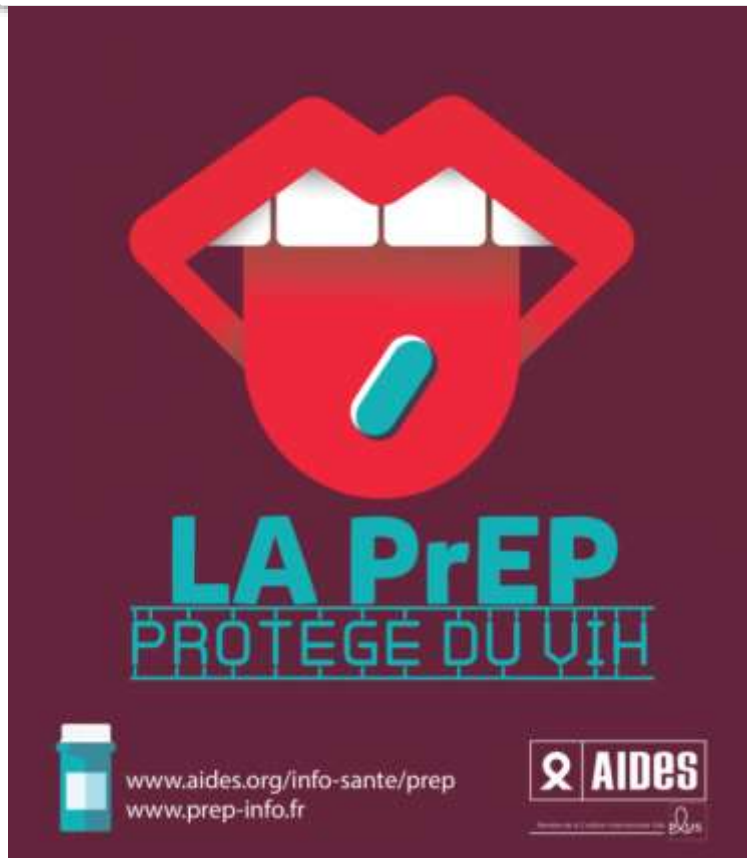


# WHO PrEP Guidance

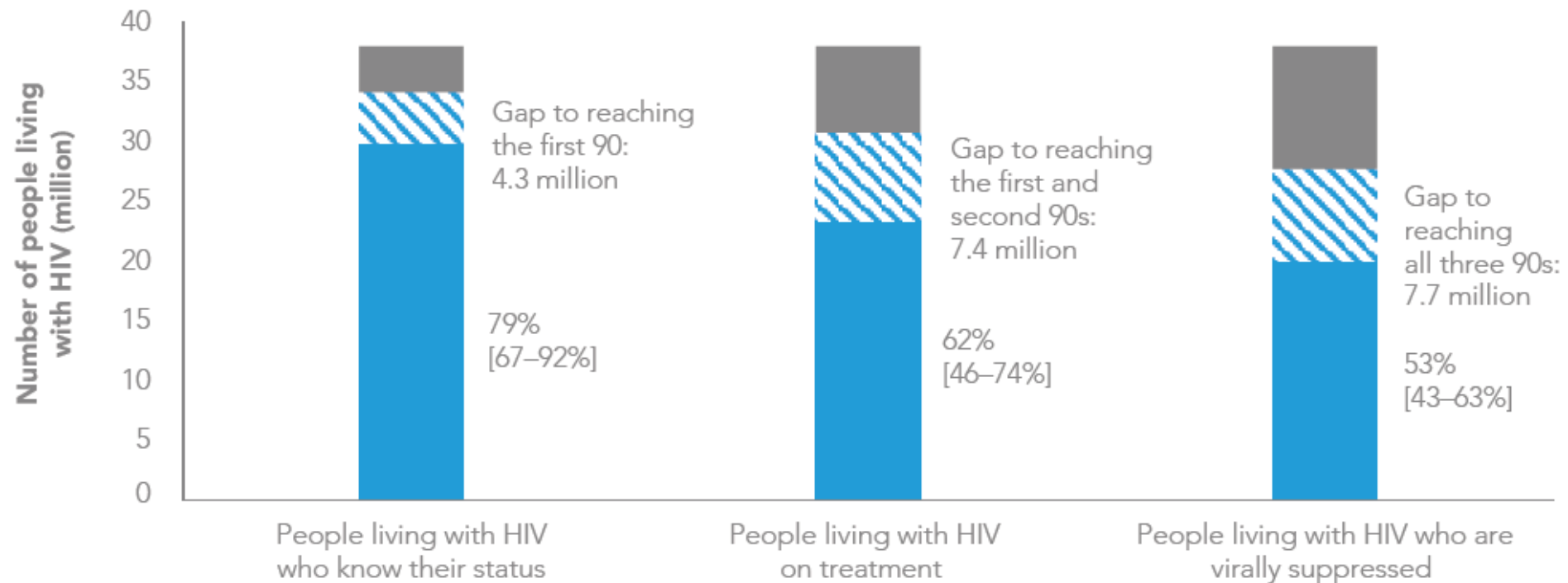


# Outline

- Public health perspective: HIV prevention matters (and PrEP is a new tool with untapped promise)
- WHO HIV strategy and WHO guidance on PrEP
- Messaging of PrEP
- Future of PrEP (research and scale-up)

From a public health perspective,  
what is the issue?

# HIV Testing, Treatment & Viral Suppression

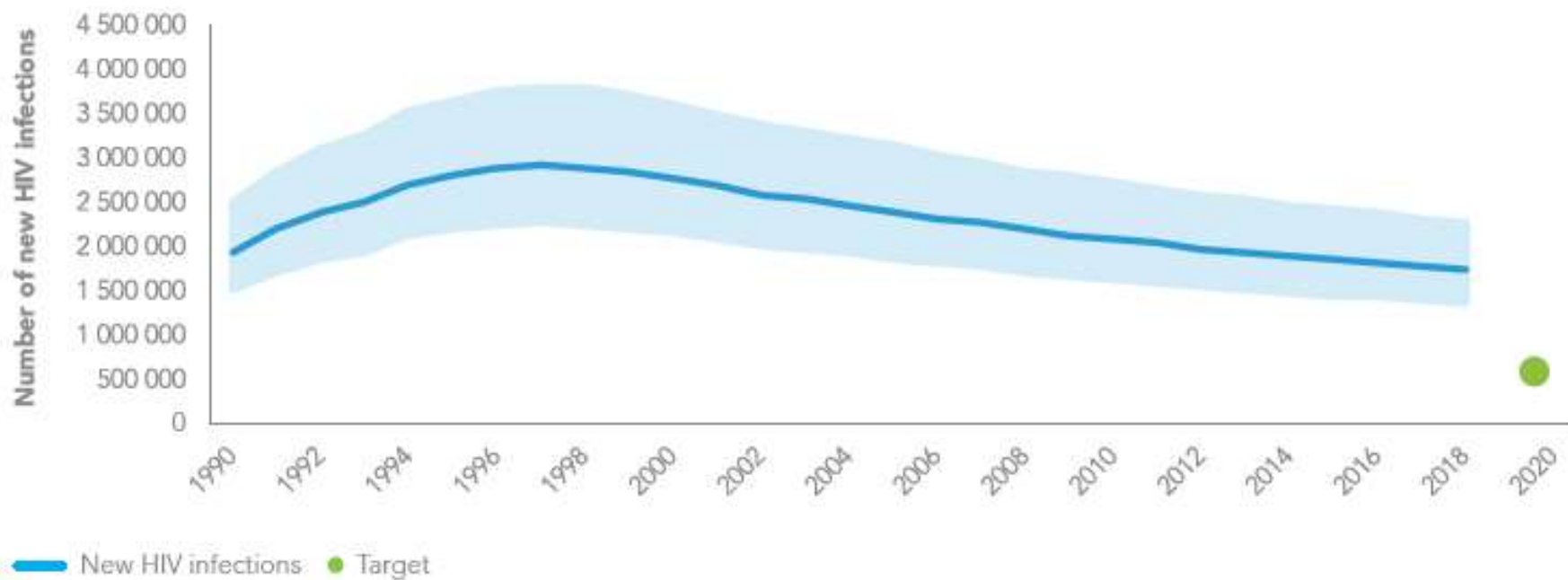


Source: UNAIDS special analysis, 2019; see annex on methods for more details.

## Global HIV transmission **PERSISTS**:

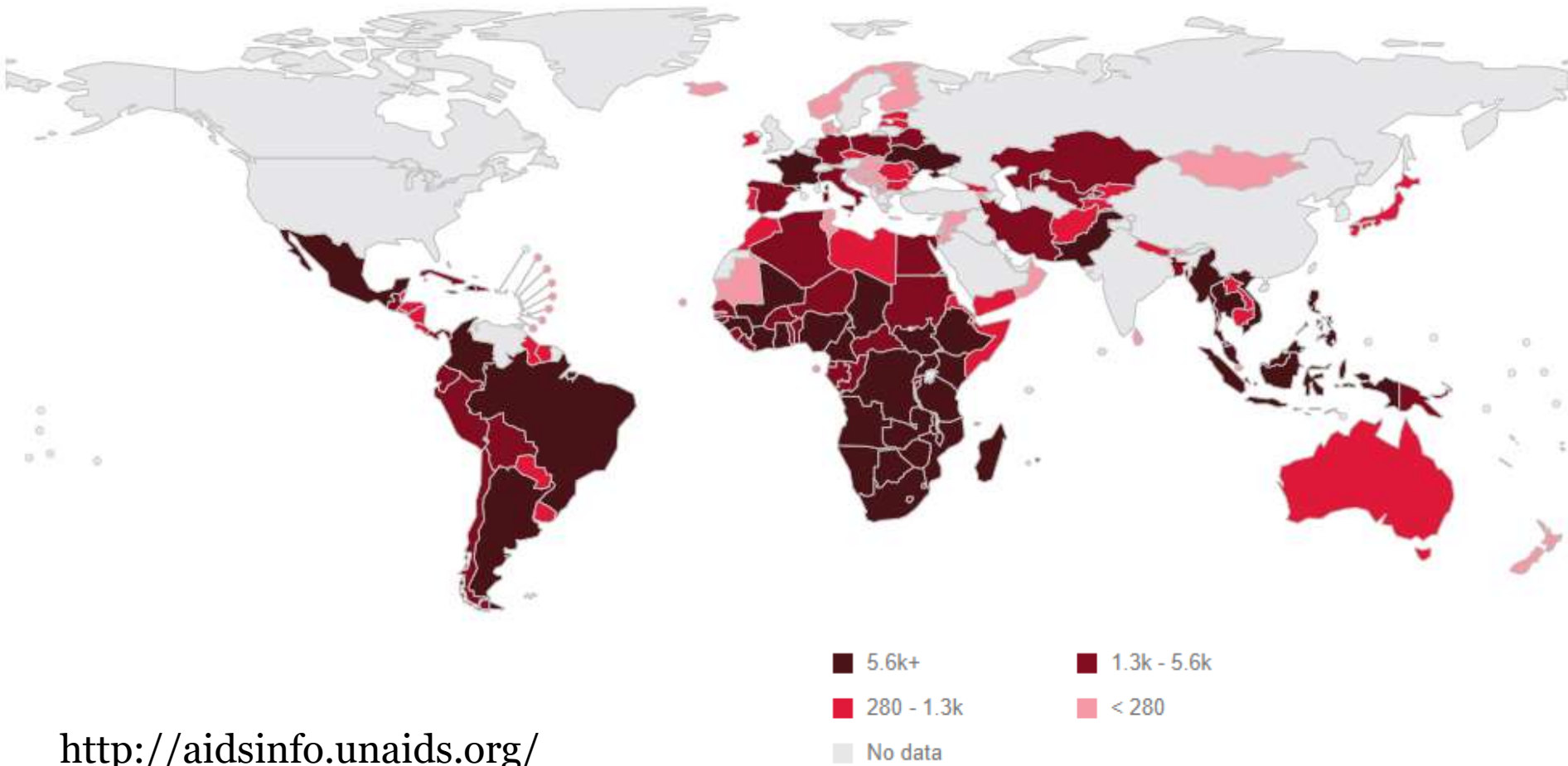
Treatment scale-up has ‘masked stagnation in the estimated annual number of new HIV infections’ (Baggaley et al, *JIAS*)

**FIGURE 2.4** Number of new HIV infections, global, 1990–2018 and 2020 target



Source: UNAIDS 2019 estimates.

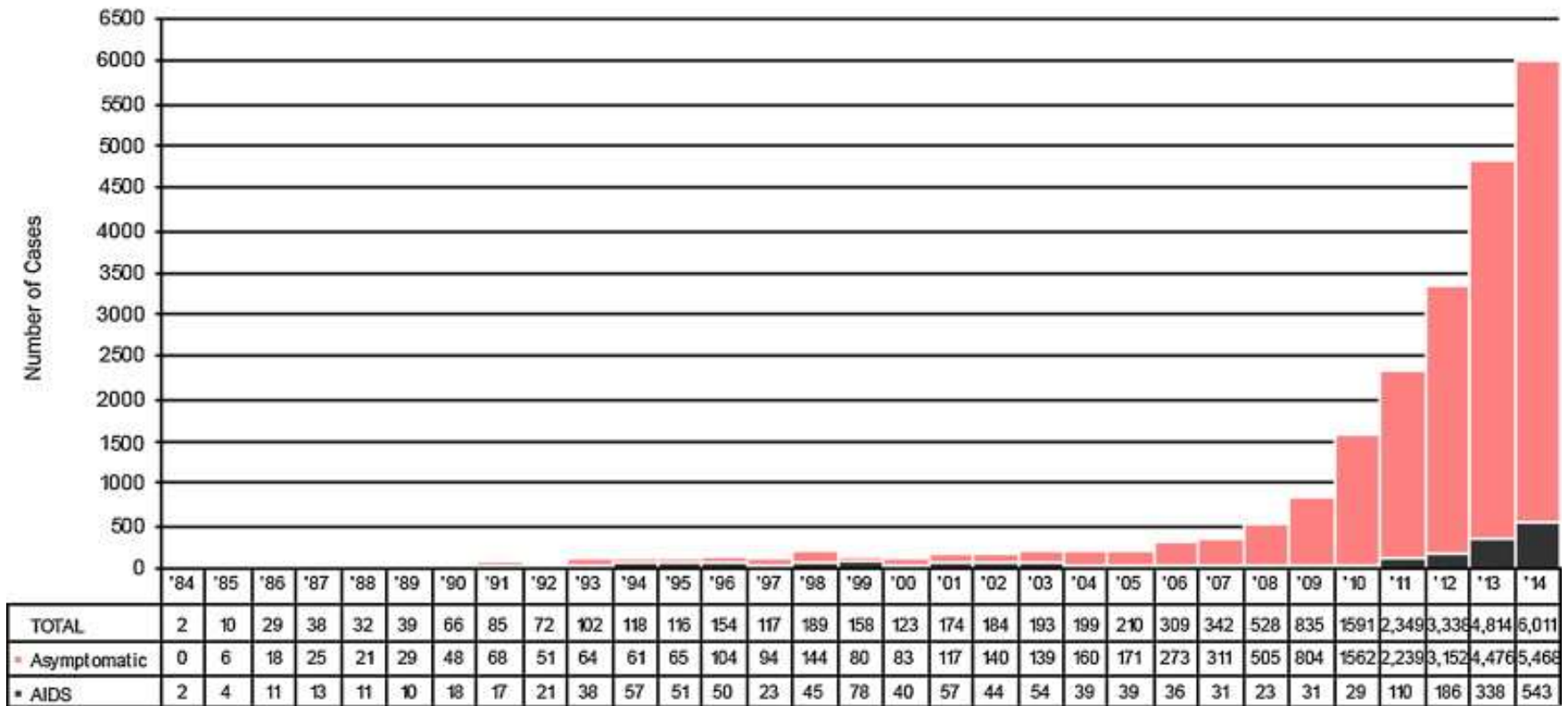
# New HIV infections Global, 2018



<http://aidsinfo.unaids.org/>

# What happens when you don't have services for certain populations: E.g. MSM HIV epidemic in the Philippines

Number of HIV/AIDS Cases Reported in the Philippines by Year, January 1984 to December 2014 (N=22,527)



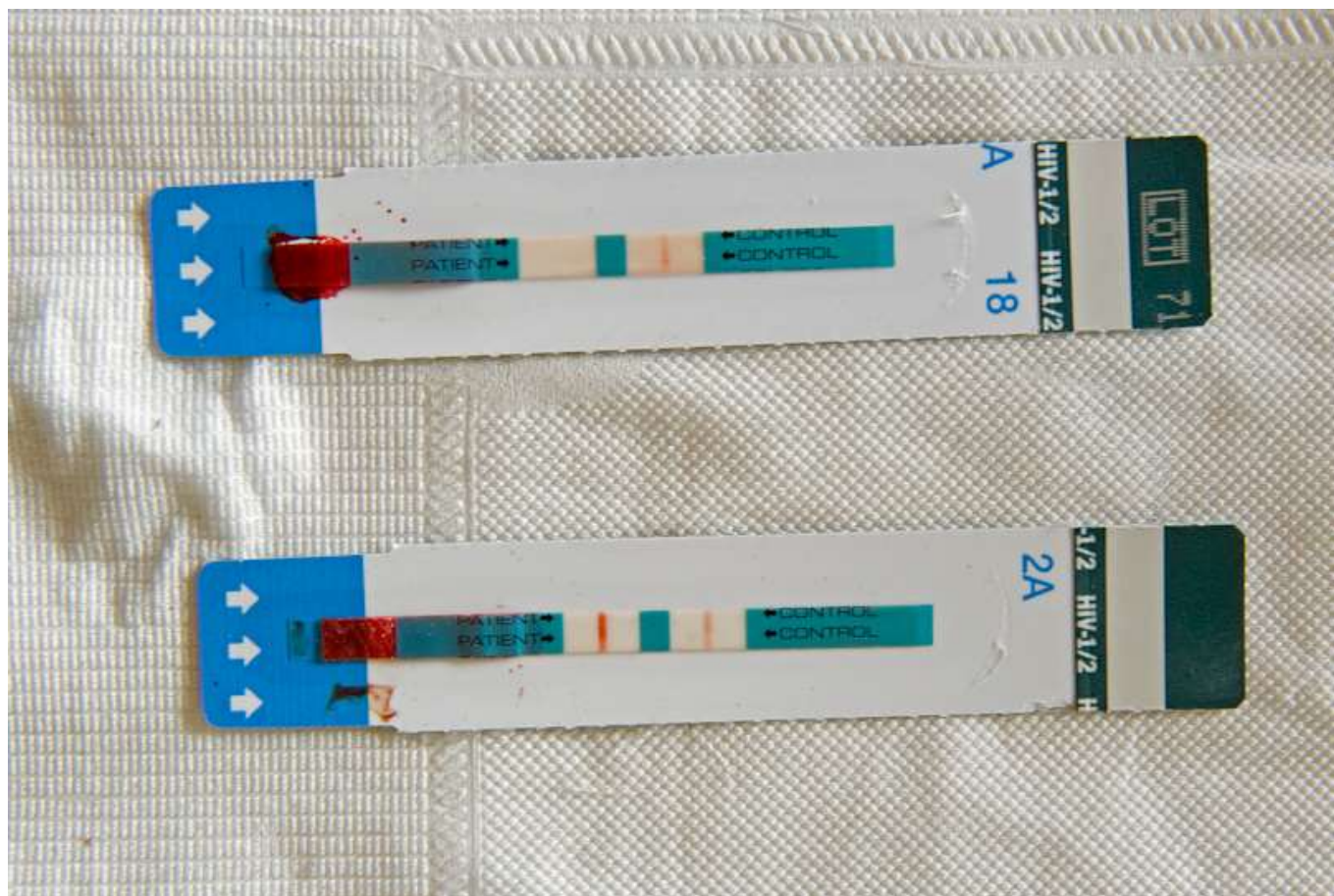
# So to summarize, thus far:

- Globally, we are not seeing a decrease in new HIV infections in adults
- We are doing a good job in scaling up treatment
- HIV prevention + treatment go together
- More to do at global, regional, national and local levels: fast-track approach
- Interventions to prevent HIV that are evidence-based should be offered to those that can benefit as part of fast-tracking to 2020 (and 2030)



We have the tools to prevent HIV  
(except a vaccine)

HIV testing technology has improved  
(e.g. rapid tests, self-testing )



WHO HIV testing guidelines (2015):

<http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/>

# Condoms + lubricants



WHO-UNAIDS-UNFPA statement on condoms:

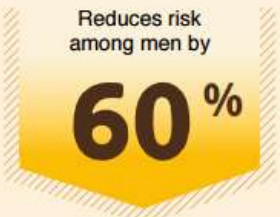
[http://www.unaids.org/en/resources/presscentre/featurestories/2015/july/20150702\\_condoms\\_prevention](http://www.unaids.org/en/resources/presscentre/featurestories/2015/july/20150702_condoms_prevention)



# VMCC (circumcision prevents HIV)

## 10 million men stepped up for HIV prevention through voluntary medical male circumcision services

Voluntary medical male circumcision reduces the risk of female-to-male HIV transmission



### New HIV infections

**5,500**  
EVERY DAY GLOBALLY

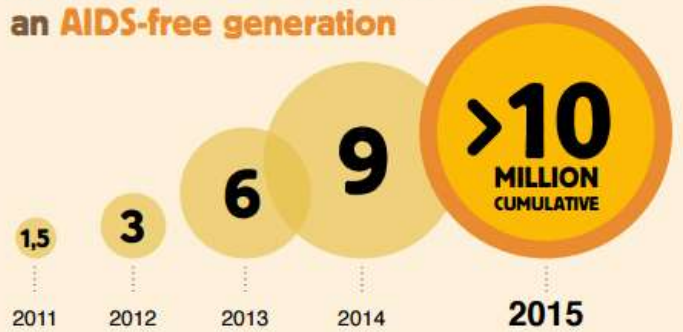


About 66% of new HIV infections are in sub-Saharan Africa

VMMC focuses in East and Southern Africa



In only 5 years more than 10 million men circumcised – contributing to an AIDS-free generation



### MEDICAL MALE CIRCUMCISION PLUS OTHER PREVENTION SERVICES FOR MEN

A package of HIV prevention services is available to men, including offer of HIV testing and links to treatment, condom promotion and provision, management of other sexually transmitted infections and safer sex education.



What is the comprehensive **harm reduction** package for people who inject drugs?

1. Needle and syringe programmes
2. Opioid substitution therapy (OST) and other evidence-based drug dependence treatment
3. HIV testing and counselling
4. Antiretroviral therapy
5. Prevention and treatment of STIs
6. Condom programmes for people who inject drugs and their sexual partners
7. Targeted information, education and communication for people who inject drugs and their sexual partners
8. Prevention, vaccination, diagnosis and treatment for viral hepatitis
9. Prevention, diagnosis and treatment of TB.



Guidelines on HIV prevention and treatment for Key Populations (WHO, 2016):

<http://apps.who.int/iris/bitstream/10665/246200/1/9789241511124-eng.pdf?ua=1>

Recent years, oral PrEP (containing TDF) has become available in some countries



TDF



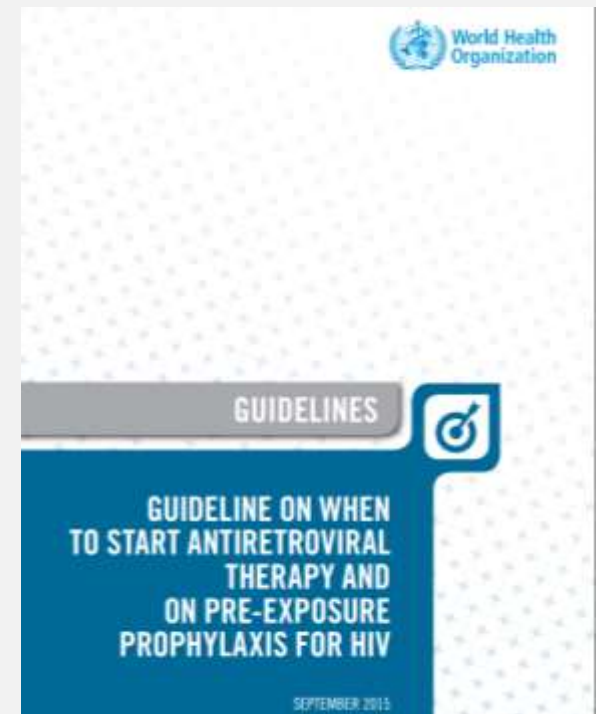
TDF/FTC

**What does the WHO actually say about  
PrEP?**

# WHO recommendation for PrEP (2015)

Oral PrEP (containing TDF) should be offered as an additional prevention choice for people at *substantial risk* of HIV infection as part of combination prevention approaches.

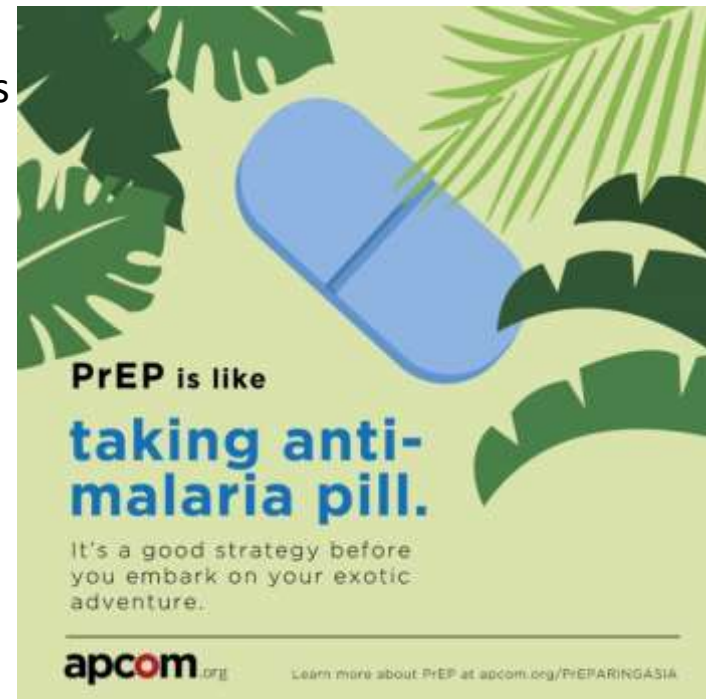
- strong recommendation
- high quality evidence





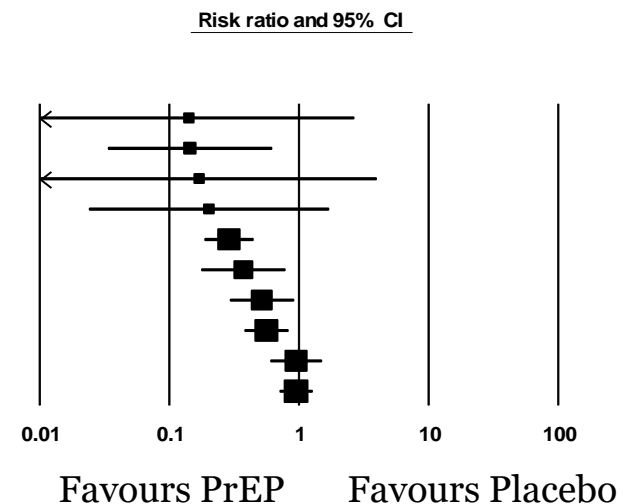
# Features of the Recommendation

- Enabling
  - **Not population specific**
  - For people **at substantial HIV risk** (provisionally defined as HIV incidence > 3 per 100 person–years in the absence of PrEP)
- An **additional prevention choice** within combination prevention
  - Condoms and lube
  - Harm reduction
  - HIV testing and links to ART
- Provide PrEP with **comprehensive support**
  - Adherence counselling
  - Legal and social support
  - Mental health and emotional support
  - Contraception and reproductive health services



# Systematic review results: HIV Infection outcome

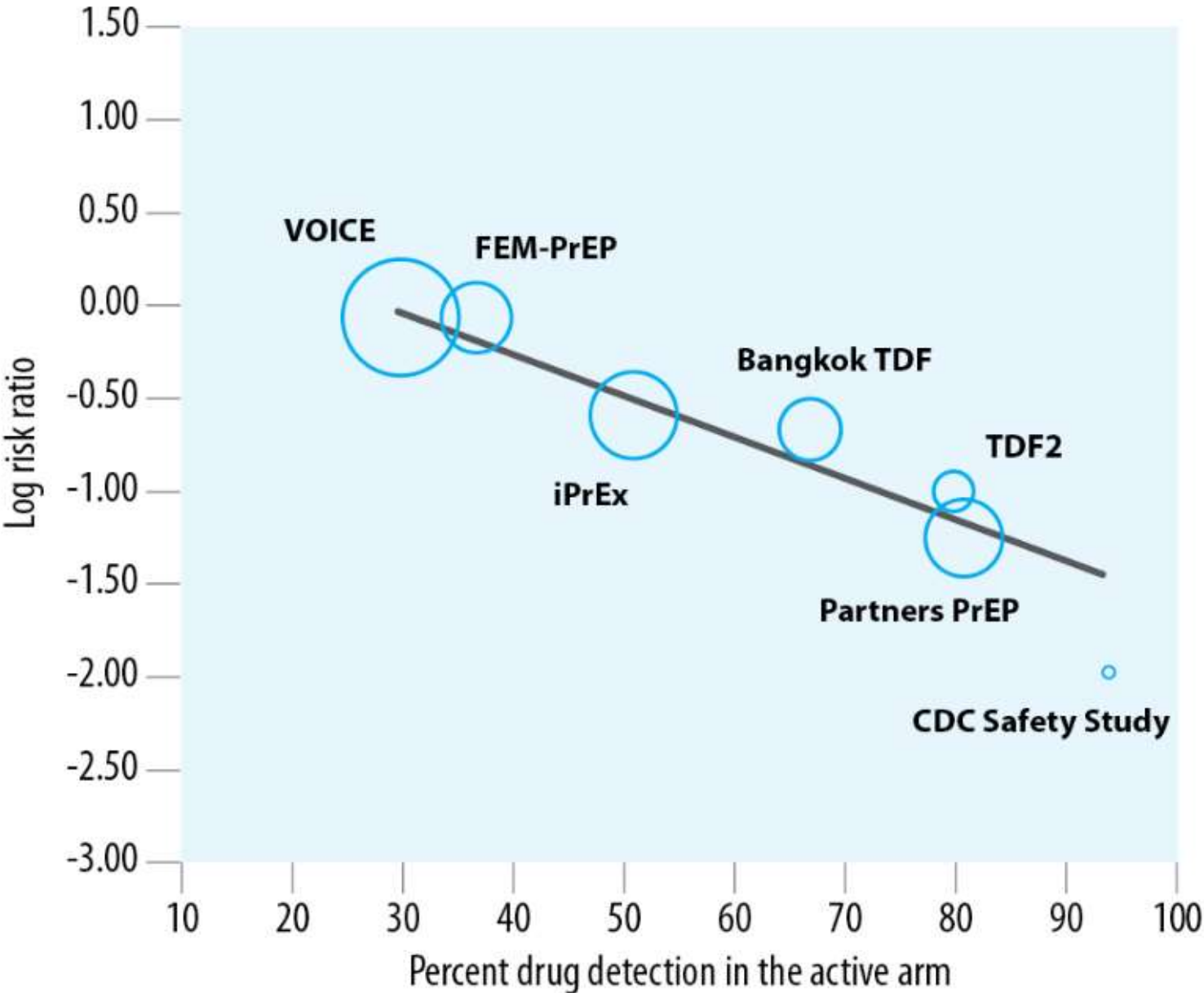
Study name	Subgroup within study	Comparison	Statistics for each study				
			Risk ratio	Lower limit	Upper limit	Z-Value	p-Value
CDC Safety Study	MSM	daily PrEP vs. placebo	0.141	0.007	2.704	-1.299	0.194
Ipergay	MSM	intermittent PrEP	0.144	0.033	0.627	-2.584	0.010
IAVI Kenya Study	MSM and FSW	multiple PrEP dosing	0.170	0.007	4.025	-1.097	0.272
West Africa Study	Women	daily PrEP vs. placebo	0.202	0.024	1.725	-1.461	0.144
Partners PrEP	Men and Women	daily PrEP vs. placebo	0.289	0.185	0.450	-5.471	0.000
TDF2	Men and Women	daily PrEP vs. placebo	0.373	0.175	0.795	-2.554	0.011
BKK TDF Study	Men and Women	daily PrEP vs. placebo	0.517	0.290	0.924	-2.229	0.026
iPrEx	MSM and TG	daily PrEP vs. placebo	0.561	0.376	0.838	-2.826	0.005
FEMPrEP	Women	daily PrEP vs. placebo	0.950	0.595	1.517	-0.214	0.831
VOICE	Women-	daily PrEP vs. placebo	0.951	0.702	1.289	-0.323	0.747



*Note: Results from overall analysis had significant heterogeneity; therefore, results stratified by adherence level for GRADE tables*

- PrEP significantly effective in reducing risk of HIV infection across gender, PrEP regimen, dosing, and mode of acquisition.
- ↑ adherence, ↑ effectiveness

# Adherence and Effectiveness



# Safety of PrEP drugs in pregnancy and breastfeeding



- Pharmacology studies
- ART
- HBV treatment
- PrEP trials
- Systematic reviews/meta-analyses

Given available safety data, there **does not appear to be a safety-related rationale for prohibiting PrEP** during pregnancy and lactation or for discontinuing PrEP in HIV-negative women receiving PrEP who become pregnant (and are at continued risk of HIV acquisition)

(Mofenson, *AIDS*, 2016)

Format: Abstract

Send to

[AIDS](#), 2016 Nov 7. [Epub ahead of print]

## Tenofovir Disoproxil Fumarate Safety for Women and their Infants during Pregnancy and Breastfeeding: Systematic Review.

[Mofenson LM](#)<sup>1</sup>, [Baggaley RC](#), [Mameletzis I](#).

### Author information

#### Abstract

**OBJECTIVES:** Pregnant/lactating women in some sub-Saharan Africa settings are at substantial risk of HIV acquisition and could benefit from pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate (TDF), but safety data in pregnancy/lactation are limited.

**DESIGN:** Systematic data review through August 2016.

**METHODS:** We reviewed research reports/conference abstracts with maternal/child adverse outcome data in HIV-infected and HIV-uninfected pregnant/lactating women receiving TDF alone or in combination with other drugs compared with non-TDF regimens.

Paper can be accessed here: <https://www.ncbi.nlm.nih.gov/pubmed/27831952>

# Recurrent concerns expressed by ministries of health

<b>Cost</b> →	Why should we prioritize PrEP when treatment is our immediate priority?
<b>Where, Who</b> →	Where do we start? Which populations ? Where to offer services?
<b>Safety</b> →	'Toxic drugs' for people without HIV
<b>Drug resistance</b> →	People taking PrEP, esp. with poor adherence: Will this result in lots of drug resistance use?
<b>Behavioral disinhibition</b> →	Offering PrEP will mean people stop using condoms, have more sexual partners, more STIs
<b>Pregnancy and hormonal contraception</b> →	PrEP isn't safe during pregnancy and should be stopped when women become pregnant What about drug interactions?
<b>Adherence</b> →	Lots of the trials had poor results with poor adherence
<b>&gt;18 years</b> →	Many concerns esp. for adolescent girls

# WHO PrEP Implementation Tool 2017

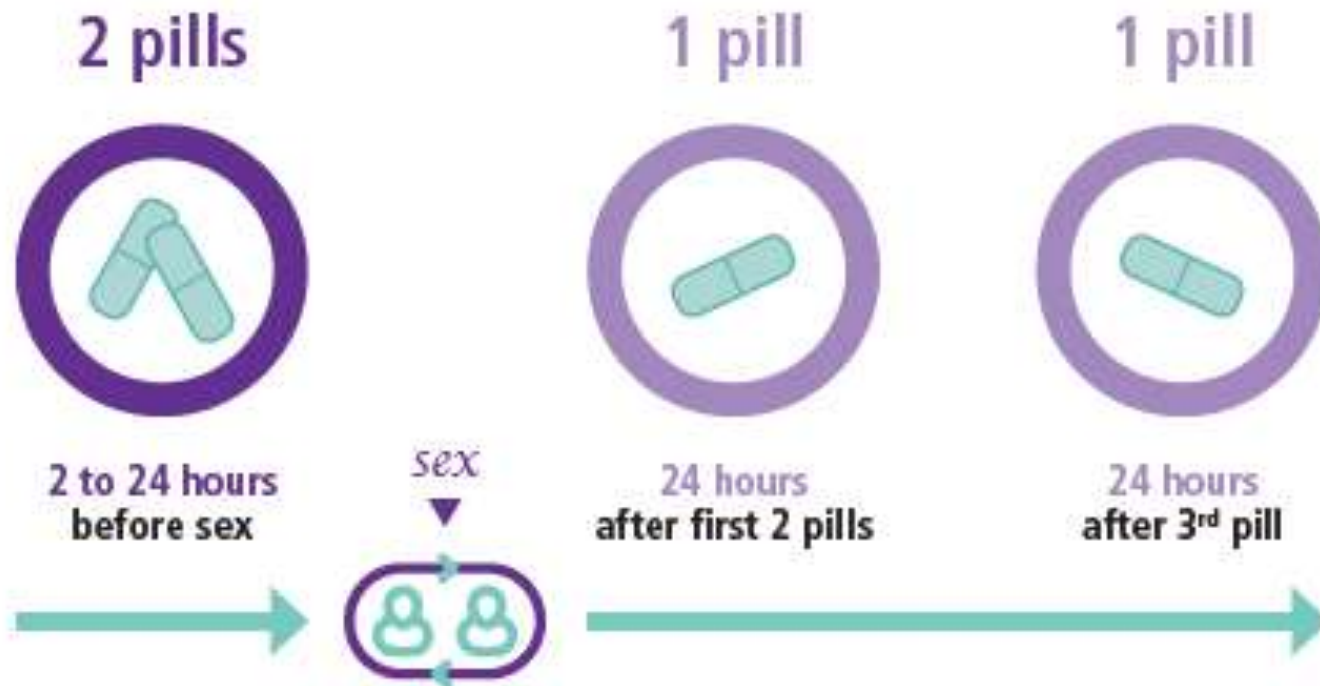
## Module

1. **Clinical** – how to provide PrEP safely & effectively – screening, monitoring, adherence
  2. **Counsellors** – how to support to people considering, starting, continuing on PrEP
  3. **Pharmacists** – how to provide PrEP drugs
  4. **Testing providers** – laboratory services, screening, monitoring
  5. **Leaders** – essentials for understanding benefits and limitations
  6. **Regulatory officials** – how to overcome regulatory issues
  7. **Strategic planning** – prioritization for maximum benefit and impact
  8. **Site planning** – organizing PrEP services at the site level
  9. **Monitoring & Evaluation** – how to monitor PrEP programmes
  10. **Community educators and advocates** – involving communities
  11. **PrEP users** – information for and by people who are taking or considering using PrEP
  12. **Adolescents & Young Adults** - for programs aiming to reach youth aged 15-24
- Evidence Annex** – a synthesis of available evidence to support the guidance

# New Dosing Regimen for MSM, 2019

86% reduction in HIV risk in the placebo controlled randomised phase

97% reduction in open label extension including in infrequent users (9.5 pills/mo)



“Loading dose”

- Is appropriate if sex can be predicted or delayed by at least 2 hours, or occurs less than 2 times per week.



**Positive messaging + marketing**

PrEP

ONE PILL.  
ONCE A DAY.  
Protect against HIV.



[PrEP4love.com](http://PrEP4love.com)

Chicago PrEP line:  
872.215.1905



SPREAD *tingle*

PrEP

ONE PILL. ONCE A DAY.  
Protect against HIV.

I'M ENDING HIV

**BE IN THE MOMENT**  
A once a day pill that keeps you HIV negative

[ TEST OFTEN ] + [ TREAT EARLY ] + [ STAY SAFE ] = [ ENDING HIV ]

2020  
ENDING  
HIV

PositiveLifeNSW  
The State of New South Wales  
© 2017

Is PrEP for you? [endinghiv.org.au/prep](http://endinghiv.org.au/prep)

**F\*CK  
W/OUT  
FEAR**

**PREP  
HERE**



**LOS ANGELES LGBT CENTER®**

**ONE PrEP PILL A DAY CAN PREVENT HIV.**

PREVENT STDs WITH A CONDOM.





# NYC PLAYS SURE

**PLAY SURE: CALL 311 OR VISIT [NYC.GOV/HEALTH](https://nyc.gov/health) TO DESIGN  
THE RIGHT HIV AND STI PREVENTION COMBINATION FOR YOU**

**NYC**  
Health

**#PLAYSURE**



# PrEP

TAKEN DAILY,  
PrEP IS AN ADDITIONAL  
PREVENTION  
OPTION  
FOR HIV-NEGATIVE PEOPLE

THE WE ARE  
GENERATION  
THAT WILL END  
HIV

Pr<sub>e</sub> = before

Exposure = coming into contact with HIV

Prophylaxis = treatment to prevent an infection from happening



Pre-exposure prophylaxis, or PrEP, is a new, safe, HIV prevention method in which HIV-negative people take a pill daily to reduce their risk of becoming infected. The pill contains medicines that prevent HIV from making new virus as it enters the body. In this way PrEP medicines can help keep the virus from establishing a permanent infection.

PrEP adds an extra HIV prevention option to the use of condoms, behavioural counselling, post-exposure prophylaxis, treatment for sexually transmitted infections, voluntary male medical circumcision, and antiretroviral therapy for partners living with HIV.

I HAVE THE RIGHT TO LIVE HIV FREE  
I HAVE THE DUTY TO HELP STOP THE SPREAD OF HIV

When used consistently and as prescribed, PrEP has been shown to reduce the risk of HIV infection by more than 90% among people at high risk for HIV infection.

**PrEP** is only for people who are HIV-negative.

PrEP is recommended for individuals with high risk for HIV exposure.



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



A health resource for  
men who have sex with men

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**WE'RE  
BRAVER  
TOGETHER**

COME AND GET TESTED FOR HIV  
WITH A FRIEND BY YOUR SIDE

A large graphic featuring two hands of different skin tones shaking. The background is a light teal color. The text "WE'RE BRAVER TOGETHER" is prominently displayed in white and red. Below it, the text "COME AND GET TESTED FOR HIV WITH A FRIEND BY YOUR SIDE" is written in a smaller, red font.

Find your nearest  
gay-friendly  
clinic



Start Search

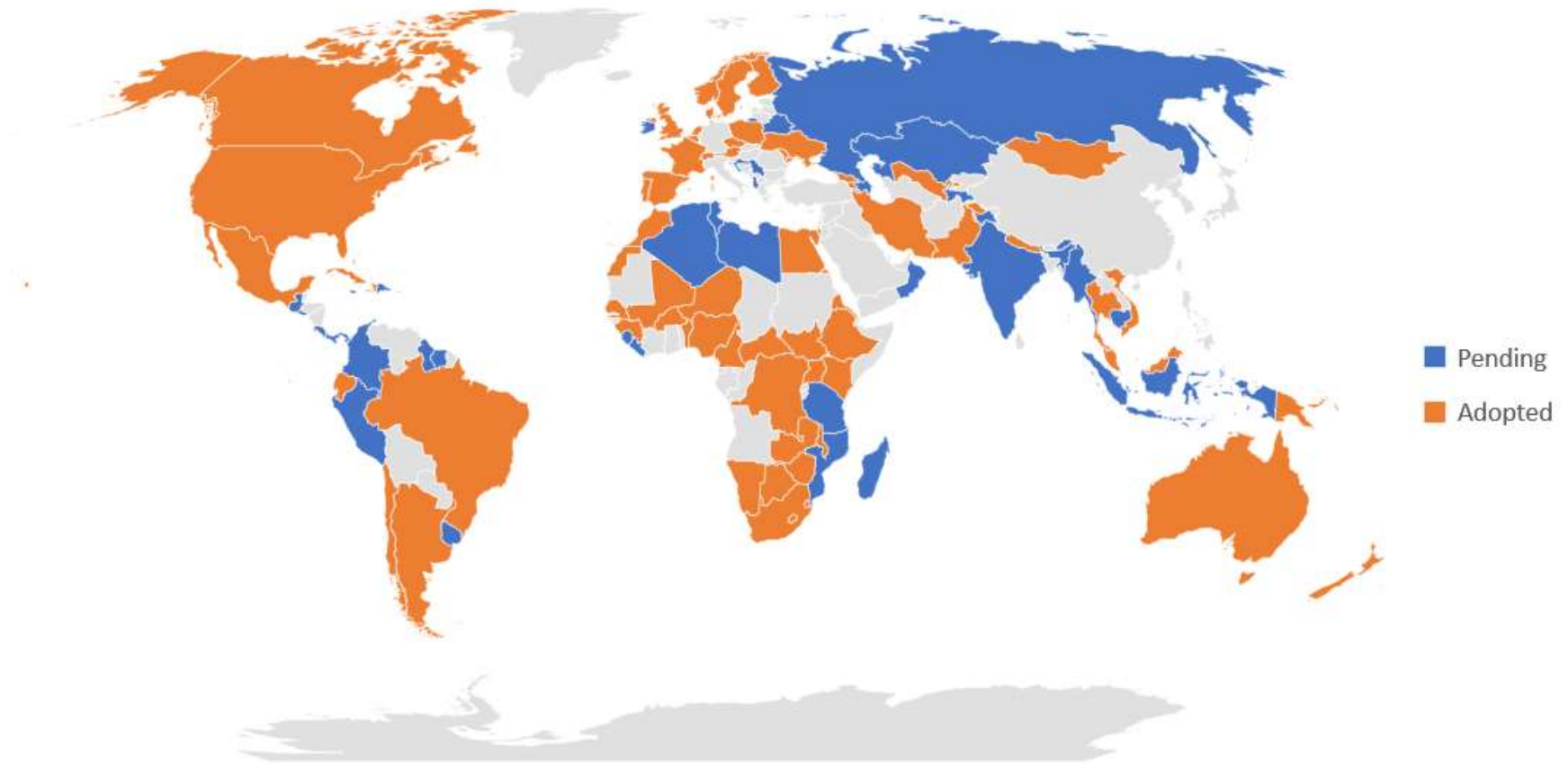


Click here to  
ask an expert



How does PrEP implementation  
look now?

# Countries With PrEP Policies, July 2019



**30+ Countries have policies pending**



Prevention is often perceived as complicated, difficult, and boring.

**But it doesn't have to be, especially in the era of PrEP.**

