2019

Queensland Pre-exposure Prophylaxis Demonstration Project Expansion (QPrEPd) Monitoring and Evaluation Final Report

THE UNIVERSITY OF QUEENSLAND
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Glossary of Acronyms

ABS	Australian Bureau of Statistics
ACCHSs	Aboriginal Community Controlled Health Services
ARTG	Australian Register of Therapeutic Goods
AMS	Aboriginal Medical Service
CDB	Communicable Diseases Branch (Queensland Health)
CGP	Community General Practice (including Community peer organisations and AMS with S100 Prescribing GP services)
CHHHS	Cairns and Hinterland Hospital and Health Service
CI	Co-Investigator
CP	Central Pharmacy
CRA	Concurrent Collaborative Research / Study Agreements
CRF	Case Report Form
CTN	Clinical Trial Notification
DoH	Department of Health (Queensland)
DSMB	Data Safety Monitoring Board
GBM	Gay, bisexual and other men who have sex with men
GP	Private S100 Prescribing General Practice
HCP	Health Care Providers
HHS	Hospital and Health Service
HIV	Human Immunodeficiency Virus
HREC	Human Research Ethics Committee
ID	Study Identification Number
ITS	Information Technology Services
LGBTIQ+	Lesbian, gay, bisexual, transgender, intersex, queer, gender diverse plus
M&E	Monitoring and Evaluation
MBS	Medicare Benefits Schedule
MSM	Men who have sex with men
NoCS	Notifiable Conditions System (Queensland)
NVivo	Qualitative data management software
PBS	Pharmaceutical Benefits Scheme
PHC	Primary Health Care
PrEP	Pre Exposure Prophylaxis

PSC	Project Steering Committee
QH	Queensland Health
QPrEP	The Queensland Pre-Exposure Prophylaxis Demonstration Project
QPrEPd	The Queensland Pre-Exposure Prophylaxis Demonstration Project Expansion
QPrEPd-X	QPrEPd Expanded
QuAC	Queensland AIDS Council
SA	Sexual Assault
SAM	Sexually Adventurous Men
SEQ	South East Queensland
SFA	Secondary Funding Agreement
SHHS	Sexual Health and HIV Service
SHS	Sexual Health Service
SMT	Study Management Team
SP	Specialist S100 Practice/Clinic
SSA	Site Specific Application
STI	Sexually Transmissible Infection
TAFE	Technical and further education
FTC/TDF	Tenofovir Disoproxil Fumarate and Emtricitabine (Truvada®)
TGA	Therapeutic Goods Administration
The Department	The Queensland Government Department of Health
UQ	The University of Queensland
UQHEC	The University of Queensland Human Research Ethics Committee
UQSPH	School of Public Health, The University of Queensland

1. Summary

This document is the final Monitoring and Evaluation Report of the Queensland Pre-Exposure Prophylaxis Demonstration Project Expansion (QPrEPd), a multi-site, open label PrEP demonstration project designed to facilitate the rapid scale up of HIV PrEP use in Queensland for up to 3000 people at high risk of HIV that launched on 7 November 2016 and closed on 30 November 2018. Following screening and enrolment, participants attended three-monthly clinical visits where they were screened HIV/STI and renal function and provided with a three months' supply of a generic co-formulated tablet formulation of tenofovir disoproxil fumarate (TDF) 300mg and Emtricitabine (FTC) 200mg (FTC/TDF), prescribed for daily oral administration.

This report presents an overview of the participants enrolled in QPrEPd and QPrEPd-X (the November 2017 to 1 April 2018 extension of the trial from 2000 to 3000 participants) and their experiences using PrEP. It also provides an overview of PrEP use among participants in the six months following the study closure along with the experiences and perspectives of the health care providers involved with the implementation and closure of the study.

1.1 Experiences During QPrEPd

Study Sites

- At the time of the QPrEPd study launch, there were 21 services registered as study sites; 12 public Sexual Health Services (SHSs); seven private S100 prescribing General Practices (GPs); one Community S100 prescribing General Practice (CGP) provided by an LGBTI peer Community Based Organisation; and one Specialist S100 Practice (SP).
- During the reporting period, one of the original private S100 prescribing GPs withdrew and four additional study sites were registered: a community General Practice (CGP) situated in a regional SEQ Aboriginal Medical Service (AMS), a specialist S100 Practice situated in a Brisbane metropolitan hospital, and two Brisbane based metropolitan S100 GP practices, making a total of 25 registered approved study site.
- Two services, while remaining registered as approved study sites for the duration of the study, did not recruit any active participants.

Recruitment, Screening and Enrolment

- Rolling recruitment and screening of eligible participants commenced from 7 November 2016
- At the time of the first annual QPrEPd report (30 June 2017)[1], 1,819 individuals had been screened and 1,678 participants were actively enrolled (84% of the 2,000 capped QPrEPd target sample).
- Screening and enrolments continued to increase at a steady rate each week, with the cap of 2,000 active enrolled participants reached on 18 November 2017.
- Recruitment of the 1,000 additional QPrEPd-X participants commenced from 20 November 2017.
- The maximum number of active QPrEPd-X participants was 598.
- QPrEPd-X screening and enrolments ceased on 1 April 2018 in response to the listing of PrEP as a price-subsidised medicine on the Australian Government National Pharmaceutical Benefits Scheme (PBS)[2] as per the QPrEPd project protocol.
- A total of 3,062 people were screened during the study period.
- The final QPrEPd-X participants exited the trial on 5 July 2018, leaving 1,689 active QPrEPd participants.
- A natural attrition of QPrEPd participants was observed following the PBS listing.
- On 1 October 2018, when the approved Early Closure Plan was executed, there were 1,195 active enrolled participants remaining.
- The final participant exited, and the 25 QPrEPd study sites were closed on 30 November 2018.

Profile of Participants

- The majority of participants identified as gay (68.2%, 1,988) or bisexual (10.1%, 295) cis-males (76.2%, 2,220), aged between 20 and 39 years (62.6%, 1,823), with high tertiary level qualifications (46%, 1,082), and were born in Australia (76.9 %, 1,754).
- 3% (69) reported that they had no Medicare Card, which was up from the 2.4% noted in the 2017 Annual report[1].
- 77.8% (1,763) were living in a major city in the South East corner of Queensland, 9% (206) inner regional and 13% (295) outer regional areas (13.0%), with 5.9% (133) travelling more than 50km to their Study Site.
- 78 participants identified as Aboriginal and Torres Strait Islander peoples (3.4%).
- There were no significant differences in the demographic profiles of the QPrEPd participants compared to the QPrEPd-X participants.

Patterns of Behaviour during the Study

- There was a significant increase in the number of self-reported sexual partners in the last six month period (P <0.001) observed between study time points (Enrolment, 3-months and 12-months).
- Condomless anal intercourse (CLAI) with regular, 'fuck buddies' and casual sexual partners also significantly increased between enrolment and 12-months (*P* <0.001).

HIV Testing and Diagnosis during the Study

- Previous HIV testing history reported on the entry survey suggests 15.6% of participants had not previously tested for HIV.
- During the screening process, eight (0.26%; 8/3062) new HIV cases in participants aged between 18 and 52 years (median age 35.4 years) were diagnosed.
- One participant had a positive HIV result reported at the 1-month visit, 35 days following a negative result on screening. Signs and/or symptoms of HIV infection were documented at screening, suggestive of recently acquired HIV infection prior to enrolment.

STI Testing and Diagnosis during the Study

- Previous STI testing history reported on the entry survey suggests, 15.6% of participants had not previously tested for STIs.
- In total at enrolment, 383 individual STIs were diagnosed among the total sample of people screened (N = 3062).
- Over the 24-month study period, a total of 1,557 individual STIs (other than HIV) were diagnosed.
- Between baseline enrolment screening and 18 months, STI positivity of any STI decreased from 3.19% to 2.42% (P_{trend} 0.007)
- A reduction in STI positivity from baseline to 18-months was observed for syphilis (2.09 to 1.18%, P_{trend} 0.03) and gonorrhoea at any anatomical site (1.94 – 1.25%, P_{trend} 0.006).
- No change in chlamydia positivity at any anatomical site was observed between enrolment and 18-months (P_{trend} 0.82).
- STI positivity was associated with lower age (aOR 0.99 95% CI 0.98, 1.00; *P* 0.01), condomless anal intercourse (CLAI) with a casual partner (aOR 1.19 95% CI 1.10, 1.28; *P* <0.001), and group sex involving two or more people (aOR 1.20 95% CI 1.11, 1.30; *P* <0.001) [3, 4].

Patterns of PrEP Use during the Study

- Most participants reported taking PrEP daily for the majority of time that they were actively enrolled in the study.
- At 3-months, 7.6% of participants reported that they had taken an intentional break from PrEP.
- Rates of intentional PrEP breaks increased significantly to 11.2% (*P* <0.001) at the 12-month survey time point, however, there was no statistically significant difference between the entry and 12-month survey time points (*P* 0.52), and there was no statistically significant difference in the rate of CLAI during the intentional PrEP breaks at these corresponding times.
- On exit from the study, the majority of the 642 participants who responded to the final exit survey question '*How likely is it that you will change to start taking PrEP on demand post PBS listing?*' reported that they would be extremely unlikely (50.9%) or unlikely (11.7%) to use on-demand PrEP following listing of PrEP on the PBS, suggesting participants intended to adhere to the recommended daily dosing.

Attitudes to QPrEPd Closure

- QPrEPd participants expressed an overwhelming feeling of positivity towards the addition of PrEP to the list of PBS-subsidised medications.
- Many participants, however, described being personally disappointed by the early closure of the study.
- Health Care Providers (HCP) and participants expressed concern that QPrEPd had ceased before the ongoing structural and financial barriers to access and uptake had been identified and addressed. There was particular concern about the barriers to access and uptake for people at risk who have been slower to adopt PrEP and for marginalised groups such as ineligible for Medicare and Aboriginal and Torres Strait Islander peoples.

1.2 Post Closure Experiences

Patterns of PrEP Use Post Closure

- At the time of the 6-month follow-up survey post study closure, 89.8% of the 265 respondents were currently using PrEP.
- 10.2% (27) of survey responders reported cessation of PrEP within the 6-month period following the closure of QPrEPd.
- The majority ceased PrEP use on commencement of a monogamous relationship with an HIV negative partner (48.1% (13/27) or because they were not sexually active (30.8% (8/27)).
- Statistical analysis suggests the proportion of those who ceased PrEP post closure was greater for those under 30 years old than those 30 years old and older (χ^2= 12.28, p<0.001).
- A greater proportion of respondents living in regional Queensland (18.5%) were no longer using PrEP compared to those living in South East Queensland (11.3%).
- Of the respondents no longer using PrEP, 40.7% (11) had not tested for HIV and 37.0% (10) had not tested for STIs since the study closure. Only one third of respondents had been tested for STIs including HIV within the last 3-months.
- Condomless vaginal and/or anal sex, with at least one partner, was reported by 63.0% (17/27) of respondents no longer taking PrEP.

PrEP Prescription Access and Dispensing Post Closure

- 75.1% (187/249) of participants who accessed PrEP did so from their previous study site. The majority of these identified the knowledge (84.4%) and attitude (72.3%) of the staff as reasons to remain with the service.
- 13% (33) reported transferring care from their study site back to their regular GP, now that GPs are able to prescribe PrEP.
- Nearly 1 in 10 participants (9.2%) reported transferring care to a service they had not previously used.
- Time required to travel to their study site (41.0%) was the most common reason for changing service provider following the closure of QPrEPd.
- The majority (96.8%, 241/249) of participants reported no difficulties in getting PrEP prescribed.
- Those who experienced difficulties, reported the GPs lack of knowledge about PrEP (5), an incorrect prescription being written (1) and poor availability of appointments (2) as reasons.
- 11 participants (4.4%) reported not having accessed a service to obtain a PrEP prescription following the closure of QPrEPd.
- The majority of respondents (86.6%) went to local community pharmacies to get their PrEP prescription dispensed.
- A significant number of respondents had imported PrEP from overseas via an online pharmacy (17.9%). Reasons for importing PrEP included convenience, ease of access, lower cost, and ability to obtain three months' supply in one delivery and for a small number, returning to their pre-study mode of access.
- Approximately 1 in 5 (21.7%) respondents reported difficulties getting their PrEP prescription dispensed, citing a lack of PrEP stock held by pharmacies (49/54, 90.7%), either because the pharmacy did not stock PrEP or had run out of stock. The majority of these reports of difficulties originated from participants residing in a major city (35/49, 71.4%) and in SEQ (40/49, 81.6%). However, the proportion of reports of difficulties were higher among those living in the inner (29.4%) and outer regional areas (32.1%) compared to those residing in major cities (16.3%).
- Participants reported either having to wait for the pharmacy to order PrEP stock in (up to 7 days), whilst other participants advised that they had to visit another pharmacy, or in some cases, several.

1.3 Interpretation and Recommendations

- QPrEPd was implemented as originally intended, which demonstrated that the provision of PrEP through public sexual health services and general practice services with S100 prescribers, both in private and community peer-based organisational settings, was a feasible and acceptable model of PrEP provision.
- QPrEPd and QPrEPd-X engaged and recruited people who would most benefit from the use of PrEP - namely those from among the priority populations identified at high risk of HIV.
- In contrast to the other Australian [5, 6] and international PrEP demonstration / implementation studies [7, 8], a gradual decreasing trend in STI prevalence was noted over time, among QPrEPd participants. The transition to the PBS model of PrEP delivery has been relatively seamless for most participants; primarily as most have decided to remain accessing PrEP from their study sites.

Points to consider

- Barriers to access and uptake remain for some sub-groups at risk of HIV, include:
    - Aboriginal and Torres Strait Islander peoples
    - people living in regional and remote areas
    - overseas born men who have sex with men (MSM)
    - Medicare ineligible people
    - transgender and gender diverse people
    - non-gay identifying MSM and women that have not been addressed by the PBS model of access (in some instances barriers to access have been increased).
- Evidence from this study suggests generalist GPs lack the willingness, knowledge, understanding and skill to prescribe PrEP. They also appear to lack the knowledge, understanding and skill to provide the comprehensive STI testing and sexual health care required.
- GPs and local community pharmacies were inadequately notified and prepared prior to the study closure to assist the smooth transitioning of study participants to the PBS model of PrEP access.
- Many of the public SHS study sites operated under a nurse-led model of care as per the QPrEPd study protocol. In the post study closure phase, these services have experienced a significant redistribution of medical and nursing workloads.
- The offset burden of the provision of PrEP through non S100 GP is yet to be seen.
- Further studies are needed to measure long-term trends in STI screening and acquisition among those taking PrEP.

Recommendations

- Ongoing monitoring and evaluation of PrEP delivery, access and barriers under the Australian Register of Therapeutic Goods (ARTG) and Pharmaceutical Benefits Scheme (PBS) mechanisms are required.
- Indicators measuring impact on the broader social and economic circumstances of individuals, communities and organisations are essential.
- Consideration of the HIV risk and need for PrEP along with barriers to access and uptake must be directed to populations and communities for whom additional barriers exist, such as young people under 29 years of age and people from marginalised populations and communities, including Aboriginal and Torres Strait Islander peoples, those living in regional and remote areas of residence or overseas born individuals on lower incomes, and persons who experience or fear discrimination and stigmatisation.
- Further education of non-S100 prescriber GPs, Practice Nurses, Nurse Practitioners and other health care providers involved with PrEP provision in primary health care and community controlled organisations is needed. It must include information on alternative PrEP dosing regimens and comprehensive sexual health and STI testing education and clinical upskilling.
- Exploration of the barriers to uptake of non-S100 prescriber GPs, Nurse Practitioners, Pharmacists and other service providers involved with PrEP prescribing and provision is warranted.
- Development of alternate models of PrEP service delivery including telehealth, are needed.
- Ongoing partnerships between communities, government primary health care (PHC) providers and pharmacists to ameliorate barriers, which contribute to suboptimal uptake and unsustained PrEP use, now and into the future, need to be a priority if Queensland and Australia as a whole is to achieve the virtual elimination of HIV.

2. Report outline

The first annual QPrEPd report (2017), presented the preliminary findings from the initial seven months (7 November 2016 to 30 June 2017) of the study implementation[1]. The results from the analysis of the participants' screening, enrolment and three-monthly follow-ups, clinical data along with the available quantitative survey and monitoring and evaluation (M&E) data collected to that point were presented in alignment with the QPrEPd primary and secondary objectives (outlined in section 5 of this report and the QPrEPd M&E aims and objectives and the deliverables listed in section 6).

This final QPrEPd report (2019) presents an overview of the participants enrolled in QPrEPd and QPrEPd-X and their experiences using PrEP during the study and in the 6-months following the study closure. This report addresses the key outcome criteria requested by The Queensland Government's Department of Health, as outlined in the 7 September 2018 amended SFA as well as associated deliverables outlined in section 6 of this report.

This report will address the following four key outcome criteria:

1. Participant's experiences of PrEP access and uptake during the study and equity by location and key priority groups.

2. Participants profile and experience withdrawing from the study

3. Participant's experiences during the trial closure period and transition to the PBS model of access

4. Service provider's experiences during the trial closure period and transition to the PBS model of access

This report is intended to be a reference document, drawing together the various clinical, survey and qualitative data sources collected during the study and closure periods into one comprehensive report for public release to key stakeholders and the community.

3. Introduction

On 26 April 2016, the then Queensland Minister for Health and Ambulance Services, the Right Honourable Cameron Dick, announced funding of $6 million over four years to provide HIV Pre-Exposure Prophylaxis (PrEP) for up to 2,000 people. This announcement closely preceded the Therapeutic Goods Administration (TGA) approval and licensing of tenofovir disoproxil fumarate and emtricitabine (FTC/TDF or Truvada®) for use as PrEP in Australia on 6 May 2016. The announcement aligned with the Australian Health Ministers' commitment to work towards the virtual elimination of new HIV transmissions in Australia by 2020, the *Queensland Sexual Health Strategy 2016-2021,* as well as the *Queensland HIV Action Plan 2016-2021* priority action to expand the availability of PrEP as a preventive measure for those at high risk of contracting HIV.

Funding for the Queensland Pre-exposure Prophylaxis Demonstration Project Expansion (QPrEPd); was conducted under three associated service agreements with:

1. The Study Sponsor, Cairns Sexual Health Service, Cairns and Hinterland Hospital and Health Service (CSHS, CHHHS). The Chief Investigator Associate Professor Darren Russell and Study Management Team (SMT) were situated within the CSHS and were responsible for the implementation of the Study Protocol and day-to-day operationalisation and management of the study.

2. The University of Queensland (UQ); School of Public Health (SPH). UQSPH was contracted to deliver the M&E component of QPrEPd and QPrEPd-X (2016 – 2020) under the Queensland Professorial HIV/STI Chair Secondary Funding Agreement (SFA) between The State of Queensland (Acting through Queensland Health) and UQ. QPrEPd M&E, led by Principal Investigator Professor Charles Gilks. This was conducted in partnership with the QPrEPd Chief Investigator, the QPrEPd SMT, and the study site location Co-Investigators. The UQSPH M&E team were responsible for the production of annual reports of the findings and evaluation of QPrEPd implementation and outcomes in relation to QPrEPd goals and objectives.

3. Queensland AIDS Council (QuAC). QuAC were contracted to provide a state-wide awareness program to support QPrEPd, including providing information and support to people who wish to access PrEP outside of QPrEPd.

Health Support Queensland in collaboration with Central Pharmacy and the Communicable Diseases Branch (CDB) led negotiation and signature of agreement with Alphapharm, a generic drug manufacturing company based in Australia. This was for the procurement and supply of the study medication (a generic co-formulated tablet formulation of tenofovir disoproxil fumarate (TDF) 300mg and Emtricitabine (FTC) 200mg (FTC/TDF) prescribed for daily oral administration.

Rolling recruitment into QPrEPd commenced from 7 November 2016. At the time of the first annual QPrEPd report (30 June 2017)[1], 1,819 individuals had been screened and there were 1,678 active enrolled participants (84% of the QPrEPd capped 2,000 target sample). Screening and enrolments continued to increase at a steady rate each week with 2,000 active enrolled participants by 18 November 2017. (See Figure 1 for screening and enrolment figures for QPrEPd and QPrEPd-X).

A proposal to increase QPrEPd funding to enable the capped target sample to increase access to PrEP up from 2,000 to up to 3,000 people was approved in October 2017, with recruitment of the additional 1,000 participants commencing from 20 November 2017. Participants in this Phase 2 of the Queensland expanded demonstration study, (hereafter referred to as QPrEPd-X participants), were enrolled with the understanding that they would receive PrEP as per the study protocol. However,

unlike QPrEPd participants, QPrEPd-X participants were required to consent with the understanding that enrolment would cease if one of the following criteria was achieved:

1. PrEP becomes available on the Pharmaceutical Benefits Scheme (PBS)

2. The cost of PrEP falls significantly; or

3. The study comes to a formal conclusion currently scheduled for 30 June 2020.

The 2017 Queensland Pre-exposure Prophylaxis Demonstration Project Expansion (QPrEPd) Monitoring and Evaluation Annual Report (Number 1)[1] (released 30 October 2017 for reporting period 7 November 2016 to 30 June 2017) reported that the QPrEPd study had been implemented as originally intended. The provision of PrEP through public sexual health services and general practice services with S100 prescribers, both in private and community peer-based organisational settings (the QPrEPd primary objective), was a feasible and acceptable model of PrEP provision. This was particularly so for the 'early adopter' gay men, living in both urban and regional settings, who self-identified that they were at risk of HIV, and had the capability and resources to actively seek out enrolment.

The report, however, identified that the needs of other key priority populations identified within the *Queensland Sexual Health Strategy 2016-2021*, and supporting the *Queensland HIV Action Plan 2016-2021,* together needed further exploration and continued support in order to ensure that PrEP access and uptake among all people at increased risk was equitable across Queensland. Key priority populations needing further exploration and support included:

1. Aboriginal and Torres Strait Islander people, particularly for those living in regional and remote areas and/or at risk due to heterosexual sex and injecting drug use

2. Less aware and/or less resourced gay men

3. Bisexual and other non-gay identifying men who have sex with men

4. Transgender and gender diverse people

5. Women

6. People born overseas

7. Young people under 18 years of age.

On 1 April 2018, FTC / TDF (Truvada®) was listed as a price-subsidised medicine on the Australian Government National Pharmaceutical Benefits Scheme (PBS) as PrEP[2]. This included the removal of its highly specialised drug (class S100) prescription requirements in order to facilitate broader community access, enabling all medical and nurse practitioners to prescribe PrEP, regardless of their HIV S100 medication prescriber accreditation [9].

Following the PBS listing, QPrEPd-X ceased enrolling new participants and the 598 active enrolled QPrEPd-X participants were offered a final three-month supply of medication and transitioned/exited out of the study as per the Study Protocol. The final QPrEPd-X participants was exited on 5 July 2018.

On 11 May 2018, the Acting Director-General of Health, Mr Russell Bowles ASM, approved the closure of QPrEPd earlier than the planned end date of 30 June 2020, with funding for the QPrEPd SMT to cease on 31 January 2019.

The proposal to cease the trial early was based on the Queensland Department of Health's (the Department) view that:

1. The primary research objective (that the provision of PrEP, through public sexual health services and general practices, is an appropriate model within Queensland) had already been demonstrated

2. In recognition that PrEP was now listed on the PBS and was widely available through routine care from any medical practitioner and some nurse practitioners and subsidised through the Pharmaceutical Benefits Scheme (PBS) (medication patient co-payments for PrEP medication through the PBS are $39.50 per month for general patients, or $6.40 for concession card holders); and that

3. Any ethical issues related to the early cessation of the trial could be addressed by the collaborative efforts of the trial partners and the Department to provide an effective transition to routine care for trial participants.

The Gold Coast Hospital and Health Service Human Research Ethics Committees approval to formally cease the trial was received on 4 September 2018. Following receipt of all appropriate HREC and study site governance approvals, the approved Early Closure Plan was executed and the transition/exit of the remaining 1,195 participants out of the study commenced on 1 October 2018.

The final participant exited and all 23 active QPrEPd study sites were closed 30 November 2018. (See Table 1 for QPrEPd timeline.)

The QPrEPd SMT conducted a final audit of all study sites during December 2018 – January 2019, and on production of a final operational report to the DoH, the SMT disbanded on 31 January 2019 at the cessation of their funding period.

The UQSPH M&E, under a revised service agreement were funded to 30 June 2019 to complete the monitoring and evaluation and develop this final M&E report.

4. Study timelines

Table 1 outlines the key study time points and coinciding target sample size and number of active study participant.

Table 1: Study timeline

Date	Event	Target Sample	Active participants Sample
09/09/2015	QPrEP Launched (6 Study Sites)	50	50
26/04/2016	Queensland Minister for Health and Ambulance Services announced QPrEPd Funding		
06/05/2016	TGA approval and licensing of tenofovir disoproxil fumarate and emtricitabine (FTC/TDF or Truvada®) for use as PrEP		
01/07/2016	Service Agreement signed and funding commenced		
07/11/2016	QPrEPd launch and rolling enrolment commenced (23 Study Sites)	2000	
30/06/2017	Annual Report No 1 reporting period end		1678
01/10/2017	QPrEPd-X Funding announced		
18/11/2017	QPrEPd reached target sample		2000
20/11/2017	QPrEPd-X launched; enrolment commenced	1000	
01/04/2018	PrEP listed as a price-subsidised medicine on the PBS		
01/04/2018	QPrEPd-X closed and participant exit commenced		598
05/07/2018	Last QPrEPd-X participants exited		
11/05/2018	Acting Director-General approved proposal to cease QPrEPd by 31/01/2019		
11/05/2018	SMT notified of proposal to close QPrEPd early		
04/09/2018	Ethical approval to formally cease QPrEPd obtained		
01/10/2018	Early Closure Plan executed; transition/exit of participants commenced from 25 study sites		1,195
30/11/2018	QPrEPd study sites closed		0
1/12/2018	Final Study Site Audit conducted during December		
31/01/2019	Study Management Team disbanded		
30/06/2019	Final Report reporting period end		
30/06/2020	Original proposed closure date.		
1/07/2019	M&E approved extension to finalise 6-month post closure M&E data collection and report writing		
31/07/2019	Original Final Report Due Date		
30/09/2019	Revised Final Report Due Date		

5. The QPrEPd Demonstration Project

5.1 Aims and Objectives

QPrEPd, and the extension QPrEPd-X, was a multi-site, open label PrEP demonstration project for the implementation of the rapid scale up of HIV PrEP use in Queensland. It was designed using lessons learnt from the small Queensland pilot study (QPrEP), and larger interstate demonstration studies [10, 11], QPrEPd aimed to provide PrEP, (a generic fixed dose co-formulation of FTC/TDF), prescribed for daily oral administration for up to 3,000 HIV negative Queensland residents at substantial risk of HIV. It was conducted at 25 study sites including public sexual health services, community clinics and general practices with high caseloads of people at high risk of HIV.

The primary objective of QPrEPd was to assess the feasibility of PrEP provision across a diverse range of clinical settings in Queensland during a period when formulated tenofovir-emtricitabine registered on the Australian Register of Therapeutic Goods (ARTG) for HIV preventative purposes [12, 13] was not listed as a price-subsidised medicine on the Australian Government National Pharmaceutical Benefits Scheme (PBS) [2].

The QPrEPd study objectives did not change with QPrEPd-X arm, and were as follows:

5.1.1 Primary Objective

1. Assess the feasibility of PrEP provision through sexual health services and general practice services (with S100 prescribers) in Queensland. This included eligibility screening; counselling about PrEP, condom use and risk reduction; testing for HIV; preventive antiretroviral (ARV) prescription, and follow-up of PrEP clients.

5.1.2 Secondary Objectives

1. Assess the acceptability of this model of PrEP provision; including uptake of PrEP among eligible clients offered PrEP, reasons for declining PrEP, patterns of PrEP, self-reported preferences for alternative schedules and/or duration of PrEP use.

2. To assess factors associated with PrEP use including:

3. Adherence to PrEP (patterns of adherence, and factors associated with optimal and sub-optimal adherence)

4. Experience and perceptions of side effects associated with PrEP use.

5. Gain information on the potential uptake and experiences of transgender gay and bisexual men (transsexual MSM) and Aboriginal and Torres Strait Islander MSM using PrEP.

6. Assess the regional interest in Queensland for PrEP and the experiences of those using PrEP, including barriers to PrEP access in regional and remote Queensland.

7. Develop guidelines for PrEP provision in Queensland.

8. Increase the involvement of general practitioners (non S100 prescribers) in PrEP provision by working with partner S100 prescriber sites.

5.2 Project Sponsor and Management Team

5.2.1 Chief Investigator

Associate Professor Darren Russell

5.2.2 Project Sponsor

Cairns Sexual Health Service, Cairns and Hinterland Hospital and Health Service

5.2.3 Study Management Team

The QPrEPd Study Management Team (SMT) were responsible for the day-to-day management and coordination of the study. The members of this team were from the Cairns Sexual Health Service and included:

Mr Simon Doyle-Adams (Project Lead)

Mr Michael Rodriguez (Research Data Manager)

Mr Rohan Pratt and Ms Jasmin Fischer (Database Developers)

Ms Sara Yeganeh, Ms Elissa Sutcliffe and Ms Simone Lukies (Pharmacy team)

Ms Sandra Downing, Ms Colette Cashman, Ms Carla Gorton.

5.2.4 Executive Committee

The Executive Committee was convened by the Queensland Chief Health Officer (CHO) and Deputy Director General (DDG) Prevention Division, DoH and CHHHS and is responsible for:

1. Corporate governance and oversight of the QPrEPd

2. Procurement of medication

3. Site-specific clinical governance arrangements including GP indemnity insurance through Clinical Trial Research Agreements and Site Specific Assessments.

5.3 Study Sites and Associate Investigators

At the time of the study launch in November 2016 there were 21 study sites: 12 public Sexual Health Services (SHS), seven private S100 prescribing General Practices (GPs), one Specialist S100 Practice (SP) and one Community General Practice (CGP) situated in a lesbian, gay, bisexual, transgender, gender diverse, intersex and queer plus (LGBTIQ+) peer community organisation (Table 2).

During the study period one of the original Brisbane-based S100 Specialist CI's working within a private General Practice withdrew as a study site[#], citing that they had decided to offer PrEP privately for clients and five services[##] were assessed and approved as study sites: a CGP situated in a regional SEQ AMS; a Specialist S100 Practice situated in a Brisbane metropolitan hospital; and two Brisbane based metropolitan S100 GP practices.

Two services* while remaining registered as approved study sites for the duration of the study did not recruit active participants. The 25 individual study sites were responsible for screening, enrolment and clinical care of participants, in line with the QPrEPd study protocol.

