# Innovating the HIV combination prevention toolbox with pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP)

#### <u>Virtual Training – 6<sup>th</sup> October 2020</u>







## **Learning Objectives**

- To increase knowledge of participants in the clinical management of PrEP and delivery of PrEP services.
- To provide participants an overview of most recent WHO recommendations on PrEP and nPEP, new scientific evidence and implementation data emerging from field.
- To present current WHO guidance on PrEP programming and provide a space for participants to share experiences among countries and prepare for PrEP/nPEP implementation planning, scale up.

#### **Expected public health result:**

<u>Innovation of HIV combination prevention services, including PrEP/nPEP</u>

- Participants encouraged to take the JHPIEGO/WHO course on clinical management of PrEP before this session (Updated version including Event driven-PrEP)
- Soon available on the PAHO Virtual Campus

Oral PrEP eLearning Course This eLearning course introduces clinicians to the Oral PrEP intervention. This course is designed based on the WHO Oral PrEP Implementation Tool to help providers identify people who are eligible for Oral PrEP, counsel about safety and efficacy, managing PrEP's usage, and addressing special situations. It is self-paced, free and open to all clinicians for enrollment. Take Clinician Course









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## **WHO PrEP App**



- Apple
- Android

On-the-go access to the following modules from the WHO PrEP Implementation Tool:

- Module 1 Clinical
- Module 3 Counsellors
- Module 6 Pharmacists
- Module 10 Testing providers
- Module 11 PrEP users

# The WHO PrEP Implementation Tool App for Health Workers

A pathway to prevention on your mobile phone.

; jhpiego Clinician's Guide MENU to Oral PrEP It's here!!

Download the WHO PrEP Implementation

Tool App for Health Workers

https://www.hivoralprep.org







## Agenda

Time (Guyana time)	Title	Responsible
11:00-11:10am	Opening remarks	Rosmond Adams (PANCAP), Sandra Jones (PAHO/WHO)
11:10-11:20am	Overview of WHO guidance and implementation tools for PrEP and nPEP and current access in the Caribbean	Giovanni Ravasi (PAHO/WHO)
11:20-11:40am	What's new on PrEP: event-driven PrEP, new evidence from science and implementation and sustaining PrEP services during the pandemic	Yanni Mameletzis (WHO consultant)
11:40am-12:00pm	Q/A	All participants
12:00-12:15pm	Overview of PrEP programme implementation	Giovanni Ravasi (PAHO/WHO)
12:15-12:30pm	An Assessment of PrEP Implementation in Barbados	Anton Best (MOH, Barbados)
12:30-12:55pm	Q/A and discussion on accelerating PrEP implementation in the Caribbean	All participants
12:55-1:00pm	Closure and next steps	Sandra Jones

Overview of WHO guidance and implementation tools for PrEP and nPEP and current access in the Caribbean

Giovanni Ravasi, MD MScPH
Pan American Health Organization (PAHO)



## **Outline**

#### **Overview of:**

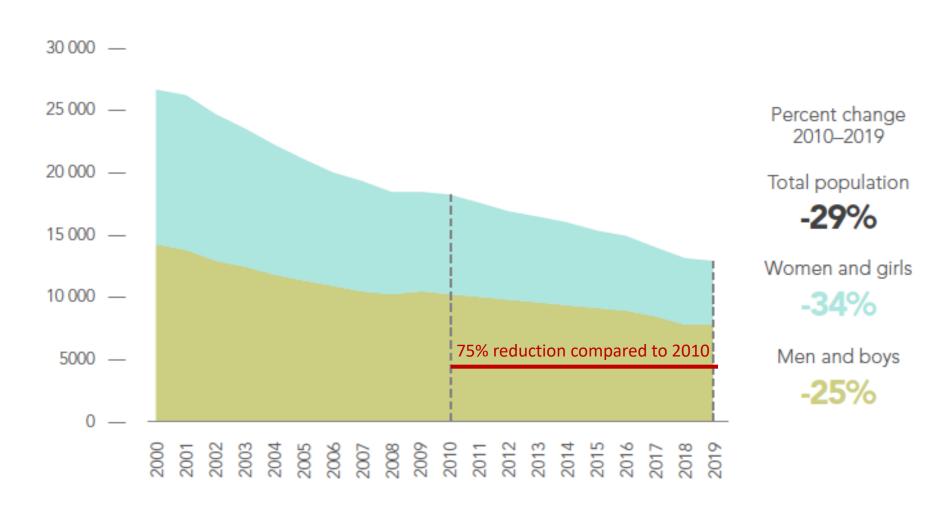
- WHO recommendations on PrEP and nPEP
- Available tools from PAHO/WHO and partners
- PrEP implementation in LAC

## **New HIV infections in the Caribbean (estimated trends 2010-2018)**

FIGUR 10.2

New HIV infections
by sex, Caribbean,
2000–2019





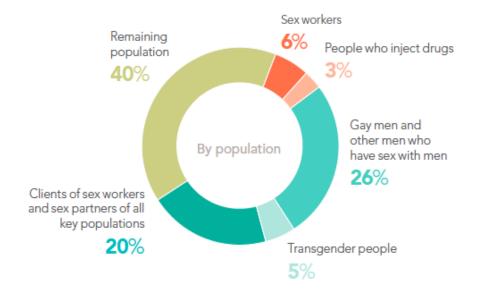
Source: UNAIDS epidemiological estimates, 2020 (see https://aidsinfo.unaids.org/).



