



Biomedical Prevention interventions for Women

What do we know?- where do we go?

Linda-Gail Bekker

The Desmond Tutu HIV Centre, UCT, Cape Town, RSA.

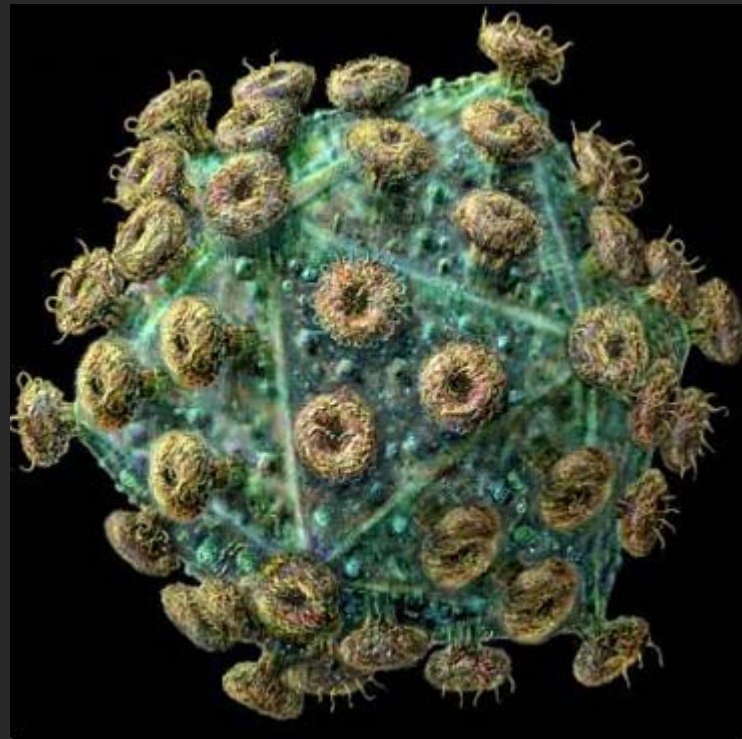
March 2017



**78 million people infected,
39 million people dead**



37 million living with HIV today



2 million people became infected in 2014

An urgent and ongoing crisis:

2 500 infections every day : 1 new infection every 30 seconds



**AVOIDING
AIDS
AS EASY AS...**

A BSTAIN
B E FAITHFUL
C ONDOMISE

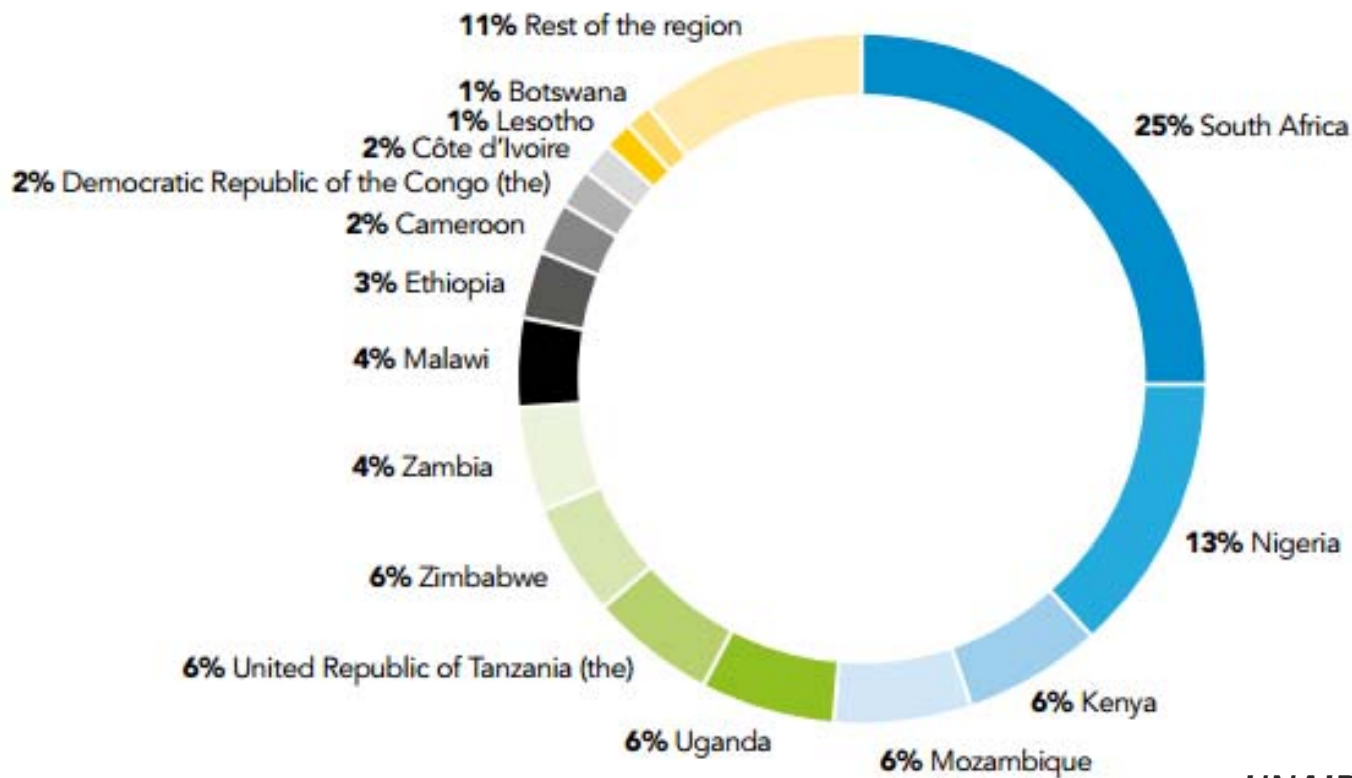


HIV in retreat....

- 15.8 million on ART June 2015
- New HIV infections ↓ by 35% since 2000
- New infections among children ↓ by 50% since 2000
- AIDS related deaths ↓ by 42% since 2004
- TB related deaths ↓ by 32% since 2004

