

14^{as}

**JORNADAS DE ATUALIZAÇÃO EM
DOENÇAS INFECIOSAS**
DO HOSPITAL DE CURRY CABRAL - CHULC

25 e 26 JANEIRO 2024 - Lisboa



The future of pre-exposure prophylaxis (PrEP) for HIV prevention

Dr Robin Schaefer

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About me

The **Forum for Collaborative Research** is a public/private partnership hosted by the **University of California, Berkeley**.

We provide a **platform for ongoing multi-stakeholder dialogue** to address **cutting-edge regulatory and policy issues**.

I previously worked for the **Global HIV, Hepatitis, and STIs Programmes at the World Health Organization**.



Declarations

The Forum receives grants from the pharmaceutical industry, but I am not a direct recipient. I declare no further potential conflicts of interest.

PrEP: The last 10 years

What is PrEP and why is it important?

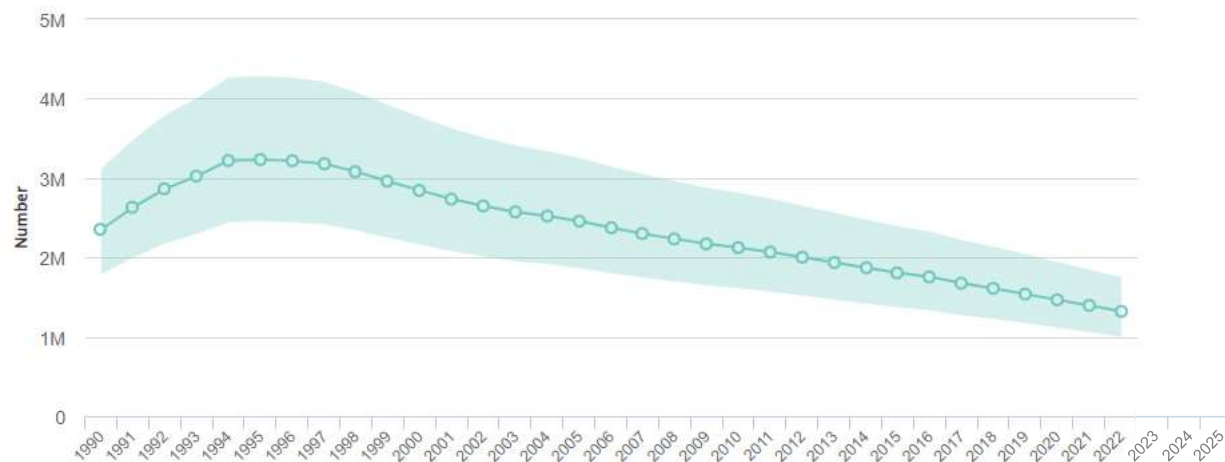


PrEP: Antiretroviral drugs used by people not infected with HIV to reduce the risk of HIV acquisition

Photo credit: pinknews.co.uk / Getty

What is PrEP and why is it important?

Trend of new HIV infections



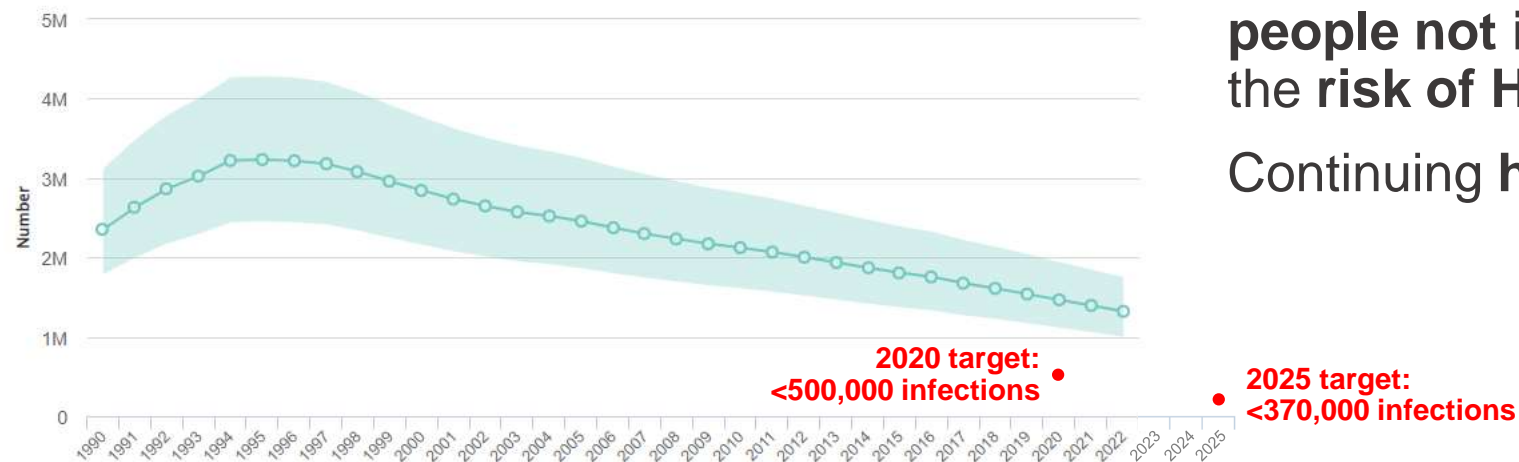
UNAIDS epidemiological estimates 2023; <https://aidsinfo.unaids.org/>

PrEP: Antiretroviral drugs used by people not infected with HIV to reduce the risk of HIV acquisition

Continuing high HIV incidence globally

What is PrEP and why is it important?

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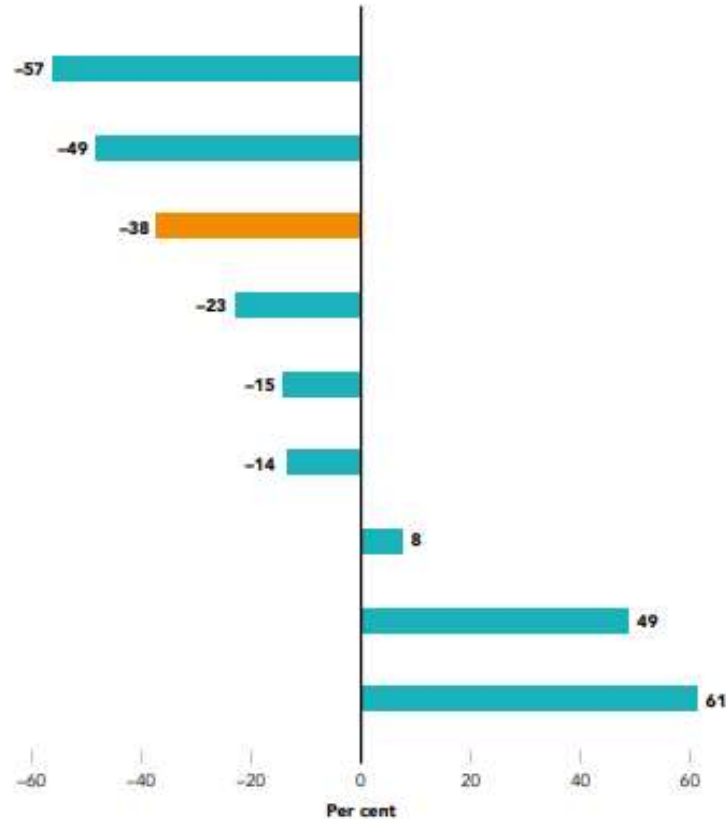


PrEP: Antiretroviral drugs used by people not infected with HIV to reduce the risk of HIV acquisition

Continuing high HIV incidence globally

UNAIDS epidemiological estimates 2023; <https://aidsinfo.unaids.org/>

What is PrEP and why is it important?



PrEP: Antiretroviral drugs used by people not infected with HIV to reduce the risk of HIV acquisition

Continuing **high HIV incidence** globally

Steepest reductions in regions with high burden but **stable / increasing epidemics** elsewhere

UNAIDS epidemiological estimates 2023; <https://aidsinfo.unaids.org/>

PrEP: A brief history

PrEP: A brief history

WHO recommends PrEP for SDC, MSM & TG (conditional rec in the context of demo projects)



2012

2015/16

WHO recommends PrEP for people at substantial HIV risk (strong rec)



FDA approved TDF/FTC for PrEP

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER
21-752

APPROVED LABELING

PrEP: A brief history

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2012

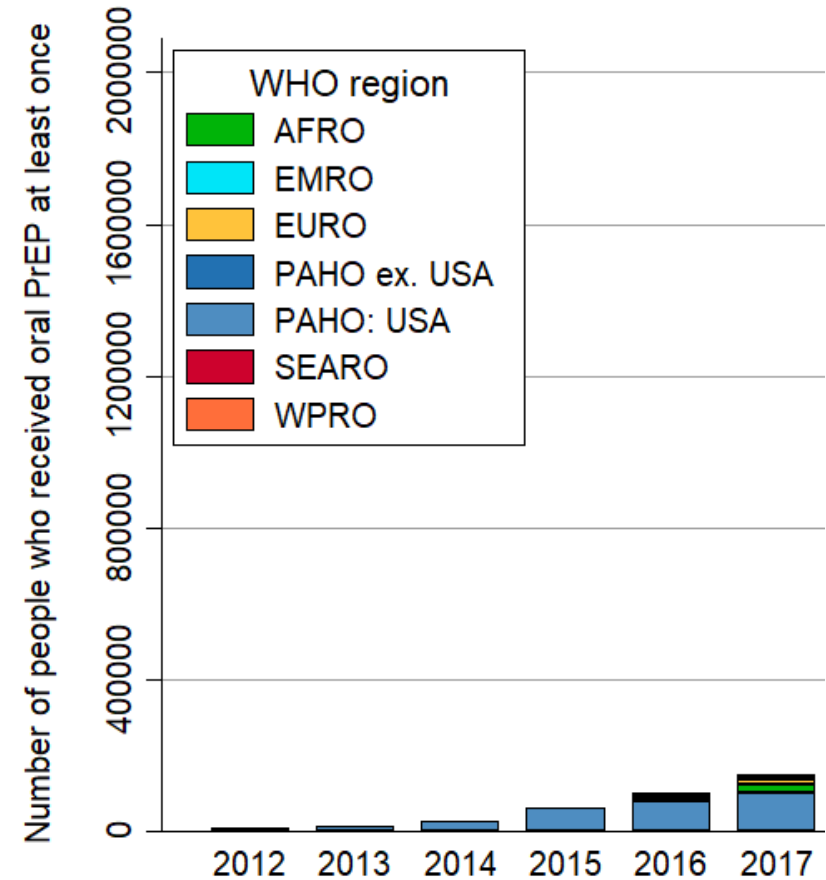
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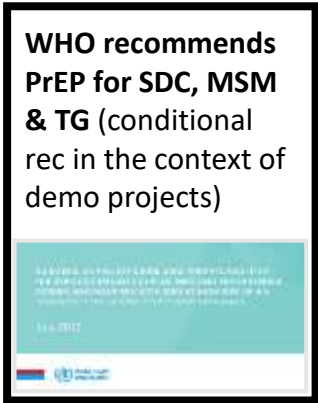
APPROVED LABELING



Source: WHO

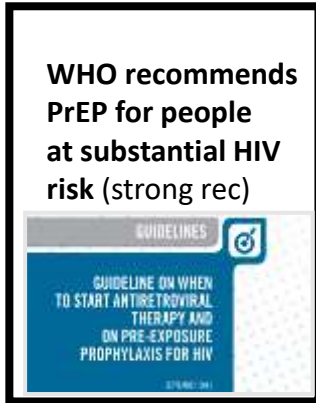
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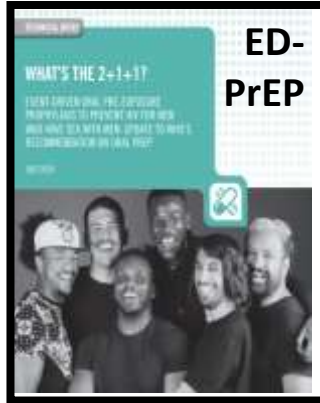


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WHO recommends PrEP for people at substantial HIV risk (strong rec)

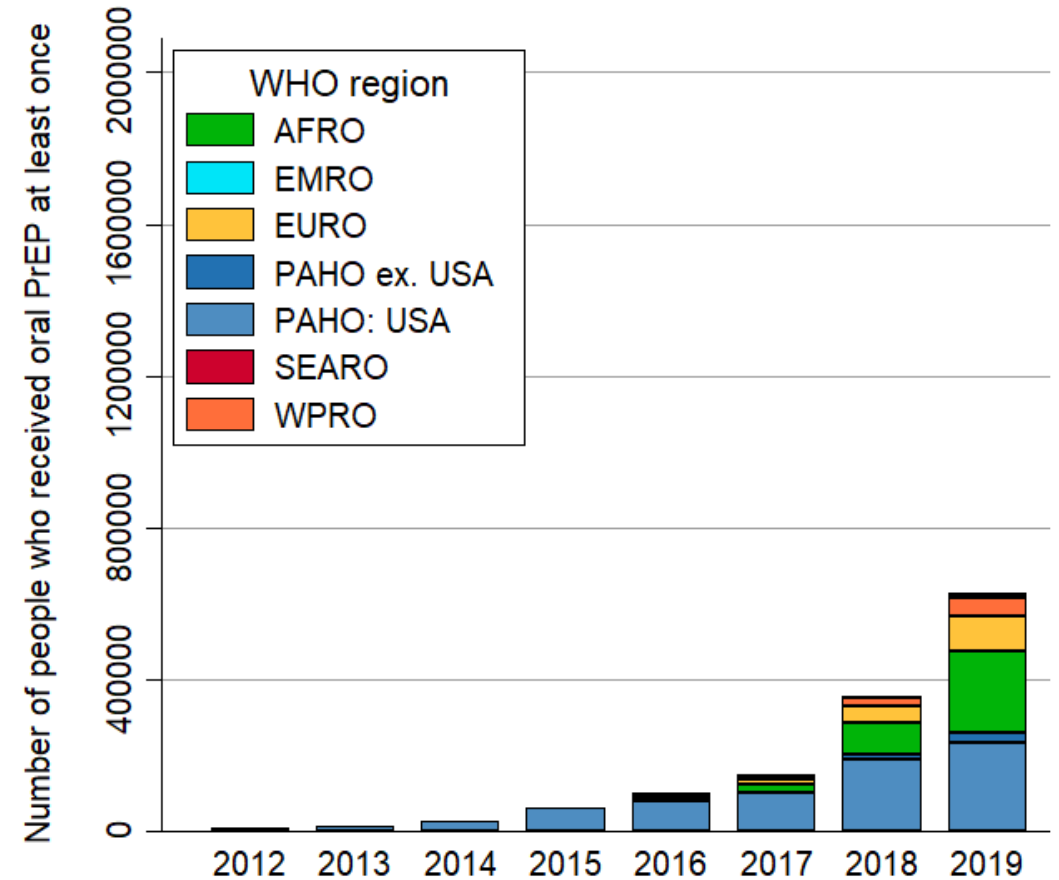
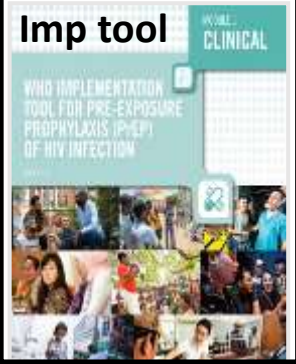
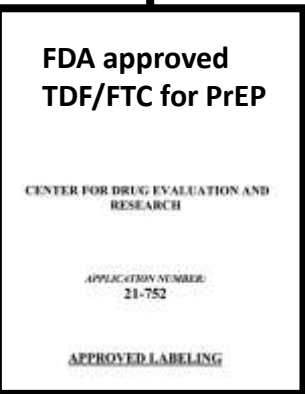


2015/16



2019


FDA approved TDF/FTC for PrEP



Source: WHO


PrEP: A brief history

WHO recommends PrEP for SDC, MSM & TG (conditional rec in the context of demo projects)



2012


WHO recommends PrEP for people at substantial HIV risk (strong rec)



2015/16


ED-PrEP

WHAT'S THE 2+1+1?



