PrEP in the water?

Challenges (and opportunities) in PrEP implementation in Europe



RESOURCES V

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Article News and analysis

HIV prevention should be like fast food. This data shows why

By Mia Malan and Laura Grant - April 19, 2022























Overview

- •From research to policy: evolution of WHO guidance on PrEP (oral and other products)
- Status of PrEP in Europe
- •What can we do as a region to increase access to PrEP in Europe?



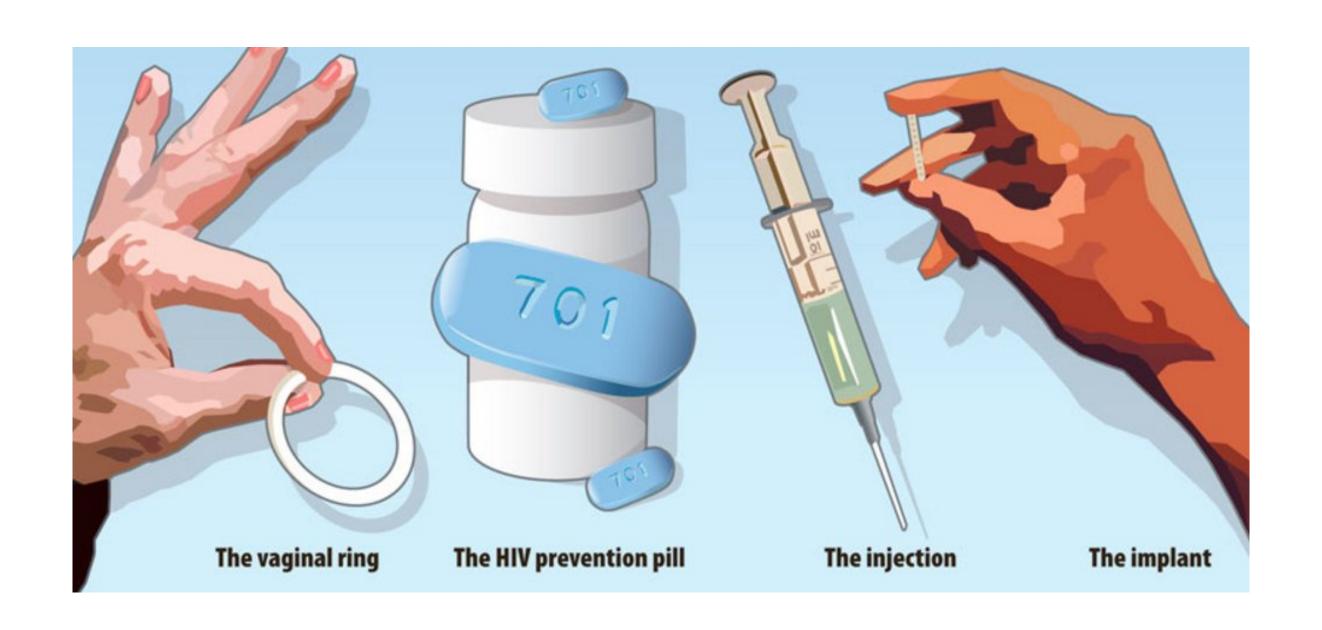
My suggestions on how to scale-up PrEP in Europe

- Differentiate service delivery, but
- Let's not make it complicated (de-medicalize/simplify); WHO will be coming out with new guidance (summer 2022)
- Everyone should know what PrEP is (not just key populations), including cisgender women
- Move away from language of 'risk'
- Every clinician doesn't need to prescribe, but every clinician should know where to refer a client for PrEP initiation
- Pharmacy models need to be leveraged: over-the-counter as a start-up pack (with pre-requisite of HIV negative test?)
- Lessons being learned from COVID-19 (and PrEP experience outside Europe) should not be ignored
- The 'west' should help the 'east' in spirit of European public health solidarity

Section 1:

From research to policy: evolution of WHO guidance

PrEP portfolio in 2022: different products studied/approved/coming down the pipeline



The evidence on oral TDF-based PrEP: very compelling

Decade of PrEP

PrEP = most effective biomedical form of HIV prevention to-date

First PrEP RCT showing efficacy was published in 2010 (iPrEx)





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ORIGINAL ARTICLE FREE PREVIEW

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., et al., for the iPrEx Study Team*





Abstract

December 30, 2010

N Engl J Med 2010; 363:2587-2599 DOI: 10.1056/NEJMoa1011205

BACKGROUND Antiretroviral chemoprophylaxis before exposure is a promising

Extensive PrEP clinical research has shown that PrEP is super effective in HIV prevention (different modalities)

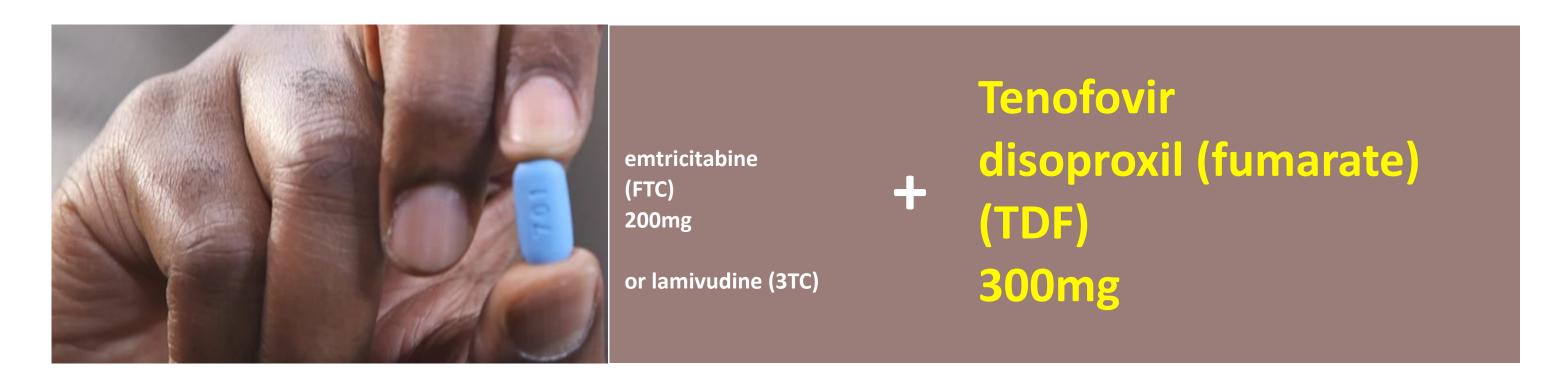


Desai et al, BMJ 2017



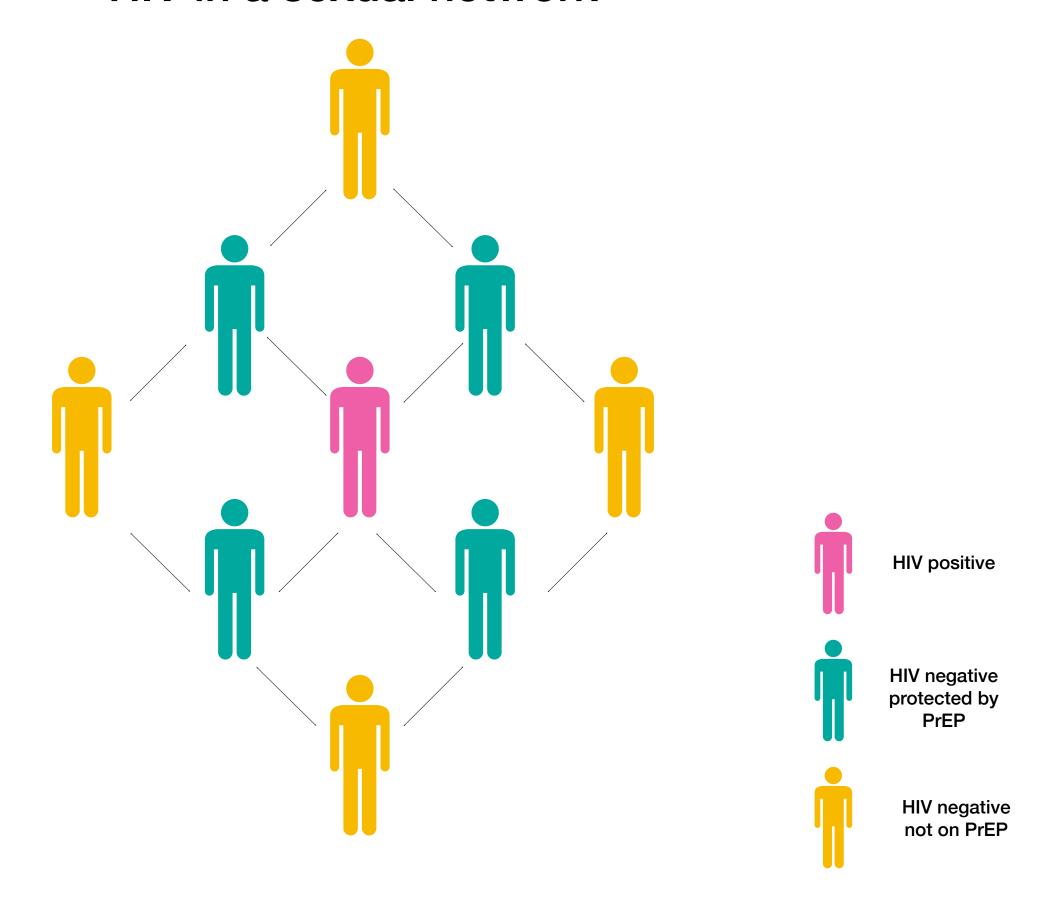
What does WHO recommend?

