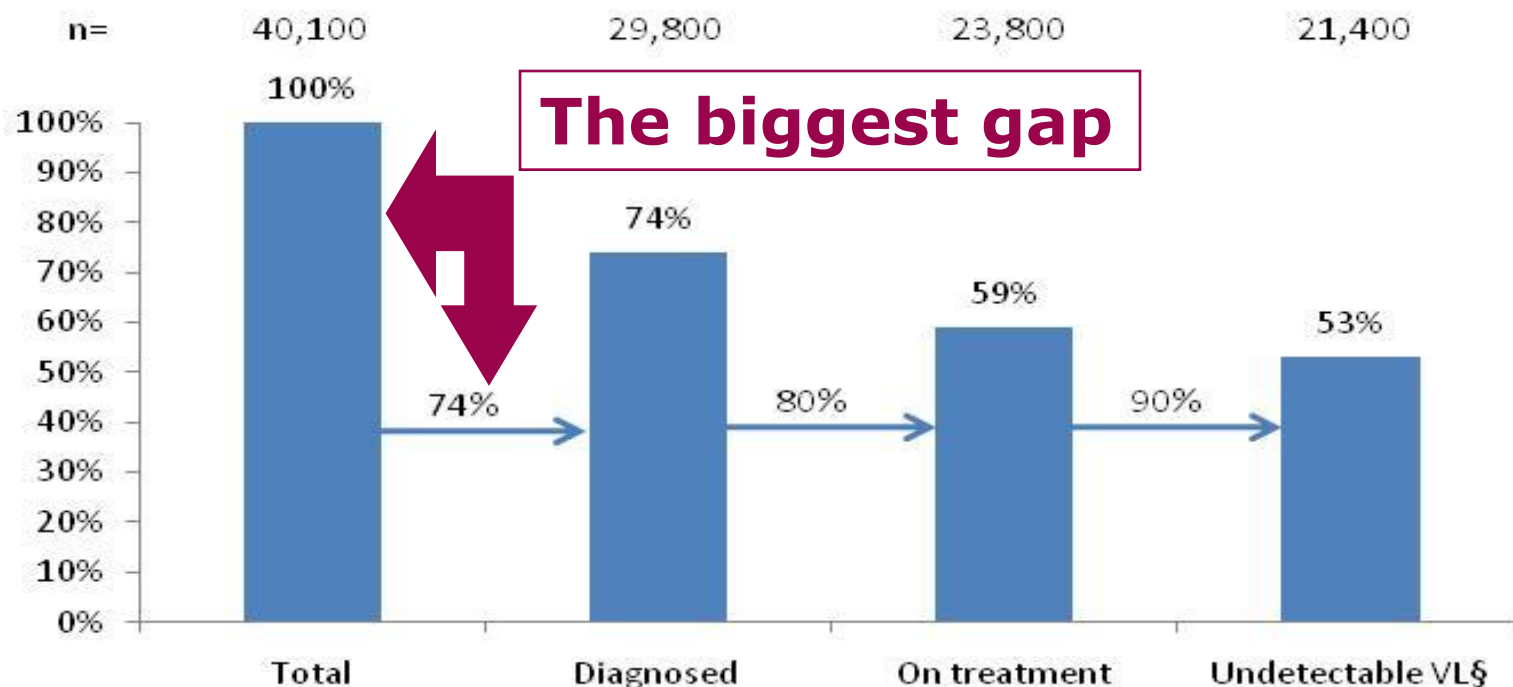
# Attitudes to early ART among 286 ART naïve individuals with CD4 $\geq 350/\text{mm}^3$



