

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



The Node is a bilingual publication dedicated to global HIV/AIDS issues by Red Ribbon Centre, the UNAIDS Collaborating Centre for Technical Support

PRESS STATEMENT

UNAIDS welcomes new tool for HIV prevention for gay men and other men who have sex with men and transgender women

Ground-breaking new study shows the efficacy of a long-acting injectable to prevent HIV

GENEVA 19 May 2020—UNAIDS warmly welcomes the announcement that the long-acting injectable cabotegravir is safe and effective in preventing HIV among gay men and other men who have sex with men and transgender women. The HIV Prevention Trials Network (HPTN) 083 study enrolled almost 4600 HIV-negative people from across more than 40 sites in North and South America, Asia and Africa.

“This is a breakthrough that will have a significant impact on the lives of gay men and other men who have sex with men and transgender women when they are at higher risk of HIV infection.” said Shannon Hader, UNAIDS Deputy Executive Director, Programme. “We are particularly pleased that the study met its targets to recruit substantial numbers of younger black men who have sex with men and transgender women, the very people for whom accessing effective HIV prevention still remains a huge challenge.”

In 2018, UNAIDS estimates that there were 1.7 million new HIV infections, 54% of which were among key populations and their partners,

including gay men and other men who have sex with men, transgender women, sex workers, people who inject drugs, people in prison, clients of sex workers and sex partners of other key populations.

Pre-exposure prophylaxis (PrEP)—HIV-negative people using antiretroviral medicine to prevent HIV infection—is an important element in the HIV combination prevention toolkit. PrEP allows people to reduce their risk of becoming infected with HIV, particularly during periods of increased risk in their lives. It may also provide reassurance and reduce anxieties when the risks are uncertain.

Once it has passed regulatory approval, and when production of affordable cabotegravir can be scaled up, gay men and other men who have sex with men will have the choice of three highly effective ways to use PrEP to prevent HIV infection: daily pills, pills taken before and after sexual activity (event-driven PrEP) or an injection every two months. Transgender women will be able to choose between injections or daily pills, since the World Health Organization does

not recommend event-driven PrEP because of possible drug interactions with some hormones. Injections of cabotegravir every two months are an important option for people who find it hard to take a pill every day, yet remain vulnerable to HIV infection.

The trial was scheduled to continue for at least another year, but the first interim analysis of the data was brought forward a few weeks because of the potential disruption that the COVID-19 pandemic might cause to high-quality clinical trial procedures. The Data and Safety Monitoring Board (DSMB) in the United States of America reviewed the data up to March 2020 and found that there was already clear evidence that cabotegravir was highly effective and not inferior to the currently recommended oral PrEP regimen.

Half of the study group were given oral PrEP and were injected with a placebo; the other half were given a cabotegravir injection and took a placebo pill. The study found a total of 12 HIV infections in the group using the injectable compared to 38 in the group taking the daily pill. The side-effects of both treatments were relatively mild, with only 2.2% of people in the injection group choosing to stop having the injections because of painful reactions. The DSMB therefore recommended that the study be halted and that all participants be notified of the result. The participants will be able to choose which regimen they wish to continue on.

Despite good adherence in the oral group and very few discontinuations in the injection group, the overall incidence of HIV infection in the study was 0.79 per 100 person-years. Planned analyses will explore why those 50 infections occurred among the 4565 trial participants.

An additional study (HPTN 084) is ongoing to establish the efficacy of the long-lasting injectable in non-transgender women. To date, more than 3000 sexually active women in seven African countries have enrolled in the study. Those results are expected in November.

“We are eagerly awaiting the results of the ongoing HPTN 084 study among African women,” said Dr Hader. “We hope that by the end of this year there will be equally good news for women around the world.”

HPTN 083 was conducted by the HPTN and funded by ViiV Healthcare and the United States National Institute of Allergy and Infectious Diseases. Cabotegravir has not yet been approved for the treatment or prevention of HIV as a single agent by regulatory authorities anywhere in the world. ViiV Healthcare plans to use the data from HPTN 083 for future regulatory submissions.

UNAIDS congratulates the research teams and urges continued investment in research and development for HIV vaccines, diagnostics, preventative medicines, treatment and a cure.

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UNAIDS report on the global AIDS epidemic shows that 2020 targets will not be met because of deeply unequal success; COVID-19 risks blowing HIV progress way off course

Missed targets have resulted in 3.5 million more HIV infections and 820 000 more AIDS-related deaths since 2015 than if the world was on track to meet the 2020 targets. In addition, the response could be set back further, by 10 years or more, if the COVID-19 pandemic results in severe disruptions to HIV services.

GENEVA, 6 July 2020—A new report by UNAIDS shows remarkable, but highly unequal, progress, notably in expanding access to antiretroviral therapy. Because the achievements have not been shared equally within and between countries, the global HIV targets set for 2020 will not be reached. The report, *Seizing the moment*, warns that even the gains made could be lost and progress further stalled if we fail to act. It highlights just how urgent it is for countries to double down and act with greater urgency to reach the millions still left behind.

“Every day in the next decade decisive action is needed to get the world back on track to end the AIDS epidemic by 2030,” said Winnie Byanyima, the Executive Director of UNAIDS. “Millions of lives have been saved, particularly the lives of women in Africa. The progress made by many needs to be shared by all communities in all countries. Stigma and discrimination and widespread inequalities are major barriers to ending AIDS. Countries need to listen to the evidence and step up to their human rights responsibilities.”

Fourteen countries have achieved the 90–90–90 HIV treatment targets (90% of people living with HIV know their HIV status, of whom 90% are on antiretroviral treatment and of whom 90% are virally suppressed), including Eswatini, which has one of the highest HIV prevalence rates in the world, at 27% in 2019, and which has now surpassed the targets to achieve 95–95–95.

Millions of lives and new infections have been saved by the scale-up of antiretroviral therapy.

However, 690 000 people died of AIDS-related illnesses last year and 12.6 million of the 38 million people living with HIV were not accessing the life-saving treatment.

“We cannot rest on our successes, nor be discouraged by setbacks. We must ensure that no one is left behind. We must close the gaps. We are aiming for 100–100–100,” said Ambrose Dlamini, the Prime Minister of Eswatini.

The world is far behind in preventing new HIV infections. Some 1.7 million people were newly infected with the virus, more than three times the global target. There has been progress in eastern and southern Africa, where new HIV infections have reduced by 38% since 2010. This is in stark contrast to eastern Europe and central Asia, which has seen a staggering 72% rise in new HIV infections since 2010. New HIV infections have also risen in the Middle East and North Africa, by 22%, and by 21% in Latin America.

Seizing the moment shows unequal progress, with too many vulnerable people and populations left behind. Around 62% of new HIV infections occurred among key populations and their sexual partners, including gay men and other men who have sex with men, sex workers, people who inject drugs and people in prison, despite them constituting a very small proportion of the general population.

Stigma and discrimination, together with other social inequalities and exclusion, are proving to be key barriers. Marginalized populations who fear judgement, violence or arrest struggle to access sexual and reproductive health services, especially those related to contraception and HIV

prevention. Stigma against people living with HIV is still commonplace. At least 82 countries criminalize some form of HIV transmission, exposure or non-disclosure, sex work is criminalized in at least 103 countries and at least 108 countries criminalize the consumption or possession of drugs for personal use.

Women and girls in sub-Saharan Africa continue to be the most affected and accounted for 59% of all new HIV infections in the region in 2019, with 4500 adolescent girls and young women between 15 and 24 years old becoming infected with HIV every week. Young women accounted for 24% of new HIV infections in 2019, despite making up only 10% of the population in sub-Saharan Africa.

However, where HIV services are comprehensively provided, HIV transmission levels are reduced significantly. In Eswatini, Lesotho and South Africa, a high coverage of combination prevention options, including social and economic support for young women and high levels of treatment coverage and viral suppression for previously unreached populations, have narrowed inequality gaps and driven down the incidence of new HIV infections.

The COVID-19 pandemic has seriously impacted the AIDS response and could disrupt it more. A six-month complete disruption in HIV treatment could cause more than 500 000 additional deaths in sub-Saharan Africa over the next year (2020–2021), bringing the region back to 2008 AIDS mortality levels. Even a 20% disruption could cause an additional 110 000 deaths.

“Those of us who survived HIV and fought for life and access to treatment and care cannot afford losing the gains that took so much effort to win. In some Latin American countries we are seeing how HIV resources, medicines, medical staff and equipment are being moved to the fight against COVID-19,” said Gracia Violeta Ross, President of the Bolivian Network of People Living with HIV. “Some good lessons and practices of the HIV response, such as meaningful participation and accountability, are being ignored. We will not allow HIV to be left behind.”

To fight the colliding epidemics of HIV and COVID-19, UNAIDS and partners are leading a global call for a People’s Vaccine for COVID-19, which has been signed by more than 150 world leaders and experts demanding that all vaccines, treatments and tests be patent-free, mass produced and distributed fairly and free for all.

UNAIDS is also urging countries to increase investments in both diseases. In 2019, funding for HIV fell by 7% from 2017, to US\$ 18.6 billion. This setback means that funding is 30% short of the US\$ 26.2 billion needed to effectively respond to HIV in 2020.

“We cannot have poor countries at the back of the queue. It should not depend on the money in your pocket or the colour of your skin to be protected against these deadly viruses,” said Ms Byanyima. “We cannot take money from one disease to treat another. Both HIV and COVID-19 must be fully funded if we are to avoid massive loss of life.”

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