2019

EMA positive opinion on DVR



2020

FDA approves CAB-LA

FDA NEWS RELEASE

FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

Ring Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic




2021

Differentiated and simplified pre-exposure prophylaxis for HIV prevention

Update to WHO implementation guidance

TECHNICAL BRIEF



2022

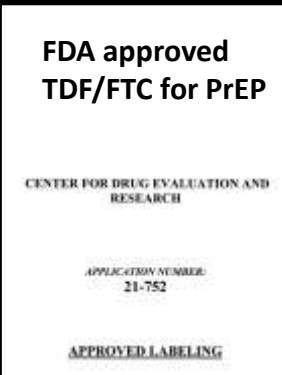
2023

FDA approved TDF/FTC for PrEP

CENTER FOR DRUG EVALUATION AND RESEARCH

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APPROVED LABELING



Imp tool

WHO CLINICAL

WHO IMPLEMENTATION TOOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) OF HIV INFECTION



WHO recommends DVR




WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection

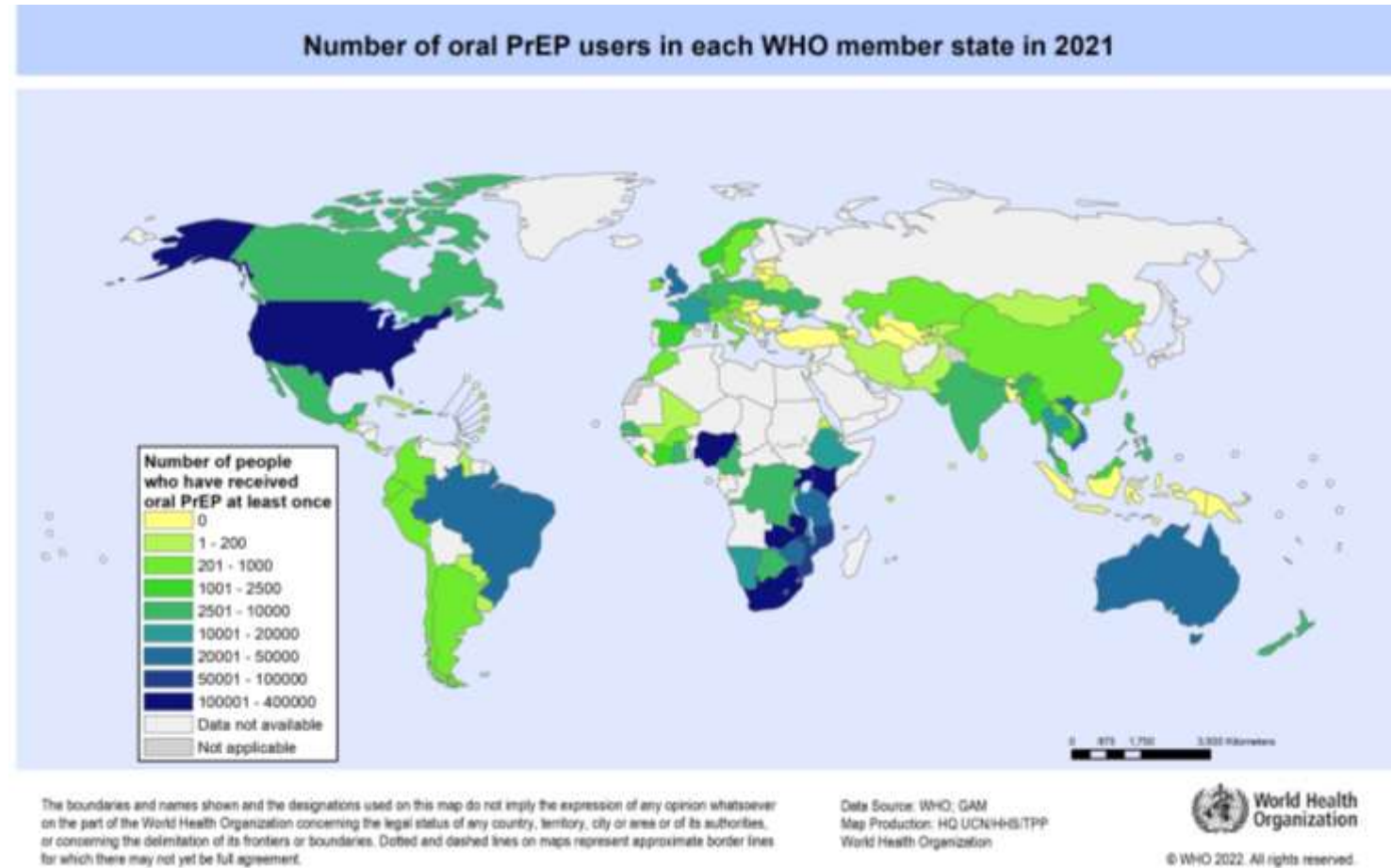
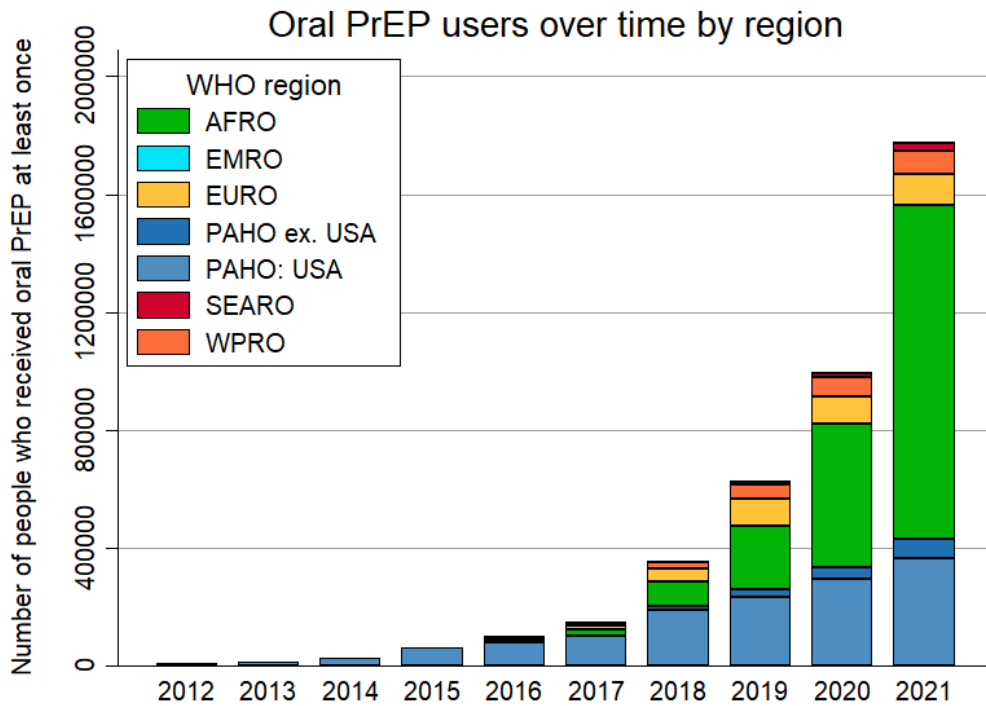
WHO recommends CAB-LA

WHO CLINICAL

GUIDELINES ON LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION



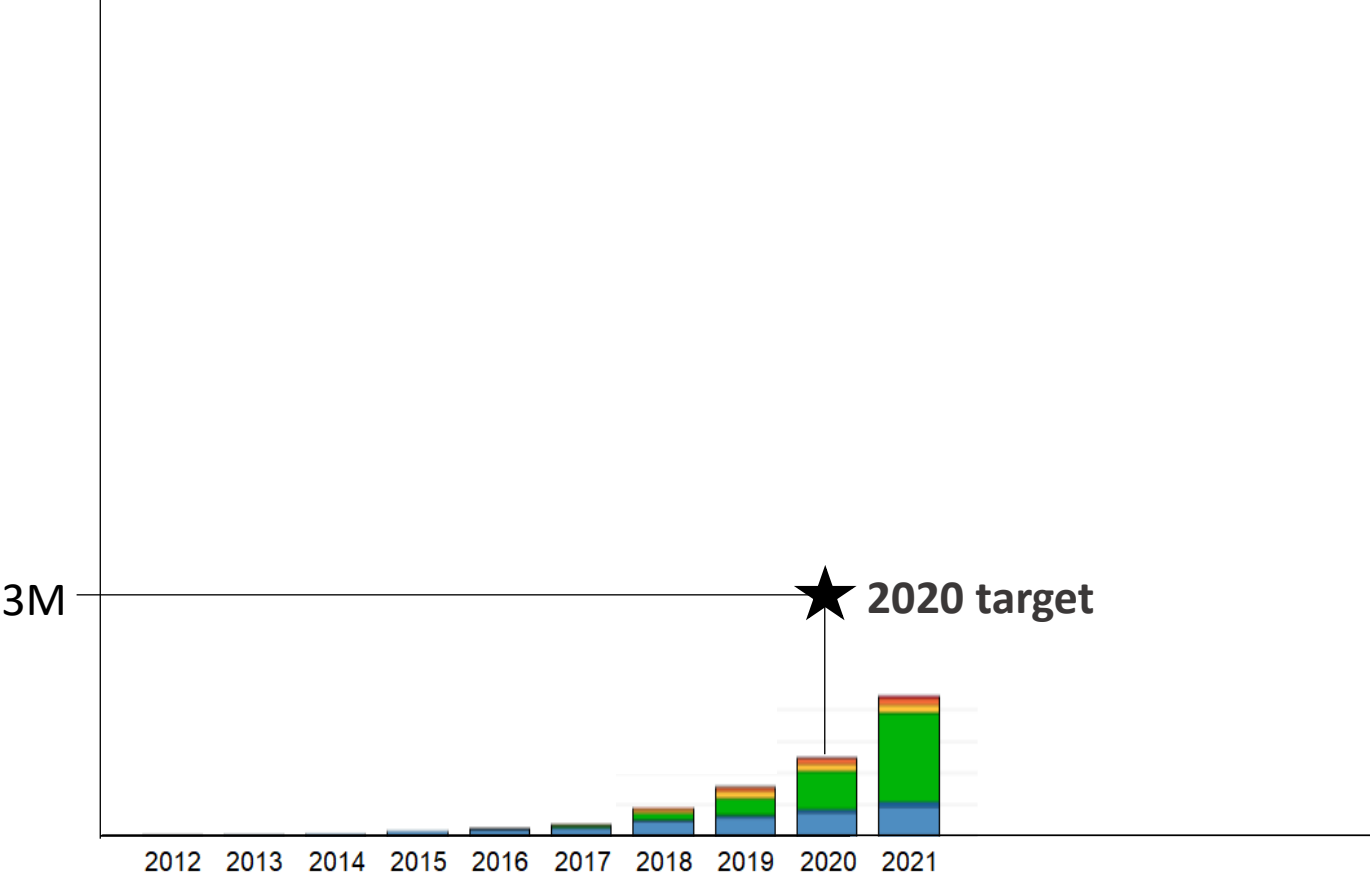
Number of PrEP users globally and over time



Schaefer et al. Lancet HIV 2021: [https://doi.org/10.1016/S2352-3018\(21\)00127-2](https://doi.org/10.1016/S2352-3018(21)00127-2)

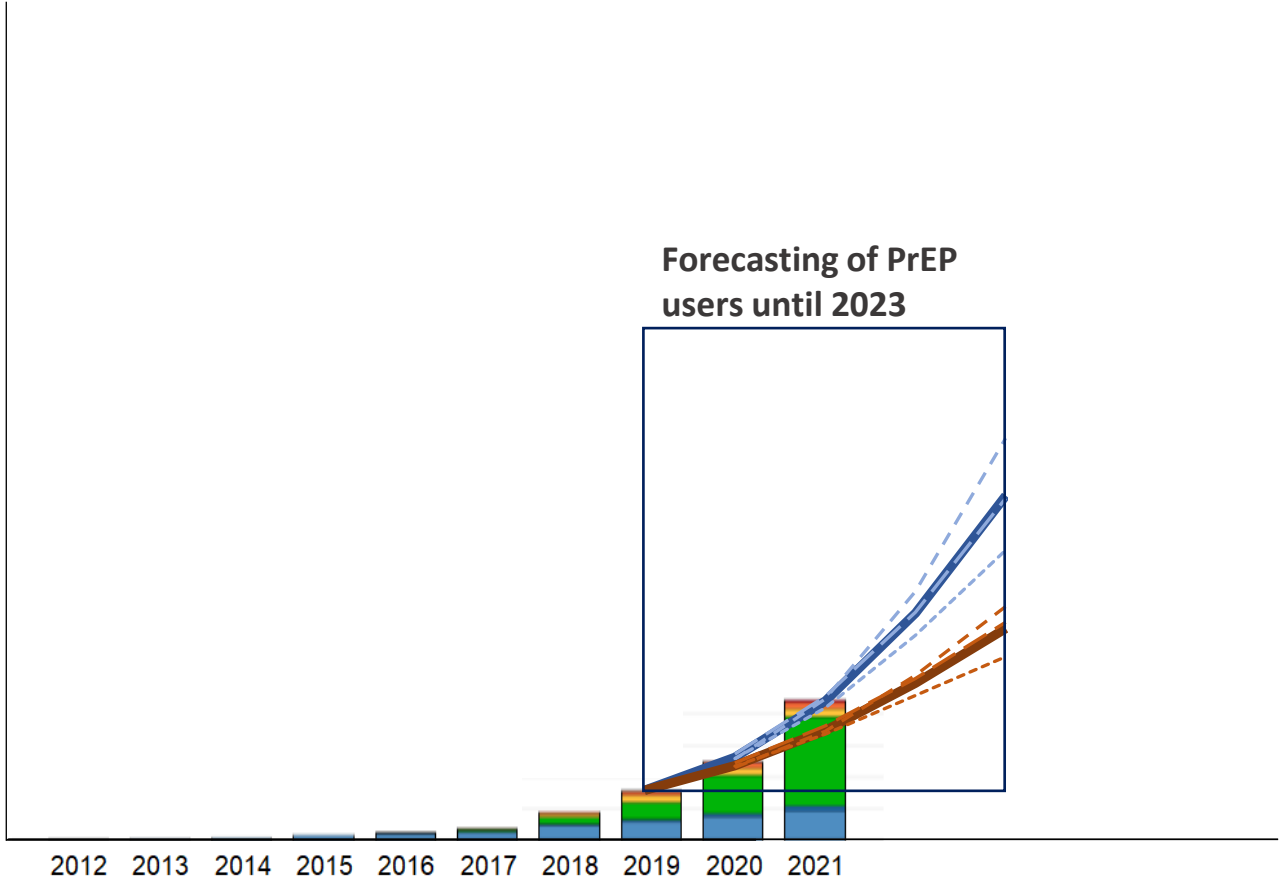
Source: WHO

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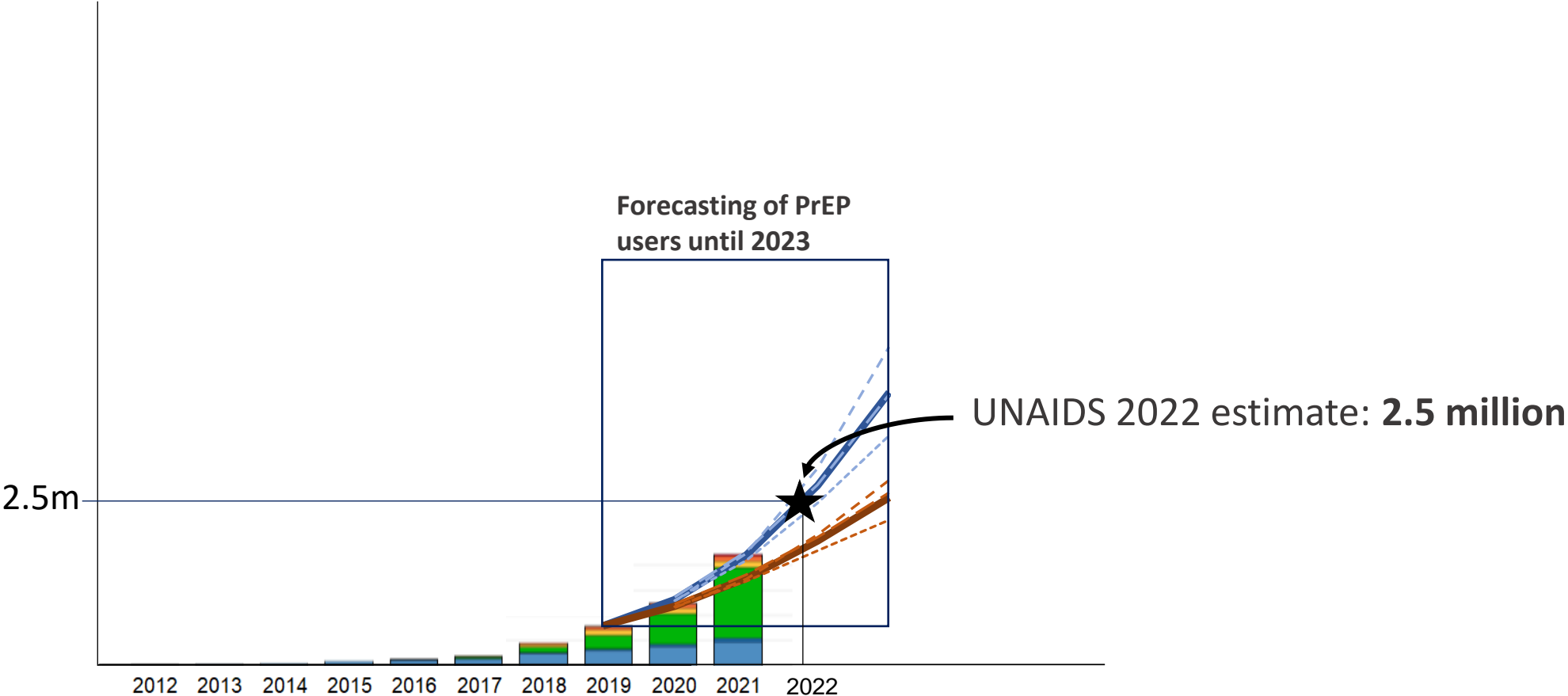
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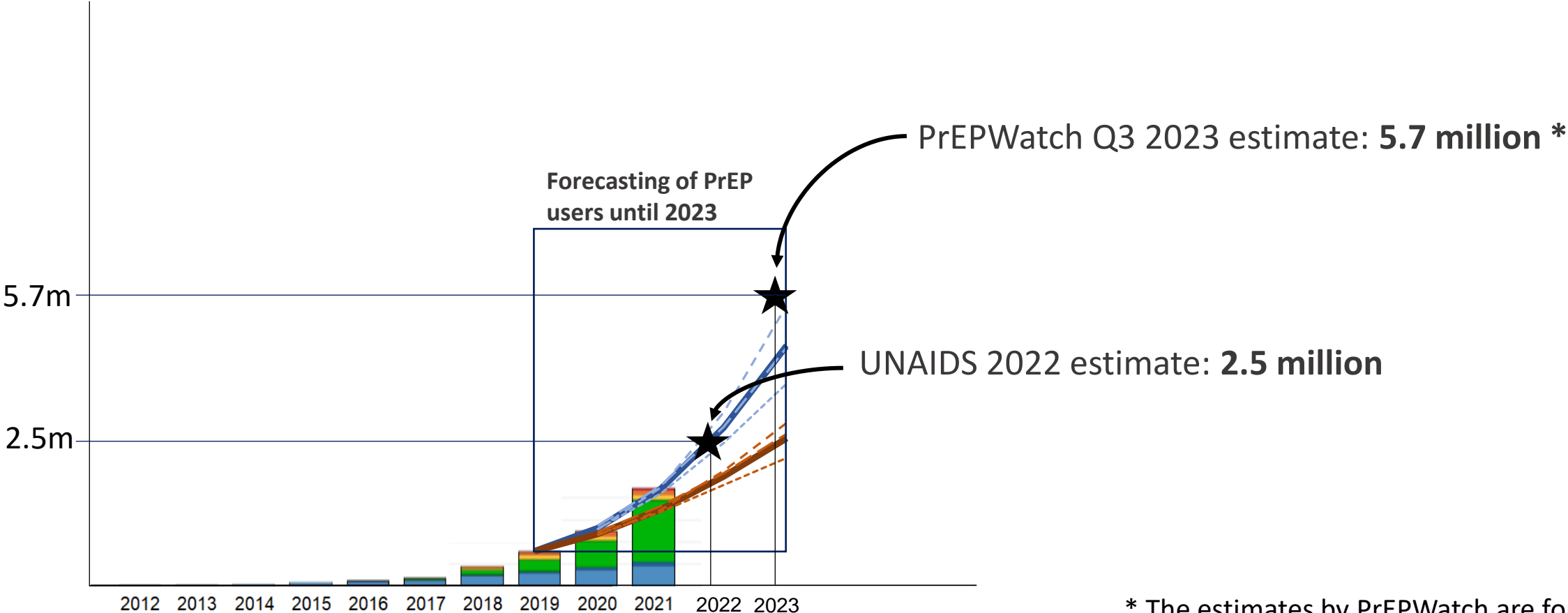
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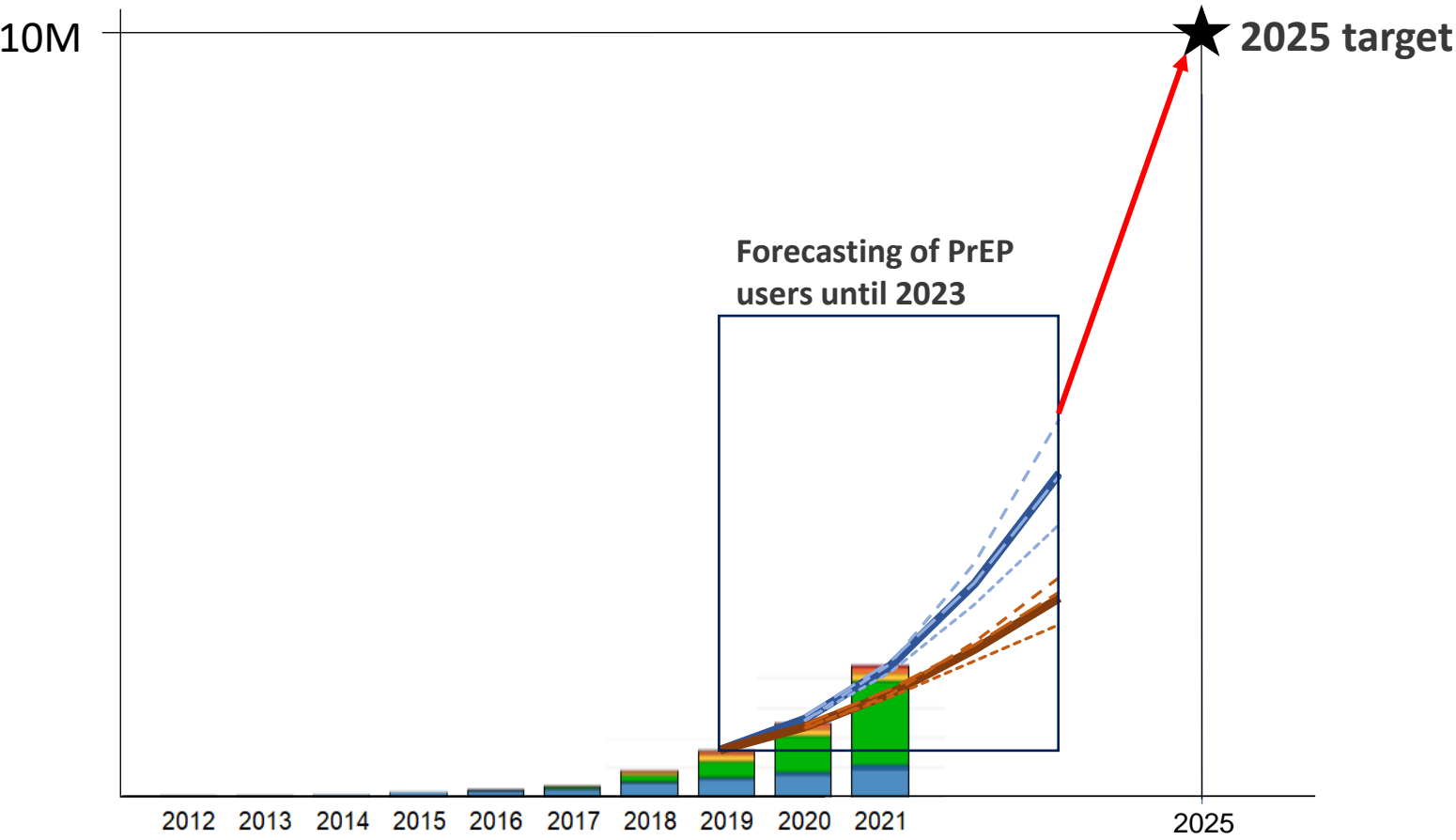
Number of PrEP users globally and over time



* The estimates by PrEPWatch are for cumulative PrEP initiations, not current users

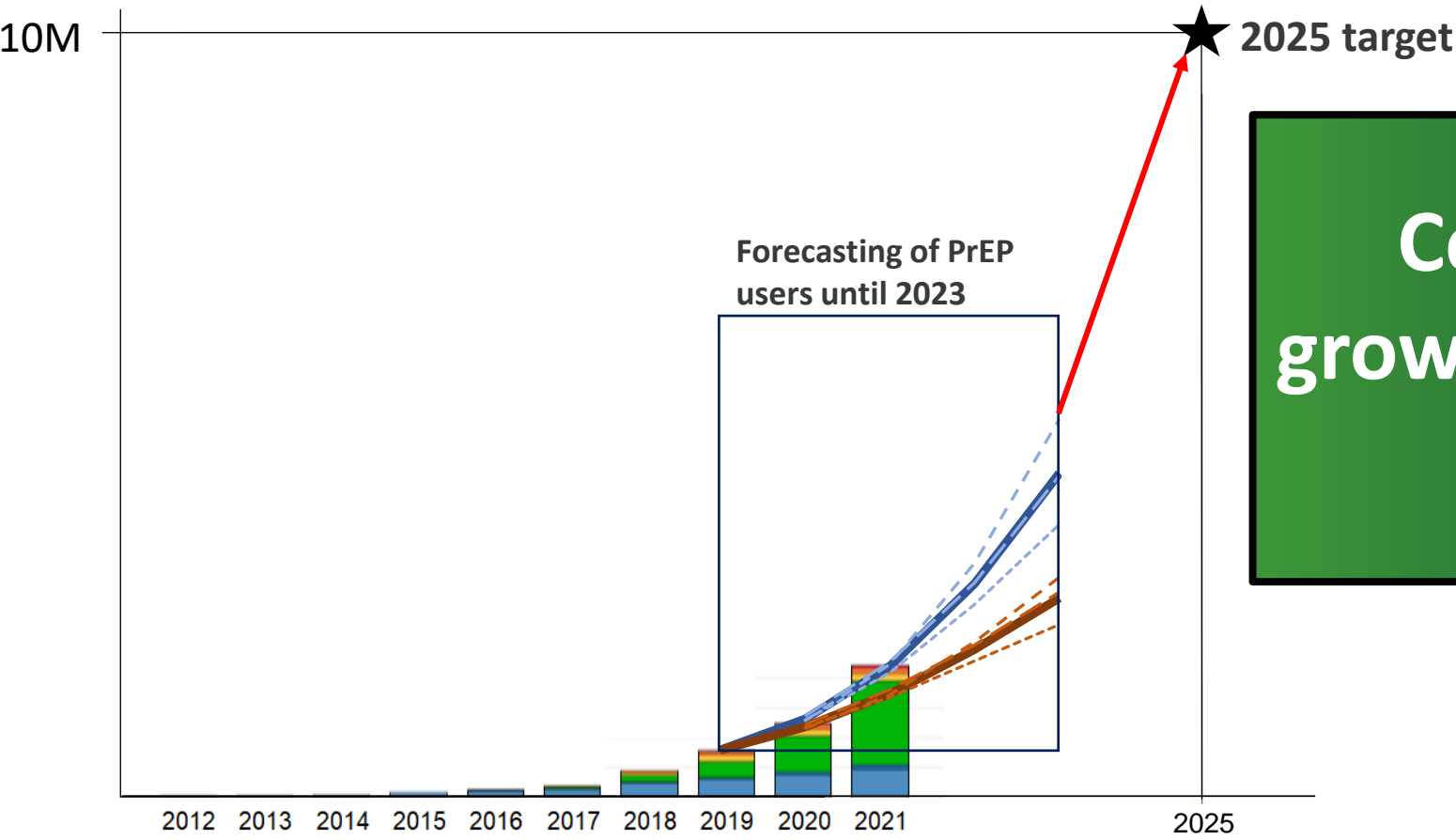
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Number of PrEP users globally and over time



