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Report on the PrEP in NSW Transition Study, 2018-2020

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Executive Summary

This is a report on the findings from the *PrEP in NSW Transition Study*. Over the period August 2018 to March 2020, 2,344 people who had been offered HIV pre-exposure prophylaxis (PrEP) as part of the *Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW)* trial agreed to be followed up for a further 12 months as part of the *PrEP in NSW Transition Study*. This was to help us understand how people transitioned out of a PrEP implementation trial to receiving PrEP through general practice and standard-of-care prescribing, and any associated changes in behaviour, attitudes or engagement with sexual health.

Summary findings were:

- Most participants continued to use PrEP for at least 12 months after the end of the EPIC-NSW trial.
- More than 10% of participants who were still using PrEP one year after the end of the *EPIC-NSW* trial had taken a break from it for at least a week once their enrolment in the trial finished.
- Almost all (85-95%) participants intended to use PrEP daily and participants on average reported being about 90% adherent to their preferred PrEP dosing schedule.
- After the end of EPIC-NSW, participants mostly bought their PrEP from local pharmacies rather than online.
- Participants were interested in novel delivery methods for PrEP like injectables and implants, and
 only one-fifth said that their preferred option would be a daily pill if alternative dosing methods were
 available and equally effective.
- Participants remained satisfied with their clinic and pharmacy experiences outside of the trial, with most continuing to find appointments convenient and health care workers to be professional, knowledgeable and non-judgemental.
- Sexual behaviour remained constant in the 12 months after *EPIC-NSW* in terms of numbers of male partners, group sex, and paid sex.
- The proportion of participants who knew their partners' HIV statuses increased while knowledge of partners' PrEP use decreased.
- Participants became more likely to indicate that they were willing to have condomless anal sex with an HIV-positive partner with an undetectable viral load but were less likely to report condomless anal sex with HIV-positive partners with undetectable viral loads.

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Glossary

ACCESS Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually

Transmissible Infections and Blood-borne Viruses

EPIC-NSW Expanded PrEP Implementation in Communities in New South Wales study

GBM Gay and bisexual men

HIV Human immunodeficiency virus

MSM Men who have sex with men

NSW New South Wales

PBS Pharmaceutical Benefits Scheme
PINTS PrEP in NSW Transition Study

PrEP Pre-exposure prophylaxis

STI Sexually transmissible infection

TDx/FTC Tenofovir disoproxil (fumarate/maleate/phosphate) coformulated with emtricitabine.

Introduction

The Expanded PrEP Implementation in Communities in New South Wales (EPIC-NSW) study was designed as a rapid implementation trial of PrEP in gay men and other individuals at high risk of HIV in New South Wales, Australia. At that time, it was the world's largest PrEP implementation study and assessed the effect of daily, single-dose oral PrEP on HIV incidence within the cohort and on HIV diagnoses at a state-wide level. Almost 10,000 participants enrolled between 1 March 2016 and 30 April 2018. The first results from EPIC-NSW were published in 2018, showing a 25.1% reduction in HIV diagnoses in NSW in the first 12 months after study enrolment [1].

The implementation of PrEP in NSW via the trial was a resounding success and it coincided with PrEP being listed on the Pharmaceutical Benefits Scheme from 1 April 2018. This listing made PrEP widely available at a publicly-subsidised price. However, questions remained about the real-world effect once a study like this concludes: Would people continue using PrEP once they no longer received it for free and in the context of a trial? Would the cost of PrEP impact its use, even when at a government-subsidised price? Would sexual behaviours and attitudes to sex and sexually transmissible infection (STI) prevention change over time? Would the quality of care provided at PrEP clinical appointments reduce over time and would non-HIV-specialist general practitioners correctly follow the national PrEP guidelines? How would people use PrEP in the real world once they were no longer receiving regular monitoring and support as part of a trial?

There has been limited previous research following up previous participants in PrEP intervention trials to answer these questions (see [2, 3]). However, it is vital to understand the real-world and longer-term effects after such a transition. The *PrEP in NSW Transition Study* was initiated to follow the actions of participants of *EPIC-NSW* beyond their last interaction with the trial. It aimed to understand changing sexual behaviour, PrEP use, and knowledge and attitudes to HIV prevention over time. It comprised a survey around the time of the end of *EPIC-NSW*, followed by two subsequent surveys six months apart.

Methods

Recruitment

The *PrEP in NSW Transition Study* recruited people who had been offered daily PrEP as part of *EPIC-NSW*. When they were originally recruited, participants were:

- 18 years of age or older
- NSW residents (or frequent visitors)
- HIV negative, and at high and ongoing risk of HIV infection as defined by the 2016 NSW HIV PrEP quidelines [4].

When they first enrolled in *EPIC-NSW*, participants were asked whether they would be willing to complete optional quarterly behavioural surveys, with 88.2% consenting. The behavioural surveys were very brief (that is, taking about 5 minutes or less to complete) to ensure the survey component did not pose any barriers to participation in *EPIC-NSW*. Additional data on participants from their clinic visits, including HIV and STI tests, were provided by the *Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections and Blood-borne Viruses (ACCESS*) system [5]. *ACCESS* collects de-identified data in electronic patient records from over 120 clinics and health services across Australia and data were linked with participant records in *EPIC-NSW* to estimate HIV incidence and other outcomes.

From August 2018 all participants who had opted in to receive surveys during the trial were sent an email asking them to complete a 'final *EPIC-NSW* survey'. During that survey, respondents were invited to consent to participate in the *PrEP in NSW Transition Study*. For those who consented to participate, the 'final *EPIC-NSW* survey' acted as the *PrEP in NSW Transition Study* baseline survey with two follow-up surveys six and 12 months after the baseline survey.

While consent to the *PrEP in NSW Transition Study* included consent to link earlier *EPIC-NSW* data and prospective *ACCESS* data, this report includes data from the three *PrEP in NSW Transition Study* surveys only. Those who completed the final *EPIC-NSW* survey but did not consent to this follow-up study (n = 1,144) were excluded for the purposes of this report.