Table 2: Study site locations and co-investigators

Study Site	Study Site Co-Investigator
1. Barrier Reef Medical Centre	Dr Andy Morice
2. Brisbane City Doctors[#]	Dr David Jardine
3. Cairns Doctors	Dr Heather McNamee
4. Cairns Sexual Health Service	Dr Darren Russell
5. Carbal Medical Services Toowoomba[##]	Dr Adrian Castelli
6. Carseldine Family Clinic	Dr Elizabeth Baer
7. Clinic 30 QuAC	Dr Tracy Schrader
8. Clinic 87 Sunshine Coast Sexual Health and HIV Service	Dr Kuong Tiang
9. Earlville General Practice	Dr Arden Dearden
10. Evandale Practice	Dr Stuart Aitken
11. Gladstone Road Medical Centre	Dr David Orth
12. Gold Coast Sexual Health Service (GCSHS)	Dr Maree O'Sullivan
13. Holdsworth House Medical Brisbane	Dr Fiona Bishop
14. Ipswich Sexual Health Service	Dr Mekala Srirajalingam
15. Kobi House Toowoomba Health Services	Dr John Hooper
16. Mackay Sexual Health and Sexual Assault Service	Dr Arun Menon
17. Mater Health Services Brisbane[##]*	Dr Paul Griffin
18. Metro North Sexual Health and HIV Service (MNSHHS)	Dr Diane Rowling
19. Mt Isa Sexual Health Service*	Dr Arun Menon
20. Newmarket 7 Day Medical Centre[##]	Dr Manuel Avivar-Fernandez
21. Princess Alexandra Sexual Health Service (PASH)	Dr Cheryn Palmer
22. Pulse Medical Algester[##]	Dr Erin Batman
23. Q Clinic Wide Bay Sexual Health	Ms Fiona Stack
24. Rockhampton Sexual Health and HIV Service	Dr Karen Quinn
25. Saltwater Medical[##]	Dr Mark Renaud
26. Townsville Sexual Health Service	Dr Arun Menon
[##]New sites; [#]Withdrawn Study Site; *No enrolments.	

Study sites hereafter have been de-identified and will be described by location (Regional, Inner Regional, and South East Queensland) and by means of the four following service model types: Public Sexual Health Services (SHS), Private S100 General Practices (GP); Community S100 GP's (CGP) and Specialist S100 Practices (SP).

5.4 Key Stakeholders

5.4.1 Department of Health (DoH)

Chief Health Officer (CHO) and Deputy Director-General (DDG) Prevention Division:

- Accountable to Director-General and Queensland Minister for Health and Ambulance Services for QPrEPd.

Communicable Disease Branch (CDB):

- Fund holder and financial approver
- Member of executive committee
- Manage and monitor budget allocation and variance reporting
- Oversight of service agreements with key partners
- Implement project governance structures, including facilitating governance sign-off with each of the Hospital and Health Services involved in the study
- Procurement of QPrEPd medication, payment of travel for site training, and payment of distribution costs of the medication to the study sites
- Regular reporting to the Minister's Office and the Department of Health
- Monitoring and reporting of expenditure against the budget allocated.

Health Support Queensland (HSQ) and Central Pharmacy (CP):

- Medication procurement and supply and contract signatory for medication
- HSQ led negotiations and signature of agreement with Alphapharm, a generic drug manufacturing company based in Australia, for the supply of a generic co-formulated tablet formulation of tenofovir disoproxil fumarate (TDF) 300mg and Emtricitabine (FTC) 200mg (FTC/TDF) to be prescribed for daily oral administration during the QPrEPd Study
- CP places orders with Alphapharm, re-labels medication for QPrEPd purposes and delivers it to CSHS pharmacy on a rolling store transfer as required.

5.4.2 Queensland AIDS Council (QuAC)

- Under a service agreement with Queensland Health, provide a state-wide awareness program to support QPrEPd, including providing information and support to people who wish to access PrEP outside of QPrEPd
- Member of Steering Committee and sub-committees
- Study site providing clinical services, in line with the Study Protocol
- Provide information and education to increase knowledge and awareness of PrEP as well as the QPrEPd Study, among target populations and service providers
- Liaising with CHHHS, develop and implement a communication plan for QPrEPd that promotes increased awareness of PrEP as an HIV prevention strategy and how PrEP is used in conjunction with other HIV prevention strategies, including how to support those who want to access PrEP outside of the QPrEPd
- Communication plan includes targeted marketing support to individual study sites and state-wide marketing and advertising including the *ComePrEPd* website, brochures, posters, business cards, advertising on dating apps, Facebook, LGBTI press and outreach at forums and events
- Increase awareness of and participation in QPrEPd Study.

5.4.3 The University of Queensland (UQ) School of Public Health

- Provide leadership on the monitoring and evaluation (M&E) component
- Members of steering committee and sub-committees
- See Monitoring and Evaluation Deliverables section on Section 6 for more details.

5.4.4 Alphapharm

- Medication supplier
- A generic drug manufacturing company based in Australia.

5.5 Project Governance

5.5.1 Data Safety Monitoring Board

The data safety monitoring board (DSMB) listed in Section 16 of the QPrEPd study protocol, which was responsible for assessing the progress of the study, including safety data and making recommendations about study modifications, suspension or termination was only required to meet in the event of a serious adverse event related to the drug. The DSMB was not required to meet at any time during the QPrEPd study.

5.5.2 Project Steering Committee

The Project Steering Committee (PSC) met seven times over the course of the project with greater frequency in the initial project development and implementation phase to review recruitment, participant follow-up, incidents and ethics. The PSC includes members of the SMT, study site CI's (or nominated representatives), the UQSPH M&E team, and representatives from Communicable Diseases Branch (CDB), the Queensland AIDS Council (QUAC) and Queensland Government Department of Health (DoH).

The PSC had four sub-committees including: Community engagement and communications; Pharmacy; Ethics, Research, Protocol; and M&E and a Aboriginal and Torres Strait Islander working group. The PSC subcommittees met on a needs basis to address specific action items identified during the PSC meetings.

5.6 Ethical Approval

A multi-site ethical approval was awarded through the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC/14/QGC/182). Additional ethical ratification and approval was required from the University of Queensland's Human Research Ethics Committee (UQHREC) as per UQ protocol when staff are involved with research projects approved under other HREC processes.

The Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC/14/QGC/182) submission and approval documentation was submitted to the UQHREC for review and approval clearance was awarded (Clearance Number: 2016001664) in March 2017. A total of 26 HREC amendments were approved by Gold Coast HREC (GCHREC) and ratified by The University of Queensland HREC during the course of the project.

5.7 Governance Agreements and Site Specific Applications

5.7.1 HHS Site Specific Application Governance Agreements

Individual Site Specific Application (SSA) governance agreements were required with each of the 12 HHS's where public sexual health service study sites were located. SSA's were amended as required during the study period

5.7.2 Collaborative Research Group Studies Agreements with Private Study Sites

The 13 non-Queensland Health study sites were each individually contracted with a Medicines Australia Clinical Trial Research Agreement – Collaborative or Cooperative Research Group Studies – Standard Form.

5.7.3 Concurrent Collaborative Research Study Agreements (CRAs) with the University of Queensland

UQ obtained 12 separate CRAs with the 12 HHS's responsible for the governance of the 12 public sexual health services study sites. Communication with the HHSs commenced in late October 2016 and all CRAs were executed by March 2017. Only three private GP sites required the additional CRA over and above the Collaborative / Cooperative Research Group Studies agreement that they had in place with CHHHS. The remaining private study sites considered the Collaborative / Cooperative Research Group Studies agreement in place with CHHHS sufficient, based on the inclusion of UQ in the Study Protocol and all other relevant study paperwork.

5.8 Regularity Approval

This study was conducted under the TGA Clinical Trial Notification (CTN) scheme. The sponsor, CHHHS, was responsible for notification prior to commencement of the study. Under the CTN scheme, the approving authority is the Institution that grants the final approval for the conduct of the study. In line with the National Statement on Ethical Conduct in Human Research 2007 Section 3.3.12, and the updated Declaration of Helsinki, this study was registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) at http://www.anzctr.org.au.

5.9 Study Site Assessments and Training

Individual training and assessment of the 25 study sites was conducted on a rolling basis upon recruitment. All initial site audits and assessment visits were completed face-to-face by two of the SMT, including a pharmacist who conducted assessment and approval of each study site - for study drug accountability, documentation, supply and storage.

5.10 Study Site Audits

The Final QPrEPd Operational Report (dated January 2019) compiled by the Study Management Team (SMT), states site audits were completed by the SMT at all active study sites at the following time points:

1. Pre-launch site visit
2. One-month self-assessment
3. Three-month site visit
4. Six-month self-assessment
5. Nine-month self-assessment
6. One-year site visit
7. Final project closure site visit.

6. Monitoring and Evaluation

6.1 Purpose of the M&E

The QPrEPd M&E plan was developed in relation to QPrEPd's aims and objectives and the deliverables stated under the Secondary Funding Agreement (SFA) between State of Queensland (Acting through Queensland Health) and The University of Queensland dated 19 October 2016.

6.2 Monitoring and Evaluation Team

6.2.1 Principal Investigator

Professor Charles Gilks, Head of School and Queensland Professorial Chair of HIV and STIs

6.2.2 Co-ordinating Co-Investigator

Dr Judith Dean, Research Fellow.

6.2.3 Co-Investigators

Dr Lisa Fitzgerald, Senior Lecturer

Dr Owain Williams, Senior Research Fellow

Ms Sara Bell, Research Officer

6.3M&E Aims and objectives during study period

The M&E component of QPrEPd was originally developed to investigate the feasibility and acceptability of the QPrEPd model of PrEP provision via public sexual health services and S100 General Practitioner primary health care settings to participants and service providers; and the factors associated with PrEP usage such as adherence and side effects. Using a longitudinal mixed methods approach, it also examined the social and structural contexts which have shaped the perceptions, expectations and experiences of QPrEPd participants. Community and service provision contexts, including changing environments in relation to implementation of the rapid scale up of PrEP in Queensland, were explored. Outcomes of the M&E were to guide policy adaptation and delivery of PrEP, shaped by the context in which it is being delivered.

The original aims and objectives of the QPrEPd M&E were to:

1. Investigate the feasibility and acceptability of the QPrEPd model of PrEP provision to participants and service providers, as well as factors associated with PrEP usage including adherence and side effects.

2. Examine the social and structural contexts which have shaped the perceptions, expectations and experiences of QPrEPd participants.

3. Explore the community and service provision contexts, including changing environments in relation to implementation of the rapid scale up of PrEP in Queensland.

In addition, the M&E procedures were guided by the following key questions:

1. Has QPrEPd achieved the goals and objectives it intended to accomplish, as outlined in the QPrEPd Study Protocol?

2. Has the provision of PrEP attracted those who would most benefit from its use?

3. What were the barriers to people accessing PrEP and how can we overcome these?

4. Was QPrEPd implemented as originally intended? Have appropriate activities been implemented, in the right way and on a large enough scale?

5. Is access to PrEP equitable across the State?

6. Has the provision of PrEP reduced new transmissions of HIV in Queensland?

7. Can progress on the goals and objectives be shown to be related to QPrEPd, as opposed to other developments that were going on at the same time?

8. Has the value or benefit of achieving QPrEPd goals and objectives exceeded the cost of producing them?

9. What have been the unintended results and consequences of interventions?

The 2017 QPrEPd Annual M&E Report[1] presented a comprehensive overview of the first seven months of data (7 November 2016 to 30 June 2017) and addressed the nine key research questions outlined above. The 2017 Annual Report (Report 1) provided local contextualised evidence invaluable to the ongoing delivery of QPrEPd and understanding of the complex array of structural and human factors influencing the roll out of PrEP access through QPrEPd.

6.4 Revised study closure M&E aims and objectives

The aim of M&E component during the study closure was revised in consultation with the DoH during the planning and development of the 'Closure Plan for Early Termination of the QPrEPd Trial'.

The project closure plan was developed by the QPrEPd SMT in consultation with the UQ M&E team to guide the trial sites and the SMT through the participant exit and early termination/closure of the trial within the announced timeframe of 31 January 2019.

The aim of the M&E component during the study closure was to explore the 'real-life' experience of the participants and the HCP during the study closure and the transition to the PBS model of PrEP delivery.

The M&E of the study closure and transition to PBS PrEP delivery was guided by the following six questions:

1. What were the experiences of participant's uptake of PrEP in urban, regional and remote areas during the trial?

2. Was there equitable access of PrEP by key priority target groups during the trial?

3. Were there any key differences between the original QPrEPd cohort and the QPrEPd-X cohort during the trial?

4. What were the experiences of participant's and service providers during the trial closure period and transition to PBS model of access?

5. Were there any negatives or positive aspects of the early closure?

6. Were there any unmet needs or barriers to uptake, access, continuance, or adherence of PrEP after closure of the trial?

The M&E data collected during the entire active study recruitment period (7 November 2016 to 30 September 2018) reported in section 8.1 of this report, provides further local contextualised evidence and understanding of the people accessing PrEP in Queensland and the factors that influenced their access and uptake of PrEP through the QPrEPd model of delivery. Section 8.1 addresses the revised M&E Research Questions 1 to 3 listed above.

The additional data collected during the closure period (1 October 2018 – 30 January 2019) and the 6-months following the closure (1 February 2019 - 30 June 2019) provides understanding of the real-life experience of the participants and the HCP working at the study sites during the study closure and as they transition to the PBS model of PrEP delivery.

Sections 8.2 and 8.3 address the revised M&E research questions 4 to 6 listed above.

6.5 Monitoring and Evaluation Deliverables

6.5.1 M&E Deliverables (19 October 2016)

The M&E deliverables outlined in the Secondary Funding Agreement (SFA) between The State of Queensland (Acting through Queensland Health) and The University of Queensland, dated 19 October 2016 included:

1. Assist with regular reporting on operations directly to the CHHHS lead investigators

2. Provide direction to CHHHS on data collection tools for evaluation purposes

3. Participate in the CHHHS PrEP Steering Committee

4. Work closely with CHHHS to ensure adherence to the QPrEPd protocol and clinical guidelines for evaluation

5. Assist CHHHS in liaising with study sites to establish and maintain data collection strategies

6. Review the uptake of QPrEPd in urban, regional and remote areas to monitor equity of access by the target groups

7. In collaboration with other partners, assess unmet need and barriers to uptake with people not accessing PrEP

8. Publish an annual update, based on data collected by clinic sites and CHHHS

9. On completion of QPrEPd, publish a final report evaluating QPrEPd, using available data and resources.

6.5.2 M&E Deliverables amended (7 September 2018)

The SFA and associated deliverables were amended in line with the early closure and adjusted study timelines on 7 September 2018 to include:

1. Review experiences of participants' uptake of trial in urban, regional and remote areas to monitor equity of PrEP access outside of the trial by the target group.

2. In collaboration with other partners, assess unmet need and barriers to uptake with people not accessing PrEP after closure of the trial.

3. Deliver an enhanced evaluation component focused on experiences of participants during the study closure as they transition to routine care.

4. Conduct and publish a final report which includes an evaluation of the QPrEPd Implementation trial using available data and resources following the trial's completion.

5. Ensure the final report includes an analysis of any key differences between the original QPrEPd cohort and the QPrEPd-X cohort.

7. M&E Data Sources, Responsibilities and Analysis

7.1 Data Responsibilities

Following screening and enrolment, participants attended three-monthly clinical visits for HIV/STI screening, renal function testing and three months' supply of a generic co-formulated tablet formulation of tenofovir disoproxil fumarate (TDF) 300mg and Emtricitabine (FTC) 200mg (FTC/TDF) prescribed for daily oral administration.

The study site personnel were responsible for collecting quantitative data at participant screening, enrolment, at each of the three-monthly follow-up and final exit visits. Data were collected using REDCap, a secure web application for building and managing online surveys and databases for research and clinical trial data maintained by the UQ Queensland Clinical Trials and Biostatistics Centre (QCTBC).

The QPrEPd SMT were responsible for the day-to-day monitoring and management of the REDCap data. The M&E Team were responsible for analysing the quantitative data, and collecting and analysing qualitative data throughout the duration of the QPrEPd study.

7.2 Data Sources

7.2.1 Quantitative Data

Quantitative data was collected via REDCap by the study site staff at the eligibility screening, informed consent and enrolment appointments. This included:

1. Screening and enrolment date; assessment of eligibility
2. Date of birth, age, gender, height and weight
3. Investigations conducted and results
4. Drug supply.

At each 3-monthly follow-up participant visit until closure (Months 1, 3, 6, 9, 12, 15, 18, 21, 24), study site staff were required to complete an online Case Report Form (CRF) via REDCap, including the reporting of:

1. Side effects and adverse events.
2. STI and creatinine screening results.
3. Early exit.

Participants voluntarily completed online surveys at the following study time points:

1. Enrolment (Entry).
2. Three-month post enrolment visit and at Year 1, and Year 2.
3. Exit or withdrawal.
4. Post study closure (6 months).

7.2.2 Qualitative Data

The original M&E plan proposed interviews with up to 30 participants and 20 HCP's and key stakeholders at two time points: the first within three to six months of enrolling in the project and a second interview at one to two years post commencement in the study or on withdrawal. The M&E team completed the first interviews as planned, however, the second round of interviews were not completed as their proposed timing coincided with the early closure announcement.

Ethical approval was gained to conduct the final round of interviews with a selection of up to 30 participants and at least 20 HCP's after the closure of the individual study sites. The aim of these final M&E interviews was to explore the real-life experiences of the participants and HCP's during the study closure and as they transition to the PBS model of PrEP delivery.

7.3 Data Analysis and Reporting Plan

7.3.1 Quantitative Data

Quantitative survey data entered in REDCap was analysed using SPSS 24 (Statistical Software for Social Sciences). Data has been described and summarised using univariate descriptive analysis, including means, standard deviations, frequency counts, percentages, medians, and interquartile ranges. Correlational analysis and cross tabulation analysis was conducted to examine the strength and direction of the relationships between confounding variables such as gender, age, location, enrolment phase (QPrEPd or QPrEPd-X) and dependent output variables. Free text responses to the open-ended survey questions were grouped and analysed for common themes, words and relationships to the relevant questions.

7.3.2 Qualitative Data

Data from the in-depth interviews were digitally recorded, and transcribed to ensure word accuracy. Transcriptions were imported and managed using NVivo 12® (qualitative data management software). Preliminary iterative qualitative analysis of the semi-structured interviews, as well as field notes of the interview proceedings and informal discussions with study site staff were conducted.

Thematic analysis was undertaken to provide multilevel contextualized insight into the ''real time'' commonalities and disparities between service providers and participants' expectations, perspectives and experiences.

8. Results

This final QPrEPd Report (2019) presents an overview of the participants enrolled in QPrEPd and QPrEPd-X and their experiences using PrEP during the study and during the 6-months following the study closure.

This chapter will address the revised M&E study closure and transition to PBS PrEP delivery questions outlined in Section 6.2 in the following three key outcome criteria sections:

1. Participant's experiences of PrEP access and uptake during the study including exploration of whether access was equitable for key priority groups by location; and reasons for withdrawing.

2. Participant's experiences during the trial closure period and transition to PBS model of PrEP access.

3. Service provider's experiences during the trial closure period and transition to PBS model of access.

8.1 Participant's experiences of PrEP access and uptake during the study including exploration of whether access was equitable for key priority groups by location; and reasons for withdrawing.

8.1.1 Screening and Enrolment Trends

Rolling recruitment into QPrEPd commenced from 7 November 2016 and at the time of the first annual QPrEPd report (30 June 2017)[1], 1,819 individuals had been screened and there were 1,678 active enrolled participants (84% of the QPrEPd capped 2,000 target sample). Screening and enrolments continued to increase at a steady rate each week with 2,000 active enrolled participants by 18 November 2017 (Figure 1).

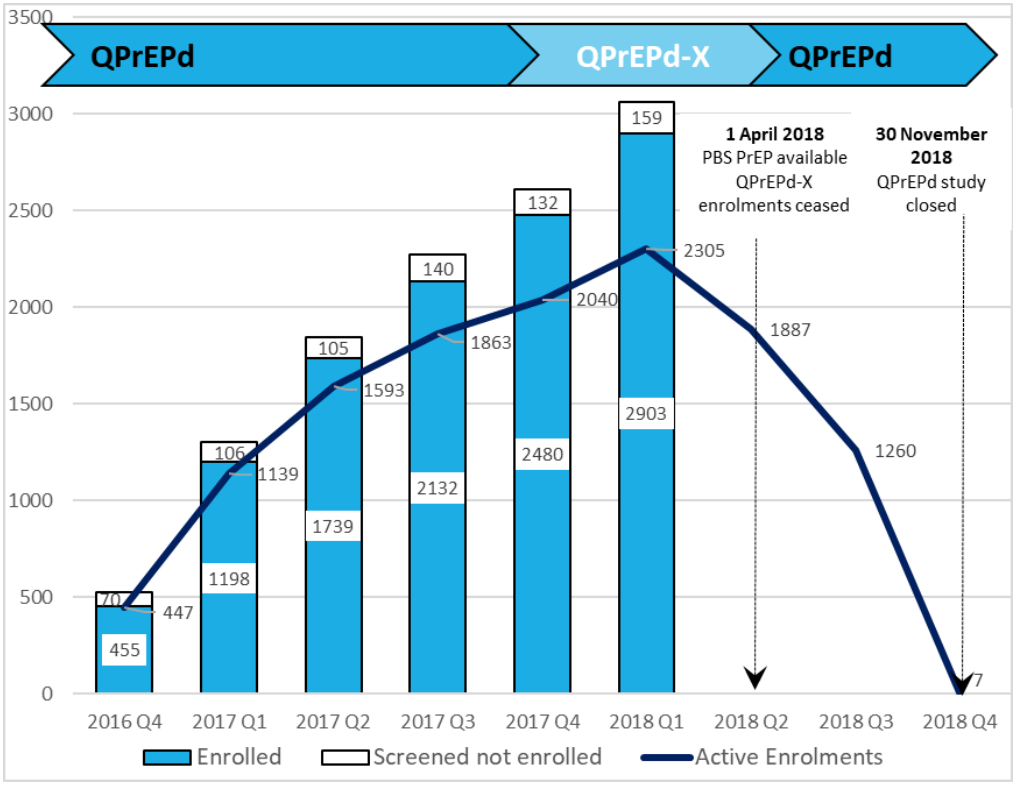


Figure 1: Screening and enrolment numbers by yearly quarters

Recruitment of the additional 1,000 QPrEPd-X participants commenced on 20 November 2017. QPrEPd-X screening and enrolments ceased on 1 April 2018 closure of the QPrEPd-X phase in response to the listing of PrEP as a price-subsidised medicine on the Australian Government National Pharmaceutical Benefits Scheme (PBS)[2]. QPrEPd-X participants were offered a final three-month supply of medication and were transitioned/exited out of the study as per the Study Protocol. During the four and a half month QPrEPd-X period, the highest recorded number of active QPrEPd-X participants was 598. The final QPrEPd-X participants were exited on 5 July 2018, leaving 1,689 active QPrEPd participants.

Following the PBS listing there was a natural attrition of QPrEPd participants, with 1,195 active participants remaining on 1 October 2018 when the approved Early Closure Plan was executed and the transition/exit of the remaining participants occurred. The final participant exited and all 23 of the active QPrEPd study sites closed on 30 November 2019.

In June 2019, The Kirby Institute released a Monitoring HIV pre-exposure prophylaxis in Australia newsletter using data generated from a de-identified 10% sample of all dispensed PBS-subsidised PrEP prescriptions from April 2018 to December 2018.[14] Figure 2 from the Kirby PrEP newsletter demonstrates an increased upward trend of the cumulative number of people in Queensland acquiring PBS-subsidised PrEP from 1,580 in November 2018 to 2,610 by December that coincides with the closure of QPrEPd and the exit of the 1,195 active QPrEPd participants remaining on 1 October 2018.

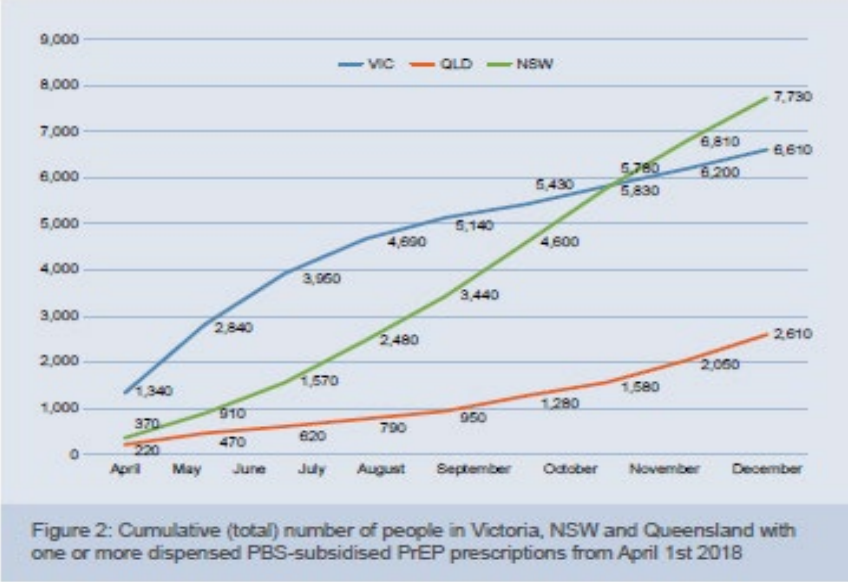


Figure 2: Cumulative (total) number of people in Victoria, NSW and Queensland with one or more dispensed PBS-subsidised PrEP prescriptions from April 1st 2018

Figure 2: Monitoring HIV pre-exposure prophylaxis in Australia Newsletter Figure 2

PBS PrEP Pharmacy Dispensing Statistics for Queensland Pharmacy services, extracted 27 September 2019 from the publicly available Medicare Australia PBS Item dataset, for the time period April 2018 to November 2018 (last six months of QPrEPd operation) mirror the increasing upward trend reported in the Kirby Newsletter. For the six month post QPrEPd closure (December 2018 to June 2019) there is a marked increase in the total amount of all the different PrEP products dispensed on a month to month basis reflective of the QPrEPd sample exiting the study and transitioning to PBS access from 30 November 2018.

Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Total
86	305	229	404	891	859	613	1,152	**4,539**
Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	**Total**	
1,497	1,464	1,469	2,152	1,621	1,758	2,420	**12,381**	

8.1.2 Sociodemographic Profile of Participants

Sample sizes through this report will vary according to the data source being reported on. For example, age and screening data including sex assigned at birth are the only demographic details captured during the screening process via the QPrEPd REDCap software, and accessible to the study team.

The majority of demographic data and details presented in the following section are captured from entry (enrolment) data (n=2,903) and the surveys completed at entry (n=2,280), 3-month (n=1,652), 12 months (n=969) and 24 months (n=75), on exit (n=883) and at 6-months post study closure surveys (n=265).

General Description

The majority of participants identified as gay (68.2%, 1,988) or bisexual (10.1%, 295) cis-males (76.2%, 2,220), aged between 20 and 39 years (62.6%, 1,823), with higher tertiary level qualifications (46%, 1,082), who were born in Australia (76.9 %, 1,754), and living in a major city in the South East corner of Queensland (77.8%, 1,763). Seventy-eight participants identified as Aboriginal and Torres Strait Islander peoples (3.4%).

Comparison of QPrEPd and QPrEPd-X participants will be outlined in the following sections in more detail, however, there were no significant differences in their general profile.

Sex

At screening, for purposes of assessing creatinine clearance levels, participants were recorded as per their reproductive gender/sex which was determined according to their assigned reproductive organs and hormonal function. The vast majority of the participants were recorded on screening as male (99.0%, 2883), with 29(1%) recorded as female (Table 3).

Table 3: Sex assigned at birth by enrolment phases (n=2913)

	QPrEPd	QPrEPd-X	Enrolled post 1 April 2018	Total	% total
Male	2297	576	10	2883	**99.0**
Female	23	6	0	29	**1.0**
Unanswered	1	0	0	1	**<0.01**
Total	**2321**	**582**	**10**	**2913**	

Gender Identity

Table 4 presents the gender diversity of the QPrEPd participants. The majority (76.2%) of the 2903 participants who completed the entry survey self-reported their gender identity as male. It is important to note that gender identity was only recorded for participants who completed the entry survey (Response Rate 78.4%, 2280/2903), and 21.7% of the survey responders did not report their gender identity.

The difference in the number of incomplete responses between the QPrEPd (17.7%) and the QPrEPd-X (36.6%) participants may account for the different percentage of males in these cohorts; 80.3% and 61.3% respectively. These missing data present limitations on our ability to present fully on the gender identity for the total QPrEPd + QPrEPd-X cohort and to determine if some key priority groups at high risk of HIV acquisition are underrepresented in the cohort accessing PrEP through the study.

Table 4: Self-reported gender identity on enrolment

	QPrEPd			QPrEPd-X			Enrolled > 1 April 2018		Total enrolments	
	n	% AE	% QE	n	% AE	% Q-XE	n	% AE	n	% AE
Male	1863	64.0	80.3	357	12.3	61.3	0	0.0	2220	76.2
Male/Two spirits	10	0.3	0.4	2	0.1	0.3	0	0.0	12	0.4
Transgender man	11	0.4	0.5	1	0.0	0.2	0	0.0	12	0.4
Transgender woman	7	0.2	0.3	2	0.1	0.3	0	0.0	9	0.3
Female	4	0.1	0.2	3	0.1	0.5	0	0.0	7	0.2
Male/Genderqueer	6	0.2	0.3	1	0.0	0.2	0	0.0	7	0.2
Genderqueer	2	0.1	0.1	1	0.0	0.2	0	0.0	3	0.1
Male/Genderqueer /fluid	2	0.1	0.1	0	0.0	0.0	0	0.0	2	0.1
Prefer not to say	2	0.1	0.1	0	0.0	0.0	0	0.0	2	0.1
Male/Female	1	0.0	0.0	0	0.0	0.0	0	0.0	1	0.0
Male/Female/Trans male	1	0.0	0.0	0	0.0	0.0	0	0.0	1	0.0
Male/Intersex	0	0.0	0.0	1	0.0	0.2	0	0.0	1	0.0
Pangender	1	0.0	0.0	0	0.0	0.0	0	0.0	1	0.0
Presenting male, internally fluid	0	0.0	0.0	1	0.0	0.2	0	0.0	1	0.0
Trans woman/Intersex	1	0.0	0.0	0	0.0	0.0	0	0.0	1	0.0
Not recorded	410	14.1	17.7	213	7.3	36.6	10	0.3	633	21.7
Total	2321	79.7	100	582	20.0	100	10	0.3	2913	100

n, number ; %AE, Percentage of all study enrolments; %QE Percentage of QPrEPd enrolments; %Q-XE, Percentage of QPrEPd-X enrolments

Age

The median age of all participants was 34 years (range 18 to 82years), lower than the 2016 census Queensland median age of 37.0 years[15] but this can be accounted for by the age of sexually active people compared to the whole population.

QPrEPd-X participants had a younger median age (Table 5) for both cohorts the majority of participants were aged between 20 and 39 years of age (Figure 3). The age range with the highest number of HIV notifications in both Queensland and Australian HIV notification data[16, 17].

The spread of QPrEPd participants across all age groups is reflective of the age groups represented in the notification data extracted from NOCS on 4 June 2019 of newly diagnosed HIV cases in Queensland for the November 2014 to October 2016 (the 2-year period prior to QPrEPd launch) and the period when QPrEPd was actively recruiting participants (November 2016 to October 2018) [17] (Figure 4).This suggests the study recruited the appropriate target age range. The spread of age groups enrolling was similar in pattern across the study site service models (Figure 5).