# PrEP and HIV Combination Prevention A person- and community-centered approach

Distribution of new HIV cases by populations, 2019

#### Caribbean





#### **BIOMEDICAL STRUCTURAL** Decriminalization of Interventions Condoms and lubricants Interventions transmission and that promote HIV testing of key populations with clinical and an enabling Antiretroviral treatment Gender and gender medical methods. environment. for all violence approach for example: Prevention of vertical Laws to protect rights for example: transmission Interventions to reduce PrEP and PEP stigma and discrimination Voluntary male circumcision Needle and syringe programs **BEHAVIORAL** Interventions that promote Counseling on risk reduction Comprehensive sex education healthy behaviors, for Peer education programs example: Social marketing campaigns (e.g., to promote condom use)

Source: Adapted from the International HIV/AIDS Alliance. An advocacy brief for community-led organisations: Advancing combination HIV prevention; 2016. Available from: http://www.aidsalliance.org/assets/000/002/472/web\_AllianceUnaids\_Comb\_prevention\_original.pdf?1459762561.

#### **Evolution of WHO recommendations on the use of HIV PrEP**







**GUIDELINE ON WHEN** 

- **Additional prevention option**
- Person at substantial risk
- **Combination prevention** approach



2014 - PrEP for MSM (strong recommendation); other key populations (conditional).

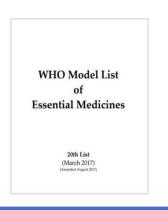
**2015** - PrEP for persons with substantial risk of HIV (strong recommendation)







http://who.int/hiv/pub/prep/prep-implementation-too









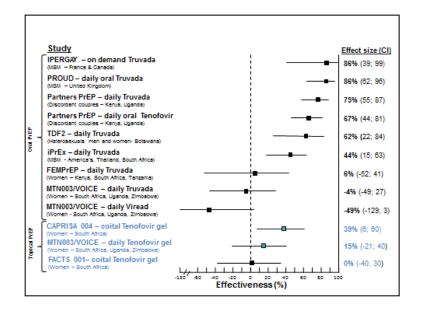
2017 – ARV for PrEP in WHO EML (TDF/FTC; TDF/3TC; TDF); WHO PrEP implementation tool modules

**2018** – PrEP for adolescents PrEP App

2019 – M&E module, Eventdriven PrEP for MSM, PrEP e-Learning (clinical module)

## WHO strong recommendation on PrEP (2015)

"Oral PrEP (containing TDF) should be offered as an <u>additional prevention</u> choice for people at <u>substantial risk</u> of HIV infection as part of <u>combination</u> prevention approaches" (strong recommendation; high quality evidence)





- Offer as an additional prevention choice
- For people at substantial HIV risk
- Provide PrEP within combination prevention
  - Condoms and lube
  - STI screening and management
  - HIV testing and counselling
  - Risk reduction/management
  - Harm reduction
- Provide PrEP with comprehensive services and support
  - Adherence counselling
  - Legal and social support
  - Mental health and emotional support
  - Sexual and reproductive health services
  - Viral hepatitis and HPV integrated services

Opportunity to link high risk and hard to reach individuals to health services

## WHO CLINICAL PREP BASICS

Indications for PrEP (by history over the past 6 months):

**HIV-negative AND** 

PrEP is for people at substantial HIV risk

Sexual partner with HIV who is not virally supressed, OR

Sexually active in a high HIV incidence/prevalence population AND any of the following:

- Vaginal or anal sexual intercourse without condoms with more than one partner, OR
- A sexual partner with one or more HIV risk factors, OR
- A history of a sexually transmitted infection (STI) by lab testing or self-report or syndromic STI treatment, OR
- Use of post-exposure prophylaxis (PEP), OR

Requesting PrEP.

Non occupational PEP ("PEP to PrEP")

#### Contraindications:

- **HIV-positive**
- Estimated creatinine clearance <60 ml/min
- Signs/symptoms of acute HIV infection, probable recent exposure to HIV
- Allergy or contraindication to any medicine in the PrEP regimen.

Rx (example): TDF 300 mg + FTC 200 mg P0 daily #90 tablets.

Counselling: Link tablet use with a daily routine.

Develop a plan for contraception or safer conception and for STI prevention.



#0fferPrEP

## **Screening for PrEP (and nPEP)**

RECORD FORM FOR PREP AND PEP SCREENING	i		
What was your sex at birth?	Male	Female	Other
What is your current gender?		Female	Other
What is your current age?			years
In the past 6 months:			
With how many people did you have vaginal or anal sex?	0 1 0 1		+* men +* women
Did you use a condom every time you had sex?	Yes	No*	Don't Know*
Did you have a sexually transmitted infection?	Yes*	No	Don't Know*
Do you have a sexual partner who has HIV?		No	Don't Know*
If "Yes," has he or she been on antiretroviral therapy for 6 or more months?	Yes	No*	Don't Know*
If "Yes," has the therapy suppressed viral load?		No*	Don't Know*
In the past 3 days:			
Have you had sex without a condom with someone with HIV who is not on treatment?	Yes**	No	Don't Know**
Have you had a "cold" or "flu" such as sore throat, fevers, sweats, swollen glands, mouth ulcers, headache or rash?	Yes***	No	Don't Know
*Consider offering PrEP; **Consider offering PEP; ***Consider acute HIV.			