HIV in SSA: the Epidemic Goes On

People living with HIV in sub-Saharan Africa, 2013



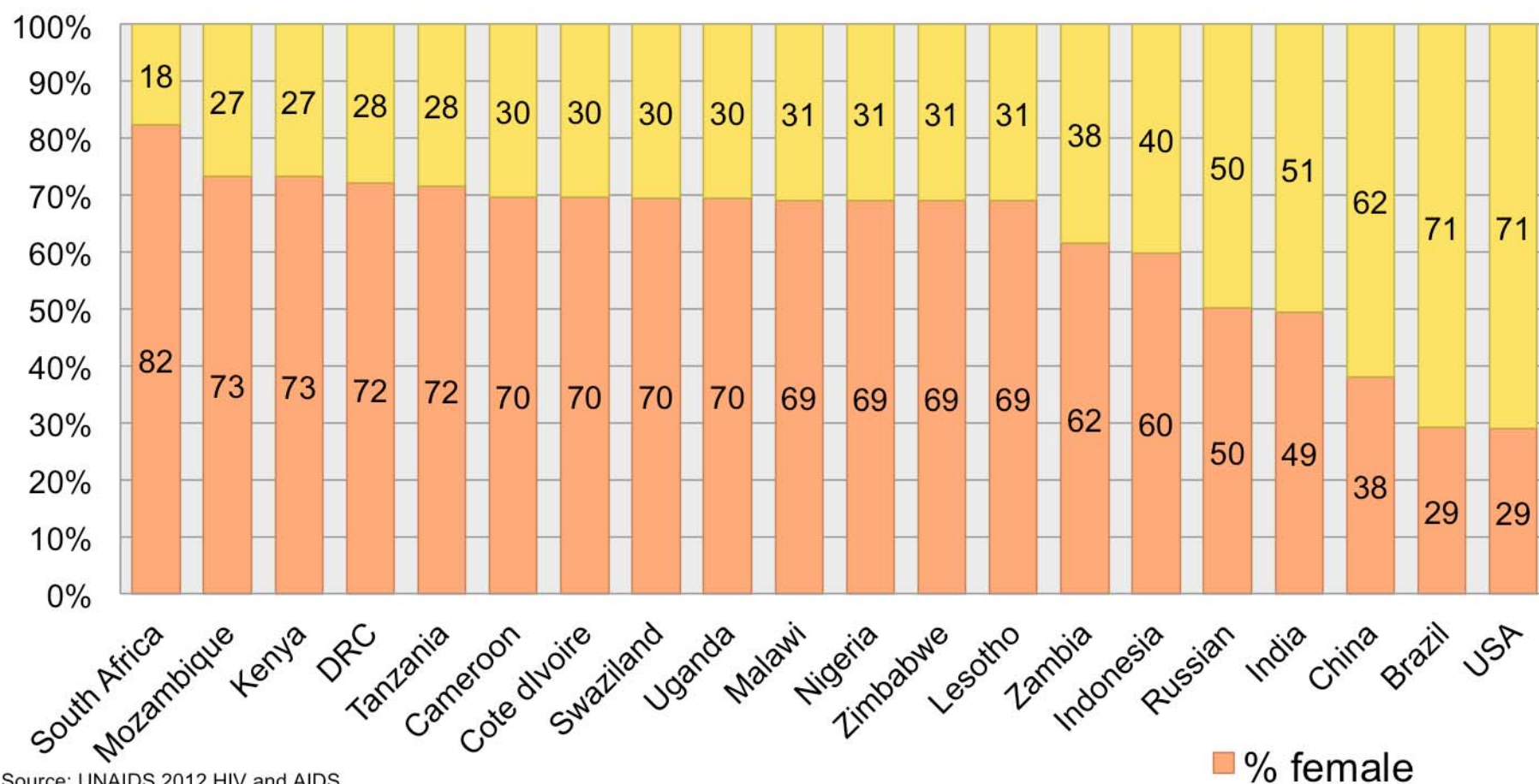
Source: UNAIDS 2013 estimates

UNAIDS Gap Report, 2014

HIV in SSA AMP Countries

Country	People living with HIV/AIDS	Adult (15-49 yr) Prevalence	Women with HIV/AIDS	Children with HIV/AIDS	AIDS Deaths
Botswana	300 000	23.4	160 000	15 000	4 200
Kenya	1, 600 000	6.2	800 000	220 000	62 000
Malawi	910 000	10.0	430 000	170 000	44 000
Mozambique	1, 400 000	11.3	750 000	200 000	74 000
SA	5, 600 000	17.3	2, 900 000	460 000	270 000
Tanzania	1, 800 000	5.6	760 000	230 000	84 000
Zimbabwe	1,200 000	14.9	600 000	200 000	58 000

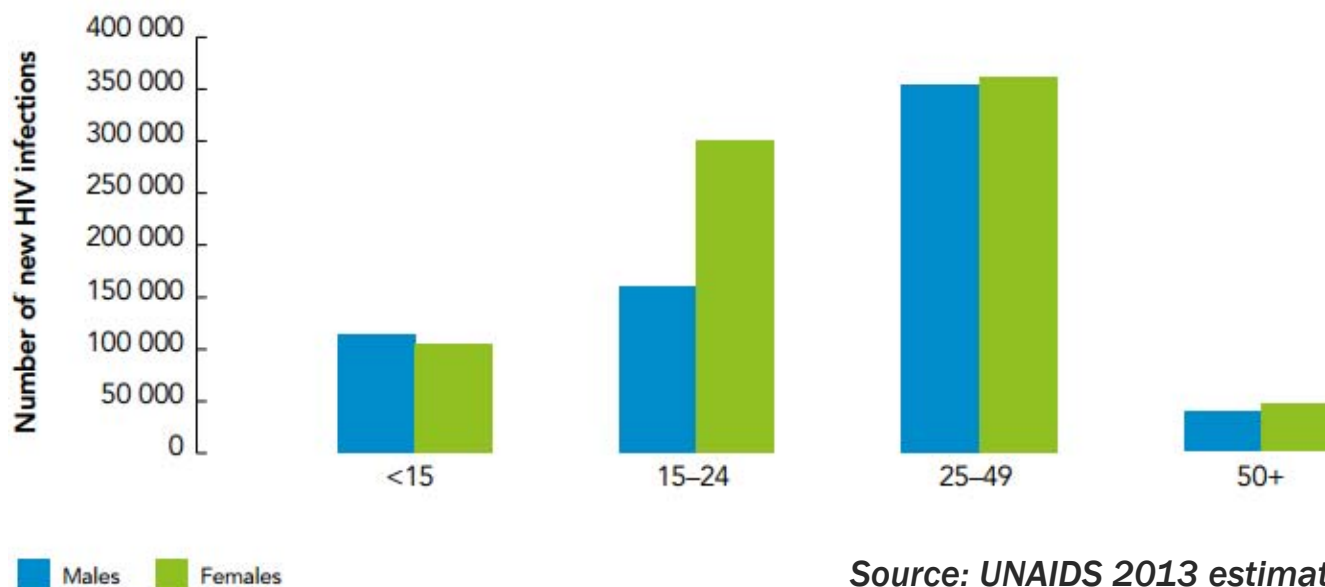
New HIV Infections in Adolescents (15-19) in 20 Countries with Highest Number of New HIV Infections, 2012