Table 5: Median Age (years), Minimum, Maximum and Inter Quartile Range by enrolment period at Screening

	QPrEPd	QPrEPd-X	Enrolled after 1 April 2018	Total
Number of participants	2321	582	10	2913
Median	34	31	30	34
Minimum	18	18	18	18
Maximum	82	72	45	82
Inter Quartile Range	27-46	26-42	26-38	27-45

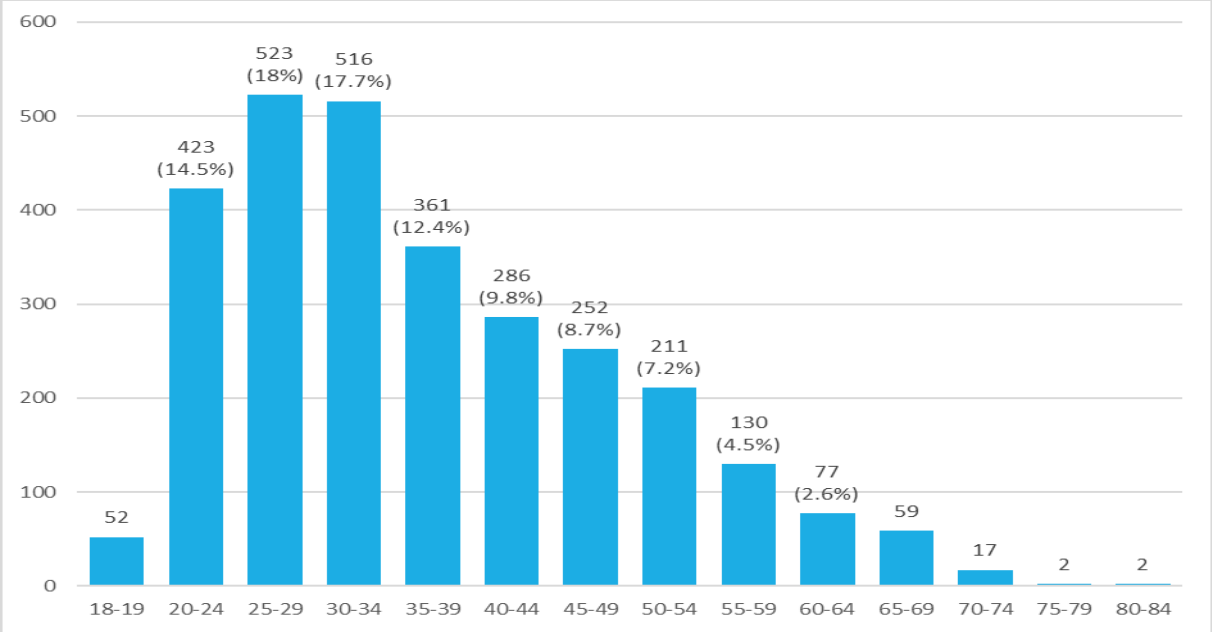
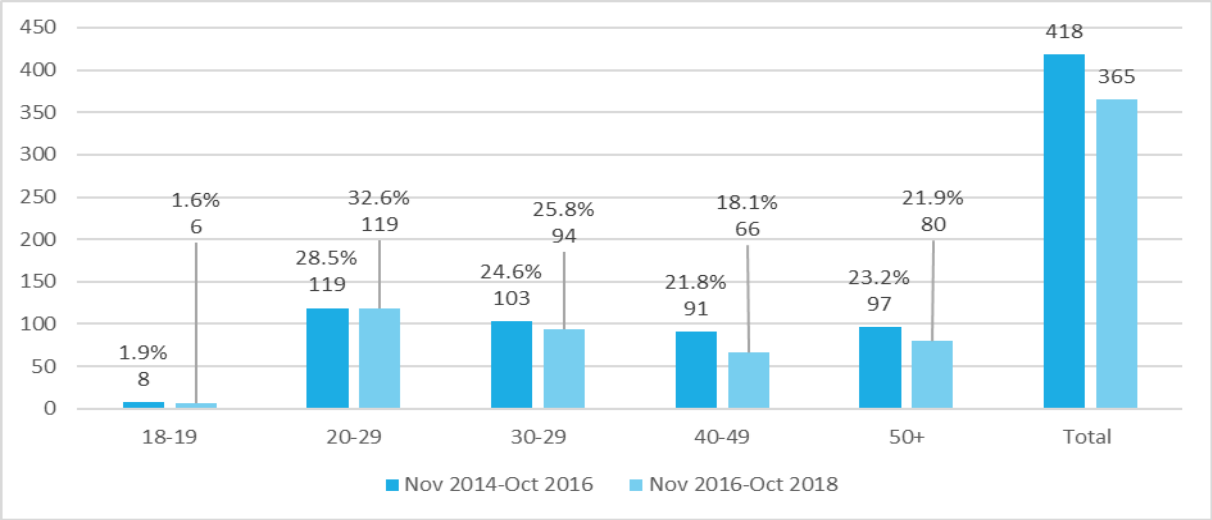


Figure 3: Enrolled participants by Age Group at screening (n = 2911)



(Source: Queensland Government Department of Health. Notifiable Conditions System (NOCS) Hospital and Health Service (HHS) (extracted from NOCS on 4 June 2019))[17]

Figure 4: Count and Percentage of notifications of newly diagnosed HIV cases in Queensland by age of onset group in the 24 months periods prior to and during QPrEPd implementation

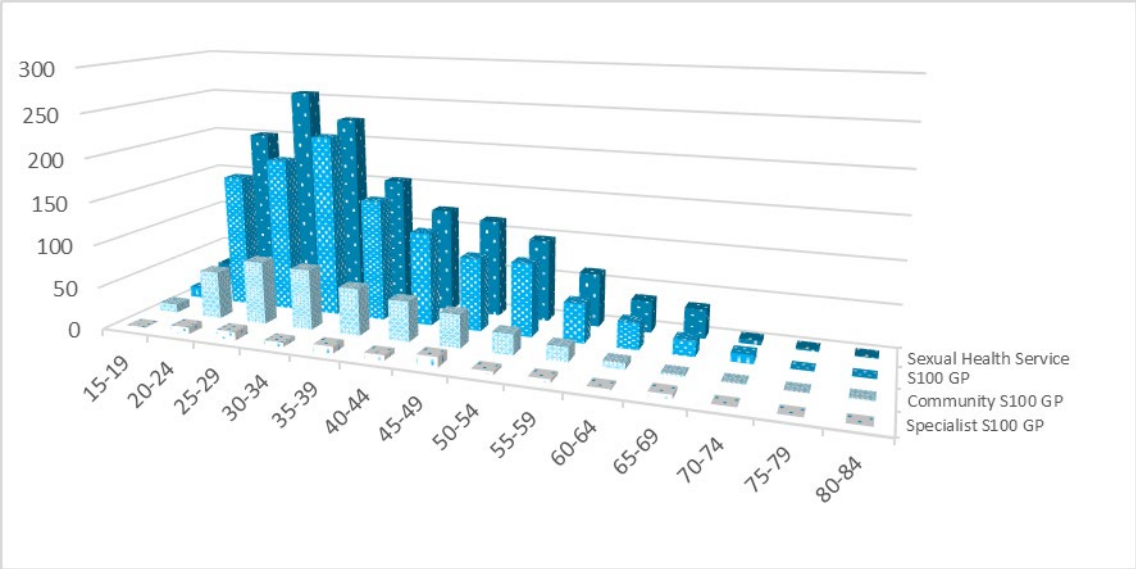


Figure 5: Enrolled participants by Age Group and Service Model at screening

Education Level

The highest education level achieved by the majority of participants enrolling into QPrEPd was an undergraduate tertiary level qualification (29.1%) (Figure 6). A slightly larger percentage of QPrEPd-X participants reported year 12 completion or less as their highest education level achieved compared to the QPrEPd cohort.

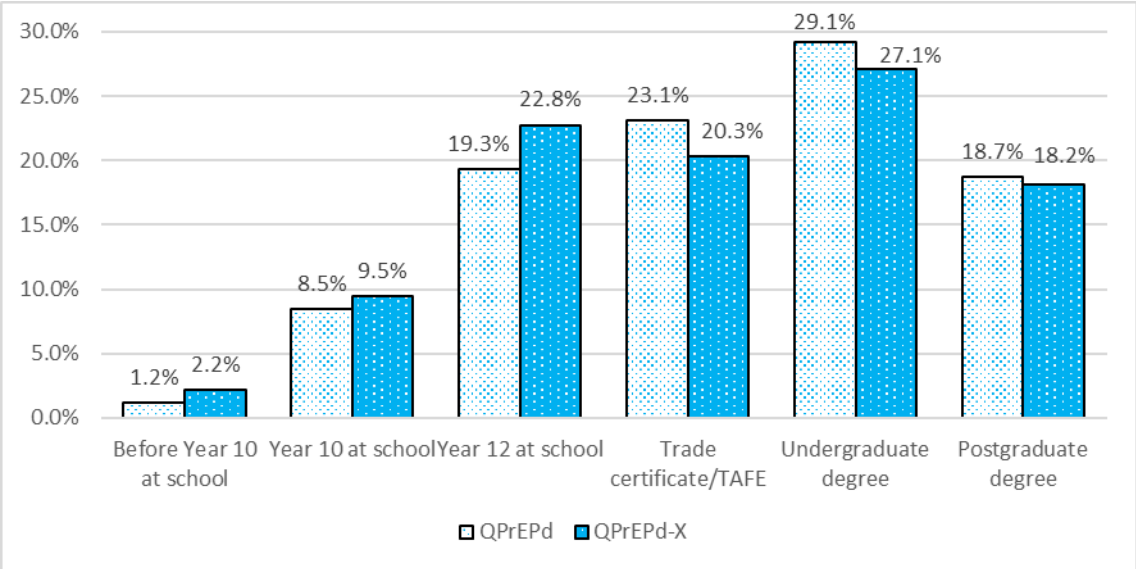


Figure 6: Highest Education Level Achieved by QPrEPd and QPrEPd-X (Entry Survey) (n=2280)

Employment and Income

At enrolment, the majority of participants who reported their main source of income on the entry survey indicated that they were engaged in full-time employment (49.9%) (Table 6) the majority earning above $50,000 gross annual income (Figure 7). Figure 8 comparing the income sources for QPrEPd and QPrEPd-X participants demonstrated very little difference in employment patterns across the two groups.

Table 6: Entry Survey - Main source of income (n=2913)

Income Source	QPrEPd		QPrEPd-X		ENR>* 1April2018		Grand Total	
Full-time employment	1239	53.4%	216	37.1%	0	0%	1455	49.9%
Part-time employment	319	13.7%	72	12.4%	0	0%	391	13.4%
Scholarship or student allowance	53	2.3%	19	3.3%	0	0%	72	2.5%
Superannuation or self-funded retirement	44	1.9%	6	1.0%	0	0%	50	1.7%
Welfare benefits/pension	159	6.9%	31	5.3%	0	0%	190	6.5%
Other (please specify)	97	4.2%	25	4.3%	0	0%	122	4.2%
Question omitted	410	17.7%	213	36.6%	10	100%	633	100%
Total	**2321**	**100%**	**582**	**100%**	**10**	**100%**	**2913**	

*ENR> = Enrolled after 1 April 2018

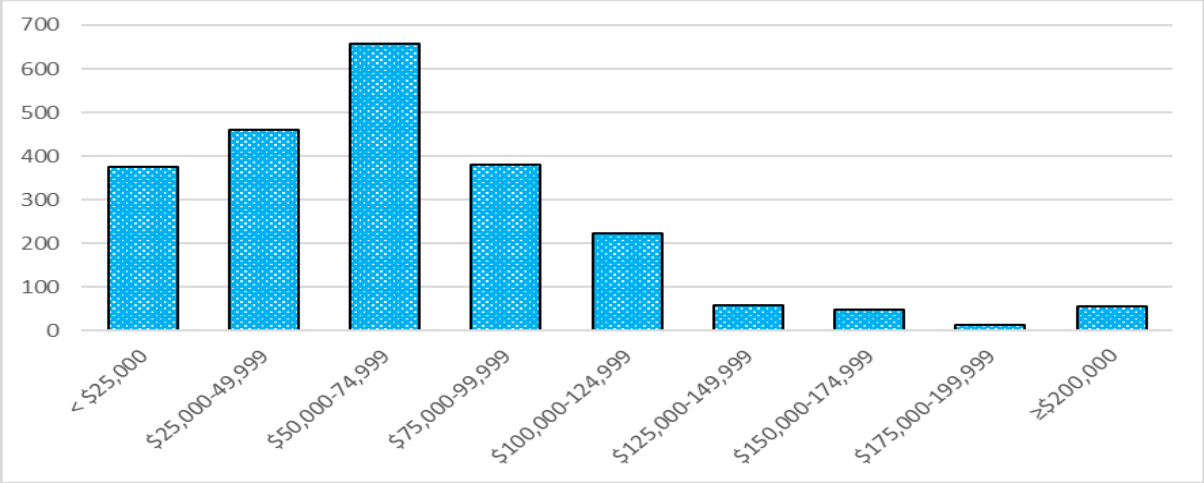


Figure 7: Gross annual income groups

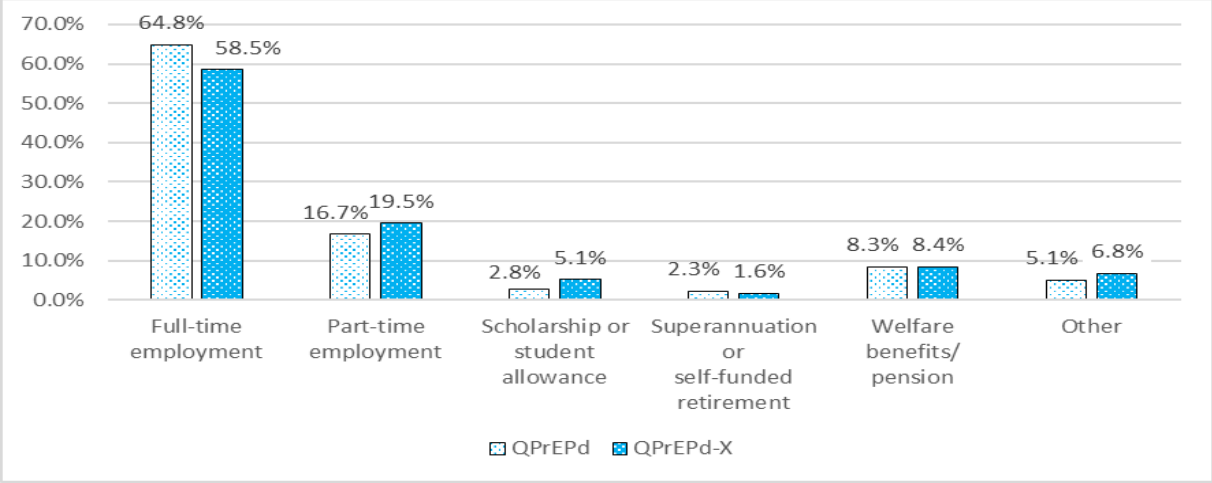


Figure 8: Entry Survey - Main source of income (n=2280)

Postcode and location ARIA

Postcodes provided on the Entry Survey were used to group participants according to the Australian Bureau of Statistics (ABS) Australian Statistical Geography Standard (ASGS) Remoteness Structure categories, which represent broad geographic regions that share common characteristics of remoteness based on the Accessibility/Remoteness Index of Australia (ARIA+) measurement of road distances to service centres.[18] Accessibility and Remoteness Index of Australia (ARIA+) is a measure of relative access to services.

The majority of participants (77.8%, 1763) resided in a major city of South East Queensland (SEQ). Just under a quarter of participant's were living outside of a city in inner regional (9%, 206) and outer regional areas (13.0%, 295). Very few participants (0.1%) reported living in a remote or very remote area (Figure 9). This geographical distribution is reflective of the Queensland population distribution whereby approximately 70% of Queensland's population live in the SEQ area and 23% of Queensland's population live in the local government Brisbane area.[19, 20]

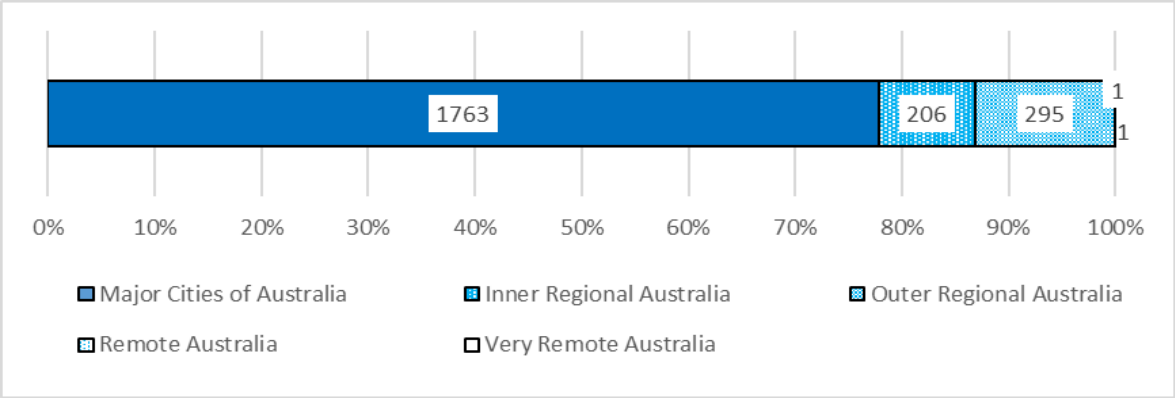


Figure 9: Participants by Accessibility/Remoteness Index of Australia (ARIA+) (n=2266)

Distance from Study Site

The majority of participants (1470/2273, 64.7%) reported the Study Site to which they were enrolled was within 10km of their usual place of residence. A further 29.5% (670) reported travelling from 10km to 50km to their Study Site. Travel distances greater than 100km were reported by 2.5% of participants (57/2273). The proportions of distance travelled to the Study Site did not vary by participants enrolled in QPrEPd and QPrEPd-X. Participants living in a major city travelled the shortest distance to their Study Site as shown in Table 7. Distance travelled to Study Site increased the more remotely participants lived, with 10.2% of participants living in inner regional; 9.9% outer regional and 100% of people living in remote and very remote areas reporting a distance of more than 100km for clinical visits and to access PrEP at their study site.

Table 7: Distance travelled to Study Site by Residential Postcode Area of Remoteness

Distance travelled to Study Site (km)	Major Cities of Australia		Inner Regional Australia		Outer Regional Australia		Remote Australia		Very Remote Australia		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
<10	1186	67.6%	119	57.8%	155	52.7%	0	0.0%	0	0.0%	1460	64.7%
10-50	523	29.8%	48	23.3%	93	31.6%	0	0.0%	0	0.0%	664	29.4%
50-100	41	2.3%	18	8.7%	17	5.8%	0	0.0%	0	0.0%	76	3.4%
>100	5	0.3%	21	10.2%	29	9.9%	1	100%	1	100%	57	2.5%
Total	**1755**	**100%**	**206**	**100%**	**294**	**100%**	**1**	**100%**	**1**	**100%**	**2257**	**100%**

Aboriginal and Torres Strait Islander People

Enrolment data indicates that 3.4% (78) of the participants were Aboriginal and Torres Strait Islander peoples (Table 8). This number has increased from the first Annual Report of 42 (2.9%) Aboriginal and Torres Strait Islander peoples among the 1,674 active participants.

It is important to note however that Aboriginal and Torres Strait Islander status was collected on the entry survey and not as a required demographic marker on the case reporting form collected at the screening or enrolment clinical visit.

As such, due to a 78.3% (2280/2903) entry survey completion rate, this means that we are unable to report on the total numbers of Aboriginal and Torres Strait Islander people screened or enrolled into QPrEPd or correlate some of the data accordingly.

Table 8: Aboriginal and Torres Strait Islander Identity by Study Enrolment (n=2280)

Aboriginal/Torres Strait Islander Identity	QPrEPd	QPrEPd-X	Total
	n (%)	n (%)	n (%)
Non-Indigenous	1847 (96.7%)	355 (96.2%)	2202 (96.6%)
Aboriginal and / or Torres Strait Islander Person	64 (3.4%)	14 (3.8%)	78 (3.4%)
Aboriginal	53 (2.8%)	13 (3.5%)	66 (2.9%)
Aboriginal and Torres Strait Islander	7 (0.4%)	1 (0.3%)	8 (0.4%)
Torres Strait Islander	4 (0.2%)	0 (0%)	4 (0.2%)
Total	**1911**	**369**	**2280**

Similar to the non-Indigenous participants (61.8%), the majority of Aboriginal and Torres Strait Islander participants were aged between 20 to 39 years of age (70.5%), on average the Aboriginal and Torres Strait Islander participants were younger with 42.3% aged between 20 to 29 years of age (Table 9).

The majority of the 78 Aboriginal and Torres Strait Islander participants resided in in a major city in Queensland (67.9%, 53) (Table 10) and 83.3% lived in South East Queensland (SEQ) (Table 11).

Just over half, 41 of the 78 (52.6%), were enrolled in a public SHS study site; 12 (29.3% 12/41) in a regional SHS and 29 (70.7%) a SHS in SEQ (Table 11). A larger proportion of Torres Strait Islander peoples and participants identifying as Aboriginal and Torres Strait Islander peoples attended a Community GP study site.

Table 9: Aboriginal and Torres Strait Islander Identity by Age Group

Age Group	Non-Indigenous		Aboriginal		Aboriginal and Torres Strait Islander		Torres Strait Islander		All Aboriginal and/or Torres Strait Islander people		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
<20	29	1.3%	0	0.0%	0	0%	0	0	0	0.0	**29**	**1.3%**
20-29	686	31.2%	31	47.0%	2	25%	0	0	33	42.3%	**719**	**31.5%**
30-39	673	30.6%	17	25.8%	2	25%	3	75%	22	28.2%	**695**	**30.5%**
40-49	410	18.6%	12	18.2%	3	37.5%	1	25%	16	20.5%	**426**	**18.7%**
50-59	282	12.8%	5	7.6%	1	12.5%	0	0	6	7.7%	**288**	**12.6%**
60-69	106	4.8%	1	1.5%	0	0	0	0	1	1.3%	**107**	**4.7%**
70+	15	0.7%	0	0.0%	0	0	0	0	0	0.0	**15**	**0.7%**
Total	**2201**	**100%**	**66**	**100%**	**8**	**100%**	**4**	**100%**	**78**	**100%**	**2279**	**100%**

Table 10: Aboriginal and Torres Strait Islander Identity of Participants by Accessibility / Remoteness Index of Australia (ARIA)

ARIA	Non-Indigenous n	Non-Indigenous %	Aboriginal n	Aboriginal %	Aboriginal and Torres Strait Islander n	Aboriginal and Torres Strait Islander %	Torres Strait Islander n	Torres Strait Islander %	All Aboriginal / Torres Strait Islander n	All Aboriginal / Torres Strait Islander %	Total n	Total %
Major City	1710	77.7%	45	68.2%	4	50.0%	4	100%	53	67.9%	1763	77.3%
Inner Regional	194	8.8%	8	12.1%	4	50.0%	0	0	12	15.4%	206	9.0%
Outer Regional	283	12.9%	12	18.2%	0	0	0	0	12	15.4%	295	12.9%
Remote	1	0.1%	0	0	0	0	0	0	0	0	1	0.0%
Very Remote	0	0	1	1.5%	0	0	0	0	1	1.3%	2	0.1%
Missing	14	0.5%	0	0	0	0	0	0	0	0	14	0.6%
Total	**2202**	**96.6%**	**66**	**2.9%**	**8**	**0.4%**	**4**	**0.2%**	**78**	**3.4%**	**2281**	**100%**

Table 11: Aboriginal and Torres Strait Islander Identity of Participants by Area of Residence and Study Site Model

		Non-Indigenous n	Non-Indigenous %	Aboriginal n	Aboriginal %	Aboriginal and Torres Strait Islander n	Aboriginal and Torres Strait Islander %	Torres Strait Islander n	Torres Strait Islander %	All Aboriginal / Torres Strait Islander n	All Aboriginal / Torres Strait Islander %	Total n	Total %
Regional	**GP**	19	0.9%	1	1.5%	0	0	0	0	1	1.3%	20	0.9%
	SHS	316	14.4%	12	18.2%	0	0	0	0	12	15.4%	328	14.3%
SEQ	**GP**	833	37.8%	11	16.7%	3	37.5%	2	50%	16	20.5%	849	36.9%
	CGP	324	14.7%	14	21.2%	4	50%	2	50%	20	25.6%	344	15.0%
	SHS	668	30.3%	28	42.4%	1	12.5%	0	0	29	37.2%	717	31.2%
	SP	42	1.9%	0	0	0	0	0	0	0	0	42	1.8%
Total		**2202**	**96.6%**	**66**	**2.9%**	**8**	**0.4%**	**4**	**0.2%**	**78**	**3.4%**	**2300**	**100%**

CGP: Community General Practice (including Community peer organisations and AMS with S100 Prescribing GP services) GP Private S100 Prescribing General Practice, SHS: Sexual Health Service, SP: Specialist S100 Practice/Clinic, SEQ: South East Queensland

Participants Born Overseas

The majority of participants were born in Australia (76.9%) (Table 12 and Figure 10).

Of the 526 participants who reported they were born overseas, 24.5% (129) were from Asia (South, East or South-East), 13.1% (69) the Americas (Latin, Caribbean and North) and 4.4% (23) were from the Sub-Saharan African region, the three regions with the highest HIV notification rates in Australia's 2017 National surveillance data.[21]

Table 12: Region of Birth by study recruitment period

Country of birth	QPrEPd n	QPrEPd %	QPrEPd-X n	QPrEPd-X %	Total n	Total %
Australia	1455	76.1%	299	81.0%	1754	76.9%
East Asia	42	2.2%	11	3.0%	53	2.3%
Eastern Europe and Central Asia	13	0.7%	1	0.3%	14	0.6%
Latin America and the Caribbean	29	1.5%	7	1.9%	36	1.6%
New Zealand	94	4.9%	11	3.0%	105	4.6%
North Africa and the Middle East	8	0.4%	2	0.5%	10	0.4%
North America	29	1.5%	4	1.1%	33	1.4%
Pacific Island nations	10	0.5%	1	0.3%	11	0.5%
South Asia	14	0.7%	4	1.1%	18	0.8%
South East Asia	53	2.8%	5	1.4%	58	2.5%
Sub-Saharan Africa	20	1.0%	3	0.8%	23	1.0%
Western and Central Europe (incl. UK)	111	5.8%	18	4.9%	129	5.7%
Other	33	1.7%	3	0.8%	36	1.6%
Total	**1911**	**100%**	**369**	**100%**	**2280**	**100%**

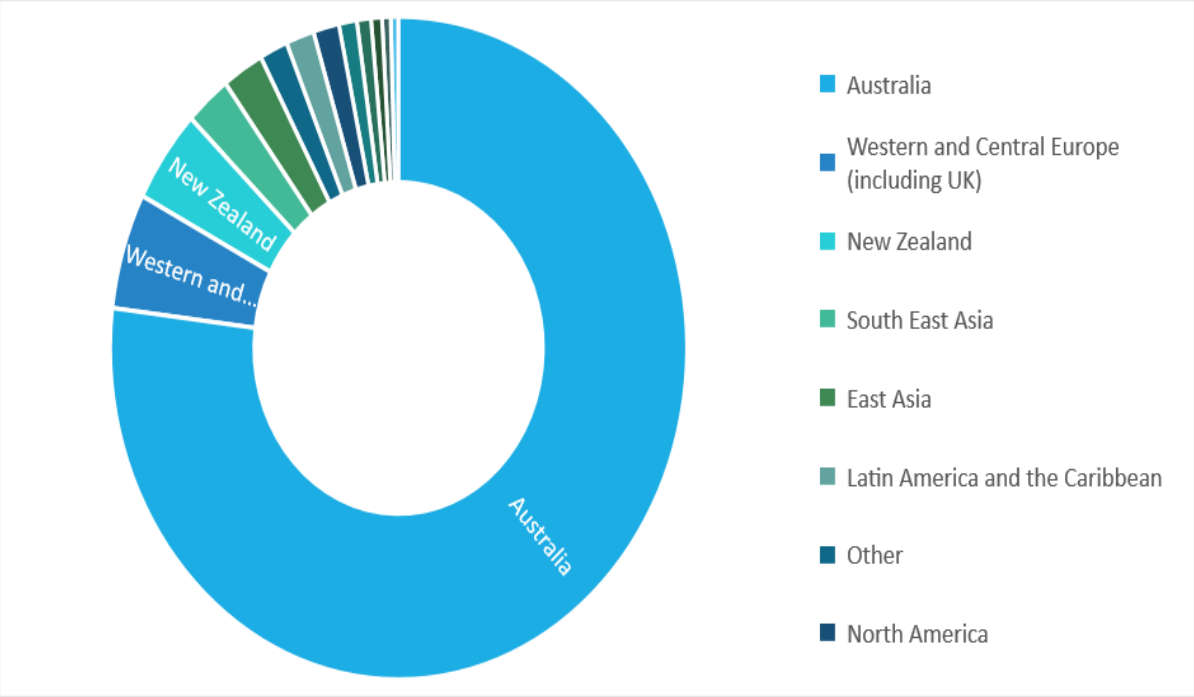


Figure 10: Region of Birth

Medicare Card Status

The majority of participants reported they had an Australian Resident Medicare Card (95.1%) (Table 13). The proportion reporting they had no Medicare Card was up slightly from the 2.4% noted in the 2017 Annual report[(1)] to 3% (69). Interestingly, while 81% of QPrEPd-X participants were Australian born compared to 76.1% of the QPrEPd participants, the proportion of participants that reported that they had no Medicare card (4.3%), a blue interim card (1.1%) or a yellow reciprocal health care agreement visitor card (1.4%) was higher for QPrEPd-X participants.

Table 13: Medicare Card Status

Medicare Card	QPrEPd		QPrEPd-X		Total	
Green (Australian Residents) card	1829	95.7%	339	91.9%	2168	95.1%
Blue (Interim) card	12	0.6%	4	1.1%	16	0.7%
Yellow (Reciprocal Health Care Agreement visitors) card	9	0.5%	5	1.4%	14	0.6%
No Medicare card	53	2.8%	16	4.3%	69	3.0%
Other	8	0.4%	5	1.4%	13	0.6%
Total	**1911**	**100%**	**369**	**100%**	**2280**	**100%**

Of the 69 participants who reported no Medicare Card, one third (33.3%, 23) were born in one of the three Asian regions listed in Table 14. Of the three Asian regions recorded, participants from East Asia 30.2% (16/53) reported the highest Non-Medicare Card rate compared to participants from South Asia 11.1% (2/18) and South East Asia 8.6% (5/58). The majority of participants with no Medicare Card from the Asian region were gay identifying cis-men (Table 15 and Table 16).

Table 14: Region of Birth by Medicare status at Enrolment (n=2913)

	Have a Medicare Card						
Region of Birth	Green#	Blue ##	Yellow ###	No Medicare card	Other	Missing	Grand Total
Australia	1729	5	4	12	4	-	**1754**
Western and Central Europe (including UK)	109	2	9	8	1	-	**129**
New Zealand	104	-	1	-	-	-	**105**
South East Asia	51	1	-	5	1	-	**58**
East Asia	32	2	-	16	3	-	**53**
Latin America and the Caribbean	20	2	-	13	1	-	**36**
North America	25	3	-	3	2	-	**33**
Sub-Saharan Africa	21	-	-	2	-	-	**23**
South Asia	15	1	-	2	-	-	**18**
Eastern Europe and Central Asia	10	-	-	4	-	-	**14**
Pacific Island nations	11	-	-	-	-	-	**11**
North Africa and the Middle East	8	-	-	1	1	-	**10**
Other (please specify)	33	-	-	3	-	-	**36**
Missing	-	-	-	-	-	633	**633**
Grand Total	**2168**	**16**	**14**	**69**	**13**	**633**	**2913**

#Green (Australian Residents) card; ##Blue (Interim) card; ###Yellow (Reciprocal Health Care Agreement visitors) card

Table 15: Region of Birth by Medicare status for Gay Identifying Men at Enrolment (n=1897)

Region of Birth	Have a Medicare Card			No Medicare card	Other	Grand Total
	Green #	Blue ##	Yellow # #			
Australia	1524	3	3	10	4	1544
Western and Central Europe (including UK)	30	2	-	13	2	47
New Zealand	9	-	-	4	-	13
South East Asia	18	2	-	12	1	33
East Asia	88	-	1	-	-	89
Latin America and the Caribbean	6	-	-	-	1	7
North America	21	3	-	3	2	29
Sub-Saharan Africa	7	-	-	-	-	7
South Asia	14	1	-	1	-	16
Eastern Europe and Central Asia	44	1	-	5	1	51
Pacific Island nations	16	-	-	2	-	18
North Africa and the Middle East	95	1	9	8	1	114
Other (please specify)	25	-	-	3	-	28
Grand Total	**1897**	**13**	**13**	**61**	**12**	**1996**

#Green (Australian Residents) card; ##Blue (Interim) card; ###Yellow (Reciprocal Health Care Agreement visitors) card

Table 16: Region of Birth by Medicare status for Bisexual Identifying Men at Enrolment

Region of Birth	Have a Medicare Card			No Medicare card	Grand Total
	Green#	Blue ##	Yellow # # #		
Australia	225	2	-	3	230
Western and Central Europe (including UK)	3	-	-	3	6
New Zealand	1	-	-	-	1
South East Asia	2	-	-	1	3
East Asia	18	-	-	-	18
Latin America and the Caribbean	1	-	-	1	2
North America	7	-	-	1	8
Sub-Saharan Africa	3	-	-	-	3
South Asia	2	-	-	1	3
Eastern Europe and Central Asia	5	-	-	-	5
Pacific Island nations	3	-	-	-	3
North Africa and the Middle East	12	1	-	-	13
Other (please specify)	6	-	-	-	6
Grand Total	**288**	**3**	**-**	**10**	**301**

#Green (Australian Residents) card; ##Blue (Interim) card; ###Yellow (Reciprocal Health Care Agreement visitors) card

8.1.3 Sexual Behaviour, Identity, and Relationships

Patterns of sexual behaviour were collected via voluntary on-line surveys completed at entry (n= 2,280), 12 months (n=969) and 24 months (n=75). On entry to the study 41.1% (938) reported more than 10 sexual partners in the last 6 month (Table 17).

Table 17: Entry Survey: Sexual Partners in last 6 months (n=2,280)

Number of Partners	n	%
None	15	0.7%
One	104	4.6%
2 to 5	652	28.6%
6 to 10	571	25.0%
More than 10	938	41.1%
Total	2280	100%

Table 18 and Figure 11 present a comparison of the number of sexual partners in the previous six months reported at the three survey time points: entry, 12 and 24 Months. The proportion of participants reporting more than 10 partners in the previous six months remained relatively stable at the 12 and 24-month time points at 40.4% and 40% respectively.

A minor modification to the 12 and 24 month survey enabling collection of more details about the number of sexual partners among this group indicated that there was an upward shift from 20.0% at 12-months survey to 28.0% at the 24-month time point for people reporting 21 or more partner in the previous six month.

Overall, between enrolment and three months and between three and 12 months there was a significant increase in the number of self-reported sexual partners in the last six month period (P <0.001). There was also an overall significant increase in condomless anal intercourse (CLAI) with regular, 'fuck buddies' and casual sexual partners between enrolment and 12-months (*P* <0.001).

Table 18: Number of sexual partners in the previous six months at Entry, 12 and 24 Months

Number of sexual partners in the previous 6 months	Entry * (n=2,280)	%	12 months (n=969)	%	24 months (n=75)	%
None	15	0.7%	7	0.7%	3	4.0%
1	104	4.6%	68	7.0%	3	4.0%
2 to 5	652	28.6%	267	27.6%	18	24.0%
6 to 10	571	25.0%	235	24.3%	21	28.0%
More than 10*	938	41.1%				
11 to 20			198	20.4%	9	12.0%
21 to 50			150	15.5%	17	22.7%
More than 50			44	4.5%	4	5.3%
Total	**2280**	**100%**	**969**	**100%**	**75**	**100%**

* At enrolment participants only had the option to choose 'More than 10 partners'

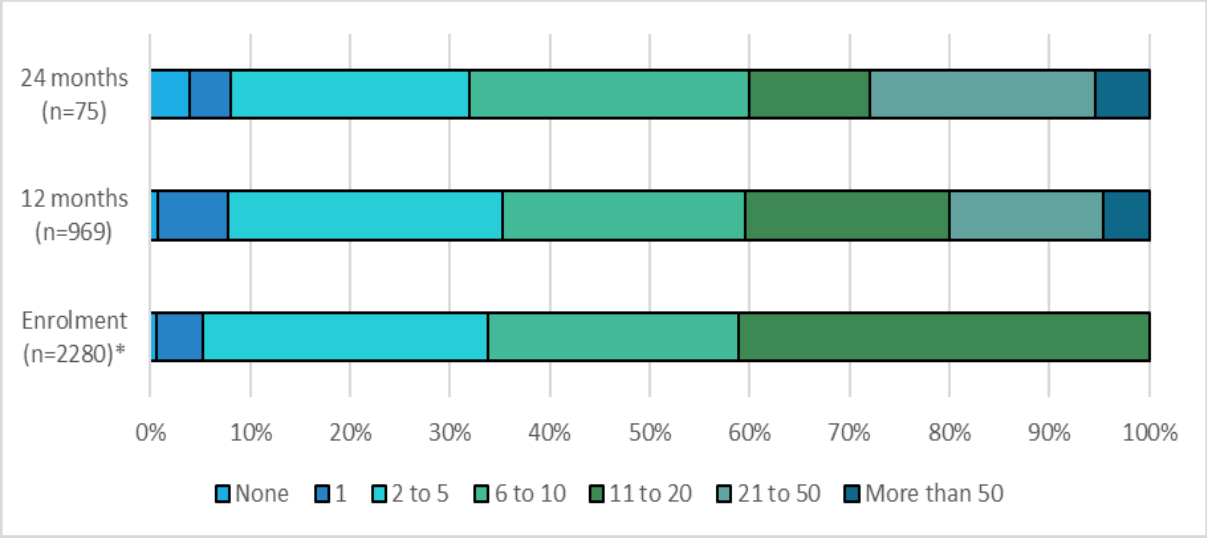


Figure 11: Number of sexual partners in the previous six months at Entry, 12 and 24 Months

Participants were able to identify more than one gender identity for their partner/s in three partner type category: regular, 'fuck buddies' and/or casual partners.* This presented opportunity to explore these relationships and identify scenarios whereby potential risk of exposure may be missed in a clinical setting by superficial or absent sexual history taking, risk assessment and or poor understanding of the diversity of sexual relationships.

The majority of the 2280 participants who completed the entry survey identified as gay men (87.2%, 1,988), the majority of whom were sexually active with a regular male partner/s (82.1%), 'fuck buddies' (80.9%) and/or casual partners (94.6%). Tables 19, 20 and 21 highlight the issues of assessing risk by labelling people into singular cohort groups by gender and sexual identity.

Table 19 highlights the gender diversity of sexual partners reported by the 1,988 gay identifying male participants across the three partner categories.

Table 20 demonstrates a similar pattern of diversity among the 295 (10.1%) participants self-identifying as bisexual.

Table 21 presents the gender identity breakdown of partners of the 10 (0.4%) participants who self-reported their gender as heterosexual, and again similar patterns of diversity observed as MSM and bisexual men.

* For the purposes of this study, a regular partner was described to participants as someone with whom they had a regular planned sexual relationship that they expected to continue in the future; a fuck buddy was a sexual partner/s with whom they had sex regularly but did not classify as their regular or casual partner/s; and a casual sexual partner/s referred to people with whom they had sex with but did not expect or plan to have sex with again.

Table 19: Gay Identifying Men and Relationship of Sexual Partners by gender identity (n=1988)

Gay Men (n=1988)	Partner/s Type		
Gender of partner/s #	Regular	Fuck Buddies	Casual
No Partner	442	442	129
Male	1633	1609	1881
Female	16	25	43
Transgender man	8	9	17
Transgender women	4	3	8
Two-spirit	2	2	4
Genderqueer	3	3	8
Intersex	0	0	2
Prefer not to say	2	3	4
Other	2	6	2
#Participants were able to identify more than one gender identity in each partner type categories.			

Table 20: Bisexual Identifying Men and Relationship of Sexual Partners by gender identity (n=295)

Bisexual Men (n=295)	Partner/s Type		
Gender of partner/s #	Regular	Fuck Buddies	Casual
No Partner	79	66	16
Male	210	225	272
Female	83	59	108
Transgender man	10	11	14
Transgender woman	8	9	12
Two-spirit	1	2	4
Genderqueer	1	0	5
Intersex	1	1	3
Prefer not to say	1	0	0
Other	1	9	0
#Participants were able to identify more than one gender identity in each partner type categories.			

Table 21: Heterosexual Identifying Men and Relationship of Sexual Partners by gender identity (n=10)

Heterosexual Men (n=10)	Partner/s Type		
Gender of partner/s #	Regular	Fuck Buddies	Casual
No Partner	4	3	1
Male	7	7	9
Female	3	2	4
Transgender man	1	1	2
Transgender woman	0	0	1
Two-spirit	0	0	1
Genderqueer	0	0	1
Intersex	0	0	1
#Participants were able to identify more than one gender identity in each partner type categories			

Table 22 presents the self-reported sexual identity of all male participants who reported having a regular female sexual partner. Without further questioning, there may be the assumption that 'a man with a regular female partner' is at low risk of HIV. However, the additional sexual identity and 'activity' data outlined in Table 23 suggests further consideration about the benefits of appropriate testing, and access to PrEP for them and their partner/s, is needed.

Table 22: Sexual Identity of Men with Regular Female Partner/s (n=95)

Sexual Identity	n	%	% of Cases
Heterosexual	3	2.8%	3.2%
Gay	16	14.8%	16.8%
Bisexual	83	76.9%	87.4%
Two Spirits	1	0.9%	1.1%
Queer	1	0.9%	1.1%
Not sure yet	2	1.9%	2.1%
Other	2	1.9%	2.1%
Total	108	100.0%	113.7%
[#]Participants were able to identify more than one gender identity in each partner type categories			

Table 23: Men with Regular Female Partner and Relationship of other Sexual Partners by gender identity (n=95)

	Partner/s Type		
Gender of partner/s [#]	**Regular**	**Fuck Buddies**	**Casual**
No Partner	9	14	11
Male	71	74	81
Female	95	35	47
Transgender man	7	4	6
Transgender women	7	8	7
Two-spirit	0	2	0
Genderqueer	1	0	1
Intersex	2	0	0
[#]Participants were able to identify more than one gender identity in each partner type categories			

8.1.4 STI and HIV testing and diagnosis numbers and patterns

Following screening and enrolment, participants attended three-monthly clinical visits for HIV and STI screening inclusive of pharyngeal and anal swab/s for gonorrhoea and chlamydia, first catch urine for chlamydia, syphilis serology and Hepatitis B screen (if the participant was not immune and vaccine is not available).

Table 24 and Table 25 display the number and prevalence of STI diagnosed at enrolment by previous HIV and STI testing history as self-reported on the QPrEPd entry survey. In total at enrolment, there were 383 STI diagnosed among the total sample of people screened (n = 3062). At enrolment, 15.6% of participants had not previously tested for STI and or HIV (Table 24 and Table 25).

Table 24: STI Diagnosis by Previous HIV Testing History Reported on Entry Survey

	Last HIV test					
STI detected at enrolment	**In the last month**	**1 - 6 months ago**	**7 - 12 months ago**	**1 - 2 years ago**	**> 2 years ago**	**Never had a previous test**
No (n)	464	1198	169	74	62	27
Yes (n)	47	183	23	16	9	5
Prevalence (%)	9.2%	13.8%	12.0%	17.8%	12.7%	15.6%

Table 25: STI Diagnosis by Previous STI Testing History Reported on Entry Survey

	Last STI test					
STI detected at enrolment	**In the last month**	**1 - 6 months ago**	**7 - 12 months ago**	**1 - 2 years ago**	**> 2 years ago**	**Never had a previous test**
No (n)	440	1141	202	100	74	38
Yes (n)	47	176	31	15	7	7
Prevalence (%)	9.7%	13.4%	13.3%	13.0%	8.6%	15.6%

Over the 24 month study period, a total of 1,557 STI (other than HIV) were diagnosed. Figure 12 presents the number and percentage of actively enrolled participants with a diagnosed STI (other than HIV) at enrolment and each consecutive three-monthly clinical visit. A gradual decreasing trend in STI prevalence was noted over time.

Change in STI positivity over time between enrolment and the 18-month clinical visit time points, was assessed using chi square test for trend. Overall, between baseline enrolment screening and 18 months, combined STI positivity rate decreased from 3.19% to 2.42% (P_{trend} 0.007).

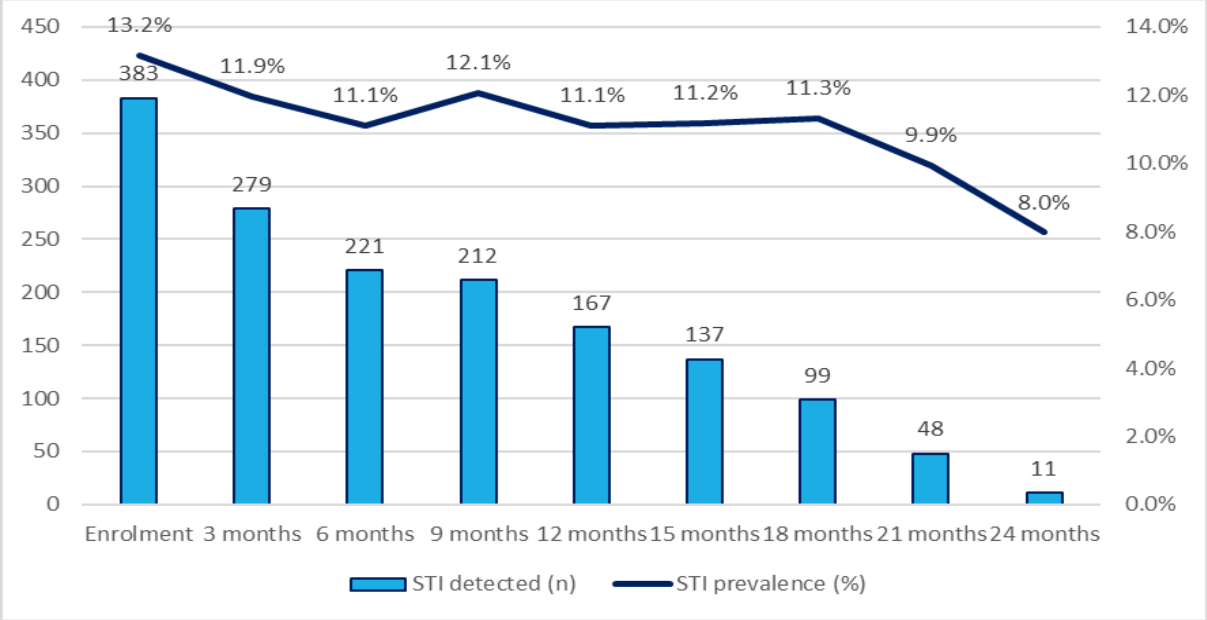


Figure 12: Enrolled participants with STI (other than HIV) diagnosed at three-monthly screening visit (total number; percentage)

For individual STI, a reduction in STI positivity from baseline to 18 months was found for syphilis (2.09 to 1.18%, P_{trend} = 0.03) and gonorrhoea at any anatomical site (1.94 – 1.25%, P_{trend} 0.006). However, no change in chlamydia positivity at any anatomical site was observed between enrolment and 18 months (P_{trend} 0.82).

STI positivity was associated with younger age groups (aOR 0.99 95% CI 0.98, 1.00; *P* 0.01), condomless anal intercourse (CLAI) with a casual partner (aOR 1.19 95% CI 1.10, 1.28; *P* <0.001) and group sex involving two or more people (aOR 1.20 95% CI 1.11, 1.30; *P* <0.001) [3, 4].

At each survey time point, participants were asked the extent to which they agreed with the statement – '*STI checks are needed every three months while taking PrEP'*. With active QPrEPd participants, the percent of people who strongly agreed or agreed with this statement remained relatively stable between 92 to 94% (Figure 13).

In contrast, of those exiting the study before 1 October 2018, who completed an exit survey (n=881), the percentage of people who agreed or strongly agreed that STI checks were needed three-monthly decreased to 79%. This drop remains unexplained and warrants closer examination of STI testing patterns post QPrEPd.

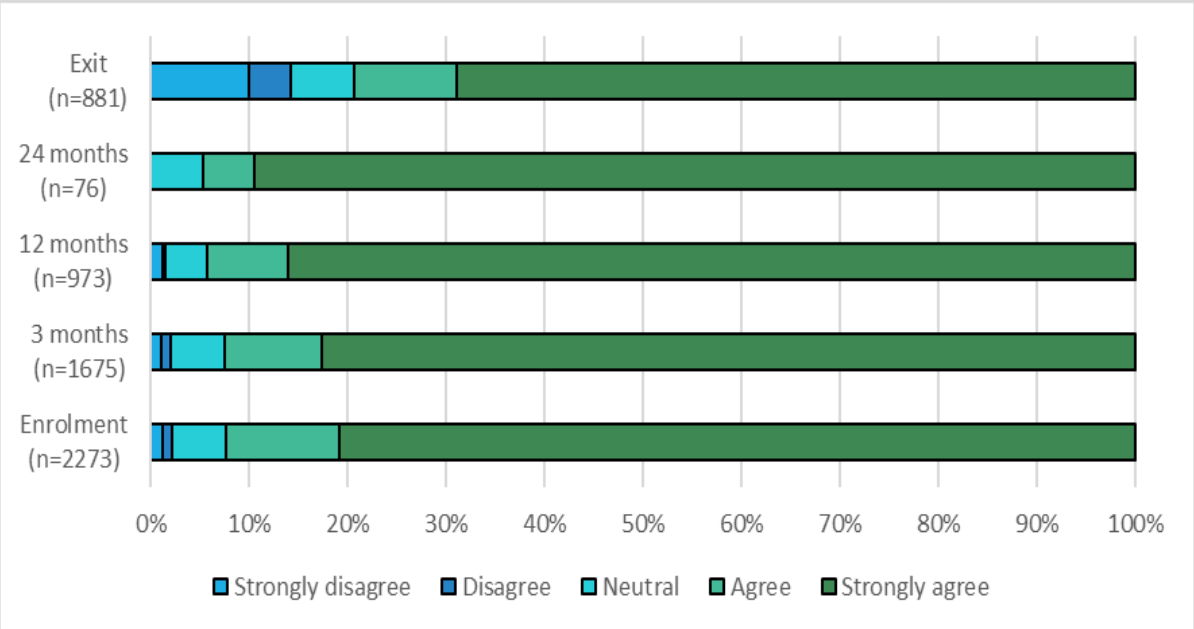


Figure 13: STI checks are needed every three months while taking PrEP?

8.1.5 HIV Cases Diagnosed during the study

New HIV Cases Diagnosed at Screening

Of the total sample screened, eight new HIV cases were diagnosed during the screening process (0.26%; 8/3065): four at public Sexual Health Services (SHS) and four at Primary Health Care/Community/General Practice study sites (Table 26). Those diagnosed on screening were aged between 18 and 52 years old (median age 35.4 years), living in the South East corner of Queensland.

At the screening interview, none of the newly diagnosed participants reported experiencing HIV-related symptoms. Three (37.5%) of the participants diagnosed with HIV were also diagnosed with another STI at the time of screening: gonorrhoea (n=2) and syphilis (n=1).

Table 26: HIV Cases Diagnosed During QPrEPd Screening and Associated STI Diagnosis

Study Site	Date	Age group	Gender	HIV symptoms	Other STI	Syphilis	NG	CT
SEQ	2016 Q4	35-39	Male	No	No	No	No	No
SEQ	2016 Q4	40-44	Male	No	No	No	No	No
SEQ	2017 Q1	50-54	Male	No	Yes	Yes	No	No
SEQ	2017 Q2	30-34	Male	No	Yes	No	Pharynx	No
SEQ	2017 Q2	35-39	Male	No	No	No	No	No
SEQ	2017 Q2	30-34	Male	No	Yes	No	Rectal	No
SEQ	2017 Q4	30-34	Male	No	No	No	No	No
SEQ	2017 Q4	18-19	Male	No	No	No	No	No
Total (n)			**8**	**0**	**3**	**1**	**2**	**0**

Q, Quarter; Dx, Diagnosed; CT – Chlamydia; NG – Gonorrhoea; Pharynx - Pharyngeal

Other Reported New HIV Cases Diagnosed during the Study

In addition to the eight participants diagnosed with HIV at screening, one participant had a positive HIV result reported at the One Month Visit, 35 days following a negative result on screening. Signs and/or symptoms of HIV infection were documented at screening, suggestive of recently acquired HIV infection prior to enrolment.

Other Reported New HIV Cases Diagnosed after the Study

Analysis of the QPrEPd clinical records identified two other new HIV diagnoses. Investigation of these diagnoses determined that:

1. the two participants were no longer enrolled in QPrEPd when HIV was diagnosed [Reasons for exiting the study were cited as unmanageable side-effects (1) and lost to follow-up (1)];

2. The HIV positive results had been entered retrospectively after the participants had exited QPrEPd by Study Site staff when they became aware of the change in the individuals HIV status.

Important Note: Study Sites were not required to retrospectively enter new HIV diagnoses identified among exited QPrEPd participants. As data *were not* routinely collected, determination of all new HIV diagnoses among participants following early exit of the study, or after the trial ceased is not possible.

Comparison to Queensland HIV Notifications Data

Table 27 outlines the newly diagnosed HIV notifications by HHS for the 2015/16 (the year prior to QPrEPd implementation) to 2018/19 financial year periods, and the percentage by which these have changed over this time period.[17] Care needs to be taken when interpreting this table as the notification numbers are low in some of the HHS areas, thus making the percentage of change, both positive and negative, appear large for some areas.

Nonetheless, the Queensland Health annual notifiable conditions data reported in Table 27 indicates the majority of HHS recorded a decrease in the percentage of newly diagnosed HIV notifications for the July 2018 to June 2019 financial year period, as compared to the July 2015 to June 2016 period. There was an overall 17.2% decrease in newly HIV diagnosed notifications noted for Queensland in total.

The implementation of QPrEPd and the increased access to PrEP for nearly 3000 people at high risk of acquiring HIV in Queensland coincided with the observed decrease in notification over this period. However, multiple factors could be contributing to this decrease and it remains unclear what contribution the increase access to PrEP had on this general decreasing trend.

Table 27: Newly Diagnosed HIV Notifications (number and % of annual notifications) by HHS and Financial Years 2015/16 to 2018/19#

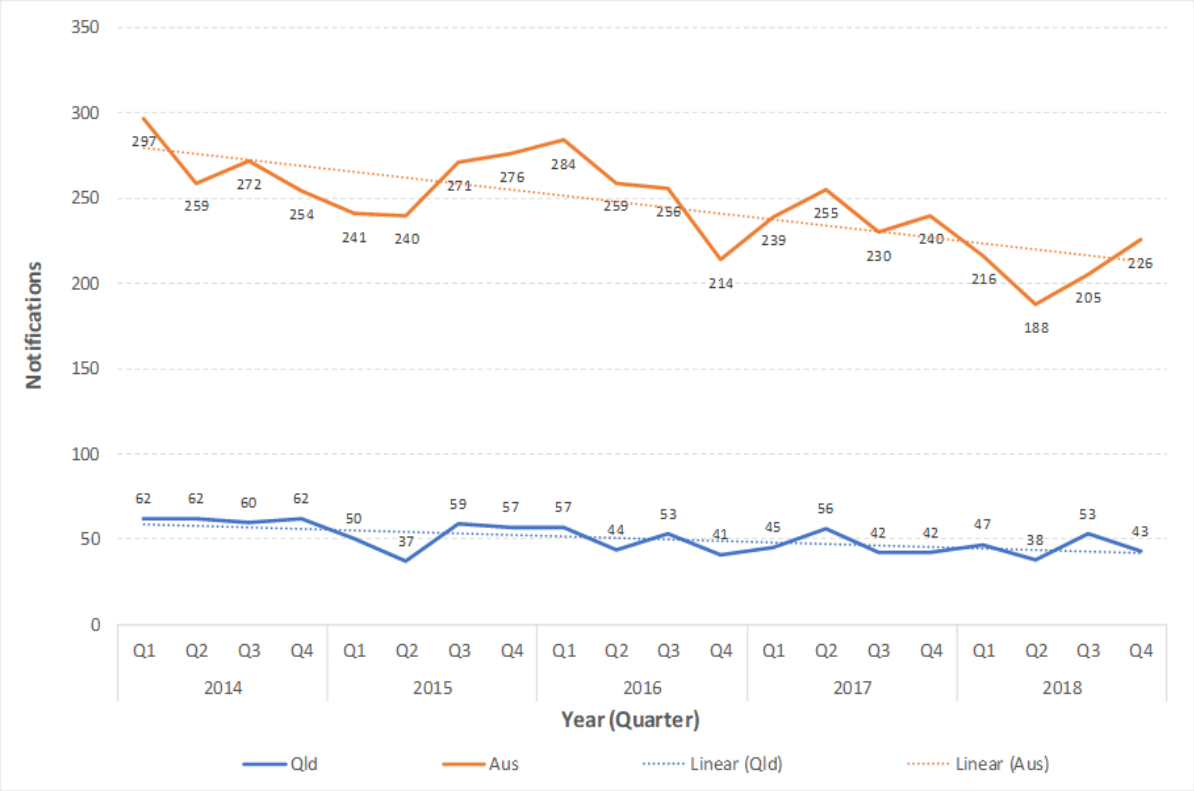
Hospital & Health Service	2015/16		2016/17		2017/18		2018/19		% change 15/16 to 18/19
	n	%	n	%	n	%	n	%	
Cairns and Hinterland	30	14.0%	17	8.7%	16	9.5%	18	10.1%	-40.0%
Central Queensland	6	2.8%	4	2.1%	3	1.8%	4	2.2%	-33.3%
Central West	1	0.5%	0	0.0%	1	0.6%	0	0.0%	-100.0%
Darling Downs	11	5.1%	5	2.6%	7	4.1%	3	1.7%	-72.7%
Gold Coast	40	18.6%	29	14.9%	27	16.0%	31	17.4%	-22.5%
Mackay	4	1.9%	5	2.6%	1	0.6%	3	1.7%	-25.0%
Metro North	53	24.7%	66	33.8%	43	25.4%	36	20.2%	-32.1%
Metro South	38	17.7%	48	24.6%	41	24.3%	49	27.5%	**28.9%**
North West	1	0.5%	0	0.0%	2	1.2%	2	1.1%	100.0%
South West	0	0.0%	0	0.0%	1	0.6%	0	0.0%	0.0%
Sunshine Coast	6	2.8%	6	3.1%	6	3.6%	6	3.4%	0.0%
Torres and Cape	0	0.0%	3	1.5%	3	1.8%	3	1.7%	300.0%
Townsville	8	3.7%	2	1.0%	5	3.0%	6	3.4%	-62.5%
West Moreton	12	5.6%	7	3.6%	11	6.5%	13	7.3%	8.3%
Wide Bay	5	2.3%	3	1.5%	2	1.2%	4	2.2%	-20.0%
Queensland Total	215	100%	195	100%	169	100%	178	100%	-17.2%

Source: Queensland Health Notifiable conditions annual reporting, Date extracted 1 July 2019[17] https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/surveillance/reports/notifiable/annual Accessed 6 July 2019
% = HHS percentage of total state-wide annual HIV diagnoses

Queensland's decrease mirrors the national population-level decrease in incidence of newly acquired HIV as demonstrated by the decreasing linear trend over time nationally for this period in Figure 14 extracted from The Kirby Institute (2019) National HIV notifications Q1 2014 – Q4 2018 report.[16]

Evidence suggests that the large PrEP Implementation projects that have been underway in New South Wales, and Victoria since early 2016 have contributed to the noted population-level decrease in incidence of newly acquired HIV [22].

The downward trend has been slower in Queensland along with the other jurisdictions of the Australian Capital Territory, Western Australia, South Australia, and Tasmania where the demonstration studies were all smaller and commenced later in 2017.



(Source: The Kirby Institute. National HIV notifications Q1 2014 – Q4 2018. Sydney, Australia: Kirby, UNSW; 2019.)[16]

Figure 14: National HIV Notifications by Quarter 2014-2018 for all Jurisdictions [16]

There was a positive percentage of change noted in four HHS areas. North West HHS, West Morten and Torres and Cape HHS had small numbers of notifications.

Table 28 presents the number of participants enrolled by HHS area. Without knowing the exact population at risk and eligible for PrEP it is difficult to determine if the uptake of PrEP influenced the varying trends in HIV notifications in the HHS areas.

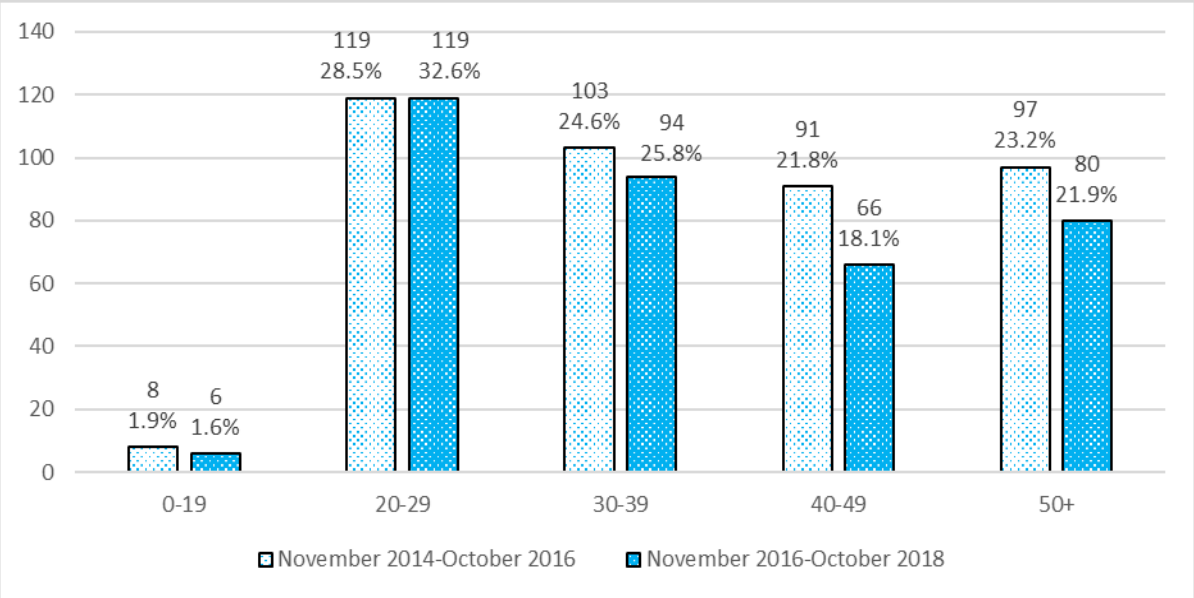
Further investigation to explore the sustained increasing trend of new HIV notification (10, 28.9%) noted in Metro South HHS is warranted.