# Spectrum of Engagement in HIV Care - USA



# MSM cascade: UK, 2010



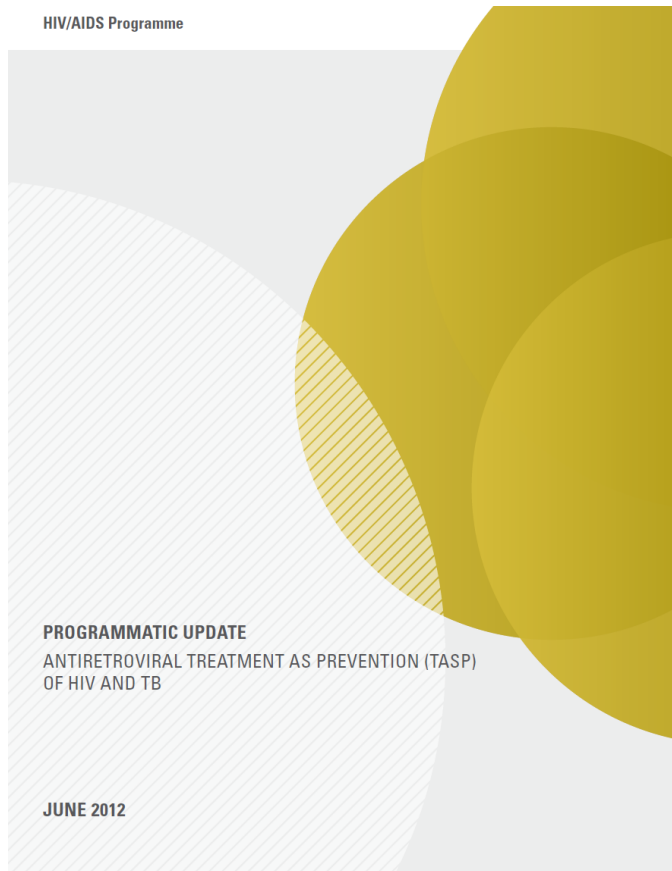
\* Numbers were adjusted by missing information and rounded to the nearest 100.

§ Viral load <50 copies/ml after HIV treatment initiation in the year of initiation.

# Ongoing / planned trials

- **HTPN 071 (PopART)**
  - Zambia, S Africa
  - SOC v ART<350 v ART all
  - 60,000
- **Iringa**
  - Tanzania
  - SOC v ART<350
  - 12,000
- **BCPP**
  - Botswana
  - SOC v ART if VL>10,000
  - 20,000
- **ANRS TasP**
  - South Africa
  - ART<350 v ART all
  - 40,000
- **HPTN 065**
  - USA
  - Testing, linkage to care, ART

# WHO 2012



- Aim: ZERO deaths and ZERO new infections
- 13/72 countries with guidelines mention serodiscordant couples
- 1<sup>st</sup> priority: ART to those who need it
- 2<sup>nd</sup> priority: those at “higher risk of transmitting the virus”

# GUIDANCE ON COUPLES HIV TESTING AND COUNSELLING INCLUDING ANTIRETROVIRAL THERAPY FOR TREATMENT AND PREVENTION IN SERODISCORDANT COUPLES