## **Baseline assessment for PrEP. Not just about HIV!**

	INVESTIGATION/INTERVENTION	RATIONALE	
	HIV test (using algorithm in national HIV testing services guidelines)	To assess HIV infection status.  If recent exposure (in the past 72 hours), consider PEP and re-test after 28 days.  To complete a symptom checklist for possible acute HIV infection.	
	Serum creatinine	To identify pre-existing renal disease (estimated creatinine clearance less than 60 ml/min).	
Γ	Hepatitis B surface antigen	If negative, consider vaccination against hepatitis B. If positive, suggest further testing and assessment for hepatitis B treatment.	
ı	Hepatitis C antibody	Consider for MSM populations If positive, consider referral for assessment and treatment for hepatitis C infection.	
ı	Rapid plasma reagin	To diagnose and treat syphilis infection.	
ı	Other screening for sexually transmitted infection (STI)	To diagnose and treat STI (syndromic or diagnostic STI testing, depending on local guidelines).	
١	Pregnancy testing	To guide antenatal care, contraceptive and safer conception counselling, and to assess risk of mother to child transmission. Pregnancy is not a contraindication for PrEP use (see section below).	
	Review vaccination history	Depending on local guidelines, epidemiology and populations, consider vaccination for hepatitis A (e.g. MSM) (31), human papilloma virus, tetanus and meningitis.	
	Counselling	To assess whether the client is at substantial risk of HIV.  To discuss prevention needs and provide condoms and lubricants.  To discuss desire for PrEP and willingness to take PrEP.  To develop a plan for effective PrEP use, sexual and reproductive health.  To assess fertility intentions and offer contraception or safer conception counselling.  To assess intimate partner violence and gender-based violence.  To assess substance use and mental health issues.	

- Screening for viral hepatitis
- Offer vaccination for HBV (HAV)
- Linkage to care and treatment for viral hepatitis
- Screening and management of STIs
- HPV/cervical cancer services
- SRH services

#### Follow-up assessment

INTERVENTION	SCHEDULE FOLLOWING PREP INITIATION
Confirmation of HIV-negative status	Every 3 months. Consider also testing at 1 month.
Address side-effects	Every visit.
Brief adherence counselling	Every visit.
Estimated creatinine clearance	Every 6 months. Consider more frequently if there is a history of conditions affecting the kidney, such as diabetes or hypertension; consider less frequently if age is less than 45, baseline estimated creatinine clearance more than 90 ml/min, and weight more than 55 kg.
Hepatitis C antibody	Consider testing MSM every 12 months.

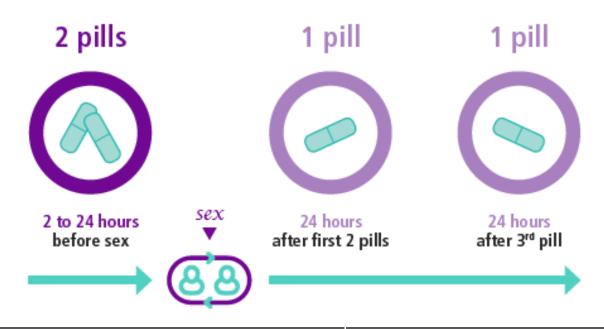
Provide screening for sexually transmitted infections (STI), condoms, contraception or safer conception services as needed.

Note: frequency of STI screening may be every 3 or 6 months depending on population and national policy.

Provide counselling regarding effective PrEP use (adherence), prevention of STIs, recognition of symptoms of STIs, and issues related to mental health, intimate partner violence and substance use.

## WHO Policy brief on ED-PrEP for MSM (PrEP "2+1+1")







For whom is ED-PrEP appropriate?	For whom is ED-PrEP NOT appropriate?
<ul> <li>a man who has sex with another man:</li> </ul>	cisgender women or transgender women
- who would find ED-PrEP more effective and convenient  - who has infrequent sex (for example, sex less than 2 times per week on average)	transgender men having vaginal/frontal sex     men having vaginal or anal sex with women
- who is able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours	people with chronic hepatitis B infection.

## PAHO/WHO technical cooperation to support PrEP uptake

- WHO guidance and implementation toolkit, PrEP 2+1+1
- WHO PrEP Apps and PAHO e-Learning platform (Virtual Campus)
- PAHO PrEP Estimates tool (needs and budget impact)
- **Technical support** from PAHO and Task Force for:
  - Needs estimate and budget impact
  - Protocol/guidelines development
  - Implementation planning
  - Training of human resources
  - Experience exchange
- Capacity building of civil society (information for advocacy, demand generation)
- PrEP visibility (campaigns)
- Partnerships











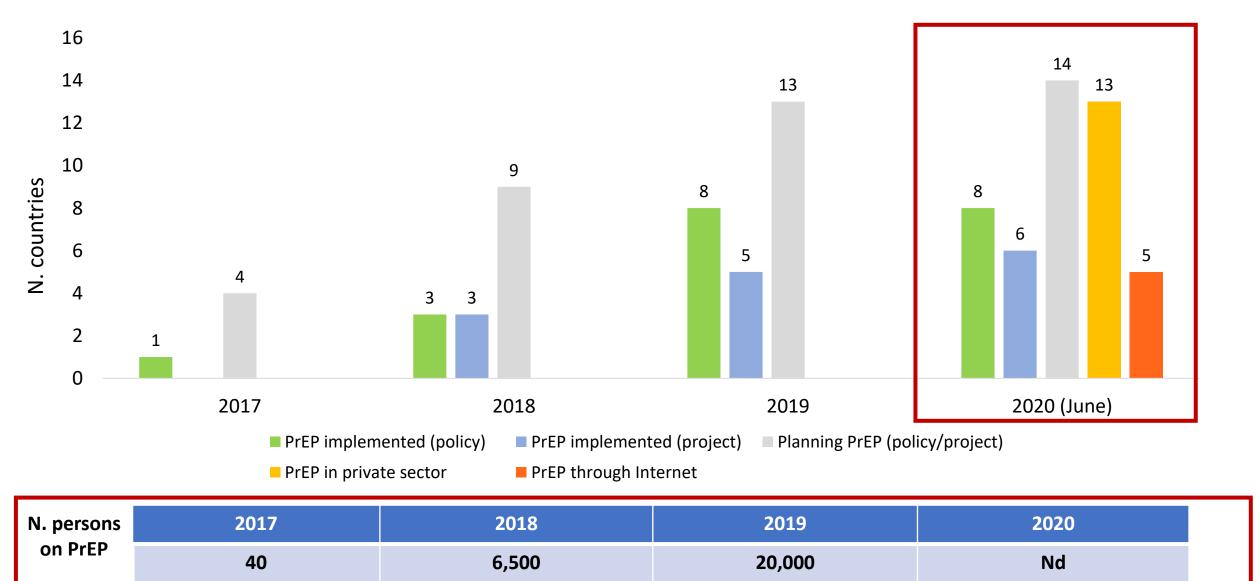








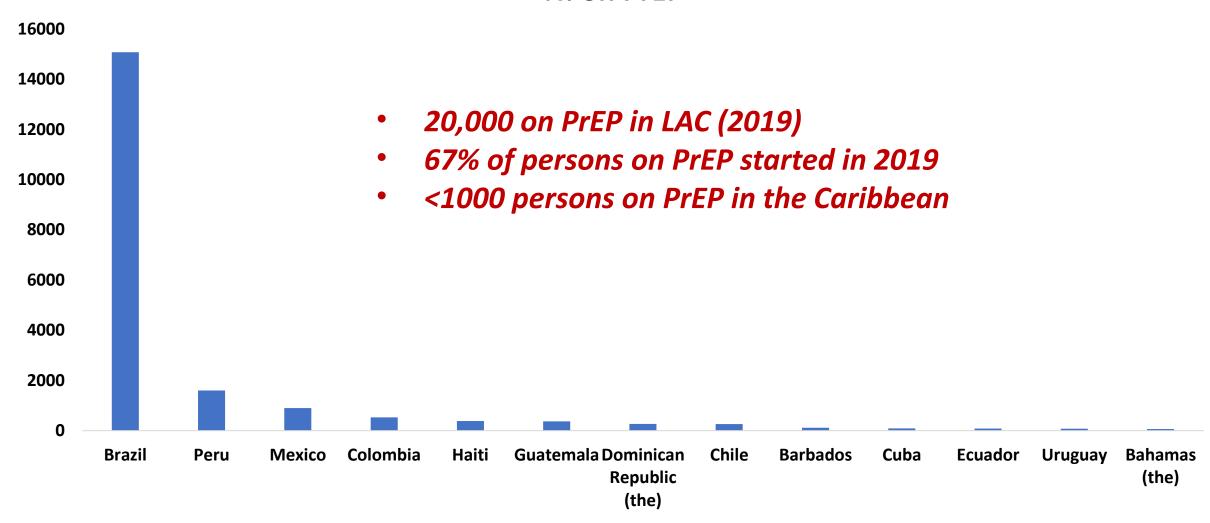
## PrEP policy uptake and implementation, LAC (2017 to Jun-2020)



Source: GAM 2020 and PAHO desk review; 2020 preliminary data.

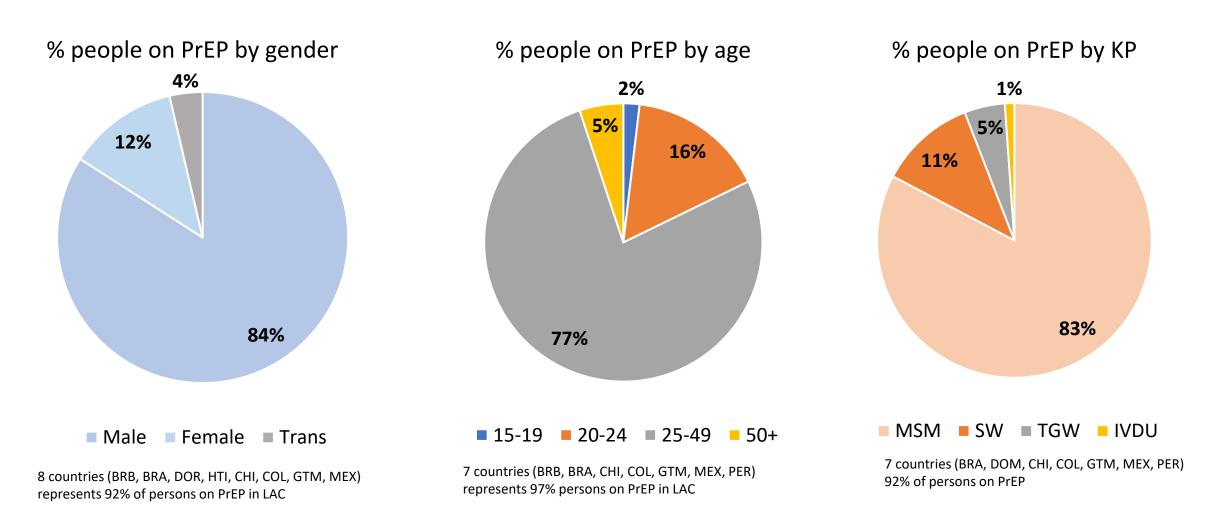
## People on PrEP in LAC by country (2019)







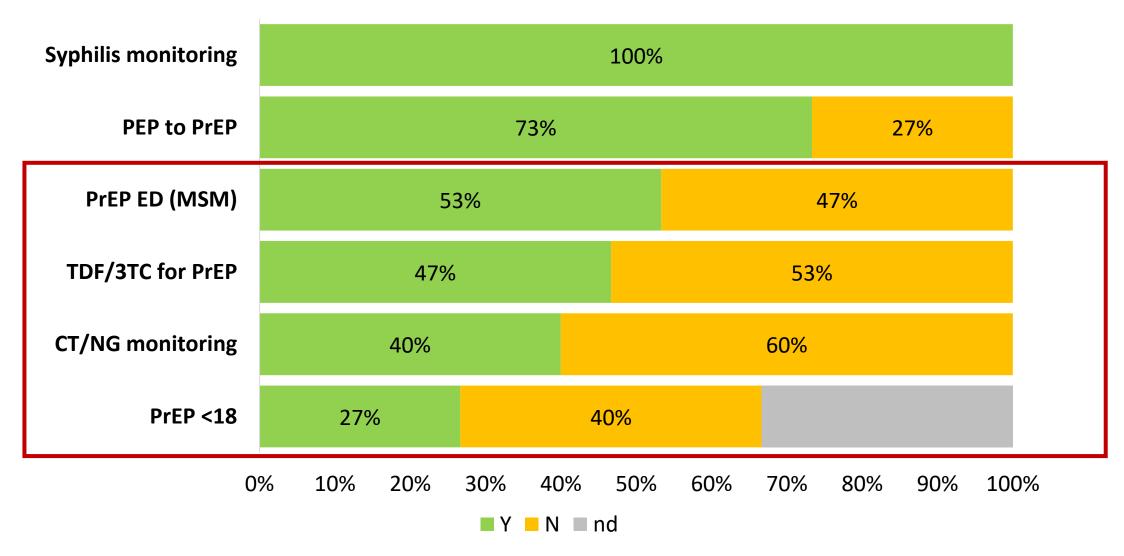
## Demographics of people on PrEP in LAC (2019)



Source: Global AIDS Monitoring 2020, preliminary data



## **PrEP Guidelines in LAC – key elements**

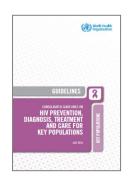




#### **Evolution of WHO recommendations on the use of PEP**







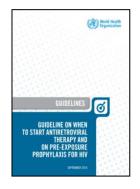
#### 2007 WHO/ILO:

occupational and sexual assault.

2 ARV (3 ARV if suspect of resistance)

2014 WHO: all exposed to potential risk. 3 ARV preferred TDF/XTC + LPV/r or ATV/r (RAL, DRV/r or EFV alternative)

**2014-16** - PEP for <u>eligible key</u> populations on a voluntary basis after possible exposure to HIV. Including people in prisons and closed settings.







**2016** – PEP is part of combination prevention interventions

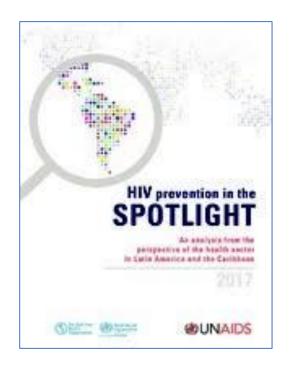
2017 – Use of nPEP is a criteria for PrEP; offer PEP if recent exposure at PrEP baseline

2018/9 – DTG-based preferred PEP regimen (e.g. TLD in adults)

http://www.who.int/hiv/pub/prophylaxis/en/

# Percentage of countries with public policies for the delivery of selected HIV prevention interventions by population

Service or intervention	MSM (%)	FSW (%)	Transgender women (%)
HIV testing and counseling	100	97	94
STI diagnosis and treatment	90	91	84
PrEP	6	6	6
PEP	39	39	39
Condoms	100	96	81
Lubricants	89	89	83
Antiretroviral treatment (ART) for all	45	45	45
Peer-led community outreach activities	89	86	83
Sexual health information and education	100	96	91



Source: PAHO. Country responses to the HIV Prevention Survey, May 2017.

Note: Percentages based on the response of 31 or 33 countries as of July 2017.

ART: antiretroviral treatment; MSM: men who have sex with men; PrEP: pre-exposure prophylaxis; PEP: post-exposure prophylaxis;

FSW: female sex workers.







#### Non-occupational PEP (nPEP) in LAC (2017)

#### All 28 surveyed countries offer PEP:

- a) in cases of work-related or occupational injuries involving a source who is HIV-positive or whose HIV status is unknown, and
- b) in cases of sexual assault.

Only 39% (11/28) offer PEP in case of potential exposure from consensual sex (with an HIV-positive sex partner or one whose HIV status is unknown).

#### **Actions needed**

- 1. Update national policies to adopt WHO recommendations on nPEP: nPEP needs to be fully adopted as additional combination prevention intervention (nPEP as linkage to PrEP; "PEP to PrEP").
- 2. Improve knowledge and awareness about nPEP (non-specialists health providers and key populations to create demand)
- **3. Expand access** to PEP/nPEP at all levels of health system and reduce barrier for prescription.
- **4. Monitor and evaluate** nPEP implementation.





