Huge Australian PrEP Study Maintains Very Low HIV Rate After Two Years

Among nearly 10,000 gay and bisexual men followed for a cumulative 18,000 years, there have been only 16 new cases of the virus.

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Indicating that pre-exposure prophylaxis (PrEP) can indeed be a highly effective long-term strategy for combating HIV on a public health level, a very large real-world Australian study of PrEP among men who have sex with men (MSM) has seen a very low rate of new infections after an average of nearly two years of follow-up among participants.

The EPIC-NSW population implementation study was initially slated to provide PrEP to 3,700 MSM in the Australian state of New South Wales but—as a result of an extraordinarily high level of interest—swelled to include 9,708 people in the new analysis. Initially, researchers reported on the first year of follow-up of the original 3,700 participants, finding that they contracted HIV at a rate of 0.51 cases per 1,000 cumulative years of follow-up. This compared with an expected infection rate without PrEP of more than 20 cases per 1,000 cumulative years of follow-up.

Thanks in part to the rapid rollout of PrEP in Australia—this study was a central part of that effort—the nation recently reported that its HIV infection rate declined by nearly 25% between 2013 and 2018.

Andrew Grulich, MD, head of the HIV Epidemiology and Prevention Program at the Kirby Institute at UNSW Sydney, presented updated follow-up data from EPIC-NSW at the 10th International AIDS Society Conference on HIV Science in Mexico City (IAS 2019).

The study enrolled the 9,596 HIV-negative participants, 98.5% of whom were men, at 31 clinics across New South Wales between March 2016 and April 2018 and provided them PrEP at no cost. Fourteen (0.2%) of the cohort members were female and 127 (1.3%) were transgender or another gender identity. A total of 91.3% of the individuals identified as gay and 7.0% as bisexual.

The statewide HIV epidemic is heavily concentrated among men who have sex with men (MSM), with about 80% of diagnoses occurring in this demographic between 2012 and 2015.

Upon entering the cohort, 11.7% of the members were 18 to 24 years old, 40.2% were 25 to 34 years old, 26.0% were 35 to 44 years old and 22.2% were at least 45 years old.

During a cumulative 19,690 years of follow-up, meaning that participants were followed for an average of about two years, 30 study members have tested positive for HIV. In all cases, evidence indicated that these individuals were not adherent to the PrEP regimen. Many of them received only one or two PrEP prescriptions, and most of them had stopped PrEP months, or even as long as two years, before testing positive for HIV.

These findings translated to an HIV incidence, or new infection rate, of 1.52 per 1,000 cumulative years of follow-up. By comparison, the study authors predicted that without PrEP, 400 of the cohort members would have tested positive for HIV during this time, for that same infection rate of 20 per 1,000 cumulative years of follow-up used in the previous analysis.

Younger participants were more likely to contract HIV in the study. The infection rate per 1,000 cumulative years of follow-up was 3.56 cases among those 18 to 24 years old, 1.64 cases among those 25 to 34 years old, 1.57 cases among those 35 to 44 years old and 0.77 cases among those 45 years old and older. Compared with those 18 to 24 years old, those 45 to 54 years old and older were 81% less likely to contract the virus.

Those without a rectal sexually transmitted infection (STI) upon entering EPIC-NSW had an HIV infection rate per 1,000 cumulative years of study follow-up of 1.11 cases, compared with 3.49 cases among those who did start the study with a rectal STI. This meant that having a rectal STI at the study's baseline was associated with a 3.15-fold increased likelihood of contracting HIV compared with not having one.

Those who did not report using methamphetamine at the study's outset had an HIV infection rate per 1,000 cumulative years of follow-up of 1.16 cases, compared with 2.86 cases among those who did report meth use when beginning the study. So reporting meth use, compared with not doing so, upon enrollment was associated with a 2.46-fold increased likelihood of contracting HIV.

Those who reported using meth andwho had a rectal STI at the study's baseline had an infection rate per 1,000 cumulative years of follow-up of 7.59 cases, compared with 1.00 cases among those about whom neither factor applied. This meant that reporting meth use and having a rectal STI upon entering the study, compared with neither factor applying, was associated with a 7.58-fold increased likelihood of contracting HIV.

The infection rate rose during each successive 12-month period after the launch of the study. For each 1,000 cumulative years of follow-up, March 2016 through February 2017 saw 0.38 new cases, March 2017 through February 2019 saw 1.17 new cases, and March 2018 through February 2019 saw 2.06 new cases. Compared with the first 12-month period, the infection rate was 3.10-fold higher during the second 12-month period and 5.44-fold higher during the third 12-month period.

Factors that did not predict to a statistically significant extent whether participants would contract the virus included: their country of birth; whether they identified as gay versus bisexual; whether one, two or three years had passed since they had received PrEP; and whether they lived in a Sydney suburb that had a male population in which more than 10% identified as gay, or "gay Sydney." That said, the researchers noted that the infection rate was somewhat higher among those who lived somewhere other than gay Sydney.

The number of HIV diagnoses per half-year period among all MSM in New South Wales declined 44% between the second half of 2015, when there were just over 80 new diagnoses, and the second half of 2018, when there were under 50 new diagnoses. This figure leveled off starting in the beginning of 2017, however. Gay Sydney saw a 60% decline in new HIV diagnoses among MSM during this overall period.

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