Data collection

Data were collected using the SurveyGizmo online survey platform (https://www.surveygizmo.com/). Those who consented to participate in the *PrEP in NSW Transition Study* were sent an email containing a link to the follow-up surveys six months and 12 months after consenting. If the participants did not complete the follow-up survey, they were sent three reminder emails, one week apart. If they still did not complete it, there was no further contact for that round. All respondents who consented to the *PrEP in NSW Transition Study* received invitations and reminders for both survey rounds. That is, if a participant did not complete the 6-month survey, they still had the opportunity to complete the 12-month survey.

Measures

The *PrEP in NSW Transition Study* surveys were substantially more detailed than the quarterly *EPIC-NSW* surveys and took about 20-25 minutes to complete. The surveys explored:

- Demographics
- PrEP use patterns and intentions
- Experiences of being on PrEP
- Attitudes to and knowledge of existing and potential PrEP modalities (e.g. injectable PrEP)
- Sexual behaviours
- Drug use
- Attitudes and knowledge about HIV and STI prevention

Presentation of results

In this report we present findings for key questions in the surveys. Results are presented for the total sample or for each survey round (number and percentage). Percentages use all non-missing responses for the denominator, and the number of missing responses is reported. For some variables of interest, we present results of subsets of the survey respondents and describe this in the relevant sections.

Some questions in the survey were asked as a series of statements with six-point scales of agreement that participants could choose from ('strongly disagree', 'somewhat disagree', 'slightly disagree', 'slightly agree', 'somewhat agree', 'strongly agree'). For those variables in this report, the number presented is the number of participants who selected 'somewhat agree' or 'strongly agree' and the reported percentage is that number divided by the number of participants who responded to each statement.

Results

Enrolment

Of the 3,488 participants who completed the *EPIC-NSW* final survey, 2,344 (67.2%) consented to participate in the *PrEP in NSW Transition Study*. Of those 2,344 who consented and completed the baseline survey, 1,576 (67.2%) completed the 6-month survey and 1,509 participants (64.4%) completed the 12-month survey. About half (52.2%) completed all three surveys (n = 1,223).

To understand how the cohorts of participants compared, Table 1 shows demographic variables comparing participant characteristics between the cohorts who completed various stages of the *EPIC-NSW* study and the *PrEP in NSW Transition Study*. Compared with full *EPIC-NSW* cohort, there were few differences in demographic characteristics but participants in the *PrEP in Transition Study* were older.

Table 1. Participant characteristics in the EPIC-NSW trial and the PrEP in NSW Transition Study

Characteristic	Full <i>EPI</i> Coh (n = 9	ort	Comp PINTS ¹ k surv (n = 2	oaseline vey	Comp PINTS ¹ 6 surv (n = 1	-month ey	Comp PIN 12-m surv (n = 1	TS¹ onth rey
Male gender identity	9,455	98.5%	2,304	98.3%	1,548	98.2%	1,487	98.5%
Gay sexual identity	8,781	91.5%	2,183	93.1%	1,457	92.5%	1,412	93.6%
Age (median, IQR²)	34	28-43	40	32-49	43	35-52	42	35-52
Aboriginal / Torres Strait Islander	129	1.7%	45	2.0%	25	1.6%	22	1.5%
Region of birth								
Australia	5,059	60.1%	1,403	60.8%	964	61.2%	913	61.2%
High-income English-speaking countries	1,049	12.5%	310	13.4%	220	14.0%	213	14.3%
Asia	1,240	14.7%	298	12.9%	204	13.0%	176	11.8%
Europe	370	4.4%	106	4.6%	72	4.6%	77	5.2%
Latin America and Caribbean	374	4.4%	97	4.2%	51	3.2%	51	3.4%
Other	326	3.9%	92	4.0%	64	4.1%	61	4.1%
Proportion of gay men in suburb ³								
≥20%	2,912	30.7%	744	31.8%	488	31.0%	495	33.0%
10 to <20%	846	8.9%	190	8.1%	128	8.1%	111	7.4%
5 to <10%	1,120	11.8%	294	12.6%	185	11.8%	195	13.0%
<5%	4,602	48.5%	1,114	47.6%	773	49.1%	700	46.6%

¹PINTS is an abbreviation for the PrEP in NSW Transition Study.

²IQR refers to interquartile range.

³Proportion of men who identify as gay was estimated for each Australian postcode using a previously published method [6].

Demographic characteristics

Gender identity

At baseline, almost all participants (98.3%) were cisgender men.

Table 2. Gender identity

	n = 2,344	%
Man	2,304	98.3%
Woman	3	0.1%
Trans man	7	0.3%
Trans woman	9	0.4%
Other ¹	21	0.9%

¹Included write-in responses such as non-binary, intersex, or non-defining.

Age

Participants were aged between 18 and 81 years old at baseline and the median age was 40 years.

Table 3. Age in years

	n = 2,344	%
18-25	131	5.6%
26-30	324	13.8%
31-40	769	32.8%
41-50	598	25.5%
51-60	381	16.3%
61+	141	6.0%

Sexual identity

While some participants identified as bisexual/pansexual (5.9%) or heterosexual (0.4%), the great majority identified as gay or homosexual (93.1%).

Table 4. Sexual identity

	n = 2,344	%
Gay / homosexual	2,183	93.1%
Bisexual / pansexual	139	5.9%
Heterosexual	9	0.4%
Other ¹	13	0.6%

 $^{^{\}rm 1} {\rm Included}$ write-in responses such as non-defining, no labels, or unsure.

Aboriginal and Torres Strait Islander status

Two percent of participants were Aboriginal and/or Torres Strait Islander people.

Table 5. Indigenous status

	n = 2,344	%
Non-Indigenous	2,243	98.0%
Indigenous	45	2.0%
Not reported	56	

Region of birth

Most participants were born in Australia (60.8%), with the rest mostly born in other high-income English-speaking countries (13.4%) or Asia (12.9%).