- WHO recommends "oral PrEP containing TDF", permissive to use of TDF/FTC, TDF/3TC, and TDF mono therapy
- Rigorous review of research data; values/preferences, implementation considerations
- All three options included in WHO EML since 2017
- In practice, countries "encouraged" to consider dual products for inclusion in their national guidelines/policies and for procurement
- Dapivirine (DPV) vaginal ring recommended in 2021
- Data on cabotegravir-long acting injectable reviewed recently during WHO guidelines development group (GDG) meeting (March 2022)



WHO consolidated HIV guidelines (2021): https://www.who.int/publications-detail-redirect/9789240031593

The wider community can be protected: How PrEP works to prevent transmission of HIV in a sexual network



Population-level effectiveness of a national HIV preexposure prophylaxis programme in MSM

Claudia Estcourt^{a,b}, Alan Yeung^{a,c}, Rak Nandwani^{b,d}, David Goldberg^{a,c,d}, Beth Cullen^c, Nicola Steedman^e, Lesley Wallace^c and Sharon Hutchinson^{a,c}

See related paper on page 691

Objective: The aim of this study was to evaluate Scotland's national HIV preexposure prophylaxis (PrEP) programme in relation to PrEP uptake and associated population-level impact on HIV incidence among MSM.

Design: A retrospective cohort study within real-world implementation.

Methods: Comparison of HIV diagnoses from national surveillance data and HIV incidence within a retrospective cohort of HIV-negative MSM attending sexual health clinics from the National Sexual Health information system between the 2-year periods pre(July 2015–June 2017) and post(July 2017–June 2019) introduction of PrEP.

Results: Of 16723 MSM attending sexual health services in the PrEP period, 3256 (19.5%) were prescribed PrEP. Between pre-PrEP and PrEP periods, new HIV diagnoses

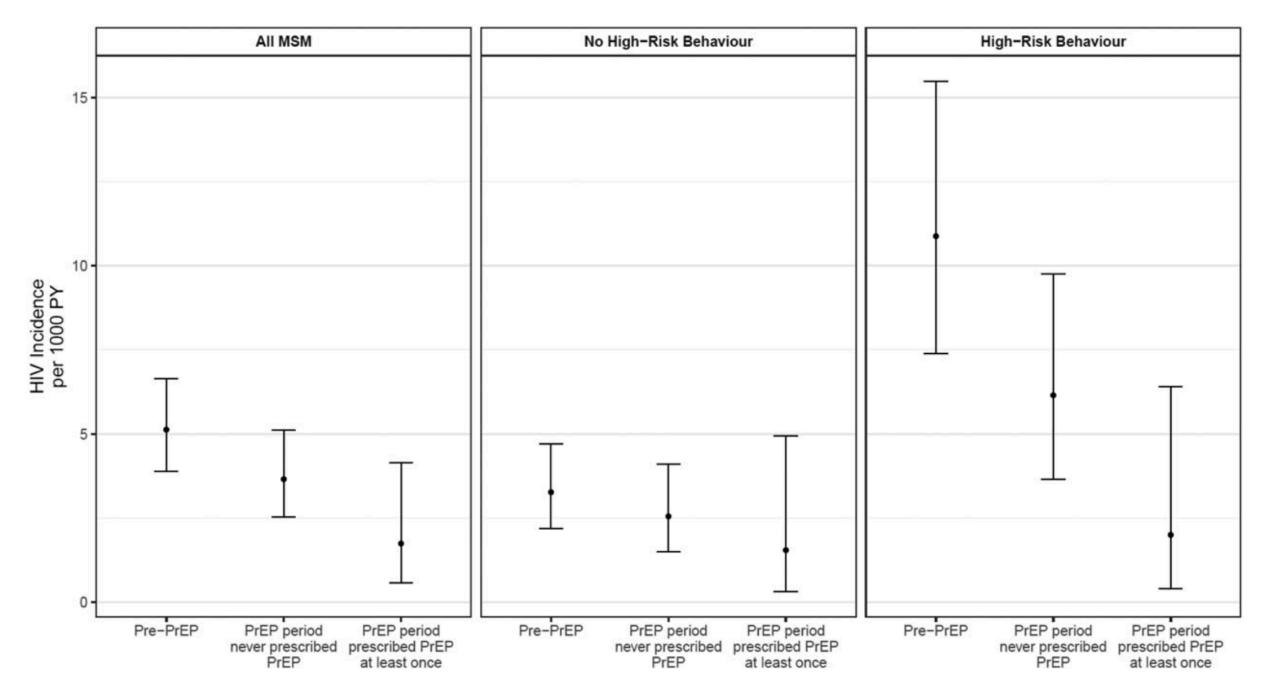
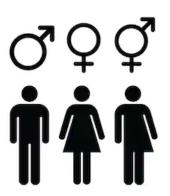


Fig. 1. HIV incidence per 1000 person-years with 95% confidence intervals according to exposure category and defined risk group. PrEP, preexposure prophylaxis; PY, person-years.

How to start + how to stop PrEP (safely) = effective use

Daily dosing (for any person)





1 pill every day / 7 days before sex



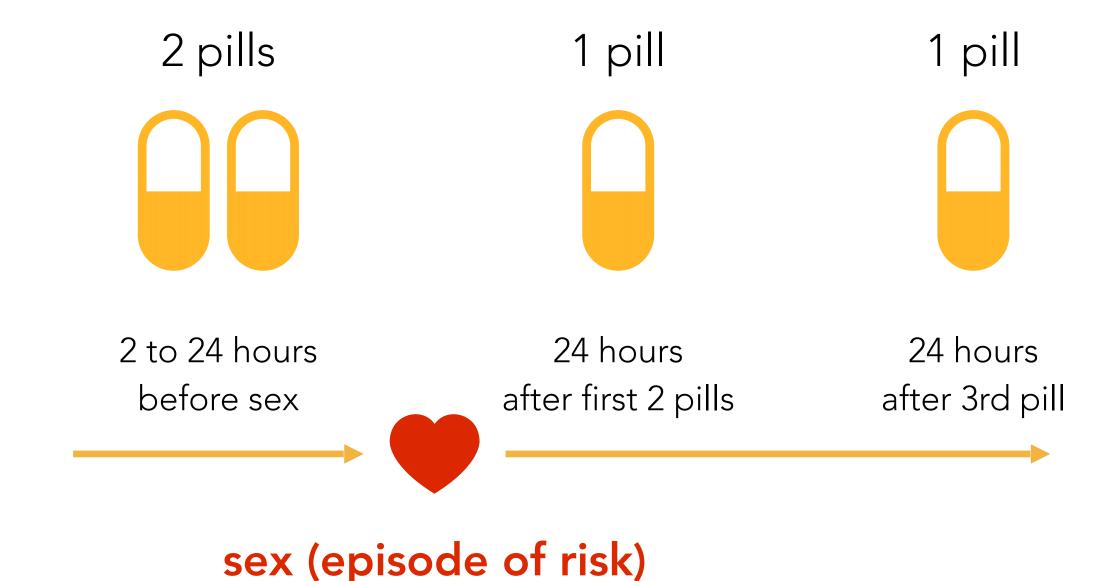
Keep taking 1 pill every day after last sexual encounter

7 days

sex (period of risk)

7 days

Option 2 (only for MSM): MSM can take PrEP around one sexual act = Event-driven PrEP (211)*



^{*} WHO will update its current guidance to state that ED-PrEP is appropriate for all individuals assigned male at birth not taking estradiol-based exogenous hormones

Recommendations (2016)

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).

PrEP for who?

Box 3.2 "Substantial risk of HIV acquisition"

When this recommendation was initially made in 2016, WHO defined substantial risk of HIV infection provisionally as HIV incidence greater than 3 per 100 person—years in the absence of PrEP. HIV incidence greater than 3 per 100 person—years has been identified among men who have sex with men, transgender women and heterosexual men and women who have sexual partners with undiagnosed or untreated HIV infection. In 2016, it was suggested that implementing PrEP in a population with this level of HIV incidence was considered cost-effective or cost saving, although PrEP may still be cost-effective at lower HIV incidence levels.

However, individual risk varies considerably within populations depending on individual behaviour and the characteristics of sexual partners. In locations with a low overall incidence of HIV infection, there may be individuals at substantial risk who should be offered PrEP services (22). PrEP programmes should consider local context and heterogeneity in risk. Individual characteristics and behaviour that could lead to exposure to HIV, rather than population-level HIV incidence, are most important when considering those who might benefit from PrEP.

Individuals requesting PrEP should be given priority to be offered PrEP, since requesting PrEP likely indicates there is a risk of acquiring HIV. Cost—effectiveness should not be the only consideration when implementing PrEP programmes, since remaining HIV negative and having control over HIV risk has intangible value to people and communities.

WHO consolidated HIV guidelines (2021): https://www.who.int/publications-detail-redirect/9789240031593

New US CDC recommendation: all sexually active adult and adolescent patients should receive information about PrEP

- encourage providers to offer PrEP as a core primary care service
- Increase knowledge of PrEP among potential users
- Increase knowledge of PrEP in the community



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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