Source: UNAIDS 2012 HIV and AIDS estimates

HIV in SSA: the Epidemic Among Women

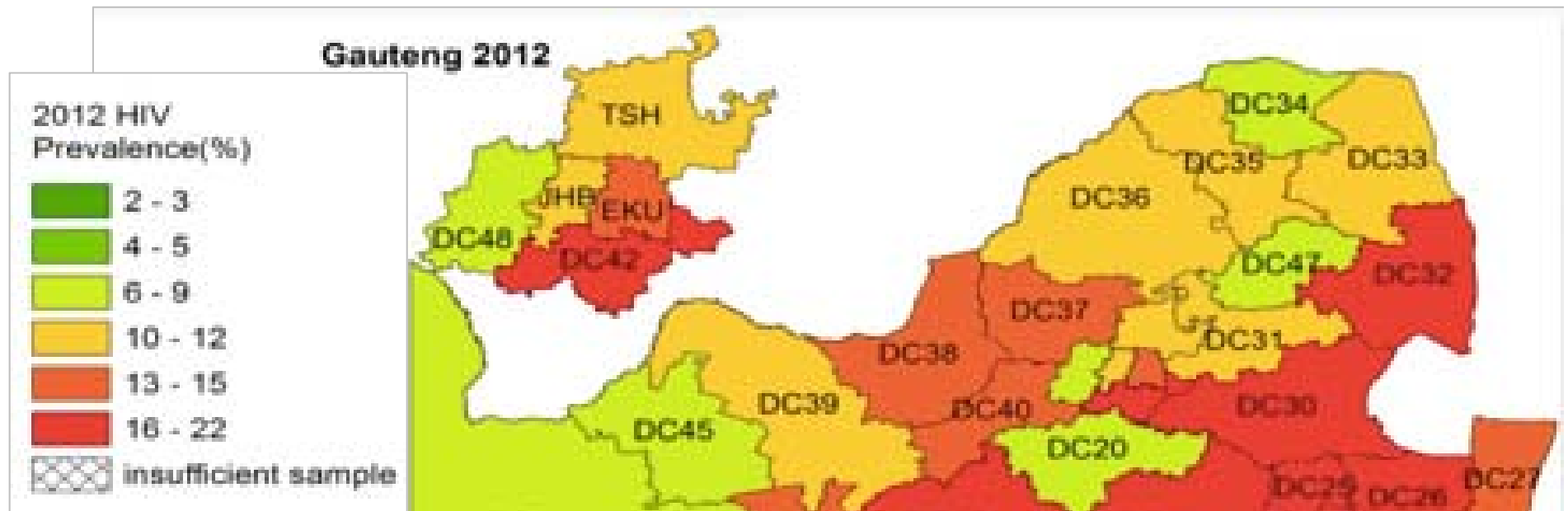
New HIV infections in sub-Saharan Africa, by age and sex, 2013



Source: UNAIDS 2013 estimates

- In 2013, of the 24.7 million people HIV infected in SSA >50% were women
- Young women are twice as likely to be infected as young men
- Women have fewer HIV prevention options than men

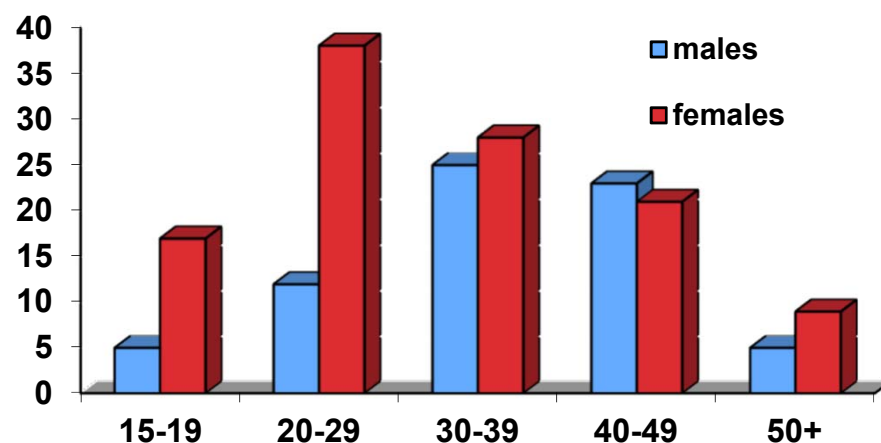
UNAIDS Gap Report, 2014



- 6.4 million live with HIV (12.2%)
- Women 30-34 years –prevalence 36%
- Men 35-39 years –prevalence 29%
- >3 million South Africans on ART
- 400 000 new HIV infections in 2012



Young women and girls.



Women: 15-24 years 4 x higher than male peers

Girls: 10-19 years 8 x higher than male peers

Highest incidence : 20-34 years females

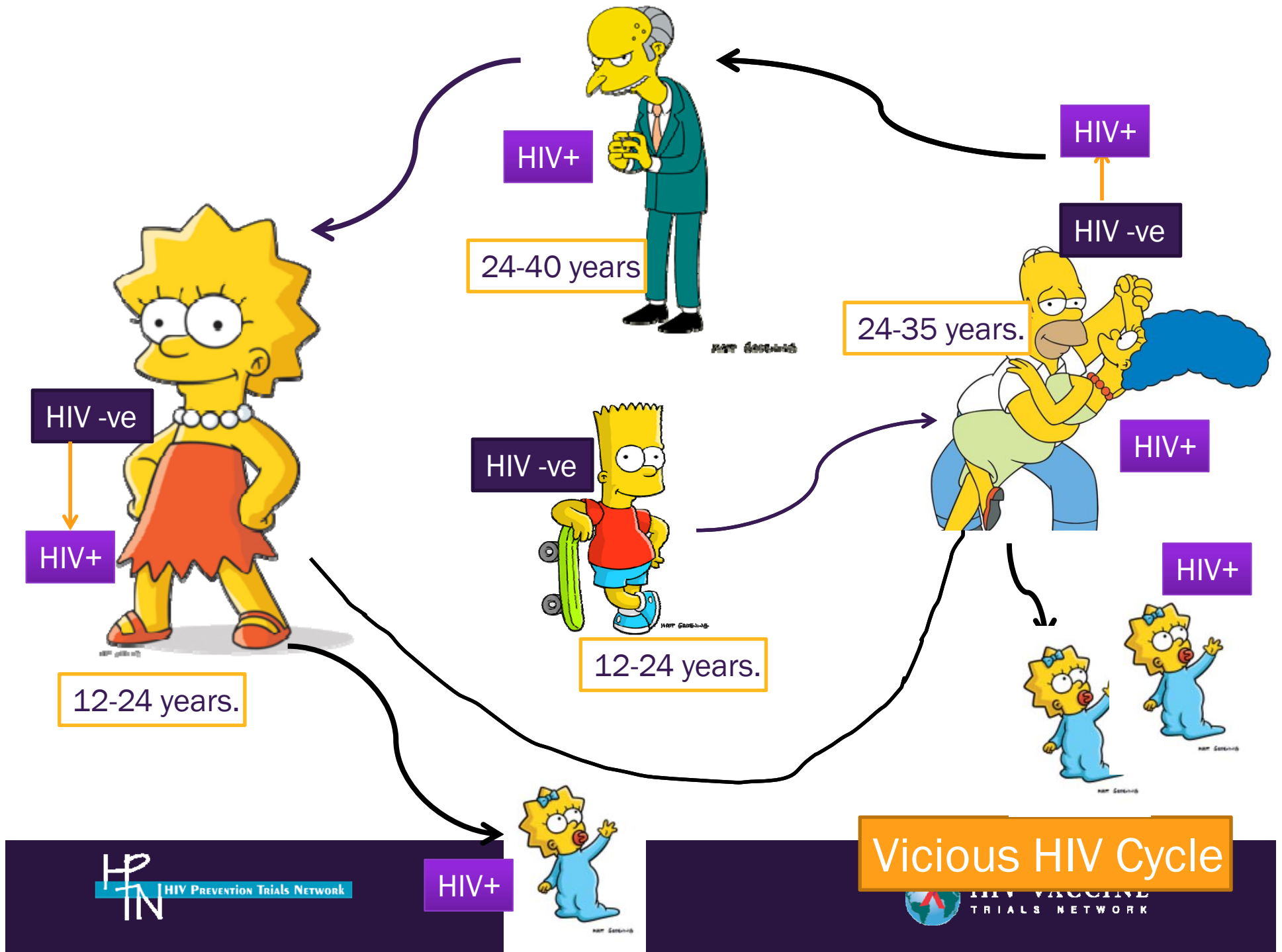
Lower incidence in those married compared with co-habiting or single.