Table 6. Region of birth

	n = 2,344	%
Australia	1,403	60.8%
High-income English-speaking countries ¹	310	13.4%
Asia ²	298	12.9%
Europe ³	106	4.6%
Latin America and Caribbean	97	4.2%
Other ⁴	92	4.0%
Not reported	38	

¹New Zealand, United Kingdom, Ireland, United States and Canada.

Of the 903 overseas-born participants in the study, we obtained data about the length of time they had lived in Australia from 603 (66.8%). Of these, 13.4% had been living in Australia for less than 5 years, 19.6% between 5 and 10 years and the remaining 67.0% for over 10 years.

Education

Participants were highly educated, with almost two-thirds (65.5%) holding a university degree.

²East Asia, South-East Asia and South Asia.

³Russia is included as part of Europe.

⁴Sub-Saharan Africa, Middle East, Northern Africa, Central Asia and the Pacific and Oceania.

Table 7. Highest level of education

	n = 2,344	%
Up to year 10	112	4.8%
Completed high school (year 12)	218	9.3%
Diploma or certificate	480	20.5%
Undergraduate degree	766	32.7%
Postgraduate degree	768	32.8%

Occupation

Almost three quarters of participants (73.7%) were employed full-time and one in six (16.3%) were working part-time or casually.

Table 8. Employment status

	n = 2,344	%
Full-time	1,723	73.7%
Part-time or casual	382	16.3%
Retired	80	3.4%
Unemployed	123	5.3%
Unable to work	30	1.3%
Not reported	6	

About one in six participants (15.9%) were studying. Of the 371 participants who were studying, 39.1% were also working full-time and 46.6% were working part-time or casually.

Table 9. Student status

	n = 2,344	%
Not studying	1,963	84.1%
Studying Full-time	166	7.1%
Studying Part-time	205	8.8%
Not reported	10	

Participants were generally earning a high annual income, with 56.8% earning \$75,000 or more.

Table 10. Individual annual income

	n = 2,344	%
Less than \$20k	192	8.2%
\$20k to less than \$35k	168	7.2%
\$35k to less than \$50k	221	9.5%
\$50 to less than \$75k	426	18.3%
\$75k to less than \$100k	435	18.6%
\$100k or more	891	38.2%
Not reported	11	

Postcode of residence

Using a previously described method based on Australian Census and survey data [6], estimates of the proportion of men identifying as gay in each Australian postcode were produced. About half of the *PrEP in NSW Transition Study* participants (47.6%) lived in postcodes in which less than 5% of the men were estimated to identify as gay. Nearly one-third (31.8%) lived in postcodes where over 20% of the men were estimated to identify as gay.

Table 11. Proportion of gay men in postcode of residence

	n = 2,344	%
≥20%¹	744	31.8%
10 to <20%	190	8.1%
5 to <10%	294	12.6%
<5%	1,114	47.6%
Not reported	2	

¹Postcodes include 2010, 2011, 2015, 2016, 2042, 2043.

Participants were also classified by their postcode of residence as living regionally, in the inner city, or in suburban areas according to the Australian Bureau of Statistics' geographical classifications [7]. Most of the participants (55.6%) lived in inner-city suburbs, with 30.0% in suburban postcodes and the remaining 14.4% in regional areas.

Medicare card

Most participants (93.7%) had a Medicare card, indicating they had access to Australia's subsidised public health system (including subsidised medicines, testing and free hospital treatment, if needed). Of those, almost all were Australian citizens or residents (their Medicare card was green) while less than one percent were covered under reciprocal healthcare arrangements or were temporary residents applying for permanent residency, that is their Medicare cards were yellow (n = 18) or blue (n = 20).

The 148 (6.3%) participants who were not eligible for Medicare were born in 41 different countries, with the most frequent countries of birth being Brazil (10.8%), China (6.8%), Indonesia (6.8%) and Thailand (6.8%).

PrEP use

Currently using PrEP

In each survey, we asked participants whether they were currently taking PrEP and whether they had taken it in the past six months. Most participants were currently using PrEP but rates of current use decreased between baseline (87.5%) and 12 months later (80.3%).

Table 12. Current PrEP use

	Baseline (n = 2,344)			onths 1,576)	12-months (n = 1,509)	
No current PrEP use or use in past six months	88	3.8%	105	6.7%	174	11.5%
No current PrEP use but used in past six months	205	8.8%	142	9.0%	124	8.2%
Currently using PrEP	2,051	87.5%	1,329	84.3%	1,211	80.3%

We asked participants who had not used PrEP for the past six months to tell us why they had stopped and they were able to select multiple reasons. The most commonly selected reasons for stopping at the 12-month follow-up survey included entering a monogamous relationship (47.7%) or having less or no sex (34.5%), while some participants reported concerns about long-term use (17.2%) or were not able to afford it (13.8%).

Breaks from PrEP

We were interested in how participants continued or altered their PrEP use as they transitioned off the *EPIC-NSW* study. Participants who were currently using PrEP reported whether they had a break from it between the end of the trial and accessing PrEP outside the trial. At the 12-month follow-up, when all participants should have finished their *EPIC-NSW* pills, there were 165 participants (13.6% of current PrEP users) who reported a break of at least a week between the end of their *EPIC-NSW* pills and their current use. Of those who indicated the length of that break (n = 123), 19.5% reported that the break was one to two weeks, 48.8% said three to 12 weeks, and 31.7% of participants had a break of three months or more.

PrEP dosing intentions

There are several ways that people can use PrEP [8]. To understand participants' patterns of PrEP use, we examined four specific dosing options, along with an opportunity for participants to write in their own option. The four options we asked about were daily PrEP, periodic PrEP, on-demand PrEP, and time-based PrEP. In the surveys, we provided participants with basic definitions of each option but they are outlined in more detail here:

• Daily PrEP refers to taking a single pill every day. This option has been extensively researched and trials have demonstrated that when one pill is taken every day, it is nearly 100% effective at preventing HIV infection [1, 9].

- *Periodic PrEP*, sometimes called 'holiday PrEP', refers to taking pills daily during periods with an increased risk of getting HIV, followed by periods of not taking PrEP when there is no perceived risk [10].
- On-demand PrEP, sometimes referred to as 'event-based PrEP', 'event-driven PrEP', or '2-1-1 PrEP', refers to taking two pills two to 24 hours before sex, followed by one pill each day for the following two days. There is strong evidence that it successfully prevents HIV infection [11] and it was incorporated into updated Australian guidelines in September 2019 [12].
- Time-based PrEP involves taking PrEP on certain days of the week and not others. Data from trials of daily PrEP suggest that taking at least four PrEP pills per week can effectively prevent HIV infection in men who have sex with men and transgender women (but not cisgender women) [11]. One specific way of doing this is called the 'Ts and Ss', referring to taking PrEP four days each week on Tuesday, Thursday, Saturday, and Sunday [13]. However, the efficacy of time-based methods has not been examined in trials and they are not currently endorsed in the Australian PrEP guidelines.

For participants who had used PrEP in the past six months (n = 2,256 at baseline; 1,471 at 6-months; 1,335 at 12-months), we asked how they had *intended* to use PrEP at the beginning of that period. The large majority (93.4%) had intended to use PrEP daily at baseline but this was reduced at later follow-up surveys because of an increase in intentions to use on-demand PrEP (from 1.8% at baseline to 5.7% at 12-months) and periodic PrEP (from 3.5% to 6.2%).

Table 13. Past six months PrEP intentions

	Baseline (n = 2,256)		6-months (n = 1,471)		12-months (n = 1,335)	
Daily	2,108	93.4%	1,303	88.6%	1,142	85.5%
Periodic	78	3.5%	75	5.1%	83	6.2%
On-demand	41	1.8%	59	4.0%	76	5.7%
Time-based	17	0.8%	21	1.4%	20	1.5%
Other	12	0.5%	13	0.9%	14	1.1%

At the 12-month survey, 88.5% of participants indicated they intended to take PrEP for the next six months. Of those who intended to use PrEP in the future, most participants (82.5%) intended to use PrEP daily but a minority planned to use it periodically (7.8%), on-demand (7.6%), or on a time-based schedule (1.7%).

PrEP adherence

PrEP adherence refers to taking the correct number of pills according to the dosing regimen an individual has chosen. Research has demonstrated that PrEP adherence is strongly correlated with effectiveness – the pills must be taken appropriately for them to prevent HIV infection [2, 14]. Given that there are several methods for taking PrEP, PrEP adherence must be assessed in relation to the intended dosing regimen.

In this study, we asked about PrEP adherence in relation to the dosing regimen each participant said they intended to use. Participants were given a sliding scale ranging from 0% to 100%, but the scale referred to different things depending on their stated intention:

- Those intending to take daily PrEP were asked what proportion of days they took a PrEP pill
- Those intending to use *periodic daily PrEP* were asked what proportion of days they took a PrEP pill during those periods they had intended to take them
- Those intending to use *on-demand PrEP* were asked what proportion of their sexual encounters were covered by taking PrEP at the time of the encounter
- Those intending to use *time-based PrEP* were asked what proportion of PrEP pills that they intended to take were actually taken.

Table 14 shows the overall combined adherence percentage, as well as the percentages for each dosing option. Percentages closer to 100 indicate higher self-reported adherence. Overall, adherence was over 90% throughout follow-up. On average, participants who indicated an intention to take PrEP daily reported that they had taken PrEP on more than 90% of days in the past six months. Adherence was lower for all non-daily dosing options. On-demand users, for example, reported that three-quarters or fewer of their sexual encounters were covered by PrEP. However, these proportions should be interpreted with caution as few participants had intended to use PrEP in a pattern other than taking it daily. Additionally, for on-demand users, some of the sexual encounters not covered by PrEP may have been covered by another effective HIV prevention method such as condoms, undetectable viral load or their sexual partner using PrEP.

Table 14. PrEP adherence according to stated intention

	Base	Baseline		nths	12-months	
	% (SD)	Range	% (SD)	Range	% (SD)	Range
Overall	93.3 (15.2)	0 - 100	92.5 (17.2)	0 - 100	91.1 (18.7)	0 - 100
Daily intent	94.2 (13.8)	0 - 100	93.9 (15.2)	0 - 100	92.9 (15.9)	0 - 100
Periodic intent	83.1 (20.2)	0 - 100	84.6 (18.7)	30 - 100	83.4 (24.0)	0 - 100
On-demand intent	76.0 (35.0)	0 - 100	72.8 (36.2)	0 - 100	72.1 (34.1)	0 - 100
Time-based intent	75.2 (27.4)	10 - 100	91.5 (8.5)	73 - 100	90.3 (13.4)	50 - 100

Where participants obtained PrEP

We asked participants where they obtained their PrEP pills. As expected, most participants at baseline had their most recent PrEP appointment within the *EPIC-NSW* study and thus received their pills at that appointment. In later surveys this was largely replaced by going to a pharmacy. At 12-months, 87.3% of participants using PrEP were getting it from a pharmacy, and 8.4% were buying PrEP online. Participants who did not have access to Medicare generally purchased their PrEP online (42.0%) and from pharmacies (40.6%).

Table 15. Where participants obtained PrEP at their most recent appointment

	Baseline (n = 2,344)		6-months (n = 1,576)		12-months (n = 1,509)	
EPIC-NSW or another PrEP trial	1,646	73.0%	157	10.7%	36	2.7%
Pharmacy	496	22.0%	1,176	79.9%	1,165	87.3%
Online pharmacy	40	1.8%	102	6.9%	112	8.4%
Other ¹	74	3.3%	37	2.5%	22	1.6%
No PrEP use in past six months	88		104		174	

¹Write-in responses included from friends and directly from a clinic.

PrEP knowledge and attitudes

Knowledge of on-demand PrEP

In the 12-month survey, participants were asked about their awareness of on-demand PrEP. At the time, the official Australian PrEP guidelines [15] did not recommend on-demand PrEP but the updated guidelines [12] released in September 2019 did. As the updated guidelines have not yet been officially endorsed by the Australian Government Blood Borne Viruses and Sexually Transmissible Infections Standing Committee, there have been no large-scale community education campaigns about on-demand dosing in NSW (although information is presented on ACON's *Ending HIV* website¹ and there has been discussion of the on-demand option in community-driven online forums, like PrEP Facts on Facebook).