## nPEP and combination prevention: the Brazilian experience



## **PEP in Brazil (2009-2018)**

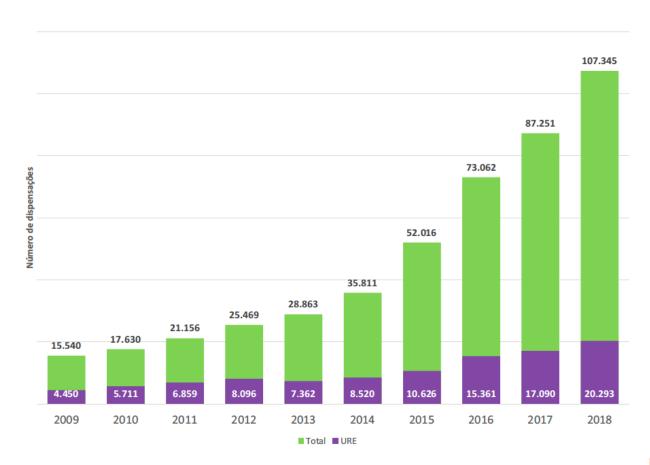


Figura 77. Número de PEP dispensadas, por ano da dispensação. Brasil, 2009-2018

Fonte: MS/SVS/DCCI. URE — Unidades de Referência em Exposição

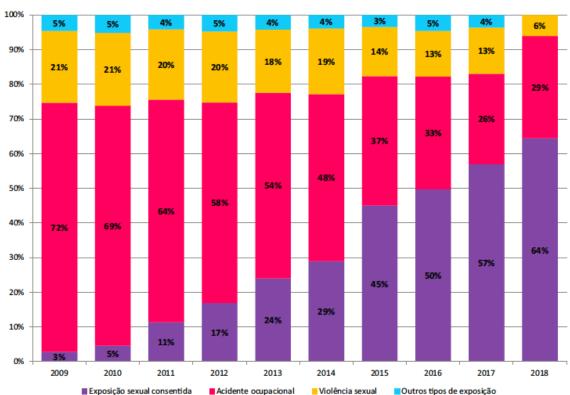


Figura 78. Distribuição das dispensações de PEP por tipo de exposição, segundo o ano da dispensação. Brasil, 2009-2018

Fonte: MS/SVS/DCCI.

- nPEP since 2009, the increase is gradual overtime
- Data show the need and demand for nPEP

## PEP in Brazil (2018)

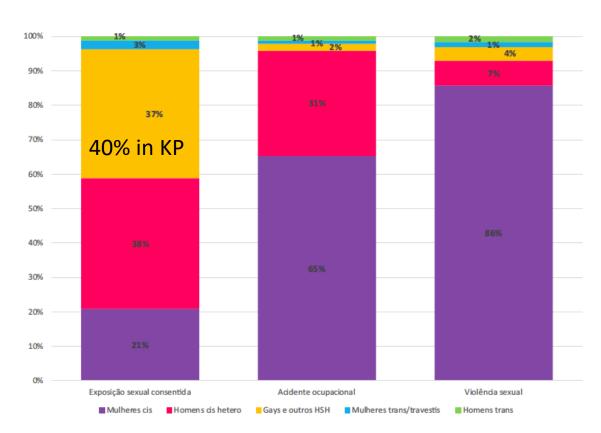


Figura 79. Distribuição das dispensações de PEP por população, segundo o tipo de exposição. Brasil, 2018

Fonte: MS/SVS/DCCI.

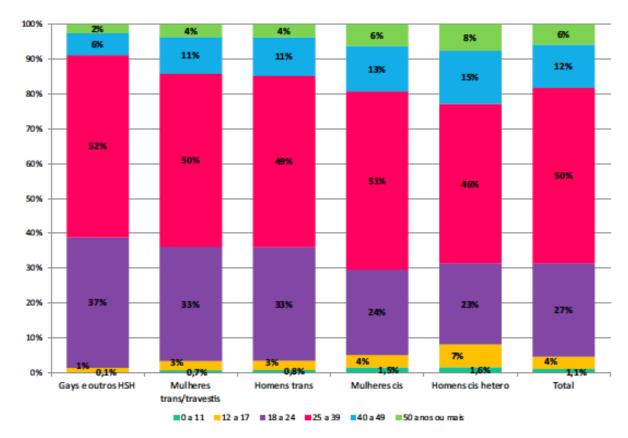


Figura 80. Distribuição das dispensações de PEP por população, por faixa etária. Brasil, 2018 Fonte: MS/SVS/DCCI.

37% PEP in MSM are youth (18-24), 1% <18 years old.



# Thank you

ravasigi@paho.org



http://who.int/hiv/pub/prep/prep-implementation-tool

# Overview of PrEP programme implementation

Giovanni Ravasi, MD MScPH
Pan American Health Organization (PAHO)



#### **PrEP Implementation tool: 12 modules**



http://who.int/hiv/pub/prep/prep-implementation-tool

http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/

## **Module 9 – Strategic planning**

- STRATEGIC PLANNING PROPHYLAXIS (Prep) OF HIV INFECTION



#### Defining substantial risk and target populations for PrEP

- Prioritizing PrEP for high risk individuals
- HIV incidence threshold and PrEP cost effectiveness
- Examples of risk calculators

#### **Steps in prioritizing and implementing PrEP services**

#### DETERMINE POPULATIONS WITH HIGH HIV INCIDENCE OR PREVALENCE

- Geographical areas
- Population groups
- Individuals with HIV secual and drug using risk behaviours.

#### WHERE TO OFFER PREP

- Sites where PrEP demand can be generated
- Integrated in existing services. that reach. populations at risk
- Facilities with: relevant services, (HIV and STI testing, ART family planning). laboratory access and follow-up capability

#### HOW TO INITIATE PREP SERVICES

- · Ensure facilities are ready (laboratory services, adherence support, monitoring systems)
- Train providers.
- Bufld awareness/ create demand.
- Mobilize communities.
- · Integrate combination. prevention

#### OFFERING PREP

- Provide comprehentsve services & links to ART for those. diagnosed with HIV at screening or who seroconvert
- Make services. welcoming and Inclusive.
- Include people who request PrEP
- · Provide other prevention services for those at risk who do not choose PrEP

#### MONITORING AND EVALUATION

- Integrate PrEP. monitoring with existing reporting services.
- Develop system. triggers for people who cannot adhere to PrEP
- Assess adherence. retention and linkages with other HIV services.
- Consider risk-based reasons for stopping PrEP

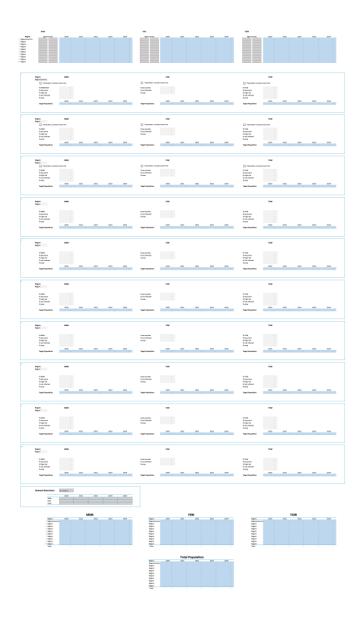
#### **Target population group for PrEP**

# DETERMINE POPULATIONS WITH HIGH HIV INCIDENCE OR PREVALENCE

- Geographical areas
- Population groups
- Individuals with HIV sexual and drug using risk behaviours

- Determine target population groups and/or geographic areas (high HIV incidence or prevalence based on available data)
- Estimate eligible population within target groups for planning and M&E purpose (e.g. estimated number of highrisk HIV-negative MSM willing to use PrEP)

## PAHO PrEP demand and budget impact estimate tool (2019)



- Excel tool (available from PAHO upon request)
- Estimates PrEP demand needs for MSM, TGW and sex workers
- Estimates budget impact of PrEP implementation (customized PrEP service)
- Estimates can be at national and subnational level
- Required inputs: population structure; information from bio behavioral surveys in key populations; cost of services
- Projections at 5 years based on customized PrEP scale-up/coverage





## **Development of Norms and Regulations for PrEP**

#### 1. PrEP in National Strategic Plans and Strategies

#### 2. PrEP guidelines/protocol

Guidelines/protocols (clinical and operational)

#### 3. Regulatory aspects of ARVs for PrEP

- Registration of generic ARVs (TDF, TDF/FTC, TDF/3TC)
- Use of ARVs for prevention (e.g. updated registration; off-label use for prevention)
- Inclusion of ARVs for PrEP in national Essential Medicine List
- Integration of PrEP in ARV Procurement plans (e.g. low-cost WHO PQ TDF/FTC generic ~5 US\$/pack 30 tab)

#### 4. Other PrEP related health system norms/regulations

 Enabling norms related to task-shifting or community delivery of PrEP.



## WHO Implementation tool - Module 1: Clinical



## A blueprint for national clinical manuals and PrEP guidelines:

- PrEP eligibility criteria
- Screening and initiation procedures
- PrEP regimens and dosing schedule
- Lab monitoring and clinical follow up
- Management of toxicities

PAHO PEP/nPEP generic guidelines available for country adaptation



## PrEP delivery model(s)

#### WHERE TO OFFER PREP

- Sites where PrEP demand can be generated
- Integrated in existing services that reach populations at risk
- Facilities with relevant services, (HIV and STI testing, ART, family planning), laboratory access and follow-up capability

- Review current service network for HIV prevention services,
   especially for PrEP population groups (integrated service delivery)
- Consider both facility- and community- based services (differentiated services for key populations; multiple PrEP delivery models)
- Review any available data on PrEP acceptability and service delivery preferences of the target population groups
- Design clinical routs and flows from PrEP promotion, HIV testing and PrEP eligibility assessment, initiation and follow up, linkage for HIV+.
- Human resources' responsibility for PrEP delivery (health professional and peer-led services)
- Lab and pharmacy services

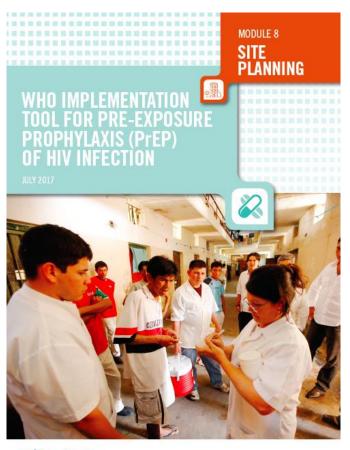
#### PrEP and COVID-19: opportunity for innovation

- Greater use of telehealth, internet, video, phone, Appbased services
- MMD, community and home-delivery (ARVs, condoms, HIVST kits, etc.)
- Digital prescriptions for ARVs
- HIV self testing, self- and home-sampling for STIs
- ED-PrEP for MSM
- Expand community-based and peer-led services

## Site planning

#### HOW TO INITIATE PREP SERVICES

- Ensure facilities are ready (laboratory services, adherence support, monitoring systems)
- Train providers
- Build awareness/ create demand
- Mobilize communities
- Integrate combination prevention





#### **Step by step guidance on planning PrEP services:**

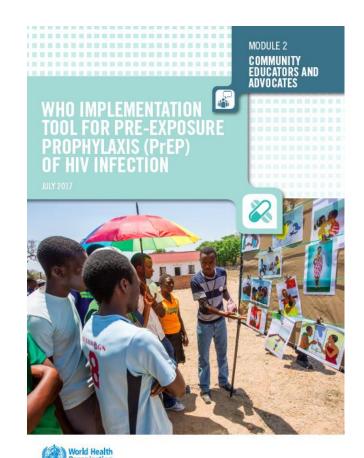
- Integration in existing HIV combination services
- Clinical protocols and SOPs
- Training
- Counselling
- Human resources
- Medicine supply
- Lab testing and vaccinations
- Documenting and monitoring

CATEGORY	DUTIES
Experienced clinical provider (physicians, clinical officer or nurse)	Provide general oversight of clinical services and be available to offer support for complex cases, including remotely (for example, via mobile phone text message, email, instant messaging, voice and video messaging, etc.).
Medical officer or nurse	Take structured sexual, drug use and medical history, measure vital signs (blood pressure and body temperature), perform philebotomy, conduct point-of-care tests (HIV antibody, hepatitis B surface antigen), screen for sexually transmitted infections (STIs). Also, provide counselling on PrEP use and adherence, family planning and contraception, hepatitis B vaccination and STIs.
Counsellor	Provide Information on PrEP and counselling on adherence, HIV prevention, sexual health and contraception.
Peer educator	Support education programmes that provide basic information on PrEP and other HIV prevention options, and how to recognize HIV risk. Support demand creation for PrEP and strategies for adherence.
Pharmacist	Assure a supply of medications. Ensure medications are stored in a secure and climate- controlled facility and dispensed using best practices. (The pharmacist does not have to be permanently onsite.)
Pharmacy support staff	Rill prescriptions, including labelling, dispense medications and collect co-payments (if required in the local context). May also be involved in assessing adherence and counselling for more effective PrEP use.

#### Community engagement and demand generation

#### OFFERING PREP

- Provide comprehenisve services & links to ART for those diagnosed with HIV at screening or who seroconvert
- Make services welcoming and inclusive
- Include people who request PrEP
- Provide other prevention services for those at risk who do not choose PrEP



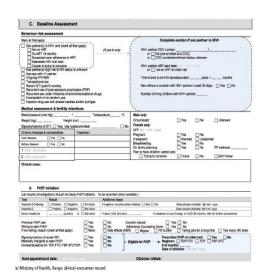
- Community engagement and participation (community-based delivery models)
- Information, education and communication
- Demand generation
- Address stigma and discrimination

## **Monitoring and evaluation**

#### MONITORING AND EVALUATION

- Integrate PrEP monitoring with existing reporting services.
- Develop system triggers for people who cannot adhere to PrEP
- Assess adherence. retention and linkages with other HIV services.
- Consider risk-based reasons for stopping PrEP





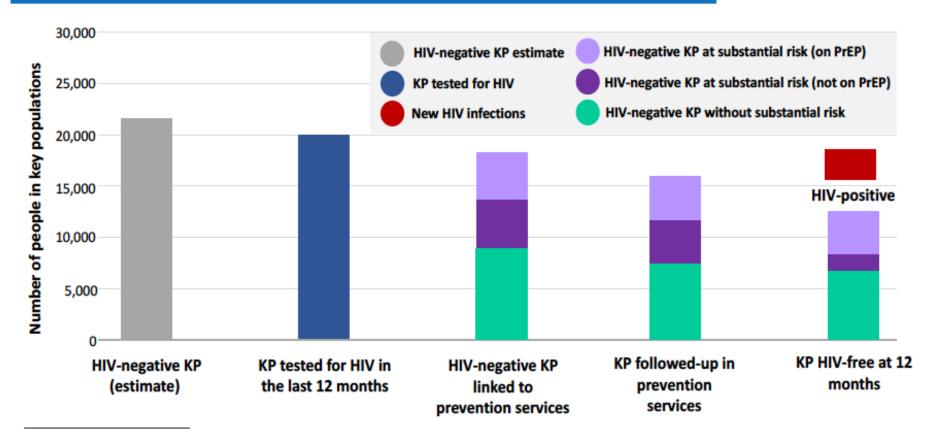
- Comprehensive HIV combination prevention monitoring and Prevention/PrEP cascade
- 4 PrEP Core indicators (1-PrEP uptake; 2- 3-months continuation; 3- serious adverse events; and 4-HIV incidence during PrEP)
- Demographic and risk profile of PrEP users
- STI monitoring
- Qualitative assessments (reasons for stopping, preferences for ED- vs daily; behavior change; etc.).

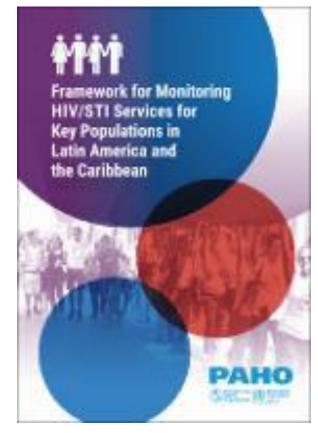


Source: Adapted from Liu et al. (2)

## Monitoring prevention services and PrEP cascade

#### Example of the HIV prevention cascade dissagregated by risk level and PrEP users





https://iris.paho.org/handle/10665.2/51682

**KP:** key populations.



# Thank you

ravasigi@paho.org



http://who.int/hiv/pub/prep/prep-implementation-tool