Table 28: Proportion of QPrEPd uptake by Hospital and Health Service (HHS)

HHS	n	%
Cairns and Hinterland	230	7.9%
Central Queensland	47	1.6%
Darling Downs	124	4.3%
Gold Coast	316	10.8%
Mackay	43	1.5%
Metro North	1159	39.8%
Metro South	600	20.6%
Sunshine Coast	103	3.5%
Townsville	104	3.6%
Wide Bay	19	0.7%
West Moreton	168	5.8%
Total	**2913**	**100.0%**

Figure 15 presents the newly HIV diagnosed notifications from the Queensland NOCS data in the 24-month period prior to QPrEPd implementation on 7 November 2016 (November 2014 to October 2016) compared by age of onset group to the 24-month period of QPrEPd delivery of PrEP (November 2016 to October 2018).

Notifications of newly diagnosed HIV cases in Queensland in each of the age groups above 30 years have declined over these two periods, however, the number of notifications of newly diagnosed HIV cases has remained stable in the 20 to 29 year old age group. Just under one third (32.5%, 946) of QPrEPd participants were aged between 20 to 29 years of age, however these notification figures suggest that promoting access and uptake of PrEP among this age group should remain the focus of PrEP campaigns.



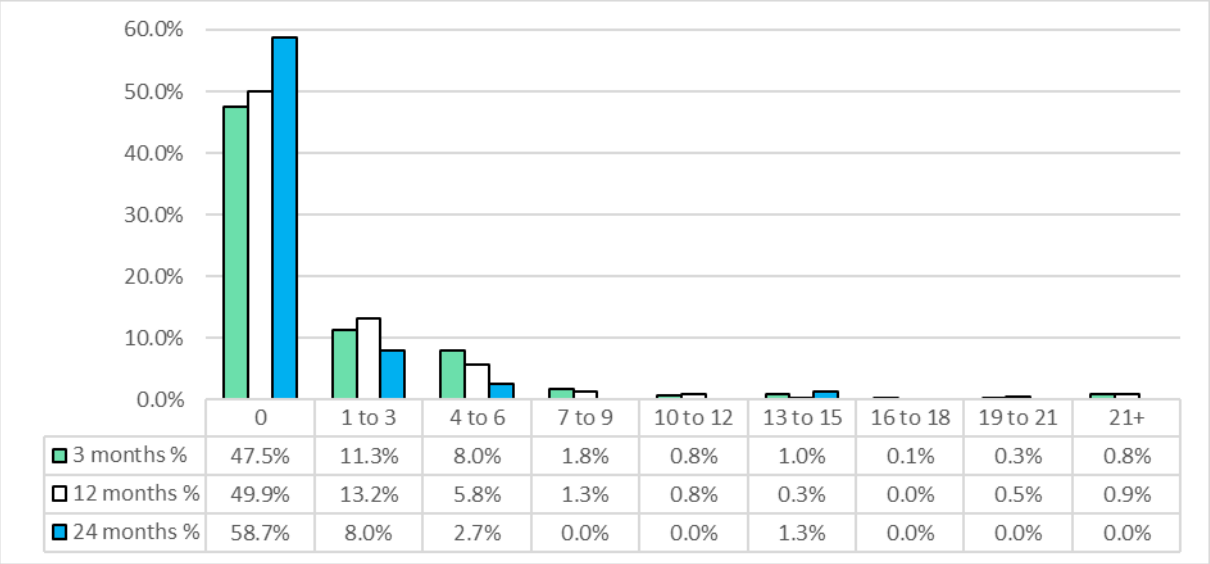
(Source: Queensland Government Department of Health. Notifiable Conditions System (NOCS) Hospital and Health Service (HHS) (extracted from NOCS on 4 June 2019))[17]

Figure 15: Count of notifications of newly diagnosed HIV cases in Queensland by age of onset group in the 24 month periods prior to and during QPrEPd implementation (7 November 2016)

8.1.6 Patterns of PrEP Use

Missed Pills

The majority of participants reported taking PrEP daily for the majority of time that they were actively enrolled in the study. There were some occasional reports of missed pills in the last 30-day period at the survey time points, but this appeared to decrease in number and frequency at the consecutive time points (Figure 16). Table 29 presents the reported reasons for missed PrEP doses.



	0	1 to 3	4 to 6	7 to 9	10 to 12	13 to 15	16 to 18	19 to 21	21+
3 months %	47.5%	11.3%	8.0%	1.8%	0.8%	1.0%	0.1%	0.3%	0.8%
12 months %	49.9%	13.2%	5.8%	1.3%	0.8%	0.3%	0.0%	0.5%	0.9%
24 months %	58.7%	8.0%	2.7%	0.0%	0.0%	1.3%	0.0%	0.0%	0.0%

Figure 16: Doses Missed in the last 30 Days at 3-, 12- and 24-month time points

Table 29: Reasons for Missing Pills

	3 months		12 months		24 months	
	n	%	n	%	n	%
I did not miss a dose	**770**	36.1%	**439**	34.5%	**45**	51.1%
I forgot	**465**	21.8%	**283**	22.2%	**17**	19.3%
My daily routine changed	**313**	14.7%	**217**	17.0%	**14**	15.9%
I was away from home	**269**	12.6%	**156**	12.3%	**6**	6.8%
I was too busy	**98**	4.6%	**52**	4.1%	**3**	3.4%
I was really tired	**83**	3.9%	**48**	3.8%	**1**	1.1%
Other	**71**	3.3%	**42**	3.3%	**1**	1.1%
I ran out of pills	**25**	1.2%	**20**	1.6%	**0**	0.0%
I did not want others to see me taking pills	**14**	0.7%	**7**	0.5%	**0**	0.0%
I wanted to save the pills for another time	**13**	0.6%	**2**	0.2%	**1**	1.1%
I lost my pills	**5**	0.2%	**3**	0.2%	**0**	0.0%
I had trouble getting a refill	**5**	0.2%	**2**	0.2%	**0**	0.0%
I was worried about what people would say	**0**	0.0%	**2**	0.2%	**0**	0.0%
I gave my pills away	**0**	0.0%	**0**	0.0%	**0**	0.0%
Total	**2131**		**1273**		**88**	

Intentional Pill Breaks

At 3-months, 7.6% of participants reported that they had taken an intentional break (Table 30). This significantly increased to 11.2% (*P* <0.001) at the 12-month survey time point. However, despite the majority of participants reporting between one and three intentional breaks at both three and 12 months, there was no statistically significant difference between the entry and 12-month survey time points (*P* 0.52), and there was no statistical difference in the rate of CLAI while not taking PrEP at these corresponding times [3, 4].

Table 30: Self-reported intentional breaks from PrEP at three- and 12-months survey time points

	3-month *n*	3-month %	12-month *n*	12-month %	*P* - value
Responses	1,652	68.7%	903	63%	-
Intentional break from PrEP	127	7.6%	101	11.2%	<0.001
Number of breaks from PrEP					
Less than three breaks	111	82.5%	81	80.2%	0.52
Greater than three breaks	22	17.5%	20	19.8%	
Median number of missed doses [IQR]		1 [0-2]		0.5 [0-2]	-
CLAI while not taking PrEP	23	18.1%	23	22.8%	0.38

A small percentage of participants reported stopping PrEP since their last clinical study visit. At 3 months, 10% (62/622) of the participants who completed the survey reported ceasing PrEP. Of the 324 participants completing the 12-month survey, 7.7% (25) reported ceasing PrEP. At 24 months 4.2% (1/24) reported ceasing PrEP. Reasons cited for ceasing PrEP are presented in Table 31.

Table 31: Reasons for Stopping PrEP since Last Study Visit (n, %)

	3 months		12 months		24 months	
	n	%	n	%	n	%
Not having sex	12	1.9%	8	2.5%		
Not feeling well	10	1.6%	3	0.9%		
Side-effects	5	0.8%	1	0.3%		
Worried about drug interactions	4	0.6%	1	0.3%		
Stressed/anxious	3	0.5%	2	0.6%		
Depressed	2	0.3%	2	0.6%		
Confident sex partner not HIV+	2	0.3%	1	0.3%	1	4.2%
PrEP was making me feel sick	1	0.2%	1	0.3%		
Using condoms	0	0%	1	0.3%		
Other	23	3.7%	5	1.5%		
Total respondents stopping PrEP	62	10.0%	25	7.7%	1	4.2%
Total respondents	**622**		**324**		**24**	

Dosing Preference and patterns

Participants were asked to rate their level of agreement with the statement *'I prefer to use intermittent PrEP rather than continuous daily doses'* at consecutive survey time points. At 3-months and 12-month survey, most participants (58.0%, 70.1%) disagreed or strongly disagreed with this statement (Table 32). However, at the 24-months survey there was an emerging shift towards a preference for intermittent, though caution needs to be taken interpreting this shift due to the small number of participants who had completed this item at each time point and particularly the 24-month time point.

Table 32: PrEP dosing preferences at 3, 12 and 24 months "I prefer to use intermittent PrEP rather than continuous daily doses"

	3 months		12 months		24 months	
	n	%	n	%	n	%
Strongly disagree	51	38.9%	57	53.3%		
Disagree	25	19.1%	18	16.8%	1	20.0%
Neutral	41	31.3%	20	18.7%	3	60.0%
Agree	7	5.3%	4	3.7%		
Strongly agree	7	5.3%	8	7.5%	1	20.0%
Total	131	100%	107	100%	5	100%

On exit from the study participants were asked to complete a final exit survey including an item exploring their likelihood of using on demand PrEP dosing. The majority of the 642 participants who responded to the question 'How likely is it that you will change to start taking PrEP on demand post PBS listing?' reported they would be extremely unlikely (50.9%) or unlikely (11.7%) to use on-demand PrEP following listing of PrEP on the PBS (Table 33).

Table 33: Likelihood of using 'On demand' dosing post PBS listing

	n	%
Extremely unlikely	327	50.9%
Unlikely	75	11.7%
Neutral	114	17.8%
Likely	59	9.2%
Extremely likely	67	10.4%
Total	642	100.0%

8.1.7 Reason for Exiting/Withdrawing from the study early

Case Reporting Form

Reasons for exiting or withdrawing from the study early (prior to October 1, 2018 when the approved Early Closure Plan was executed, and the transition/exit of the remaining participants commenced) were reported in the Case Report Forms and the Exit survey. Side effects such as nausea and vomiting, abdominal pain, constipation and/or diarrhoea, decreased libido, dental pain and sensitivities which resolved four weeks after ceasing PrEP, muscular aches, headaches and dizziness, peripheral neuropathy in the lower limbs, insomnia, extreme fatigue, tiredness, dreams, worsening dermatitis, paraesthesia in extremities and increased anxiety and feelings of depression; were noted on the CRF as common factors for exiting the study, consistent with side effects recorded in the first annual reporting period[1].

Other reasons for exiting from the study reported on the completed Exit CRF included: relocation interstate or overseas; monogamous relationship; not having casual sex but will return in the future if needs change; transport issues and lost to follow up. QPrEPd-X clients, were by Protocol, withdrawn due to PBS listing.

Exit Survey

All participants were able to self-report open text their reason for withdrawing from the study through the Exit survey. Some described PrEP as a mechanism for encouraging CLAI "*I felt that it was encouraging me to become more promiscuous and have unprotected sex with many people*" and *"Felt like it was my ticket to having unsafe sex*" though there were a range of other structural and personal issues described as outlined in Table 34.

Table 34: Reason for withdrawing

Reason for withdrawing		n
Reduced Risk	I was confident my sex partner was not HIV positive	22
	I was not having sex	22
	I was using condoms	7
	In a relationship now	4
Structural Barriers	I am moving away from Queensland	26
	Coming each three months was inconvenient	9
	I did not like having to get an STI test every three months	3
	Participating in this study became a burden	2
	Expense of GP appointment fee	2
Physical issues	I had side-effects from taking them	22
	I was not feeling well	16
	I thought the pills were making me feel sick	11
	My doctor advised me to stop taking PrEP	8
	I was worried about interactions with other drugs	5
Psychological Issues	I felt depressed/overwhelmed	10
	I was stressed/anxious	8
Beliefs and influence of others	My partner wanted me to stop taking PrEP	5
	Being on PrEP increased sexual risk behaviour	2
	I don't believe the drugs protect me from HIV	1
Other [#]		8

[#]Other: Visa problems; Joined the Australian Defence Force; Unable to make appointments outside of my normal working hours; Started on another PrEP trial; Distance to travel too great; Personal problems; Wasn't reminded to make an appointment; Low sperm count, Weight gain

8.2 Participant's quantitative experiences during the trial closure period and transition to PBS model of access

At their final exit clinical visit post the October 1 2018 commencement of study closure proceedings, all active enrolled participants were asked if they were willing to be contacted by a member of the UQ M&E team for post study follow up monitoring and evaluation purposes. This was to take the form of an interview with up to 20 participants exploring their experience of exiting the study and transitioning to PrEP access under the PBS model.

In response to the overwhelming number of exiting participants who provided informed consent to be contacted (646, 50.9% of the 1270 still actively enrolled on 1 October 2018), ethical approval was sought to add dissemination of an additional voluntary on-line follow-up survey to examine PrEP practices and access experiences in the 6-month period post cessation of the study. A small sub-set of the follow-up survey participants were purposively selected by age, location and PrEP use to be interviewed to explore their experiences in more depth.

This following section presents the results of the 265 completed follow-up surveys (41.0% response rate) with supporting findings from the thematic analysis of the interviews and free text survey items.

8.2.1 Demographics

Of the 265 follow-up survey responses, 249 (94.0%) reported having taken PrEP in the 6-months post study closure. Eleven (4.4%) of those reported they had taken PrEP after closure but they were no longer taking PrEP. Therefore, at the time of the follow-up survey post study closure, 89.8% of participants were currently using PrEP.

Patient demographics were stratified by PrEP use post study to assess for differences between those who continued to take PrEP and those who had ceased. Caution should be taken in interpreting differences due to the small number of patients who reported ceasing PrEP. Overall 10.2% (27) of survey responders reported cessation of PrEP within the 6-month period following QPrEPd closure.

Age

Table 35 details PrEP use by age group at follow-up. Statistical analysis suggests the proportion of those who ceased PrEP post closure was greater for those under 30 years old than those 30 years old and older (χ^2= 12.28, p<0.001).

Table 35: Age group by use of PrEP since QPrEPd closure

Age group	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
Years	n	%	N	%	n	%	n	%
18-19	1	6.3%	1	9.1%	1	0.4%	3	1.1%
20-29	5	31.3%	5	45.5%	38	16.0%	48	18.1%
30-39	4	25.0%	0	0.0%	69	29.0%	73	27.5%
40-49	2	12.5%	2	18.2%	55	23.1%	59	22.3%
50-59	3	18.8%	3	27.3%	56	23.5%	62	23.4%
60-69	1	6.3%	0	0.0%	15	6.3%	16	6.0%
70+	0	0.0%	0	0.0%	4	1.7%	4	1.5%
Total	**16**	**100%**	**11**	**100%**	**238**	**100.0%**	**265**	**100%**

Gender and sexual identity

Table 36 shows the self-reported gender identity of respondents by PrEP usage. The majority of respondents (96.2%) identified as cis male and were current PrEP users at the time of the follow-up survey. The number of respondents not identifying as male are too small to identify a pattern of continued PrEP usage.

Table 36: Self-reported gender identity by use of PrEP since QPrEPd closure

Self-reported gender identity	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
Male	15	5.9%	8	3.1%	232	91.0%	**255**	**96.2%**
Transgender man	0	0.0%	0	0.0%	1	100%	**1**	**0.4%**
Male/Genderqueer/Gender Fluid	0	0.0%	1	100%	1	100%	**2**	**0.8%**
Transgender woman	0	0.0%	1	50.0%	1	50.0%	**2**	**0.8%**
Prefer not to say	0	0.0%	1	100%	0	0.0%	**1**	**0.4%**
No response	1	25.0%	0	0.0%	3	75.0%	**4**	**1.5%**
Total	**16**	**6.0%**	**11**	**4.2%**	**238**	**89.8%**	**265**	**100%**

In total, 224 (84.5%) respondents self-reported their sexual identity as ‘gay’; and 27 (10.2%) identified as bisexual (Table 37). As with self-reported gender identity, the number of respondents identifying as bisexual or other are too small to identify a pattern of continued PrEP usage.

Table 37: Self-reported sexual identity by use of PrEP since QPrEPd closure

Self-reported sexual identity	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
Gay	13	5.8%	8	3.5%	204	91.1%	225	84.9%
Bisexual	1	3.7%	1	3.7%	25	92.6%	27	10.2%
No response	2	15.4%	2	15.4%	9	69.2%	13	4.9%
Total	**16**	**6.0%**	**11**	**4.2%**	**238**	**89.8%**	**265**	**100%**

Postcode and location ARIA

Most respondents (82.7%) resided in major cities in Queensland. Numbers are small, nonetheless, these data are suggestive that those living outside of major cities were more likely to have ceased taking PrEP following the closure of QPrEPd (Table 38).

The majority of respondents (87.9%) lived in SE Queensland. A greater proportion of respondents living in regional Queensland (18.5%) were no longer using PrEP compared to those living in SE Queensland (11.3%) (Table 39).

Table 38: Accessibility and Remoteness Index of Australia (ARIA) by use of PrEP since QPrEPd closure

ARIA	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
Major Cities of Australia	11	5.1%	8	3.7%	196	91.2%	**215**	**82.7%**
Inner Regional Australia	2	11.8%	1	5.9%	14	82.3%	**17**	**6.5%**
Outer Regional Australia	2	7.1%	2	7.1%	24	85.7%	**28**	**10.8%**
Total	**15**	**5.8%**	**11**	**4.2%**	**234**	**90.0%**	**260**	**100%**

Table 39: South East Queensland residence by use of PrEP since QPrEPd closure

Area of residence	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
South East Queensland	12	5.1%	10	4.3%	211	90.6%	**233**	**87.9%**
Regional Queensland	4	12.5%	1	3.1%	27	84.4%	**32**	**12.1%**
Total	**16**	**6.0%**	**11**	**4.1%**	**238**	**89.8%**	**265**	**100%**

Aboriginal and Torres Strait Islander People

Only three (1.1%, 3/265) of the six month follow-up survey respondents identified as Aboriginal (n=1) or Aboriginal and Torres Strait Islander (n=2). All were enrolled in a community GP located in SEQ with two living in a major city (n=2), and one in an inner regional are of SEQ (n=1) (Table 40).

Table 40: Aboriginal and Torres Strait Islander People by Area of Residence

	Aboriginal		Aboriginal and Torres Strait Islander		Non-Indigenous		Aboriginal status missing		Total	
SEQ	1		2		226		4	100%	233	87.9%
Regional	0	0	0	0	32	100%	0	0	32	12.1%
Total	**1**	**0.4%**	**2**	**0.8%**	**258**	**97.3%**	**4**	**1.5%**	**265**	**100%**

Of the three Indigenous people who reported taking PrEP post trial, two were still taking PrEP at the six months' time point when surveyed.

One participant had ceased PrEP during the six month follow-up period stating;

> *"I am in a monogamous relationship and always use condoms. Though if that changes (if the relationship should end, or if we open it up, for example) then I would go back on it to keep myself safe."*

Participants born overseas

Consistent with the total QPrEPd sample profile, the majority of participants were born in Australia and a quarter (24.2%, 64) were born overseas (Table 41). These data suggest that equal proportions of Australian born participants (10.4%, 21/201) and those born overseas (9.4%, 6/64) were no longer taking PrEP at the six month follow-up.

Table 41: Self-reported region of birth by use of PrEP since QPrEPd closure

Region of birth	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
Australia	11	5.5%	10	5.0%	180	89.6%	201	100%
Western and Central Europe (including UK)	1	4.0%	1	4.0%	23	92.0%	25	100%
New Zealand	1	10.0%	0	0.0%	9	90.0%	10	100%
East Asia	0	0.0%	0	0.0%	6	100.0%	6	100%
North America	0	0.0%	0	0.0%	6	100.0%	6	100%
Latin America and the Caribbean	0	0.0%	0	0.0%	4	100.0%	4	100%
South East Asia	1	25.0%	0	0.0%	3	75.0%	4	100%
South Asia	0	0.0%	0	0.0%	2	100.0%	2	100%
Africa	0	0.0%	0	0.0%	2	100.0%	2	100%
Eastern Europe and Central Asia	1	100.0%	0	0.0%	0	0.0%	1	100%
Missing	1	25.0%	0	0.0%	3	75.0%	4	100%
Grand Total	**16**	**6.0%**	**11**	**4.2%**	**238**	**89.8%**	**265**	**100%**

Medicare card status

The majority of participants who completed the post closure survey who had a Medicare card of any form (green, yellow or blue) continued to use PrEP post closure (90.2%, 231/256) (Table 42). Of those who had no Medicare Card, 20% (1/5) ceased taking by six months compared to 9.8% (25/256) of those with a Medicare card

Table 42: Medicare care status by use of PrEP since QPrEPd closure

Medicare Card Status	Ceased at closure		Continued post closure but ceased by 6 months		Continued post closure i.e. Current users		Total	
	n	%	n	%	n	%	n	%
No Medicare card	1	20.0%	0	0.0%	4	80.0%	5	1.9%
Medicare card Green	13	5.1%	11	4.3%	229	90.5%	253	95.5%
Yellow	1	100.0%	0	0.0%	0	0.0%	1	0.4%
Blue	0	0.0%	0	0.0%	2	100.0%	2	0.8%
Missing	1	25.0%	0	0.0%	3	75.0%	4	1.5%
Total	16	6.0%	11	4.2%	238	89.8%	265	100%

[#]Green Medicare Card (Australian Residents); [##]Blue Medicare Card (Interim); [###]Yellow Medicare Card (Reciprocal Health Care Agreement visitors)

8.2.2 PrEP access following closure

Following the closure of QPrEPd, 75.1% (187/249) of participants who accessed PrEP did so from their previous Study Site; 24.9% (62) tried to get prescriptions from places other than their QPrEPd Study Site.

Table 43 details the reasons people chose to stay at their previous Study Site. A considerable majority identified the knowledge and attitude of the staff as reasons to stay at the service, 84.4% and 72.3% respectively. Other reasons provided for staying at the same service included; comprehensive STI screening, bulkbilling and continuity of care.

Table 43: Reasons for accessing the same service provider

	n	%	% of Cases
Knowledgeable staff	146	37.2%	84.4%
Non-judgemental staff	125	31.8%	72.3%
Convenient location	78	19.8%	45.1%
Don't want to discuss PrEP with regular GP/primary care provider	44	11.2%	25.4%
Total	**393**	**100.0%**	**227.2%**

* Multiple responses allowed

Respondents cited the time required to travel to their study site (41.0%) as the most common reason for changing service provider following the closure of QPrEPd (Table 44).

Table 44: Reasons for accessing a different service provider

Reason	n	%	% of Cases
Previous service too time consuming to travel to	16	35.6%	41.0%
Medicare gap payment / Out-of-pocket expense too high	9	20.0%	23.1%
Wanted full STI testing at each PrEP appointment, including rectal, oral and urine tests for chlamydia and gonorrhoea	8	17.8%	20.5%
Poor appointment availability and/or times	7	15.6%	17.9%
Previous service too expensive to travel to	3	6.7%	7.7%
Other negative experience at previous service	2	4.4%	5.1%
Total	**45**	**100%**	**115.4%**

* Multiple responses allowed

Cost of accessing services, regarding out-of-pocket expenses (23.1%) and travel charges (7.7%) were also cited as reasons for changing service. Of note were the 20.5% (8) of respondents who changed service because they wanted full STI testing at each PrEP appointment.

Other responses as to why they accessed a prescription from a different service included: interstate relocation; to keep all care with one Dr (i.e. GP); convenience of GP location; closer proximity to place of residence; concerns with the lack of confidentiality with associated phlebotomy service.

Peoples experience at the new services ranged from good…

"I have a great relationship with my GP, who is also gay…"

"Fortunately, my GP is free thinking and had already researched PrEP after my mentioning it at an earlier appointment."

To not so good:

"Nowhere near as knowledgeable or approachable about the subject. I asked for a script for PrEP and he had to google what it was."

"…did not ask any of the questions or offer any of the screening tests that the sexual health clinic would ask/offer"

"One campus refused to prescribe PrEP because they felt as though they didn't know enough to safely prescribe it."

Over half of the respondents (53.4%) accessed a service provider that charged no consultation fee (Table 45). The identified out of pocket cost for consultations ranged between $6.50 and $120, and median cost was in the $40-$49.99 price range. However, it should be noted that ascertaining the out of pocket cost to the individual for consultations to obtain a prescription was difficult as there were suspected data discrepancies in how people reported expenses, i.e. with and without the Medicare rebate (Table 46).

Table 45: Medical appointment fee to obtain most recent PrEP prescription

	n	%
No cost: Bulk billing GP	52	20.9%
No cost: Sexual Health Clinic	81	32.5%
Fee charged	116	46.6%
Total	249	100%

Table 46: Out of pocket expense paid for medical appointment to obtain most recent PrEP prescription

Appointment cost AUD$	n	%
<$10	1	0.9%
10-19.99	1	0.9%
20-29.99	2	1.8%
30-39.99	32	29.4%
40-49.99	40	36.7%
50-59.99	10	9.2%
60-69.99	3	2.8%
70-79.99	9	8.3%
$80+	11	10.1%
Total	109	100%

Experiences getting a PrEP prescription written

The majority (96.8%, 241/249) of participants reported no difficulties in getting PrEP prescribed. Those that had experienced difficulties reported GPs lack of knowledge about PrEP (5), incorrect prescription written (1), and poor availability of appointments (2).

Most participants (73.1%) reported the last prescription they acquired following the closure of QPrEPd was from the 'study site' service they were enrolled at during QPrEPd (Table 47). This is not an unexpected result. Many participants were enrolled at a public sexual health clinic or S100 GP study site where they had already been a registered for more than one year as a client/customer prior to screening for QPrEPd[(1)].

A small number (33, 13%) reported that they had transferred care from their study site back to their regular GP, now that GPs are able to prescribe PrEP, and nearly 1 in 10 participants (9.2%) reported transferring care to a service they had not used before QPrEPd.

Eleven (4.4%) reported not having accessed a service to obtain a PrEP prescription following the closure of QPrEPd. Table 47 details the breakdown of services accessed by former study site and type of service provider.

Table 47: Current location where prescription is written

	n	%
I go to a sexual health clinic that was my study site	103	41.4%
I go to a general practice that was my study site	79	31.7%
I go to a general practice that was my regular GP before the study	33	13.3%
I go to a general practice that was not my study site	14	5.6%
I go to a sexual health clinic that was not my study site	9	3.6%
I am not currently taking PrEP	11	4.4%
Total	**249**	**100%**

Experiences getting PrEP prescriptions dispensed

The majority of respondents (86.6%) went to local community pharmacies to get their PrEP prescription dispensed. A significant number of respondents had imported PrEP from overseas via an online pharmacy (17.9%) (Table 48).

Accessing PrEP via an overseas online pharmacy is usually cheaper than payment of a dispensing fee in Australia and also has the advantage of three months of PrEP being dispensed at one time. Australian pharmacies generally will only dispense one month's supply at a time, unless specified by the prescribing physician, requiring PrEP users to visit the pharmacy every month.

However, importation does require a degree of planning to allow time for the postage of the medication.

Table 48: Types of pharmacies used to get your PrEP prescriptions dispensed / filled since the end of the study

	n	%	% of Cases
Local community pharmacy (e.g. Chemist Warehouse)	213	71.2%	86.6%
Importing PrEP from overseas via an on-line pharmacy	44	14.7%	17.9%
Sexual health clinic pharmacy	25	8.4%	10.2%
Local public hospital pharmacy	14	4.7%	5.7%
Buying PrEP from an Australian on-line pharmacy	3	1.0%	1.2%
Total	**299**	**100%**	**121.5%**

* Multiple responses allowed

Approximately 1 in 5 (21.7%) respondents reported difficulties getting their PrEP prescription dispensed / filled. The majority (49/54, 90.7%) reported issues with a lack of PrEP stock held by pharmacies, either because the pharmacy did not stock it or had run out of stock, requiring PrEP to be ordered in.

The majority of the reports of difficulties originated from participants residing in a major city (35/49, 71.4%) and in SEQ (40/49, 81.6%). However, the proportion of reports of difficulties were higher among those living in the inner (29.4%) and outer regional areas (32.1%) compared to those residing in major cities (16.3%) (Table 49).

Table 49 Accessibility and Remoteness Index of Australia (ARIA) by difficulties getting a PrEP prescription dispensed / filled

ABS ARIA Regions	Reported Difficulties n	Post Survey (Total) n	Post Survey (Total) %	Continued Post Closure i.e. Current Users n	Continued Post Closure i.e. Current Users %
Major Cities	**35**	215	16.3%	196	17.9%
Inner Regional	**5**	17	29.4%	14	35.7%
Outer Regional	**9**	28	32.1%	24	37.5%
Total	**49**				

Some participants reported having to wait for the pharmacy to order PrEP stock in (up to 7 days) while other participants described approaching another pharmacy, in some case several. For those who approached another pharmacy, it was not clear from the responses if participants were aware a pharmacy could order stock in, or if the service was not offered by the pharmacy and the participants were directed elsewhere.

"Not enough pharmacies will dispense, especially in [regional town name]."

"They didn't know what it [PrEP] was, they didn't keep it in stock, they were unaware of the community it was for, it was expensive for them to keep, they held you to coming and getting the script filled since it was expensive. They seem to have a handle on it now though since they understand, recognise the importance of it and the demand has increased that they now keep it in stock."

Participants also discussed the issue of only being able to collect one month of medication at a time.

"I once wanted all three bottles (I was about to travel) and the pharmacy did not have enough."

"Cannot collect full 3 months. Must return every 30 days to collect repeats."

Two participants raised issues of stigma including;

"…at one chemist I believe active discrimination by the dispensing chemist given the nature of the medication. And living in a rural area."

Cost of most recent PrEP prescription

A wide range of dispensing fees / prescription costs were reported by 248 participants, ranging from $0 to $190. The average cost of a prescription for one month of PrEP was $42.98.

Current Dosing Regimes

The majority of respondents continuing to take PrEP did so on a daily basis (92.4%, 220) as opposed to on demand or event driven dosing (7.6%, 18). As illustrated in Table 50, of those taking PrEP as a 'daily dose', adherence of 6 to 7 days per week is achieved by 94.5% (208/220) of respondents.

Table 50: Current PrEP dosing regimen

PrEP dosing regimen	n	%
Daily dosing - Usually 6 to 7 days per week	208	87.4%
Daily dosing - Usually 4 to 5 days per week	10	4.2%
Daily dosing - Usually less than 4 days per week	2	0.8%
On demand / event driven (potential HIV exposure happens irregularly or for short periods of time e.g. during travel)	18	7.6%
Total	238	100%

STI diagnosis following closure among PrEP users

Of respondents currently taking PrEP, 28.2% reported having an STI diagnosed since the closure of QPrEPd (Table 51) with 67 participants being diagnosed with 87 cases of STI. Chlamydia and gonorrhoea were the most commonly reported STI with chlamydia being diagnosed in 38 (58.5%) respondents who had an STI detected, and the same number of respondents being diagnosed with gonorrhoea (Table 52).

