

# **Gilead Australia Fellowships: Research Grants**

## **Report for Gilead**

### *Non-uptake of PrEP among PrEP-eligible men in the Flux Study*

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## **Gilead Australia Fellowships: Research Grants**

### ***Research Report***

#### **Project name**

Non-uptake of PrEP among PrEP-eligible men in the Flux Study

#### **Project description**

Previous research conducted by the Kirby Institute provided the basis for determining the Australian eligibility criteria for gay and bisexual men to access HIV pre-exposure prophylaxis (PrEP). To date, most research has focused on PrEP efficacy and adherence among gay and bisexual men. However, there is little information about men who are eligible for PrEP but choose not to use it.

This project identifies reasons why men who meet the Australian eligibility criteria for PrEP access choose not to use it and assists health professionals in making clinical decisions and recommendations for changes in their patients' PrEP using behaviours.

#### **New and revised data collection**

A new section of the study questionnaire focusing specifically on PrEP was added to the Flux questionnaire to assess in greater detail the reasons why men do not access PrEP. These include, but are not limited to:

- a qualitative and quantitative component for the reasons these men choose not to use PrEP;
- a scale assessing the attitudes and beliefs about PrEP use; and
- measures of perceptions of peer norms regarding PrEP use.

Further to this, among men who are currently enrolled in the Flux cohort study, a new section has been added to the questionnaire which looks at changes in their PrEP using behaviours. That is, if someone was using PrEP six months prior, and has since ceased, we further explore their reasons to gain further understanding as to why they stopped.

## Introduction

Flux (Following Lives Undergoing Change) is the only study of its kind in the world. It is Australia's first and only large-scale longitudinal study of drug use among gay and bisexual men. The study explores critical issues in the lives of gay and bisexual men, including sexual health, mental health, and drug use, since 2014.<sup>1</sup>

## PrEP prescribing guidelines

Based on behavioural components of the Australian PrEP prescribing guidelines, PrEP eligibility for this sample was defined as:

- Any condomless anal intercourse (CAI) with a regular HIV-positive partner not on treatment or with detectable viral load;
- Any receptive condomless anal intercourse with a casual partner; or
- Any methamphetamine use.<sup>2,3</sup>

The clinical guidelines use a 3-month period because most data collected in Australian clinic settings are for that time period,<sup>3</sup> However, the Health in Men (HIM) study, upon which the guidelines were based, used a 6-month time period,<sup>4</sup> as is commonly reported in behavioural research.<sup>5</sup> The Flux Study used measures that were drawn from the HIM study and hence also used a 6-month time period. Level of HIV risk for sexual behaviour in this study were categorised using a previously-used classification system, ranging from lowest risk to highest risk (no such partner, no anal sex with this type of partner, consistent condom use, insertive only condomless anal intercourse, and any receptive condomless anal intercourse with casual partners).<sup>6</sup> Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis in the prior three months is also a criterion for the PrEP prescribing guidelines, but those data were not included in Flux and therefore did not form part of the eligibility criteria for the study.

## Methods

### Study aims

The aims of the Flux study are to:

1. Identify contextual and individual factors associated with the use, and changes in use, of licit and illicit drugs among gay and bisexual men, and associations with risk behaviours over time;
2. To describe the relationship between social and community norms, and the shared understandings of risk and pleasure, and licit and illicit drug use behaviours and beliefs among gay and bisexual men with differing social connections to other gay and bisexual men; and
3. To describe the role of particular gay community subcultures, sexual and social networks, in influencing attitudes and beliefs about licit and illicit drug use and in affecting drug-using behaviours.

## Eligibility

To be eligible to participate in the analyses included here, participants had to:

- Be male, above the age of 16 years and 6 months;
- Have had sex with another man in the preceding 12 months OR identified as gay or bisexual;
- Be willing to consent to the study requirements;
- Report a non-HIV positive serostatus.

## Recruitment and enrolment

Participants were identified through Facebook targeted advertising, popular online hook-up websites and smart phone applications. Participants were also encouraged to refer other men into the study. In 2017, men who were enrolled in EPIC-NSW, the HIV Pre-Exposure Prophylaxis clinical trial coordinated by the Kirby Institute, UNSW Sydney, were invited to enrol. Men were also invited to enrol at gay events including the Gay and Lesbian Mardi Gras Fair Day in Sydney. Those who consented to follow-up were asked to complete a follow-up questionnaire at six monthly intervals.

## Protecting confidentiality

Confidentiality of all data is strictly maintained at all times. Participants were assigned a unique study identifier which is used to identify all data sources. The questionnaires are electronically coded and stored in a secure database. Questionnaires do not contain individuals' identifying details. Access to any data or identifying information is protected by secure barriers at each level of access. The data are only accessible to the research team directly involved with managing or analysing the data.

## Innovative methodologies

### Follow-up Automated Management eSystem – FAME

Survey data collection provides contextual and explanatory information to existing health surveillance systems about psycho-social factors associated with behavioural prevention of infectious diseases but is usually not easily integrated with those systems. Such behavioural research, especially cohort studies, are viewed as optional, expensive add-ons. For behavioural researchers, online survey data collection platforms offer the potential for efficient, integrated data collection and management.

A unique integrated system of digitally linking individually tailored questionnaires, study databases, and communications with participants, was developed for this study and was named the Follow-up Automatic Management eSystem (FAME).<sup>1,7</sup> It was designed to be specific to the Flux study but has been adapted to other research projects.

FAME enables maximum digital management of the study to ensure a simple, straightforward experience for participants, which protects participant confidentiality and ensures data integrity. Each participant is digitally assigned a unique study identifier (USID) through the survey platform upon entry to the consent form. The USID is used to link to their unique records on all study data sources. It will remain the participants' unique identifier throughout the study and is central to the implementation of FAME. This ensures participant confidentiality. All communications with participants are automatically generated using their USID to automatically link to their own records. Individual participants' records from the consent form, baseline questionnaire, and all follow-up

rounds have been, and will continue to be matched through the USID. Access to any data or identifying information has been protected by secure barriers at each level of access.

## **Results**

### **Overview**

Only participants who reported a non-HIV positive serostatus and who had not used PrEP prior to baseline were included. A total of 1,257 participants were included who responded to baseline and six-monthly follow-up questionnaires between 2014 and 2018.

### **Gender**

Nearly all participants included in this sample identified as male. There were eight transgender men and one participant who identified as intersex.

**Table 1. Gender**

N=1,257	
Male	99.3%
Transgender male	0.6%
Intersex male	0.1%

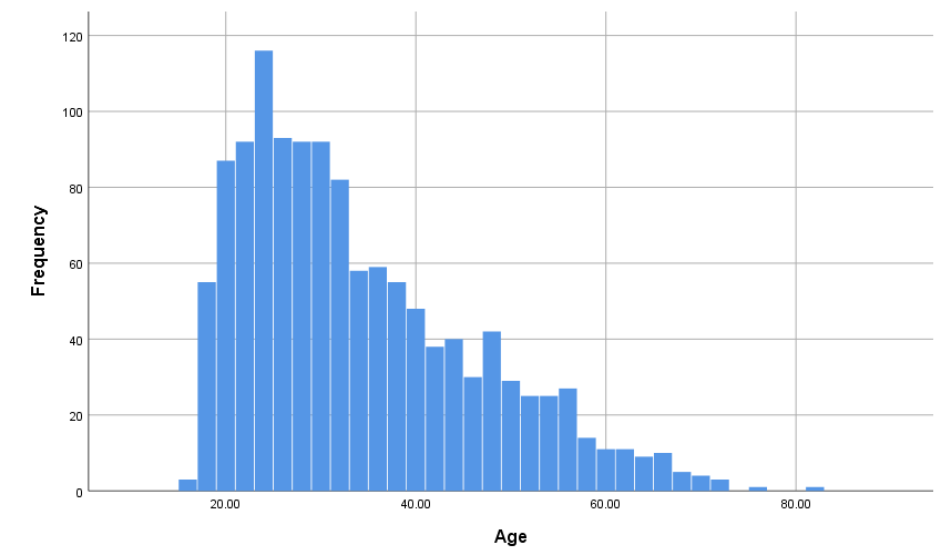
### **Age**

Ages ranged from 16 to 81 years. The mean age was 33.6 years (SD 12.3). The most frequent age of participant was 23.0 years and the median age was 30.0 years. Figure 1 below demonstrates the preponderance of younger men in the sample.

**Table 2. Age**

N=1,257	
16 to 24 years	28.1%
25 to 29 years	22.0%
30 to 39 years	24.0%
40 to 81 years	25.9%

**Figure 1. Distribution of Age**



## Country of Birth

The majority of participants were born in Australia.

**Table 3. Country of Birth**

	N=1,257
Australia	81.8%
Oceania (excluding Australia)	2.9%
Asia	3.4%
North America	2.1%
South/Central America	0.3%
Europe	6.0%
Middle East	0.2%
Africa	0.9%
Did not answer	2.3%



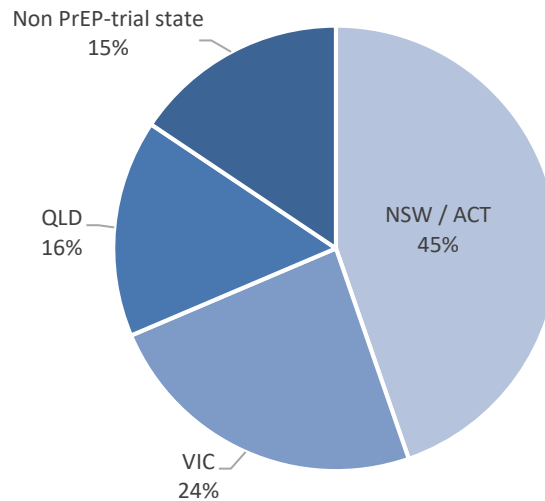
## State of Residence

Most participants were born in a state where a large PrEP implementation trial was being conducted at the time of data collection with approximately one in six living in a state where there was no PrEP implementation trial being conducted at that time.

**Table 4. State of Residence**

N=1,257	
New South Wales and ACT	44.7%
Victoria	23.9%
Queensland	15.8%
State outside large PrEP implementation trial	15.6%

**Figure 2. State of Residence**



## Sexual Identity

Most men identified as gay, with another one in fourteen identifying as bisexual. No participants in this sample identified as heterosexual. There were a small number of participants who identified otherwise such as 'uncategorised', 'queer', 'pansexual', 'bi-curious', 'asexual', and 'fluid'.

**Table 5. Sexual Identity**

N=1,257	
Gay	90.4%
Bisexual	7.2%
Heterosexual	0.0%
Other	2.4%

## Aboriginal or Torres Strait Islander Status

A total of 27 men indicated they were of Aboriginal or Torres Strait Islander descent.

**Table 6. Aboriginal or Torres Strait Islander status**

N=1,257	
Aboriginal or Torres Strait Islander	2.1%
Anglo-Celtic	76.5%
Other	21.4%

## Education

Over half of the men were university educated.

**Table 7. Aboriginal or Torres Strait Islander status**

N=1,257	
University educated	58.9%
Less than university educated	41.1%

## Employment

Over half of the men were in full time employment and approximately one in eight were in part time employment. Just over one fourth of participants were not employed.

**Table 8. Aboriginal or Torres Strait Islander status**

N=1,257	
Full time employment	59.1%
Part time employment	12.9%
Not in employment	28.0%

## High Risk HIV Behaviours

As previously stated, using behavioural components of the Australian PrEP prescribing guidelines, individuals were categorised as eligible for PrEP if they had:

- Any condomless anal intercourse with a regular HIV-positive partner not on treatment or with detectable viral load;
- Any receptive condomless anal intercourse with a casual partner; or
- Any methamphetamine use in the last six months.

Factors including having a high number of sexual partners, engaging in group sex, and using illicit drugs to enhance sex have also been associated with increased risk of HIV infection.

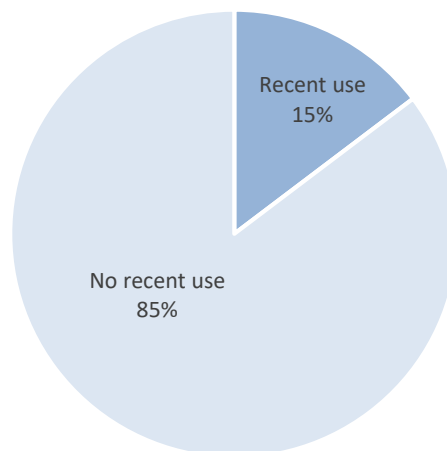
### **Methamphetamine use**

Most participants reported no recent methamphetamine use, with approximately one in seven reporting use within the previous six months of completing the questionnaire.

**Table 9. Recent use of methamphetamine**

N=1,257	
Recent methamphetamine use	14.7%
No recent methamphetamine use (including never used)	85.3%

**Figure 3. Proportion of men who used methamphetamine within the previous six months**



## Sexual Behaviours with Regular Partners

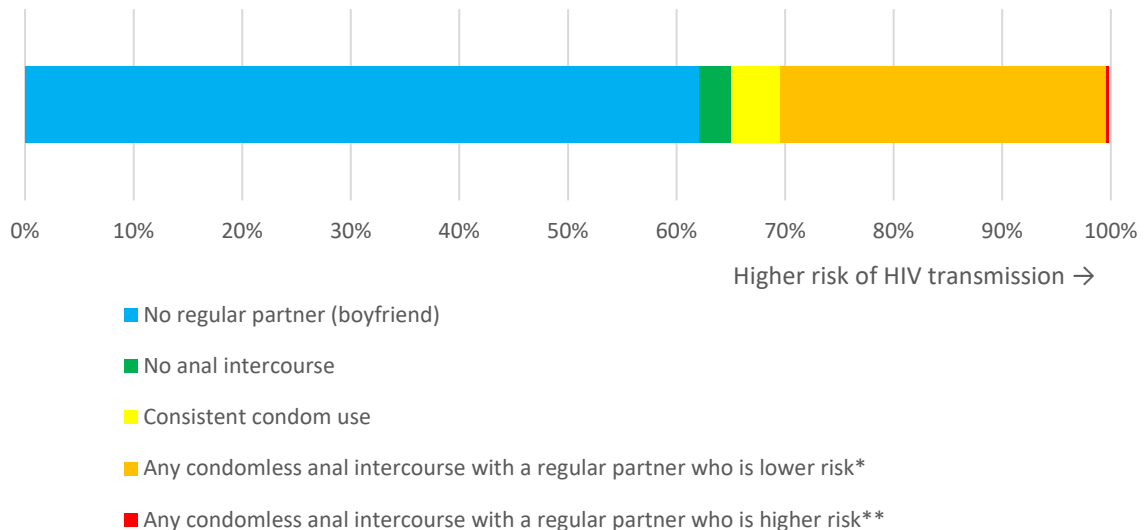
Just under two thirds of participants did not have a regular partner who they considered their boyfriend. Less than one third of men reported condomless anal intercourse with regular partners that was considered low risk of HIV transmission (HIV negative, or HIV positive and on treatment / undetectable).

There were two participants who reported engaging in condomless anal intercourse with an HIV-positive partner who had a detectable viral load or was not on treatment, and neither reported using PrEP. Most of the participants who engaged in condomless anal intercourse with an HIV-positive partner and were not using PrEP reported that their partner had an undetectable viral load or were on treatment.

**Table 10. Sexual behaviours with regular partners**

	N=1,257
No regular partner (boyfriend)	62.1%
No anal intercourse	2.9%
Consistent condom use	4.5%
Any condomless anal intercourse with a regular partner who is:	30.1%
• HIV-negative, or	
• HIV-positive with an unknown or undetectable viral load, or	
• HIV-positive and on treatment	
Any condomless anal intercourse with an HIV-positive partner who:	0.2%
• Has a detectable viral load, or	
• Is not on treatment	
Did not answer	0.2%

**Figure 4. Sexual behaviours with regular partners**



\* Any condomless anal intercourse with an HIV-negative partner, or an HIV-positive partner with an unknown, undetectable serostatus, or is on treatment

\*\* Any condomless anal intercourse with HIV-positive partner (detectable viral load or not on treatment)

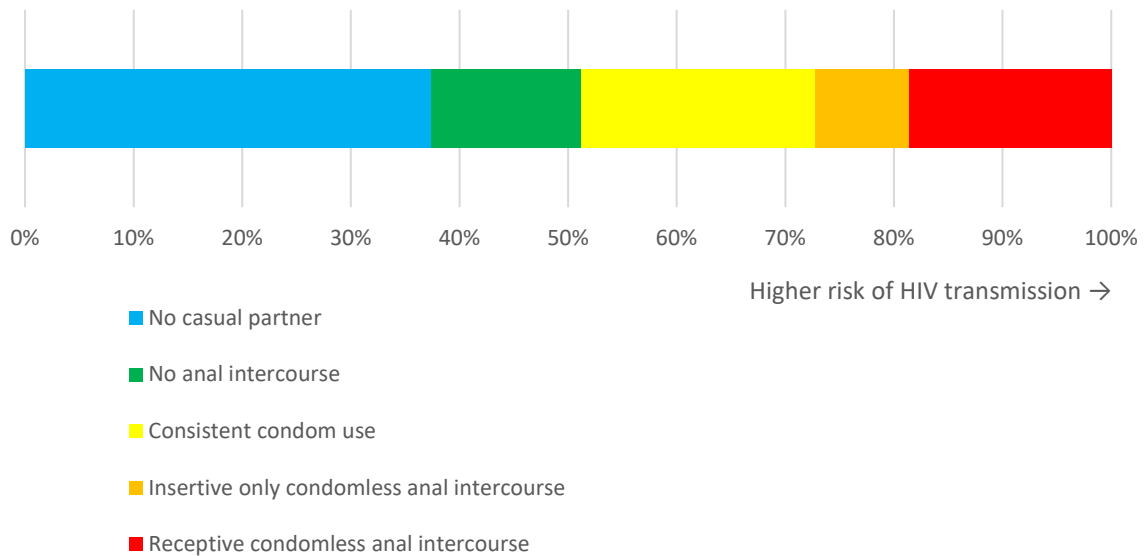
## Sexual Behaviours with Casual Partners

Condomless anal intercourse with casual partners represents the highest HIV risk behaviour that corresponds with the national PrEP prescribing guidelines. Nearly one in five men reported receptive condomless anal intercourse with a casual partner within the six months prior to completing the questionnaire.

**Table 11. Sexual behaviours with casual partners**

	N=1,257
No casual partner	36.7%
No anal intercourse	13.5%
Consistent condom use	21.2%
Insertive only condomless anal intercourse	8.4%
Receptive condomless anal intercourse	18.3%
Did not answer	1.8%

**Figure 5. Sexual behaviours with casual partners**



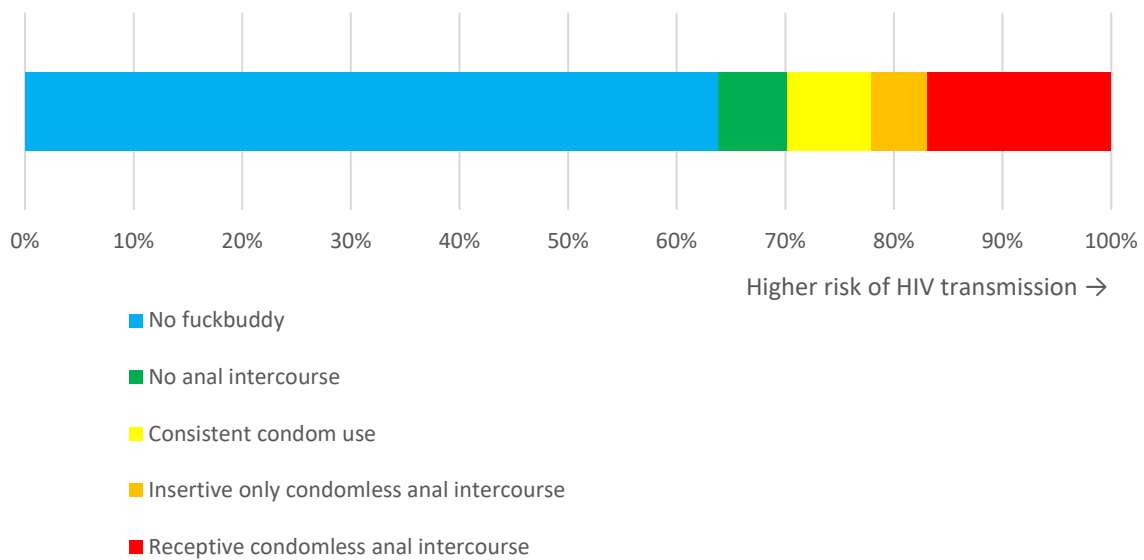
## Sexual Behaviours with Fuckbuddies

Nearly two thirds of participants did not have a regular partner whom they considered to be their boyfriend (such partners are commonly known as a “fuckbuddy”). One in six reported engaging in any receptive condomless anal intercourse with a fuckbuddy.

**Table 12. Sexual behaviours with fuckbuddies**

	N=1,257
No fuckbuddy	63.4%
No anal intercourse	6.3%
Consistent condom use	7.6%
Insertive only condomless anal intercourse	5.2%
Receptive condomless anal intercourse	16.8%
Did not answer	0.8%

**Figure 6. Sexual behaviours with fuckbuddies**



## Number of Sexual Partners

Most participants reported having more than one sex partner in the previous six months.

**Table 13. Number of sexual partners**

	N=1,257
No sex partners	8.7%
One sex partner	21.1%
Up to 10	41.5%
Up to 50	25.6%
More than 50	2.8%

## Group Sex

One in five reported engaging in group sex in the previous six months.

**Table 14. Group sex**

	N=1,257
No recent group sex	80.0%
Recent group sex	20.0%

## Using illicit drugs to enhance sexual pleasure (chemsex)

Most participants had never used illicit party drugs (ecstasy, speed, cocaine, crystal, GHB, ketamine, or LSD) to enhance sexual pleasure.

**Table 15. Using illicit drugs to enhance sexual pleasure (chemsex)**

	N=1,257
No recent drug use (including never used)	71.6%
Recent drug use (not for sex)	13.1%
Recent drug use (used to enhance sex)	15.3%

## Prevalence of PrEP eligibility

Among the 1,257 non HIV-positive men who reported never having used PrEP at baseline, 43.7% (n=549) were eligible for PrEP during the study period. At baseline, 28.6% (n=359) of men were eligible for PrEP, 26.7% (n=335) were eligible at 6 months follow-up, 24.1% (n=303) at 12 months, 22.8% (n=287) at 18 months, and 26.2% (n=329) at 24 months follow-up.

Among men who were eligible for PrEP at baseline, 30.2% (n=166) initiated PrEP during follow-up, leaving 69.8% (n=383) PrEP-eligible men who did not initiate PrEP. The overall incidence of PrEP use among PrEP-eligible men was 19.5 per 100PY (95% CI 16.4-23.1).

## Factors associated with non-use of PrEP among men eligible to access PrEP

The following sample was restricted to the 560 men who formally met the eligibility criteria during the study period.

By definition, PrEP-eligible men had engaged in behaviours consistent with the PrEP eligibility criteria either at baseline or during follow-up. However, not all eligible men reported these behaviours during every follow-up period, and those who did not initiate PrEP were less likely to report those behaviours consistently between survey visits than those who did initiate PrEP. Hence, PrEP-eligible men who did not initiate PrEP were less likely to consistently report either receptive receptive condomless anal intercourse with casual partners or condomless anal intercourse with an HIV-positive regular partner who had a detectable viral load or was not on treatment between survey rounds. They were also less likely to have engaged in other HIV risk behaviours such as the use of drugs for sex or group sex during each follow-up period. PrEP eligible men who did not initiate PrEP reported fewer sexual partners compared to men who initiated PrEP.

In multivariate analysis among PrEP-eligible men, those who did not initiate PrEP were less likely to report a study visit in recent years (see Table 16). PrEP initiation was less likely among men living in an Australian state that had not commenced a PrEP trial prior to 2017 and among men who were less socially engaged with other gay men. Men who did not initiate PrEP were also less likely to have used drugs to enhance sexual pleasure. Men who were eligible for PrEP but did not initiate it were less likely to report group sex, or any condomless anal intercourse compared to eligible men who did initiate PrEP.



**Table 16. Factors associated with the non-use of PrEP among gay and bisexual men who met the eligibility criteria**

Factor	aOR	95 % CI		p value
		Lower	Upper	
<b>Year of visit</b>				
2015	1			
2016	0.08	0.01	0.63	0.016
2017	0.02	0.00	0.18	<0.001
<b>Age</b>				
16-24	1			
25-29	0.54	0.28	1.03	0.062
30-39	0.44	0.23	0.83	0.012
40-84	0.60	0.32	1.13	0.115
<b>State of residence</b>				
New South Wales and ACT	1			
Victoria	1.30	0.77	2.19	0.331
Queensland	1.30	0.65	2.62	0.463
Other	2.11	1.16	3.85	0.014
<b>Social engagement with other gay men</b>				
	0.78	0.68	0.91	0.001
<b>Reasons for party drug use</b>				
No recent drug use	1			
Recent drug use (not for sex)	0.37	0.21	0.64	<0.001
Recent drug use (to enhance sex)	0.57	0.32	1.00	0.049
<b>Group sex</b>				
No group sex	1			
Recent group sex	0.59	0.37	0.93	0.025
<b>Sex with casual partner</b>				
No casual partner	1			
No anal intercourse	0.45	0.18	1.14	0.092
Consistent condom use	0.51	0.21	1.25	0.143
Insertive only CLAI	0.21	0.09	0.51	0.001
Any receptive CLAI	0.20	0.10	0.41	0.000
Did not answer	0.14	0.03	0.63	0.011

## Factors associated with initiation of PrEP

Among the 1,257 non HIV-positive men who reported never having used PrEP at baseline, the proportion of men who reported current use of PrEP at follow-up increased to 18.0% at 24 months ( $p$ -trend  $<0.001$ ). A total of 226 initiated PrEP during follow-up. 2.5% ( $n=32$ ) initiated by 6 months, and an additional 2.6% ( $n=33$ ), 4.0% ( $n=50$ ), and 8.8% ( $n=111$ ) by 12, 18, and 24 months, respectively. The overall incidence of PrEP use within the whole sample was 11.57 per 100PY (95% CI 10.00–13.40). Over the 24 months of follow-up, 20 men (3.6%) discontinued PrEP use after having previously initiated it after baseline. Overall, 8.8% of gay and bisexual men did not meet the eligibility criteria but nonetheless initiated PrEP, and 9.5% of gay and bisexual men met the eligibility criteria and initiated PrEP.

In multivariable analysis, PrEP initiation was more likely in more recent years. The incidence of PrEP initiation increased from 2.06 per 100PY (95% CI 1.08-3.90) in 2016 to 7.24 (95% CI 3.97-13.19) per 100PY in 2017 ( $p <0.001$ ).

The incidence of initiation was higher among those who were more highly socially engaged with other gay men (2.12 per 100PY; 95% CI 0.86-5.20) compared to gay and bisexual men who had little or no social engagement with other gay ( $p <0.001$ ). Incidence of initiation was also higher among men who had recently used methamphetamine (1.50 per 100PY; 95% CI 1.10-2.05) compared to men who had never used or reported no recent use ( $p <0.001$ ).

PrEP initiation was also associated with having a higher number of sexual partners. Compared to gay and bisexual men who had one sex partner in the previous six months, gay and bisexual men with up to 10 sexual partners in the previous six months had a PrEP incidence rate of 3.78 per 100PY (95% CI 2.75-22.73). The incidence rate increased to 7.91 per 100PY (95% CI 2.75-22.73) and 8.03 per 100PY (95% CI 2.40-26.87) when gay and bisexual men had up to 50, and over 50 sexual partners in the previous six months, respectively ( $p <0.001$ ).

Among gay and bisexual men who engaged in insertive only condomless anal intercourse with casual partners, this incidence rate was 1.75 per 100PY (95% CI 0.87-3.51). The incidence of PrEP initiation was higher among gay and bisexual men who engaged in receptive any receptive condomless anal intercourse with casual partners (2.46 per 100PY; 95% CI 1.29-4.67) ( $p <0.001$ ). Among those who reported having any condomless sex with an HIV-positive boyfriend who had a detectable viral load or who was not on treatment, the PrEP incidence rate was 14.74 per 100PY (95% CI 28.83) ( $p <0.001$ ).

**Table 17. PrEP incidence ratios per 100-person years**

Factor	Multivariate associations			P trend
	IRR	95 % CI		
		Lower	Upper	
<b>Year of visit</b>				<0.001
2015	1			
2016	2.06	1.08	3.90	
2017	7.24	3.97	13.19	
<b>Socially engagement with other gay men</b>				<0.001
Not at all	1			
A little	0.94	0.37	2.37	
Mostly	1.34	0.54	3.36	
Very much	2.12	0.86	5.20	
<b>Methamphetamine use</b>				0.012
No recent use	1			
Recent use	1.50	1.10	2.05	
<b>Number of recent sex partners</b>				<0.001
1 sex partner	1			
Up to 10	3.78	1.35	10.61	
Up to 50	7.91	2.75	22.73	
More than 50	8.03	2.40	26.87	
<b>Sex with casual partner</b>				<0.001
No casual partner	1			
No anal intercourse	0.81	0.36	1.84	
Consistent condom use	0.96	0.44	2.09	
Insertive only CLAI	1.75	0.87	3.51	
Any receptive CLAI	2.46	1.29	4.67	
Did not answer	1.38	0.35	5.41	
<b>Sex with boyfriend</b>				<0.001
No boyfriend	1			
No anal intercourse	0.77	0.33	1.81	
Consistent condom use	0.32	0.12	1.22	
Any condomless anal intercourse with a boyfriend*	1.31	0.97	1.76	
Any condomless anal intercourse with a boyfriend**	14.74	7.53	28.86	
Did not answer	-	-	-	

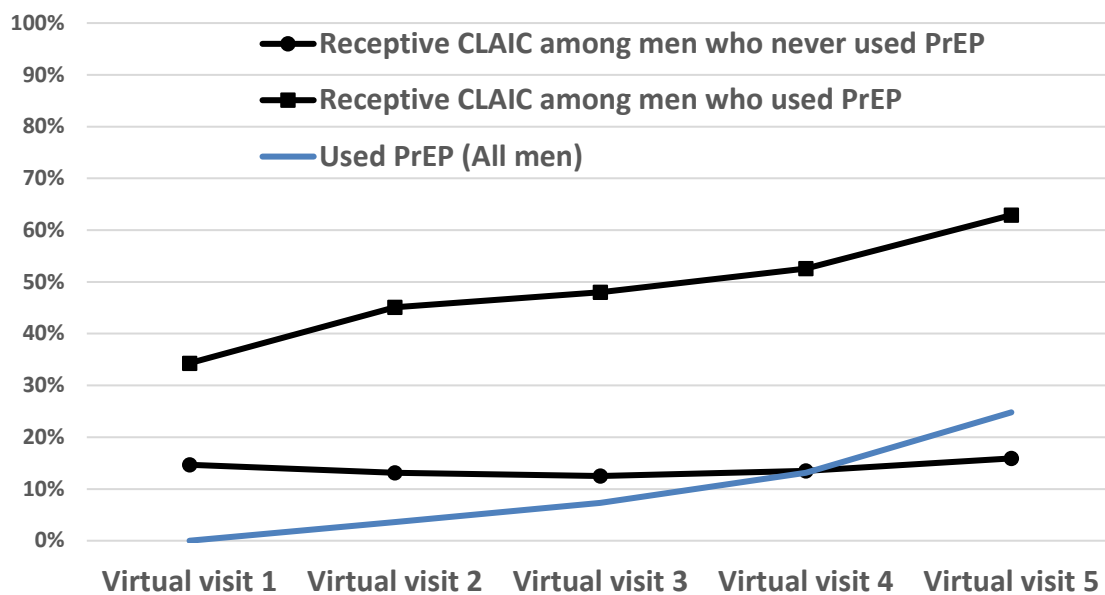
\* Any condomless anal intercourse with an HIV-negative partner, or an HIV-positive partner with an unknown, undetectable serostatus, or is on treatment.

\*\* Any condomless anal intercourse with HIV-positive partner (detectable viral load or not on treatment).

## Changes in behaviours following PrEP initiation

The proportion of men reporting receptive receptive condomless anal intercourse in the previous six months increased by 18.8% between virtual visits 1 and 4 ( $p$ -trend=0.050), and by a further 19.2% between virtual visits 4 and 5 ( $p$ -trend=0.001). The proportion of men who reported methamphetamine use in the previous six months remained stable at about one in seven over time. Very few men reported condomless sex with an HIV-positive 'boyfriend' whose viral load was detectable. By virtual visit 5, the proportion of men using PrEP had risen from zero at baseline to one quarter of the sample (Figure 8). In total, 175 men (25.5%) initiated PrEP during follow-up.

**Figure 7: Prevalence of PrEP use and receptive condomless anal intercourse over time**



Over time, the proportion of men who initiated and used PrEP and who also engaged in condomless anal intercourse rose from a small number of men to nearly one in five. Few of those who commenced PrEP subsequently stopped using it (2.1%), and just two of them (0.3%) subsequently engaged in receptive condomless anal intercourse. The proportion who engaged in insertive only condomless anal intercourse remained stable during follow-up, but the proportion of men who engaged in any receptive condomless anal intercourse that was not protected by PrEP ('unprotected CLAIC') use declined over time by 39.1% from 19.7% to 12.0%. Much of this decline was due to some men commencing PrEP.

Among the 175 men who initiated PrEP during follow-up, likelihood to report having engaged in receptive condomless anal intercourse at each virtual visit increased over time, from 34.3% at visit 1 to 62.9% at visit 5 ( $p < 0.001$ ). Comparing the survey period prior to commencing PrEP with the same follow-up as when they commenced PrEP, the proportion who reported having engaged in receptive condomless anal intercourse increased from 55.4% to 80.0% (McNemar  $< 0.001$ ). They tended to sustain this higher rate of receptive condomless anal intercourse, thereafter.

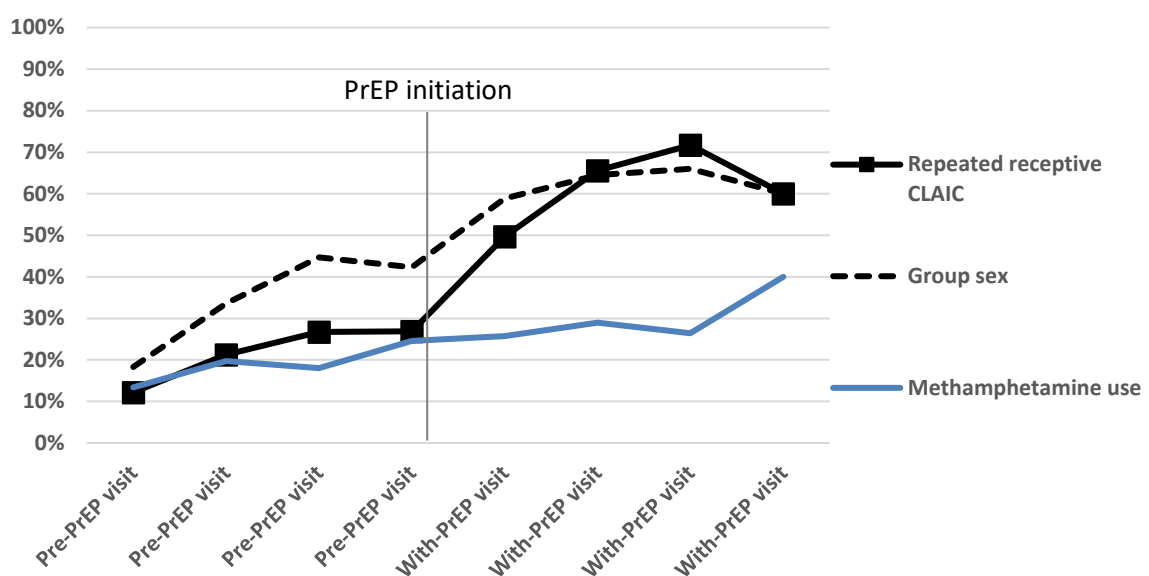
Among the 510 men who did not use PrEP throughout the study period, the prevalence of receptive condomless anal intercourse remained stable: 14.7% reported receptive condomless anal intercourse at baseline, and 15.9% did so at 24 months' follow-up. About half of these men reported continuing receptive condomless anal intercourse from one virtual visit to the next; the majority did not consistently engage in receptive condomless anal intercourse over time.

It was uncommon for men who never used PrEP during follow-up to report using drugs for sex or, specifically, using methamphetamine or erectile dysfunction medication in the previous six months for any survey period. Those who had commenced PrEP during any follow-up period were more likely to use such drugs than were those who never used PrEP, but initiation of PrEP had marginal or no effect on their likelihood to use drugs for sex, including erectile dysfunction medication or methamphetamine, during subsequent follow-up periods. Among the 175 men who commenced PrEP use during follow-up, 28.0% reported having used methamphetamine during the survey period prior to commencing PrEP and 30.3% used methamphetamine during the same survey period that they initiated PrEP (McNemar=0.481).

It was less common for men who did not use PrEP throughout the study period to report repeated instances of receptive condomless anal intercourse or group sex during any survey period, compared to men who reported any PrEP use. Those who had commenced PrEP were more likely to report both of these behaviours, and they became even more likely to do so both during the same follow-up period that they initiated PrEP and during subsequent follow-up periods. Among the 175 men who commenced PrEP during follow-up, 42.3% reported having engaged in group sex during the follow-up period prior to commencing PrEP and 58.9% engaged in group sex during the same follow-up period as when they commenced PrEP (McNemar<0.001). They tended to sustain this higher rate of group sex thereafter.

Combining men who commenced PrEP at differing virtual visits, the behavioural trends show some increases in repeated incidents of receptive condomless anal intercourse and group sex prior to commencement of PrEP, rapid increases accompanying commencement of PrEP, and maintenance of these increased rates following PrEP uptake. There was a gradual, and less pronounced increase in methamphetamine use over time, with little evidence that commencement of PrEP affected its use.

**Figure 8: Trends in repeated receptive condomless anal intercourse, group sex, and methamphetamine use over time among men who commenced PrEP (n=175)**

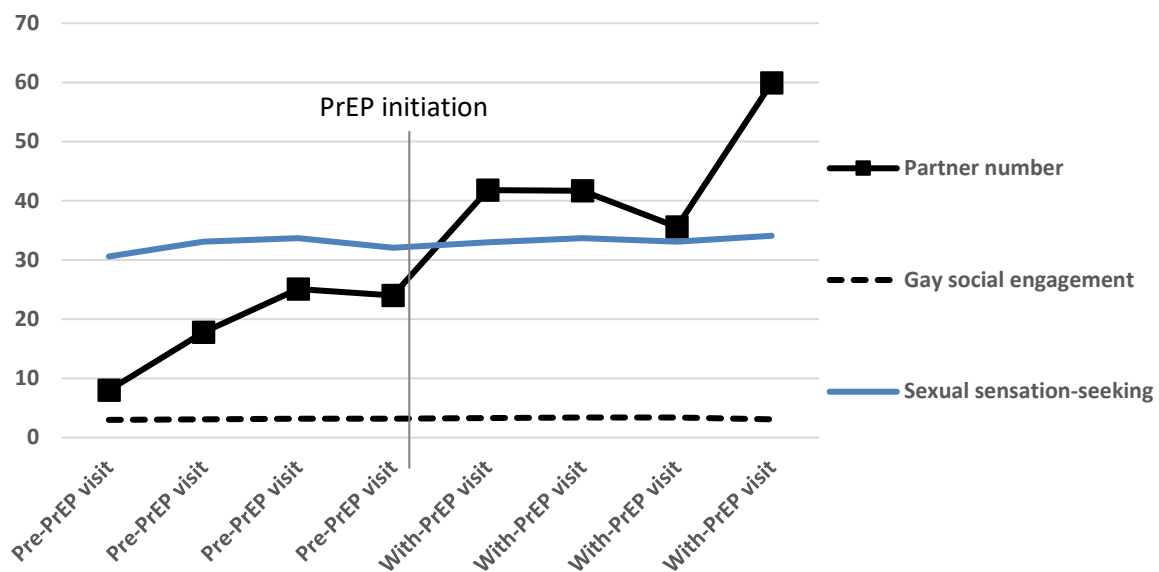


The mean number of male sex partners that men reported for the previous six months was also lower among men who never used PrEP compared with those who commenced PrEP ( $p < 0.001$ ). Also, men who commenced PrEP tended to report a greater number of partners over time, both during the follow-up period that they initiated PrEP and during subsequent periods. The 175 men who commenced PrEP use during follow-up reported a mean of 24.0 partners during the period prior to commencing PrEP and 41.7 partners during the same period that they initiated PrEP ( $p < 0.001$ ), sustaining this higher number of partners thereafter.

Men who never used PrEP had lower scores on gay social engagement ( $p < 0.001$ ) and sexual sensation-seeking ( $p < 0.001$ ) compared with those who commenced PrEP. Time of commencement of PrEP had little association with gay social engagement or sexual sensation-seeking over time.

Combining men who commenced PrEP at differing virtual visits, there were gradual increases in partner numbers prior to commencement of PrEP, a rapid increase accompanying commencement of PrEP, and maintenance of these increased partner numbers following PrEP uptake. There was little change in gay social engagement or sexual sensation-seeking over time, with little evidence that commencement of PrEP affected scores on these measures.

**Figure 9: Trends in partner number, gay social engagement, and sexual sensation-seeking over time among men who commenced PrEP (n=175)**



Overall, these data indicate that men who initiated PrEP were more likely to engage in behaviours that would otherwise be considered high risk for HIV than were men who did not initiate PrEP, and that their likelihood to engage in such behaviours also increased following PrEP initiation. Also, the men who initiated PrEP were more likely to have desired those behaviours (as indicated by the sexual sensation seeking measure) both prior to and following PrEP initiation than were men who did not initiate PrEP. So, while they may have always been more likely to desire engagement in behaviours that would otherwise be considered high risk for HIV infection, the men who initiated PrEP were probably somewhat more restrained in acting on those desires prior to initiating PrEP than they were after commencing use of PrEP.

## PrEP use among gay and bisexual men who use drugs to engage in chemsex

Gay and bisexual men often use illicit drugs to enhance sexual pleasure, commonly referred to as 'chemsex' or 'party n play'. In particular, the use of methamphetamine and Viagra™, and other erectile dysfunction medications, both together and separately are strongly predictive of subsequent HIV infection. HIV-negative gay and bisexual men in intensive sex partying networks may be adding PrEP to their drug regimen to actively reduce the possibility of HIV transmission during chemsex.

We describe the prevalence and context of concurrent use of methamphetamine, Truvada™ (or its generic formulations), and Viagra™ (or other erectile dysfunction medication) collectively, MTV.

Between January and July 2017, 1,831 gay and bisexual men provided details about their use of MTV. Binary logistic multiple regression analysis was used to estimate the adjusted odds ratios (aOR) and associated 95% confidence intervals (95%CI).

Concurrent MTV use was reported by 6.0% of participants; 3.1% used methamphetamine and Viagra™ or other erectile dysfunction medication ('MV only') and 11.2% used Truvada™ as PrEP ('T only'). In multivariate analysis, compared to use of 'MV only', MTV was independently associated with condomless anal intercourse with casual partners (aOR = 6.78; 95%CI = 1.42–32.34) and 'fuckbuddies' (aOR = 3.47; 95%CI = 1.41–8.56) in the previous six months. Greater social engagement with other gay men (aOR = 1.44; 95%CI = 1.18–1.76) and having more sexual partners (aOR = 2.30; 95%CI = 1.10–4.82) were independently associated with use of MTV compared to use of 'MV only' or 'T only'.

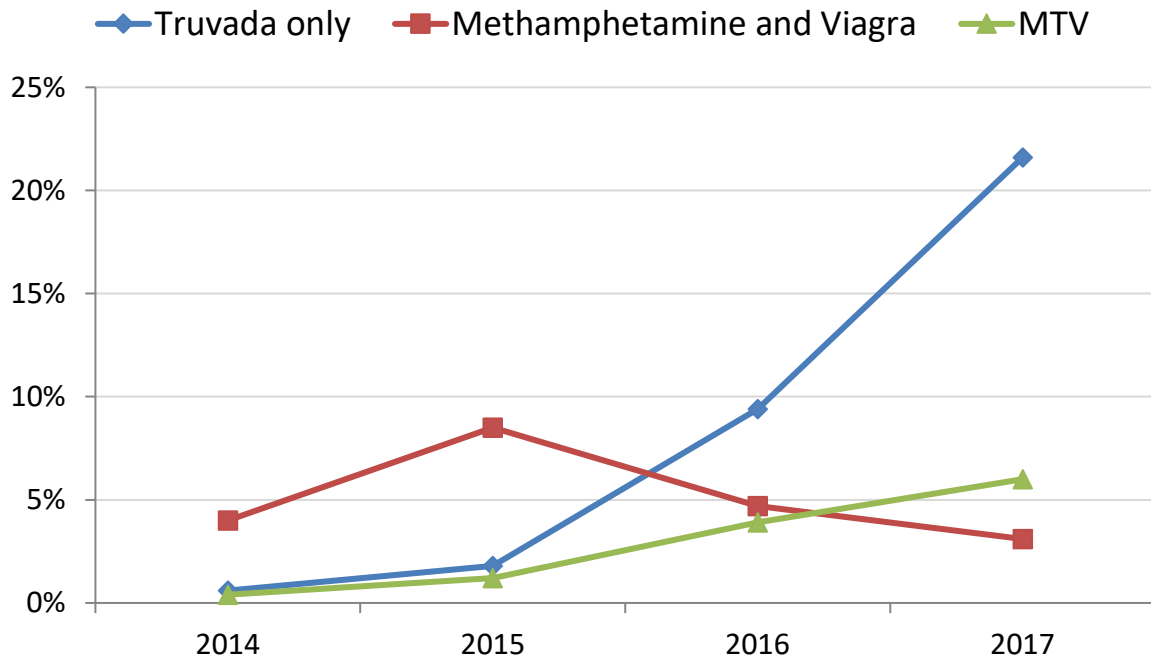
Some men have begun to use PrEP to mitigate against the risk of HIV infection through what would otherwise be considered high HIV risk behaviours in the context of intensive sex partying networks. The introduction of PrEP can complement drugs used for chemsex. Gay community peer norms and social connections play a strong role in how drug use is enacted among gay and bisexual men, making gay community networks a key context in which to promote the uptake of PrEP as an addition to their drug use repertoire, particularly among those at-risk men who participate in chemsex subcultures. Health promotion initiatives can help to normalise PrEP among these men and to develop tools for peer-based support for harm reduction. However, some men who are not connected to these networks also engage in the same high-risk behaviours. More information is required about these less socially connected men to enable the development of appropriate harm reduction interventions.

**Table 18. Associations with PrEP use among gay and bisexual men who use drugs to enhance sexual pleasure**

	MV vs. MTV n=167							
	Univariate analysis				Multivariate analysis			
	OR	CI 95 Lower - Upper		p	aOR	CI 95 Lower - upper		p
<b>Characteristics</b>								
<b>Socially engaged with other gay man</b>	1.60	1.27	2.02	<0.01	1.60	1.19	2.13	<0.01
<b>Sexual behaviours</b>								
<b>More than 10</b>	7.35	3.32	16.25	<0.01	2.99	1.00	8.91	0.05
<b>Condomless anal intercourse with fuckbuddies</b>								
No partner	1				1			
No anal	0.98	0.13	7.27	0.98	0.37	0.04	3.78	0.40
Condom only	1.46	0.23	9.23	0.69	3.49	0.38	32.34	0.27
Any condomless sex	4.73	2.26	9.90	<0.01	3.47	1.41	8.56	0.01
<b>Condomless anal intercourse with casual partners</b>								
No partner	1				1			
No anal	1.05	0.19	5.76	0.94	0.71	0.09	5.26	0.73
Condom only	1.40	0.28	6.98	0.68	0.98	0.13	7.19	0.98
Any condomless sex	14.91	4.49	49.53	<0.01	6.78	1.42	32.34	0.02
<b>Condomless anal intercourse with boyfriend</b>								
No partner	1							
No anal	0.424	0.06	3.16	0.40				
Condom only	0.424	0.03	7.02	0.55				
Any condomless sex	0.653	0.34	1.27	0.21				



Figure 10: Prevalence of MTV use over time. Categorise are mutually exclusive.



## List of peer reviewed journals generated from this funding

Hammoud MA, Vaccher S, Jin F, Bourne A, Maher L, Holt M, Bavinton BR, Haire B, Degenhardt L, Grulich A, Prestage G. ***HIV pre-exposure prophylaxis (PrEP) uptake among gay and bisexual men in Australia and factors associated with the non-use of PrEP among eligible men: Results from a prospective cohort study.*** 2019. Submitted.

Prestage G, Maher L, Grulich A, Bourne A, Hammoud MB, Vaccher S, Bavinton B, Holt M, Jin F. ***Changes in behavior following PrEP initiation among Australian gay and bisexual men. Journal of acquired immune deficiency syndromes (1999).*** 2019 Feb.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Prestage G. ***The new MTV generation: Using methamphetamine, Truvada™, and Viagra™ to enhance sex and stay safe.*** International Journal of Drug Policy. 2018 May 1;55:197-204.

## List of conference presentations generated from this funding

Hammoud MA, Vaccher S, Keen P, Philpot, Prestage G. ***Sex, drugs, and PrEP in Flux.*** Kirby Institute Seminar Series. Sydney, Australia. 2019.

Prestage G, Maher L, Jin F, Degenhardt L, Vaccher S, Bourne A, Hammoud MA. ***A longitudinal analysis of the impact of PrEP on sexual behaviour and drug use among Australian gay and bisexual men.*** Poster Presentation. Association for the Social Sciences and Humanities in HIV (ASSHH), Amsterdam, the Netherlands. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Grulich A, Bavinton B, Holt M, Degenhardt L, Prestage G. ***Predictors of non-use of PrEP among gay and bisexual men.*** Oral Presentation. Association for the Social Sciences and Humanities in HIV (ASSHH), Amsterdam, the Netherlands. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Prestage G. ***The new MTV generation: Using methamphetamine, Truvada and Viagra to enhance sex and stay safe.*** Oral Presentation. Association for the Social Sciences and Humanities in HIV (ASSHH), Amsterdam, the Netherlands. 2018.

Prestage G, Maher L, Jin F, Degenhardt L, Vaccher S, Bourne A, Hammoud MA. ***A longitudinal analysis of the impact of PrEP on sexual behaviour and drug use among Australian gay and bisexual men.*** Poster Presentation. 22nd International AIDS Conference, Amsterdam, the Netherlands. 2018.

Hammoud MA. ***PrEP in the Real World.*** Panel Discussion. 22nd International AIDS Conference, Amsterdam, the Netherlands. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Prestage G. ***The new MTV generation: Using methamphetamine, Truvada and Viagra to enhance sex and stay safe.*** Oral Presentation. 22nd International AIDS Conference, Amsterdam, the Netherlands. 2018.

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Presentation. Poster Presentation. 22nd International AIDS Conference, Amsterdam, the Netherlands. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Grulich A, Bavinton B, Holt M, Degenhardt L, Prestage G. ***Incidence and factors associated with the initiation of HIV Pre-Exposure Prophylaxis (PrEP) among Gay and Bisexual Men in Australia.*** Oral Presentation. Australasian HIV & AIDS Conference, Sydney, Australia. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Grulich A, Bavinton B, Holt M, Degenhardt L, Prestage G. ***Factors associated with the non-use of pre-exposure prophylaxis (PrEP) among eligible men in Australia.*** Oral Presentation. Australasian HIV & AIDS Conference, Sydney, Australia. 2018.

Hammoud MA, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Grulich A, Bavinton B, Holt M, Degenhardt L, Prestage G. ***Increase in Uptake and Incidence of HIV Pre-Exposure Prophylaxis (PrEP) among Gay and Bisexual Men in Australia.*** Oral Presentation. Australasian HIV & AIDS Conference, Sydney, Australia. 2018.

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Prestage G, Vaccher S, Jin F, Bourne A, Haire B, Maher L, Lea T, Grulich A, Bavinton B, Holt M, Degenhardt L, Hammoud MA. ***Factors associated with the non-use of pre-exposure prophylaxis (PrEP) among eligible men in Australia.*** Oral Presentation. International Union against Sexually Transmitted Infections, Asia Pacific, Auckland, New Zealand. 2018.

Philpot S, Hammoud M, Prestage G. ***Why are Some Australian Gay and Bisexual Men Choosing not to Initiate PrEP?*** International Union against Sexually Transmitted Infections, Asia Pacific, Auckland, New Zealand. Oral Presentation. 2018.

Vaccher S, Hammoud MA, Jin F, Bourne A, Haire B, Maher L, Lea T, Prestage G. ***Methamphetamines and PrEP: Helping or Hindering Health Outcomes in Gay Men?*** Methamphetamine and Health Symposium, New York, United States of America

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