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The Node ... where a leaf arises from a stem

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PRESS RELEASE

UNAIDS and UNDP call on 48* countries and territories to remove all HIV-related travel restrictions

New data show that in 2019 around 48 countries and territories still have restrictions that include mandatory HIV testing and disclosure as part of requirements for entry, residence, work and/or study permits*

GENEVA, 27 June 2019—UNAIDS and the United Nations Development Programme (UNDP) are urging countries to keep the promises made in the 2016 United Nations Political Declaration on Ending AIDS to remove all forms of HIV-related travel restrictions. Travel restrictions based on real or perceived HIV status are discriminatory, prevent people from accessing HIV services and propagate stigma and discrimination. Since 2015, four countries have taken steps to lift their HIV-related travel restrictions—Belarus, Lithuania, the Republic of Korea and Uzbekistan.

"Travel restrictions on the basis of HIV status violate human rights and are not effective in achieving the public health goal of preventing HIV transmission," said Gunilla Carlsson, UNAIDS Executive Director, a.i. "UNAIDS calls on all countries that still have HIV-related travel restrictions to remove them."

"HIV-related travel restrictions fuel exclusion and intolerance by fostering the dangerous and false idea that people on the move spread disease," said Mandeep Dhaliwal, Director of UNDP's HIV, Health and Development Group. "The 2018 Supplement of the Global Commission on HIV and the Law was unequivocal in its findings that these policies are counterproductive to effective AIDS responses."

Out of the 48 countries and territories that maintain restrictions, at least 30 still impose bans on entry or stay and residence based on HIV status and 19 deport non-nationals on the grounds of their HIV status. Other countries and territories may require an HIV test or diagnosis as a requirement for a study, work or entry visa. The majority of countries that retain travel restrictions are in the Middle East and North Africa, but many countries in Asia and the Pacific and eastern Europe and central Asia also impose restrictions.

"HIV-related travel restrictions violate human rights and stimulate stigma and discrimination. They do not decrease the transmission of HIV and are based on moralistic notions of people living with HIV and key populations. It is truly incomprehensible that HIV-related entry and residency restrictions still exist," said Rico Gustav, Executive Director of the Global Network of People Living with HIV.

The Human Rights Council, meeting in Geneva, Switzerland, this week for its 41st session, has consistently drawn the attention of the international community to, and raised awareness on, the importance of promoting human rights in the response to HIV, most recently in its 5 July 2018 resolution on human rights in the context of HIV.

"Policies requiring compulsory tests for HIV to impose travel restrictions are not based on scientific evidence, are harmful to the enjoyment of human rights and perpetuate discrimination and stigma," said Dainius Pūras, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health. "They are a direct barrier to accessing health care and therefore ineffective in terms of public health. I call on states to abolish discriminatory policies that require mandatory testing and impose travel restrictions based on HIV status."

The new data compiled by UNAIDS include for the first time an analysis of the kinds of travel restrictions imposed by countries and territories and include cases in which people are forced to take a test to renew a residency permit. The data were validated with Member States through their permanent missions to the United Nations.

UNAIDS and UNDP, as the convenor of the Joint Programme's work on human rights, stigma and discrimination, are continuing to work with partners, governments and civil society organizations to change all laws that restrict travel based on HIV status as part of the Global Partnership for Action to Eliminate all Forms of HIV-Related Stigma and Discrimination. This is a partnership of United Nations Member States, United Nations entities, civil society and

the private and academic sectors for catalysing efforts in countries to implement and scale up programmes and improve shared responsibility and accountability for ending HIV-related stigma and discrimination.