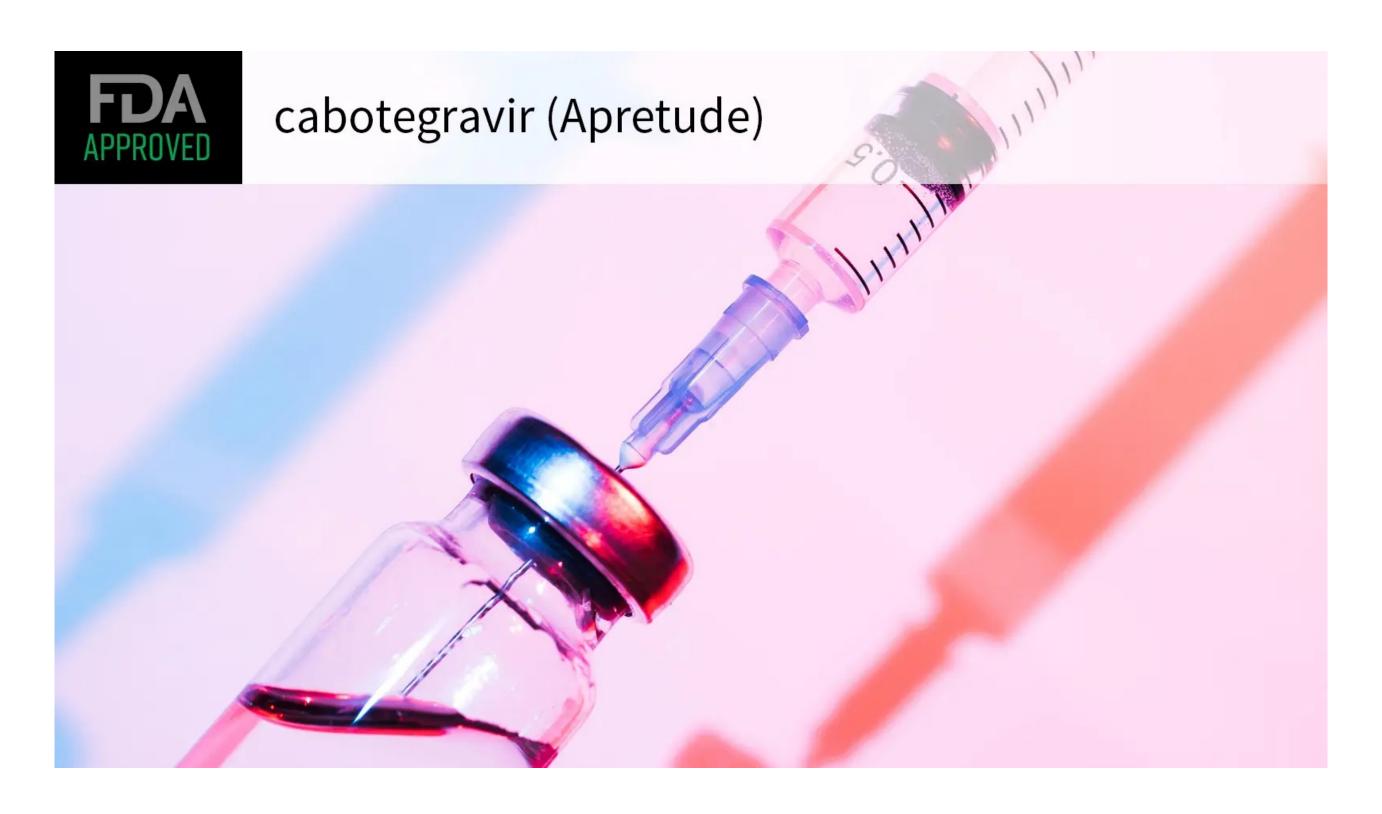
WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection











https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention? fbclid=lwAR0IQU_4R16pHtfJZuoQHZuJflEyPBQzPn-pBEQkGN5XPsHOcruS8g7tYLY

HIV testing for oral PrEP

HIV testing is required prior to starting or restarting PrEP and should be conducted regularly (e.g., every 3 months) during PrEP use.

- Use WHO serial testing strategies, within a validated testing algorithm, using WHO prequalified assays.
- Individuals may be tested at POC following the national testing algorithm, usually a combination of 3rd generation RDTs
- If the initial HIV test -ve and no history or signs/ symptoms of an acute viral syndrome, offer same day initiation
- Once initiated on PrEP, HIV testing is suggested every 3 months and whenever restarting PrEP after a gap in use.
- Additional HIV testing 1 month after starting or restarting PrEP may also be beneficial



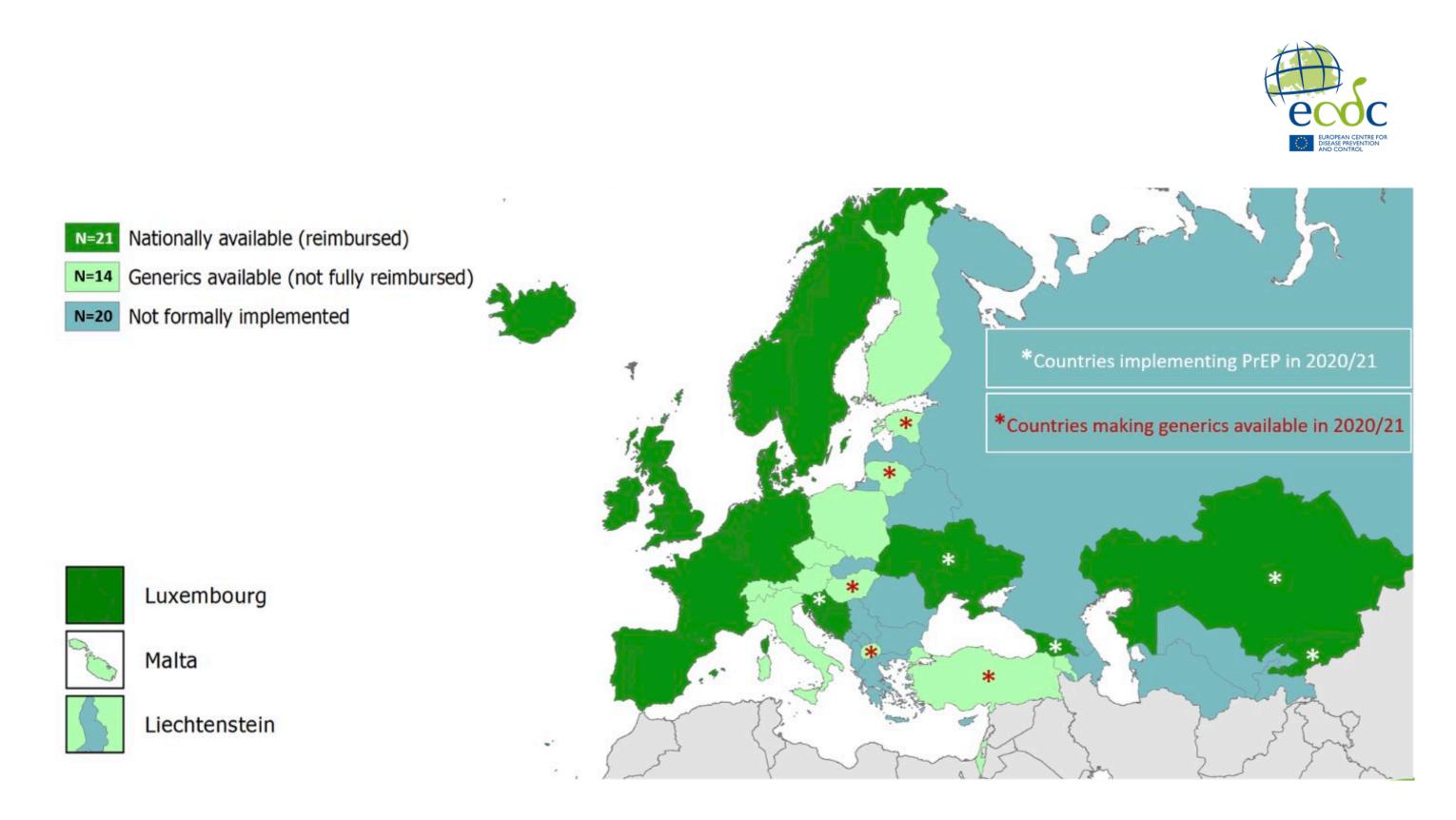
Section 2:

Status of PrEP in Europe

Why is PrEP not as available/accessible in many countries?

- Political will
- Traditional ART delivery structures (think beyond the HIV clinic)
- Communities not involved in onset designing research/policy/programmates
- COVID-19 exacerbating the gap in access (HIV prevention is constantly de-prioritized)
- Cost; reflected in budget lines for HIV prevention

Status of formal PrEP implementation in Europe (October 2021)



Source: Teymur Noori, ECDC (unpublished data)

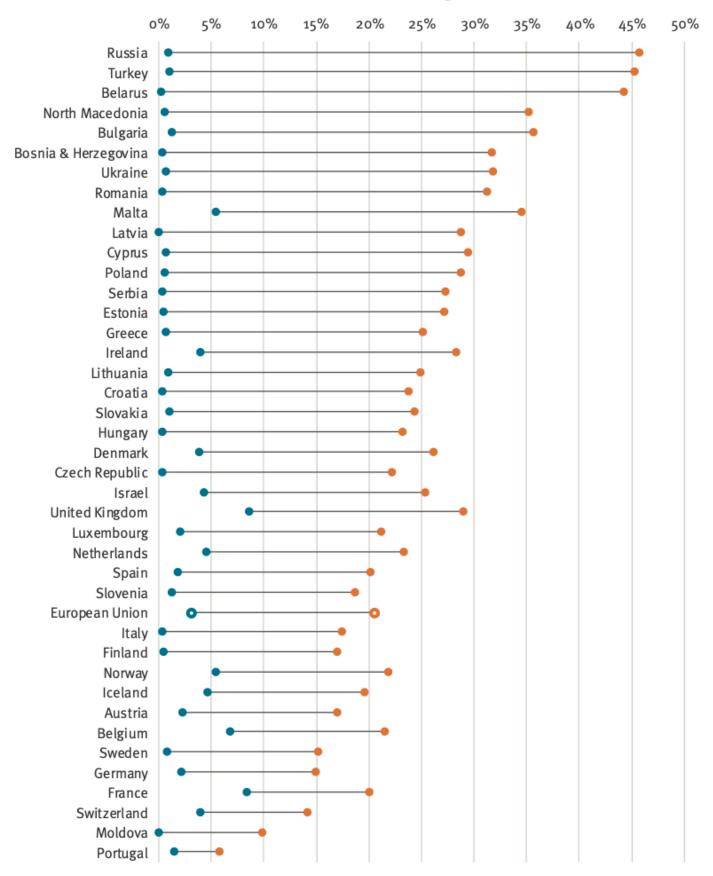
PrEP should/can be available through:

- 'National programme' (within national health system) (e.g. France, Spain, Belgium, Ukraine)
- Generically available in pharmacies (out-of-pocket) (e.g. Italy)
- Country allows for importation of drug for personal use (e.g. Switzerland)
- "Pilot" (e.g. North Macedonia, Latvia) or "access" trial (Switzerland)

"The PrEP Gap": the proportion of non-HIV-diagnosed MSM 'very likely' to use PrEP if accessible, compared with the proportion currently using PrEP from any source, EMIS-2017 qualifying countries, January 2018 (n=44 countries; n = 112,748 respondents)

Hayes et al. 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6794989/

Percentage



- % of non-HIV-diagnosed respondents currently taking PrEP daily or on demand
- % of non-HIV-diagnosed respondents who would be 'very likely' to use PrEP if it was available to them

Adoption of guidelines on and use of oral pre-exposure prophylaxis: a global summary and forecasting study



Robin Schaefer, Heather-Marie A Schmidt, Giovanni Ravasi, Antons Mozalevskis, Bharat B Rewari, Frank Lule, Kouadio Yeboue, Anne Brink, Nabeel Mangadan Konath, Mukta Sharma, Nicole Seguy, Joumana Hermez, Ahmed S Alaama, Naoko Ishikawa, Boniface Dongmo Nguimfack, Daniel Low-Beer, Rachel Baggaley, Shona Dalal



Summary

Background In 2016, the UN General Assembly set a global target of 3 million oral pre-exposure prophylaxis (PrEP) users by 2020. With this target at an end, we aimed to assess global trends in the adoption of WHO PrEP recommendations into national guidelines and numbers of PrEP users, defined as people who received oral PrEP at least once in a given year, and to estimate future trajectories of PrEP use.