Table 51: Diagnosis of STI by participants who have taken PrEP since the QPrEPd study closure

	n	%
No	171	71.8%
Yes	67	28.2%
Total	**249**	**100%**

Table 52: STI diagnosed in participants who have taken PrEP since the QPrEPd study closure

STI diagnosed	n	%	% of cases
Chlamydia	38	43.7%	58.5%
Gonorrhoea	38	43.7%	58.5%
Syphilis	6	6.9%	9.2%
Mycoplasma genitalium	1	1.1%	1.5%
Herpes simplex virus	3	3.4%	4.6%
Human papilloma virus	1	1.1%	1.5%
Total	**87**	**100%**	**133.8%**

* Multiple responses allowed

These diagnoses indicate an incidence of 15.3% (38/249) for both chlamydia and gonorrhoea in the cohort of current PrEP users. Six (9.2%) of the respondents had been diagnosed with an STI were diagnosed with syphilis. The post closure incidence has been calculated based on self-reported STI diagnosis, however, it is worth noting that it is higher than the incidence of laboratory notified chlamydia and gonorrhoea at any of the 3-monthly study screening visits (Figure 17).

Direct comparison between study and post-study incidence is cautioned due to the difference in time intervals of reporting periods (3-monthly during the study period and six months for the post study period). Potential for bias of the population responding to the post study follow-up survey also needs consideration.

It should be noted that on the CRF an STI diagnosis was reported only as a positive or negative result. This limited the ability to report on STI diagnosis in more detail including syphilis stages, tests conducted, sensitivity test results and other relevant clinical information such as treatment regimens.

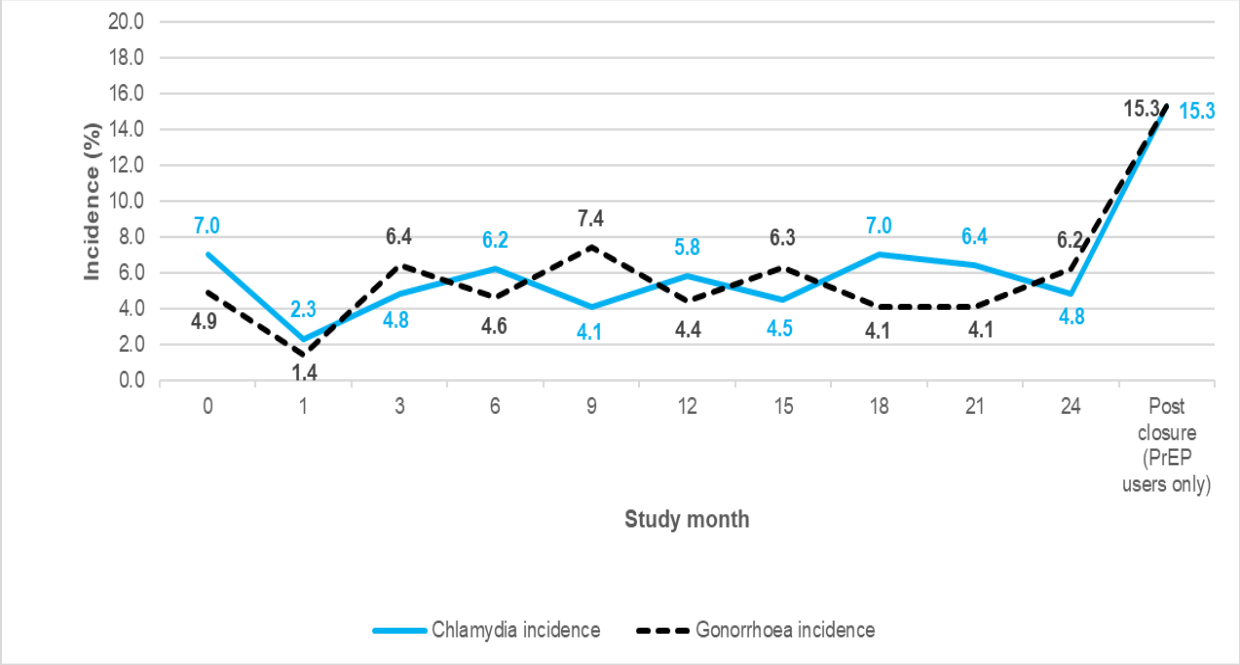


Figure 17: Chlamydia and N. gonorrhoea incidence at study screening visits (laboratory notified) and post QPrEPd closure (self-reported)

8.2.3 Participants not currently taking PrEP

Half of the respondents (13/27) who had ceased PrEP since the end of QPrEPd did so because they had entered a monogamous relationship with an HIV negative partner (Table 53).

Not being sexually active was reported by 30.8% (8) of respondents no longer using PrEP. Almost one quarter (6, 23.1%) of respondents were concerned about the long-term side effects of taking PrEP. Structural barriers (appointment times, transport difficulties) and financial barriers (cost of medication and doctor appointments) were other reasons cited for PrEP cessation.

Other reasons for ceasing PrEP included;

"Can't be bothered with the hassle."

"After a recent injury I needed to have surgery and was told by the hospital to stop taking PrEP for the moment (until after the operation and healing) as PrEP can increase the risk of blood clots and as there were other risk factors also it was good to reduce the risk."

"I don't trust other people who say they are taking it but can't prove it."

Table 53: Reasons for stopping PrEP (Participants = 27)*

	n	%
Reduced Risk		
I am in a monogamous relationship; my partner is HIV negative	13	50.0%
I am not sexually active at the moment	8	30.8%
I have decreased the number of my sexual partners	4	15.4%
I always have sex with a condom	3	11.5%
I feel I am not at risk of HIV	2	7.7%
I have reduced my alcohol/drug use	1	3.8%
Structural Barriers		
I found it difficult to find the time attend regular Dr appointments	4	15.4%
I cannot afford the regular prescription cost	4	15.4%
I cannot afford regular Dr consultation fees	4	15.4%
I found transportation difficult to attend regular Dr appointments	1	3.8%
Physical issues		
I am worried about the long-term effects of taking PrEP	6	23.1%
Beliefs and influence of others		
My partner does not like me taking PrEP	1	3.8%
Total	**51**	**%**

* Multiple responses allowed

STI and HIV testing and diagnosis among non-users

Of the respondents no longer using PrEP, 40.7% (11) had not tested for HIV since the study closure and 37.0% (10) had not tested for STI since the study closure (Table 54). Only one third of respondents had been tested for STI including HIV within the last 3-months.

Table 54: Time period since last STI and HIV testing of participants not currently taking PrEP

	HIV test		STI tests	
	n	%	n	%
within the last 3 months	9	33.3%	9	33.3%
4 to 6 months ago	7	25.9%	8	29.6%
Not tested since QPrEPd closure	11	40.7%	10	37.0%
Total	**27**	**100%**	**27**	**100%**

Just over one in five (22.2%, 6) of those no longer taking PrEP reported being diagnosed with an STI following the closure of QPrEPd (Table 55). Respondents reported diagnoses of chlamydia (3), gonorrhoea (2) and mycoplasma genitalium (1) (Table 56).

Table 55: Diagnosis of STI by participants currently not taking PrEP

	n	%
No	11	40.7%
Yes	6	22.2%
No response	10	37.0%
Total	**27**	**100%**

Table 56: STI diagnosed by participants currently not taking PrEP

	n	%
Chlamydia	3	50.0%
Gonorrhoea	2	33.3%
Mycoplasma genitalium	1	16.7%
Total	**6**	**100%**

Condomless vaginal and/or anal sex, with at least one partner, when not taking PrEP was reported by 63.0% (17/27) of respondents (Table 57).

Table 57: Number of partners participants not currently taking PrEP have had condomless vaginal and/or anal sex with when not taking PrEP

	n	%
None	10	37.0%
1	13	48.1%
2 to 5	4	14.8%
Total	**27**	**100%**

Likelihood of recommencing PrEP among non-users

Likelihood of recommencing PrEP was skewed towards 'extremely likely' with 63.0% of respondents scoring between 6 to 10 on a 0 to 10 Likert scale (Table 58). Those most likely to recommence PrEP, scoring 9 or 10, reported their confidence in the safety of the medication and the protection it provides from HIV acquisition, especially for those who prefer CLAI or have multiple partners. Respondents scoring 6 to 8 felt that due to the nature of their monogamous relationship they did not require PrEP now but could in the future should the relationship change.

Cost also factored as a reason why respondents may not recommence PrEP. Those scoring 3 to 5, whilst also discussing issues of cost and monogamy, referred to the issues of access in regional areas. Cost and monogamous relationships were the reasons cited by those scoring 0 to 2.

Table 58: On a scale of 0 to 10, how likely are you to recommence PrEP in the future?

	n	%	Cumulative %
Not at all likely 0	1	3.7%	3.7%
1	0	0.0%	3.7%
2	2	7.4%	11.1%
3	0	0.0%	11.1%
4	0	0.0%	11.1%
5	7	25.9%	37.0%
6	1	3.7%	40.7%
7	1	3.7%	44.4%
8	4	14.8%	59.3%
9	3	11.1%	70.4%
Extremely likely 10	8	29.6%	100%
Total	**27**	**100%**	

8.2.4 Attitudes towards addition of PrEP to the PBS

Participants were asked if they thought the addition of PrEP in the Pharmaceutical Benefit Scheme has resulted in more people accessing PrEP (Table 59). The majority (55.1%) believed PrEP use had increased due to the PBS listing, 36.9% were unsure, and only 8.0% thought that PBS listing had not increased PrEP use.

Table 59: Participants view that PrEP use by people at risk of HIV has increased due to the availability of PrEP on the Pharmaceutical Benefits Scheme (PBS)

	n	%
No	21	8.0%
Unsure	97	36.9%
Yes	145	55.1%
Total	263	100%

Whilst the subsidising of PrEP has reduced the cost of medication for users to a maximum of $40 per month, many noted that the reduced PrEP cost was still beyond the means of some and that accessing it via community or public hospital pharmacies in Australia remains more expensive than acquiring PrEP through the trial.

Structural barriers of stigma, pharmacy availability and cost were cited as reasons respondents thought PrEP use would not increase. Less than half of respondents (44.1%) thought the ability of all doctors to prescribe PrEP would increase PrEP use, and most (46.0%) were unsure (Table 60).

Some respondents were optimistic that all doctors being able to prescribe PrEP would increase accessibility to PrEP, especially for those living long distances from sexual health services. However, there was a strong feeling that GPs knowledge of PrEP was insufficient, with many GPs not knowing that they could, or even how to prescribe PrEP.

Table 60: Participants view that PrEP use by people at risk of HIV has increased due to any medical doctor being able to prescribe PrEP on the Pharmaceutical Benefits Scheme (PBS)

	n	%
No	26	9.9%
Unsure	121	46.0%
Yes	116	44.1%
Total	263	100%

Among the people who perceived or considered PrEP use had increased, a number also commented on having observed increased condomless sex, with many people listing ‘PrEP user’ in their profile on dating apps. Respondents felt promotion of PrEP was insufficient, *“community and the government has not done enough to help promote* [PrEP]”. One person reported going to a dentist who thought the respondent was HIV positive because they were taking PrEP.

There was also a perception of stigma toward LGBTIQ+ people and their sexual health needs by some GPs. Some respondents spoke of GPs declining to prescribe PrEP based on religious beliefs, or cautioning against the use of PrEP in favour of safe sex practices. Equally, respondents spoke of a reticence to disclose risk factors to GPs.

8.2.5 Comments about the QPrEPd study and potential future concerns

The positive mental impact of PrEP availability was evident through the free text survey response as illustrated in the following quotes;

> *"It's changed my life. I am so grateful to you guys for this. Growing up in the era of AIDS deaths scared the hell out of me. I never thought I'd be confident to enjoy sex again."*
> *(40-44 year old man)*

There was also an overwhelming feeling of positivity towards PrEP among the free text survey responses and thanks for the provision of free PrEP through the QPrEPd trial:

> *"The QPrEP trial was an amazing implementation of research that will likely be one of the strongest steps towards eradicating HIV in Australia."*

> *"Thank you, thank you, thank you! You guys have me my confidence back!"*

A number of people, however, described being personally disappointed by the early closure of the trial. In addition, it was suggested that a longer trial period may have allowed for more cautious slower adopters to commence PrEP with greater confidence due to the rigour of the trial. A number of responses suggest STI testing is less comprehensive and less frequent than during the trial period, with some observing an increase in CLAI in themselves and others.

> *"Many people have used the opportunity (including myself) to try sex for the first time without a condom. My age and demographic meant that was something I'd never considered due to the high risk of being infected with HIV as a gay man."*

Participants were keen to be kept informed of the outcome of the trial, though several participants were not aware of the available material such as the First Annual Report already disseminated and made publically accessible on the ComePrEP website. Finally, participants commented that now a payment for PrEP is required, they take medication less frequently to 'stretch out' their supply.

8.3 Participant's qualitative experiences of the closure and transition to PBS model of access

Based on the interviews with the HCP and the quantitative results of this study that suggested those living outside of major cities were more likely to have ceased taking PrEP following the closure of QPrEPd, a decision was made to concentrate the participant interviews in regional areas.

Thirteen interviews were conducted with participants living in five outer regional locations who were accessing PrEP from different models of PrEP provision including public SHS and S100 GP study sites and other non-S100 GP settings.

All interviewed were cis males; 11 gay identifying and two bisexual, aged between 20 to 60 years (mean 41.5 years). Most were still taking PrEP daily. Some were using alternate dosing regimens, or had ceased PrEP at some point between QPrEPd closure and the interview.

8.3.1 QPrEPd experience

On the whole the participants interviewed consider QPrEPd to have achieved its goal of increasing access to PrEP for people at risk of HIV across the State, reducing new diagnoses of HIV and increasing STI testing rates in general. For some it was the start of their sexual health learning as described by one 24 year old regional gay man: *'[I] just literally had no idea about anything until the study*'. There was consensus that QPrEPd had provided a platform to increase HIV and general sexual health knowledge among people who may not have previously had the opportunity to have access to sexuality education and/or appropriate STI testing.

> *'it's [PrEP] starting to become a culture. And even though the trial was shortened, it is, it had started to condition people and get them, it got them into, like getting tested regularly and into that routine' [Regional 52yr old gay man]*

> *'I feel like I've been lucky to… well, this trial and then what this trial's achieved. I think it's been good in reducing new exposures but it's also been a great educational tool in getting some conversations on the table regarding good sexual health.' [Regional 33yr gay man]*

8.3.2 Experiences and perspectives of the early closure

Feelings concerning the early closure were mixed. Some were not surprised when they were informed about the closure as they considered this an obvious step following the 1 April PBS listing.

> *'Don't think I was really surprised. I was just really glad that it was obviously going to go onto the PBS and that access was still going to be there I didn't really have any feelings, both positive or negative. I guess the slight negative was; although it's on the PBS I do have to pay for it. Whereas the study, I had it completely free. But you know, I didn't really have any feelings, I thought it was a good thing and I thought yahoo, it's obviously a hurdle that's been won and jumped and it's now on the PBS. So the study has done what it was there to do'. [Regional 40yr old gay man]*

There was however a general sense of disappointment that the study had been ceased before the full four year period. A few who considered they had been consented and agreed to participate for the full 4-year duration of the study also expressed anger describing the closure as a broken promise.

> *'To have that ripped away from you halfway through, it's sort of like, well hang on a second, why doesn't the study continue even though, yes it's been approved, the tests should have kept going for the full four years…..We were told we were signing on for*

four years and that should have stayed, but obviously that's not our decision'.
[Regional 31yr old gay man]

Many interviewed did not personally consider they had a financial barrier to paying the PBS dispensing fee, however to some this was their initial concern on hearing about the closure. Concern was also expressed for people who may have to make decision to stop using PrEP based on their financial situation and Medicare card status.

'Personally, can I afford it? Yes. I was affording it beforehand…..But I certainly felt for those that can't….that might change the whole scope for a whole lot of people'.
[Regional 50yr old gay man]

'For some participants they might have stopped using it and because it's now costing forty bucks a month if they're taking it daily. So, it could result in a drop in participation'.
[Regional 52yr old gay man]

Others initially were concerned about the need to access GP and local pharmacies without preparation and thought this might also influence people's choices to stop using PrEP.

'I wouldn't be at all surprised if a lot of guys had gone off PrEP because of it, because they don't want to go and tell their GP. They don't want to go to their local chemist …I think if it don't continue well then, that's when a lot of people will probably go off it and they you see the spread of the disease start up again you know'. [58yr old bisexual man]

To many, QPrEPd attracted the 'out' gay and bisexual men who were aware of their HIV risk and had the health literacy and resources to seek out PrEP from one of the study sites. There was however concern that the study had stopped before PrEP had reached more marginalised hidden populations at risk, with particular concern expressed about the knowledge, awareness and uptake among non-gay identifying, and/ or married MSM, and Aboriginal and Torres Strait Islander peoples:

'I believe you got a saturation in the core target market, target area, in some of the fringe ones, some of the Bi's some of the not out people, they would have missed out'.
[Regional 52yr old gay man]

'impact on those that may be a little vulnerable; maybe those that aren't aware that there still is a plan in place for them to be able to get access…..psychologically it might just cut them off'. [Regional 50yr old gay man]

'bi-males that are married that don't seem to know about [PrEP……they have no idea…..No and you say 'PrEP' and they have no idea what you're talking about… …this is probably a third or a quarter of the gay people in [Town name]'.
[Regional 60yr gay man]

One of the participants, while accepting of the rationale for closure provided to him by his study site HCP, expressed concern about the waste of study medication. This was raised by a small number of the participants and is echoed on the HCP provider interviews presented in Section 8.4 of this report.

'I believe that they had a lot left over for the, from the trial and it was destroyed, rather than sent overseas or something to, someone could have used it……; I hope it gets sent somewhere where they can benefit from it….. If not give it to the participants to use, you know, but I'd hate to see it go to waste and not be, you know, utilised'.
[Regional 52yr old gay man]

8.3.3 Accessing PrEP prescriptions and STI screening post study closure

The majority of the participants interviewed had experienced very few issues with accessing PrEP prescriptions post study closure as they had chosen to stay at their study site. Most, particularly those accessing PrEP through an S100 GP study site, had experienced very little change in their clinical pathway.

'I'm just continuing on basically under the, I was doing the quarterly reviews and running basically in line with what the study was doing anyway'. [52yr old gay man]

'The only difference is I walk out with a… I walk out with a script. Perfectly happy with the service here'. [50yr old gay man]

A few attending the public SHS service commented that they were seeing the doctor more frequently now compared to when in the study, but on the whole *'it was business as usual'*. Public SHS were seen to be flexible and while some commented on the time they have to wait to be seen, the convenience, no fee for service and the expertise: '*they're the experts on the, on anything, you know, sexual, and with the health';* and non-judgemental nature of the staff were seen as good reasons to stay and not change to another location or local GP service.

'But if the majority of the traffic coming through here has got a bit more flexibility with how they…because I think some of the biggest deterrents for this place was something the amount of time that people would have to sit because you had your initial triage. Then you were seen by the nurse. Then you had to go and then you had to be seen by the doctor. It could be quite a lengthy afternoon particularly'.
[Regional 33yr gay man]

'I've just stayed going there, I think it's easy, it's convenient. I don't feel like you're going to bump into someone there, because I still think there's some sensitivity around the whole – what are you doing here. So yes, I don't know, yes I just keep going to the clinic, I like it in there and it's just easy. You don't need to go in there and tiptoe around a particular conversation. You can go in there and say how it is. If you've got a sore here or you want to talk about this, you can just say it how it is and I think that's good'.
[Regional 40yr old gay man]

For many of the former public SHS study site QPrEPd participants, the cost and the need to explain what PrEP was along with past experiences of inadequate STI testing were deterrents to changing to a GP or returning to their regular GP.

'I pay to see the GP …. It's not Medicare, so I'm not going there every three months… if push came to shove, I wouldn't have a problem approaching that service about the drug, yeah. It was $110 and then you get back…you end up paying $38 or something at the end of the day. It's not huge, but it's every three months, that's going to start adding up'.
[Regional 33yr gay man]

A few of the interviewees had considered returning to their regular GP 'as this was more convenient and closer to home' but for some this was 'daunting' as they were not 'out' to the GP and or had not disclosed their PrEP use.

'No I was; it was probably a little bit daunting to start with because my GP doesn't know that I'm on PrEP or anything like that, which I probably should tell him…'
[Regional 58yr old bisexual man]

Many of the interviewees did not have a regular GP, describing how they generally just attended any local 'large' bulk billing GP services if medical care was needed. However, their past experiences of seeing a different doctor each visit, long waiting hours, not getting adequate STI testing, needing multiple appointments and having to potentially explain their behaviour, and/ or what PrEP was and what tests were needed each time, together made this a non-viable option for accessing their PrEP prescriptions:

'bulk billing GPs here if you're prepared to sit around for eight hours and wait…just not a pleasant experience and lots of waiting around, yeah'. [Regional 33yr gay man]

'They don't do the anal swabs or anything like that, it's mainly done on blood tests and urine samples… and it takes longer because it's a bulk billing doctors surgery. It's sort of, yes we'll get to it when we've got time. Whereas here [study site name], it's a specialised area, they put it in and they sort of fast track the results through. If there's any problems you get a text message, either your results are clear or you need to come in and see us. Whereas the doctor; you've got to go and get the test and you've got to rebook another appointment, go in and get the results'.
[Regional 31yr old gay man]

8.3.4 PrEP dosing and adherence post study

Daily dosing remained the most common dosing regimen among the interview participants, consistent with the post closure survey findings. To many, daily PrEP reduced their anxiety knowing they were covered and didn't have to worry, use condoms, or not have sex if the opportunity presented itself:

'I know that you can change the dosage because it's a seven-day uptake, but for me, I just take it daily because then I know I don't have to worry about it'.
[Regional 34yr old gay man]

Cost

Having to now pay for PrEP, even for those with a health care card, was raised by many of the ex-QPrEPd participants interviewed as a factor influencing PrEP dosing patterns. One participant who raised concerns about how the closure of QPrEPd may have led people to stop PrEP described how he would prioritise PrEP if he was financially insecure, as he considered the security and protection against HIV offered by PrEP to be very important:

'The cost to me isn't even a factor, for some people I guess it would be. If you're on a minimum wage and you're struggling and things aren't cheap, it could be a factor. For me it would be something that I'd have to be really on the bare bones of my arse before I would consider stop taking it'. [Regional 40yr old gay man]

However, many discussed how having to pay for PrEP may force people to cease PrEP or change to using on-demand / event based dosing as a means of reducing the expense associated with taking PrEP daily. Though none of the interviewees who had ceased taking PrEP at the time of the interview gave this as a reason for their own decision.

'You probably would have had quite a few of the test subjects that would have stopped taking it, because I almost had to because I can't afford it'. [Regional 31yr old gay man]

Ceasing PrEP

Among those interviewed a couple had stopped taking PrEP. For some the decision was due to their sexual inactivity as reported by 30.8% (8) of the post closure survey respondents. As described by a regional 50 year old gay cis-man who had not been sexually active for more than 1-year, his decision to stop was based on a suggestion from their PrEP prescriber who considered his HIV risk low in comparison to potential long-term health issues associated with PrEP use in combination with his other chronic health issues:

> *'I came in, had a check-up, and doctor [name] recommended… said, "You're not being busy, you're not doing…. because consequently it's… you know, ultimately not good for your bones, not good for your kidneys, all that sort of stuff."……. I just haven't been active, so he sort of almost sort of said like taking antibiotics for something you don't have'. [Regional 50yr old gay man]*

Some of the interviewees cited being in a monogamous relationship as another reason for ceasing PrEP, consistent with 50% of the post closure survey participants who had ceased PrEP since the end of the QPrEPd. One regional 39 year old gay man described making the joint decision for him to cease PrEP with his new partner as they had negotiated and agreed upon a monogamous *'closed'* relationship. At the time of the interview, the participant was still daily dosing as he was waiting to arrange for both of them to have a final screen for HIV and other STIs before ceasing PrEP:

> *'I'm about to come off them, because I'm actually now in a closed relationship, so I think I can step back… It's closed, and I'd like to just make sure that….No, he hasn't been on PrEP, no, it's only me, which is fine, and I'm happy with that, and you know, I'll get both of us tested ….just to make sure everything is still okay, then we can think about coming off PrEP [Regional 39yr old gay man]*

Another participant was in a new monogamous long distance relationship, and while he hadn't '*strayed'* and '*didn't feel the urge',* he was also uncertain if stopping PrEP was a viable option for him given his '*track record'* in past relationships.

> *'I am happy within my relationship, so I haven't strayed since I have stopped. That's only a month, or so, but I don't feel the urge to stray, or do anything on the side. It most probably wouldn't happen. I suppose it's a safe guard to have just in case it did happen'. [Regional 52yr old gay man]*

To others being in a relationship with a regular partner was not an indicator for ceasing PrEP as they would continue to want an open relationship as described by on younger participants when asked if they would stop PrEP if they had a regular partner:

> *'…No, because I'd probably be a hoe, still, and want an open relationship' [Regional 24yr old gay man]*

The number and gender diversity of regular, 'fuck buddies' and/or casual partners sexual partners reported by the 1,988 gay identifying male participants who completed the entry survey, highlighted the importance for HCP being aware of the need to explore relationships and potential HIV risk in more depth among people reporting they have a 'regular partner'.

The interviews highlight the importance of exploring what a monogamous relationship means for people, and ensuring that they have the knowledge and skills to negotiate to use or not PrEP.

It also highlights an ongoing need for regular HIV and STI testing as part of their HIV risk reduction strategies within regular monogamous relationships, as well as with casual partners.

Alternative dosing regimens

Some interviews had been informed about alternative dosing regimens by their PrEP prescribers and others had read about it through a range of sources, including on-line, friends, and sex partners. HCP willingness to discuss and or recommend alternate dosing patterns varied dependent on where the participant were accessing their prescriptions and their patterns of behaviour. Some participants described being actively counselled by their PrEP prescribers against the use of on-demand / event based PrEP as daily dosing was the national guideline.

Two interviewees had been advised that on-demand/event based dosing would be appropriate for them by their HCP based on their current level of sexual activity, pattern of 'hooking up' and considered potential risk of HIV exposure:

> *'I have spoken to my doctor, or the doctor there at the sexual health clinic and we have talked about options, where I have continued to do it as a daily dose, or I just keep the tablets for times when I may have, you know, a sexual contact that I wouldn't normally have and then take it as prescribed by the doctor. He said, "Take two tablets before you have sex, one the next day and then another one the day after and it would still do what it's supposed to do. So, I was happy with that, but I would be more happy if it was more freely available. Not for free, but not at that sort of expense'.*
> *[Regional 52yr old gay male]*

To some, on-demand / event based PrEP was of interest and being used, particularly among the participants who did not do '*casual hook ups'* and planned their sexual encounters with '*regular friends with benefits*' and around certain events such as a trip to the 'city' or parties.

> *'I have, I suppose, friends with benefits, so I wouldn't be on the market to go to like gab nightclubs, or on the scene, or any beats, or anything like that. I wouldn't be into that that all… If I go up there [town name] something may happen. I have got a friend in [town name], who claims that he is bisexual, but sometimes he is all women and sometimes he is men and he just doesn't know what he's doing, but we have hooked up in the past and that sort of thing, so there is always that possibility'.*
> *[Regional 52yr old gay male]*

However, others questioned the value given their more '*spontaneous*' and *'open'* type of relationships.

> *'I think that would run the risk of, if you want to be spontaneous, you know, you couldn't do that. So to me, I'm just a creature of routine, I just think well just do it every single night, so it's [daily] just what I do'. [Regional 40yr old gay man]*

One participant described moving between daily and on-demand / event based dosing dependant on their patterns and frequency of sexual engagement. They described using on-demand in Australia '*because it's a smaller town and not as much happening*' and daily PrEP while travelling overseas to areas with higher HIV prevalence and less access to testing, treatment and PrEP. Here they generally engaged in sex with 'regular friends with benefits', but were also more likely to have casual partners. This demonstrated a level of health literacy and confidence in their ability to plan and manage dosing patterns around their behaviour and considered level of risk:

> *'I've gone between on demand and taking it every day to moulding and shaping to my behaviour at any given time. …….. I feel good about the conversations I've had and the information that I've been directed here and yeah, monitoring my own behaviour with it as well. Yeah, so I think I'm very well equipped to be keeping myself safe and protected'. [Regional 33yr gay man]*

This participant also described 'dabbling' with a dosing method they had read about on-line until being advised by their PrEP prescriber that this was not a recommended regimen. This highlights the importance of having an open relationship with HCP whereby people are comfortable and able to discuss PrEP and broader sexual health topics and obtain evidence informed advice on PrEP dosing. It also highlights the need to have evidence informed information freely accessible on-line for people that is updated to reflect emerging evidence and address topics discussed on social media and other platforms that may place people at risk of HIV:

> *'Presently, I'm taking it every day. I did dabble with the Ts and Ss method that's advertised on the website, so you take it every Tuesday, Thursday, Saturday and Sunday. But I had had a conversation with one of the doctors here alluding to it's probably not the best way to be going about things. Yeah, so that was interesting.'*
> *[Regional 33yr gay man]*

There appeared to be a general lack of knowledge, uncertainty and even mistrust of on-demand / event based PrEP regimens among some of the interviewees. Some due to concern about the efficacy of the drug taken in this manner, while other concerns were based on anxiety and a residual underlying fear of HIV. Among these participants, who were generally aged 50 years and over, many continued to use condoms consistently with daily PrEP as additional protection:

> *'No [confidence in on-demand] …Simply because I know that I'm not topping up my system every day. I still have a little trepidation anyway, even on the daily plan as well. It's just like, 99.9 per cent effective, still leaves an element of doubt for me. You know, even though it's been over the last 10 years that it's been in the marketplace, I think there's now four cases or whatever of people that have… you know, become HIV positive or whatever; that's still, for me, throws an element of doubt. But for me, it's another barrier. Another barrier of protection, is the way it's used.'*
> *[Regional 50yr old gay male]*

To others, daily dosing remained their preference due to concerns about their ability and need to remember, plan and manage the dosing around their sexual encounters and lifestyle:

> *'Well situational, there's planning involved, you actually have to have it organised. I'm not that organised, so having it in my system daily takes that stress away of; it doesn't matter what situation I find myself in, I'm protected against HIV because I'm always taking it. Yes it means I've got to spend more money because I'm taking it every day and you only get 30 tablets to a jar. So I've got to buy it every month but it takes away that risk and that stress of have I taken it long enough. For me it is a big thing, because I'm allergic to all condoms, latex free or otherwise, I can't use them at all. So I have to go unprotected, I don't have a choice in that side of things. So I sort of need that security to know that it doesn't matter what situation I find myself in, I'll be fine.'*
> *[Regional 31yr old gay man]*

8.3.5 PrEP script dispensing and access

The interviewees were accessing their medication at four primary locations: a public HHS pharmacy onsite; at their SHS or at the local hospital; through a local community pharmacy; or importation from overseas via an online pharmacy.

For the couple of participants obtaining their script from a public SHS with an onsite pharmacy there appeared to be very little disruption to their pathway to obtaining the medication. For them the biggest 'challenge' was timing their 3-monthly clinical visit to coincide with the Pharmacy opening hours.