**The 48 countries and territories that still have some form of HIV related travel restriction are: Angola, Aruba, Australia, Azerbaijan, Bahrain, Belize, Bosnia and Herzegovina, Brunei Darussalam, Cayman Islands, Cook Islands, Cuba, Dominican Republic, Egypt, Indonesia, Iraq, Israel, Jordan, Kazakhstan, Kuwait, Kyrgyzstan, Lebanon, Malaysia, Maldives, Marshall Islands, Mauritius, New Zealand, Oman, Palau, Papua New Guinea, Paraguay, Qatar, Russian Federation, Saint Kitts and Nevis, Samoa, Saudi Arabia, Saint Vincent and the Grenadines, Singapore, Solomon Islands, Sudan, Syrian Arab Republic, Tonga, Tunisia, Turkmenistan, Turks and Caicos, Tuvalu, Ukraine, United Arab Emirates and Yemen.*

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Editor's highlights of the WHO's recommendation on event-driven HIV pre-exposure prophylaxis (ED-PrEP)

Background

WHO recommends offering oral pre-exposure prophylaxis (PrEP) to people at substantial risk of HIV as part of comprehensive HIV prevention. PrEP is the use of oral tenofovir disoproxil fumarate (TDF) or co-formulated TDF/emtricitabine (TDF/FTC) or co-formulated TDF/lamivudine (TDF/3TC) by HIV-negative people to prevent HIV acquisition. PrEP has been shown to be effective in a wide range of HIV-negative populations. WHO considers FTC and 3TC interchangeable, both for treatment and for prevention of HIV infection

PrEP has been shown to be effective in a wide range of HIV-negative populations. Emerging evidence from clinical research that different dosing strategies can be effective provides an opportunity to offer flexibility, choice and convenience to individuals who can benefit from PrEP and is considered by WHO in updating its guidance to countries. These new strategies have the potential to reduce the cost of drugs, to reduce pill burden and toxicity and to improve continuation among those who find daily pill-taking challenging.

In 2016 World Health Organization (WHO) published the "Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed." This publication described the high efficacy of PrEP dosing both before and after sex among men who have sex with men who reported frequent sexual activity in the IPERGAY trial – a regimen now called event-driven PrEP (ED-PrEP).

Event-driven PrEP (ED-PrEP) consists of the use of a double dose (two pills, which serves as the loading dose) of TDF/FTC (or TDF/3TC) between two and 24 hours in advance of sex; then, a third pill 24 hours after the first two pills, and a fourth pill 48 hours after the first two pills. ED-PrEP has been described as "2+1+1" dosing.

Findings from latest PrEP demonstration project

Prevenir, an ongoing observational study, sponsored by the French research agency l'Agence française de recherche sur le sida (ANRS) and launched in May 2017, is designed to demonstrate a 15% reduction in new HIV infections among study participants using daily or ED-PrEP. Prevenir aims to enrol 3000 HIV-negative individuals, largely men who have sex with men, but including transgender men and women, heterosexual men and women, sex workers and migrants, in Île-de-France (Paris region). Prevenir is one of the largest demonstration/ implementation projects for oral PrEP since WHO recommended daily dosing of PrEP for any person at substantial risk of HIV.

An interim analysis presented in July 2019 at the International AIDS Conference reported only two HIV infections among 3,057 Prevenir participants taking either ED-PrEP or daily dosing (1073 person-years in daily PrEP arm and 1133 person-years in ED-PrEP arm). There were two HIV infections in the ED-PrEP group in participants who had discontinued PrEP, and no HIV infections in the daily group. Only 3 participants discontinued PrEP due to drug-related adverse events, thus supporting the safety of this dosing

strategy. The HIV incidence per 100 person-years (95% confidence interval) for daily PrEP and ED-PrEP are 0 (0-0.3) and 0.18 (0.02-0.6) respectively. Among those on ED-PrEP, 18% did not use ED-PrEP at their last sexual intercourse, but when PrEP was used adherence was high (79%), and reflected that participants were able to predict when they would have sex and use ED-PrEP. An important observation in Prevenir interim analysis was that 20% of participants overall also used condoms, irrespective of the dosing strategy.