Methods In this global summary and forecasting study, data on adoption of WHO PrEP recommendations and numbers of PrEP users were obtained through the Global AIDS Monitoring system and WHO regional offices. Trends in these indicators for 2016–19 by region and for 2019 by country were described, including by gender and

Lancet HIV 2021

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https://doi.org/10.1016/
S2352-3018(21)00127-2

Global HIV, Hepatitis and STIs Programmes, World Health Organization, Geneva, Switzerland (R Schaefer PhD,

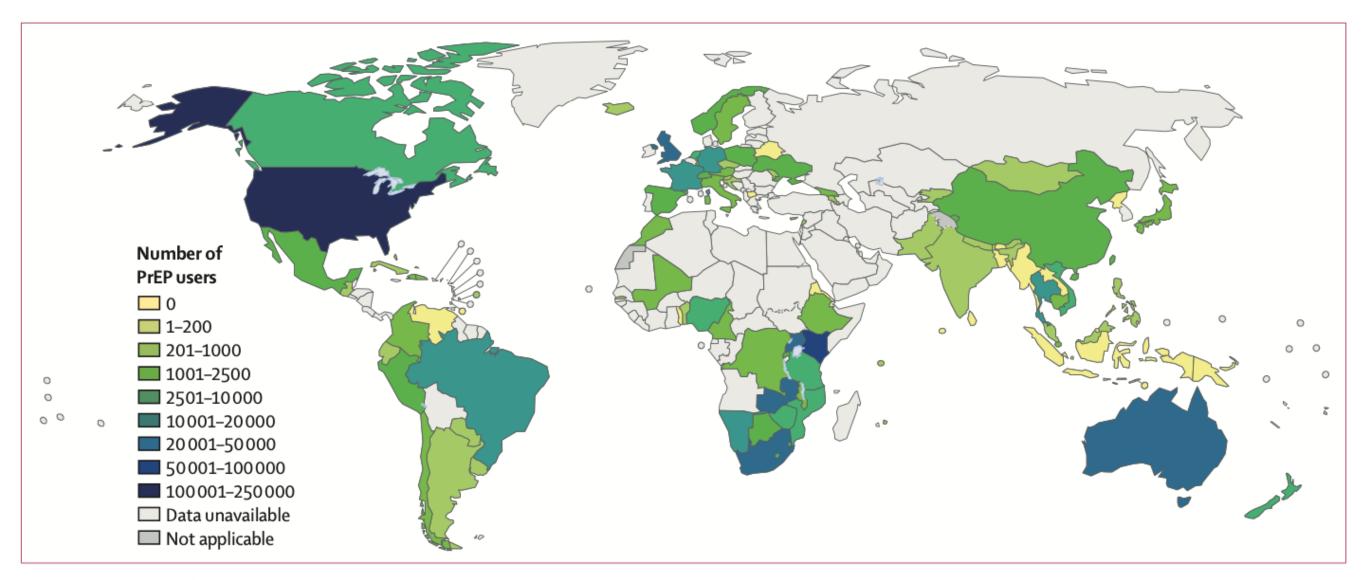
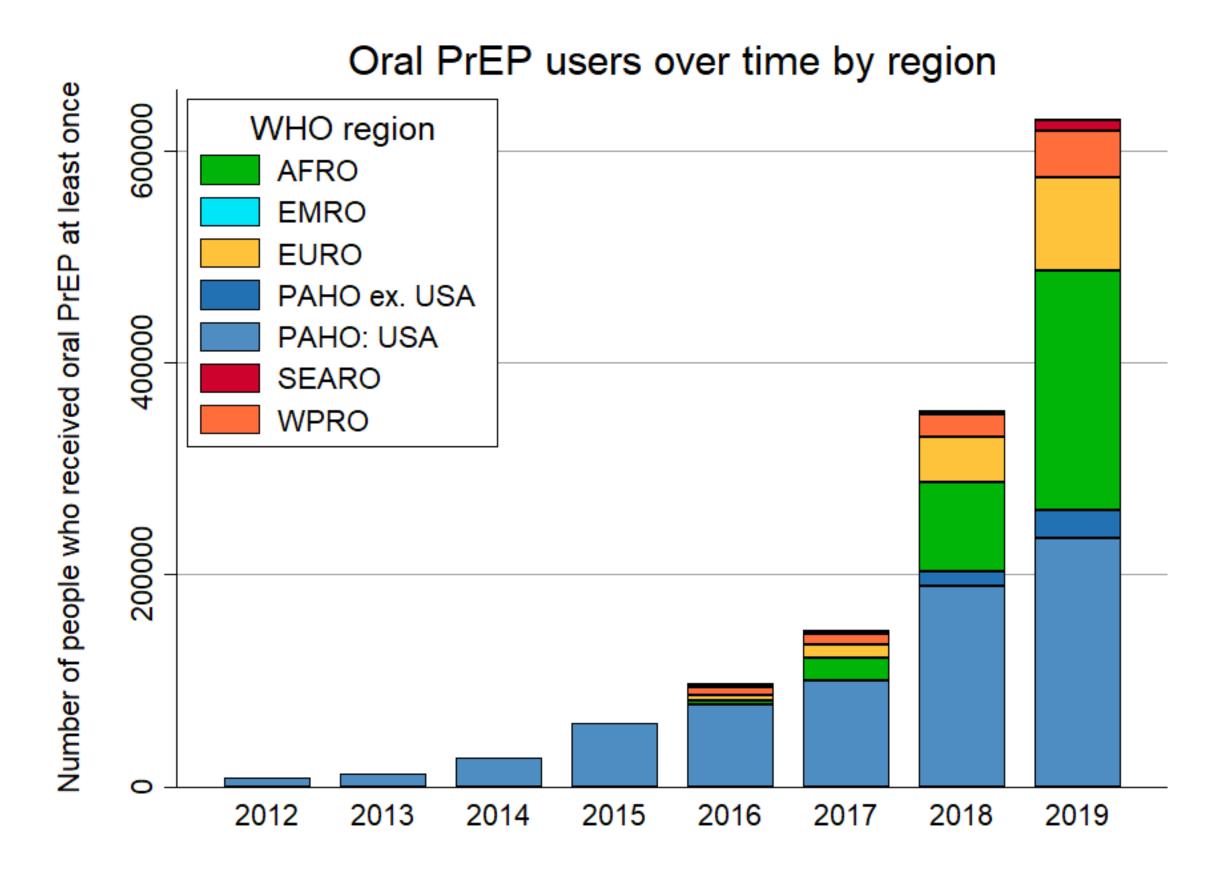
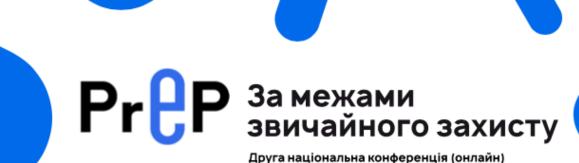


Figure 3: Numbers of people who have received oral PrEP at least once (PrEP users) globally in 2019



PrEP in Ukraine

- Pilot in Kyiv (in MSM) transitioned into national programme in 2019
- PrEP offered for free under Ukrainian health system (medically prescribed in AIDS centers) with referrals from NGOs
- National 'standard' for PrEP provision based on WHO guidance
- Focus on key populations (MSM, transgender persons, sex workers, SDCs)
 - At least 5000 people (including 500 PWIDs) prescribed PrEP prior to February 24, 2022



9-11 червня 2021

will be held on June 9-11, 2021

Second National PrEP Conference "PrEP Beyond Regular Protection"

June 9, 2021 (Wednesday)

Conference opening

13:00-13:20 Welcome speech

Ihor Kuzin, Deputy Minister of Health Care, Chief State Sanitary Doctor of Ukraine

Roman Rodyna, General Director of Public Health Center of the Ministry of Health of Ukraine

Darren Dorkin, Senior Portfolio Manager of the Global Fund

Martin Donoghoe, Senior Adviser TB, HIV and Hepatitis, WHO Country Office in Ukraine

Ezra Barzilay, Country Director of the CDC Office in Ukraine (U.S. Centers for Disease Control and Prevention)

Roman Haylevych, Director of the UNAIDS Country Office in Ukraine

Andrii Klepikov, Executive Director of the ICF «Alliance for Public Health»

Dmytro Sherembei, Chairman of the Coordination Council of the CO «100% Life»





War is the worst thing to public health (including HIV prevention)



A bombed hospital in Volnovakha in Ukraine's Donetsk region.