About two-thirds (68.2%) of participants said that they had heard of on-demand dosing. We asked three multiple choice questions about how to take on-demand PrEP, all of which included an 'I don't know' option:

- 1. How many pills need to be taken before sex? (38.2% of participants who had heard of on-demand dosing correctly answered that two pills should be taken before sex.)
- 2. When should the first dose be taken? (25.9% correctly answered 'at least two hours before sex'.)
- 3. For how many days after sex should you take one pill per day? (25.0% correctly answered 'two days'.)

Of those who had heard of on-demand dosing, 12.3% (n = 127) correctly answered all three questions. Many participants indicated that they did not know the answer to these questions, with the proportion of participants answering 'I don't know' ranging from 38.3% to 47.0%.

PrEP modality preference

The only PrEP options currently available in Australia are oral fixed-dose combinations of TDx/FTC. As shown above, most participants knew about and used daily oral PrEP, and a small but growing proportion used on-

demand PrEP. New PrEP modalities are being developed and researched, including long-acting injectable and implantable PrEP. Injectable PrEP is currently being investigated in large-scale phase III clinical trials to determine its efficacy (as compared to daily oral PrEP) [16-18]. This option involves getting an injection every two to three months. PrEP subdermal implants are in an earlier stage of development. PrEP implants would work in a similar way to contraceptive implants – they would be inserted under the skin and slowly release the medication over time. It is currently unclear how long a single implant would last.

In the 12-month survey, we asked participants – in a hypothetical scenario of all options being available, equally effective, and similar in cost – which ones they would want to use and what their most preferred option would be. Despite most participants being daily PrEP users, only half (52.0%) of participants said they would want to use daily oral PrEP if all options were available.

When asked for their top preference in this scenario, participants favoured the novel technologies over daily or on-demand PrEP. A common preference by those who selected 'other' was for a long-acting oral pill.

Table 16. Desire to use and preference for different PrEP modalities at 12-months

		to use 1,509)¹	Top preference (n = 1,509)		
Daily oral	785	52.0%	319	21.4%	
On-demand oral	646	42.8%	316	21.2%	
Injectable	901	59.7%	455	30.5%	
Implant	684	45.3%	393	26.3%	
Other	14	0.9%	11	0.7%	
Not Reported			15		

¹As participants could select multiple responses, percentages do not add to 100%.

Experiences of being on PrEP

Most participants were completely or very (94.2%) satisfied with their experience of PrEP at baseline (i.e. around when they finished the *EPIC-NSW* study) and at the 12-month follow-up (91.1%).

Table 17. Overall satisfaction with being on PrEP

	Baseline (n = 2,344)			onths 1,576)	12-months (n = 1,509)	
Not at all	8	0.3%	3	0.2%	7	0.5%
Slightly	18	0.8%	15	1.0%	19	1.3%
Somewhat	111	4.7%	114	7.2%	108	7.2%
Very	722	30.8%	546	34.6%	548	36.3%
Completely	1,485	63.4%	898	57.0%	827	54.8%

Participants generally remained positive about their experiences of going to PrEP appointments and obtaining PrEP after *EPIC-NSW* ended. At 12-months, 89.4% of participants somewhat or strongly agreed that it was easy to get appointments, and 88.6% somewhat or strongly agreed it was easy to get PrEP pills (only 2.7% lower than at baseline, when most participants were provided pills as part of their participation in the *EPIC-NSW* trial).

Table 18. Number and proportion of participants who somewhat or strongly agreed with statements about clinic and pharmacy experiences

	Baseline (n, %)			onths %)	12-months (n, %)	
It was easy to get a PrEP appointment at my clinic	2,114	92.8%	1,381	89.6%	1,321	89.4%
The time of my PrEP appointment was convenient	2,052	90.5%	1,370	88.7%	1,302	88.2%
I had to wait too long at the clinic for my PrEP appointment	264	11.6%	176	11.4%	168	11.4%
My doctor or nurse was knowledgeable about PrEP	2,169	95.7%	1,447	94.2%	1,356	92.0%
It was easy to get my PrEP pills	2,062	91.3%	1,359	88.4%	1,303	88.6%
My doctor or nurse were judgmental of me and my sex life	106	4.7%	59	3.8%	68	4.6%
I felt comfortable talking to my doctor or nurse about my sex life	2,013	88.9%	1,319	85.8%	1,233	83.6%

Note: Proportions are of the total number of participants who responded to each question which varies by cell.

We asked participants which STI tests had been performed at their most recent PrEP appointment. More than 90% of participants reported receiving most STI tests at their last appointment. About 65% reported having a kidney function test at their last appointment, but more than one in five participants throughout the study were unsure whether this had occurred. There was no decline in HIV, STI or eGFR testing over time.

Table 19. Tests performed at most recent PrEP appointment

	Baseline (n, %)		6-months (n, %)		12-months (n, %)	
Blood sample for an HIV test	2,216	97.6%	1,489	97.0%	1,447	96.3%
Blood sample for a syphilis test	1,989	87.8%	1,357	88.6%	1,336	89.2%
Urine sample for STI tests	2,199	97.0%	1,480	96.5%	1,438	96.0%
Rectal swab for STI tests	2,157	95.3%	1,439	93.9%	1,395	93.0%
Throat swab for STI tests	2,143	94.5%	1,445	94.4%	1,404	93.7%
eGFR (kidney function / side effects)	1,395	61.5%	977	63.8%	987	65.9%

We also asked participants what they had discussed with their clinician at their most recent PrEP appointment. As expected, discussion of issues to do with getting PrEP after the end of *EPIC-NSW* declined over time as participants transitioned out of the study. Compared to baseline, fewer participants reported discussing issues like missing pills (67.8% vs 58.4%), side effects (59.9% vs 50.3%), and recent sexual behaviour (73.5% vs 66.8%) at the 12-month survey.