'I am still getting it through the pharmacy at [service name] they are really good there….. Try a community pharmacy…...No, but I suppose because I went to the sexual health clinic and the pharmacy was part of that clinic. It was there, so, I suppose, it was advantageous to be able to pick up your script from there, rather than having to go somewhere else. [however] if I could get it at that better pricing, then I would be happy to go to any chemist that I could get it from, or pharmacy.' [Regional 52yr old gay man]

One interviewee accessing their prescriptions through a public SHS service with no onsite pharmacy was getting their medication dispensed at the HHS pharmacy based at the tertiary hospital facility in their area. They had chosen this option as they felt this was more anonymous than going to a local community pharmacy following a negative experience at their local small town community pharmacy:

'I did it at the chemist one over near home here, but then I got given an information sheet on HIV/AIDS when it was handed out. I was like, right okay ……I'm in a retail job and I spotted three familiar faces in the shop that were working behind the counter. So now I've just changed to the hospital pharmacy…. I don't want some 16 year old girl seeing me in my job and going oh that guy comes in and telling what she thinks is okay to mum and dad or something like that.' [Regional 40yr old gay man]

Though interestingly, while this participants said picking up the medication from the HHS pharmacy was quick, they could not just drop in, and similar to the local community pharmacies, they had to give the HHS pharmacy staff a minimum of two days' notice. This again indicates the need for PrEP users to have the ability and capacity to manage time and plan ahead.

'No you've got to ring two days in advance and then you walk in and you go script for me and they tell you to go down to the office and then pay for it and then come back and then they dispense it. You can be in and out within half an hour.'
[Regional 40yr old gay man]

The couple of participants who were accessing their PrEP medication on-line had been doing so before becoming a QPrEPd participant, and so just returned to this method. As described below, it was cheaper or of similar cost to access it under the PBS subsidy, and they could obtain a 3-months' supply on one order:

'I went back to Green Cross, which I did initially, before we were on the PrEP trial, ….I found that by the time you paid the freight on it, as well, it worked out… maybe slightly more expensive that me going and buying it from the chemist here…… worked out at maybe 41 dollars a bottle or something, by the time you paid freight. Whereas it's just under that, 39 or something'. [Regional 50yr old gay man]

At the time of the interview, the majority of interviewees were getting their PrEP dispensed at a local community pharmacy. Transition to this model of access had not been streamlined initially. For some this was not their first choice as their local HHS pharmacy was not stocking or dispensing PrEP as part of standard care. The majority of participants accessing PrEP at a local community pharmacy described either needing to visit a number of local community pharmacies before finding one that had stock or was willing to order stock in:

'No because what he was telling me was that it was very expensive to stock. So they refused to stock it unless they got a lot of people coming in asking for it.'
[Regional 58yr old bisexual man]

'The only thing I found, that was tricky was right at the start being that we had access to the drug itself here quite freely during the study, the moment that all of a sudden the study ends and people are now having to source the drugs from other locations, I found it hard to access the drug initially. I think because there has been a wave of people suddenly requesting the drug, that's since fixed itself. But during that exit, there was a couple of pharmacies that weren't sure of the drug, didn't supply the drug or were ordering it in but in small quantities. It was depleted immediately. Yeah, it was fortunate 'myself and my partner were taking it so we could dip into each other's supply.'
[Regional 33yr gay man]

Such waiting was not an issue for many in the initial period post study closure as they disclosed having some 'stockpiled' PrEP, or were using partner's medication as described by the participant above. However, many expressed frustration and anger at the apparent lack of preparation and warning given to the local pharmacies that QPrEPd was ending, with many expressing concern for people where this may have resulted in a potential exposure due to a forced or unintended pill break.

'I don't know that initially if most pharmacists knew exactly why there was this influx of people wanting it all of a sudden, and that's why when they were ordering it in, they were ordering it in these small quantities and then they…but they've obviously I suppose, in a bigger place like Sydney where I'm from, it is more accessible than up her a little bit. Well, there was initially, but that's since sorted itself out, I guess'.
'[Regional 33yr gay man]

'it wasn't overnight or anything like that …..I think it was a couple of weeks'.
[Regional 58yr old bisexual man]

One participant living in a larger regional city expressed frustration, suggesting pharmacies should have been better prepared given they were not the first group to transition to PBS access. Acknowledging that they were aware the QPrEPd-Xers had been accessing PrEP under the PBS model through local community pharmacies since April 2018.

'It shouldn't have to be a wait. We're not a small country town. There's quite a large gay population up here and what I see on Grinder, there's quite a lot of people on it. That's the thing as well. I know that this trial, I believe I was in group two. There was another group before me. So, there should be…I shouldn't have to wait three days. I should be able to just walk into the chemist like any other script and get it.'
[Regional 34yr old gay man]

Some participants described how having to manage their supply including having to remember to ring their local pharmacy to get them to order supply monthly was a challenge at first. Other participants described shopping around and settling on access via the larger chain type community pharmacies that have a system of reminders:

'The only problem with that is they don't have a stockpile here [town name]. So, they have to order it in. So, I have to remember when I'm getting low to call them. But what I've noticed the last couple of times is now they're sending me text messages to say, "Your scripts due," with my other one. … So, last week I got a text message saying, "Your script's up for renewal," for my other medication and then a couple of days ago, I got a text message saying that the PrEP script was up as well. Yes, to dispense or no. So, then that's why I leave it all with the Chemist Warehouse because I don't have to pick up the phone or go in. I can just text back yes, and then I get a text message once it's been dispensed and ready for pick up and then I just walk in. I don't have to wait with a buzzer in the queue and all that…' [Regional 34yr old gay man]

Limited stock as a barrier to access seems to have settled with time as the participants and local community pharmacies are balancing ordering stock supplies and regular client demand:

> *'We've gone into our local pharmacy, they now know that we buy it just from them, so they're now starting to order ahead. It was getting to the point where we'd go in and it would take a week for them to get it in. So we had to start adjusting as to when we were actually going in and getting it because there is no guarantee it was going to be on the shelf.' [Regional 31yr old gay man]*

Some barriers to access remain an issue 6-months post study closure. Particularly for those living in small regional rural towns and communities where there remained considerable concern about privacy and confidentiality, accessing the medication at their one local community pharmacy. As described by one participant they and their friends travel monthly to a larger town rather than risk experiencing stigma or discrimination in their home town:

> *'Well if you live in [small town name]… you actually have to go to the chemist. And I know the one bloke who lives in [small town name], he comes into [bigger regional city name] deliberately to get it from the chemist, so that they don't know… that it's a small country town'. [Regional 60yr gay man]*

Pharmacist and pharmacy assistant knowledge and attitudes had resulted in some negative experiences for participants. For example, a number of participants in each location where interviews took place described being asked inappropriate questions such as '*how long have you been positive'* by pharmacy staff in front of other customers in a manner that inadvertently outed them as gay and or living with HIV. Such incidents demonstrates a lack of knowledge and awareness of PrEP and HIV and suggest that processes for protecting customer privacy and confidentiality need to be reviewed and improved.

> *'One of the chemists asked 'why do I want the medication?". I meekly said 'No, I have not got HIV AIDS, I'm actually taking it to prevent if that's okay'. And she said 'Oh no need to get upset'. …..the absolute questioning of me ….. They do it at the front desk and I've actually got to answer with people on either side of me. And, you know…yeah…we…let's put it this way a chemist should not have the right to out us in front of people……..imagine someone whose eighteen, living out in the middle of freakin' nowhere…and you want then to take this medication and they've got to go to the chemist to get it, you know. There's no other choice for them…' [Regional 60yr gay man]*

8.3.6 Generalist GP and HCP prescribing PrEP

All interviewees were in agreement that PBS listing of ART medication for HIV prevention and the lifting of prescribing restrictions allowing any physician to prescribe PrEP was a positive move as it increased options and flexibility for accessing PrEP. Including when traveling and in locations where specialist services, both public SHS and private S100 GP services, are unavailable and or have long waiting lists and expensive Medicare gap fees:

> *'I think that's great. It just means…because especially if you travel as well and if you need urgent access to it, if you forget and run out, then you can just go to a GP, any GP, and get it. Whereas if it's specialised, then it's harder to get in so I think it's good that all GPs can prescribe it'. [Regional 34yr old gay man]*

Most thought it was appropriate and acceptable that any generalist GPs can now prescribe PrEP. However, there was a strong consensus among the participants that GPs and any other HCP involved with prescribing PrEP needed some foundational understanding of PrEP along with HIV and broader sexual health issues, research and base practice care:

'It should be available to all GPs. They should be up to date with research …PrEP, to sexual health practises in general, as well; simply because most people feel very comfortable with their GP….the main thing is that as long as the GP has some sort of foundational understanding'. [Regional 50yr old gay man]

There were mixed thoughts on whether generalist GPs were prepared with the necessary knowledge, skills and attitudes to prescribe PrEP safety and appropriately. Lack of knowledge about comprehensive STI testing again was raised again as an example of why HCP who specialise in sexual health are best placed to provide PrEP care:

'[GPs] probably not prepared, I don't know whether it's a good idea. I believe that it should be just handled from the Sexual Health Clinic point because that's what you guys do. You are experts in all STI's, not just HIV. Where, a GP, he's just a broad-spectrum type of doctor that doesn't specialise in too much at all. Even though he would know, it gets back to the example where some of my mates there are going and getting tested for STI's and they're not doing the correct test. It's because the GP doesn't know, which he should know really that gonorrhoea and chlamydia, there's got to be swabs to be tested.' [Regional 58yr old bisexual man]

'They go, what's that? What is PrEP? I'm going, ah, if I have to explain to you what's PrEP, then maybe you should read up… No, surprisingly – I was surprised that the GPs weren't aware of PrEP… I had to ask for a full test. They go, what do you mean? I said, including swabs.' [Regional 39yr old gay man]

Many of the 13 interviewed described how they felt PrEP was openly being spoken about in the gay community. For some QPrEPd and the ongoing increasing access to PrEP and circulating PrEP information had been the much needed catalyst for increasing openness in conversation for people.

'I noticed that moving from Sydney to [regional town name] …Sometimes up here it was, "You don't talk about those things." But I think something like this … study that's been positive, yeah, it makes people comfortable talking about things …. the study … has put the conversation on the table and it's not taboo talking about these things as much'. [Regional 33yr gay man]

However, in the regional areas unless people were engaged with the gay community or a network of gay friends either locally or in bigger centres significant barriers remained to them talking openly about PrEP, HIV and being gay with HCP family, friends and sexual partners. Of particular concern are young LGBTIQ+ people living in regional areas:

'People out in smaller areas in communities, because it is a shame thing and that goes back to that whole being gay and you know. I'm always an advocate for the young ones if they need to speak. Because we know that in our gay community, LGBT community, that suicide in our younger ones is quite high and it's because they don't feel like they can come out. They don't feel that they can talk to somebody and have that relationship where they can express themselves, so they end up committing suicide. It's a huge issue'. [Regional 52yr old gay man]

Participants suggested there are still a lot of people at risk of HIV who appeared to have limited knowledge about HIV and PrEP. A common misconception described by participants was a belief that PrEP was also providing protection from other STIs:

> *'There is a lot of guys out there thinking just because they're on PrEP that protects them against all STI's which is not the case….. I think we need a little bit more education and maybe that might be why gonorrhoea and bloody chlamydia is so rampant around'. [58yr old bisexual man]*

> *'I have heard from a couple of people that have said, "I'm on PrEP, I don't have to worry about wearing protection at all, I'm protected against everything…. we're protected against all the STI's". I'm like; no you're not, go and do some reading. It's to stop the HIV virus attaching to your cells; that's it'. [Regional 31yr old gay man]*

Many suggested more community and HCP education is needed and, despite closing QPrEPd based on the proven feasibility of the QPrEPd model of delivery and availability of PrEP on the PBS, the state and federal governments have an ongoing responsibility to ensure all at risk have equitable access not only to PrEP but evidence informed information and competent LGBTIQ+ friendly HCPs in both sexual health services and primary health care general practice settings across Queensland:

> *'I think there's got to be more advertising for what PrEP is actually for. It's a preventative for HIV; nothing else. I think there's got to be more advertising……get tested every three months… the Government should look at. If they're serious about knocking the bloody disease on the head, you know, that's what they should be looking at is making it accessible to everybody. There's a lot of students; a lot of people coming here to study here in Australia that aren't eligible for Medicare. So, what do they do – and a good percentage of them are gay – so what do they do. They just say, oh stuff it, I can't afford it, I'm flat out paying for my bloody fees. So, they go without and that's where they can spread the bloody thing, if they get it, do you know what I mean and there's always chances of that happening'. [Regional 58yr old bisexual man]*

8.4 Service provider's qualitative experiences during the trial closure period and transition to PBS model of access

8.4.1 Demographics

In total 28 nurses, seven SH/HIV physicians and two general practitioners(n=37) (Table 61) were interviewed between April and June 2019, from 15 of the 25 active study sites, five to six months after each of the study sites had been closed. The health care providers (HCP) interviewed were conveniently sampled, however an attempt was made to purposively sample across disciplines, roles and geographical location of services (Table 62).

The semi structured interviews, conducted face-to-face or via video call, using ZOOM video conference technology, were digitally recorded and transcribed verbatim.

Table 61: Study Site Service Provider Roles

Role		n	%
Medical	Sexual Health / HIV Physician	7	18.9
	General Practitioner (S100 prescriber)	2	5.4
Nursing	Clinical Nurse Consultant / Nurse Unit Manager	11	29.7
	Clinical Nurse	6	16.2
	Nurse Practitioner	4	10.8
	Practice Nurse	2	5.4
	Public Health Nurse	2	5.4
	Contact Tracing Support Officer (Nurse)	2	5.4
Pharmacist		1	2.7
	Total	**37**	**100.0**

Table 62: Service Model and Interviewee numbers by location

Service Locations	Services		Interviewees	
	n	%	n	%
SEQ Public SHS	6	40.0	20	54.1
Regional Public SHS	5	33.3	12	32.4
SEQ Private S100 GP	3	20.0	4	10.8
SEQ Community GP	1	6.7	1	2.7
Total	**15**	**100.0**	**37**	**100.0**

8.4.2 Experiences and perspectives of being a QPrEPd Study Site

The HCP were asked to reflect on their overall experience of the QPrEPd study.

The majority of HCP interviewed described QPrEPd in a positive light having achieved its intended goal of increasing access to PrEP for Queenslanders. There were also a number of other positives associated with being a study site identified that they hoped would continue past study closure. For example, several HCP described how QPrEPd had attracted new clients to their service, including never and infrequent testers at high risk of HIV, who may otherwise be now among the newly diagnosed notifications:

> *'I thought the study was great and definitely, certainly, there are some of my patients, who would definitely be HIV positive if it wasn't for QPrEPd, absolutely, for sure' [Urban S100 GP]*

Others described how being a study site had improved their clinic reputation within the community, with one regional SHS nurse stating '[QPrEPd] *helped make the community see our service as legit and acceptable…. It has raised our profile and credibility'.* This unintended consequence was particularly noted by a HCP located in inner and outer regional areas who went on to describe a noticeable change in the number of MSM accessing their service since the implementation of QPrEPd:

> *'We've seen more gay guys more often…the knock-on into the community has been education, safer sex practises, that kind of thing and then access to PrEP. I think it's been a cumulative thing over a number of years. And the big part of the PrEP trial was the icing on the cake. We were seen as actually being part of a bigger organisation that uses proper research-based practises to reinforce an underlying practice.' [Regional SHS nurse]*

> *'The profile was mostly 80 per cent women … I think we see now 55 to 60 per cent of our clients are male. So that's been an increase, for men accessing the service; and particularly men who have sex with men. So it's [services for MSM] been an area that's always been sort of lacking in [service name], and I think the trial has just highlighted the relevance of the service here, and made people aware, and they're now accessing that. So it's been of great benefit to us'. [Regional SHS nurse]*

The negatives of being a QPrEPd study site were also discussed, the most notable being the increased workload and lack of financial compensation for staff time, as well as additional pathology costs as a result of increased new client numbers and additional testing requirements of the study.:

> *'We weren't generating money for recruitment but we were also putting our most expensive staff doing the recruiting because of the consenting process. There was no compensation for that time, for any of the appointment times, for any of the pathology, for any of the ongoing – the additional medications that we had to use for the STI's that were involved in it and the additional appointments that were associated with the tests and cures of those and also things like data cleaning, the logging of the medications. So there was quite a big financial impost on the service. I haven't actually quantified it but it would not be insignificant'. [Inner Regional public SHS physician]*

8.4.3 Experiences and perspectives of the early closure of QPrEPd

It's mostly fine and appropriate given it was now on PBS but we were surprised

Overall, most HCP interviewed described their clients as being '*mostly fine'* with the study closure. Very few HCP interviewed were able to provide a positive response to the early closure: '*Positives [of] early closure… Well, I can't say that there actually was one…',* however, all were in agreement that PBS listing of PrEP was a '*good thing'* as it provided people seeking PrEP with the opportunity to find a prescriber and community pharmacy with more flexible outside of business hours appointments than many of the study sites:

> *'I'm very happy that it got PBS-listed. I mean, it wouldn't have bothered us if the trial continued, but the fact that it got PBS-listed is a great thing, very good outcome.' [SH Physician]*

> *'I guess the positives were that people had access more readily, access available to them, they had other options other than coming here. Another positive I suppose is just the, I suppose the extra, data entry and stuff from clinicians wasn't as great so, it left time for clinicians to do the process with PrEP.' [Regional SHS nurse]*

Some HCP interviewees described the closure as *'unexpected'* and a disappointment. Concerns remained regarding potential barriers to access for some participants post closure, however, very few HCP described any significant difficulties managing the exit of their remaining active participants by the required study site closure date:

> *'The only difference being obviously that they now need to pay for the medication. I know there have been a couple of people say that they wouldn't be able to afford, that was another reason why people don't continue, I think is the cost.'*
> *[Regional SHS nurse]*

> *'I was quite surprised. Because the PrEP was available on the PBS, I knew that sooner or later we were going to reach the deadline of 2020. But I never thought that it was going to be so close.' [Urban based S100 GP]*

> *'There's a bit of disappointment about the early closure and I have a couple of very high risk clients. Some people were expecting [it] because we went on PBS and a few people saw when it was on PBS they thought the trial would close anyway. So, I supposed there were sort of mixed feelings about it.' [Urban S100 GP]*

As described by one urban public SHS based physician, many thought that, '*it was appropriate to close early given it was now on the PBS'* and despite the relatively short time frame for exiting the participants, *and that, 'it was a manageable number to exit safely in the timeframes*'. Interestingly, HCP across the state and study site service models reported that, prior to notification of the 'early closure' a natural attrition of participants had commenced with some participants self-initiating PrEP access under the PBS from study sites and other services as they thought closure of the study was probably imminent due to the PBS listing.

Managing the closure was generally OK

Attitudes of study sites towards to the closure, from an operational and client management perspective differed. The variation depended on the number of remaining active participants, staffing mix, service capacity, and geographical location and availability of other health services offering access to PrEP prescriptions. There was a general consensus that the time from notification of study closure to close the study to having to commence (1 October 2018) and complete the exit of all active participants (30 November 2018) was relatively short and rushed.

A few services, particularly those with a greater number of active participants, experienced some logistical issues to undertake 'exit appointments' with everyone in the relatively short timeframe, due to staffing capacity and clinical space limitations.

The additional workload contacting all participants within the allocated timeframes created logistical burdens and due to a lack of funds allocated to the individual study sites to manage the QPrEPd process and closures also created issues continuing to provide other services to clients:

> *'For us to have to close down the numbers that we had in that sort of timeframe was quite difficult. We dealt with it by directly contacting all of the clients that were involved but also that created another logistics burden on the service which again like the rest of the trial itself was completely non-resourced.' [Inner Regional public SHS physician]*

Many queried the rationale and need to close the study so quickly suggesting it could have run until purchased stock medication supplies were exhausted. Some questioned what had happened with the remaining stock that could not be repurposed and expressed ethical concerns about the '*destruction and waste of medication'* that occurred with the early closure.

Some HCP considered the closure was driven by a health economics decision rather than on evidence or best practice research procedures for closing a multi-site trial:

> *'I felt that it was very rushed. I felt like it was closed purely on a financial basis rather than it being wrapped up appropriately….rather than a researched reason…' [Regional SHS Nurse]*

A small number also expressed concern about the potential loss of data and valuable understanding of PrEP use and behaviour by not completing the full four years:

> *'Terribly sad that the trial ended early. As a research project, the findings over the full period would have been very valuable.' [Regional SHS nurse]*

Others described a sense of a '*broken promise*' to clients based on the assumption they agreed to be part of a trial until 2020. One clinician queried whether there was an ethical obligation to continue for the full four years given many participants perceived that they had consented and agreed to be provided PrEP for that period:

> *'I think it was probably disappointing to your patient, because you tried to recruit patients and one of the incentives was that the trial was going to be for four years until 2020. And nobody was predicting at first that it was going to close halfway through. So, I think it was, well, a few patients already told me, "Didn't you say it was until 2020?" So, I have to explain that it was because PrEP was already available of the PBS. It's always a bit disappointing and frustrating to explain those things to patients when everything is outside your control area.' [Urban S100 GP]*

Communication could have been better

Some HCP suggested the decision to close the study could have been better communicated to reduce the clinical workload burden on staff, and enable a more streamlined 'best practice' exit of all participants. Resources and information provided to prepare their study site for staff and participants sufficiently for the closure were considered inadequate by a few HCP. There were suggestions that the communication from the SMT could have been timelier and more comprehensive to prevent study sites feeling they were left to do it themselves. It was also considered that direct communication about the closure to the participants from the QPrEPd SMT could have alleviated some of the client's disappointment and anger which was directed at the study site staff.

> *'from a research point of view….for something like this I would have expected there to be a multi-site teleconference and better communication about what was going on ….there was…a feeling sort of like that sites were then asked to each manage how they would manage themselves…everybody was left to do a bit of a DIY, however they saw fit… no resourcing in terms of information to be provided. There was a closure letter. I will acknowledge that, but I don't think it was particularly well supported in terms of the process for which clinics were supposed to conduct the closure of the study… We got this letter, please figure out how you're going to send this to all your patients … rather than us having to do that that could have actually been done centrally from [STM].' [Inner regional SHS Physician]*

> *'It was kind of like pulling the rug out a little bit. It was very sudden, very quick. From discussion, obviously they were discussing behind the curtains before letting us know; but from notification of the sites that were running the trial, and then actually actioning the closure was very… what I deem to be quite quick.' [Urban Community GP nurse]*

Some HCP described their participants as being '*miffed*' and '*angry*', and as described above feeling like the rug had been pulled out'. These feelings were particularly noticeable among clients who were not aware of the closure until they arrived for their scheduled study visit:

> *'Clients when they were coming in weren't aware that that was going to be their end visit, so it did lead to a few clients that were quite annoyed. They felt they had consented to a four-year trial.' [Regional SHS Nurse]*

At the time of writing the report, CDB have advised the QPrEPd pharmacy team to hold unused study medication and not destroy it. This information had not been communicated to the study sites at the time of the post closure interviews. The lack of communication contributed to the concern and discourse around the '*destruction and waste of medication'* discussed earlier in this section.

We managed but were the participants, community GPs and pharmacist ready?

While many considered it operationally feasible, in theory, to exit all participants due to the specialist skills and existing models of care across the study sites, a large number of HCP expressed concern about the preparedness of participants for the rapid transition to alternate non-study site models of PrEP dissemination. As stated earlier, QPrEPd had attracted a new group of non and infrequent testing high-risk men to sexual health care, and a number of HCP expressed concerns that this group were among the people who had or may have *'fallen by the wayside'* at their service since the trial ended. Most were unsure if this group have transitioned to GP care:

> *'I suppose the only thing was that the information about the tail-off…to pick up that last script was probably a little bit too short for the clients, rather than the clinicians. I think the clinicians were very aware that PBS was there.' [Urban public SHS nurse]*

> *'I think it's the very short time to termination that didn't allow patients enough time to get themselves sorted, to organise GPs, to organise alternate access to PrEP.' [Inner Regional public SHS physician]*

There was also considerable concern about the lack of time for notification and upskilling of non-S100 GP and community pharmacists prior to closure, to help facilitate a smooth transition out of the study for participants:

> *'I think there was a pressure to throw everybody out into the community for GPs to prescribe and there was very little GP readiness and preparation in terms of the dissemination of PrEP knowledge, in terms of prescribing….the repercussions of that is that we are seeing some patients who come in who have dutifully gone to their GP and either had really bad experiences, being either turned away or that the GPs have little knowledge, or that the GPs were taking it on but not doing the right and appropriate tests. So it does become sort of like a bit of a patient safety issue as well.' [Inner Regional public SHS physician]*

There was a strong consensus across the HCP that the study should have been continued for longer so that there could have been more time and active communication and education to prepare non S100 GPs and other PHC staff along with the communities at risk of HIV for the transition to PBS.

As described by one community based GP practice nurse, a longer transition period would have allowed time to get education and processes in place for generalist HCPs and the broader community:

> *'Right, we're heading towards the checkpoint, we've got plenty of time to get education happening… more where you get [PrEP] services. We could have better communication and translation of what's expected from the medical side, and what's expected from the*

patient side. And then obviously it gives PBS time to catch up and everything, and everything would just settle and flow cohesively, when everyone knew where the checkpoint was. But you've shifted that goalpost, then we have to just do the best we can, and compensate for that, and I think we just… I think we did a good job, but things could have been done better, and other parties could have done better as well, just to all make it best with clients.' [Urban Community GP nurse]

Barriers to access still exist

The majority acknowledged that PBS listing would address a number of barriers to access by increasing options for access across the state. Nonetheless, a number of HCP interviewed expressed concern about people ceasing PrEP due to a range of remaining potential barriers. Of particular concern was ongoing barriers for groups with known access issues such as Medicare ineligible people, Aboriginal and Torres Strait Islander peoples, people with financial and /or geographical barriers to accessing health care and other high-risk complex clients, often people at high risk of HIV with limited resources and/or the health literacy to navigate health systems. Of particular concern were the people at high risk who were living in areas with limited choice of alternative service to access PrEP, and having to negotiate access with non-S100 GP or PHC centres with limited Sexual health, HIV and or PrEP literacy among the health staff. In the same way, some did not wish to access a PHC or pharmacy in their local area and thus continuing to travel long distances:

'I was seeing a lot of low socioeconomic people, lot of high-risk demographic, and a lot of young MSM…..when the trial was going to end, I knew they would be our most problematic sort of demographics. So to soften that blow, I generated PrEP transition packs. I liaised…cold-called all these doctors and GPs, and said, "Look, this is what's happening; this PrEP trial, they need this PrEP, or at least access to services to get sexual health screening. I'm only there once a month." I said, "They need help in between." Out of the 20-odd GPs I called, only two were available. One was s100 and one was a peri-s100, so being trained under that GP. So they were the only two that were happy to take them. Others [GPs] stated "Just not competent, or didn't believe in PrEP, or didn't feel there was a need for PrEP".' [Urban Community GP nurse]

One regional based study site investigator described how no longer having a '*cupboard full of medication'* to dispense at the time of each 3-monthly visit, at no expense to the client, added challenges and barriers for some clients to continue taking PrEP. In particular those without the resources or skill to access PrEP via community PHC and pharmacies and or via on-line ordering:

'I think it was a bit disappointing, because I did feel that some of the patients undoubtedly would not continue on PrEP, even though it was going to be listed on the PBS, and some people might argue that the price, you know, clearly isn't that much for some people, but still was going to be too much, and they weren't going to pay that. So yeah, it was disappointing, and people had said – and patients had said that to us that they wouldn't continue. If we look at the patients that we had on PrEP, some of them indeed haven't continued PrEP.' [Regional public SHS nurse]

'The early closure was a source of disappointment with lots of patients. Even those ones who actually were on PBS, they have a Medicare card and could get it on PBS, but it was a bigger disappointment to those who did not have Medicare cards, and they have to learn to go and also get it online, and they were not sure how they can obtain the medications.' [Urbans SHS nurse]

Missed opportunities to engage priority populations

Some HCP felt the early closure limited theirs and the Study Management Team's opportunity to continue to target those hard to reach groups that had not been among the early PrEP adopters enrolling in the first two years of QPrEPd implementation. There was particular concern expressed with regard to Aboriginal and Torres Strait Islander peoples, Medicare ineligible, people in or moving between correctional facilities or those recently released, and non-gay identifying MSM. One regional public SHS HCP reported around 16% of their service consultations were with Aboriginal and Torres Strait Islander peoples, but that to date they had not commenced any Aboriginal and Torres Strait Islander peoples at risk of HIV on PrEP.

As described by a regional public health nurse, closure QPrEPd meant that any plans to target PrEP promotion and recruitment for Aboriginal and Torres Strait Islander peoples at risk of HIV were cut short without sufficient time for planning and implementation of new strategies:

> *'So from my perspective… I just feel like we didn't make any difference…. Whether or not we would have made at all if it went the full how many years it was supposed to go, but I don't think it made a difference. I didn't see an increase in PrEP in Indigenous people, people talking to them about it. … I just think it's a bit of a waste of time really. They'd [QPrEPd team] done all this work. I think they were just starting to build momentum, particularly around trying to reach Indigenous people and I think they shut the door before they made any inroads…another thing … talked to a lot of people across Queensland, particularly in some of those regional areas and those GPs had never heard of PrEP and there wasn't a chance to actually reach out and make sure that they had the information.' [Regional public PH nurse]*

Many described that over the life course of the QPrEPd study their workloads had increased due to a continued increase in people seeking PrEP. Interestingly, one study site also described experiencing a noticeable increase in work load as the study was closing due to large numbers of people who had exited from other QPrEPd study sites wanting to access their service as it was free and a more convenient location than their study site:

> *'I guess it was the unanticipated amount of people that were actually coming…..transferring from other centres… we didn't anticipate ….we think, maybe 50, 100, and we wound up getting – numbers-wise 250, it just exploded….from the study sites that were closing, the transitioning of their patients over to us..[Why]...Cost, it's free.... Convenience, secondly.' (Urban public SHS nurse)*

8.4.4 QPrEPd participants continuing to access PrEP from Study Sites

Most sites did not appear to have a system, plan or the resources for monitoring or tracking PrEP users post study closure, other than the regular clinic data bases, with one regional SHS Nurse stating that: '*Once we transitioned over to PBS, we just stopped collecting data on them'*. Another HCP questioned the need to keep track of numbers saying:

> *'With PrEP, we don't really keep a count, because – I'm not sure…..Whether we need to, is the other thing….it's become just like any other medicine, isn't it, so – because keeping track is also a lot of work.' [Inner regional SHS physician]*

The ability to record PrEP as a reason for attendance was possible on some clinical / practice management software programs, though other services were using packages with limited capacity to collect PrEP related data:

'I have a big issue with us having no review of data, we don't monitor our data at all, which hi find very frustrating. So, I'm currently in the process of… We're implementing a legend system. Because Best Practice has very limited capability in that regard. So, we can search by conditions, but we can't search conditions of transgender, PrEP, non-PrEP, private, lots of stuff.' [Urban community GP]

At the time of the interview, no service, when asked, had run a report or examined occasions of PrEP related service in any depth, so were unable to give verified numbers of QPrEPd participants who remained as clients with the service. The number of new clients who had commenced PrEP post closure. HCP estimates of QPrEPd clients who had remained with their study site varied from '*I think most stayed with us'* to '*not sure',* with one regional public SHS nurse explaining that they thought most had stayed as:

'[A] lot of the guys were actually linked into us anyway before the trial for their regular STI screening, they pretty much stayed here and then got the script from us.' [Regional public SHS nurse]

Another service reported that they thought they had similar numbers of clients accessing the service for PrEP care at the time of interview compared to at the time of QPrEPd closure. However, they also acknowledged they felt the staff were seeing increasing numbers of new clients seeking PrEP:

Must have had at least 200 [at closure]. I reckon we have 200 or 300 people on PrEP now…. suppose people coming off and then more and more people are actually going onto PrEP because we're really advocating for PrEP for all our MSM.' [Regional public SHS nurse]

8.4.5 Who stopped taking PrEP at the end of the study and why?

As described by one urban based S100 GP, the HCP on the whole thought very few people stopped taking PrEP just because the study closed; '*the majority just came back….the majority of them stayed on PrEP, whether it's with me or with their own GP'*:

'I'm not aware of anyone that stopped because the study ended. I mean, some people stopped because of side effects, and also kidney function, and other ranges of reasons, and moving away; but not because of the… No, they were very keen to learn about what are the next steps, "How do I continue taking PrEP?" It was really quite a nice transition. So, before the trial ended, we made an appointment in the future for them at our service, and they just transitioned onto the PBS PrEP very, very easily.' [Regional public SHS nurse]

Most services were, however, unaware of actual numbers of how many QPrEP participants had stopped taking PrEP at the end of the study with some HCP stating that they '*don't know'* while others estimated that, '*up to 50% had gone elsewhere*', though they were unsure where. However, as one regional SHS HCP described, that by having minimal queries or referrals from GPs in the local area, '*we assume all is going well'.*

HCP were broadly of the opinion that QPrEPd had helped make clients more health literate and confident to tell GPs what they want, possibly resulting in fewer people choosing to return for their final study exit visit or stay with a study site for ongoing prescription provision:

'Most of the clients are pretty savvy. And they would tell the GP what tests they need to be done. Which could be confronting for some GPs.' [Regional public SHS nurse]

There were a range of reasons provided as to why people may have stopped taking PrEP -with financial factors and other geographical and structural barriers experienced by some of their clients being common across the HCP interviewed. Other reasons for clients stopping PrEP included: '*don't need it as in a relationship', 'changed circumstances and perception of risk*', '*no partners', 'lifestyle choice'*, and most commonly '*they were having monogamous relationships'.*

Concern was raised about Aboriginal and Torres Strait Islander peoples and people with complex social and health related issues, with one service provider describing the QPrEPd participants who had dropped off their service records as '*some of our more chaotic, at risk and disadvantaged clients*'. Many posited that they thought these groups were also the ones most unlikely to have transitioned to GP care or continuing with regular three-month STI/BBV testing.

