

# State-of-the-Science: When treatment is prevention, what then do WE mean by prevention?

## Who is PrEP for? What is needed for access?

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Controlling the HIV Epidemic with Antiretrovirals:  
Leveraging progress, seizing opportunities  
Geneva, Switzerland, October 14, 2016

# Who is PrEP for? What is needed for access?

Why PrEP?

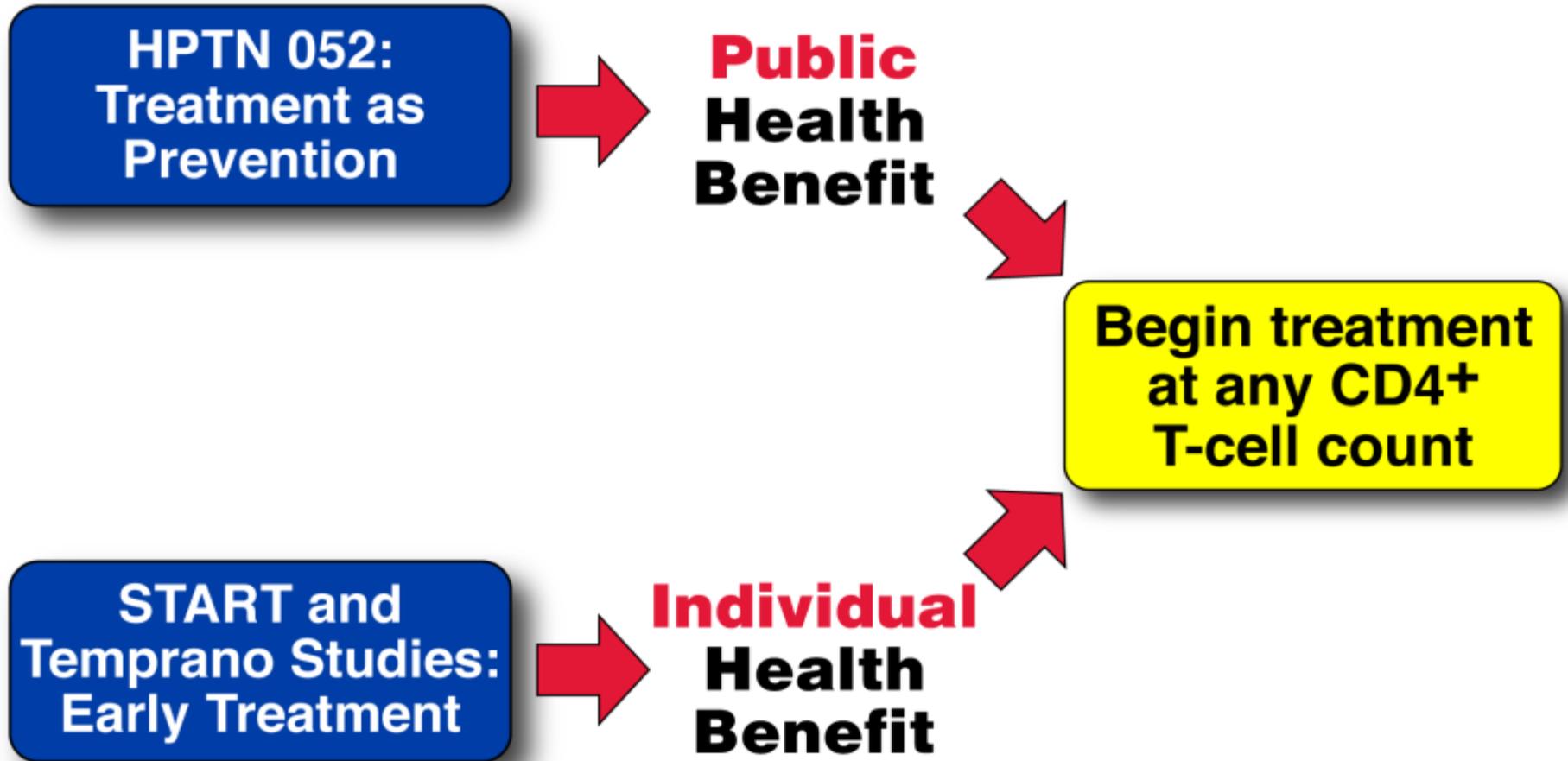
Who is PrEP for?

- Key populations at higher risk of HIV acquisition
- PrEP and combination prevention: the complementarity of PrEP

Real world findings

- Open label and demonstration projects
- Cost effectiveness and uptake
- Regulatory status

# The New Paradigm: Treatment as Prevention



## Original Investigation

**Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy**

Alison J. Rodger, MD; Valentina Cambiano, PhD; Tina Bruun, RN; Pietro Vernazza, MD; Simon Collins; Jan van Lunzen, PhD; Giulio Maria Corbelli; Vicente Estrada, MD; Anna Maria Geretti, MD; Apostolos Beloukas, PhD; David Asboe, FRCP; Pompeyo Viciana, MD; Félix Gutiérrez, MD; Bonaventura Clotet, PhD; Christian Pradler, MD; Jan Gerstoft, MD; Rainer Weber, MD; Katarina Westling, MD; Gilles Wandeler, MD; Jan M. Prins, PhD; Armin Rieger, MD; Marcel Stoeckle, MD; Tim Kummerle, PhD; Teresa Bini, MD; Adriana Ammassari, MD; Richard Gilson, MD; Ivanka Krzmaric, PhD; Matti Ristola, PhD; Robert Zangerle, MD; Pia Handberg, RN; Antonio Antela, PhD; Sís Allan, FRCP; Andrew N. Phillips, PhD; Jens Lundgren, MD, for the PARTNER Study Group

During follow-up, couples reported condomless sex a median of 37 times per year (IQR, 15-71), with MSM couples reporting approximately 22,000 condomless sex acts and heterosexuals approximately 36,000.

**No phylogenetically linked transmissions** during median follow-up of 1.3 years per couple (upper 95% confidence limit: 0.30/100 couple-years of condomless sex and 0.71/100 couple-years of condomless anal sex)

75 clinical sites in 14 European countries and enrolled 1166 HIV serodifferent couples

**AJ Rodger and Coauthors**

**Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy**

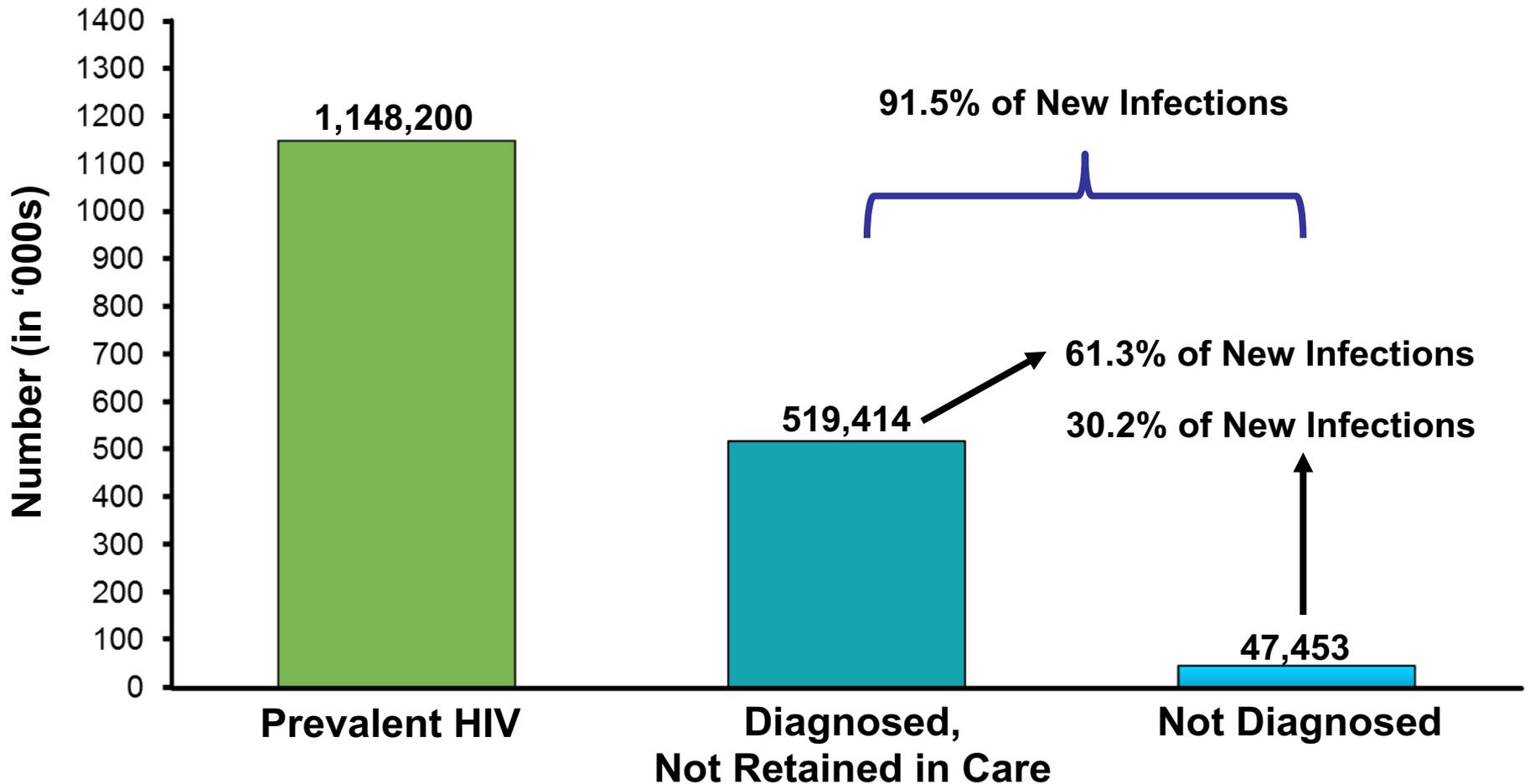
Published July 12, 2016

Available at [jama.com](http://jama.com) and on The JAMA Network Reader at [mobile.jamanetwork.com](http://mobile.jamanetwork.com)



The **JAMA** Network

# Why not just rely on TasP? The U.S. Example



Chronic HIV in the US (2009): estimated new HIV infections and awareness of HIV serostatus.

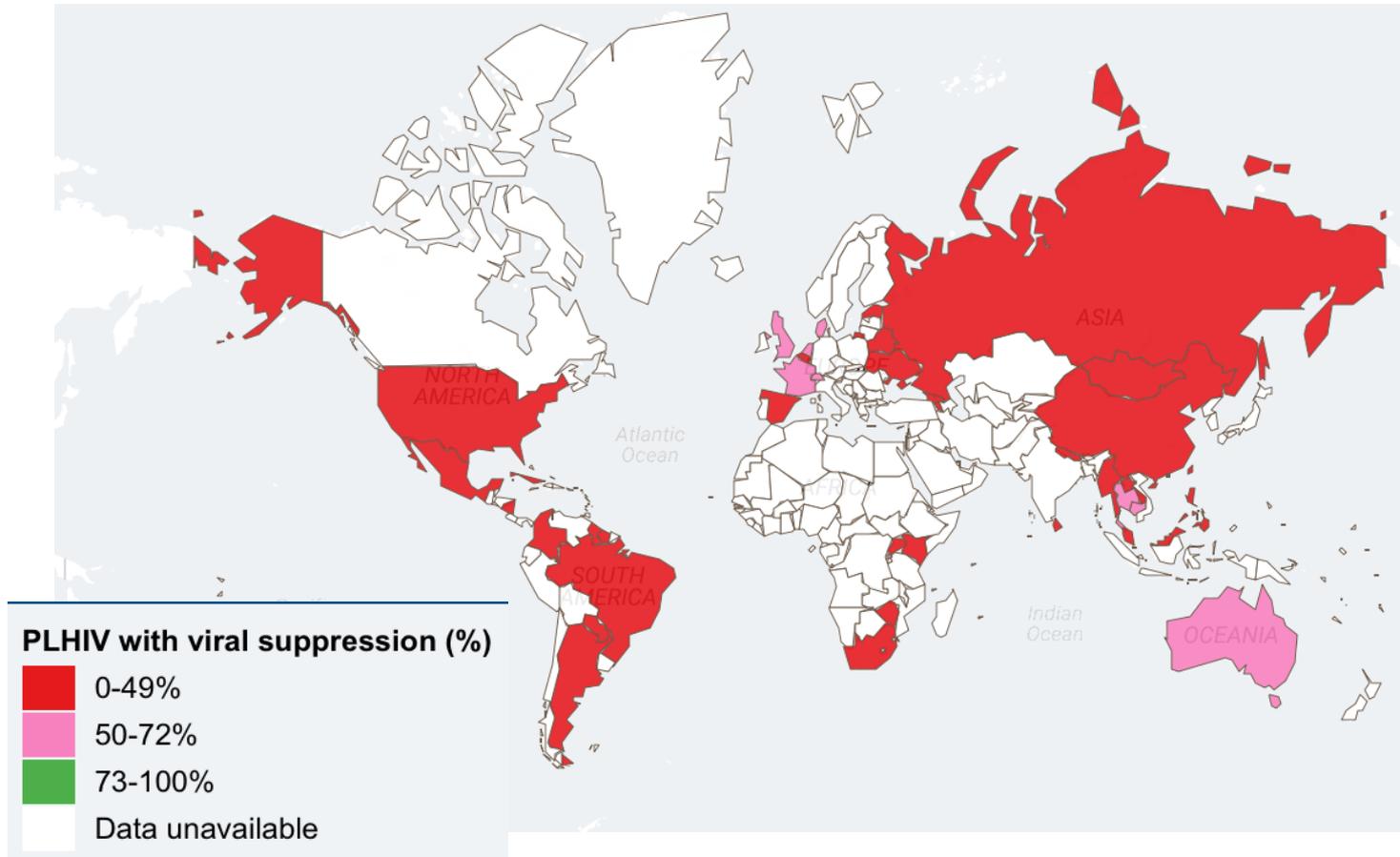
Skarbinski J, et al. *JAMA Intern Med.* 2015;175:588-596.

