

Novel intervention halves rate of death among people living with HIV who inject drugs

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A counselor listens to and advises a client. Credit: NIAID



An intervention designed to facilitate treatment for HIV and substance use was associated with a 50 percent reduction in mortality for people living with HIV who inject illicit drugs, a study has found. In addition, the people who received the intervention were nearly twice as likely to report being in treatment for HIV and substance use after one year as those who received their national standard of care. They also were about twice as likely to have suppressed their HIV to undetectable levels after one year. The intervention consisted of psychosocial counseling along with guidance and support navigating the healthcare system. These findings were reported today in the journal *The Lancet*.

People who inject drugs often have high rates of HIV infection, poor access to and use of <u>treatment</u> for HIV and substance use, and high mortality in the United States and globally. Needle sharing among people who inject drugs is the main route of HIV transmission in some parts of the world.

"People living with HIV who inject drugs often encounter multiple obstacles to beginning and adhering to treatment for HIV infection and substance use," said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. "This study demonstrates that providing guidance and counseling can help such individuals overcome barriers to starting and staying in care and treatment, leading to a significantly higher rate of HIV suppression and a much lower rate of death."

NIAID co-funded the study with the National Institute on Drug Abuse (NIDA), also part of NIH. The NIH-funded HIV Prevention Trials Network (HPTN) implemented the trial, called HPTN 074.

"People who inject drugs and are living with HIV have potentially fatal co-occurring conditions, yet they and their at-risk partners often face different and confusing care delivery systems," said NIDA Director



Nora D. Volkow, M.D. "This study shows that integrated interventions, including help from systems navigators, can dramatically reduce mortality for both conditions."

None of the few new HIV infections in the trial occurred among the injection partners of people living with HIV who received the study intervention. Scientists could not draw a firm conclusion about the impact of the intervention on HIV transmission through injection drug use, however, because the study was not statistically powered to measure that effect.

HPTN 074 took place in three countries with HIV epidemics driven by injection drug use: Indonesia, Ukraine and Vietnam. The study team enrolled 502 men and women ages 18-60 years who are living with HIV and inject drugs, and 806 HIV-uninfected men and women who inject drugs with them (injection partners). At least one injection partner of every person in the study living with HIV enrolled. The people living with HIV were assigned at random to receive either the national standard of care for HIV infection and substance use or the standard of care plus an integrated and flexible intervention designed to facilitate treatment. The <u>study participants</u> were followed for one to two years.

Study participants assigned to receive the intervention were immediately referred to local health-care providers for anti-HIV therapy to treat their infection, prevent sexual transmission of HIV, and potentially prevent HIV transmission via needle sharing. In addition, each participant who received the study intervention was assigned a systems navigator who helped the participant identify and overcome structural barriers to starting and staying in care and treatment for HIV and substance use. Such barriers could include unfamiliarity with how to enroll in medical care for HIV or difficulty keeping treatment-related appointments. Finally, psychosocial counselors helped each study participant overcome their unique psychological obstacles to starting and staying in treatment,



such as lack of interest in therapy, difficulty establishing a medication-taking routine, or stigma.

In addition, all study participants, including the HIV-uninfected injection partners, received their country's standard of care for people who inject drugs. This typically included referral for treatment of substance use; referral to needle/syringe exchange programs, if legal and available; injection risk reduction counseling; sexual risk reduction counseling; HIV counseling and testing; and referral for diagnosis and treatment of sexually transmitted infections, hepatitis B and C viruses, and tuberculosis, as appropriate. Those study participants living with HIV who received only the standard of care also were referred to local health-care providers for anti-HIV therapy according to national guidelines for when to start treatment.

At the end of the study, 15 percent of participants with HIV who had received the standard of care had died, compared to seven percent of participants with HIV who had received the intervention, corresponding to a 53 percent reduction in mortality.

Some 26 percent of deaths among study participants who had HIV were considered clearly HIV-related, and 3 percent were due to drug overdose. Among the 42 percent of deaths with unknown cause, 24 percent occurred among people whose immune systems were in poor health. Non-HIV-related medical events caused 21 percent of deaths overall, and trauma and suicide accounted for the remaining eight percent.

After one year, 41 percent of study participants who received the intervention had undetectable levels of HIV in their blood, compared to 24 percent of participants who received only the standard of care. Also, 72 percent of study participants who received the intervention reported being in treatment for HIV at the end of one year, compared to 43



percent of those who received only the standard of care. Forty-one percent of study participants who received the intervention reported being in treatment for substance use at the end of one year, compared to 25 percent of those who received only the standard of care.

"The intervention in this study had a remarkably positive impact on people living with HIV who inject drugs," said Protocol Chair William C. Miller, M.D., Ph.D. "It was designed to be scalable to other settings, and we hope that it can help this important population worldwide." Dr. Miller is professor and chair of the Division of Epidemiology at The Ohio State University College of Public Health in Columbus.

Previous studies have demonstrated that when a person takes anti-HIV medication that suppresses the amount of virus in the blood to undetectable levels, it both protects the health of the individual and prevents sexual transmission of the virus. Whether viral suppression also prevents HIV transmission through needle sharing with injection partners remains unknown. The HPTN 074 study was not designed to determine whether the intervention would reduce the rate of HIV infection among injection partners of the participants living with HIV, but rather to determine the feasibility of a larger study that could measure this effect. In HPTN 074, seven injection partners of participants living with HIV who received only the standard of care became infected, while no injection partners of participants living with HIV who received the study intervention became infected. This result is promising, according to the investigators, but because the overall HIV incidence among injection partners was so low, a larger clinical trial to test the effect of the study intervention on HIV transmission among injection drug users would not be feasible.

Given the success of the study intervention at reducing mortality and increasing the rates of both participation in treatment and viral suppression, investigators have offered the intervention to all the HPTN



074 study participants living with HIV. In addition, all participants living with HIV are being followed for a second year to determine whether the positive effects of the intervention are maintained.

More information: WC Miller, et al. A scalable, integrated intervention to engage people who inject drugs in HIV care and medication-assisted treatment: A randomized, controlled vanguard trial (HPTN 074). *The Lancet* DOI: 10.1016/S0140-6736(18)31487-9 (2018).

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