Recommendations for a public health approach

APRIL 2012



World Health  
Organization

## RECOMMENDATIONS

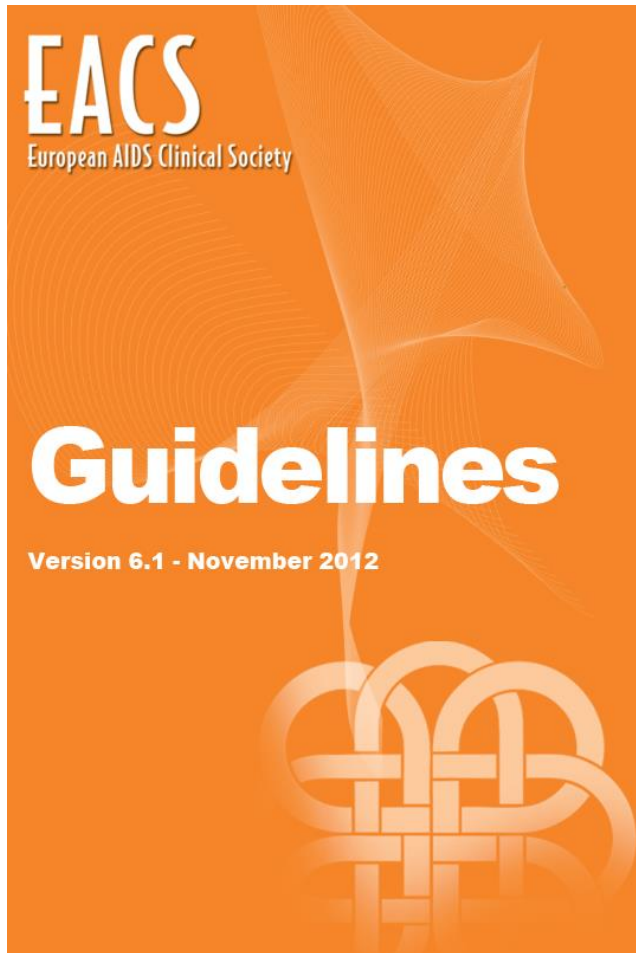
1. Couples and partners should be offered voluntary HIV testing and counselling with support for mutual disclosure. *Strong recommendation, low-quality evidence.*



5. HIV-positive partners with  $>350$  CD4 cells/ $\mu\text{L}$  in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners. *Strong recommendation, high-quality evidence.*

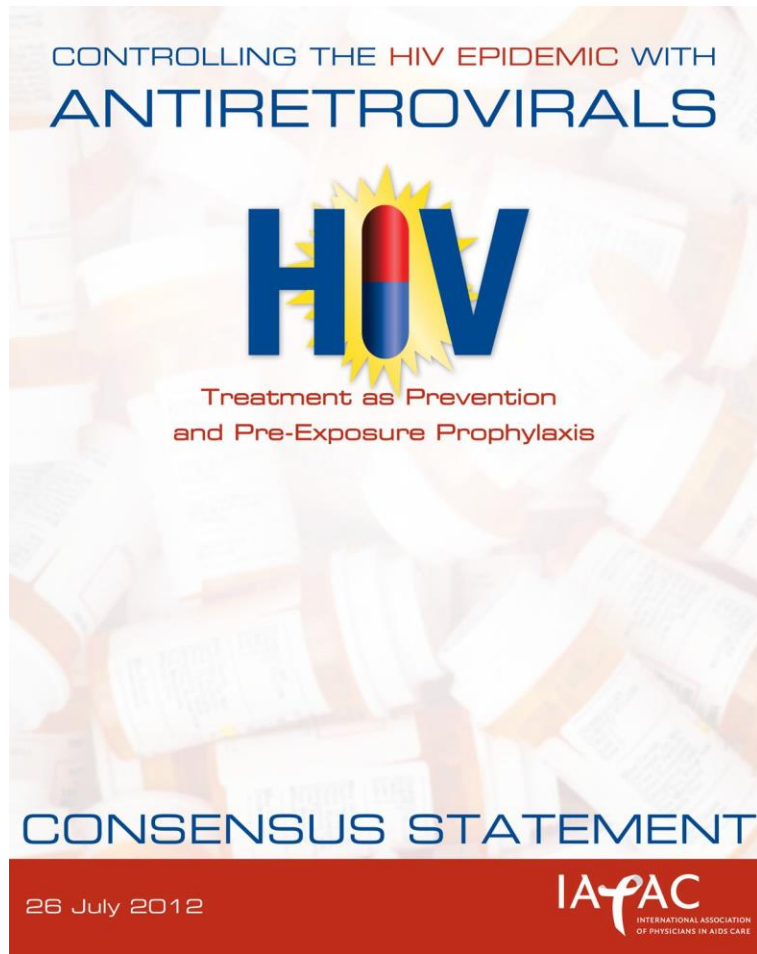


# EACS 2012



- *“In serodifferent partners, early initiation of ART as one aspect of the overall strategy to reduce HIV transmission should be strongly considered and actively discussed”*

# IAPAC 2012



- “Paradigm has shifted”
- TasP: evidence justifies use in patients who want to start early
- PrEP: evidence supports use in high-risk groups now

# Target specific groups for TasP?

- Individual factors:
  - CD4 count (350-500 or all?)
  - Viral load (>10,000; >1500?)
- “High risk groups”
  - Serodiscordant couples
  - Female sex workers
  - MSM
  - IDUs

# Using Plasma Viral Load to Guide Antiretroviral Therapy Initiation to Prevent HIV-1 Transmission

Pamela M. Murnane<sup>1,2\*</sup>, James P. Hughes<sup>3</sup>, Connie Celum<sup>1,2,4</sup>, Jairam R. Lingappa<sup>2,4,5</sup>, Nelly Mugo<sup>2,6,7</sup>, Carey Farquhar<sup>1,2,4</sup>, James Kiarie<sup>2,6,7</sup>, Anna Wald<sup>1,8,9,10</sup>, Jared M. Baeten<sup>1,2,4</sup> for the Partners in Prevention HSV/HIV Transmission Study Team<sup>†</sup>

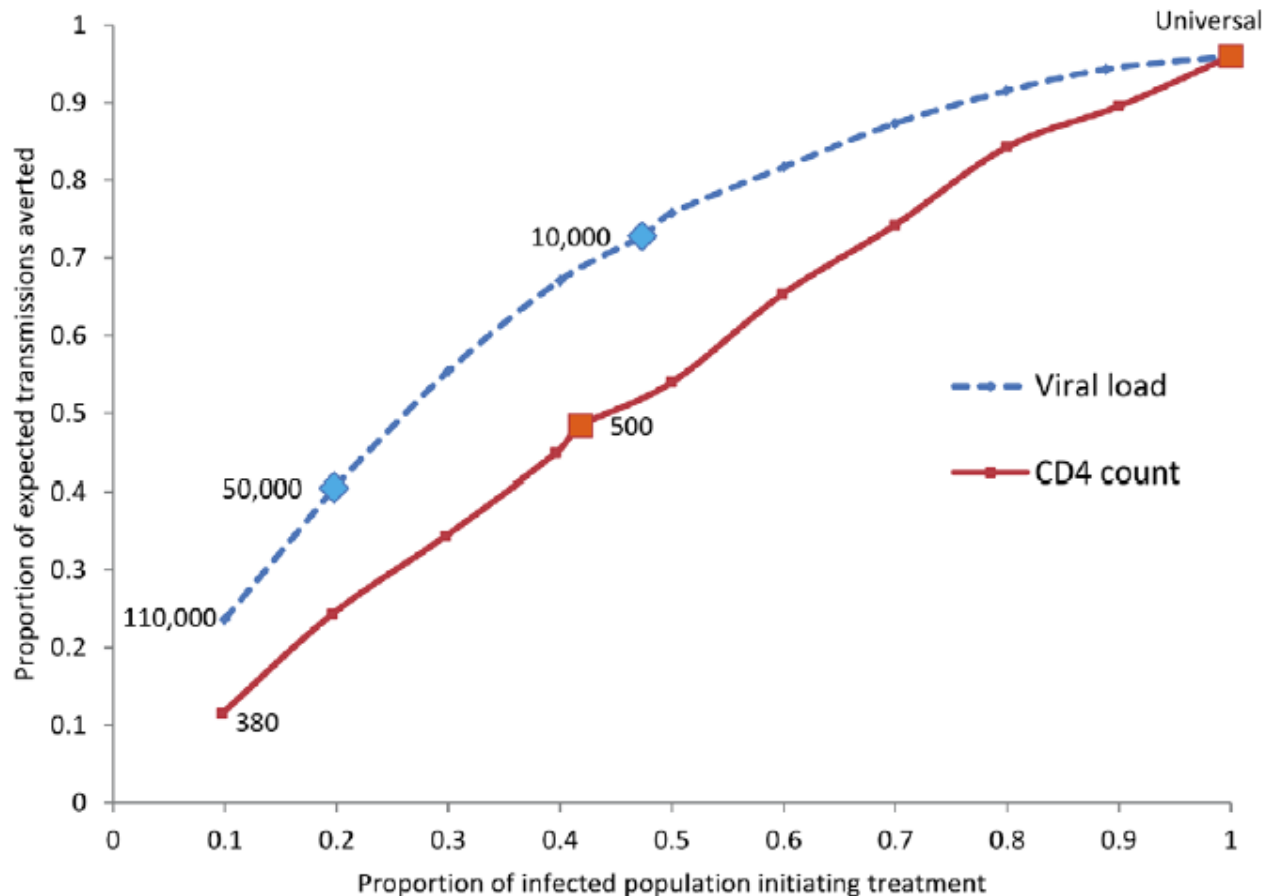
Effect of initiating ART on transmission:

- VL > 50,000 and CD4 >350
  - Need to treat 19.8% of population
  - Avert 40.5% of transmissions (ratio of 2.0)
- CD4 < 500
  - Need to treat 41.8% of population
  - Avert 48.4% (ratio of 1.1)

***“The incorporation of viral load in ART initiation guidelines could have a greater impact on HIV transmission than initiation based on CD4 count”***

## Using Plasma Viral Load to Guide Antiretroviral Therapy Initiation to Prevent HIV-1 Transmission

Pamela M. Murnane<sup>1,2\*</sup>, James P. Hughes<sup>3</sup>, Connie Celum<sup>1,2,4</sup>, Jairam R. Lingappa<sup>2,4,5</sup>, Nelly Mugo<sup>2,6,7</sup>, Carey Farquhar<sup>1,2,4</sup>, James Kiarie<sup>2,6,7</sup>, Anna Wald<sup>1,8,9,10</sup>, Jared M. Baeten<sup>1,2,4</sup> for the Partners in Prevention HSV/HIV Transmission Study Team<sup>†</sup>



## **Position statement on the use of antiretroviral therapy to reduce HIV transmission January 2013. The British HIV Association (BHIVA) and the Expert Advisory Group on AIDS (EAGA)<sup>†</sup>**

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With the level of evidence available, it is recommended that health care professionals discuss with all people living with HIV the impact of ART on the risk of viral transmission to sexual partners. For those not yet taking ART and wishing to reduce the risk of transmission, the possibility of starting ART for this purpose should be discussed. Such discussion should establish that there is no evidence of coercion and that the person with HIV is fully informed of the need to commit to long-term adherence to ART, frequent STI screening (3–6-monthly dependent on risk)\* and regular viral load measurements, and is aware of the potential side effects of therapy.

BHIVA and EAGA believe that giving an actual figure for the risk of transmission for one episode of sex in a serodiscordant couple is not currently meaningful for an individual and that any figure proposed would be misleading, for the reasons outlined below. In the absence of such a figure, BHIVA and EAGA have therefore adopted the term 'extremely low' whilst recognising the difficulty inherent in the imprecise nature of such a term.

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The published data are largely from heterosexual couples and there are insufficient data to conclude that successful ART use can provide similar levels of protection in relation to other sexual practices, including unprotected anal intercourse between men or between men and women. However, it is expert opinion that an extremely low risk of transmission can also be anticipated for these practices, provided the same conditions stated above are met.

The decision to start ART is the patient's choice and must not be due to pressure from partners or others.

ART lowers, rather than eliminates, the risk of transmission; other prevention strategies, including male and female condoms continue to be recommended to address concerns of any residual risk of transmission.

# Hot Topics – September 2013

- **PrEP**
  - Should it be widely recommended?
  - Are we using the right drug?
    - Role of long acting agents and nanoformulations
- **TasP**
  - Will it make a difference at a population level?
  - How important is primary infection and will that impact on the effect of TasP
- **“Test and Treat”**
  - Remember the “test” as well as the treat!