WHO's recommendation on ED-PrEP

- Daily oral PrEP is still recommended for all people at risk of HIV, including men who have sex with men.
- Based on the available evidence, WHO updated the current recommendation on oral PrEP to **include an option of event-driven dosing for men who have sex with men**.
- Since ED-PrEP data are limited in other populations, such as cisgender and transgender women, transgender men without anal sex and heterosexual men, and for women showed lower coverage of sex acts than daily dosing, event-driven dosing is not currently recommended for other population groups. Since TDF is also a drug treatment for hepatitis B, chronic hepatitis B carrier should only use daily PrEP.

Recommendation on switching between daily and ED-PrEP

For all people at risk for HIV, daily oral PrEP should be used once daily during periods of frequent sex or when sex is unpredictable. PrEP can be stopped when no sex occurs. Frequency of sex will vary from person to person, based on several factors, including sexual practices, lifestyle, relationship status, sexual dynamics, age, and risk of HIV is affected by the background community prevalence of HIV. For men who have sex with men oral daily PrEP and ED-PrEP can be offered as options, and the choice can be based on a person's circumstances and preferences, as determined by what best fits their lifestyle, including the frequency and predictability of sex and whether sex is anticipated.

Daily dosing is appropriate for clients where the occurrence of sex cannot be predicted and for those whose potential exposures to HIV are more frequent than 2 times per week, such that ED-PrEP would be taken so frequently that it would effectively resemble daily PrEP.

If sex continues beyond one day, a user of ED-PrEP can stay protected by taking another pill each day as long as sex continues and stopping 2 days after the last sex act. Conversely, if an individual starts daily oral PrEP, but then sex becomes infrequent and predictable, ED-PrEP can be used instead.

Potential benefits of ED-PrEP in Men who have sex with men

ED-PrEP is highly effective in reducing the risk of HIV acquisition in men who have sex with men, and it has the following additional benefits:

- Provides choice and convenience for men who have sex with men who may be at high HIV risk for brief periods or have sex less than 2 times per week on average;
- Serves as an option for men who have sex with men who can anticipate, plan, or delay their sex events;
- Reduces pill burden;
- Saves costs, since fewer pills may be needed, including costs to the user if he buys PrEP.

Potential risks of ED-PrEP in Men who have sex with men

- There are concerns that using ED-PrEP, and

consistently taking the correct regimen, may be difficult for some people.

- Some clinicians have raised concerns that drug resistance risk may be higher with ED-PrEP because drug exposure is episodic and HIV testing may not occur before PrEP use. People taking ED-PrEP infrequently may theoretically become HIV infected in periods where they are off PrEP, with subsequent increased risk of resistance if ED-PrEP is taken without prior HIV testing ruling out HIV infection. Hence, monitoring ED-PrEP implementation and ensuring that follow-up monitoring every three months for HIV testing is an important component of PrEP interventions.

Conclusions

- **ED-PrEP is safe and highly effective** in reducing risk of HIV acquisition through receptive and/or insertive sex between men. It can be offered as an alternative to daily PrEP dosing for men who have sex with men. Data from available trials and open label extension studies and a recently completed two year demonstration study in Amsterdam show that ED-PrEP is as effective in preventing HIV infection as daily PrEP in men who have sex with men.
- **Education and support** for both ED-PrEP and daily dosing are necessary to aid people's choice between the two dosing strategies and their understanding of the requirements to maintain protection against HIV.
- **HIV testing is recommended every three months** whether a person is using daily oral PrEP or ED-PrEP. People taking ED-PrEP infrequently may not need prescriptions filled as often, or may have fewer bottles of PrEP prescribed, and so specific counselling to test for HIV every three months should be emphasized.
- Oral PrEP, irrespective of the dosing strategy, is an **opportunity to engage with individuals around sexual health**, particularly the management of bacterial and viral STIs. WHO will be providing additional guidance in STI management for PrEP users later in 2019.

Source: Event-Driven Oral Pre-exposure Prophylaxis to Prevent HIV for Men Who Have Sex With Men: Update to WHO's Recommendation on Oral PrEP (WHO, 23 July 2019)

https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf