

First-of-its-kind HIV Cure Case Among Scientific Highlights at AIDS 2024

New global HIV projections and advances in STI and HIV pre-exposure prophylaxis also unveiled ahead of AIDS 2024, the 25th International AIDS Conference

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A unique HIV cure case will be among the scientific highlights of AIDS 2024, the 25th International AIDS Conference, which will take place in Munich, Germany and virtually from 22 to 26 July.

For the first time, scientists will share information about the "next Berlin Patient", who appears to be the world's seventh person cured of HIV following a stem cell transplant. This is the first HIV cure case in which the donor had a single, rather than double, CCR5-delta32 mutation, which could have promising implications for future research.

Other scientific highlights include:

- UNAIDS-led projections showing that without bold action, there could be nearly 35 million new
 HIV acquisitions and nearly 18 million AIDS-related deaths between 2021 and 2050
- Research suggesting that doxycycline pre-exposure prophylaxis (DoxyPrEP) is a promising strategy for preventing sexually transmitted infections (STIs)
- A study suggesting that less frequent monitoring visits could reduce the burden on HIV PrEP users without increasing STIs
- Real-world evidence that long-acting injectable cabotegravir (CAB-LA) is a popular and feasible HIV prevention option for women and men in Africa

AIDS 2024 will also include a presentation with late-breaking full results from the PURPOSE 1 trial of long-acting injectable lenacapavir for HIV prevention. Last month, topline results from an interim analysis of the trial indicated that injectable lenacapavir demonstrated 100% efficacy for

HIV prevention in cisgender women.

"We're seeing impressive innovation across the entire spectrum of HIV research," Sharon Lewin, President of IAS – the International AIDS Society, AIDS 2024 International Co-Chair and Director of the Peter Doherty Institute for Infection and Immunity at the University of Melbourne in Australia, said. "For these advances to have a real-world impact, we must put people first and keep delivery and access concerns front and centre."

Hosted by the IAS, AIDS 2024 will bring together thousands of scientists, policy makers and advocates to examine the latest advances in HIV research and forge a more equitable and innovative HIV response. This year's conference will call on the global HIV community to unite behind a simple principle: Put people first!

"In every aspect of the HIV response, people living with and affected by HIV must be not just beneficiaries, but the actors driving our efforts," Lewin said.

Today's scientific highlights press conference featured six studies selected from the thousands of abstracts that will be presented next week.

The "next Berlin Patient" appears cured of HIV following stem cell transplant; case is first of its kind

Christian Gaebler of Charité – Universitätsmedizin Berlin presented a study on the "next Berlin Patient", an adult male who appears to be the world's seventh person cured of HIV following a stem cell transplant. Importantly, this appears to be the first HIV cure case in which the stem cell donor had a single, rather than double, CCR5-delta32 mutation – a fact that could have promising implications for future, more scalable HIV cure strategies.

The "next Berlin Patient" had both leukaemia and HIV. He received a stem cell transplant for leukaemia in late 2015; then, in late 2018, he stopped taking antiretroviral treatment for HIV. About five-and-a-half years later, he remains in HIV remission.

"A healthy person has many wishes, a sick person only one," said the next Berlin Patient, who has chosen to remain anonymous.

Any case of sustained HIV remission without antiretroviral treatment is noteworthy. But in most HIV cure cases following stem cell transplants, the donors had naturally inherited two copies of the CCR5-delta32 mutation – one from each parent. Also known as homozygous, these individuals are essentially immune to HIV.

This is the first HIV cure case in which the donor had inherited just one copy of the CCR5-delta32 mutation – known as heterozygous. These individuals can acquire HIV, but the virus generally progresses slowly if they do not receive antiretroviral treatment. Significantly more people have the heterozygous mutation than the homozygous mutation.

The study concludes that "effective reservoir reductions, durable HIV remission and potential cure can be achieved with functional viral co-receptors, suggesting that allogeneic immunity fundamentally contributes to HIV eradication".

"The next Berlin Patient's experience suggests that we can broaden the donor pool for these kinds of cases, although stem cell transplantation is only used in people who have another illness, such as leukaemia. This is also promising for future HIV cure strategies based on gene therapy, because it suggests that we don't have to eliminate every single piece of CCR5 to achieve remission," Lewin said.

Abstract and session: The next Berlin patient: sustained HIV remission surpassing five years without antiretroviral therapy after heterozygous CCR5 WT/ Δ 32 allogeneic hematopoietic stem cell transplantation, <u>AIDS 2024 Co-Chairs' Choice</u> (12163, Track A)

Failing to meet global HIV targets would have dire long-term consequences, projections show

If global HIV targets are not met, there could be nearly 35 million new HIV acquisitions and nearly 18 million AIDS-related deaths between 2021 and 2050, according to a new analysis.

The study, presented by UNAIDS economist Erik Lamontagne, estimated the human and economic cost of failing to meet "95-95" targets in 114 countries. These targets are achieved when 95% of people who are living with HIV know their HIV status, 95% of people who know that they are living with HIV are on antiretroviral treatment, and 95% of people who are on treatment are virally suppressed.

The study team compared the incremental costs, benefits and economic returns of a scenario that fulfils the 95-95-95 targets to a "business-as-usual" scenario maintaining coverage of HIV-related services at 2020 levels every year until 2050.

The analysis found that failing to meet global targets would entail tremendous human and economic consequences. The human cost would include an estimated 34.9 million new HIV acquisitions and 17.7 AIDS-related deaths between 2021 and 2050. The economic cost would be an estimated USD 8,291 per person among all low- and middle-income countries by 2050, with an average cost of inaction per capita of USD 670.

"The world is at a critical juncture in the response to HIV. This study reminds us just how much is at stake if we fail to act, and what can be achieved if we act now," Lewin said.

Abstract and session: The cost of inaction of failing to meet global targets to end the AIDS epidemic: looking beyond 2030, Poster exhibition (11028, Track E)

Doxycycline pre-exposure prophylaxis (DoxyPrEP) significantly reduces STIs in two studies

Results from two small studies suggest that doxycycline pre-exposure prophylaxis (DoxyPrEP) is a promising strategy for preventing STIs.

In recent years, studies have shown that DoxyPEP – taking doxycycline within 72 hours after sex – can prevent bacterial STIs among men who have sex with men and trans women, and evidence suggests that DoxyPEP is now helping to lower STI incidence in some communities. However, there has been less research on DoxyPrEP, which involves taking doxycycline before sex.

AIDS 2024 features two studies of DoxyPrEP. The first is a pilot, randomized controlled trial that enrolled 52 men who have sex with men in Toronto and Vancouver, Canada. All of the men were living with HIV and had a history of syphilis. They were randomized to receive 100mg of doxycycline daily or a placebo and followed for 48 weeks.

Forty-one participants (78.8%) completed the study protocol. There was a 79% reduction in syphilis, a 92% reduction in chlamydia and a 68% reduction in gonorrhoea in the doxycycline arm compared with the placebo arm. There were no differences between arms related to drug adherence or sexual behaviours. New doxycycline resistance developed in three of 19 and two of $19 \ (p=0.57) \ S$. aureus isolates from baseline to week 48 in the doxycycline and placebo arms, respectively.

According to presenter Troy Grennan of the British Columbia Centre for Disease Control, these pilot findings support further evaluation of DoxyPrEP compared with DoxyPEP in an ongoing larger trial.

The second DoxyPrEP study enrolled 40 female sex workers in Tokyo, Japan; the women were each provided with 100mg of doxycycline daily and followed over time. After initiating DoxyPrEP, the overall STI incidence rate declined from 232.3 to 79.2 per 100 person-years. Syphilis incidence was reduced to zero, there was a marginally significant reduction in chlamydia and there was no significant change in gonorrhoea. Incidence of bacterial vaginosis and vulvovaginal candidiasis did not significantly increase.

Follow-up interview summaries revealed that adherence to DoxyPrEP was high. Nausea and vomiting were reported by 22.7% of respondents, but no serious doxycycline-related adverse events were observed. Notably, 72.7% of respondents indicated a reduction in their fear of STI transmission.

According to presenter Seitaro Abe of the National Center for Global Health and Medicine in Japan, these findings support the introduction of DoxyPrEP in populations that are highly vulnerable to STIs.

Abstracts and sessions: A pilot, randomized controlled trial of doxycycline pre-exposure prophylaxis versus placebo for prevention of bacterial sexually transmitted infections in men who have sex with men living with HIV, Poster exhibition (11987, Track B); Doxycycline PrEP prevents STIs without affecting vaginal bacterial flora in female sex workers, HIV and STI prevention: Understanding preferences and perceptions (7497, Track C)

Less frequent monitoring visits could reduce the burden on HIV PrEP users without increasing STIs

Implementing less frequent monitoring visits could reduce the burden on HIV PrEP users and cut costs without increasing STIs, according to a study from the Netherlands.

The study, known as EZI-PrEP, examined the impact of screening HIV PrEP users for STIs every six months, rather than every three months, which is the standard of care in the Netherlands. A total of 469 men who have sex with men were randomized to come in for STI screening every six months or every three months, and followed over time; additional STI testing between monitoring visits was also available.

The overall visit rate in the six-monthly arm was lower than the three-monthly arm, and the additional STI visit rate in the six-monthly arm was higher than the three-monthly arm. There was no difference in STI positivity between arms, although the 6-monthly arm showed a slightly higher positivity of asymptomatic STIs.

According to presenter Marije L Groot Bruinderink of Public Health Service Amsterdam, the findings suggest that implementing PrEP monitoring every six months as a standard of care could bring down the number of visits without increasing STIs; this could reduce costs and help reduce a barrier to PrEP uptake and adherence.

Abstract and session: STI testing rates among PrEP users randomized to 3-monthly (standard of care) or 6-monthly monitoring within the EZI-PrEP trial, the Netherlands: preliminary results, <u>New strategies for optimizing person-centred care</u> (3295, Track E)

Note: The above summary reflects updated information provided by the study team.

New evidence that long-acting injectable cabotegravir is a popular, feasible HIV prevention option

Long-acting injectable cabotegravir (CAB-LA) is a popular and feasible prevention option for women and men who are vulnerable to HIV acquisition, according to new real-world evidence from Africa.

Previous studies have shown that CAB-LA is safe and highly effective for HIV prevention. To inform implementation of CAB-LA, researchers assessed knowledge, awareness, feasibility and acceptability among participants who used CAB-LA in the ongoing SEARCH Dynamic Choice HIV prevention randomized implementation study in rural Uganda and Kenya.

The study enrolled women and men aged 15 and older who were vulnerable to HIV acquisition. The intervention arm included a choice of oral PrEP, CAB-LA, or PEP (post-exposure prophylaxis) and participants had the flexibility to switch between products over 48 weeks of follow-up. Of 487 intervention arm participants, 56% started CAB-LA during follow up; of these, 72% used CAB-LA for 24 weeks or more. At initiation, 64% chose CAB-LA because it was easier to take an injection and 49% because of difficulty remembering to take oral pills. At CAB-LA initiation, 99% of participants had basic to no knowledge of CAB-LA, consistent across gender and age groups. Awareness, acceptability and feasibility were high at 24 weeks and persisted to 48 weeks.

According to presenter Elijah Kakande of the Infectious Diseases Research Collaboration in Uganda, the findings show that CAB-LA was a popular choice for women and men and was feasible to deliver with a high level of satisfaction.

"Long-acting PrEP has the potential to strengthen HIV prevention progress worldwide. I hope these results will accelerate efforts to make long-acting injectable cabotegravir available and accessible to all those who can benefit," Lewin said.

Abstract and session: Knowledge, awareness, feasibility, and acceptability of long-acting cabotegravir for HIV prevention: results from the SEARCH Dynamic Choice HIV prevention trial, Welcome to the prevention choice agenda! (6353, Track E)

Except where otherwise noted, the summaries above are based on submitted abstracts. Final data presented at the conference may change.

On 24 July, during the <u>"Co-Chairs' Choice" session</u> starting at 10:30 CEST, Linda-Gail Bekker will present full results from the PURPOSE 1 trial of twice-yearly injectable lenacapavir for HIV prevention. The embargo for that presentation will lift at that time.

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https://www.poz.com/blog/firstofitskind-hiv-cure-case-among-scientific-highlights-aids-2024