Courtesy Ken Mayer

# Proportion of people living with HIV with viral suppression (90-90-90 goal is 73%)



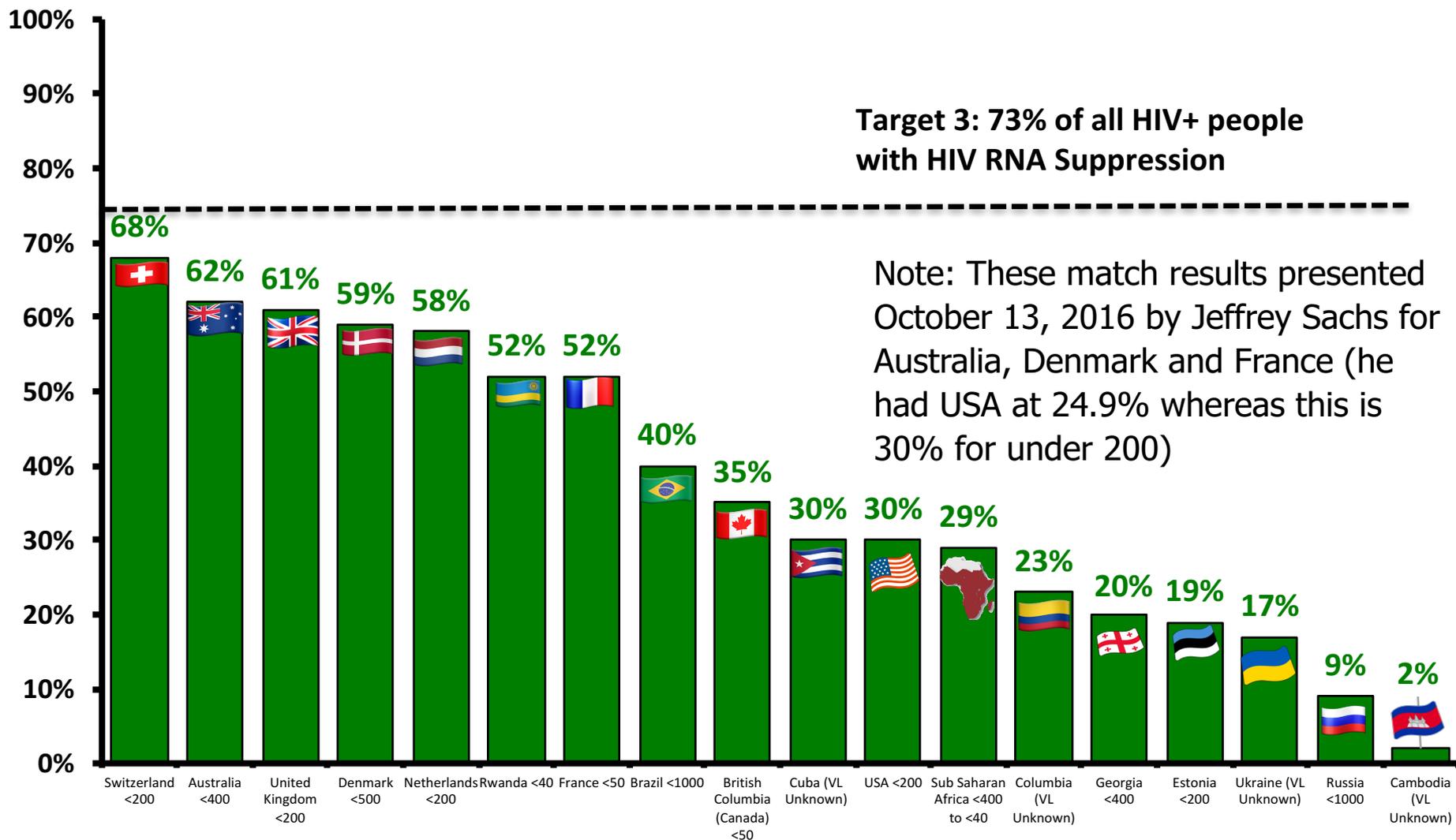
(40 countries with available data)



Hirschsall October 13, 2016:  
**Viral suppression 38% (35-41%)**

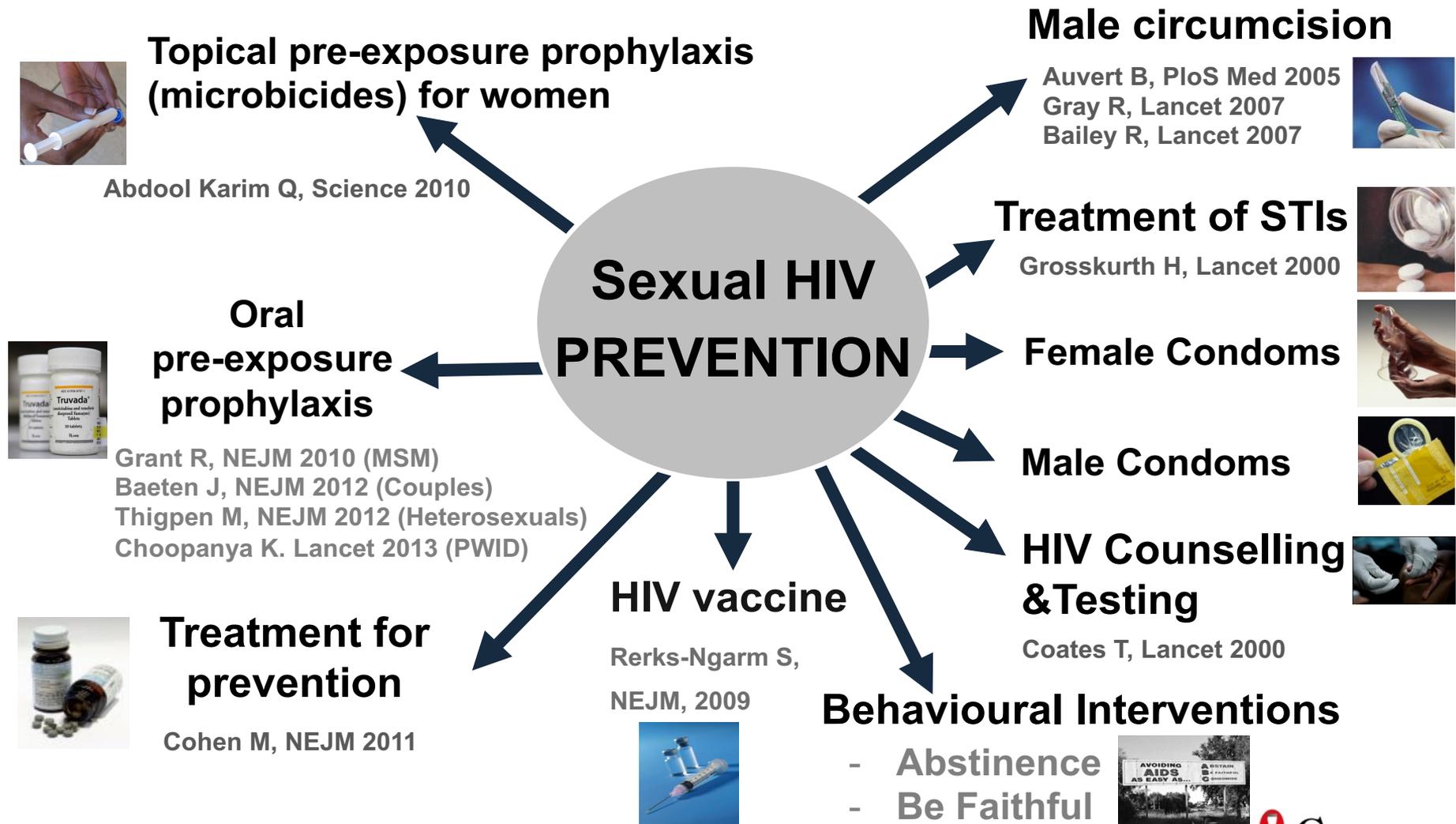
[www.HIV90-90-90watch.org](http://www.HIV90-90-90watch.org)  
Accessed October 13, 2016

# Target 3 – Percentage of HIV+ People with HIV RNA suppression - Results



# HIV prevention with antiretroviral drugs (since 2010)

# HIV prevention (before 2010)



*Note: preventing mother-to-child transmission, screening transfusions, harm reduction, structural interventions, etc. have not been included*



# 12 populations being left behind



**I am a person living with HIV.**

Worldwide, 19 million of the 35 million people living with HIV today do not know that they have the virus.



**I am a young woman.**

76% of adolescent girls in sub-Saharan Africa do not have comprehensive and correct knowledge about HIV.



**I am a prisoner**

HIV prevalence among prisoners in some settings is 50 times higher than among the general population.



**I am a migrant.**

Around the world, 39 countries have an HIV-related travel restriction.



**I am an injecting drug user.**

Only 55 of 192 countries offer a needle-syringe programme.



**I am a sex worker.**

HIV prevalence among sex workers is 12 times greater than among the general population.



**I am a man who has sex with other men.**

Same-sex sexual conduct is criminalised in 78 countries.



**I am a transgender woman.**

Transgender women are 49 times more likely to acquire HIV than all adults of reproductive age.



**I am a pregnant woman.**

Only 44% of pregnant women in low- and middle-income countries received HIV testing and counselling in 2013.



**I am a child.**

Of the 3.2 million children under the age of 15 living with HIV, 2.4 million are not accessing antiretroviral therapy.



**I am a displaced person.**

At the end of 2013, there were 51.2 million people forcibly displaced worldwide.



**I am a person living with a disability.**

23% of men with a disability do not return to seek health care because they were treated badly at a previous visit.



**I am 50+.**

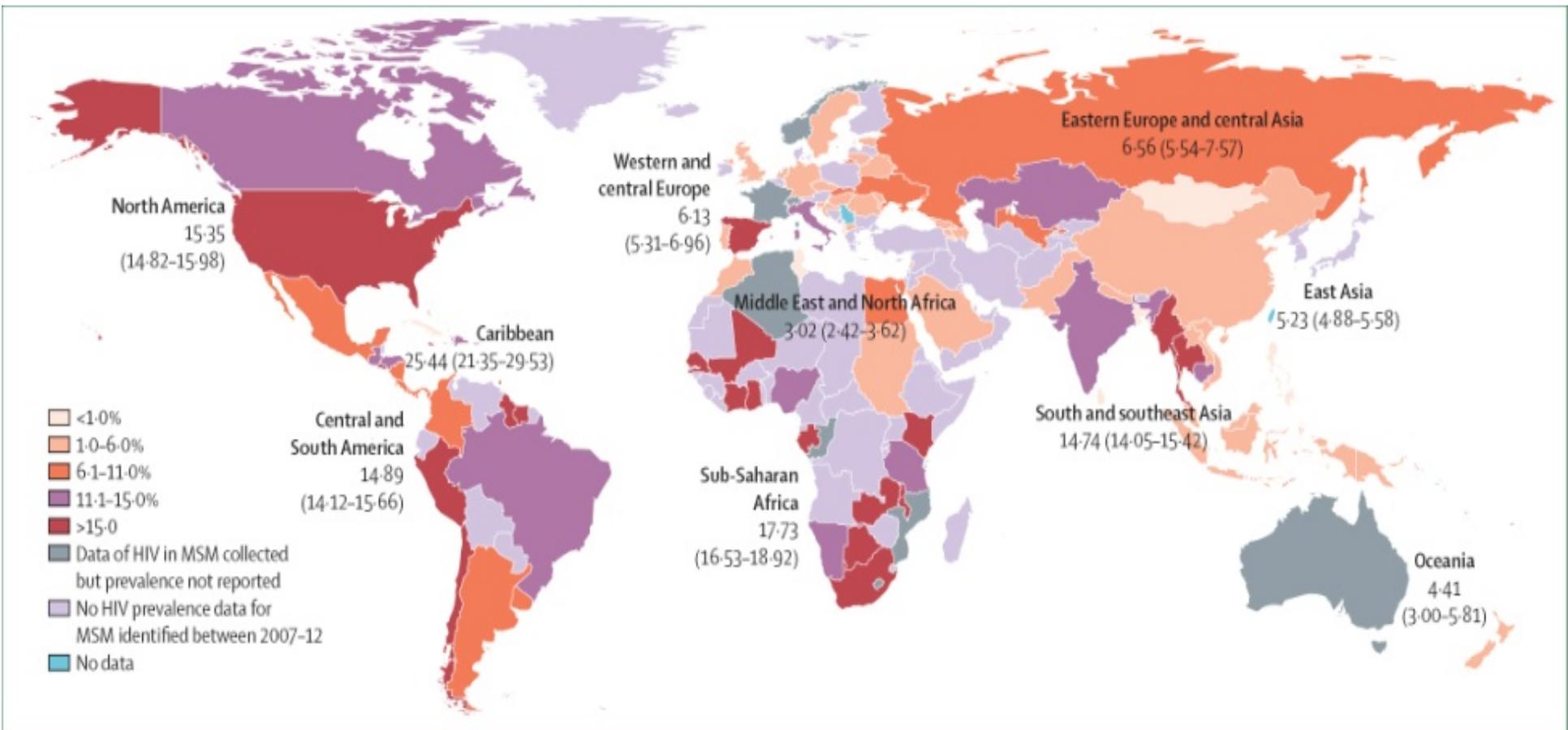
The life expectancy of people aged 50 and older living with HIV and accessing treatment is the same as the life expectancy of others of the same age.

# Combination Prevention: Basic Attributes



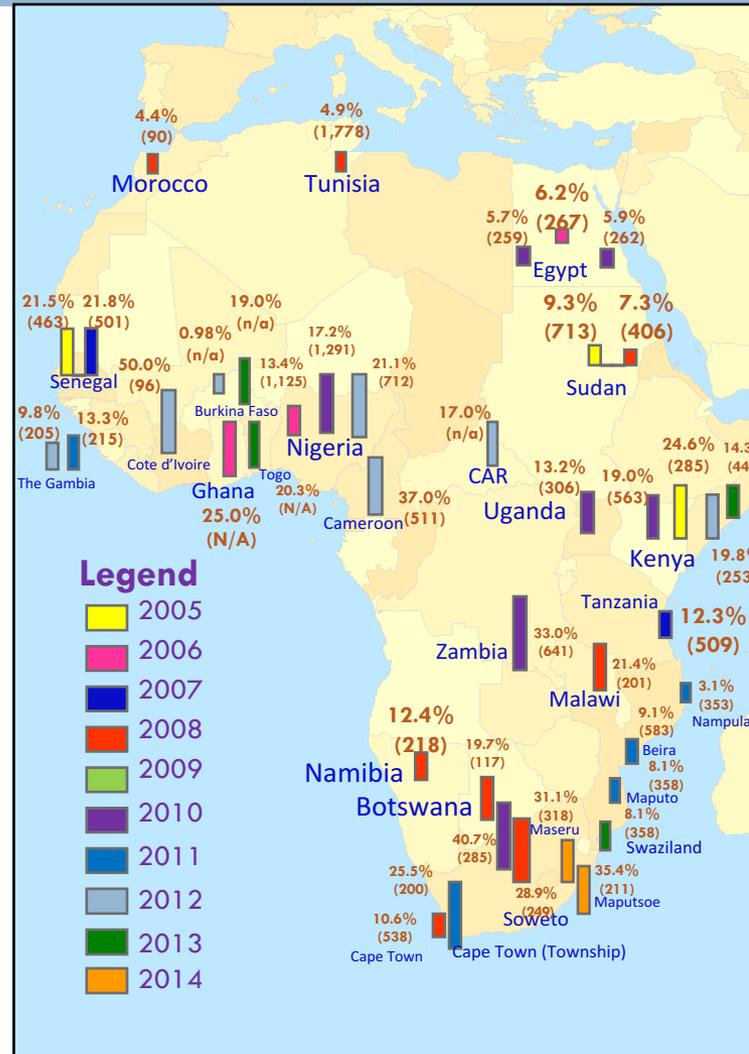
- Tailored to national and local needs and contexts
- Combines biomedical, behavioural and structural elements—to reduce both immediate risks and underlying vulnerabilities
- Fully engages affected communities, promoting human rights and gender equality
- Operates synergistically on multiple levels—individual, family and society
- Invests in decentralized and community responses and enhances coordination and management
- Flexible—adapts to changing epidemic patterns and can rapidly deploy innovations

# Global HIV prevalence among MSM, 2007-2011



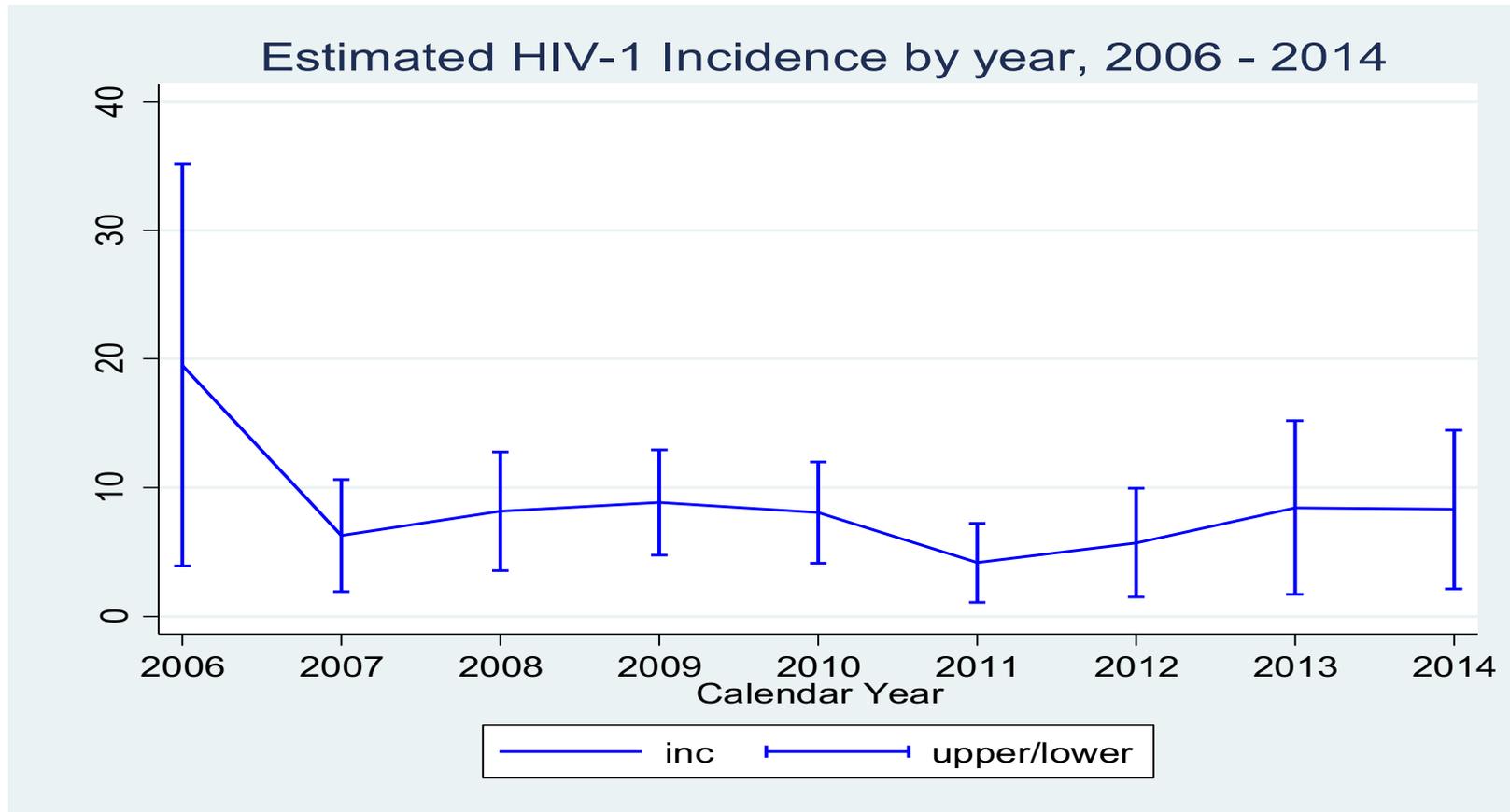
Source: Beyrer, Baral, van Griensven, Goodreau, Chariyalertsak, Wirtz, Brookmeyer, *The Lancet*, 2012

# HIV Prevalence among MSM in Africa



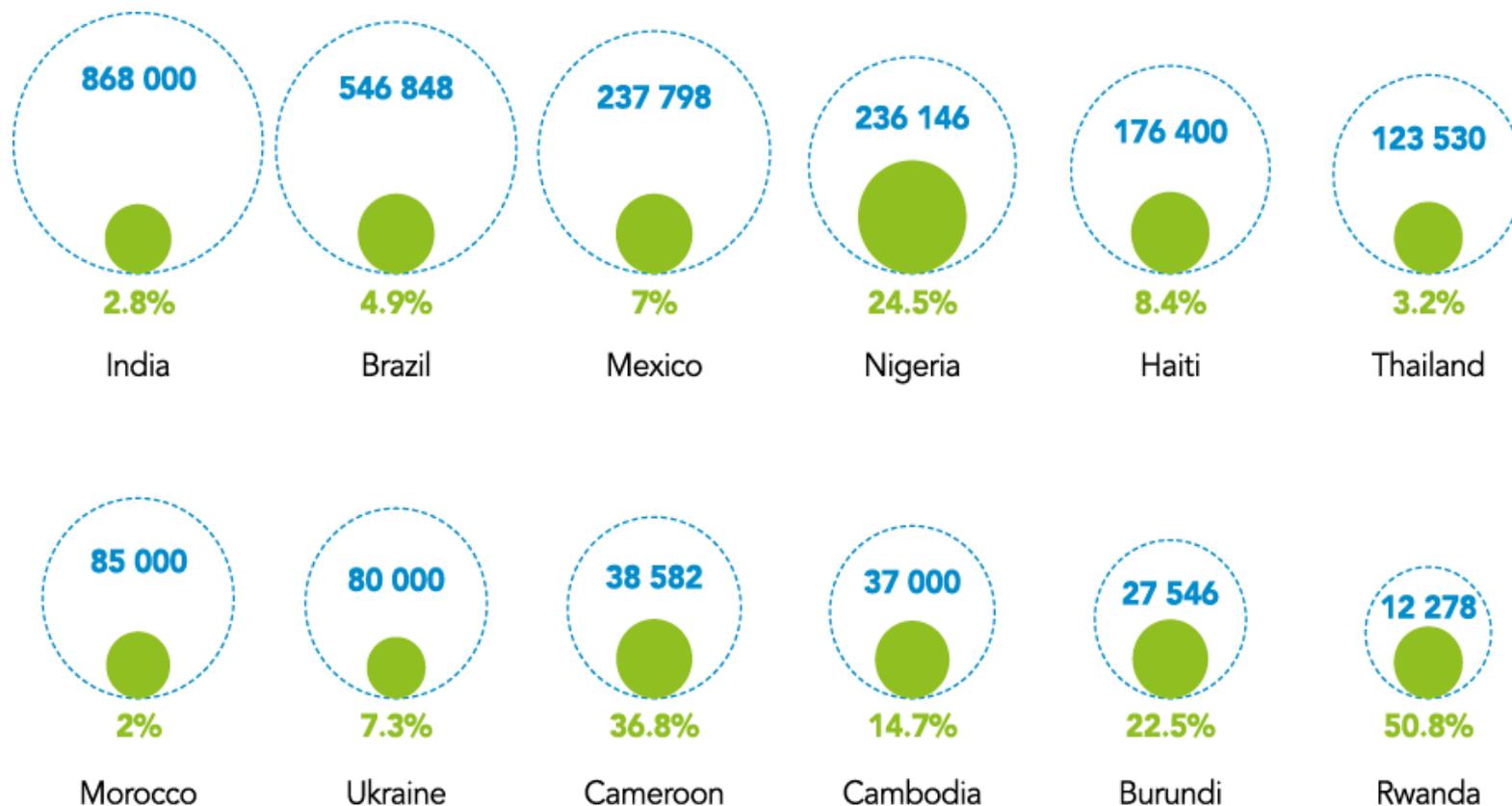
Courtesy Stef Baral

# HIV Incidence among MSM in Kilifi, Kenya



Source: Sanders, Mugo, van der Elst, Smith, Graham. High HIV-1 incidence, correlates of HIV-1 acquisition, and high viral loads following seroconversion among MSM JAIS ,2013

## Estimated population size of sex workers, with the estimated proportion who are HIV-positive, in selected countries

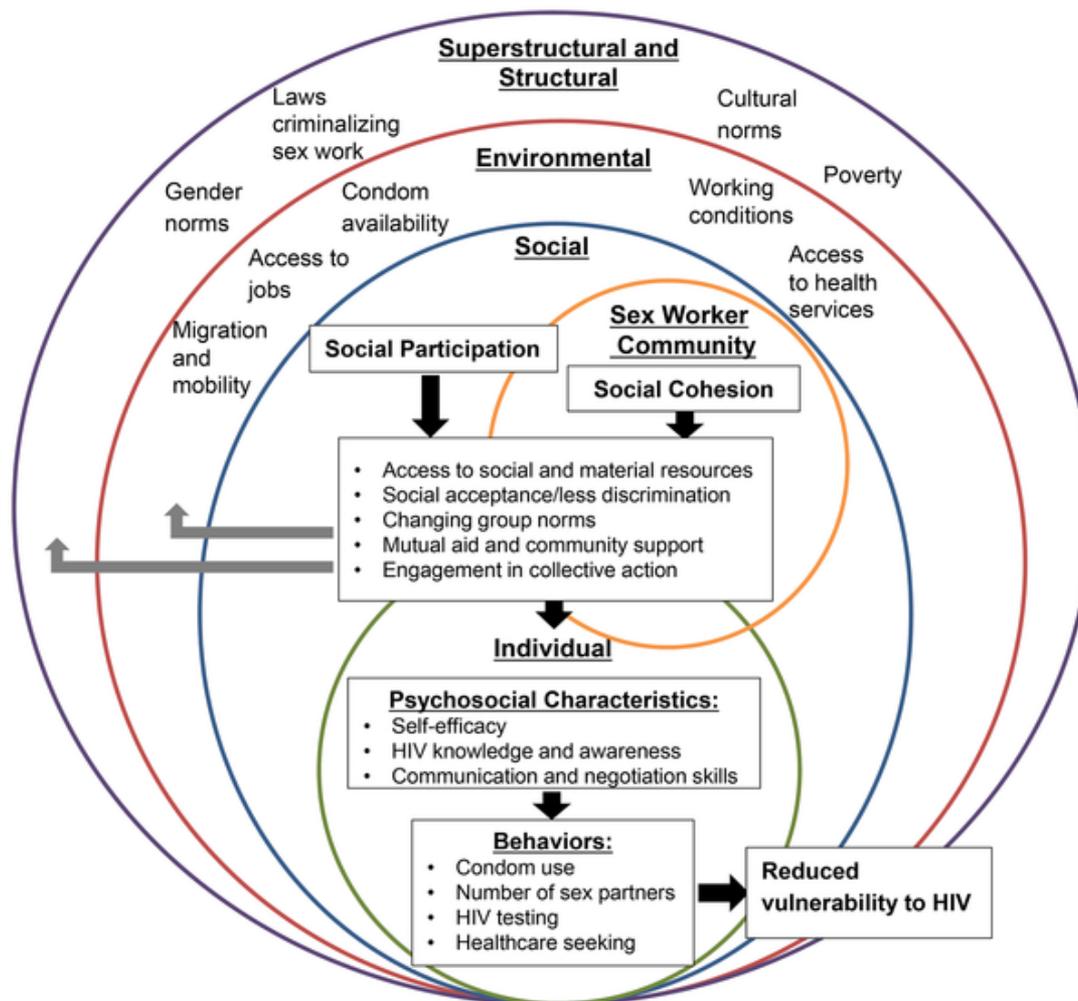


Pooled OR for HIV infection among FSW compared to other women of reproductive age (Baral et al Lancet ID 2012)

**13.49 (95% CI 10.04-18.12)**

Source: UNAIDS

# Theoretical framework of social capital and HIV-related risk among female sex workers in Swaziland.

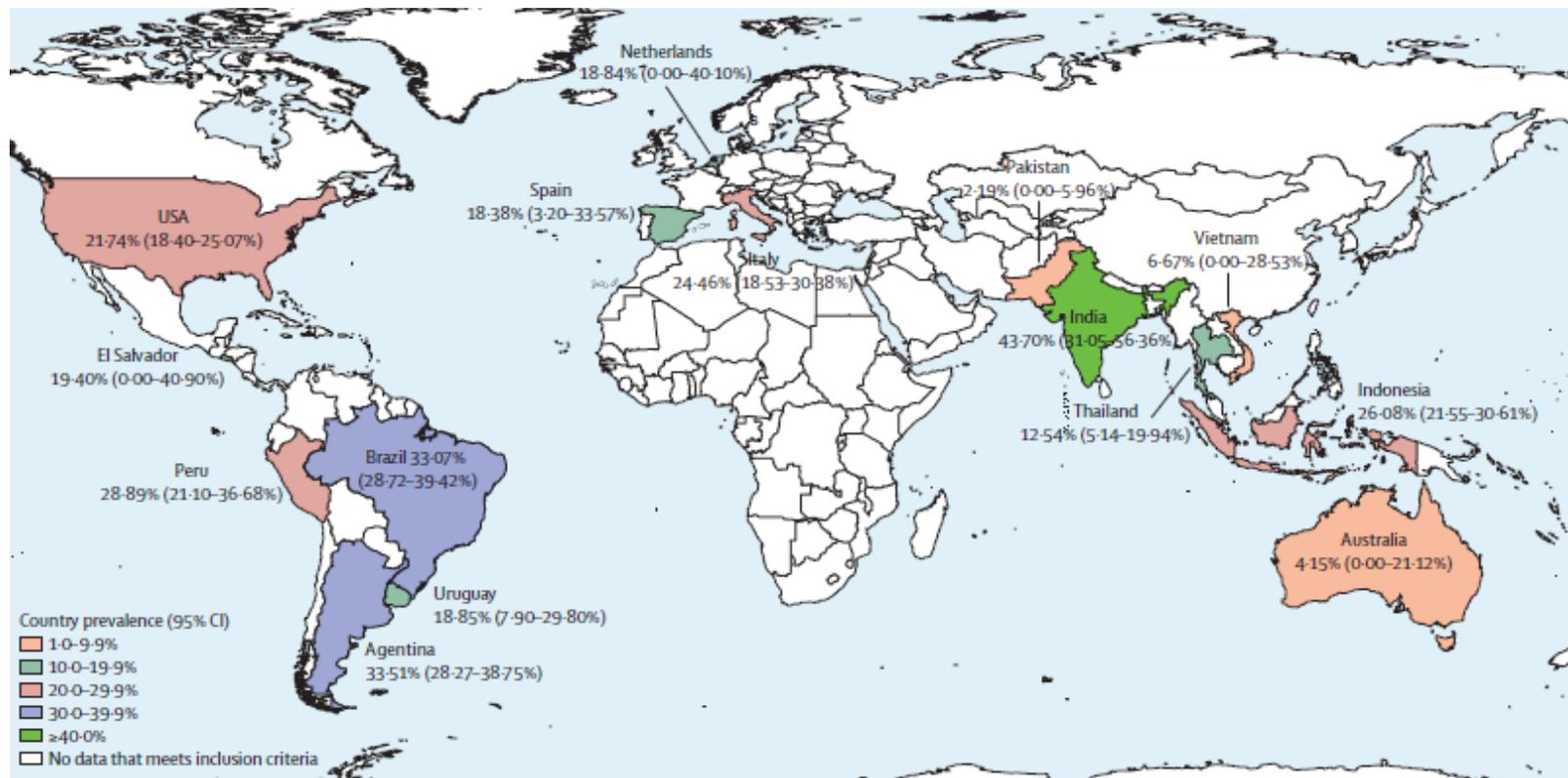


Source: Fonner VA, Kerrigan D, Mnisi Z, Ketende S, Kennedy CE, Baral. (2014) Social Cohesion, Social Participation, and HIV Related Risk among Female Sex Workers in Swaziland. PLoS ONE 9(1): e87527. doi:10.1371/journal.pone.0087527

<http://127.0.0.1:8081/plosone/article?id=info:doi/10.1371/journal.pone.0087527>

Courtesy Stef Baral

# Burden of HIV among Transgender Women



- Pooled OR for HIV infection among transgender women compared to other people of reproductive age
  - 48.8 (95% CI 31.2-76.3)

# UNODC World Drug Report 2015



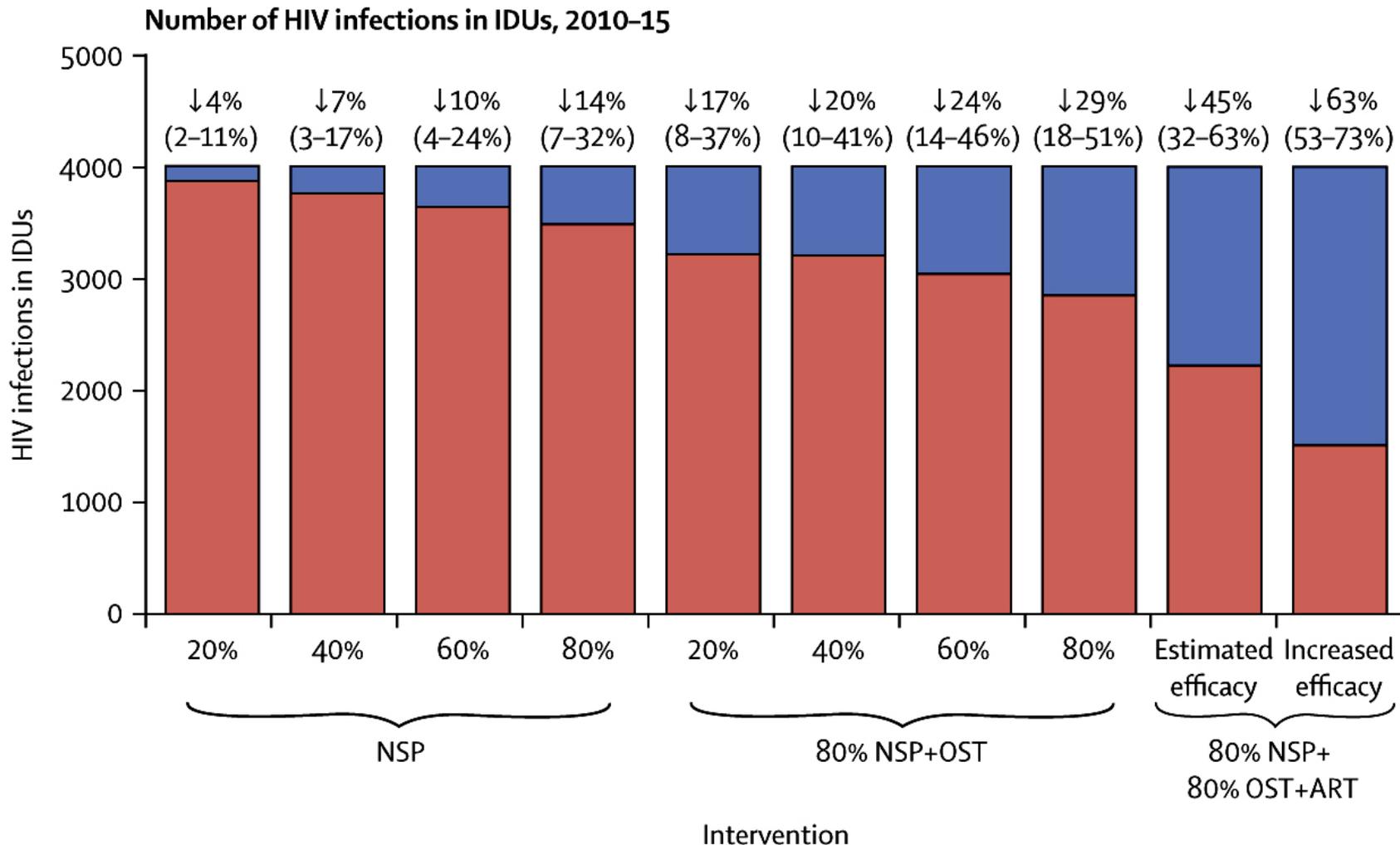
- 246 million people aged 15-64 years used an illicit drug in 2013 (> 1 out of 20 people)
- 27.4 million people are **problem drug users** (>10% of all drug users)
- 12.2 million people who use drugs (PUD) are people who inject drugs (PWID)
- 1.7 million PWID are living with HIV

## HIV prevalence among PWID by region

Africa	11.2%
Eastern Europe	22.8%
West and Central Europe	7.6%

# Combination Prevention to Optimize Intervention Coverage and Efficacy when Force of Infection is High: Nairobi

Strathdee et al Lancet 2010



# I am a young woman. I face these issues.



Girl Effect  
<http://www.girleffect.org/about-us/breaking-through-invisible-barriers>



People

# Young women at high HIV risk: Who? Why? What works?

**Why?**

**Who - source of infection?  
Why so vulnerable?  
What works for prevention?**

**Who?**



**What works?**

**Young women  
at high HIV risk**



Courtesy Slim Abdool Karim

# Community-wide phylogenetic study

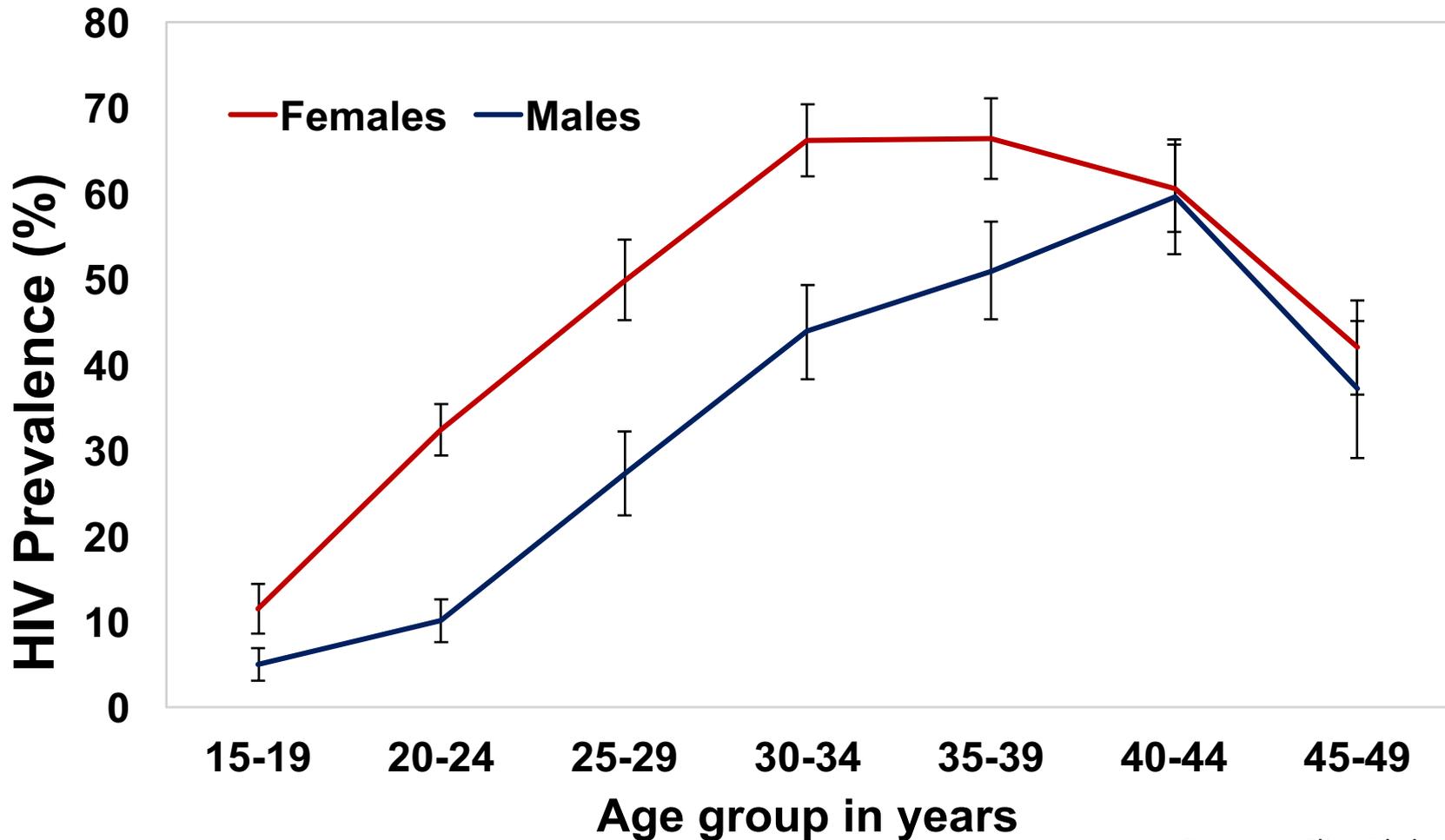


Location of Greater Edendale and Vulindlela study area in KwaZulu-Natal, South Africa

- **Cross-sectional multi-stage random sampling**
- **Duration: 2014 - 2016**
- **86% consent rate**
- **People tested for HIV: 9 812**
- **HIV positive: 36.3%** (CI: 35-38) (n=3,969)
- **Knew HIV+ status: 59.8%** (n=2,337)
- **On ARVs: 42.3%** (n= 1,590)
- **Viral load >1000: 47.1%** (n= 1,847)

Courtesy Slim Abdool Karim

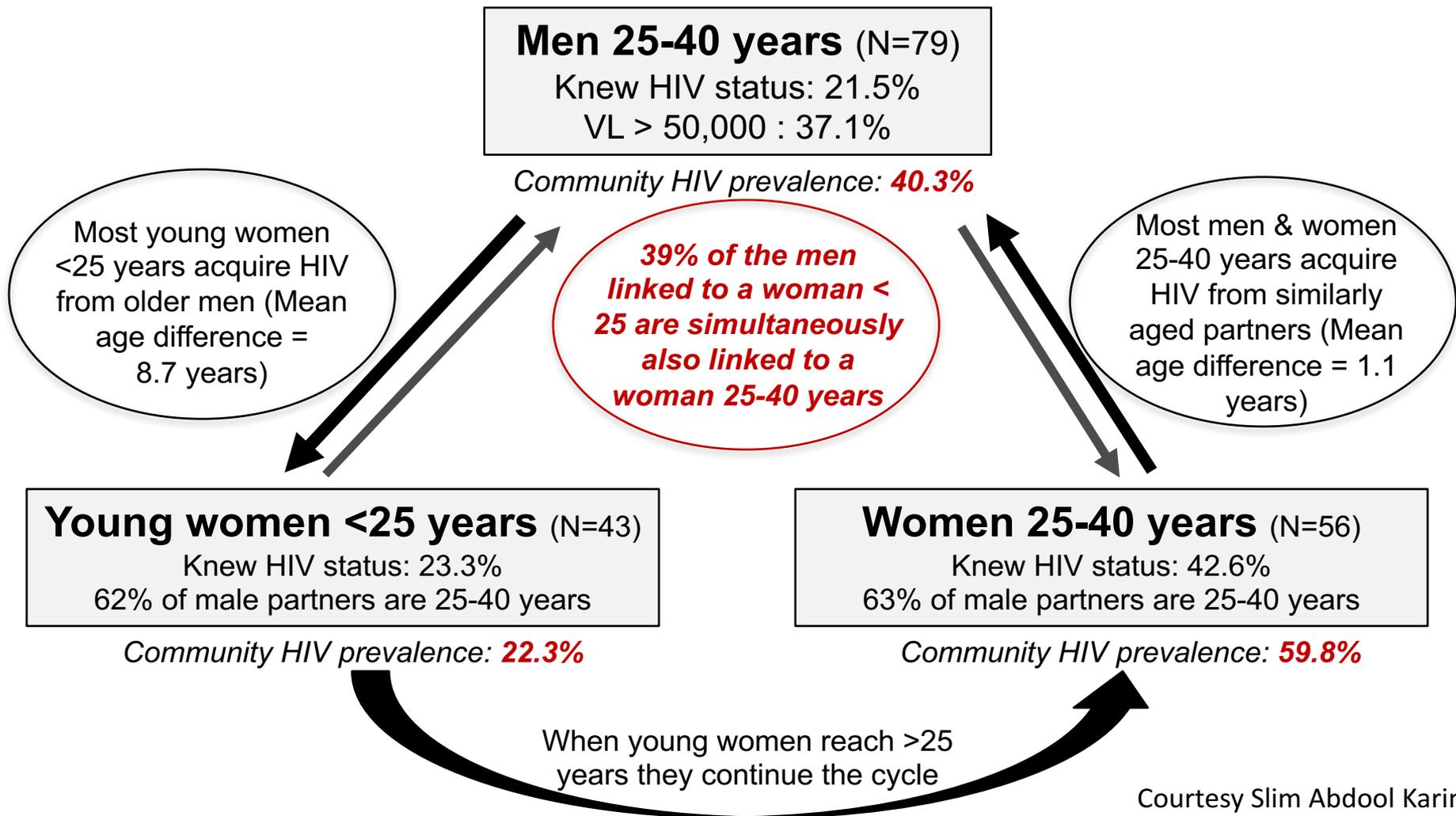
# HIV prevalence rises earlier and faster in women, peaking at 66.4% in the 30s