Table 20. Topics discussed at most recent PrEP appointment

	Baseline (n, %)		6-months (n, %)			onths %)
How many pills taken/missed since last appointment	1,536	67.8%	1,002	65.4%	870	58.4%
Side effects	1,354	59.9%	859	56.3%	751	50.3%
Recent sexual history/behaviour	1,661	73.5%	1,106	72.2%	995	66.8%
Continuing PrEP after end of EPIC-NSW	1,974	87.1%	1,029	67.4%	755	50.8%
How/where to get PrEP after end of EPIC-NSW	1,917	84.6%	1,026	67.0%	735	49.3%

Sexual behaviour

For this section, we included only those participants who identified as gay or bisexual men (GBM), who comprised 97.9% of the sample at baseline, 97.8% at 6-months and 98.1% at 12-months.

Sexual partners

At baseline, most GBM (65.4%) reported having had sex with between two and 20 male partners in the past six months. At 12-months, a greater proportion of participants than at baseline had no (3.2%) or one (8.8%) partner in the past six months.

Table 21. Number of male sexual partners in past six months among GBM

		Baseline (n = 2,294)		onths 1,542)	12-months (n = 1,481)	
0	29	1.3%	32	2.1%	47	3.2%
1	117	5.1%	110	7.1%	130	8.8%
2 - 5	491	21.4%	357	23.2%	347	23.4%
6 - 10	513	22.4%	334	21.7%	276	18.6%
11 - 20	497	21.7%	317	20.6%	314	21.2%
More than 20	647	28.2%	392	25.4%	367	24.8%

Almost all GBM who had sex in the past six months reported sex with men only but at least 4% reported sex with men and women at the time of each survey.

Table 22. Gender of sex partners in past six months among GBM

	Baseline (n = 2,294)		6-months (n = 1,542)		12-months (n = 1,481)	
Men only	2,166	95.6%	1,441	95.4%	1,377	96.0%
Women only	1	0.0%	0	0.0%	0	0.0%
Men and women	99	4.4%	69	4.6%	57	4.0%
No sex in past six months	28		32		47	

Anal intercourse

Among GBM, 97.8% reported any anal sex at baseline, and this was 96.7% at 6-months and 95.7% at 12-months. Of those GBM who reported having sex with men in the past six months, most reported having both receptive and insertive anal sex.

Table 23. Anal sex in past six months among GBM

	Baseline (n = 2,294)		6-months (n = 1,542)		12-months (n = 1,481)	
No anal sex	22	1.0%	19	1.3%	16	1.1%
Receptive only	324	14.3%	190	12.6%	201	14.0%
Insertive only	305	13.5%	207	13.7%	213	14.9%
Receptive and insertive	1,614	71.3%	1,094	72.5%	1,004	70.0%
No sex with men in past six months	29		32		47	

Overall, 90.5% of GBM had condomless anal sex in the past six months at baseline, 90.9% at 6-months, and 89.1% at 12-months. Among the GBM reporting any anal sex in the past six months, the proportions who reported condomless anal sex were 92.6%, 94.0% and 93.1% at baseline, 6-months and 12-months, respectively.

For those GBM who reported any anal sex in the past six months, we asked about the types of sex they had with partners based on HIV status and biomedical HIV prevention. Table 24 gives the proportions of GBM who reported any type of condomless anal sex with various types of partner.

Table 24. Types of partner with whom GBM reported condomless anal sex in the past six months¹

	Baseline (n = 2,294)		6-months (n = 1,542)		12-months (n = 1,481)	
HIV-positive and undetectable	924	40.3%	611	39.6%	590	39.8%
HIV-positive and detectable or unknown viral load	475	20.7%	286	18.5%	263	17.8%
HIV-negative and on PrEP	1,723	75.1%	1,159	75.2%	1,046	70.6%
HIV-negative and not on PrEP or unknown whether they were on PrEP	1,556	67.8%	1,030	66.8%	979	66.1%
HIV status unknown	1,408	61.4%	902	58.5%	857	57.9%

¹Participants could select multiple responses.

Group sex

We asked participants about any group sex with at least two other men in the past six months. The results were consistent over time, with over a third of men reporting they had never had group sex in that period and about 14% having had group sex at least monthly.

Table 25. Group sex involving at least two other men in the past six months

	Baseline (n = 2,294)		6-months (n = 1,542)		12-months (n = 1,481)	
Never	796	35.1%	563	37.3%	539	37.6%
Once or twice	601	26.5%	398	26.4%	348	24.3%
A few times	535	23.6%	326	21.6%	343	23.9%
Monthly or more	333	14.7%	223	14.8%	204	14.2%
No sex with men in past six months	29		32		47	

Paid sex

A minority of participants reported having been paid for sex by a man in the previous six months. At baseline, 107 GBM (4.7%) had been paid at least once, and 58 participants (3.9%) had been paid for sex by men in the 12-month survey.

Disclosure

For those participants who reported having sex with a man in the past six months (98.6% of participants at baseline, 97.8% at 6-months and 96.7% at 12-months), we asked a series of questions about disclosure of HIV status and PrEP use with their sexual partners.

Regarding knowledge of sex partners' HIV status, 17.2% knew all their partners' HIV statuses at baseline, while this increased to over 22% by 6- and 12-months.

Table 26. Knowledge of sex partners' HIV status

	Baseline (n = 2,312)		6-months (n = 1,541)		12-months (n = 1,459)	
None	287	12.4%	145	9.5%	157	10.8%
Some	792	34.3%	519	33.9%	456	31.4%
Most	832	36.1%	522	34.1%	506	34.9%
All	396	17.2%	347	22.6%	332	22.9%
Not reported	5		8		8	

About a third of participants in each survey told all their casual male sexual partners that they were taking PrEP. The proportion of participants who did not disclose their PrEP use to any of their casual male partners before sex remained low: 7.0% at baseline to 6.8% at the 12-month follow-up. Just over one-third disclosed their PrEP use to all casual male partners at each survey.