Considerable further growth is required to reach the 2025 target

Schaefer et al. Lancet HIV 2021: [https://doi.org/10.1016/S2352-3018\(21\)00127-2](https://doi.org/10.1016/S2352-3018(21)00127-2)

How to reach PrEP targets? (the future of PrEP)

Differentiated services

Differentiated services



Differentiated services

Differentiated and simplified pre-exposure prophylaxis for HIV prevention

Update to WHO implementation guidance
TECHNICAL BRIEF



*A differentiated PrEP service delivery approach is **person- and community-centred** and adapts services to the **needs and preferences of the people who are interested in and could benefit from PrEP**. Differentiated PrEP service delivery may also support more **efficient and cost-effective** use of health care resources.*

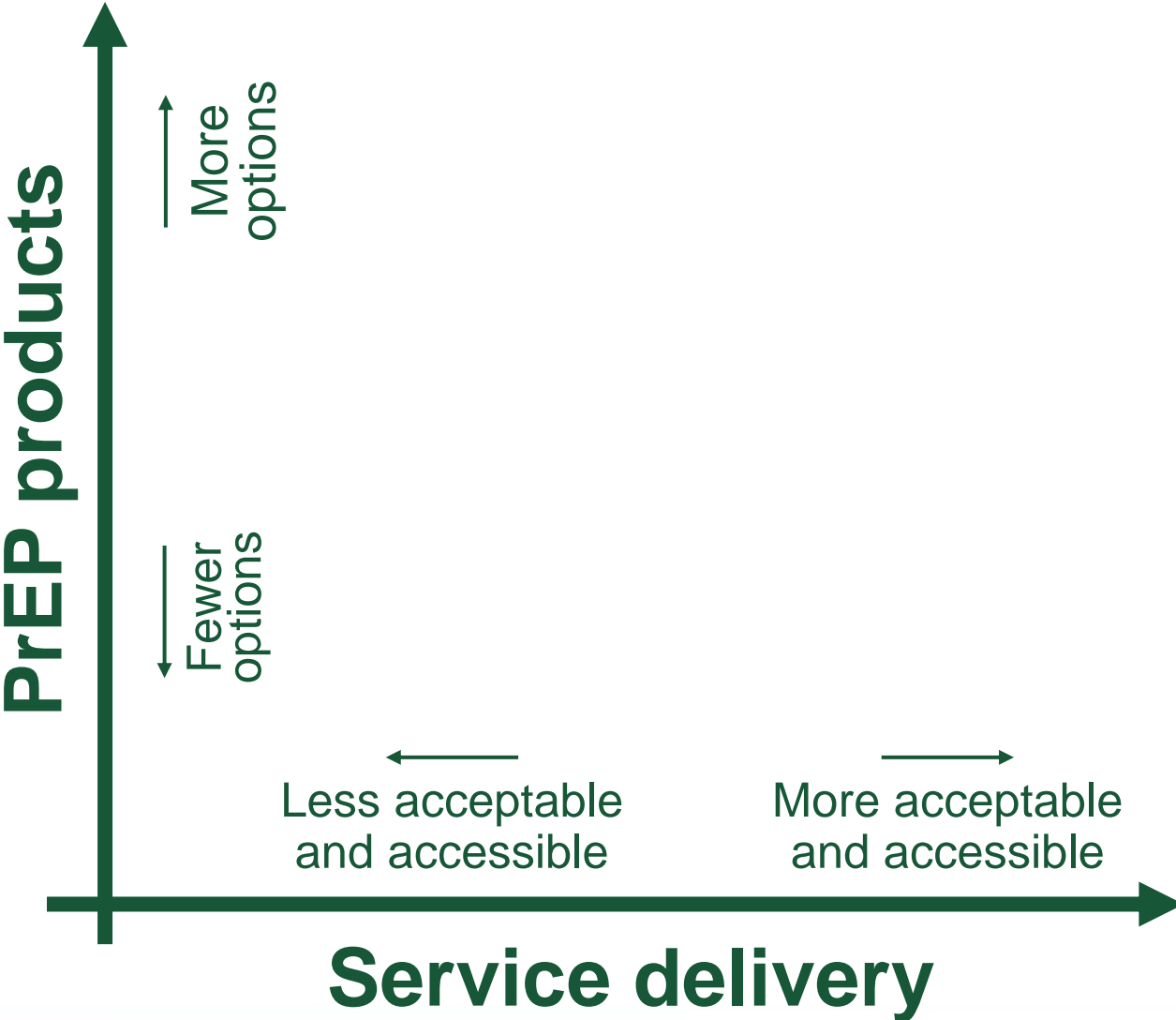
Differentiated services



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- Make services more **acceptable and accessible**
- Support **uptake, persistence, effective use**
- Maintain **quality** and **safety** of services
- Support achievement of **global goals for PrEP**

Differentiated services



Differentiated service delivery

Building blocks of differentiated service delivery

Common framework for differentiated PrEP service delivery: **four building blocks**

Building blocks can differ between PrEP initiation, continuation, and reinitiation, and between PrEP products.



Building block	PrEP initiation, initial follow-up (0–3 months), and re-initiation			PrEP continuation (3+ months)	
	Initiation	Initial follow-up (0–3 months) (if required)	Re-initiation after discontinuation	PrEP refill	Follow-up
Where? Service location (e.g., primary health care facility, community setting, virtual setting)	Locations for PrEP assessment and initiation	Locations for initial follow-up	Locations for PrEP re-initiation	Locations where PrEP refills can be collected	Locations where follow-up services will be provided
Who? Service provider (e.g., physician, nurse, pharmacist, peer)	Service provider/s authorized to assess for and initiate PrEP	Service providers who can carry out initial follow-up visit/s	Service provider/s authorized to re-initiate PrEP	Service provider/s who can dispense PrEP refills	Service provider/s who conduct follow-up
When? Service frequency (e.g., monthly, every 3 months)	Timing of PrEP assessment and initiation	Timing of initial follow-up	Timing of PrEP re-initiation	Frequency of PrEP refill visits (length of supply)	Frequency of follow-up services
What? Service package (including HIV testing, clinical monitoring, PrEP prescription and dispensing, and comprehensive services)	Service package for PrEP assessment and initiation	Service package at initial follow-up	Service package for PrEP re-initiation	Service package with PrEP refill	Service package with follow-up

Where: Service location

Viet Nam: Mobile PrEP



Photo credit: PATH Viet Nam

Brazil: Telehealth for PrEP



Photo credit: Project1519

Kenya: Pharmacy PrEP



Photo credit: Fred Hutch/Katrina Ortblad


Who: Service provider

Task sharing with nurses has enabled global expansion of HIV testing and treatment

Nurse-led PrEP services: Nurses lead all steps of PrEP provision, including prescription

Original research

Nurse-led PrEP-RN clinic: a prospective cohort study exploring task-Shifting HIV prevention to public health nurses

Patrick O'Byrne , Amanda Vandyk, Lauren Orser, Marlene Haines

VIEWPOINT | VOLUME 9, ISSUE 5, E363-E366, MAY 01, 2022

Scaling up access to HIV pre-exposure prophylaxis (PrEP): should nurses do the job?

Heather-Marie A Schmidt, PhD • Robin Schaefer, PhD •

Van Thi Thuy Nguyen, PhD • Mopo Radebe, PhD • Omar Sued, PhD •

Michelle Rodolph, MPH • et al. [Show all authors](#)

[Open Access](#) • Published: March 28, 2022 •

DOI: [https://doi.org/10.1016/S2352-3018\(22\)00006-6](https://doi.org/10.1016/S2352-3018(22)00006-6) •

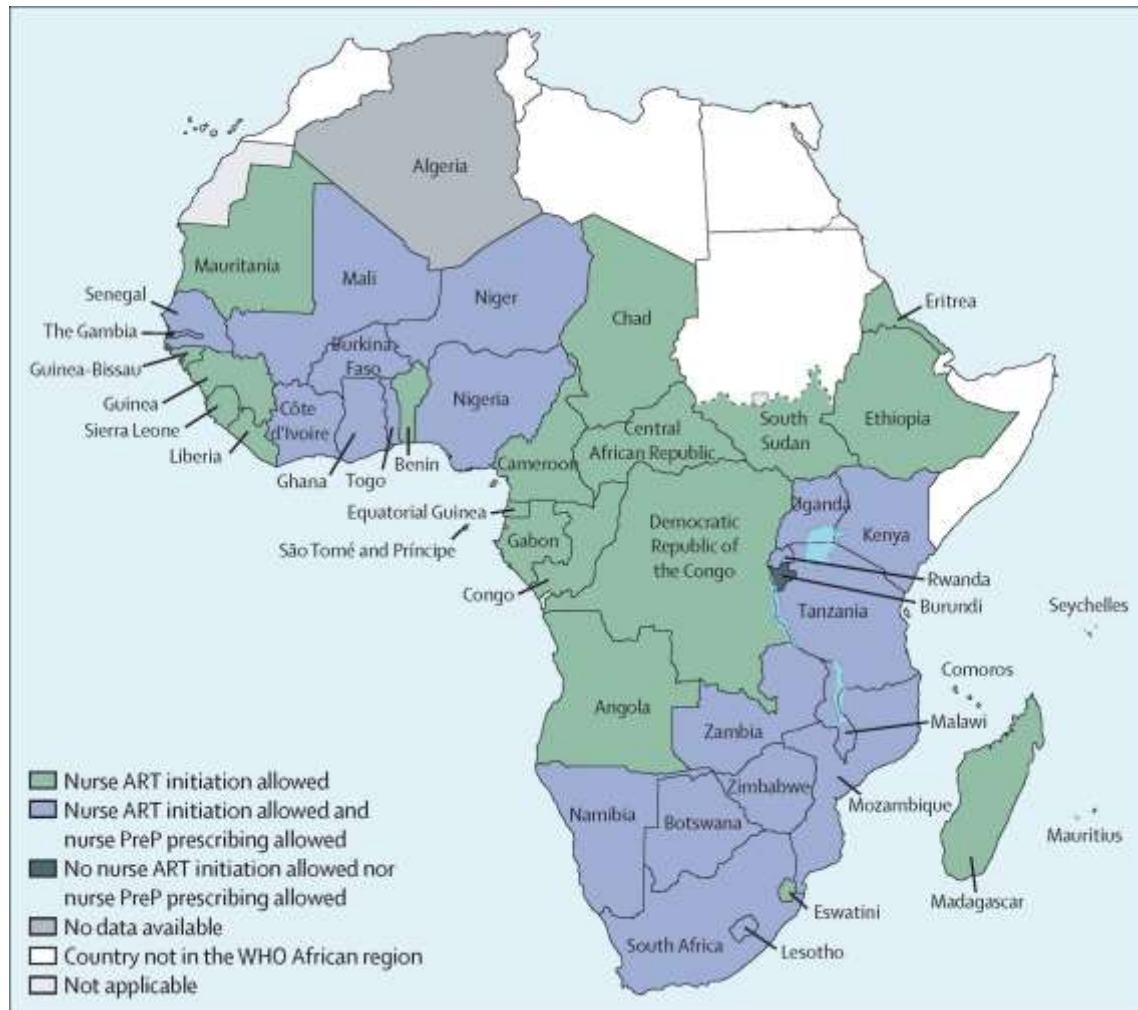
CORRESPONDENCE | VOLUME 9, ISSUE 7, E458, JULY 01, 2022

Non-ART trained health-care workers needed to prescribe PrEP in South Africa

Aurelie Nelson  • Andy Gray • Linda-Gail Bekker • Anna Grimsrud •

Lynne S Wilkinson • Dvora Joseph Davey

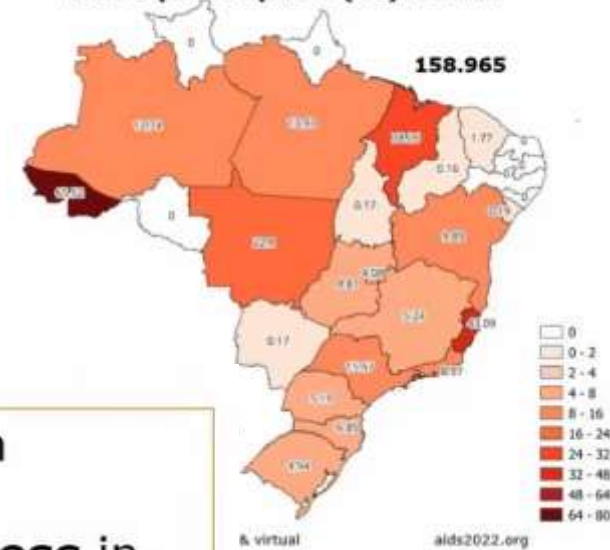
Published: July, 2022 • DOI: [https://doi.org/10.1016/S2352-3018\(22\)00139-4](https://doi.org/10.1016/S2352-3018(22)00139-4)



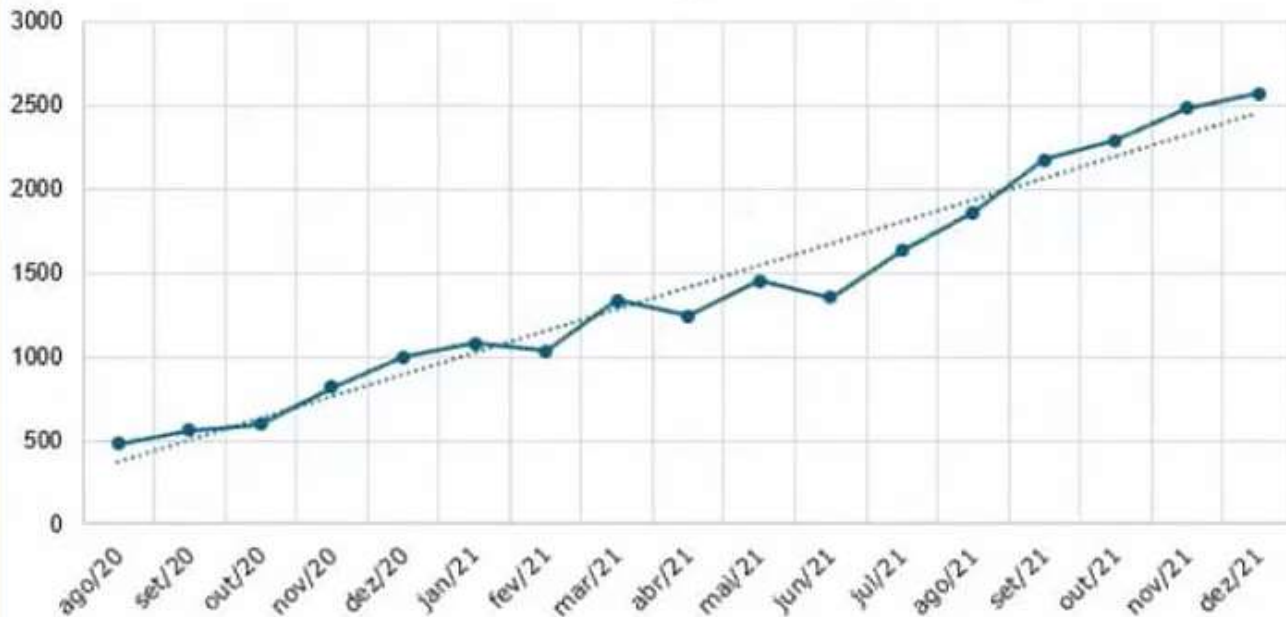
Who: Service provider

Nurse-led PrEP in Brazil

Nurse prescription (%): Brazil



Nurse-led PrEP (prescriptions)



Nurse-led PrEP had an important impact on **expanding PrEP access** in Brazil, representing a growth rate of 10,63% (CI 95%: 9,42-11,85); R Squared (0,96) in relation to total prescriptions

15,29%
prescriptions made by Nurses

Credit: Ana Francisca KOLLING, MoH Brazil

Presented at 2022 AIDS Conference

Who: Service provider

Key population-led services in Thailand

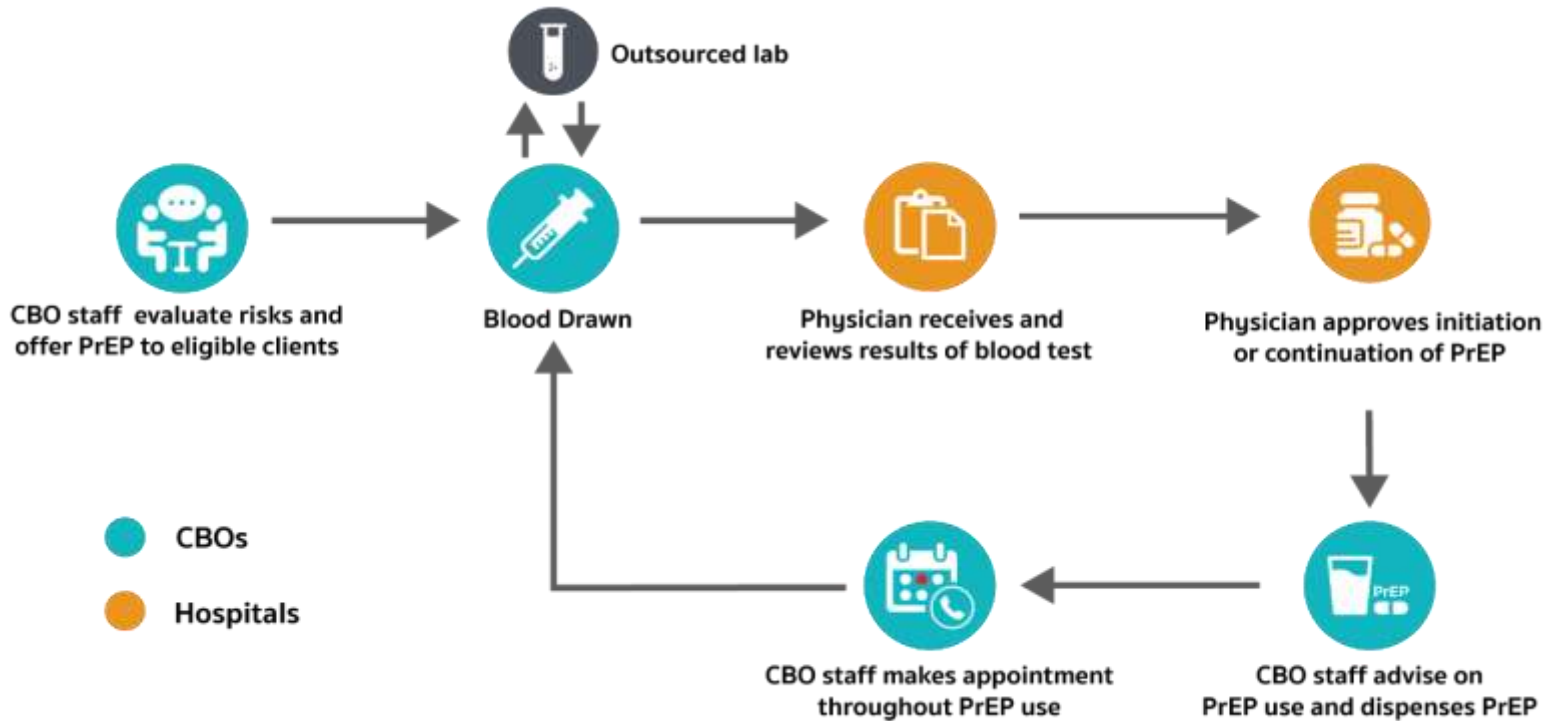


Photo: MPLUS Foundation, Thailand, 2022

Trained members of key populations lead PrEP services

Clinical oversight by physician (remotely)

When: Service frequency / schedule

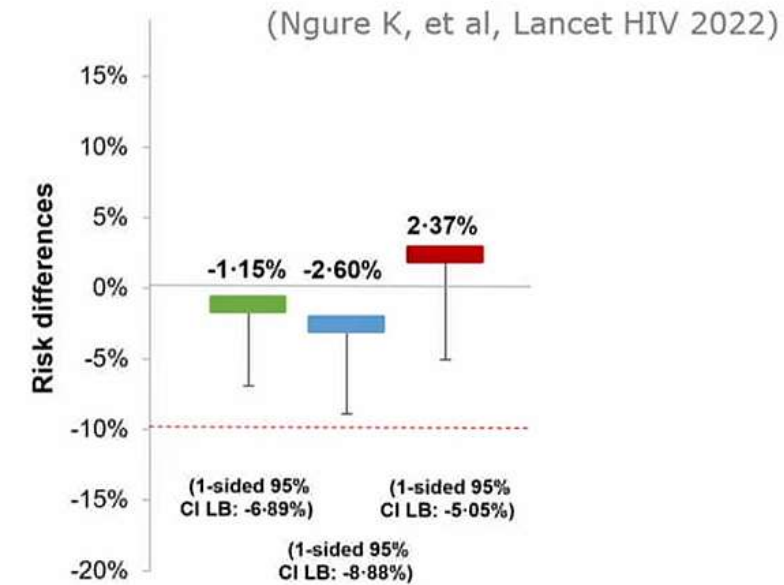
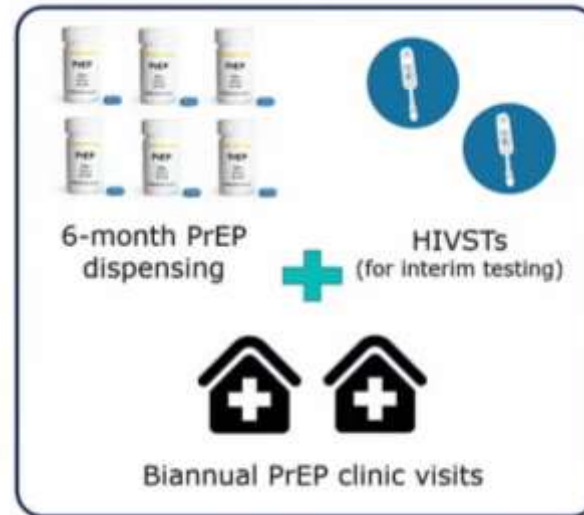
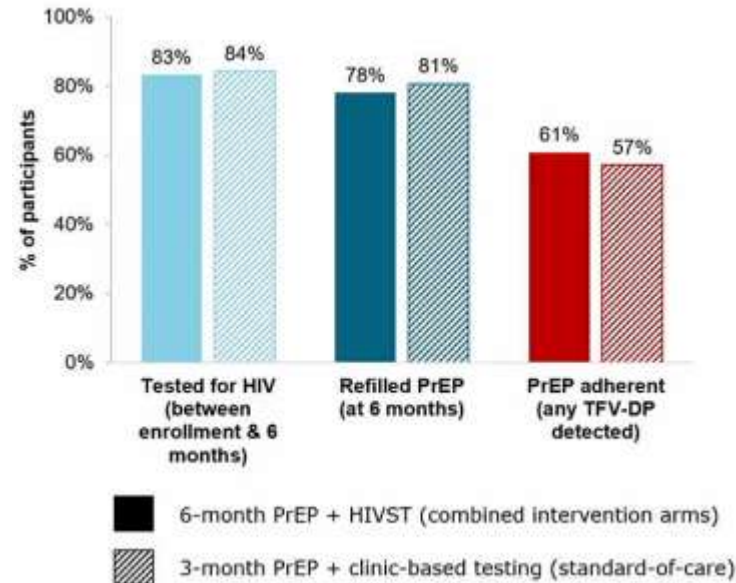
Dynamic use of PrEP

Client-centered: follow-up and dispensing tailored to needs of PrEP clients

Multi-month dispensing: Regular follow-up (e.g., every 3 months) beneficial for many clients but longer intervals could be considered

HIV self-testing can support

Could **separate clinical visits and refills** (e.g., clinical every 6 months and refills 3 months)



HIVST-supported PrEP continuation was non-inferior to standard of care



ARTICLES | VOLUME 9, ISSUE 7, E464-E473, JULY 2022

Efficiency of 6-month PrEP dispensing with HIV self-testing in Kenya: an open-label, randomised, non-inferiority, implementation trial

Kenneth Ngure, PhD • Katrina F Ortblad, ScD • Peter Mogere, BSc • Ashley R Bardon, MPH • Katherine K Thomas, MS • Dorothy Mangale, MPH • et al. [Show all authors](#)

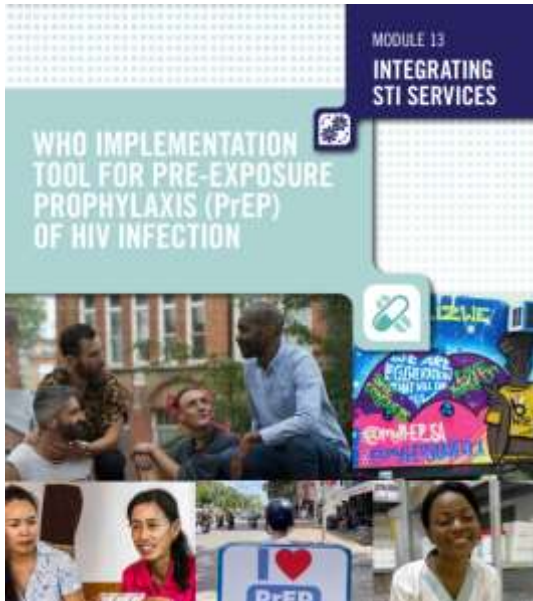
Published: July, 2022 • DOI: [https://doi.org/10.1016/S2352-3018\(22\)00126-6](https://doi.org/10.1016/S2352-3018(22)00126-6) • [Check for updates](#)

What: Service package

Integrated service package that is responsive to the needs and preferences of a client

Integration and co-delivery with STIs, family planning / contraceptive services etc.

Pathogen	Prevalence					Incidence				
	No. of Studies Pooled	Total Sample Size, No.	Prevalence (95% CI)	I ² Statistic, %	P Value	No. of Studies Pooled	Total Sample Size, No.	Incidence per 100 Person-Years (95% CI)	I ² Statistic, %	P Value
<i>Chlamydia trachomatis</i>										
Any site	12	4918	10.8 (6.4-16.1)	97	<.001	14	6756	21.5 (17.9-25.8)	97	<.001
Genital	6	1019	4.0 (2.0-6.6)	66	.01	9	1698	10.4 (9.2-11.8)	0	.78
Anorectal	8	1660	8.5 (6.3-11.0)	61	.01	11	2171	29.9 (24.1-37.1)	87	<.001
Oropharyngeal	5	939	2.4 (0.9-4.5)	63	.03	7	1237	4.6 (3.3-6.3)	46	.10
<i>Neisseria gonorrhoeae</i>										
Any site	14	6340	11.6 (7.6-16.2)	96	<.001	13	6462	37.1 (18.3-25.5)	96	<.001
Genital	6	2166	2.1 (0.9-3.7)	70	.01	8	1564	9.9 (8.3-11.8)	28	.20
Anorectal	8	1558	9.3 (4.7-15.2)	92	<.001	11	2171	21.6 (16.4-28.4)	90	<.001
Oropharyngeal	5	940	4.9 (1.9-9.1)	83	<.001	8	1646	19.7 (16.0-24.3)	76	<.001
<i>Treponema pallidum</i> ^a										
Hepatitis A virus	1	1049	5.4 (4.1-7.0)	NA	NA	NA	NA	NA	NA	NA
Hepatitis B virus	4	4370	1.3 (0.1-3.5)	95	<.001	2	1353	1.2 (0.6-2.6)	0	.53
Hepatitis C virus	4	2555	2.0 (0.8-3.7)	84	<.001	8	3786	0.3 (0.1-0.9)	87	<.001
<i>Mycoplasma genitalium</i>	1	198	17.2 (12.2-23.2)	NA	NA	NA	NA	NA	NA	NA
<i>Trichomonas vaginalis</i>	2	1379	5.9 (4.7-7.2)	NA	NA	1	50	0	NA	NA
Any <i>C trachomatis</i> , <i>N gonorrhoeae</i> , or <i>T pallidum</i>	16	8431	23.9 (18.6-29.6)	97	<.001	11	6301	72.2 (60.5-86.2)	95	<.001



Significant benefits of integrating PrEP and STI services

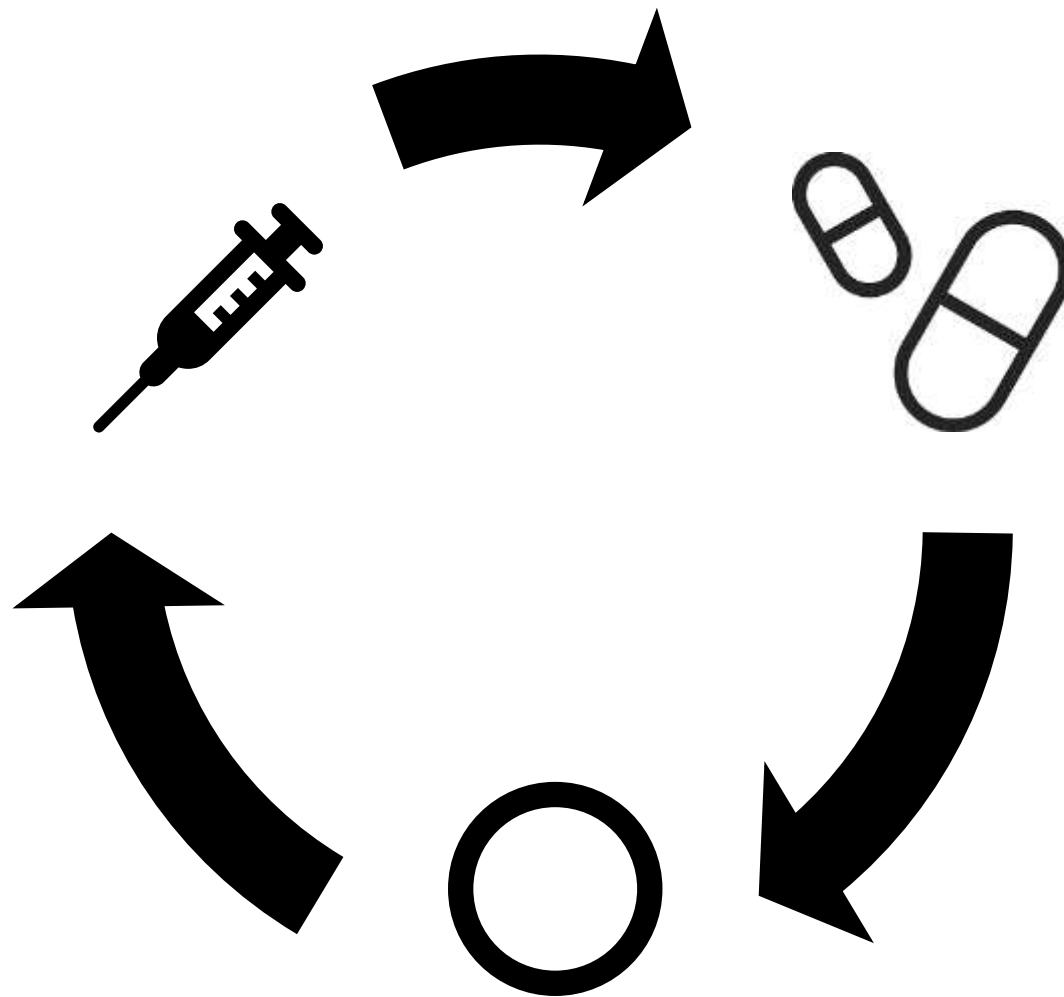
Offering HIV prevention options

The benefits of choice

Offering HIV prevention options
= differentiating service

People can choose what suits
their **needs and preferences**

May improve **uptake** and
effective use of PrEP



WHO recommends multiple PrEP products (+ PEP)

Oral PrEP containing tenofovir disoproxil fumarate (TDF) (2015)

Oral pre-exposure prophylaxis (PrEP) containing TDF should be offered as an additional prevention choice for people at substantial risk^a of HIV infection as part of combination HIV prevention approaches (*strong recommendation, high certainty evidence*).

^aSee Box 3.2 for reflections on the definition of substantial risk of HIV infection.

Source: *Guidelines: updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring (12)*.

Dapivirine vaginal ring (DVR) (2021)

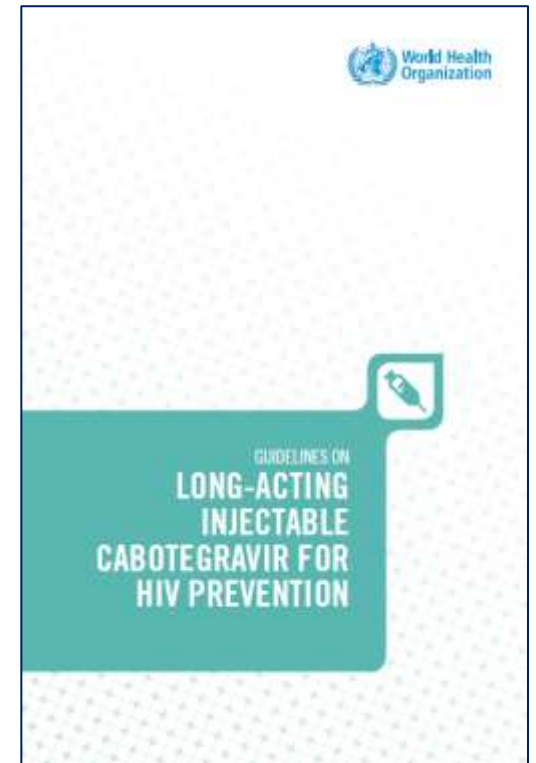
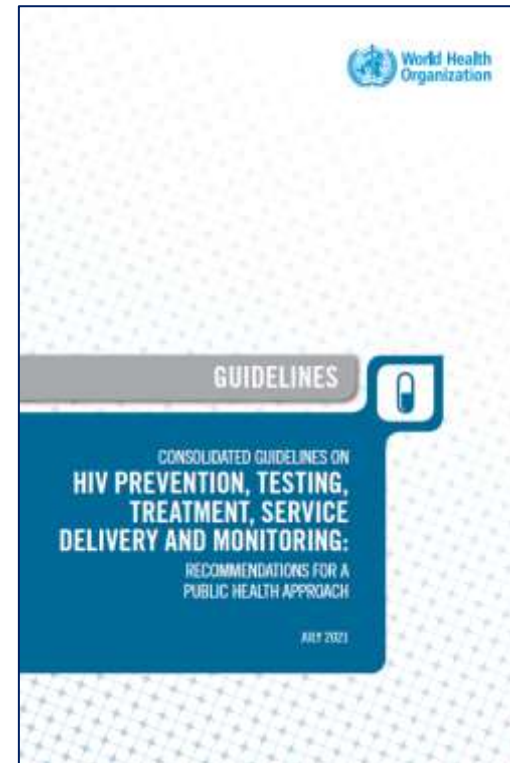
The dapivirine vaginal ring may be offered as an additional prevention choice for women^a at substantial risk of HIV infection as part of combination prevention approaches (*conditional recommendation, moderate-certainty evidence*).

^aFor the recommendation on the dapivirine vaginal ring, the term women applies to cisgender women, meaning women assigned female at birth. There is no research at this time to support the dapivirine vaginal ring for other populations.

Source: *Guidelines: updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring (12)*.

Long-acting injectable cabotegravir (CAB-LA) (2022)

Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (*conditional recommendation; moderate certainty of evidence*).



↓
Don't forget PEP

Dapivirine vaginal ring (DVR)

Women-initiated, long-acting, discreet

Phase III trials support **safety and efficacy** (although efficacy imperfect); **OLE suggest higher efficacy**

WHO recommendation Jan 2021

Regulatory approval in several African countries (plus pending)

Ongoing studies in the African region

High price currently but fewer health system resources

Global Fund procurement

PEPFAR support for implementation science



Long-acting injectable cabotegravir (CAB-LA)

Intramuscular injection every 8 weeks

Phase III trials showed high efficacy; ongoing OLEs

Studies suggest acceptability and preference

WHO recommendation Jul 2022

Regulatory approval in several countries

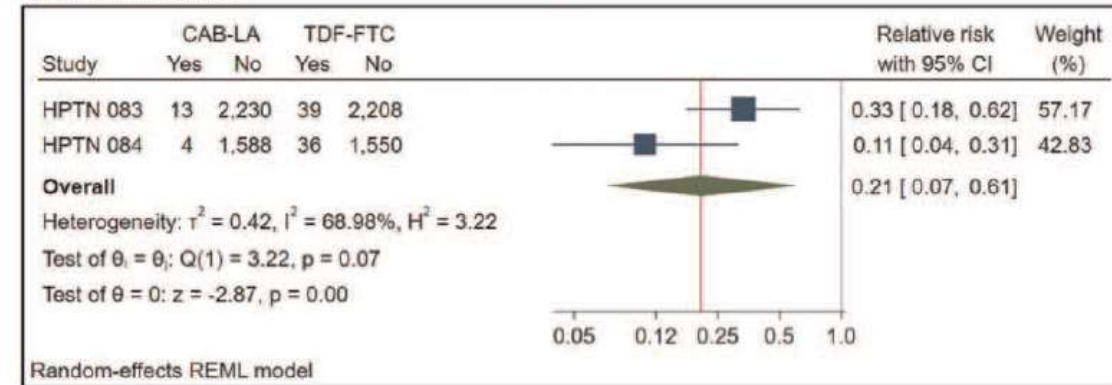
Voluntary licensing agreement with Medicine Patent Pool, granted to 3 manufacturers

Planned implementation projects in sub-Saharan Africa, Americas, Asia

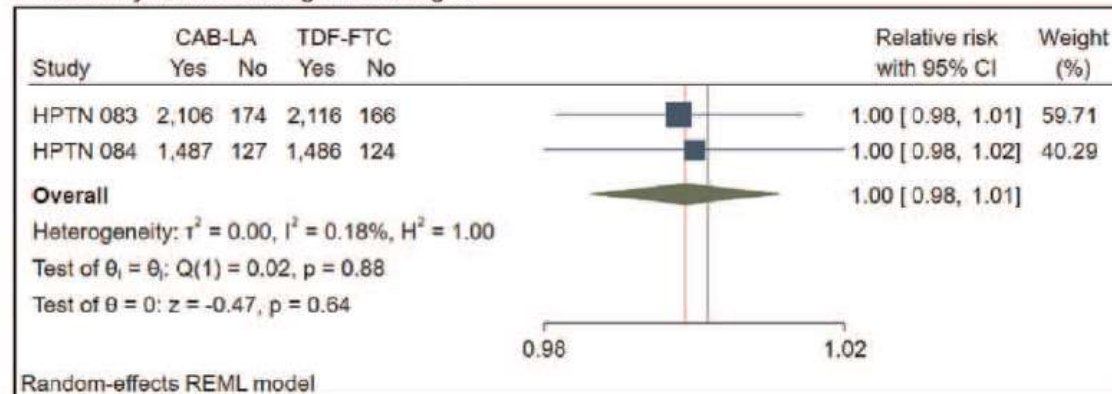
PEPFAR + Global Fund procurement

Still limited availability and outstanding issues (e.g., drug resistance)

Panel A: HIV Infection



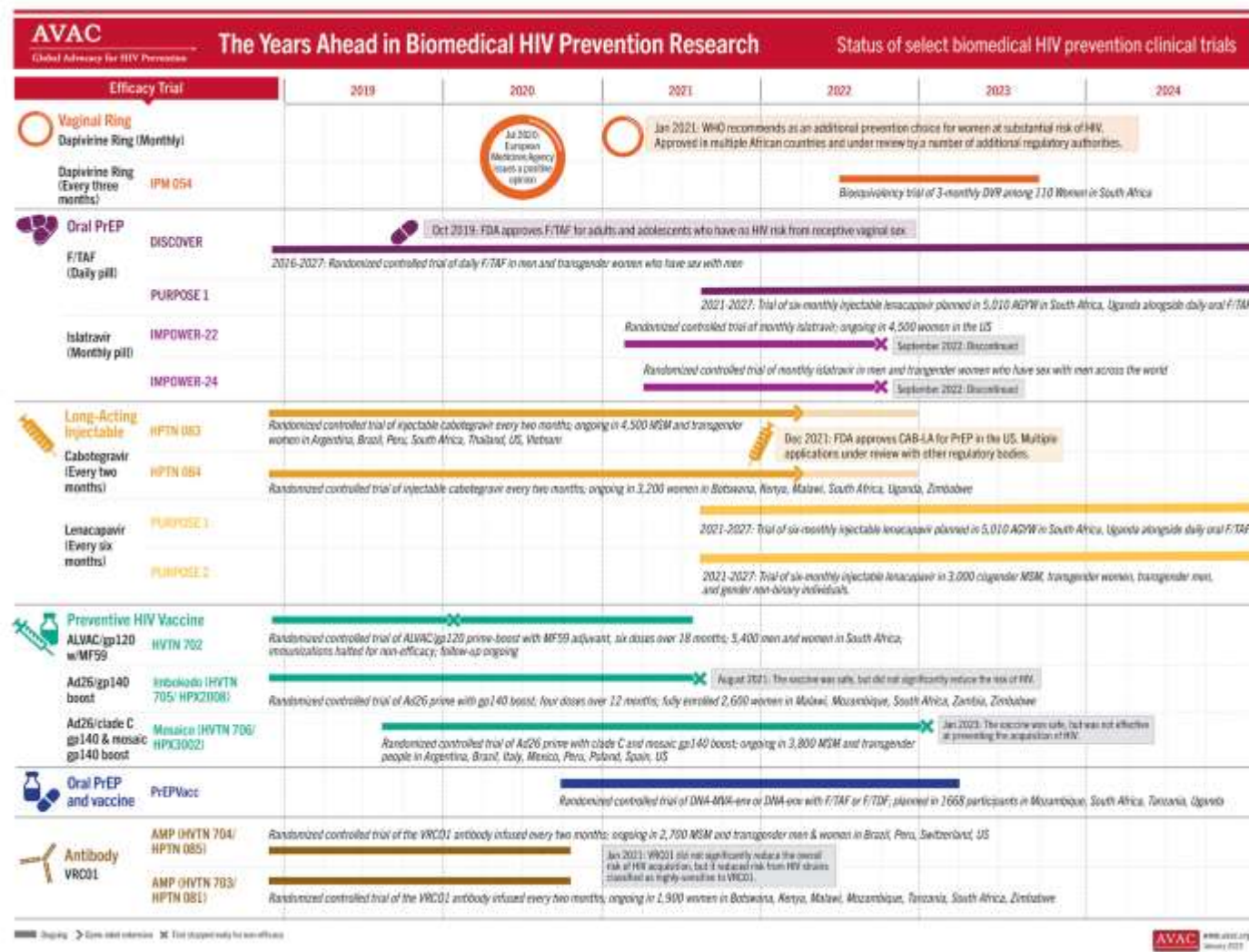
Panel B: Any adverse event grade 2 or higher



Review by Fonner et al., AIDS

The biomedical prevention pipeline

Exciting biomedical prevention pipeline



The biomedical prevention pipeline

Exciting biomedical prevention pipeline

But...

- Need to demonstrate **efficacy**



THE FORUM
For Collaborative ResearchSM

**Working group
on trial designs**

- **Placebo-controlled trials unethical;** highly efficacious standard of care
- **Very large sample sizes** to demonstrate non-inferiority / superiority
- **Innovations in trial design:** Using a counterfactual HIV incidence estimate based on the HIV recency assay

The biomedical prevention pipeline

Exciting biomedical prevention pipeline

But...

- Need to demonstrate **efficacy**
- ...and **safety**



THE FORUM
For Collaborative ResearchSM

Working group
on LA PrEP

- Current focus: **Pregnancy and lactation**
- **High HIV acquisition risk** in many countries but **limited safety data**
- Need for **post-approval surveillance**
- Unique challenges for long-acting PrEP (e.g., how to define exposure?)

The biomedical prevention pipeline

Exciting biomedical prevention pipeline

But...

- Need to demonstrate **efficacy**
- ...and **safety**
- Unclear **regulatory pathways**



THE FORUM
For Collaborative ResearchSM

**Working group
on MPTs**

- **Many MPTs in (early) development**, particularly HIV prevention + contraception
- Could offer more **streamlined product delivery and use**
- Questions around **how to each regulatory approval** (study designs etc.)

The biomedical prevention pipeline

Exciting biomedical prevention pipeline

But...

- Need to demonstrate **efficacy**
- ...and **safety**
- Unclear **regulatory pathways**
- ...and **product introduction timeline** (approvals, availability, costs, etc.)



Focus on what we have now

PEP: Need for improving access and use

Limited availability, access, and use globally

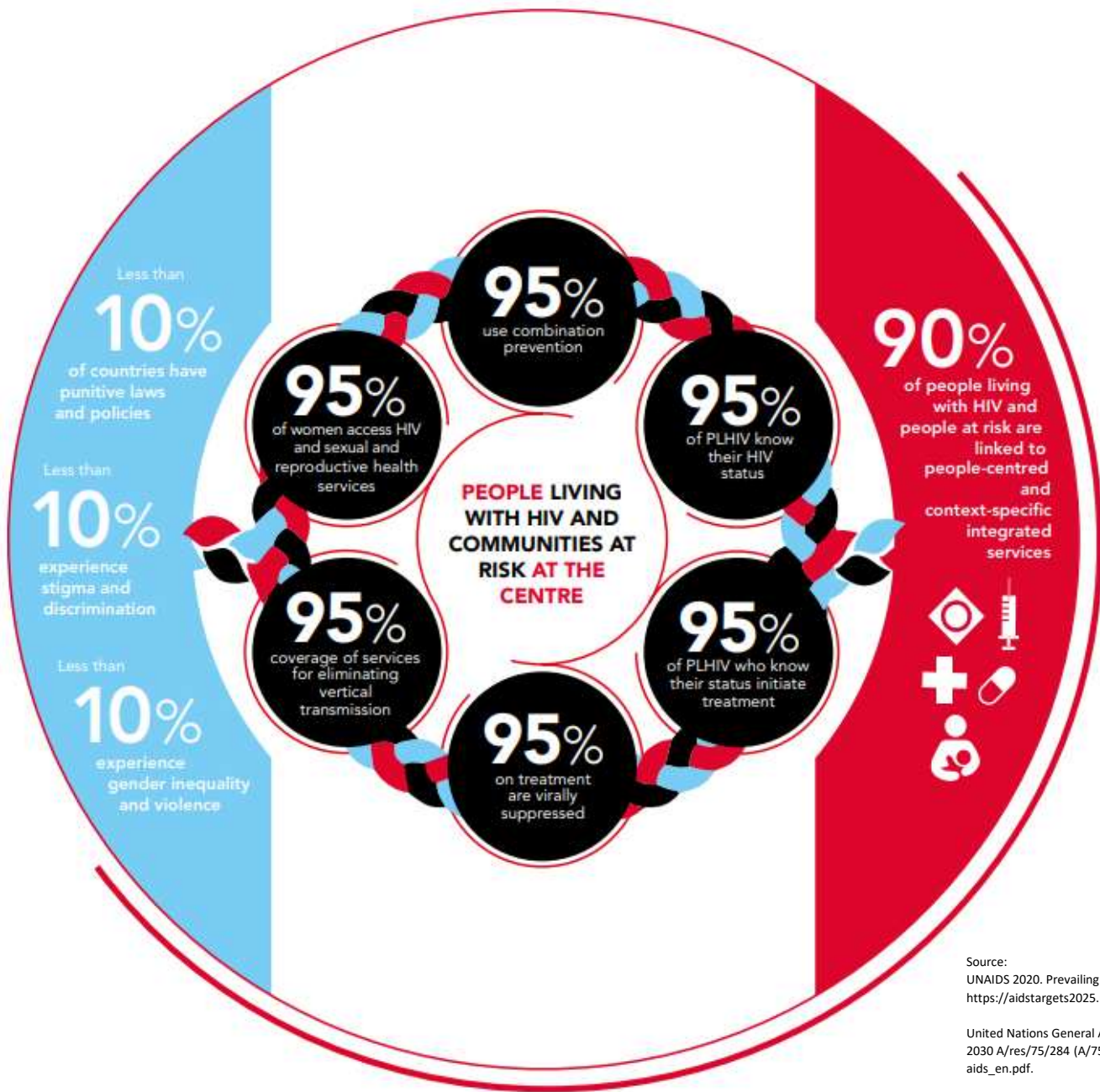
Commonly only occupational PEP and in situations of sexual violence

Evidence suggest that **easy access to PEP is critical** for timely use

Make access simple, particularly through pharmacies, linked with HIV self-testing

New **WHO guidance and guidelines in 2024**

The future of PrEP within the context of global HIV prevention targets

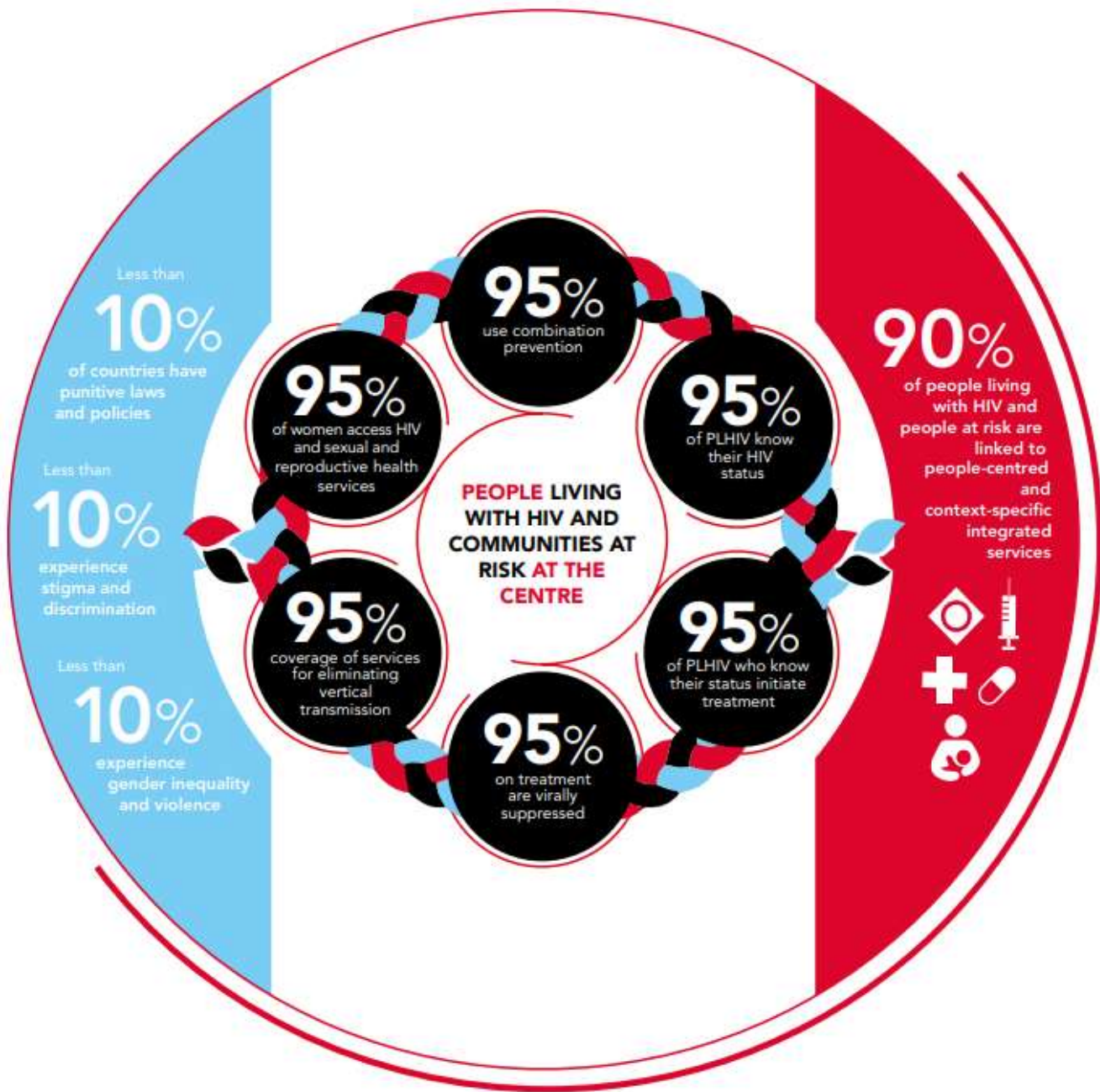


UNITED NATIONS
GENERAL ASSEMBLY

POLITICAL DECLARATION ON HIV AND AIDS: ENDING INEQUALITIES AND GETTING ON TRACK TO END AIDS BY 2030

Source:
UNAIDS 2020. Prevailing against pandemics by putting people at the centre.
https://aidstargets2025.unaids.org/assets/images/prevailing-against-pandemics_en.pdf

United Nations General Assembly 2021. Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030 A/res/75/284 (A/75/L.95). https://www.unaids.org/sites/default/files/media_asset/2021_political-declaration-on-hiv-and-aids_en.pdf.





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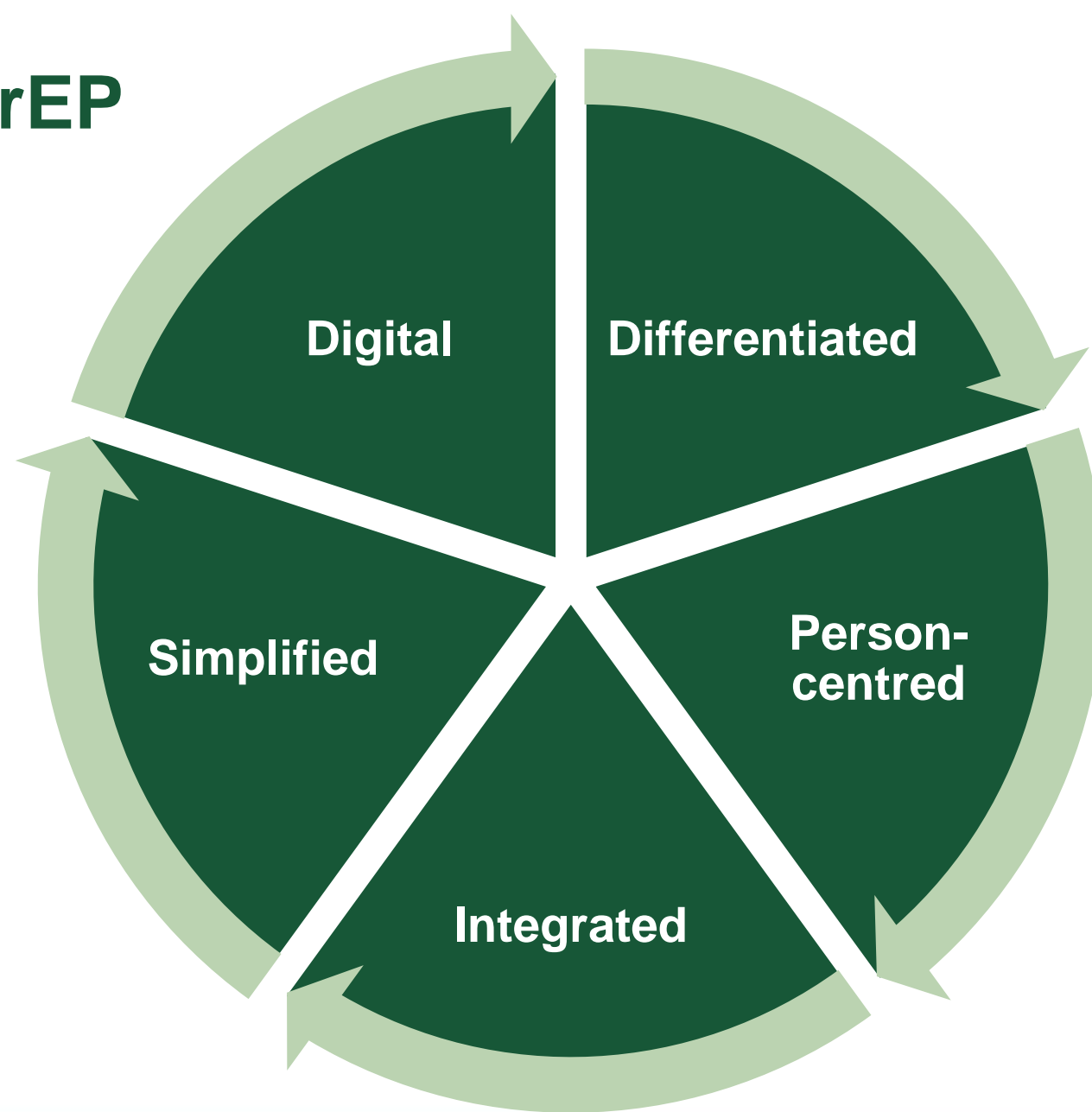
95% of people at HIV risk use **appropriate, prioritized, person-centred, and effective** combination prevention options.

95% of reproductive age women have **HIV and sexual and reproductive health** needs met.

Adoption of **people-centred and context-specific integrated approaches**. At least 90% individuals at heightened risk of HIV infection **linked to services ...** they need for **overall health and well-being**.

The future of PrEP is...

The future of PrEP



The future of PrEP – in Portugal

4.2. Make PrEP accessible: more people, more settings for delivery

To enable PrEP scale-up, we recommend focusing on person-centered services, where streamlining, defragmenting, simplifying, and task-shifting PrEP-related care are needed. The current PrEP delivery model characteristics do not enable scalability at a country level or match the acceptability studies results from key populations (13,46,62). In addition, they exclude people in prison or other closed settings and often exclude people between 13 and 17 years old.

New delivery models should be endorsed and supported. Future delivery models should consider the following service characteristics (59,60,63–65) to enable scalability:

1. Nesting PrEP services in health settings where HIV testing and comprehensive prevention services to HIV-negative people are already in place, such as outpatient STI clinics, CAD (*Centro de Aconselhamento e Detecção Precoce VIH*), and community-based sexual health centers.
2. Online (re)scheduling appointments, with the possibility to book to any region site where the person is presently working, studying or living.
3. Pre-appointment online self-administered questionnaires about health for both in-person and telemedicine appointments.
4. Diverse (non-HIV specialist) medical prescribers.
5. Telemedicine appointments of PrEP-related follow-ups, as standard practice. Telemedicine for medical follow-up monitoring and renewal of laboratory requisitions or medical prescriptions. Remote medicine prescriptions and lab monitoring results access.
6. Clinical guidelines/protocols for nurse-led follow-ups (task-shifting).
7. Medicine dispensing with a home delivery or at a street pharmacy. Multi-month dispensing, as standard practice.
8. Laboratory specimens self-sampling/self-collection methods, with a postal delivery option, as standard practice.



The HIV PrEP ^{UP} project: technical report

Key findings on PrEP implementation in Portugal
and scale-up recommendations | 2023

The future of PrEP – in Portugal

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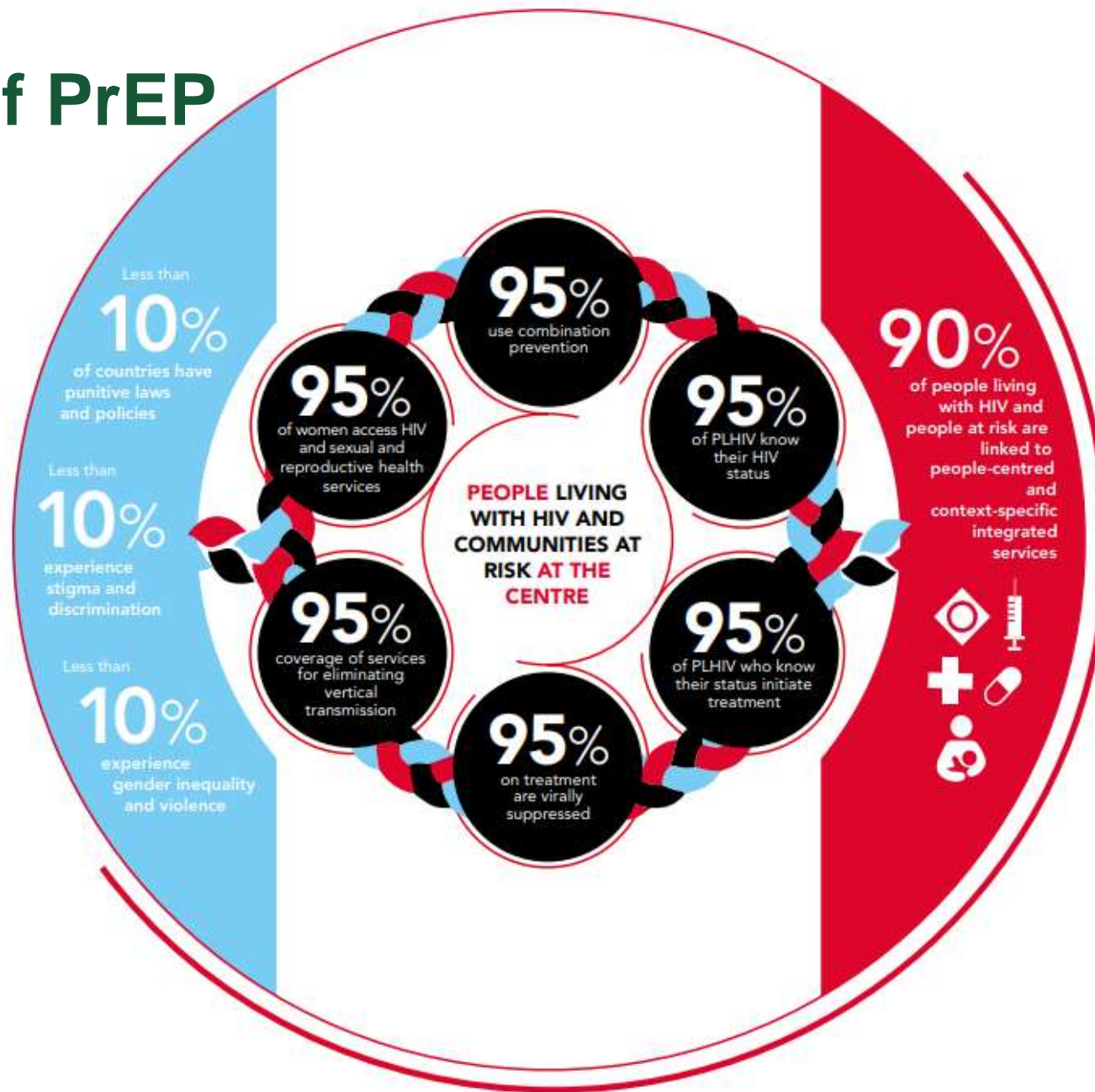
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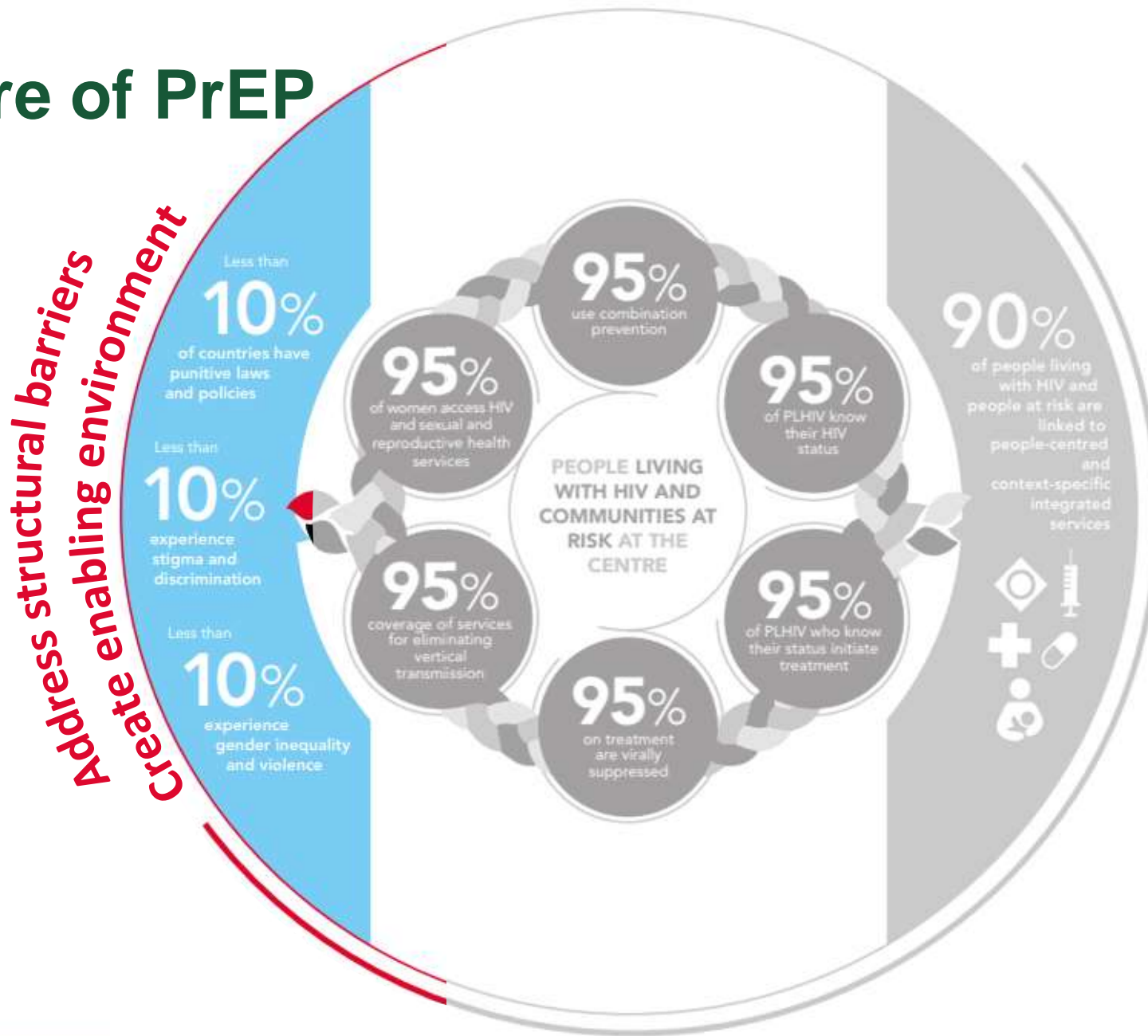
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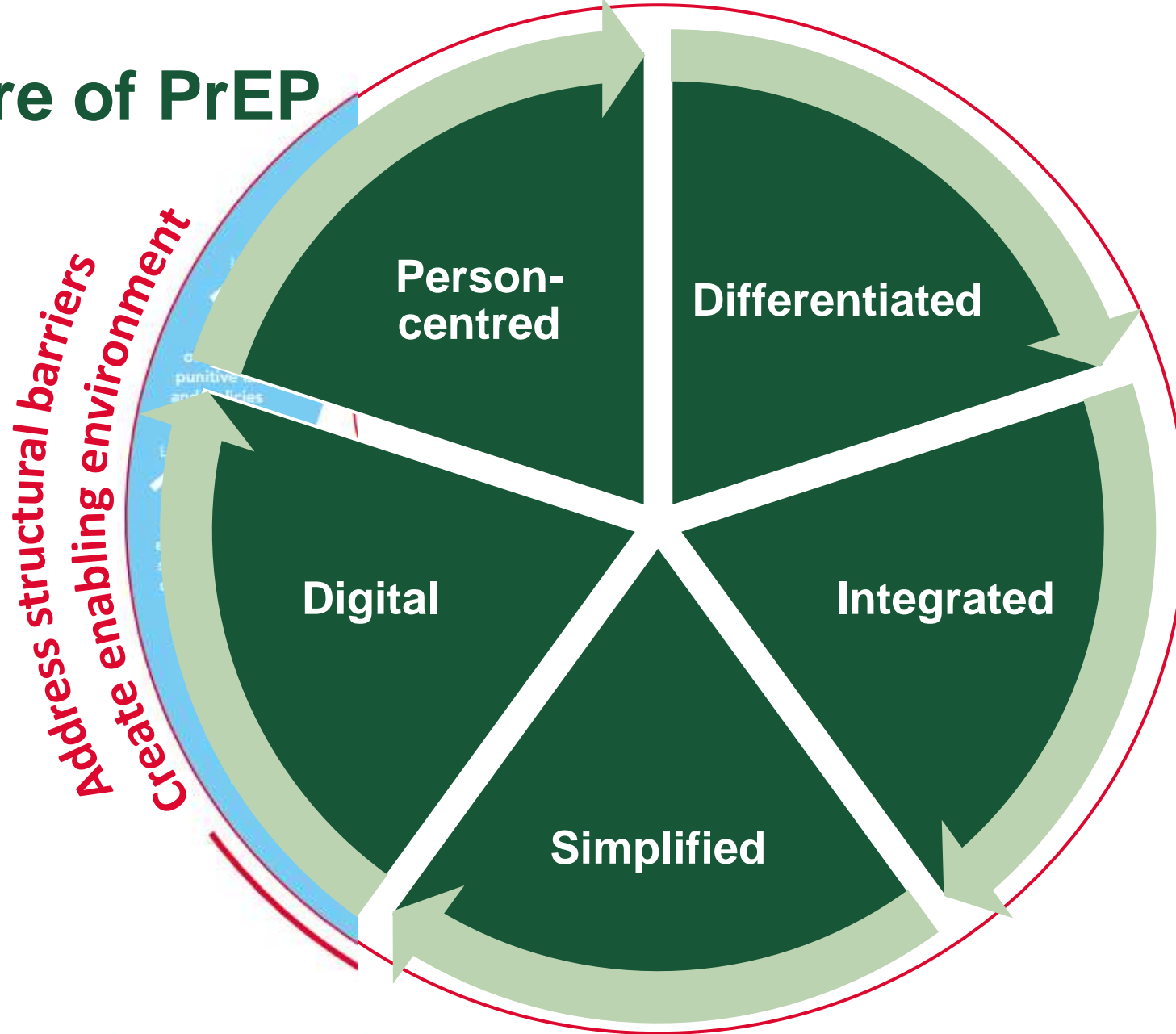
The future of PrEP



The future of PrEP



The future of PrEP



The future of PrEP

Address structural barriers
Create enabling environment

Articles

National sex work policy and HIV prevalence among sex workers: an ecological regression analysis of 27 European countries

Dr Aaron Reeves PhD ^{a, b}, Sarah Steele PhD ^c, Prof David Stuckler PhD ^b, Prof Martin McKee MD ^d, Andrew Amato-Gauci MD ^e, Prof Jan C Semenza PhD

ed

Feature

Drug legislation may be key to ending HIV epidemic

Ed Holt

Combating HIV stigma in low- and middle-income healthcare settings: a scoping review

M. Kumi Smith, Richie H. Xu, Shanda L. Hunt, Chongyi Wei, Joseph D. Tucker, Weiming Tang, Danyang Luo, Hao Xue, Cheng Wang, Ligang Yang, Bin Yang, Li Li, Benny L. Joyner Jr, Sean Y. Sylvia

First published: 26 August 2020
<https://doi.org/10.1002/jia2.25553>

In

Review

Stigma reduction: an essential ingredient to ending AIDS by 2030

Laura Nyblade PhD ^a, ... Melissa A Stockton PhD ^b

Can a national government implement a violence prevention and response strategy for key populations in a criminalized setting? A case study from Kenya

Parinita Bhattacharjee, Giuliana J Morales, Timothy M Kilonzo, Robyn L Dayton, Reuben T Musundi, Janet M Mbole, Serah J Malaba, Bernard E Ogwang, Shajy K Isac, Stephen Moses, Helgar K Musyoki

Integration and scale-up of efforts to measure and reduce HIV-related stigma: the experience of Thailand

Siraprapasiri, Taweessap^a, Srithanaviboonchai, Kriengkrai^{b,c}, Chantcharas, Parichart^d, Suwanphatthana, Nisat^e, Ongwandee, Sume^f, Khemngern, Porntip^g; Benjarattanaorn, Patchara^h; Mingkwan, Piaⁱ; Nyblade, Laura^h

The future of PrEP



**Thank you!
And thanks to...**

Acknowledgement

Thanks to my Forum colleagues for contributions to this presentation:

Veronica Miller

Logan Donaldson

Nicholas Murdock

Visit us at: <https://forumresearch.org/>

Thanks to my former WHO colleagues:

Rachel Baggaley

Michelle Rodolph

Heather-Marie Schmidt

WHO's work on PrEP: <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>

14^{as} JORNADAS DE ATUALIZAÇÃO EM DOENÇAS INFECIOSAS

DO HOSPITAL DE CURRY CABRAL - CHULC

25 e 26 JANEIRO 2024 - Lisboa



**Please contact me with questions or comments or
to discuss collaborations.**

Thank you!

Dr Robin Schaefer

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