Young and vulnerable

Age Group (Years)	KZN HIV Prevalence ANC (N=1029)	CT HIV Prevalence General Female (N=600)
≤16	8.4%	12%
17-18	18.6%	17%
19-20	25.4%	30%

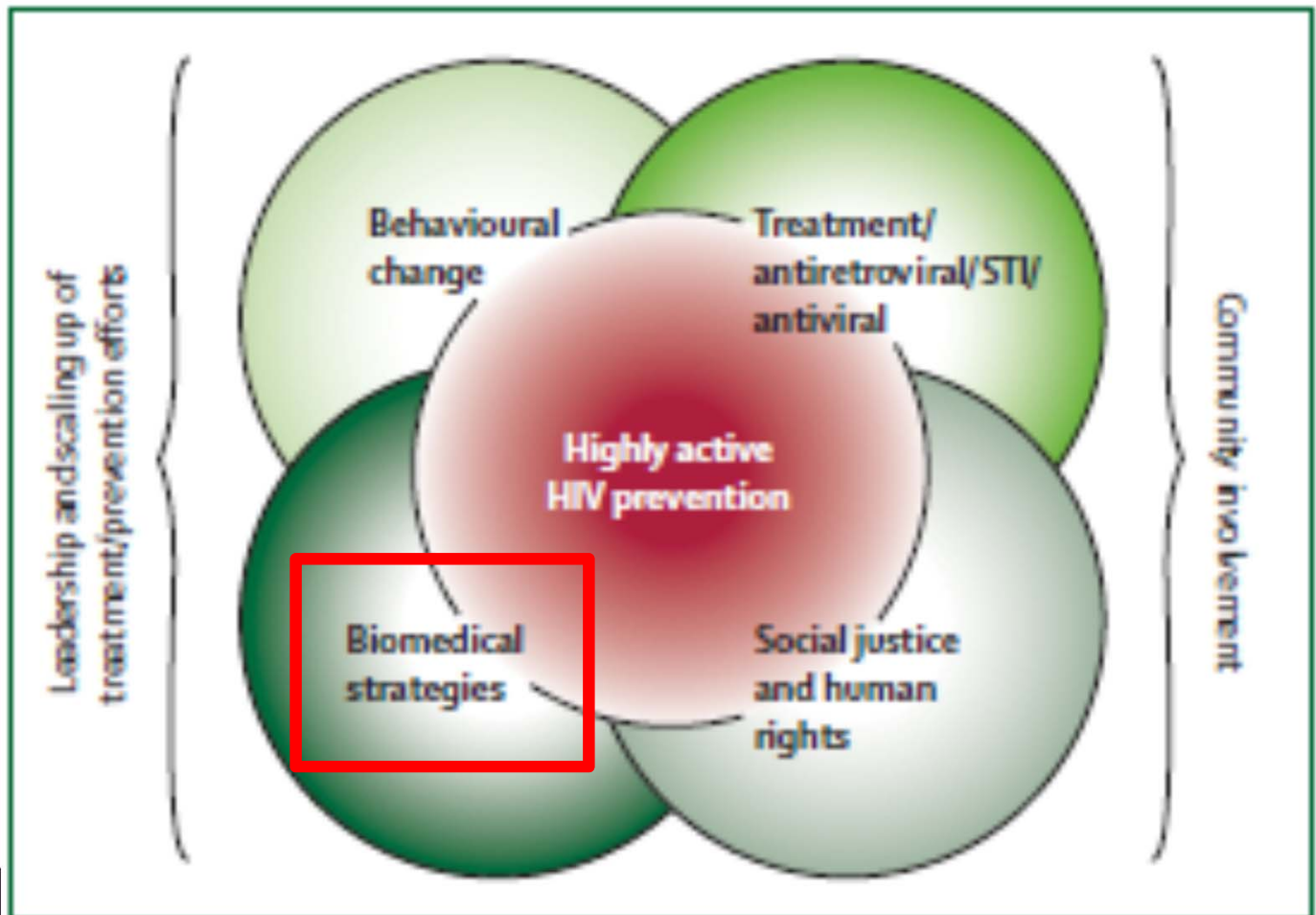


Incidence KZN (16-35 yo) : 9% and Cape Town (16-20) yo : 8%



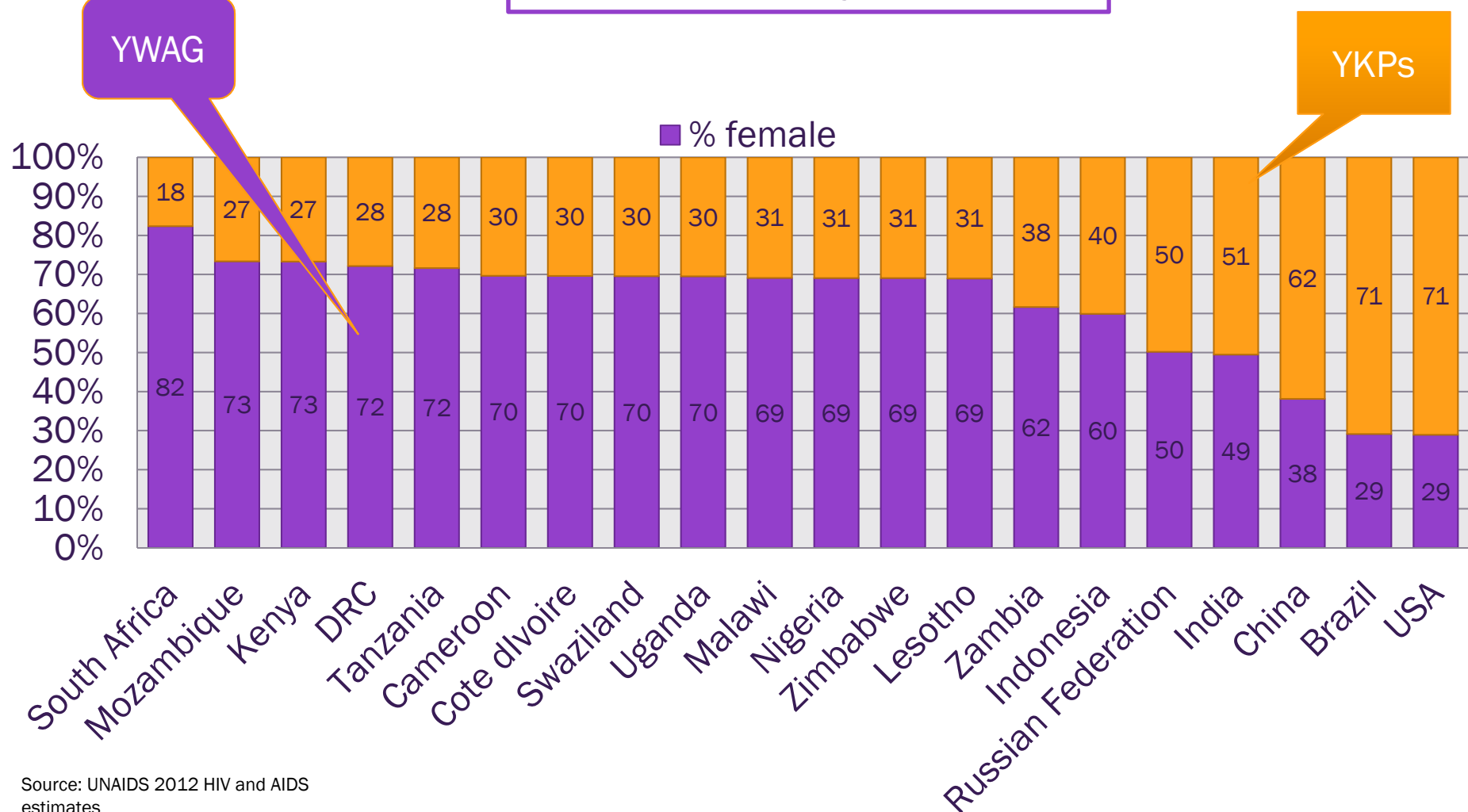
Highly active HIV prevention.

A term coined by Prof K Holmes, University of Washington School of Medicine, Seattle, WA, USA.⁵



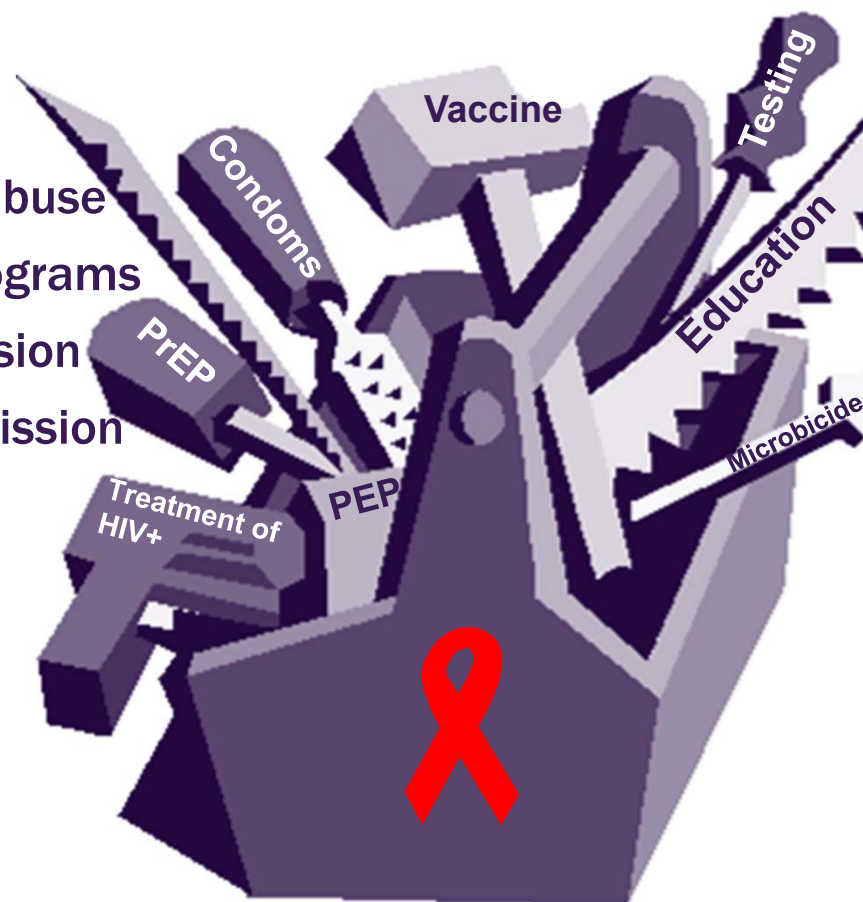
We need a biomedical Revolution!!

Why?



What Do We Have to Address the Epidemic?

- Education and behavior modification
- Condoms, and other barrier methods
- Treatment/prevention of drug/alcohol abuse
- Clean syringes, i.e. needle exchange programs
- Interruption of mother-to-child transmission
- Circumcision for female-to-male transmission
- HIV/STI Testing
- Antiretroviral treatment as prevention
- Post-exposure prophylaxis (PEP)
- Pre-exposure prophylaxis (PrEP)*
- Topical microbicides[†]
- Vaccination[‡]