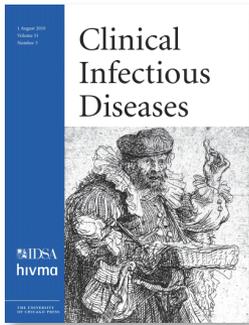
Courtesy Slim Abdool Karim

# Cycle of HIV transmission

Schematic of sexual networks from clusters with heterosexual transmission

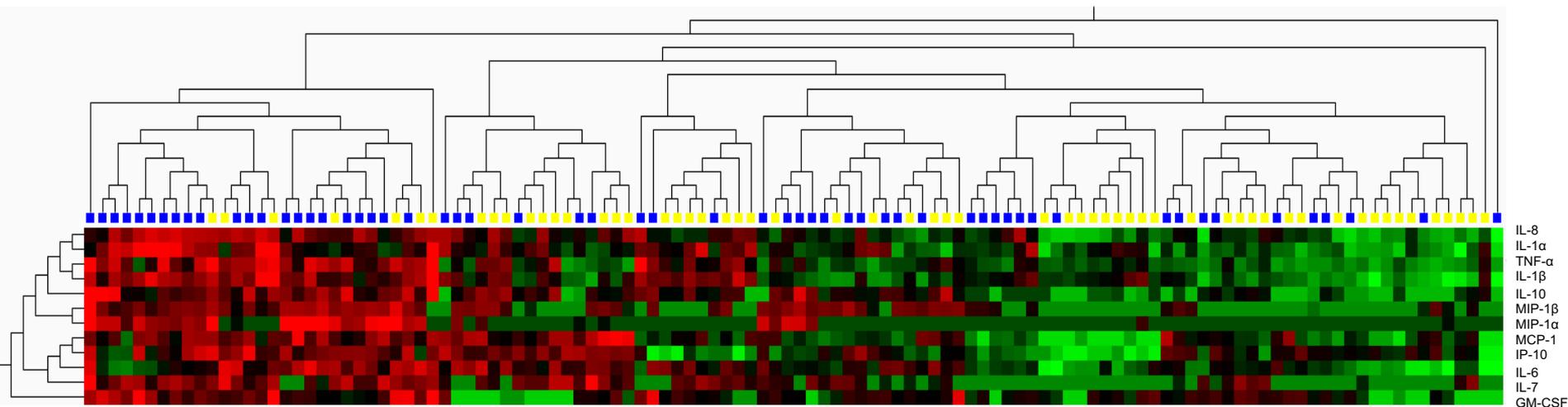


Courtesy Slim Abdool Karim



# Genital Inflammation and the Risk of HIV Acquisition in Women

Lindi Masson,<sup>1,2,a</sup> Jo-Ann S. Passmore,<sup>1,2,3,a</sup> Lenine J. Liebenberg,<sup>1,a</sup> Lise Werner,<sup>1</sup> Cheryl Baxter,<sup>1</sup> Kelly B. Arnold,<sup>4</sup> Carolyn Williamson,<sup>1,2</sup> Francesca Little,<sup>5</sup> Leila E. Mansoor,<sup>1</sup> Vivek Naranbhai,<sup>1</sup> Douglas A. Lauffenburger,<sup>4</sup> Katharina Ronacher,<sup>6</sup> Gerhard Walzl,<sup>6</sup> Nigel J. Garrett,<sup>1</sup> Brent L. Williams,<sup>7</sup> Mara Couto-Rodriguez,<sup>7</sup> Mady Hornig,<sup>7</sup> W. Ian Lipkin,<sup>7</sup> Anneke Grobler,<sup>1</sup> Quarraisha Abdool Karim,<sup>1,8</sup> and Salim S. Abdool Karim<sup>1,8</sup>



IL-8  
IL-1 $\alpha$   
TNF- $\alpha$   
IL-1 $\beta$   
IL-10  
MIP-1 $\beta$   
MIP-1 $\alpha$   
MCP-1  
IP-10  
IL-6  
IL-7  
GM-CSF

1.4 Max  
1.2  
1.0  
0.8  
0.6  
0.4  
0.2  
-0.0  
-0.2  
-0.4  
-0.6  
-0.8  
-1.0  
-1.2  
-1.4 Min

■ Later became HIV-infected (n=58)    ■ Remained HIV-uninfected (n=58)

**Women who later became HIV-infected had pre-infection genital inflammation – what is the cause?**

Only **20%** of HIV infections could be attributed to an STI  
*T. vaginalis* was the most strongly predictive of genital inflammation

# Association between genital inflammation and HIV acquisition

	HIV+	HIV-	Total
Genital inflammation present*	19	6	25
Genital inflammation absent	39	52	91
Total	58	58	116

**Odds Ratio**

**3.2 (95% CI: 1.3 – 7.9)**

**p-value**

**0.014**

\*Women with 5 or more **pro-inflammatory cytokines or chemokines** (MIP-1a, MIP-1b, IL-8, IP-10, TNF-a, MCP-1, IL-6, IL-1a, IL-1b) above the 75<sup>th</sup> percentile  
Significant after adjusting for age, urban/rural, condom use, hormonal contraceptives, number of sex acts, number of returned used applicators, HSV-2 status

# Combination prevention to break the cycle of HIV transmission

**Men 25-40 years (N=79)**

Knew HIV status: 21.5%

VL > 50,000 : 37.1%

**Male circumcision for  
HIV negative men <25  
&  
Antiretroviral therapy  
for HIV positive men**

**Young women <25 years (N=43)**

**Women 25-40 years (N=56)**

**PrEP**

**Changing  
community norms on  
age-disparate sex &  
patriarchy**

**Test & Treat**

Courtesy Slim Abdool Karim

# Scale-up PrEP implementation in women - with BV screening & treatment

One approach: Integration of PrEP scale-up with sexual & reproductive health services ie. STI & FP services



Link to  
SRH services



Vaginal pH testing

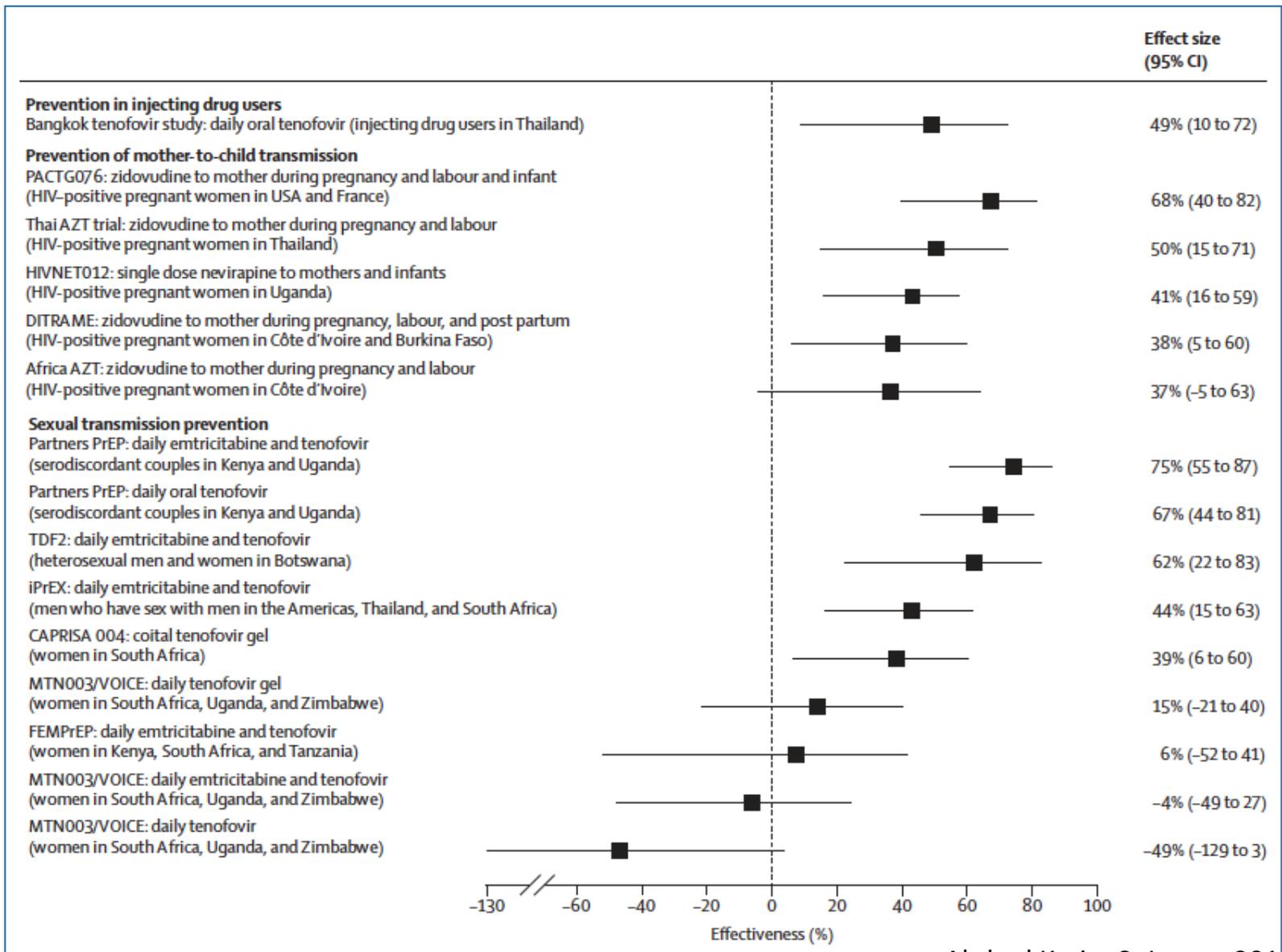
Metronidazole treatment to promote a “healthy” (Lactobacillus dominant) vagina



If pH > 4.5

Courtesy Slim Abdool Karim

# Results of placebo-controlled randomised controlled trials assessing ARV PrEP effectiveness



# Adherence drives trial results: Consistent adherence to daily drug gives high levels of protection



	<b>CASE-CONTROL / CASE-COHORT ANALYSES: DETECTION OF TENOFOVIR IN PLASMA</b>	
	<b>HIV seroconverters</b>	<b>HIV uninfected</b>
<b>iPrEx</b>	9%	51%
<b>Partners PrEP: TDF arm</b>	35%	83%
<b>Partners PrEP: FTC/TDF arm</b>	25%	81%

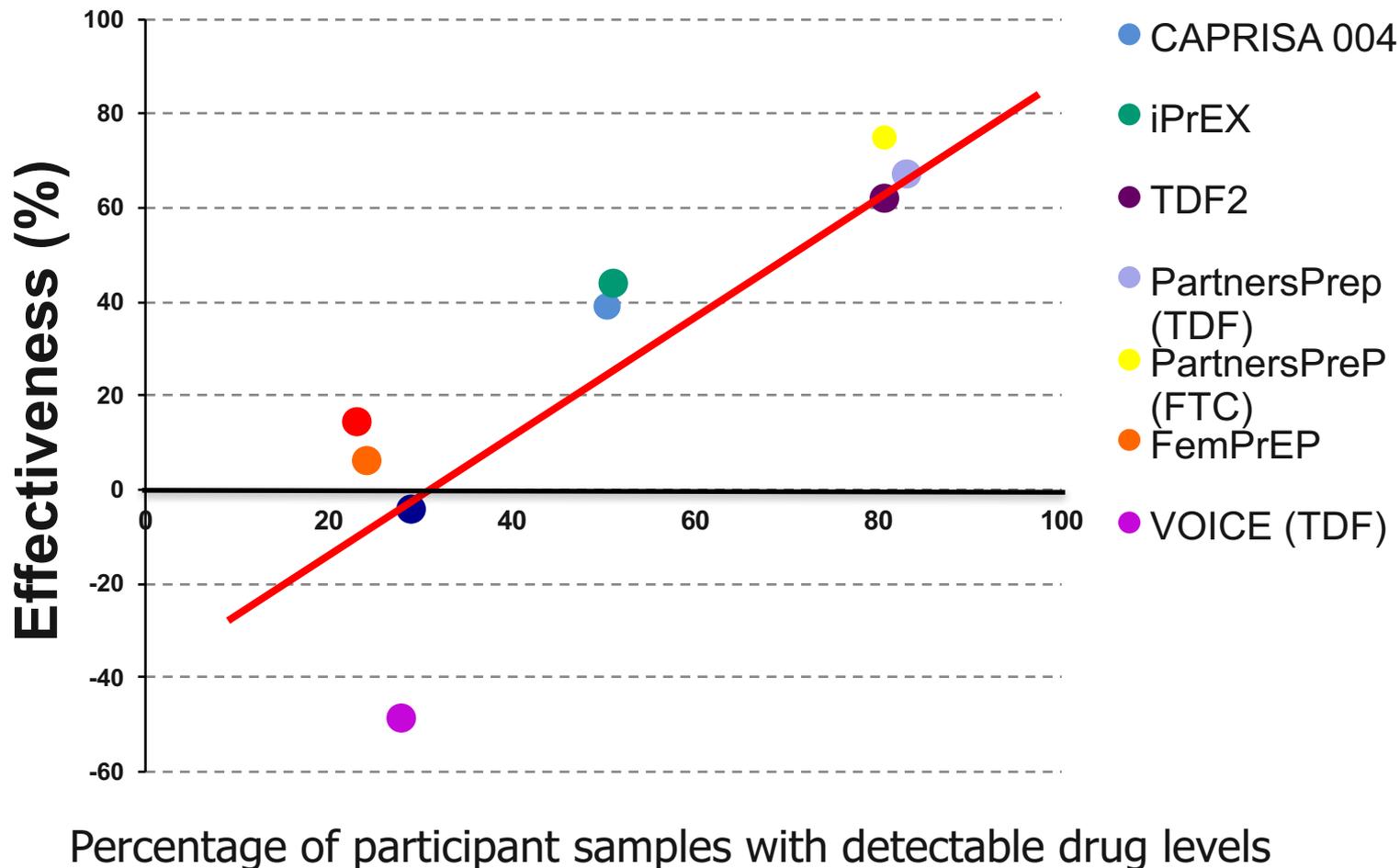
## Relative risk reduction associated with detectable tenofovir

**iPrEx:** **92%** (95% CI 40-99%),  $p < 0.001$

**Partners PrEP TDF:** **86%** (95% CI 57-95%),  $p < 0.001$

**Partners PrEP FTC/TDF:** **90%** (95% CI 56-98%),  $p = 0.002$

# Relationship Between Effectiveness and Adherence in Topical and Oral PrEP Trials



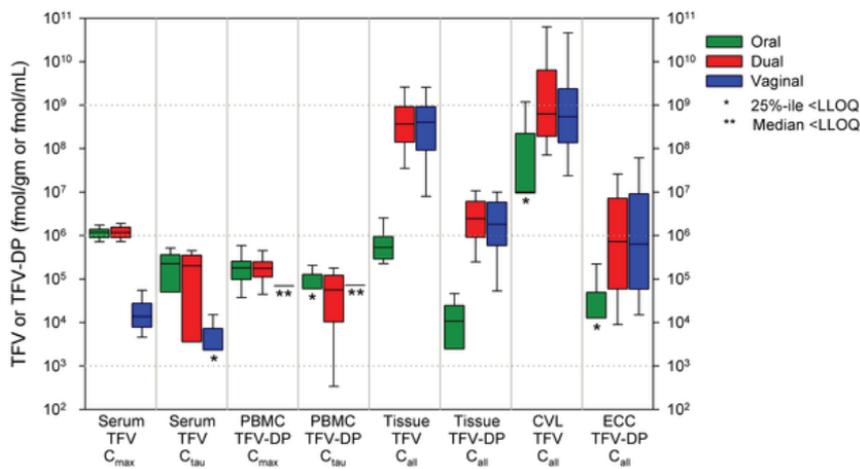
# Systemic Versus Topical Administration

Tenofovir and emtricitabine are phosphorylated intracellularly to form active agents that inhibit HIV replication

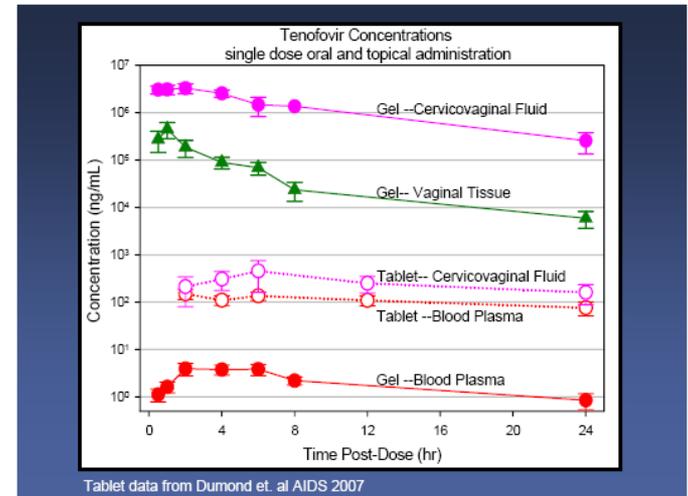
Tenofovir diphosphate concentrations are:

- **100-fold higher** in rectal tissue than in cervicovaginal tissue with oral TDF/FTC [Patterson 2011]
- **1000-fold higher** in vaginal tissues with tenofovir gel than with oral TDF/FTC [Dumond 2007, Gengiah 2012]

Figure 3. Boxplots of TFV and TFV-DP concentrations by anatomic site.



Hendrix et al *PLoS ONE* 2013



Tablet data from Dumond et. al AIDS 2007

Dumond et al *AIDS* 2007

# Key requirements for effective PrEP

- **Right drug** (safe, effective, minimal resistance)
- **Right place** (sufficient concentrations at site of HIV exposure)
- **Right time** (short onset of activity and long half-life to optimize efficacy with variable adherence)
- **Right population** (at risk, motivated to use)
- **Right timing** (during periods of highest risk)
- **Right delivery** (cost-effective and efficient)
- **Right decision-making** (equity issues: prioritising key populations at highest risk of exposure – MSM, SW, PWID, young women while fully scaling up ART)

Adapted from C Celum

People

# Modelling PrEP cost and impact



OPEN ACCESS Freely available online



## The Cost and Impact of Scaling Up Pre-exposure Prophylaxis for HIV Prevention: A Systematic Review of Cost-Effectiveness Modelling Studies

Gabriela B. Gomez<sup>1\*</sup>, Annick Borquez<sup>2</sup>, Kelsey K. Case<sup>2</sup>, Ana Wheelock<sup>3</sup>, Anna Vassall<sup>4</sup>, Catherine Hankins<sup>1,4</sup>

<sup>1</sup> Department of Global Health, Academic Medical Centre, University of Amsterdam and Amsterdam Institute for Global Health and Development, The Netherlands, <sup>2</sup> School of Public Health, Imperial College London, United Kingdom, <sup>3</sup> Centre for Patient Safety and Service Quality, Imperial College London, United Kingdom, <sup>4</sup> London School of Hygiene and Tropical Medicine, United Kingdom

- 13 studies of cost and impact among heterosexual couples, men who have sex with men (MSM), people who inject drugs (PWID) in generalised and concentrated epidemics in southern Africa, Ukraine, USA, and Peru
- Cost-effectiveness depends on **cost, epidemic context, PrEP programme coverage, prioritisation strategies, and adherence**
- Most cost-effective strategy: **delivery of PrEP to key populations at highest risk of HIV exposure**

Gomez et al *PLoS Medicine* 2013

# International PrEP Demonstration Projects With Emtricitabine/Tenofovir DF (2011-2015)

Individual PrEP demonstration projects with emtricitabine/tenofovir DF

- 32 projects in 16 countries
- 8478 participants with 7061 cumulative years exposure

HIV seroconversion rate was 0 in

- 17 projects with 2467 participants
- Follow-up: 1315 person-years exposure

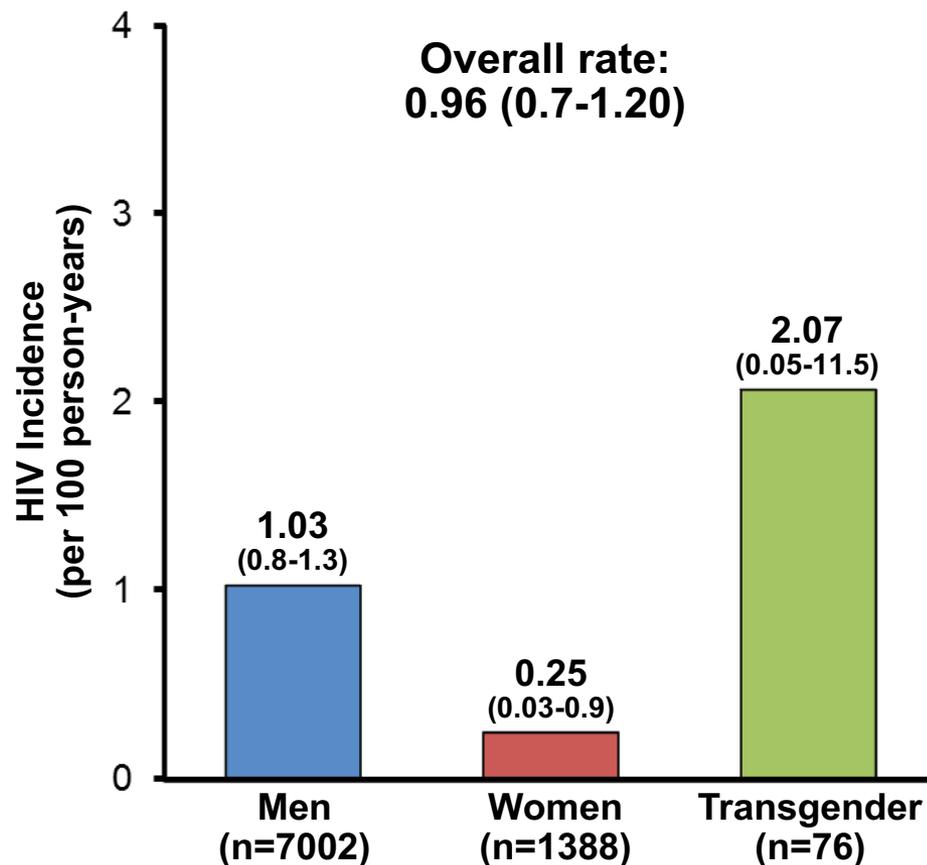
Total HIV seroconversions (n=67) in 15 projects

Highest rates in MSM 18 to 25 years of age (7.7/100 person-years)

Available intracellular data showed undetectable or very low TFV-DP levels (<2 tablets/ week) in nearly all of those with seroconversion

Courtesy Ken Mayer

## HIV Seroconversion Rates



Mcallister S, et al. ASM Microbe 2016. Boston, 2016.

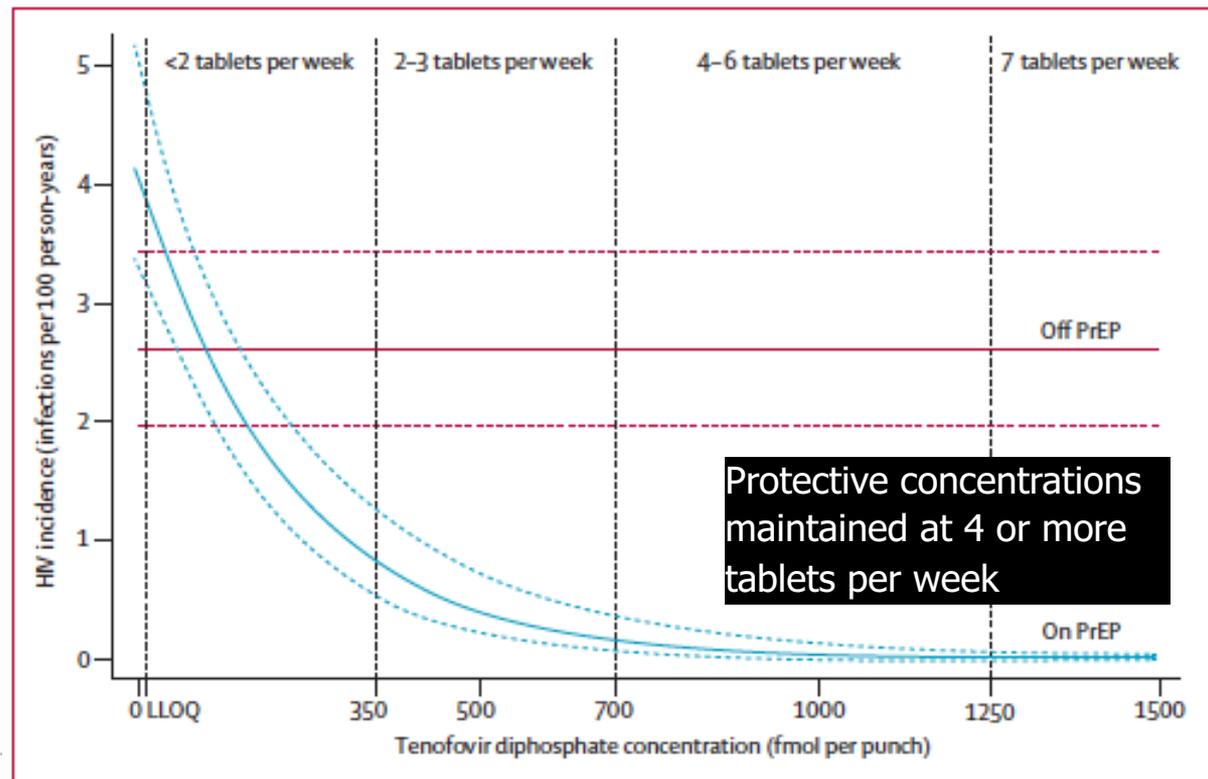
# Post-trial cohort: ATN 082, iPrEx, US Safety Study



- 72-week open label extension n=1603 [76% took PrEP]
- Uptake, adherence, sexual practices in clinical practice
- Use dried-blood spot (DBS) and plasma tenofovir levels, integrated next-step counselling
- Those with riskier sexual practices and STI more likely to join the study

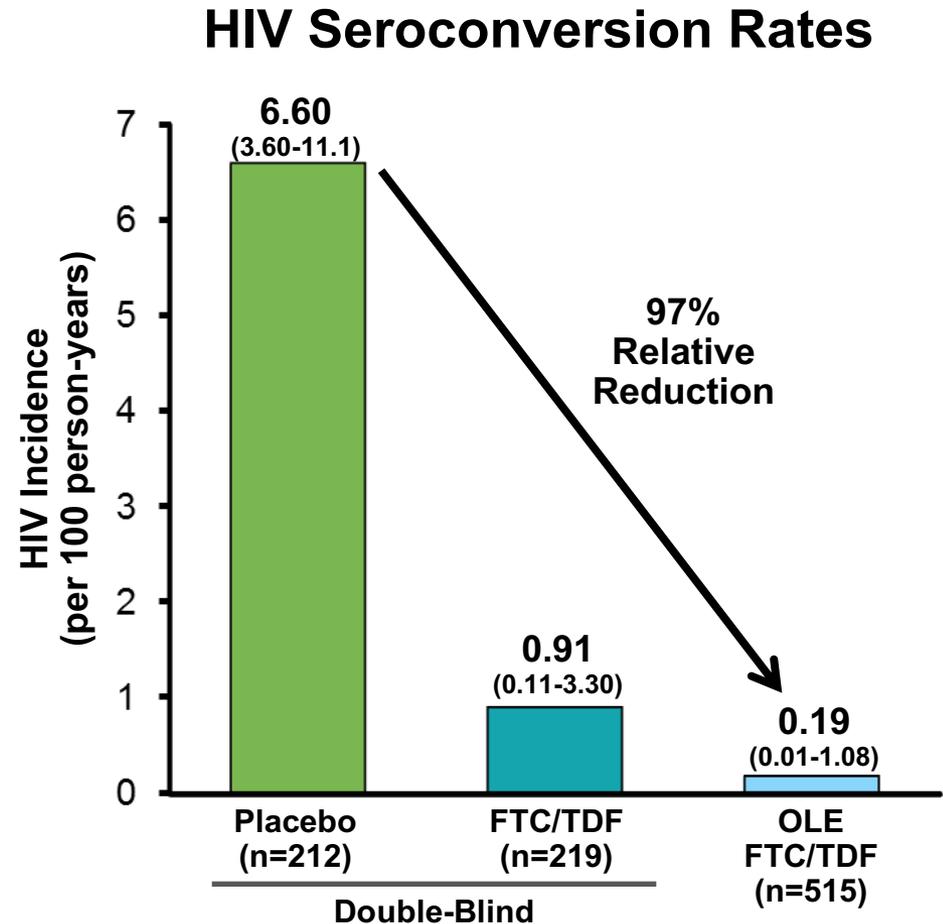
PrEP and  
HIV  
incidence

[Grant et al  
*Lancet ID* 2014]

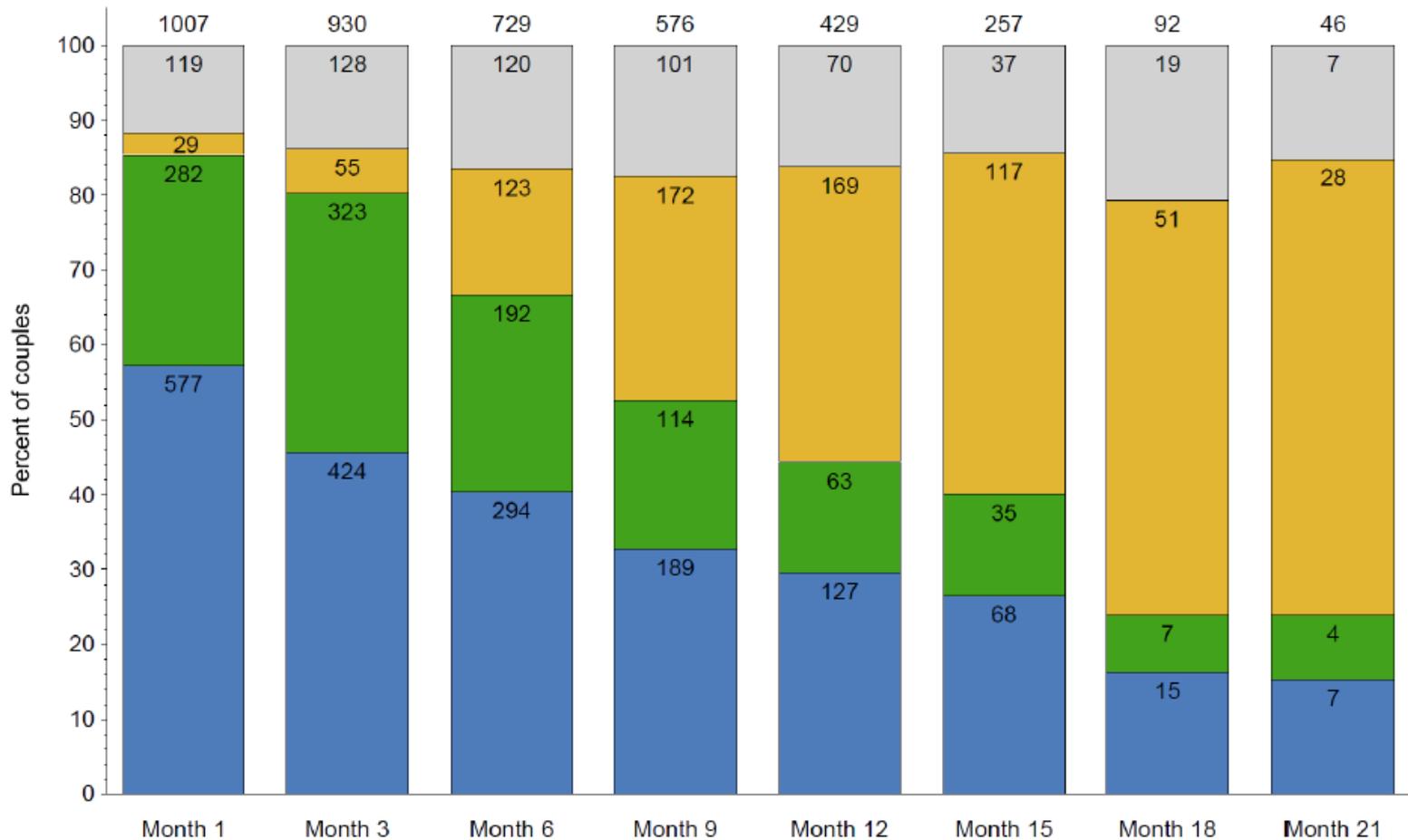


# ANRS Ipergay Trial Open-Label Extension Study: Efficacy of On-Demand PrEP in High-Risk MSM

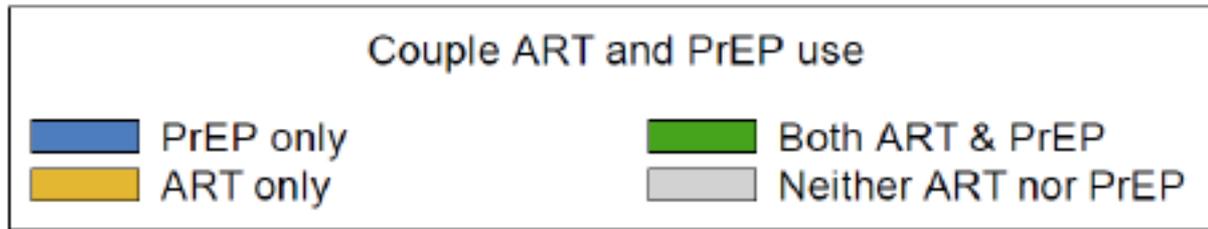
- Median follow-up: 18.4 months
- **New STIs during OLE (33%)**
- Generally well tolerated
  - Drug-related GI AEs (10%)
- Sexual behaviour
  - No significant difference compared with double-blind phase
- **Single HIV infection**
  - No PrEP use in 40 months
  - Emtricitabine or tenofovir not detectable at time of HIV diagnosis
- **Estimated efficacy**
  - **97% relative reduction in HIV transmission versus placebo**



# Couple ART and PrEP use over time in Partners Demonstration Project in Kenya and Uganda

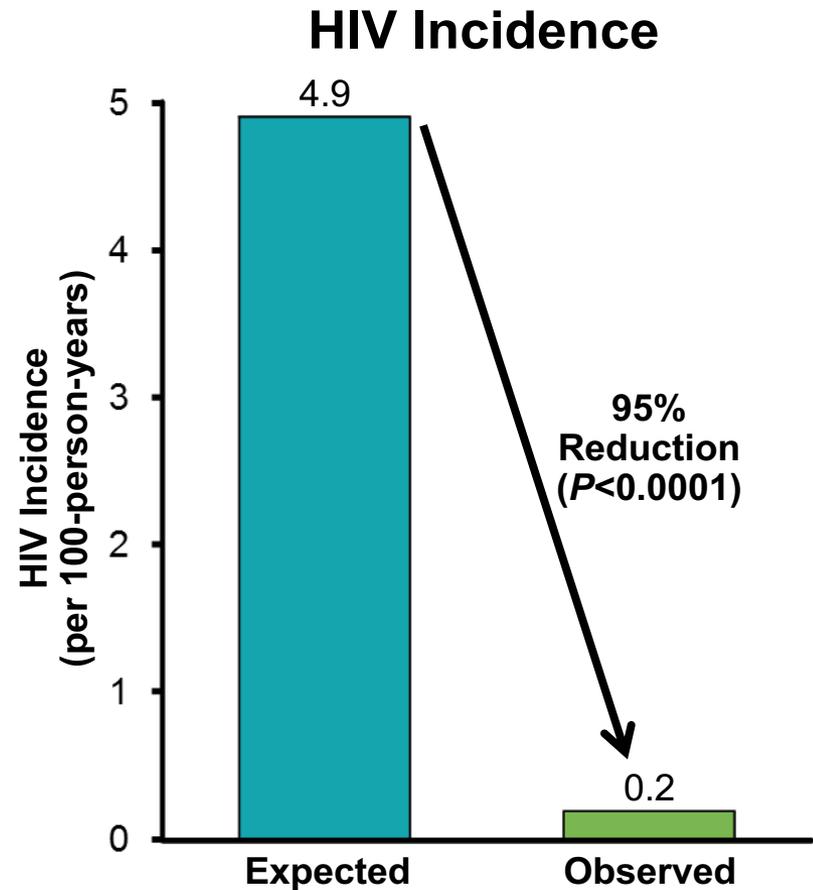


Source: Baeten et al  
PLoS Medicine 2016



# Partners Demonstration Project: HIV Incidence

- Observed HIV infections (n=4, none with resistance to PrEP)
  - No detectable TDF (n=3)
  - Declined PrEP, had multiple partners (n=1)
- Reduction in HIV incidence compared with expected ( $P<0.0001$ )
  - Overall: 95%
  - Males: 97%
  - Females: 93%
  - HIV- partner <25 years of age: 95%
  - Baseline HIV RNA  $\geq 50$ K copies/mL: 95%



# Pre-exposure prophylaxis strategies



Tenofovir (TDF)



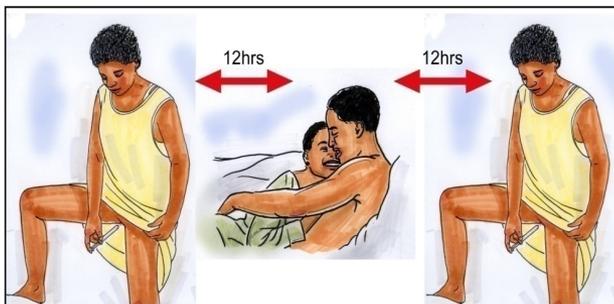
✓ **Partners**

Tenofovir/emtricitabine TDF/FTC



✓ **iPrEx**  
✓ **Partners PrEP**  
✓ **TDF2**

Topical PrEP: 1% tenofovir gel



✓ **CAPRISA 004**



ASPIRE and IPM trials



Injectable PrEP: subcutaneous or intramuscular (Phase 1 trials)

Intermittent PrEP trials

# How to improve chemoprophylaxis effectiveness?

## Novel adherence strategies



## Hard-to-reach populations; PWUD

## Alternative delivery systems and formulations



## Injectables: ARVs and mAbs (Cabotegravir, VRC01)



## Intravaginal rings (Dapivirine, Tenofovir) +/- Contraception)



Courtesy Ken Mayer

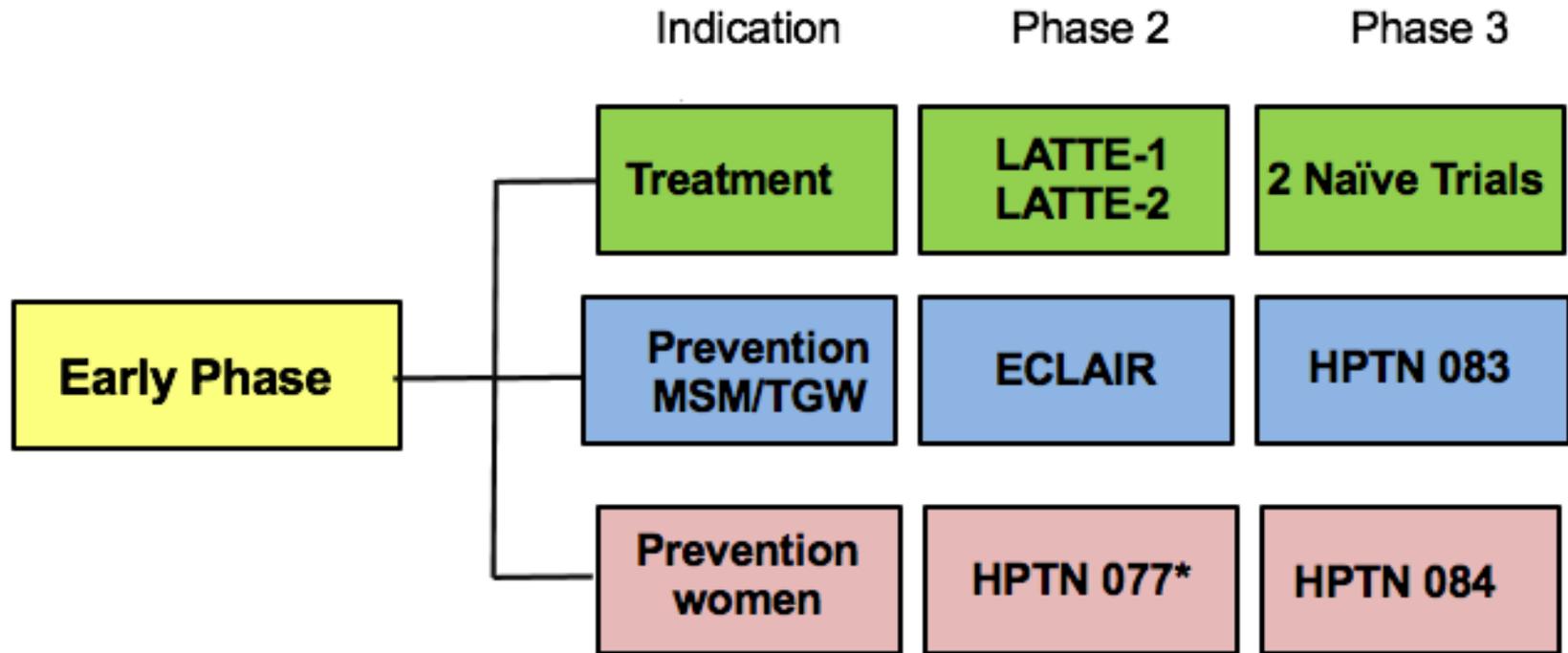
## Vaginal & Rectal Microbicides (MTN 017)



## New oral PrEP drugs and dosing strategies



# Cabotegravir development



HPTN: HIV Prevention Trials Network

\*HPTN 077 included both men and women

Courtesy Mike Cohen

# Long-acting biomedical prevention

- Long acting (LA) injectables: HPTN 083 & 084 to test LA INSTI: Cabotegravir q 8 weeks; safe in Phase II study (Éclair)
- Infusion of broadly neutralizing antibodies – HPTN 081 & 085 to test VRC01 q 8 weeks; others coming
- Building on the results of Thai vaccine study RV144 (2 vaccines to stimulate antibodies and CTLs), HVTN beginning combination vaccine study in Africa
- Altering microbiome (Abdool Karim, IAS 2016)
- **TDF/FTC is PrEP 1.0, what we have now**



A tablet of Descovy

TREATMENT NEWS

# Gilead Plans Major Clinical Trial of Descovy vs. Truvada as PrEP

Descovy is an updated version of Truvada containing a new form of the drug tenofovir that is safer for bones and the kidneys, at least among those with HIV.

emtricitabine (FTC) with tenofovir alafenamide (TAF) versus emtricitabine (FTC) with tenofovir disoproxil fumarate (TDF)

October 13, 2016

# Research and Development Pipeline



Vaginal and rectal gels



Silicon rings



Oral



Injectable



Other gels

pH transition  
Subliming Solid matrix



Rings with other polymers



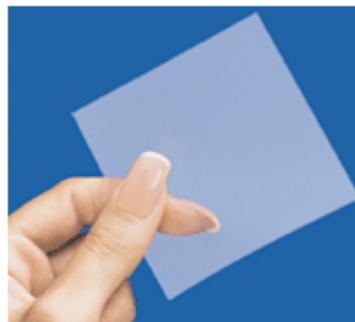
Pod Rings



Segmented Rings



Devices +/- Gels

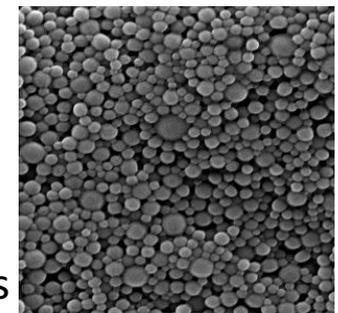


Vaginal Films



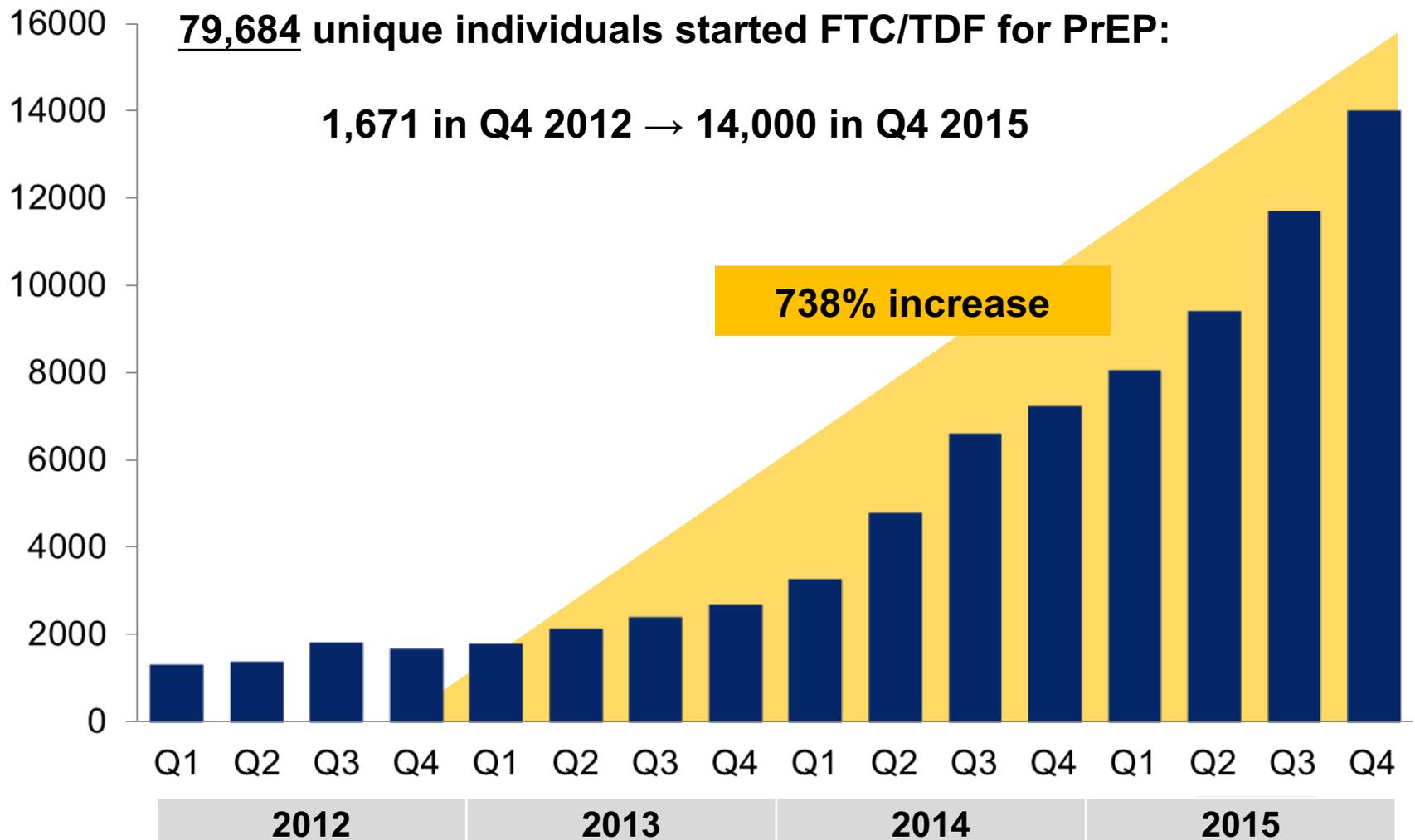
Quick Dissolve Tablets

Implants



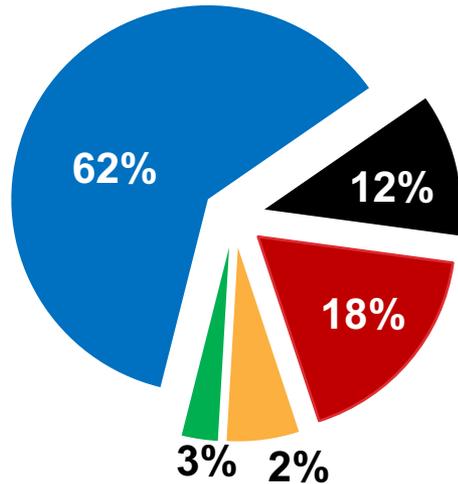
Drug in nanoparticles for films & rings

# Unique Individuals Starting FTC/TDF for PrEP in USA 2012 to 2015 (by quarter)

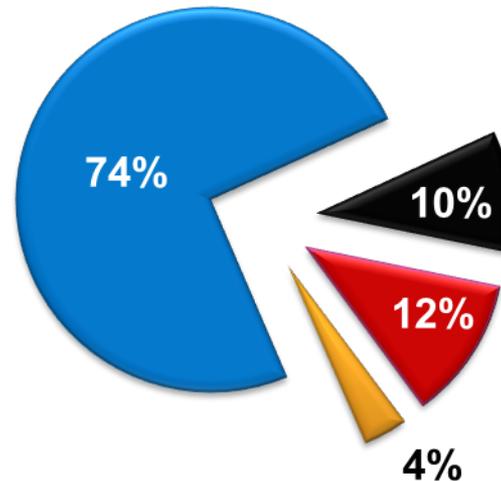


# FTC/TDF for PrEP Utilization Compared With Population and New HIV Infections

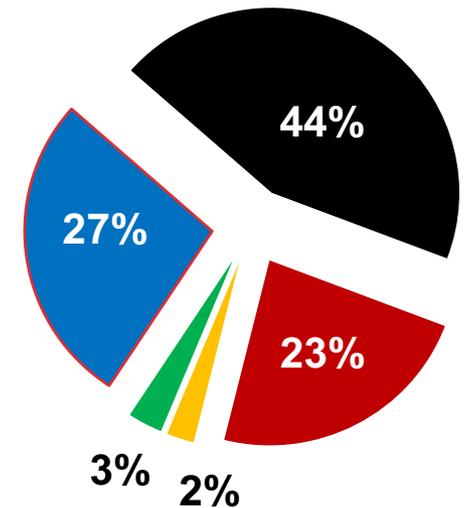
Estimated Population Distribution by Race/Ethnicity, 2014, US<sup>a</sup>



Total FTC/TDF for PrEP Utilization by Race/Ethnicity, Sept 2015, US<sup>b</sup>



Estimated New HIV Infections, 2014, US<sup>c</sup>



■ AA ■ White ■ Hispanics ■ Asians ■ Multiracial/Other

**FTC/TDF for PrEP use among AA and Hispanics is low relative to the rate of new HIV infections**

b. These data represent 43.7% (n=21,463) of unique individuals who have started TVD for PrEP from 2012-3Q2015.

# Shocked HIV Charities Blast NHS For “U-Turn” On Drug That Prevents HIV

The NHS has scrapped plans to make Truvada available, prompting fury from HIV organisations.

posted on Mar. 21, 2016, at 7:28 p.m.



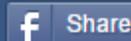
**Patrick Strudwick**  
BuzzFeed LGBT Editor, UK



Courtesy Ken Mayer



# I Want PrEP Now

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## Buy PrEP Now

### Where to buy PrEP online, now, in the UK

So far we have independently verified 4 different companies who reliably sell PrEP that you can trust. For full details on our independent verification process, [click here](#).

[United Pharmacies UK](#) (£44 per month)

Buy Now



United Pharmacies UK is our personally recommended supplier of PrEP, you do not need to upload a prescription after purchasing and they have some of the cheapest prices on the internet. In addition to independently verifying their product, we also use United Pharmacies to buy PrEP ourselves. The only minor issue is that due to running out of stock, orders occasionally have a delay of around 1 - 2 weeks.

1 months supply = £45.79 per month.

3 months supply = £41.69 per month, (£125.07 in total).

Delivery to the UK costs £6.75 and takes 7 - 14 business days.



Courtesy Ken Mayer



## Where do you fit on the map?

Communities across the globe are at varying stages of implementation of daily oral PrEP. TDF/FTC is approved for use as oral PrEP in a handful of countries, and access is expanding globally. In some places there is growing uptake; in others, access is limited to pilot projects. Other countries are not yet exploring implementation. Learn more about access and advocacy below.



### Countries with PrEP demonstration projects

Australia  
Belgium  
Brazil  
Canada  
France

India  
Kenya  
Malawi  
Netherlands  
Nigeria

Peru  
South Africa  
Thailand  
Uganda

United Kingdom  
United States of America  
Zambia  
Zimbabwe

### Countries without current access to PrEP

Daily oral PrEP involves drugs that are also used in HIV treatment. This means the strategy may only be available via off-label use in some places. Much work is needed to see innovative, impactful introduction.

[Learn about access](#)

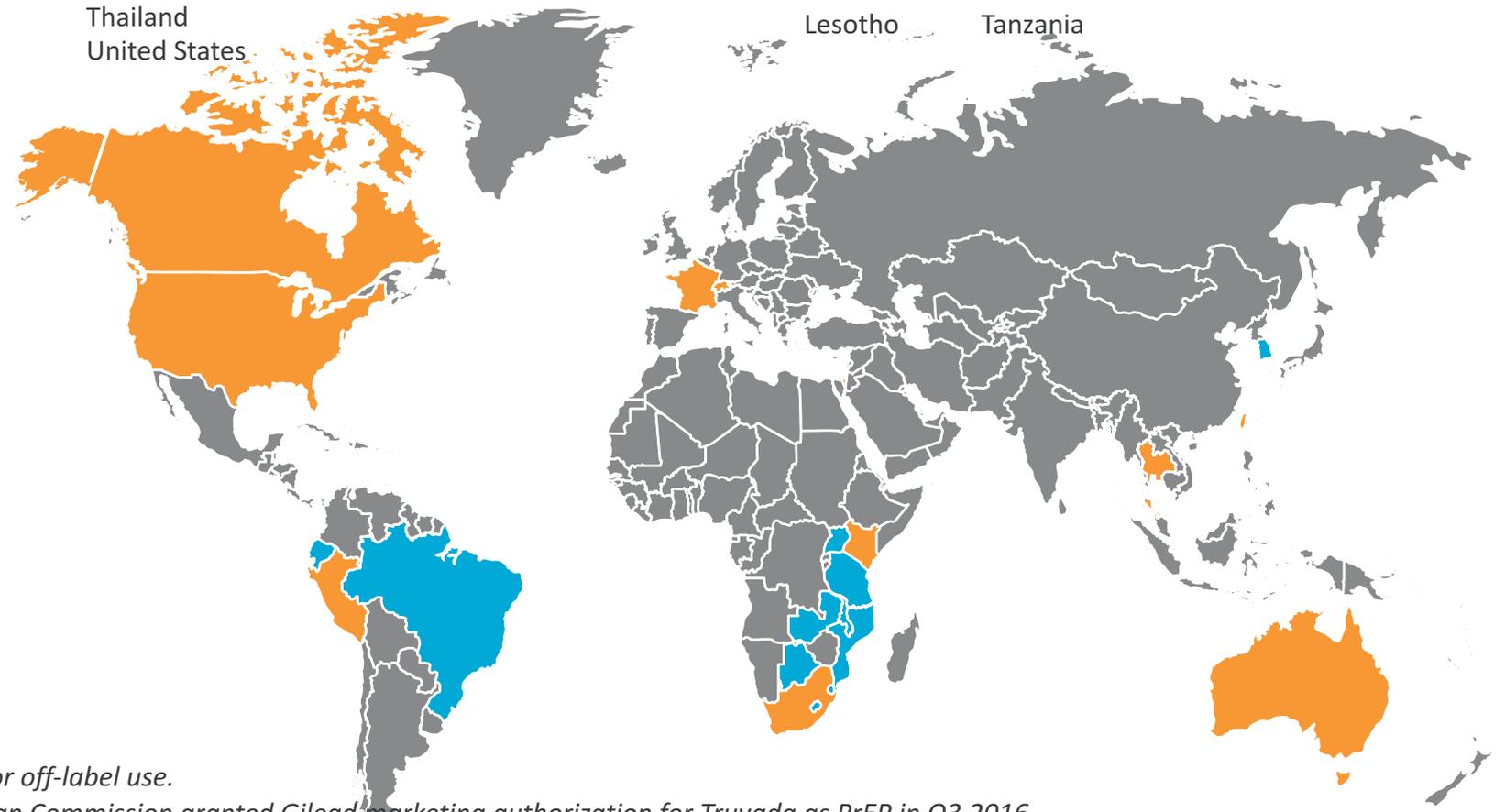
# Regulatory Status of Truvada for PrEP

 Truvada approved for prevention

 Regulatory application filed for a prevention indication for Truvada <sup>2, 3</sup>

- |           |                          |
|-----------|--------------------------|
| Australia | Peru                     |
| Canada    | South Africa             |
| France    | Switzerland <sup>1</sup> |
| Israel    | Taiwan                   |
| Kenya     | Thailand                 |
|           | United States            |

- |          |             |        |
|----------|-------------|--------|
| Botswana | Malawi      | Uganda |
| Brazil   | Mozambique  | Zambia |
| Ecuador  | South Korea |        |
| Korea    | Swaziland   |        |
| Lesotho  | Tanzania    |        |



1. Approved for off-label use.

2. The European Commission granted Gilead marketing authorization for Truvada as PrEP in Q3 2016. This should encourage countries within the EU to make PrEP available within their national health systems, based on cost factors and individual country regulatory requirements.

3. Expected filing in Zimbabwe in 2016.

# Who is PrEP for? What is needed for access?

Why PrEP?

Who is PrEP for?

- Key populations at higher risk of HIV acquisition
- PrEP and combination prevention: the complementarity of PrEP

Real world findings

- Open label and demonstration projects
- Cost effectiveness and uptake
- Regulatory status

# Contribution of PrEP to controlling the HIV epidemic

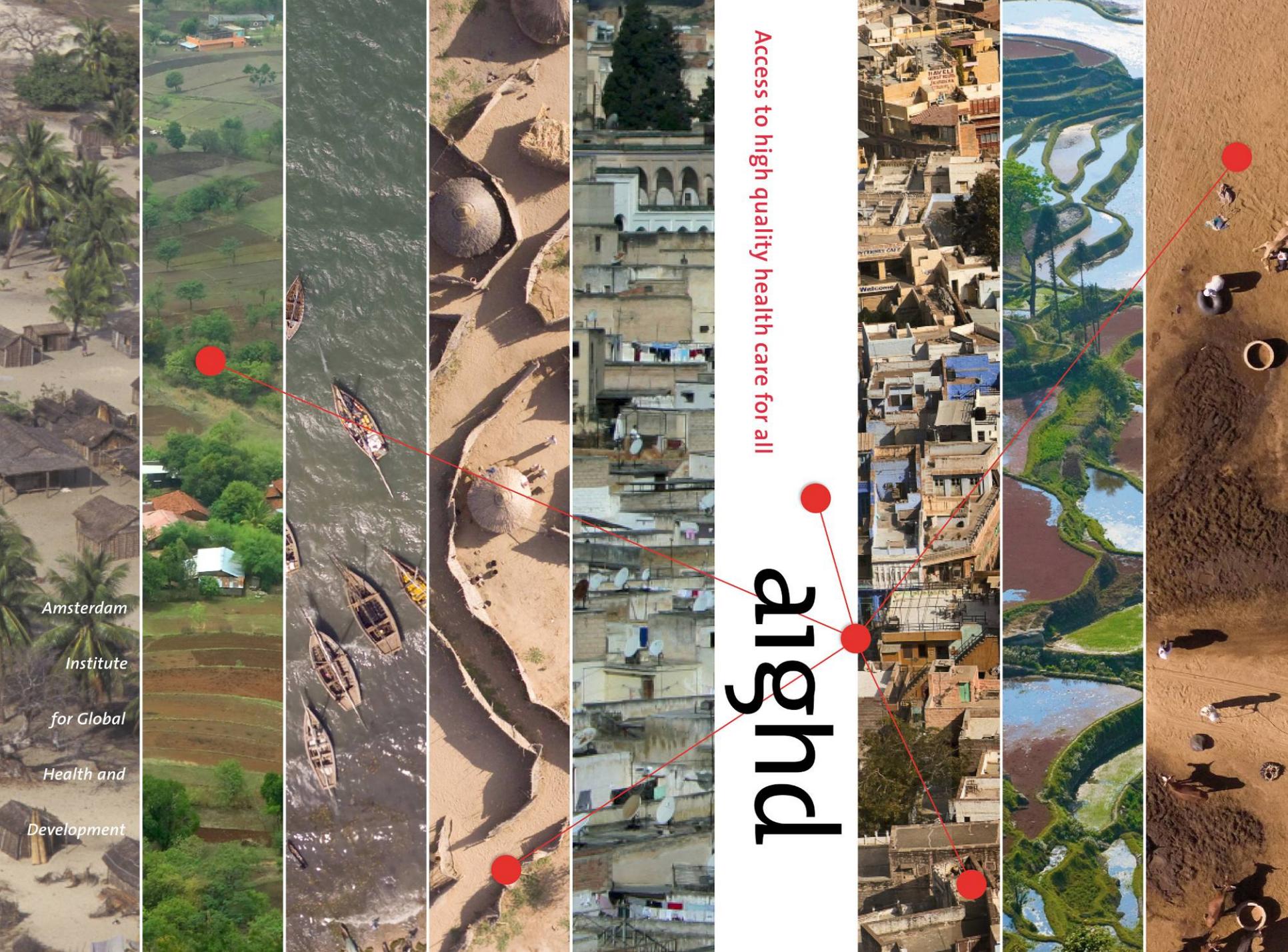


Nothing will ever be attempted if all possible objections must first be overcome.

Samuel Johnson  
1709-1784

## Thanks for ideas, photos, and slides to:

- Ken Mayer
- Stefan Baral
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- Andrew Hill
- Anton Pozniak



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Development



**“Be creative and think big to tackle the real problems”**

Joep Lange  
September 25, 1954 - July 17, 2014