SURGE OF HIV, TUBERCULOSIS AND COVID FEARED AMID WAR IN UKRAINE

Infectious diseases are likely to spread as Russia's invasion displaces people and disrupts health services

Recent movement of HIV-infected people might change existing network structures, disturbing the firewall effect and accelerating HIV flows within Ukraine. Enabling sustainable prevention services and treatment provision in locations where services have been physically disrupted because of the armed conflict is a priority

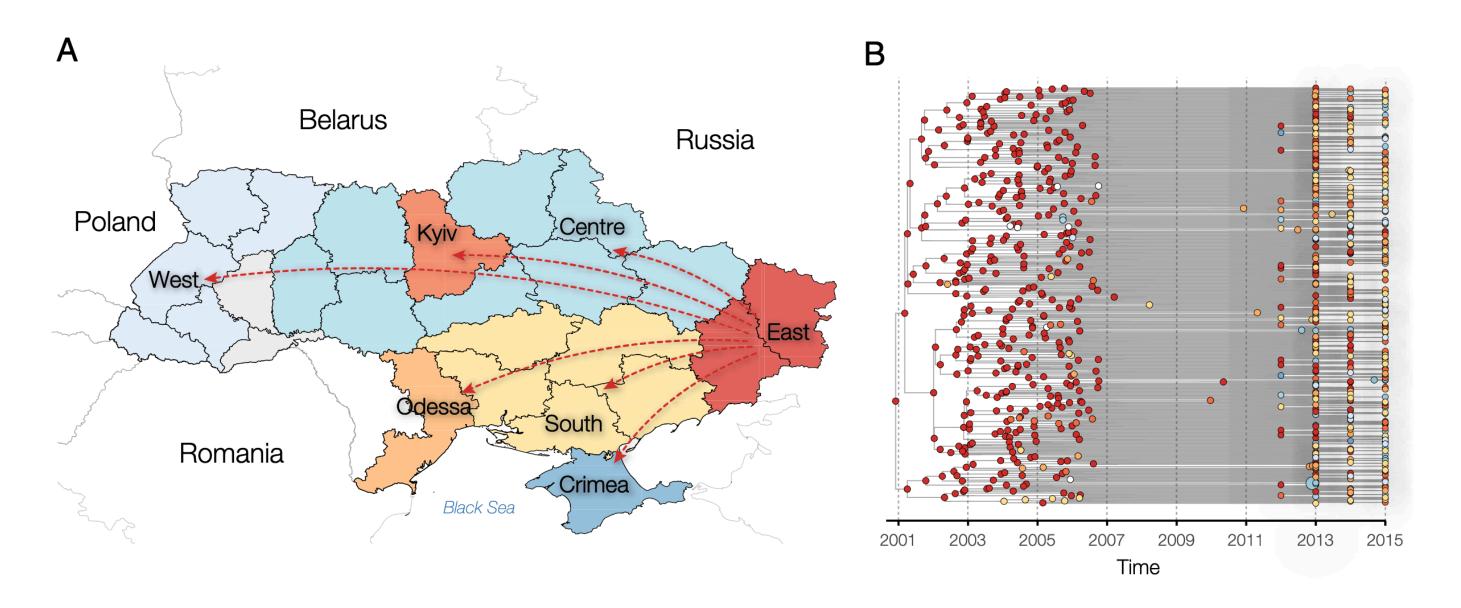


Fig. 2. (A) A geographical map of Ukraine. Colors indicate the grouping of the sequences in locations used in phylogeographic analysis. The arrows indicate the directionality of virus gene flow movement from the East. (B) Results of the discrete trait phylogeographic analysis based on the Ukrainian dataset (n = 427). Colors indicate the ancestral state locations of the internal nodes reconstructed by robust count phylogeographic method and the sampling locations of the tips.











INFORMATION TO GUIDE INDIVIDUAL HEALTH ASSESSMENT OF REFUGEES FLEEING THE WAR IN UKRAINE

Considerations for Health Care Workers

April 5, 2022

BACKGROUND

The war in Ukraine will have direct and indirect health consequences on conflict affected people, including internally displaced people and refugees. Governments in countries receiving refugees are providing them with access to healthcare.^{1,2}

AUDIENCE

This document aims to provide information to guide individual health assessment carried out by frontline health providers at border areas, reception centres, transit centres and individual clinics as well as national public health agencies / authorities in countries receiving refugees and third country nationals.

IMMEDIATE RESPONSE

- Rapid screening and triage of wounded and severely ill that require urgent medical care, refer serious cases to pre-identified partners and hospitals.
- 2. Provide Psychological First Aid (see here3).
- Assess and manage initial curative care needs for acute conditions and unattended chronic conditions requiring immediate management or referral.

https://www.ecdc.europa.eu/sites/default/files/documents/ Individual-Health-Assessment-Final-April-05-2022.pdf

Section 3:

What can we do as a region to increase access to PrEP in Europe?

PrEP is not just a pill



Package of services

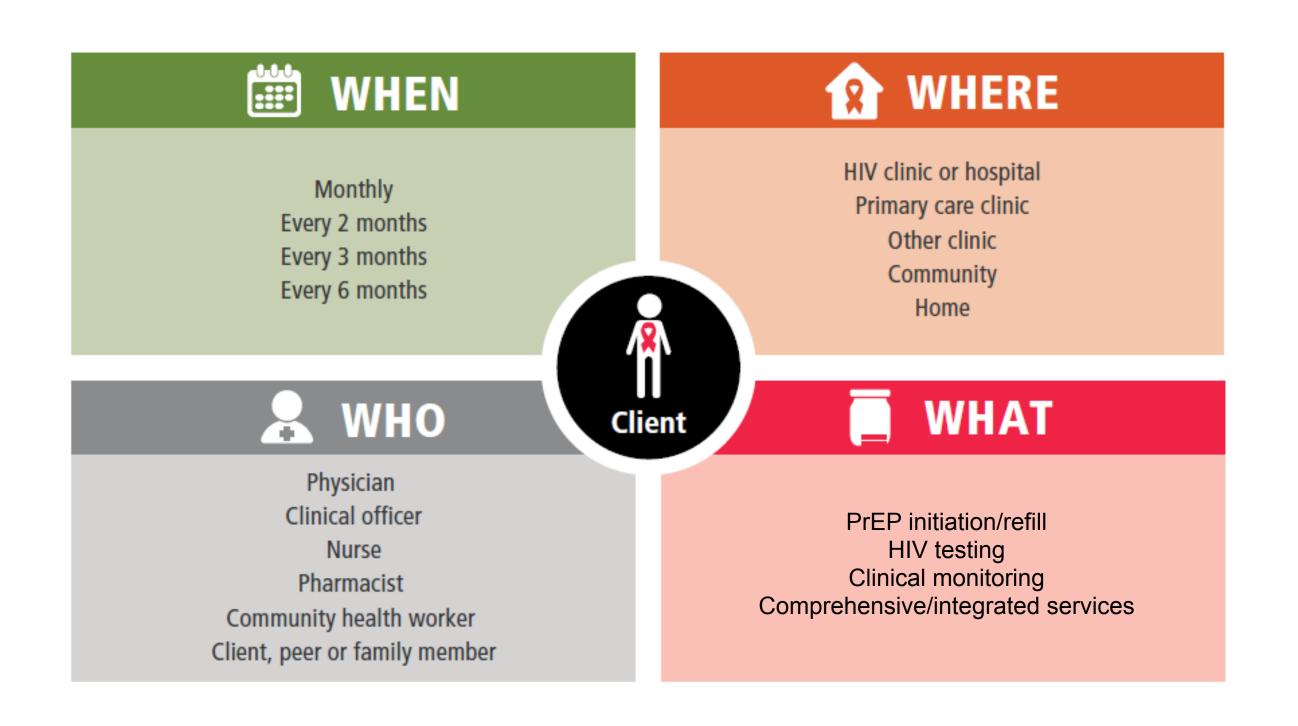


That should be tailored

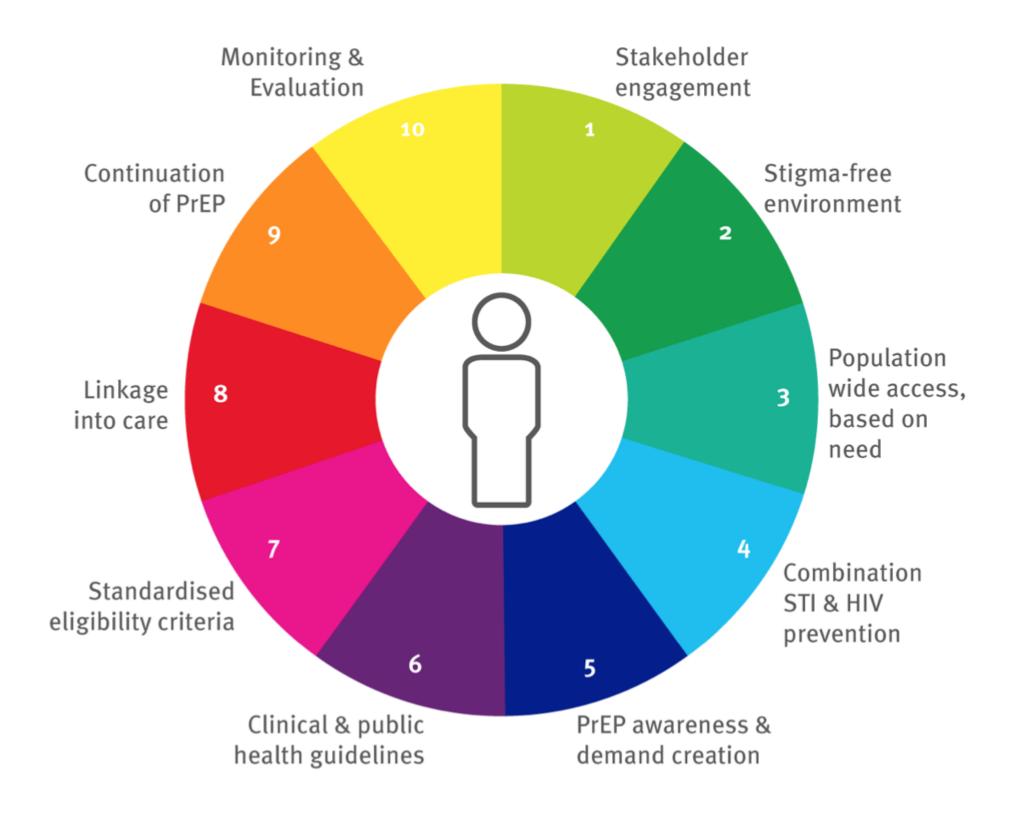


•A one-size-fits-all model of HIV services does not work for all 37 million people living with HIV today (and for
 everyone else who can benefit from PrEP). Differentiated service delivery is a responsive, client-centred approach that simplifies and adapts HIV services across the cascade to better serve individual needs and reduce unnecessary burdens on the health system.

What are the building blocks for a PrEP programme? Differentiated service delivery approach



10 elements for a successful national PrEP programme: to what extent have you considered these?



PrEP is not for life

Continuation/persistence must be re-evaluated and adapted to fit people's lives

Emerging consensus that:

Effective PrEP use does not have to be continuous

Cycling on and off PrEP based on risk is common and often driven by individual needs

Intentional discontinuation can be a feature of effective PrEP use

Commonly Used Terminologies	Definition
Continuation/ Continued Use	Ability to use a method effectively over time
Effective use	Having sufficient drug concentration to achieve protection from HIV infection over time
Adherence	Taking medication as prescribed to achieve sufficient drug concentrations to confer protection in a 24 hour period
Persistence	Use as recommended, over a period of weeks, months, or years

PrEP is an entry point for other sexual health services (e.g. STI testing/treatment)

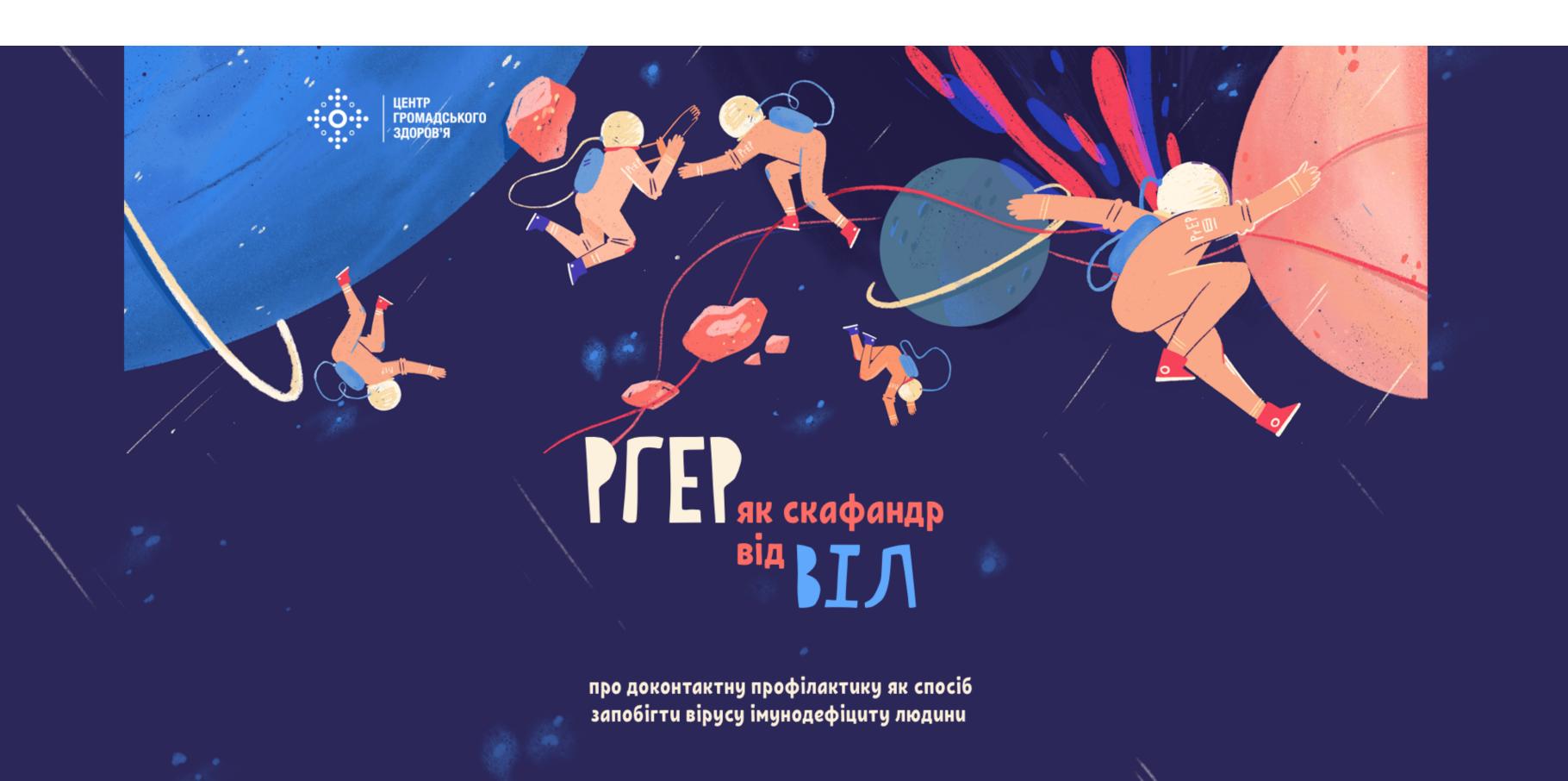


Create OPPORTUNITIES for access (access to basic PrEP information)

e.g. information campaign in London



e.g. Ukraine PrEP portal: http://prep.theukrainians.org



- Access trials are a start: but we need to move to far wider access



Nearest centres Frequently Asked Questions Partners, Sponsors & Scientists Links Contact



- Australia (EPIC-NSW)
- Impact trial (UK)
- Switzerland (https:// www.swissprepared.ch)
- Bridge-to-Scale (Kenya)





PrEP in Latvia

Pilot community-based PrEP programme

Consortium of 4 established NGOS





Promotional campaign

Screening for HIV, HepB, HepC, syphilis, CT, NG

Visit with infectious disease doctor

Adherence counselling

Direct line with Programme Manager

PrEP provision for free



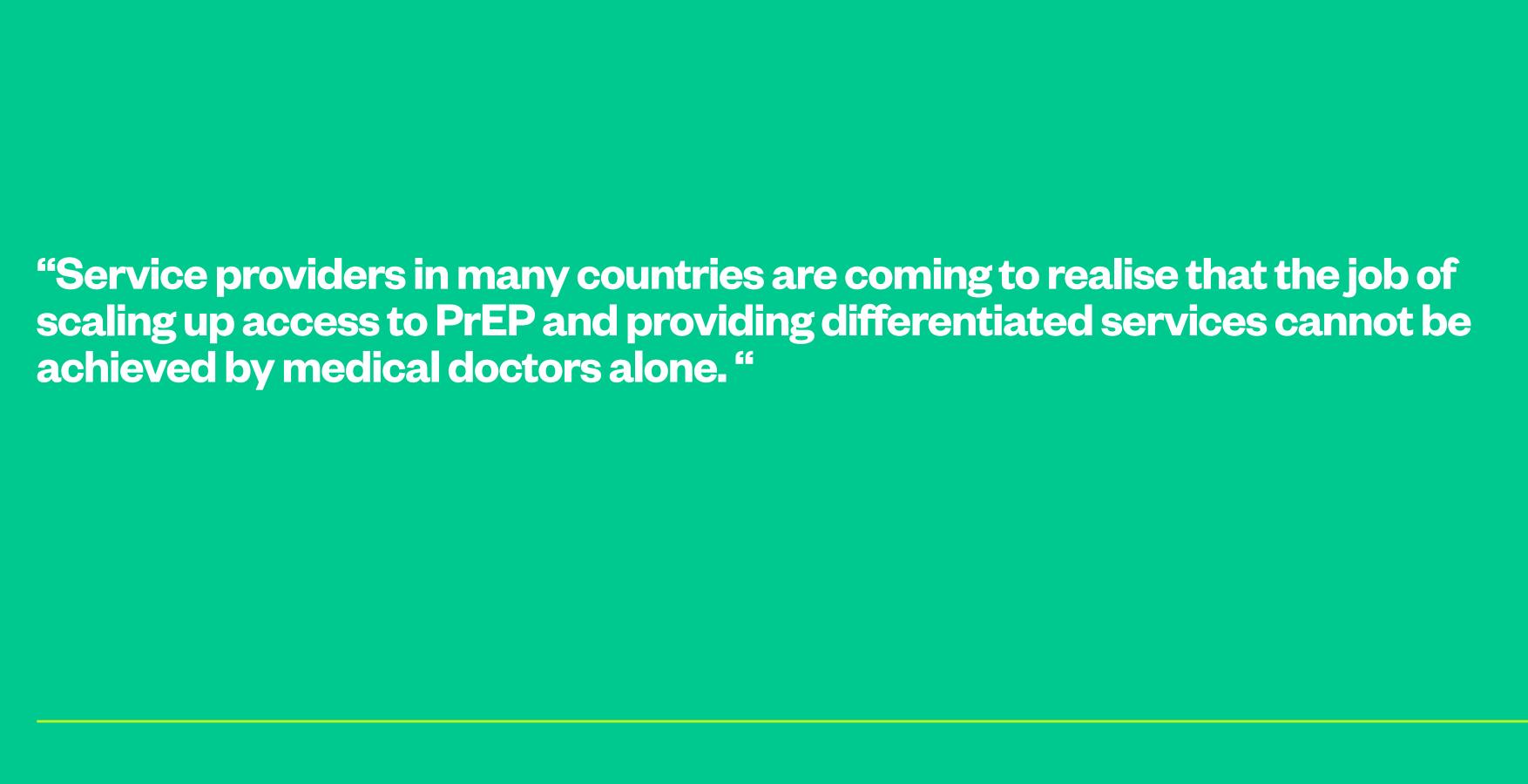
Show me the money

Financing PrEP

- External donor funding
- Integration into existing services covered by national health systems
- Willingness to pay (although will present challenges in equity)
 - Consider regulatory 'enabling' policies to allow for people to also get PrEP in private sector

Coming to an HIV/ART clinic can be a burden

Involve and train more professionals to support PrEP use



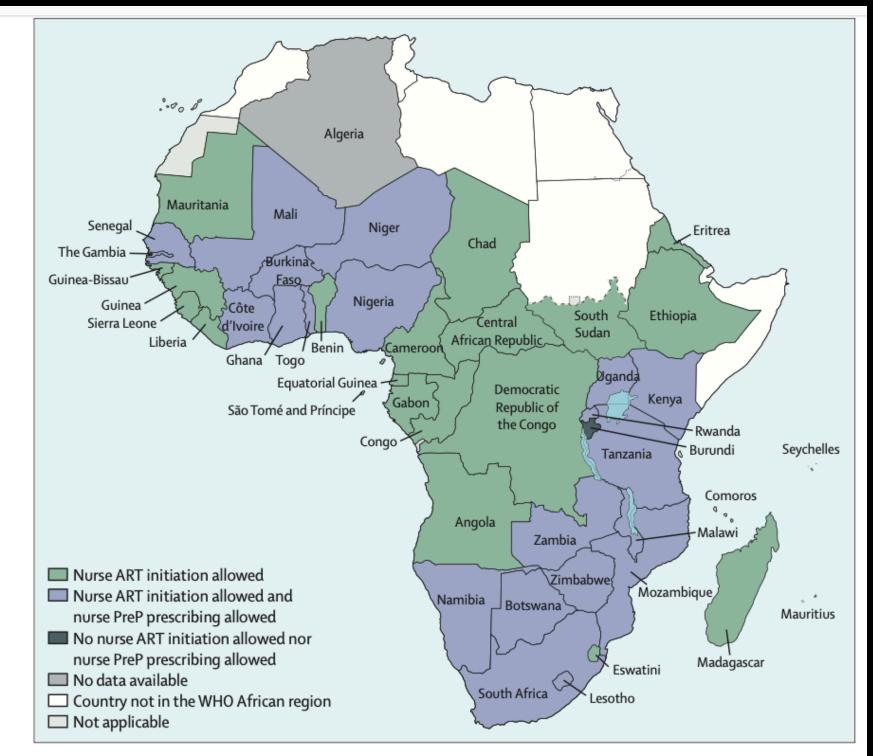


Figure: Policies allowing nurse prescribing and ART initiation in the WHO Africa region, 2018-20

This map depicts polices reported via the Global AIDS Monitoring system. Existence of a policy does not necessarily imply that the nurse prescribing is widely practised. Insufficient data were available from other regions to allow for global reporting. Reproduced from Global AIDS Monitoring. ART=antiretroviral therapy. PrEP=pre-exposure prophylaxis.

e.g. Thailand (lay providers trained can dispense PrEP; still medically prescribed remotely)



To initiate PrEP, medical prescription is typically required

California Makes H.I.V.-Prevention Drugs Available Without a Prescription

The state is the first in the nation to allow pharmacists to dispense PrEP and PEP, drugs that can prevent new H.I.V. infections.



STRACT

this paper, it is argued that oral ceptives should be available prescription. Prescription stabilisheavy costs, including the time, and psychological costs ing a physician to obtain a preson, the financial and human funintended pregnancies that from the obstacle to access by medicalization of oral conives, and administrative costs nealth care system.

fter a review and evaluation of sons for strict medical control contraceptives in the United safety concerns anticipated in se to the proposal discussed

Should Oral Contraceptives Be Available without Prescription?

James Trussell, BPhil, PhD, Felicia Stewart, MD, Malcolm Potts, MB, BChir, PhD, Felicia Guest, MPH, and Charlotte Ellertson, MPA, MA

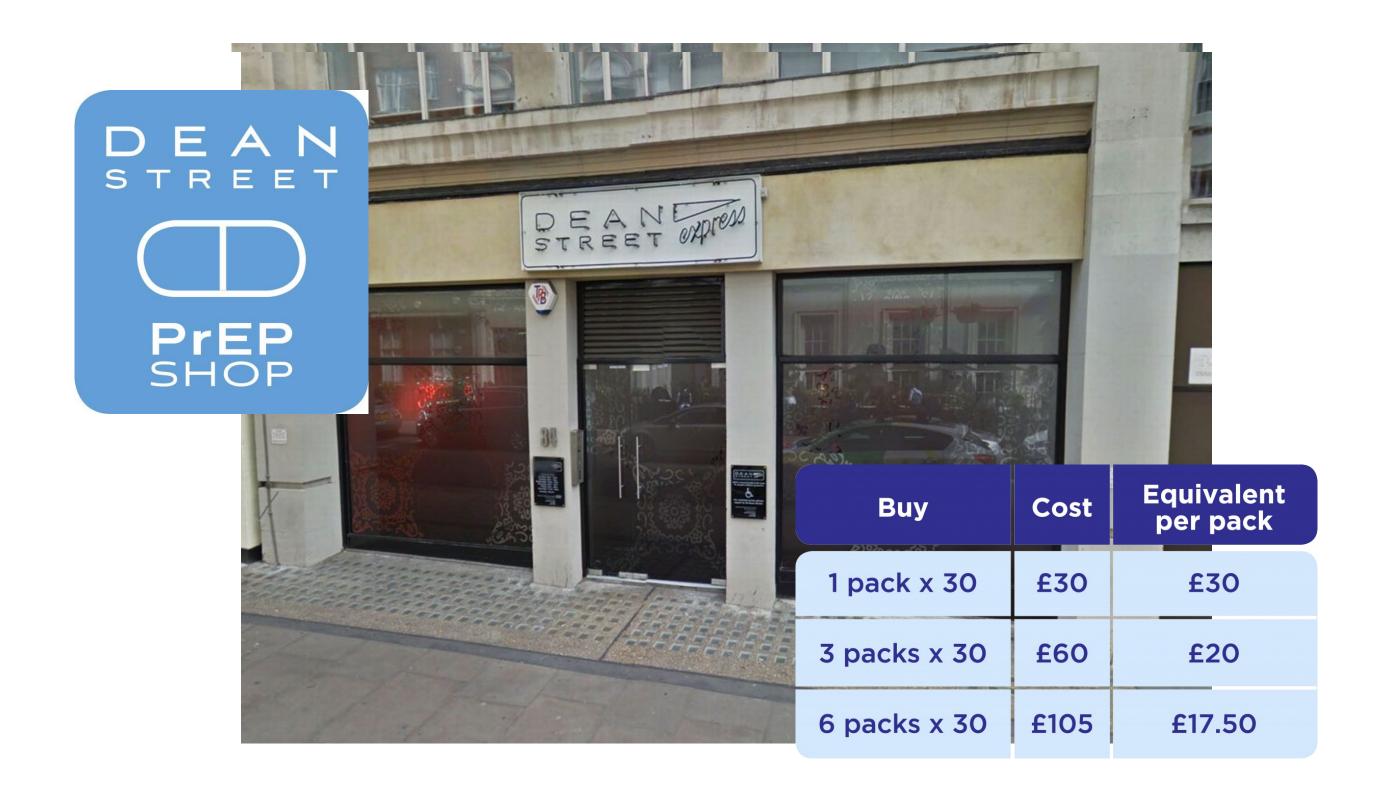
Introduction

Empowering women to choose the number and timing of pregnancies is widely recognized as a primary goal of reproductive rights advocates. It follows that such advocates should endorse women's full and direct access to contraception. Indeed, if this goal is central, then only compelling health concerns could justify restrictions such as a prescription requirement.

In the United States, historical circumstances and health concerns once restricted all decisions regarding access to contraceptives to physicians. Eighty percent of American women now use oral of family planning in this country. The influence of the 1873 Comstock Act, which made it a criminal offense to import, mail, or transport in interstate commerce any literature about birth control or any device designed to prevent conception or cause abortion, persisted for more than a century.² Birth control advocate Margaret Sanger challenged this legislation but succeeded in circumventing it only by making physicians the key to contraceptive distribution. In 1936, the Supreme Court, in United States v One Package (the package being three diaphragms imported from Japan), allowed the "importation, sale, or carriage by mail of things which might in-

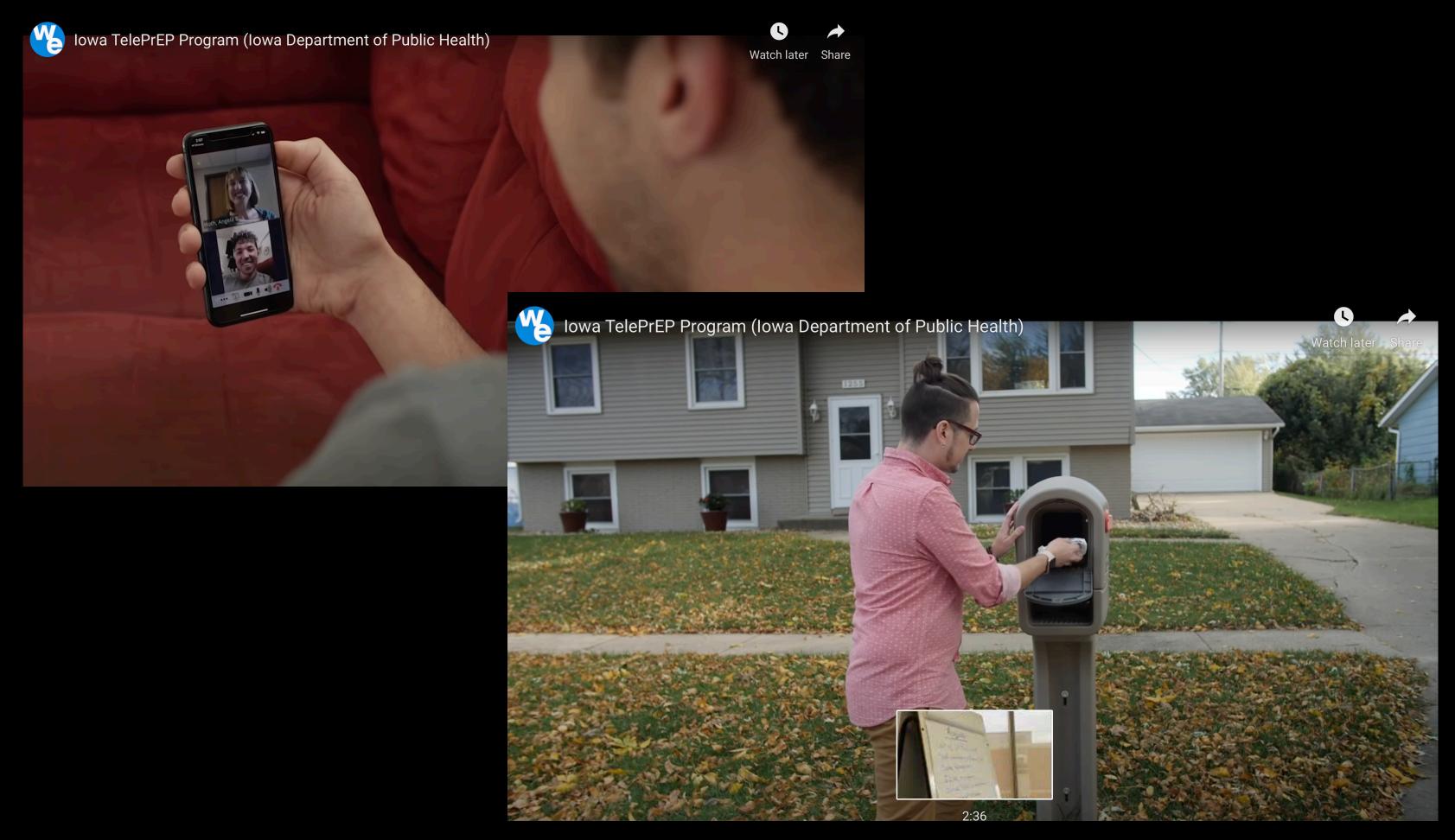
Can you buy your PrEP?