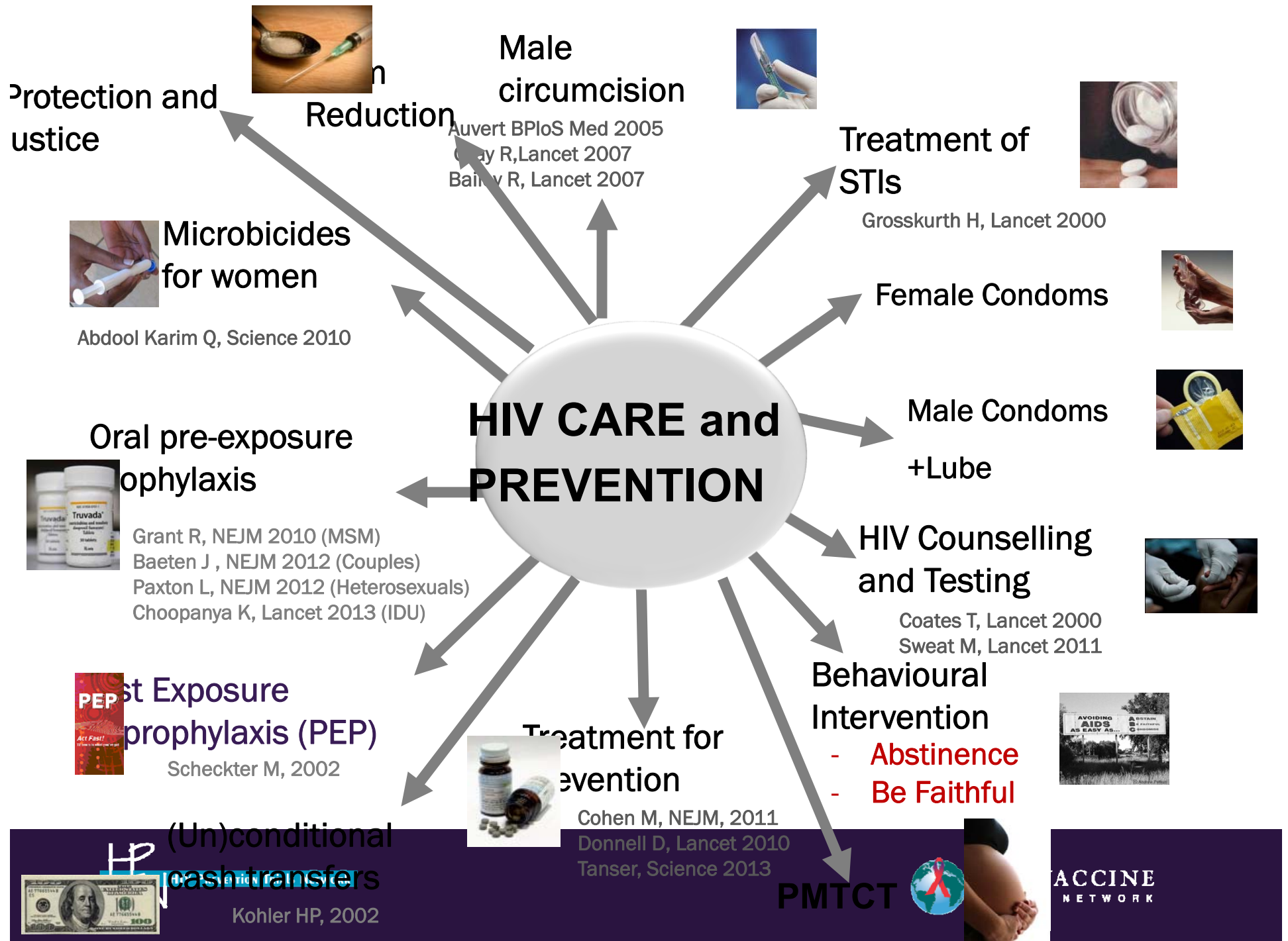


*Daily Truvada®; alternate regimens still in research

[†]Still in research

With thanks to Carl Dieffenbach & Jeff Schouten

HIV CARE and PREVENTION



New technologies

- Depot PrEP (vaginal rings)
- Long Acting Injectable PrEP
- On Demand PrEP- pills, films
- Passive/Active immunisation
- Multifunctional products, eg contraception



New biomedical in the pipeline

modality	Women	MSM	PWID	FSW	Adols
LA PrEP	+	+	+	+	++?
Vaginal rings	+			+	++?
Rectal MB		+			+?
Vaccines	+	+	+	+	+
Passive IM	+	+	?	?	?
New oral agents (Maraviroc)		+			?



Evidence for biomedical in women

Tenofovir-based prevention results, as of June 2013

Product (Study, Results published)	Effect size (95% CI)
------------------------------------	----------------------

Immediate ART for HIV+ partner
(HPTN 052, 2011)

96% (82, 99)

TDF/FTC oral PrEP
(Partners PrEP, 2011)

75% (55, 87)

TDF oral PrEP
(Partners PrEP, 2011)

67% (44, 81)

TDF/FTC oral PrEP
(TDF2, CDC, 2011)

62% (22, 83)

1% tenofovir gel
(CAPRISA 004, 2010)

39% (6, 60)

1% tenofovir gel
(MTN003/VOICE, 2011)

15% (-21, 40)

TDF/FTC oral PrEP
(FEM-PrEP, 2011)

6% (-52, 41)

TDF/FTC oral PrEP
(MTN003/VOICE, 2011)

-4% (-49, 27)

TDF oral PrEP
(MTN003/VOICE, 2011)

-49% (-129, 3)



Methadone

**Male
circumcision**

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



**Treatment of
STIs**

Grosskurth H, Lancet 2000



Female Condoms



**Male Condoms
+Lube**



HIV Testing

Coates T, Lancet 2000
Sweat M, Lancet 2011



**HIV
PREVENTION**

**Treatment for
prevention**

Cohen M, NEJM, 2011
Donnell D, Lancet 2010
Tanser, Science 2013



**Post Exposure
prophylaxis (PEP)**

Scheckter M, 2002



**Oral pre-exposure
prophylaxis**

Grant R, NEJM 2010 (MSM)
Baeten J, NEJM 2012 (Couples)
Paxton L, NEJM 2012 (Heterosexuals)
Choopanya K, Lancet 2013 (IDU)



