



EPIC-NSW Trial Summary of Results for Study Participants

The Expanded PrEP Implementation in Communities (EPIC-NSW) started enrolment on 1 March 2016 in NSW and was completed on 30 April 2018. Enrolment in the ACT commenced on 12 September 2017 and was completed on 28 February 2018.

Overall, 9,709 participants were enrolled in 31 study clinics - 29 clinics in NSW and 2 clinics in the ACT. EPIC-NSW enrolled participants who were at high-risk of HIV and provided them with oral tenofovir 300mg/emtricitabine 200mg, one pill once a day as pre-exposure prophylaxis (PrEP) for the duration of the trial.

Demographics (characteristics of the trial participants):

NSW participants (9,407):

Most of the participants were male (98%) and identified as gay/homosexual (91%). Most participants were aged between 25-34 years or 35-44 years. 52% of participants were Australian-born. Almost half of the participants (46%) lived in suburbs with a lower concentration of gay men (<5%), and 31% of the participants lived in suburbs with a high concentration of gay men (≥20%).

ACT participants (302):

All participants were male, and the majority identified as gay (90%). Most participants were aged between 25-34 years (44%). 81% of participants were Australian-born. Most of the participants (91%) lived in metropolitan Canberra.

Primary results of the trial:

1. New HIV diagnoses in the trial population:

Study follow-up was completed on 31 March 2019. Overall, 30 out of the 9,596 participants (who were dispensed study PrEP at least once) became HIV positive during the trial. In an Australian population of gay and bisexual men reporting PrEP eligibility criteria, the trial would have expected more than 400 HIV diagnoses in the absence of PrEP. There was no HIV diagnosis in the ACT participants during the study. Not using daily PrEP was a factor in all participants who became HIV positive.

2. Impact of the trial:

The impact of PrEP on new HIV diagnoses in NSW cannot be easily untangled from other efforts to end HIV, including increased HIV testing, early commencement of anti-retroviral therapy in those diagnosed HIV positive, and treatment as prevention more broadly. However, a large and sustained decline in new HIV infections across NSW was observed following the initiation of the EPIC-NSW study in early 2016, highlighting the crucial role PrEP has played in bringing new HIV diagnoses in NSW to their lowest level on record.

A comparison was made between the number of recently acquired (evidence of infection in the past 12 months) HIV infections in men who have sex with men (MSM) in the 6-month period before EPIC-NSW



enrolment began (July-December 2015) and the 6-month period following the end of enrolment (July-December 2018). There was a 44% decline in recently acquired HIV infections in MSM, an internationally unprecedented reduction in HIV transmission.

Secondary results of the trial:

1. *PrEP adherence:*

PrEP adherence in the trial participants was measured by the 'medication possession ratio' (MPR). The MPR was calculated as the total number of tenofovir/emtricitabine (TDF/FTC) pills dispensed over a specific time period divided by the days of follow-up from first dispensing. It can be thought of as the proportion of days on which participants took a pill

Overall, 9,596 participants were enrolled in the EPIC-NSW and were dispensed study PrEP at least once by 30 April 2018. TDF/FTC adherence as measured by MPR was generally high among the EPIC-NSW participants. During study follow-up, the majority of participants had sufficient TDF/FTC in possession to allow daily dosing.

Groups of participants who had difficulties in maintaining high PrEP adherence were younger participants (age less than 25), those who lived in suburbs with lower concentration of gay men, and those participants who reported methamphetamine use and rectal sexually transmitted infection at study enrolment.

2. *Sexual transmitted infection (STI) at baseline/enrolment:*

Looking at the baseline STI positivity in EPIC-NSW participants provides an indication of sexual risk at the time of study enrolment. STI positivity is defined as the proportion of individuals tested who had a positive result for gonorrhoea, chlamydia, or infectious syphilis.

Overall, of the EPIC-NSW participants with STI tests at enrolment between 1 March 2016 and 30 April 2018:

- 9.6% and 8.9% had a positive test result for chlamydia and gonorrhoea respectively
- 2.0% of participants had infectious syphilis at enrolment.

Throughout study enrolment, the number of individuals who tested positive for gonorrhoea and chlamydia at enrolment remained relatively high, and the number of individuals who tested positive at enrolment for infectious syphilis remained stable, suggesting that EPIC-NSW continued to reach individuals at high risk of HIV.

3. *STI during study follow-up:*

During study follow-up, STI tests were recommended to be done every 3 months. The number of tests and test results were reviewed in each 3-month testing period. The rate of positivity to all infections was high but fairly stable over time.