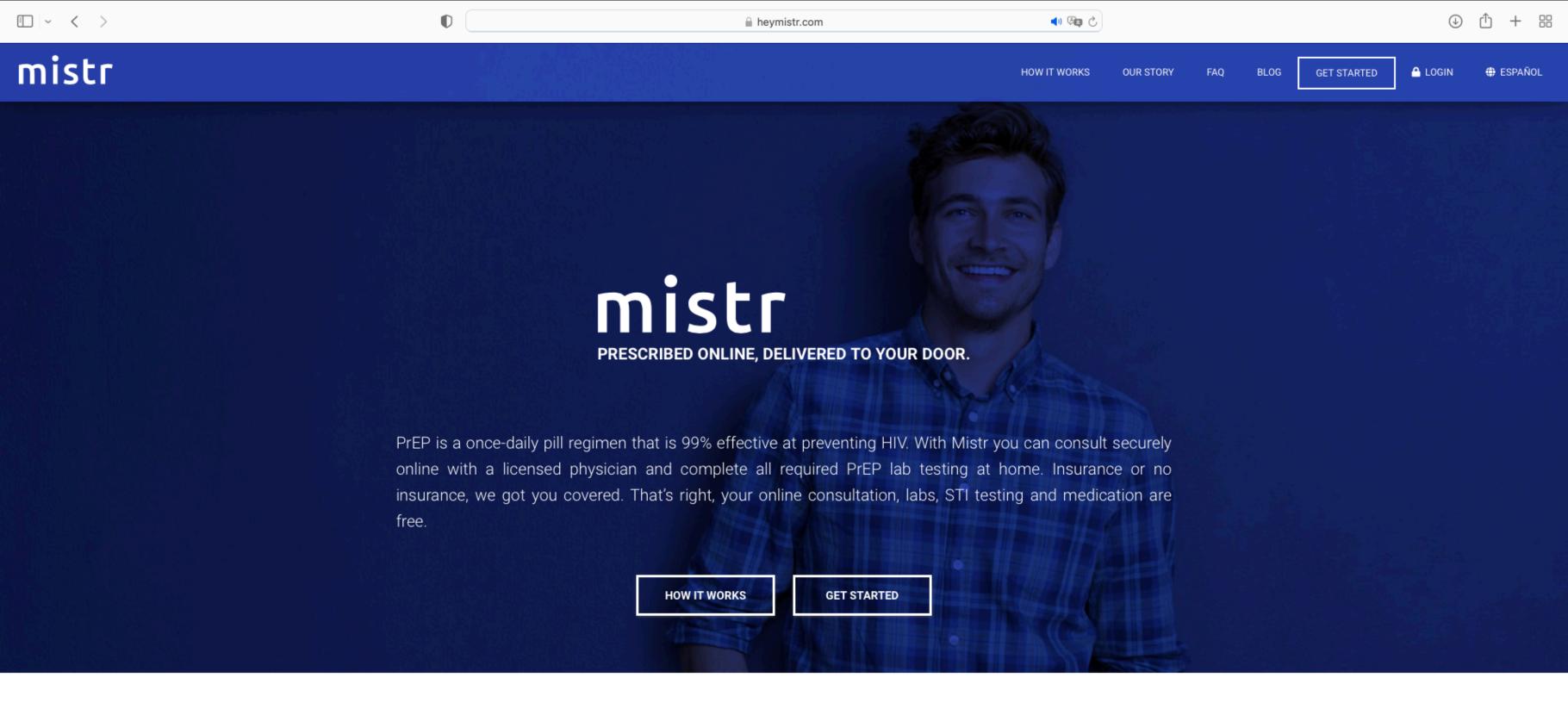




Leverage technology = telePrEP







We handle everything

mistr

HOW IT WORKS

⊕
⊕
+

□

No doctor's office, no needles and no paperwork - get started now.

How it works?



1. HEALTH REVIEW

Answer some basic health questions and create a profile. Confidential and judgement free.



3. DOCTOR CONSULT

Our licensed physicians will review your results and prescribe PrEP if appropriate for you.



2. LABS

Simple at home testing. No needles, no doctor visit.



4. FREE DELIVERY

Our pharmacy network will ship your medication in our discreet packaging and refill automatically each month free of charge.



5. NO PAPERWORK

6. FOLLOW-UP

We'll work with your insurance company and the various patient assistance programs to ancura you have no out-out pocket costs. We do everything for

Prescription renewals every 3-months are even easier.

Prep for PWID? (Neglected population for Prep)*

* Methadone/BUP + needle syringe programmes should not be undermined



Ever Injected Drugs? Assess sexual risk for all PWID Injected Prescribe if past 6 requested months? Shared injection equipment? Prescribe Prescribe if Prescribe if PrEP requested requested

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

Messaging on starting PrEP

- "PrEP is a very strong medication with side effects, you should consider if those risk are worth it for you or not."
- "Many studies have proven that PrEP is safe. There are predictable side effects for some people that go away in time. I will also run tests to make sure you are healthy before starting PrEP."

Models of PrEP care should be creative

Models of PrEP care should be creative, person-centred

Models of PrEP care should be creative, person-centred, equitable

PrEP is (or should be) easy to prescribe

But some PrEP users may require more enhanced clinical management



Complex PrEP: the factors requiring consultant-led review of PrEP users

Victoria Tittle , ¹ Rebecca Dalton, ¹ Diarmuid Nugent, ¹ Nicolo Girometti, ¹ Gary Whitlock, ¹ Alan Mcowan, ¹ Sheena McCormack , ¹, ¹ on behalf of the Dean Street Collaborative Group

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi. org/10.1136/sextrans-2021-055277).

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Correspondence to
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ABSTRACT

Introduction HIV-1 pre-exposure prophylaxis (PrEP) has been available in England since March 2020 on the National Health Service using generic emtricitabine and tenofovir disoproxil. 56 Dean Street (56DS) provided PrEP through (1) additional private care from September 2015, estimated to be providing 11% of England's PrEP in 2019; and (2) the IMPACT trial, as well as monitoring those self-sourcing PrEP. Providing PrEP at scale through a nurse-led service required a safety net for complex individuals. 56DS introduced a consultant-led PrEP outpatient service, the PrEP review clinic, in January 2018 and we report the outcomes of this service.

56 Dean Street (56DS) provided PrEP through additional private care from September 2015 (and are estimated to have provided 11% of England's PrEP in 2019) and England's PrEP IMPACT trial from October 2017 to October 2020.³

Providing PrEP at scale through a nurse-led service required a safety net for individuals with complex needs, and 56DS introduced a consultant-led PrEP outpatient service in January 2018. In contrast to people living with HIV, who can switch to an alternative drug, there is only one option for PrEP users, TD/FTC, with limited guidance for managing toxicities (online supplemental figure 1).

Table 1 PrEP review clinic outcomes and renal PrEP outcomes

Reason for referral to PrEP review clinic

Reason for referral	Unique PrEP users, n (%)
Renal	114 (51.8)
Abnormal eGFR and/or high creatinine	89 (40.5)
Proteinuria (>30 mg/mmol and/or ≥1+ protein on urine dipstick)	15 (6.8)
Other renal issues not presenting with abnormal eGFR or proteinuria	10 (4.5)
Side effects	59 (26.8)*
Comorbidities	38 (17.2)
Concerns about safety of PrEP	15 (6.8)
Drug-drug interactions	8 (3.6)
Hepatitis B	8 (3.6)
Bone health	7 (3.2)
Other	9 (4.1)

Renal eGFR cases: possible cause and management following consultation (n=89)

Referral eGFR (mL/min/1.73 m²)	Protein supplements: to stop these and retest	Alternative explanation, already being monitored	Alternative explanation, no extra monitoring needed	No explanation, further investigated or monitored	Total (n=89)
≥90 (had abnormal eGFR or raised creatinine and normalised on repeat)	2	2	0	1	5
60–89	13	17	4	5	39
45–59	18	8	1	8	35
30–44	3	6	0	1	10

^{*}Out of 59 PrEP users, 47 (76.7%) obtained PrEP on at least one other occasion following their initial PrEP review clinic appointment, 9 (15.3%) had unknown outcomes and 3 (5.1%) have not restarted PrEP due to reasons including an allergic reaction with bullous lesions which recurred on rechallenge and led to discontinuation of PrEP. The regimen for increasing tolerance is provided in online supplemental table 4.

For effective introduction/roll-out, PrEP 'marketing' and education efforts need to focus on 'wellness/protection' as opposed to 'risk'





#PrEP. To me it's like multivitamins. It's for my health.

3:56 PM · Jan 23, 2018 from Johannesburg, South Africa · Twitter for Android

833 Retweets 124 Quote Tweets





Tweet your reply







□ 19 □ 65 □ 247 □

Acknowledgments

- •All the people who trust in PrEP
- WHO Ukraine and EURO/WHO colleagues
- Teymur Noori, ECDC
- EACS
- Global Fund/PEPFAR

@mylittlebaklava (Twitter) mameletzisi@who.int