Table 27. Disclosed PrEP use to casual male partners before sex

	Baseline (n = 2,312)		6-months (n = 1,541)		12-months (n = 1,459)	
None	152	7.0%	102	7.1%	89	6.8%
Some	553	25.4%	360	25.1%	343	26.2%
Most	693	31.9%	425	29.6%	407	31.1%
All	777	35.7%	547	38.1%	469	35.9%
No PrEP use in past six months	73		84		138	
Not reported	64		23		13	

We asked participants how many of their casual male partners said they were taking PrEP. About 14% of participants said that all of their casual male partners had indicated they were taking PrEP.

Table 28. Number of casual male partners who indicated PrEP use to participants before sex

	Baseline (n = 2,312)		6-months (n = 1,541)			onths 1,459)
None	261	11.6%	215	14.2%	230	16.0%
Some	925	41.1%	595	39.2%	563	39.1%
Most	748	33.3%	489	32.3%	452	31.4%
All	314	14.0%	217	14.3%	194	13.5%
Not reported	64		25		20	

Social networks

At each timepoint more than 80% of participants said that some, most, or all of their friends were gay men. Very few (less than 2%) had no gay friends.

Table 29. Number of friends who are gay men

		Baseline (n = 2,344)		6-months (n = 1,576)		onths 1,509)
None	33	1.4%	28	1.8%	27	1.8%
A few	374	16.1%	257	16.4%	234	15.6%
Some	802	34.5%	517	33.0%	486	32.4%
Most	1,067	45.9%	735	46.9%	715	47.7%
All	47	2.0%	29	1.9%	36	2.4%
Not reported	21		10		11	

At each survey, about three quarters of participants said that they spent some or a lot of their free time with gay men.

Table 30. Free time spent with gay men

		Baseline (n = 2,344)		6-months (n = 1,576)		onths 1,509)
None	40	1.7%	40	2.6%	40	2.7%
A little	529	23.0%	358	23.1%	324	21.9%
Some	892	38.7%	587	37.9%	547	37.0%
A lot	842	36.6%	562	36.3%	568	38.4%
Not reported	41	41		29		

We also asked participants to estimate the proportion of their friends taking PrEP. On average, participants thought that 61.5% (SD = 22.1%) of the gay men in their personal network were taking PrEP.

Drug use

One-fifth of participants reported using crystal methamphetamine at some point in the past six months at each survey, while one-quarter reported using GHB, and over half of participants had used an erectile dysfunction medication. These proportions remained stable over time.

Table 31. Drug use in the past six months

	Baseline (n = 2,344)		6-months (n = 1,576)			onths 1,509)
Crystal meth	491	20.9%	312	19.8%	292	19.4%
GHB	581	24.8%	385	24.4%	364	24.2%
Erectile dysfunction medication	1,272	54.3%	894	56.7%	862	57.2%

PrEP campaigns

We asked participants about their interaction with public messaging about PrEP, such as from ACON² (NSW's primary HIV community organisation) or *Ending HIV*³ (a multi-year community education campaign implemented by ACON).

At baseline, 79.6% of participants said they had seen any public campaigns or messages about PrEP. Of those participants, 71.8% said that the campaigns informed or motivated them to start taking PrEP either 'somewhat' or 'a lot'.

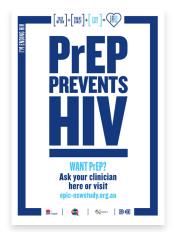








Figure 1. ACON PrEP campaigns, 2016-2018. (Reproduced with permission from ACON.)

Attitudes

In each survey, we asked participants how much they agreed with several statements on attitudes to PrEP, STIs, and HIV prevention, on a six-point scale from 'strongly disagree' to 'strongly agree'. For each of the statements, the tables below report the proportion of participants who somewhat or strongly agreed to them.

Almost all participants (at least 96.0% in each survey) somewhat or strongly agreed that they were willing to take PrEP for as long as they are at risk of HIV. While participants' attitudes to PrEP remained relatively consistent over time, more participants found visiting the clinic every three months to be a burden by 12-months (12.3%) compared to baseline (8.2%).

Table 32. Number and proportion of participants who somewhat or strongly agreed with statements about PrEP

	Baseline (n, %)		6-months (n, %)		12-months (n, %)	
PrEP is affordable for me	1,542	66.3%	1,084	69.0%	1,039	69.3%
Visiting the clinic every three months for PrEP appointments is too much of a burden	188	8.2%	178	11.5%	183	12.3%
I am concerned about the long-term side effects of PrEP	800	34.9%	527	34.0%	564	38.0%
Visiting the pharmacy to get my PrEP pills is a hassle	343	15.0%	185	12.0%	185	12.5%
Remembering to take my PrEP pills is easy	1,735	75.8%	1,183	76.5%	1,078	73.0%
I am happy that I am taking PrEP	2,044	89.5%	1,363	88.0%	1,253	85.2%
I am willing to take PrEP for as long as I am at risk of HIV	2,197	96.0%	1,515	96.6%	1,442	97.1%
I am worried about using PrEP now that I have to pay for it	941	41.3%	586	37.7%	584	39.6%

Note: Proportions are of the total number of participants who responded to each question which varies by cell.

Participants' attitudes to STIs remained relatively stable over time in some aspects but there were reported decreases in trying to avoid STIs (from 75.4% at baseline to 67.1% at 12-months), decreases in using condoms to avoid STIs (from 18.9% to 16.2%), and an increase in the proportion of participants who somewhat or strongly agreed that they were getting more STIs at 12-months (30.9%) compared to baseline (25.9%).

Table 33. Number and proportion of participants who somewhat or strongly agreed with statements about STIs

	Baseline (n, %)		6-months (n, %)		12-months (n, %)	
I am concerned about getting STIs	1,727	74.1%	1,151	73.2%	1,093	73.5%
I am concerned about passing STIs on to sexual partners	1,679	72.4%	1,123	71.8%	1,063	71.8%
I try to avoid getting STIs	1,745	75.4%	1,127	72.2%	993	67.1%
I talk to sexual partners about our STI testing results	1,592	69.0%	1,054	67.8%	974	66.1%
I use condoms to avoid getting STIs	439	18.9%	280	17.9%	239	16.2%
Condoms are effective at preventing STI transmission	1,912	82.7%	1,313	84.2%	1,228	83.5%
I get more STIs now than I did before I started taking PrEP	600	25.9%	451	28.8%	454	30.9%

Note: Proportions are of the total number of participants who responded to each question which varies by cell.

Participants were asked for their level of agreement on a series of statements related to HIV prevention. More participants somewhat or strongly agreed at 12-months (78.7%) than baseline (69.8%) with the factual statement that an undetectable viral load is effective at preventing HIV transmission. This change was reflected in over half (54.8%) of participants at 12-months somewhat or strongly agreeing that they would have anal sex without condoms with an HIV-positive partner who had an undetectable viral load, an increase from 46.3% at baseline.

Table 34. Number and proportion of participants who somewhat or strongly agreed with statements about HIV prevention

	Baseline (n, %)		6-months (n, %)			onths %)
An HIV-positive person having an undetectable viral load is effective at preventing HIV transmission	1,608	69.8%	1,192	76.3%	1,148	78.7%
I prefer not to use condoms for anal sex	1,743	75.8%	1,243	79.3%	1,175	80.5%
Condoms are effective at preventing HIV infection	2,079	90.6%	1,438	91.8%	1,320	90.4%
I prefer to have sex without condoms with a partner who is on PrEP	1,996	86.9%	1,369	87.6%	1,272	87.3%
I am willing to have anal sex without condoms with an HIV-positive partner who has an undetectable viral load	1,062	46.3%	815	52.1%	799	54.8%

	Baseline (n, %)		6-months (n, %)		12-months (n, %)	
I only use condoms if my sex partner wants us to	1,359	59.3%	958	61.3%	828	57.1%
I have been rejected by sex partners because I was taking PrEP	182	7.9%	127	8.1%	121	8.3%
I have been rejected by sex partners because I wanted to use condoms	403	17.7%	253	16.2%	214	14.7%
I have rejected sex partners because they wanted to use condoms	351	15.4%	255	16.3%	293	20.1%
When I am taking PrEP, I still worry about getting HIV	580	25.3%	345	22.1%	311	21.4%
My sexual behaviour has changed since I've been on PrEP	1,438	62.7%	1,017	65.1%	974	67.0%

Note: Proportions are of the total number of participants who responded to each question which varies by cell.

Conclusion

The *PrEP in NSW Transition Study* aimed to understand changing sexual behaviour, PrEP use, knowledge and attitudes to PrEP, STIs, and HIV prevention over time in people transitioning out of one of the largest PrEP implementation trials in the world to date, *EPIC-NSW*. Almost one-quarter of participants in *EPIC-NSW* agreed to take part in this continuation, which involved three detailed behavioural surveys over a 12-month period. As in *EPIC-NSW*, participants were almost entirely sexually active gay and bisexual men. The results of the *PrEP in NSW Transition Study* showed that most participants continued to use PrEP consistently after the end of the trial but more than one in ten participants took a break of one week or longer from accessing PrEP on the trial and starting PrEP from an alternate source.

Adherence to PrEP – meaning taking the pills appropriately to ensure coverage during any potential exposure to HIV – is vital to its efficacy [8] and in Australia, self-reported measures of adherence have been shown to reflect biological measures of adherence [19]. Participants in this study on average reported being about 90% adherent to their preferred PrEP dosing schedule, similar to the high levels of self-reported measures of adherence in previous trials and implementation studies [14]. For those using daily PrEP, 90% adherence equates to six pills per week, which is above the threshold needed for effective HIV prevention [9].

Relevant to adherence to a medication is ease of access. During *EPIC-NSW*, participants received PrEP for free as part of their participation. In this follow-up study, participants suggested that it continued to be satisfactory to access PrEP and a large majority of participants (87.3%) bought their PrEP from local pharmacies rather than online. This is similar to another recent report in Australia suggesting that 13.4% of current PrEP users bought their PrEP online from overseas vendors [20].

While past research has asked about acceptance of potential novel PrEP delivery models [21-23], ours is one of the first studies in the world to report on a large sample of PrEP users about their desire to use and preference for a long-acting implantable PrEP delivery device compared with other novel and existing options. Provided that all options had similar effectiveness, availability and cost, almost one-third of participants selected long-acting injectables as their top preference followed by one-quarter of participants who stated that an implant was their most preferred option. The only previous Australian data on these preferences showed that half of participants favoured long-acting injectables, ahead of daily pills (22.3%) and implants (17.7%) [20].

Participants remained satisfied with their experience of being on PrEP after transitioning out of the trial and continued to be happy with their clinic and pharmacy experiences. In addition, the quality of care remained stable outside of the trial as demonstrated by the STI tests done during appointments and topics discussed with clinicians. A common concern raised about increases in PrEP use globally is whether changes in sexual behaviours like having more condomless sex could lead to increases in other STIs [24, 25]. In this study, slightly more participants over time reported being less likely to use condoms to avoid STIs and that they felt like they

were getting more STIs. But there was very little change in participants' sexual behaviour in terms of partner numbers, group sex or condomless anal sex during the study period.

It has been several years since landmark trial [26] and cohort studies [27, 28] confirmed that HIV transmission is not possible by an HIV-positive a partner with an undetectable viral load. In this study, participants appeared to become more likely to indicate that they were willing to have condomless anal sex with an HIV-positive partner with an undetectable viral load. However, despite this sentiment, participants were less likely to report condomless anal sex with HIV-positive people with an undetectable viral load over time.

The PrEP in NSW Transition Study has shown that in an environment of regulated access to PrEP at a subsidised price in Australia, participants of a large-scale PrEP demonstration study transitioned to using PrEP outside of the study environment with consistently high levels of uptake and adherence. Further investigation of these data are needed in issues such as the noteworthy proportion of participants who had taken breaks from PrEP once the trial ended as well as during this follow-up study, but the overall picture of a cohort of participants accessing and adhering to PrEP on their terms is a positive one.

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