**Microbicides
for women**












Abdool Karim Q, Science 2010



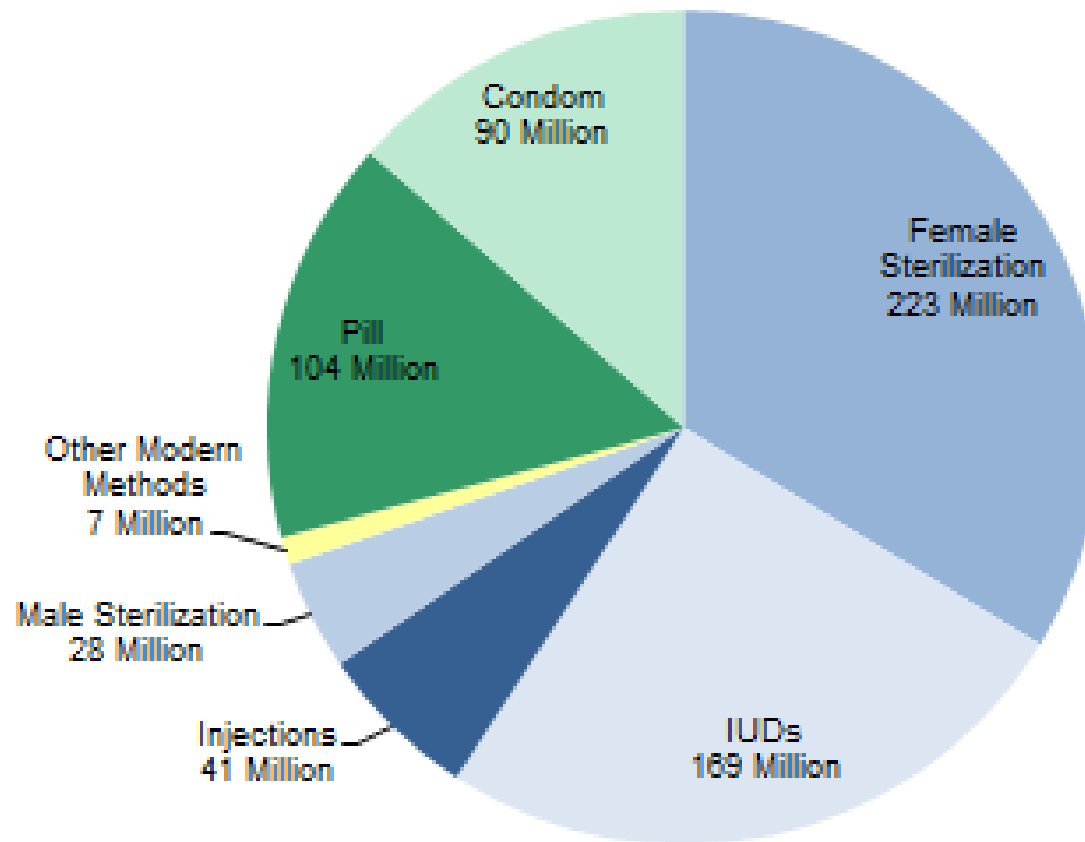
HIV Prevention in SSA Women: The Gap

- **HIV-1 prevention interventions demonstrated to be effective in reducing HIV-1 risk are inadequate**
 - **Condom use, HIV/STI testing** - Require participation/consent of male partner
 - **PrEP** - Achieving high adherence, especially among young SSA women, has been a central challenge (VOICE, Fem-PrEP)
 - **Microbicides** - Data suggest young SSA women wanted a product they could use to reduce their risk, but that microbicides did not fit into the realities of their daily lives (VOICE, FACTS 001)
- **Inadequate prevention options for women unable to negotiate safe sex practices**
- **Developing HIV-1 prevention options that SSA women can use remains a global concern**

Consider an Analogy

PREGNANCY PREVENTION	HIV PREVENTION
Education & behavior modification	Education & behavior modification
Condoms 	Condoms 
Birth control pill 	PrEP 
“Morning-after pill” 	PEP 
Spermicide 	Topical microbicides 
Implantable birth control 	Antibody-mediated Prevention (bnAbs) 
Vasectomy/Tubal Ligation	Vaccination 

World Modern Contraceptive Prevalence by Method, Latest Year



Couples Using Any Modern Method: 661 Million

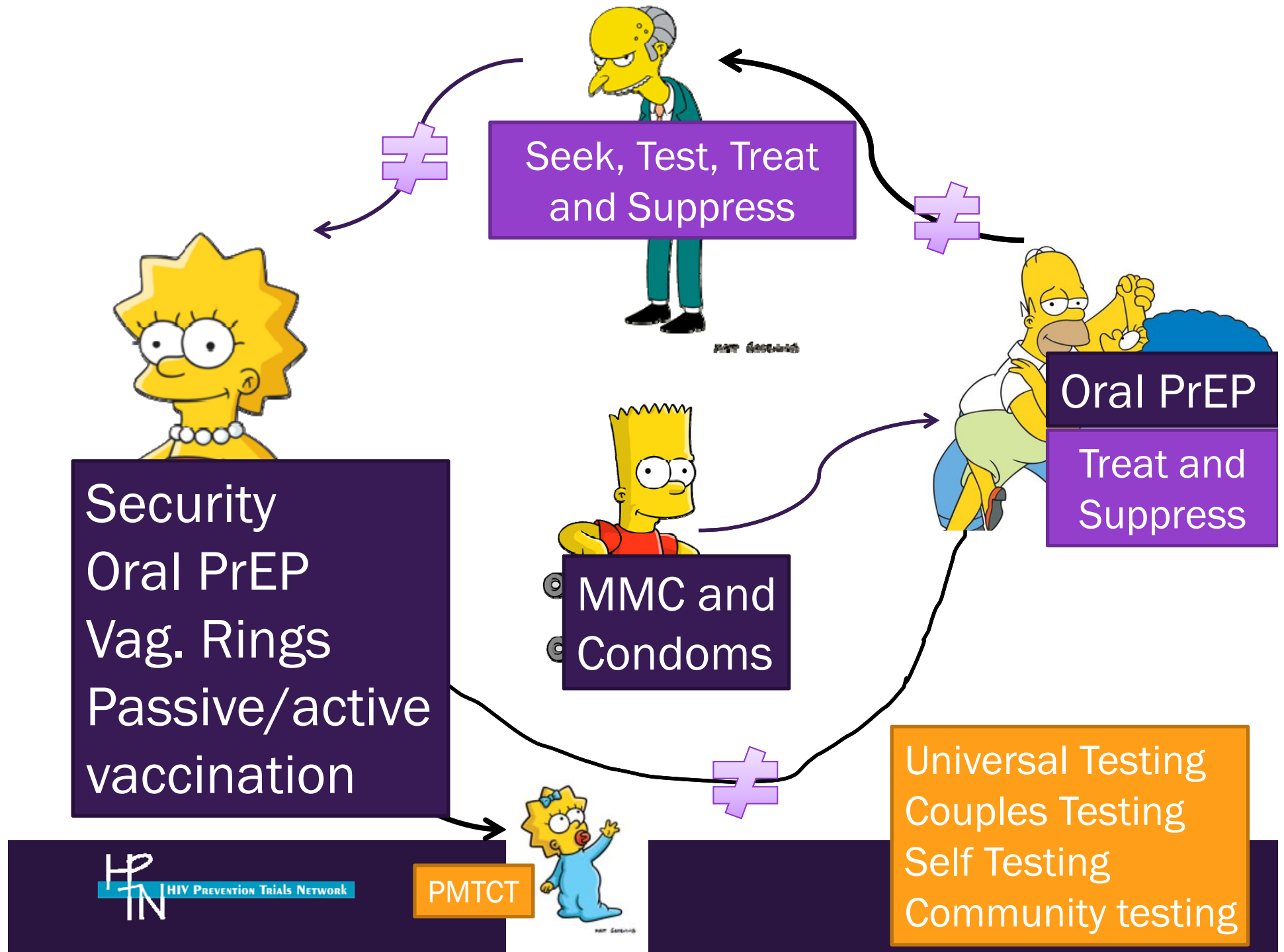
Earth Policy Institute - www.earth-policy.org

Source: EPI from UNPop

Systematic review of contraceptive medicines “Does choice make a difference?”

October 2006

“It supports the contention that increased choice is associated with increased uptake and with better health outcomes (such as lower pregnancy rates and fewer STIs), and that women, given a choice, exercise it and continue use of their chosen contraceptives to a greater degree than those denied their choices.”



The HVTN 703/HPTN 081 AMP Study: Filling the Gap

AMP = Antibody Mediated Prevention

This is the idea of using an **antibody** made by scientists and giving it to people directly, i.e. using an intravenous (IV) **infusion**, to **prevent** HIV infections.

Combination prevention: Hep B

- Universal precautions
- Safer sex
- Vaccinate with Hep B vaccine (active)
- Passive immunization with anti Hep B immunoglobulins



Rabies

- Avoid stray dogs
- Immunize pets
- Wash wound
- Active immunization
- Passive immunization with anti rabies immunoglobulin



TAILORED, Client-Centred Prevention Packages



HIV VACCINE
TRIALS NETWORK

The Prevention Revolution



“Scientists have developed an array of effective tools which if implemented could reverse the AIDS epidemic”

- Professor Francoise Barré Sinoussi.



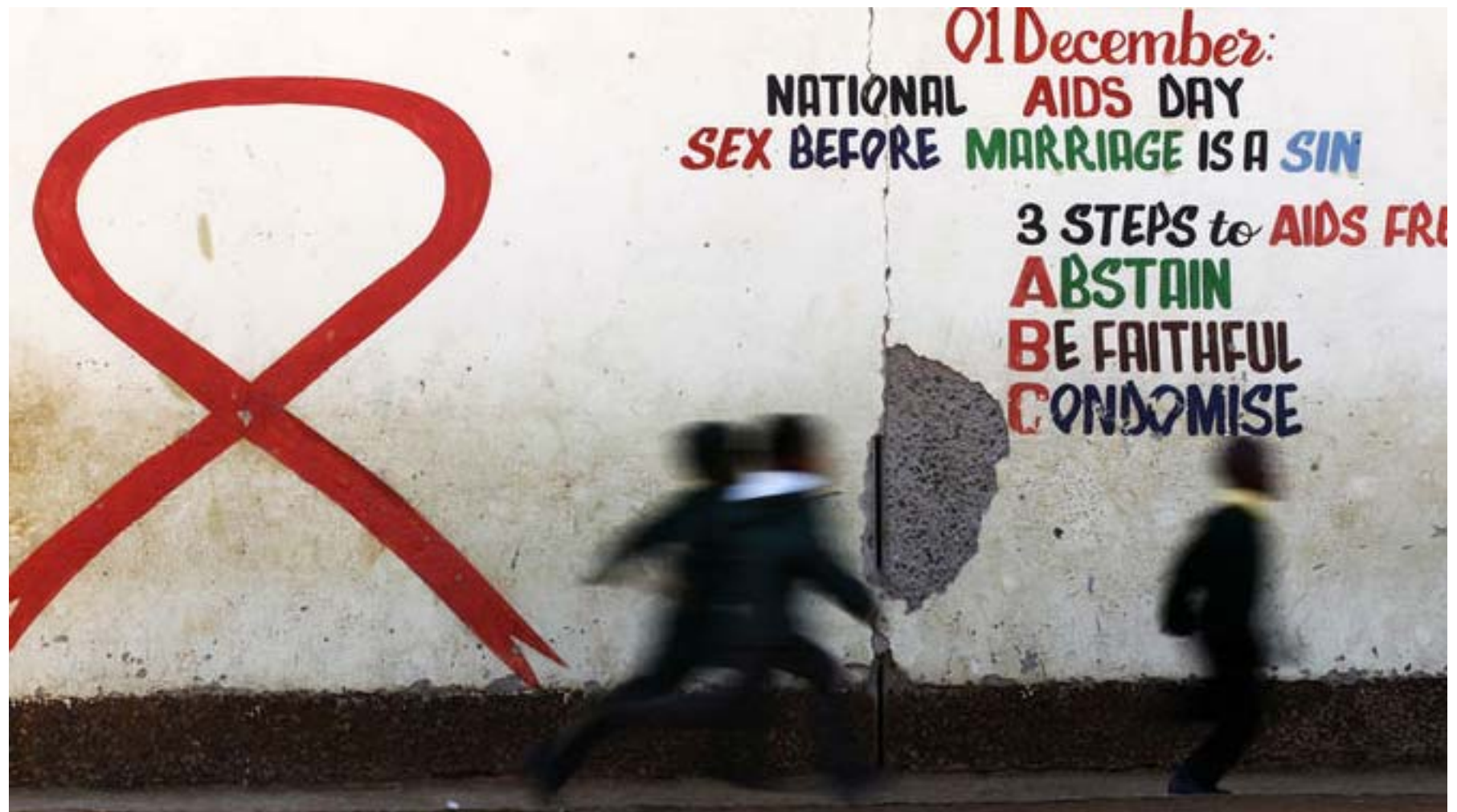
The Prevention Revolution



“Prevention activism is indispensable to overcome the epidemic”

- Archbishop Tutu.





The Citizen

#HIV

MUST
FALL

McDonald's

McCafe



HIV PREVENTION TRIAL

HIV VACCINE
TRIALS NETWORK

HVTN 703/HPTN 081 Protocol Team

- Chairs: Larry Corey & Mike Cohen
- co-Chairs: Sri Edupuganti & Nyaradzo Mgodini
- Protocol Team Leader & Core Medical Monitor: Shelly Karuna
- DAIDS Medical Officers: Marga Gomez & David Burns
- Statisticians: Allan DeCamp, Deborah Donnell, Peter Gilbert, Michal Juraska, Nidhi Kochar
- Laboratory Representatives: John Hural, Sue Eshleman, On Ho, David Montefiori, Vanessa Cummings, Estelle Piwowar-Manning
- VRC Representatives: Julie Ledgerwood, Barney Graham, John Mascola
- Investigator Representatives: Ken Mayer, LaRon Nelson, Manuel Villaran, Sinead Delany-Moretlwe
- Social & Behavioral Scientist: Michele Andrasik
- DAIDS Protocol Pharmacist: Scharla Estep
- Regional Medical Liaison: Simba Takuva
- Clinical Safety Specialist: Maija Anderson
- Protocol Development Manager: Carter Bentley
- FHI360/HPTN LOC Director: Niru Sista
- Senior Research Clinician: Phil Andrew
- Clinical Research Manager: Liz Greene
- Clinical Trials Manager: Carissa Karg
- SDMC Representatives: Lynda Emel, Gina Escamilla, Evangelyn Nkwopara
- Regulatory Affairs Representative: Meg Brandon
- Communications Representatives: Jim Maynard & Eric Miller
- Community Engagement Representatives: Gail Broder, Jonathan Lucas, Jontraye Davis
- Clinic Coordinators: Deb Dunbar, Lilian Saavedra, Elaine Sebastian
- CAB Representatives: Likhapha Faku, Mark Hubbard, Jim Wick
- Community Educators/Recruiters: DaShawn Usher & Luciana Kamel
- Technical Editor: Erik Schwab