8.4.6 Experiences of clients that chose to go to another service for PrEP

'I've had a couple [of clients] who have gone to GPs just purely because it's more accessible in terms of appointment times, and they're quite happy with that, they've got good relationship with GPs. I think there might be one or two that might go between, depending… They might come in here, but if they can't, they'll go to the GP. But on the whole, I think the majority come here. I don't recall hearing any negative experiences…' (Urban based SHS Nurse)

Most HCP interviewed were unable to accurately report how many clients chose to go to another service or where the clients who '*dropped off'* went. Some HCP interviewees, particularly those working in regional study sites, described PrEP users having very little choice in services, other than the SHS, offering or willing to offer PrEP in their local area.

One regional SHS based nurse stated, '*we have no S100 authorised GPs and other GPs really aren't doing a lot of sexual health*', another regional SHS nurse said *'I only know of one gay doctor, who is openly gay, and supporting the community …he doesn't do HIV medicine anymore'.* As a result of limited information to the contrary, there was the assumption that most participants had continued to access PrEP through the study site.

Numerous HCP described the lack of other services willing to prescribe PrEP and an overall shortage of GPs in their local area, particularly those providing bulk billing services, as a significant barrier to people seeking PrEP elsewhere. Among those participants the HCP were aware had sought PrEP from services other than a known QPrEPd study site, many HCP described a common theme of people seeking care in non-S100 GP practices being informed, '*I just don't know what I'm doing, please go somewhere else'*.

This reaction from GPs was not unique to regional areas as explained by an urban based S100 GP who had enrolled participants from a wide range of postcodes across their city area:

'They were travelling far and wide [to enrol in QPrEPd]……I was quite willing and [at closure] they were going to transfer onto local GPs… I [gave information], "This is what PrEP is." …. set up the patients to transfer them and the story is, "Oh, the doctors took it away and went out of the room for 10 minutes, came back and said they just weren't comfortable doing, prescribing PrEP." So, they have come back to me…flicked back…. I was a bit surprised.' [Urban-based S100 GP]

Multiple HCP interviewees when describing QPrEPd clients who chose to go to a GP, including their regular GP, were 'bouncing back', felt that GPs unwillingness to prescribe PrEP was due to a general lack of awareness, interest or knowledge of PrEP and wider sexual health issues. As one regional public SHS staff member described and 'we *are still seeing MSM not having comprehensive testing with GPs …. Never had anal swabs… if GPs not testing ….query if doing with PrEP'* with another HCP reporting a number of clients had stated '*you do an awful lot more testing than elsewhere*'. This raised concerns among both regional and urban based public SHS and GP setting study site HCP that PrEP users may not be getting appropriate or adequate HIV and STI screening done:

> *'we had a few that were sent from their GP to here, the GPs weren't comfortable in writing up a PrEP script, and even that's happening now, to a degree, not feeling comfortable in prescribing. I talked to some that didn't know about testing or didn't even perform any testing before writing up a script.' [Urban based public SHS nurse]*

> *'A lot of the GPs weren't sure what they were supposed to do. Like, they'd write the script, and they may have done a blood test, but they didn't do a full sexual health screen, like swabs and pathology….come back ….most of them did, and then they phoned a friend, so they brought more. We still get new ones, the occasion new ones, now, but once it had finished, and word got out, we have had lots of clients come in, new clients, looking for PrEP.' [Regional based public SHS nurse]*

There were accounts of positive experiences of non-S100 GPs seeking support to prescribe PrEP when approached by QPrEPd participants:

> *'I had one young fellow tell me a really positive experience, where the GP didn't know about prescribing PrEP, gave an appointment a week later, and did all his research and then wrote him the script. I thought that was pretty positive. Obviously, the GP was interested enough to find out what he needed.' [Urban based public SHS nurse]*

HCP described client's word of mouth was generally how study sites and people seeking PrEP heard about non-study site HCP who were prescribing PrEP. However, despite some services actively providing support to local GP practice staff, many GPs were unprepared to prescribe PrEP and, in some instances, not interested in providing this service.

> *'So I'm sitting there on the phone talking to a GP, that I don't know who is not going to be seeing any of my clients, and running through what PrEP is and at the end he says, "I don't think I'd like to be involved in that. Somebody came in and asked for it and I didn't know what it was."' [Inner Regional public SHS physician]*

There was concern among the HCP that this experience, especially if accompanied by enacted and perceived stigma, may be a significant barrier for people seeking and accessing PrEP from another service:

> *'People were going to GPs asking for PrEP, the GPs didn't seem to be very well-equipped at dealing with that issue, so then they were referring them to us [public SHS], rather than actually prescribing them PrEP. I think that's another barrier for people getting it, because you know, someone has gone to the GP asking for it, and then they're saying sorry, you know, I don't know anything about it, or I can't do it, or you need to go to the sexual health clinic. Some people might go on and do that, but other people might just give up at that point, and not bother. I don't know if that's around education or whether it's about the GP not necessarily agreeing.' [Regional based public SHS nurse]*

'A few GPs down here aren't monitoring; they're just writing prescriptions. Our biggest concern, I think, was the lack of knowledge amongst GPs. Feedback from clients saying they didn't know what it was, they didn't believe it in, or, "I got shamed", or, "I didn't feel comfortable." [Urban based community GP nurse]

8.4.7 Experiences of prescribing PrEP post study closure

PrEP remains core business

Most study sites continue to consider PrEP core business post closure and are actively educating and recommending PrEP to people at risk of HIV presenting to their service:

'Men who have sex with men, sexual health, PrEP is very much core. Although not all affected men are on PrEP but certainly it's a continual conversation we have with them.' [Regional SHS nurse]

And as described by one regional SHS nurse people seeking PrEP, either initiating PrEP or seeking a repeat prescription are considered a priority within their service:

'I absolutely support PrEP to the hilt and I consider….that people who run out of PrEP…so important that we will fit that person in as an extra patient through the day… we don't want anybody running out of it, it's that important.' *[Regional SHS nurse]*

Conversely, one HCP described how their service had decided to recommend transition of all their QPrEPd participants to local GP services in order to allow for redistribution of funding and staffing to target other areas of priority, including youth health. Some complex '*reliable QPrEPders*' stayed with the service but the majority of the ex-study participants were actively assisted to find a local GP; '*we gave them the options of which GPs and, you know, talked them through it'*.

To facilitate a smooth transition both clients and local GPs were provided with guidelines and offered support and there was a sense that '*lots of local GPs are doing PrEP'* as referrals for PrEP to the service from local GPs were '*dropping off*'.

Shifting Workloads

Many HCP described absorbing or integrating PrEP into standard care and clinic workload post study closure. Some, primarily the private GP study site services, saw little or no change in workload with the closure or post closure describing it as '*business as usual';* describing how post study workload had reduced without the administrative study requirements:

'There is a decrease in workload because we don't need to enter anything after.' [Urban based S100 GP]

However, particularly for the public SHS, the QPrEPd model of PrEP delivery was not reflective of '*real life'* implementation. The study workflow in SHS, during the demonstration project, was mostly conducted using nurse-led models with annual medical officer involvement or more frequently if medically indicated. During the study closure and with PBS authorisation, all clients had to be seen by a medical officer (MO) or nurse practitioner (NP) in order to acquire a prescription required for obtaining non-study PrEP medication:

'Mostly the doctor [sees PrEP users]…nurses have very little to do with it now. We [nurse] were seeing them and doing all the workup and the doctor would then come in.'
[Urban S100 GP Practice Nurse]

For many of the study sites the redistribution of workloads from the nurses to MO and or NP during the study closure period created considerable increases in workloads and client flow issues due to the short time frame and limited, often inadequate, MO/NP staffing. Of note, client ratios:

'…significantly increased the workload in the clinic because all the guys that were on PrEP then had to be seen by a medical officer every three months for their script…. we almost ground to a halt with all clients having to be seen by the medical officer.'
[Regional SHS Nurse]

One HCP described how the inability of their IT systems to print pathology forms and prescriptions had further increased workload issues as valuable specialist MO time was required to hand write prescriptions:

'A doctor… writes a script, but it has increased the workload. Our software system, is so hopeless, it doesn't print out prescriptions, so it's all got to be handwritten, and there's bits of paper floating around, and they get lost, and it increases everyone's workload.'
[Regional SHS Physician]

In some settings IT systems limited the MOs and NPs capacity to provide services to complex clients and conditions outside of the expanded advanced scope of nursing practice and authorisation to supply drugs:

'I don't think any of us realised the fallout of once it all ends, how big the impact was on clinical services with appointments. So some days at [service name] in particular, my entire clinical day will be PrEP. Not that that's an issue, because we're doing sexual health within that as well, but I guess, you know, if you're trying to get other sexual health people in, or symptomatic people and referrals in, sometimes that can be tricky.'
[Urban public SHS nurse]

One service estimated that 70% of PrEP work during QPrEPd was independently conducted by the nursing staff and the rapid shift of workload to medical officers required an urgent review of clinic processes and client management pathways:

'The workload in the clinic, we had to sort of do workarounds, because we only have limited doctor hours. 70 percent of the clients are seen by nurses in the clinic, about 30 percent by doctors, so suddenly, all the PrEP folk, and we had 180 or so, I think, here, from memory, had to see a medical officer to get a prescription.'
[Regional SHS Physician]

An inner regional SHS HCP described providing a private 3-month prescription to accompany the final provision of study drug for all QPrEPd participants active at the time of the study closure announcement, when they presented for their final study exit consultation. This was implemented as a risk mitigation strategy to facilitate a smoother transition to the PBS model of access and limit the risk of missed pills. Interestingly they prepared all these prescriptions in advance to streamline the exit consultation times and these scripts provided an indication of the number of QPrEPd participants not presenting for a final exit visit:

'For each of them that was terminating we also provided a private three-month script, just because of that safety issue of they're on drugs and suddenly the drug's withdrawn. So we tried to mitigate any potential risk by providing private scripts, but even having

done that, quite a percentage of those people didn't present toward the end… didn't show up ever again…. by the end of the time we were still left with this pile of unclaimed scripts which basically was a surrogate marker that those patients hadn't been in, that they just heard that it was terminating and that was the end of it.'
[Inner Regional public SHS physician]

The adjusted medical and nursing workload ratio has continued to be an issue for some services post study closure, creating the need to establish alternate models of PrEP delivery. Some services are conducting a two-appointment system whereby nurses screen and assess clients with a consecutive MO appointment to write the prescription. This model of care is functioning but has some limitations such as difficultly getting consecutive MO and nurse appointments and longer waiting time for clients. Other services were still in the process of establishing these workflow processes at the time of the interview:

'Since the study ended, we're still in a bit of limbo about how to manage the clients and the model of their care, yeah, because there's a bit of a demand on the service… I think we've got a bit of an idea of what we're doing, but yeah, we do see quite a lot, and there's a bit of, like, who will see them? Will it be nurses that will see them, will it be the doctors that will see them, or will it be shared… or the nurse practitioner?'
[Urban public SHS nurse]

Visit schedule and PrEP self-management

To limit the need for additional consultations and expense for clients, HCP in general practice settings were scheduling 3-monthly appointments for PrEP users and providing private pathology forms at each visit for people to self-manage the required pathology testing in time for their next visit.:

'I just give them the form for a week before...I mean, I make the appointment for three months' time and when the appointment is made, I just print the [pathology] form with a date a week before that date.' [Urban S100 GP]

Interestingly though, HCP from a range of study sites described how many of the ex-study participants who exited to another service for PrEP were still accessing the public SHS study sites for STI screening explaining that '*some [clients] separate STI from PrEP – still come to* [study site name] *for STI screening and treatment as free'.* This may suggest private pathology costs could be a barrier for some people accessing PrEP via the general practice setting.

However, these scenarios require further exploration to determine if additional factors are also involved including if the 'new' PrEP prescribers are 1) conducting the necessary pathology testing prior to providing a PrEP prescription, 2) relying on clients to report their results from testing done at other services or 3) clients are testing for STI at public SHS in between the regular 3-monthly PrEP consultation with their 'new' prescriber.

Most HCP interviewed described supporting and / or expecting PrEP users to self-manage their 3-monthly testing and prescription appointments post-study closure. There was a general sense that clients were attending 3-monthly, and some services were booking the next three month appointment at each visit, but very few HCP described having a system of recall; '*we don't chase … we leave it to the client*'. To assist with this some described educating their clients to use pill numbers as a system of reminder for when their 3-monthly screening and script was due for renewal:

'Last bottle is the egg timer - get pathology done when ½ a bottle of pills are left'
[Regional public SHS nurse]

One regional public SHS described a system for clients living in regional areas whereby the nursing staff have a 3-monthly reminder set up to post a pathology form to the client and then arrange a chart review of results by the MO, and in some instances for remote users, arranging for a script to be posted to either be filled locally or on-line. On average this could take about five working days, so clients still needed to have the health literacy and skills to self-manage time, pill supply and potential HIV risk if there was an issue with supply.

> *'We've got them on a recall system, so they get a text message obviously the month of their review, just to say, "Hey, your PrEP screen is due," and they've only just gone into the third bottle or something. But for us it was about educating them to be self-reliant … It's a simple way to do it.' [Regional public SHS nurse]*

8.4.8 Patterns of PrEP use post study closure

Daily but on-demand is increasing

Overall, most HCPs interviewed thought that there had been no noticeable change in PrEP dosing patterns with most clients still taking PrEP daily. Most HCP interviewed considered that there is emerging evidence supporting event based/on-demand/intermittent dosing. Nonetheless, in most services it was standard practice to recommend daily dosing '*as this is the guidelines'*:

> *'I'm assuming they talk about it amongst themselves, but it's not our policy. Episodic, you don't know when you might get lucky, basically, so it's more – we still encourage the daily, so one tablet daily. It's up to them, though.' [Regional public SHS nurse]*

In some cases, HCP described actively discouraging supporting event based/on-demand/intermittent dosing even telling clients '*it's risky'* with one SH Physician stating that 'we *need more evidence before recommending demand*' or promoting other alternative dosing regimens. However, there were reports of increasing numbers of people asking about on-demand across the state.

> *'Still with their continuous. But, yes, people are inquiring a bit more for the PrEP on demand… young people that they are not having regular sex for whatever reason and they say, "Well, why am I going to be on a medication if I don't need it every day and second, I'm spending money in something that I don't use?" So they always ask for the PrEP on demand… or you cannot afford it, the other option is, yes, going on PrEP on demand.' [Urban S100 GP]*

Most of the HCP were aware of clients self-managing their dosing regimens depending on their social and sexual context so they were providing information on alternate dosing regimens to ensure that the clients were informed and dosing appropriately to minimise potential risk:

> *'Most of them are doing daily. I do talk to some of them about whether they are going to do intermittent and I think some of them have done intermittent. Some of them have stopped for periods of time where they haven't been sexually active. Some of those do have periods of thing where they are busy professionals, or whatever, or they are travelling and they do actually stop. I do talk to them about maybe getting them to start up beforehand and taking it for a period of time afterwards. We have conversations like that. But- I think some of them are doing intermittent dosing, is the reality of what is happening. But a lot of them really have to take it daily. Some of them really, do have quite a large number of sexual partners and have to take it daily. I know because they are coming in with STIs, so they are at risk.' [Urban S100 GP]*

In line with recent global changes in recommendation for event-driven PrEP for MSM [23, 24], one HCP reported that at their service they actively encouraged conversation about on-demand PrEP among their clients and were prescribing this regimen for appropriate clients, particularly with clients known to only intermittently engage in HIV related risk behaviour.

For example MSM who only engage in higher risk behaviours when they travel overseas, or when attending planned gay events; older clients with chronic health and kidney issues who don't engage in much sex. Financial constraints were also stated as a reason for using on-demand dosing.

> *'very, very comfortable with on demand…depends if some of our clients that are busier, you know, probably more once a day is [best]…a lot of guys travel off to Brisbane, Sydney, Melbourne, overseas. There is a few guys now that are on PrEP that have female friends that live in Bali and Thailand and some of the fly-in fly-out miners are now on PrEP and they use it very much intermittently.' [Regional SHS nurse]*

This risk behaviour profile of PrEP users was consistent with other HCP reports about their clients who were taking or interested in event based/on-demand/intermittent dosing:

> *'Because they're not that sexually active, and taking a pill a day was a bit useless for them, so they were just taking it when they needed to take the medication….you know, if you're not having sex every weekend or every day….just a backup plan … I kind of suggested maybe condoms, but I don't think he liked that idea.' [Urban based public SHS nurse]*

> *'[The] on-demands are probably more people engaged in group settings. Because it's more planned, in that sense; so they'd know about the orgies or big things coming up, so they can plan for it. So on-demand would apply more in that situation. But definitely the day-to-day ones, "I've just hooked up with a guy last night, got drunk", whatever. I find they're probably more every day, but I would hate to think they do it on-demand in that situation…As long as they're knowledgeable about what it is, and side effects, and how the patient can best use it, fantastic. As long as they're monitoring properly, according to PBS guidelines and all that, I don't see why they can't prescribe this.' [Urban community GP Nurse]*

PrEP naive people are still presenting seeking PrEP

The majority of HCP interviewed felt that requests from PrEP naive people to initiate PrEP were continuing. Some HCP reported that as '*lots of local GPs are doing PrEP'* clients seeking to initiate PrEP and referral from GPs for PrEP had dropped off, however in some services there was a perception of ever increasing numbers of new clients requesting PrEP.

On the whole, these were thought to be mainly MSM with the same risk and demographic profile as the QPrEPd participants, however, PrEP requests included PrEP naive people, people who think that now PrEP is not a trial the drug has been proven to work.

Others included Heterosexual people at risk while travelling for work or pleasure, people with newly HIV diagnosed partners seeking PrEP while viral loads are stabilising or partners living with HIV overseas who may not have reliable access to HIV care. Some services expressed concern of the continuing limited numbers of Aboriginal and Torres Strait Islander peoples seeking PrEP despite being a priority population within their HHS area:

'It's interesting, though, anecdotally, we've got a new cohort of people, only a small number, who were never on the demonstration project, and a couple of them have commented, now that it's not a trial, and been proven, yes I do want PrEP, and I guess their thinking was, they saw it on websites that there was a trial, but they didn't think that it was absolutely, 100 percent, ridgey-didge.' [Regional public SHS Nurse]

Interestingly, some HCP described that some clients are still reluctant to use PrEP. One urban based HCP described clients expressing fear about perceptions of changed behaviour among the community and increased risk of other STIs. There also appears to still be a value judgement associated with PrEP use among some clients that hasn't changed over time.

The HCP could broadly identify a range of PrEP promotion strategies, however, many considered people hearing about PrEP by 'word of mouth' from friends and or sexual partners were common reasons stated when clients presented asking about PrEP:

'I would feel that word of mouth is probably the biggest. So peer discussion is probably the biggest impact. Because most of my clients will say, "A friend told me", or, "A friend's on it", or, "I got told to do this." It's not, "I read a poster in a toilet", or, "On the condom packet I saw this ad." No, it's never that. It's always just, "My friend said."' [Urban community GP Nurse]

8.4.9 Pharmacy and Script Dispensing Medication

All QPrEPd sites were visited by the trial pharmacist and QPrEPd Clinical Director from the SMT for a final closure audit. The remaining unused study medication was returned from study sites to the sponsor pharmacy at Cairns Sexual Health Service. Drug accountability was communicated to sites in the closure audit feedback (Table 63).

Table 63: Drug accountability – Unused study medication

Batch number	Quantity (number of bottles)	Expiry date
#3057022	287	July 2019
#3068798	10,725	May 2020
Total	**11,012**	

Negative experiences such as feeling judged; Comments on waiting times, or need to pre-order?

Dispensing of PrEP from the local HHS hospital-based pharmacy varies according to HHS policy. A few of the HHS public pharmacies informed the public SHS that they '*did not want to stock PrEP'* or keep stock on hand:

'Not from the hospital pharmacy…No, definitely not. [People living with HIV] can but not PrEP. There was a big memo that came out about that, and they don't supply any of that stuff through our hospital pharmacy, and I can't remember why, but there is a reason.' [Regional SHS Nurse]

This had resulted in some of the SHS HCP engaging in time consuming consultation and negotiation processes with the public HHS pharmacy to maintain access for clients wishing to access PrEP via this pathway. Negotiations were ongoing in some locations, but for one HHS these ended with the realisation that there was a financial incentive to the HHS to dispense PrEP, though all funds acquired were directed to the central HHS pharmacy budget not the SHS operational funds:

> *'…we did a fair bit of work, and were able to get them to do it, only once they found that we could make some money on it. I'm not quite sure exactly how that system works, but there is a financial incentive for the HHS to do it, so then they came on board. But you're right, they initially were very negative about the whole thing.'*
> *[Regional SHS Physician]*

A small number of SHS have onsite pharmacies making script dispensing streamlined and convenient for the clients. At other SHS, clients must attend the HHS pharmacy located at the tertiary hospital precinct. This, however, was not the preferred option among some clients as the HHS pharmacy was often located on the tertiary hospital precinct that was a considerable distance from the SHS with expensive onsite parking. Clients reported to HCP that there were often long waiting times, in excess of two hours, at the hospital-based pharmacies and in some cases HHS pharmacies also held limited stock and needed 1 to 7 days to fill PrEP scripts:

> *'the costs to go out to the hospital is too great to most of them, you can't get 'Close The Gap' scripts out there….You can't get parking, so if there's no public transport…the location from where you are, it creates barriers for them.' [Regional SHS Nurse]*

Services, both public SHS and GPs, were mostly recommending and/or assisting clients to obtain their PrEP from local community pharmacies as these were more convenient and flexible for most clients' needs. In some instances, study site investigators described actively visiting local pharmacies during the study closure period to negotiate pathways of access for clients:

> *'The two pharmacists that I have personally approached are within two walking blocks from this clinic and they're the ones that are holding it on their shelf. '*
> *[Regional SHS Nurse]*

Some of the S100 GPs and practice nurses working in high case load practices, and staff working in SHS located in community health settings, both described having an existing relationship with a local community pharmacy, so keeping the process as simple as walking up the road to let them know clients would be coming in to get PrEP: '*He keeps it on [the] shelf. He stocks lots of it for me. He has heaps.' [Urban-based S100 GP]*:

> *'The clinic is in a group of shops, there is a pharmacy, so the first thing that I did when this happened… even before the closure of the PrEP trial, I went to talk to them …. because many of my HIV patients follow me as well, so I offered the possibility of PrEP … the patient… as soon as they leave my practise….they can just get the PrEP from next door.' [Urban S100 GP]*

> *'We have a chemist right next door to us that keeps stock of it, obviously because we're right next door. I think there have been maybe one or two, since the beginning of this year, that have struggled to find a pharmacy, and they generally ring us, and we'll just direct them to the pharmacies that we know either stock it or order it in.'*
> *[Regional SHS nurse]*

Services with established pathways for accessing ART for people living with HIV (PLHIV) from community pharmacies and those community pharmacies involved with dispensing Hepatitis C treatment reported a relatively streamlined pathway of access for PrEP users through this network. One regional public SHS staff member reported that their hospital pharmacy did not stock or encourage clients to access PrEP through this avenue, and that dispensing from community pharmacies was the preferred option as per the model of care in place for all Hepatitis C and B treatment:

'You can't, you're not allowed to go [HHS Pharmacy] they can't go they'll be turned away and told to go and find a community pharmacy… like the Hepatitis C treatment. No-one can go for Hepatitis C treatment'. [Regional SHS Nurse]

Some of the larger chain community pharmacies use mobile phone applications as a recall system to remind clients their script is due to be filled with clients receiving a text message that their order is ready to pick up. These limit waiting times, facilitates more timely access and is a service not widely offered at public HHS pharmacies:

'The community pharmacies…are good, because they've got those reminder systems in place, so they'll SMS them and tell them when they need to go in for their next script and all that kind of stuff, which is much better than the hospital pharmacy.' [Regional SHS Nurse]

Many of the HCP interviewed reported that clients had described some initial issues with accessing PrEP from community pharmacies such as pharmacy not willing to stock PrEP due to potential cost and loss of profit, no stock on shelf for same day script dispensing and having to wait two to seven days for their script to be filled. Some also described clients being turned away and having to go to several pharmacies to find one willing to dispense. Some HCP raised the concern that for some clients this may result in missed PrEP doses:

'A lot of pharmacies still didn't have any shelf stock, and just, "Yeah, we'll order it in, come back in three days' time." Which doesn't really help some people, so we get a bit anxious about that. And also we did have an issue where some pharmacies were turning people away, and not dispensing the PrEP….. Couple of days later you go to get the drug; in those couple of days, you could have contracted HIV, and we're putting you at risk." So we had this big argument between pharmacists…' [Urban community GP Nurse]

'We did have clients that weren't able to get it from local chemist, they come back to us, and I actually myself called around for one patient. Out of seven pharmacies, only one accepted, provide the medication for that person. I think the reason is twofold… medication is very expensive, and they have to wait almost three months to get GST back… second part of it is, they don't know how to dispense this medication.' [Urban public SHS staff]

There was a sense of a general lack of PrEP knowledge among pharmacist and serving staff. There were also reports of other negative experiences including: stigmatisation and discriminatory attitude from pharmacy staff and inappropriate questions at the service counter that raised concerns about client confidentiality especially those who are not 'out' within their community:

'When they go to get their PrEP script filled… there is the assumption that they are positive… also happening with the specialists, the specialists are treating a lot of my patients as if they have got HIV. Yeah, and they just don't get it. Oh, they are discrimination against people when they pick up with their TRUVADA, because they think that they have got HIV.' [Urban S100 GP]

These reports have decreased over time, as one HCP described, it had been a '*long-time since we have had any complaints re pharmacy.*' However, some of the regional/rural based HCP thought that there were still barriers to access for people living in these areas, as some clients where reluctant to use the local pharmacy and were having to travel over one to two hours to access a community pharmacy. Access was further restricted if these pharmacies didn't stock PrEP for same day dispensing and clients were trying to coordinate an appointment with a script dispense..

This required people to have the health literacy and support to self-manage their supply chains, and for clinicians to consider on a case-by-case basis whether someone in these situations are eligible for a Regulation 24 or special authorisation allowing access to supply of three to six month supply at one dispense:

Some services were actively assisting people to order PrEP online. The ability to access PrEP via internet ordering, particularly from overseas websites, has particular benefits for regional residents, those traveling, and Medicare ineligible people. In most instances, the HCP reported that clients felt that this was cheaper than PBS and more convenient as they could routinely access 3-month supply compared to having to return monthly to the pharmacist under PBS.

> *'I think the concern we had is for the Medicare-ineligible people. So that would be the greatest concern that I had, for those people….There were some people Medicare-ineligible… decided that the costs from getting medication, generic medication from overseas, was a little bit cheaper than paying the co-payment at the pharmacy, so they chose to… There was a couple… they were actually importing it before the trial started, so they went onto the trial and then they've sort of just gone back to importing, because of the costs.' [Regional SHS nurse]*

8.4.10 PrEP prescription in Primary Health Care – who should be responsible?

There was general consensus that it was not necessary for a Sexual Health/HIV specialist or S100 authorised GP to prescribe PrEP. A generalist GP should be able and willing to prescribe PrEP: '*GPs in the ideal world should be able to do this'* with a person's regular GP the best suited as they know the client and can provide comprehensive primary health care:

> *'Let's face it, this is not rocket science, it's not difficult. It's just a sexual health check with a couple more tests and someone who is confident enough and legally able to prescribe. It's not difficult.' [Regional SHS nurse]*

> *'I mean, it's a bit like Hep C treatment, isn't it? I think that there's no reason why they can't do it, provided that they monitor that patient, have all checks and balances in place in regards to bringing that person back and doing all those things.' [Regional SHS nurse]*

However, a common theme of concern was the preparedness of some generalist GP to prescribe PrEP correctly and safely. Many study HCP expressing concern that they were not sure if some GPs were doing STI screening or renal testing as per the guidelines. Some interviewees even queried if GP were checking if their clients were getting the recommended pathology done, as they felt many PrEP users were still coming to the SHS services for free STI and renal testing, and the PrEP users were not requesting their results to be shared with their PrEP prescribing GP or other primary health care provider. All expressed the need for the GP to have some foundational knowledge of PrEP and broader sexual health awareness and competence:

'I think the conservative nature of a lot of the GPs here, there's not a lot of bulk-billing that goes on, it's five-minute medicine, so the questions aren't being asked, swabs aren't being taken. Historically, we've had – so many of our clients have never had rectal swabs and throat swabs and things like that done, and they've only had blood tests done and nothing else. In an ideal world, it should be being done, but unfortunately it isn't ideal, and I think that's why a lot of clients keep coming back to us, because they feel safer. For those we've helped, they feel safer, that they're getting things done in a more systematic, correct way, with a specialist service. We don't have huge waiting lists or anything.' [Regional SHS nurse]

Others thought that there was also a danger of less monitoring of PrEP knowledge, risk behaviour and testing by generalist GPs, and expressed concern that new users may lack preparedness and understanding about the importance of regular testing, and the dangers of stopping and starting PrEP as with on-demand regimens without knowing their HIV status:

'One of the concerns that I had with the closure was if people were given a script by a GP and they kept it in their top drawer for a month, then they went to the pharmacy and they didn't pick it up for three weeks, you know, then they haven't had an HIV test before they start their PrEP, so they've had.' [Regional SHS Nurse]

Several services described how they had actively engaged in teaching local GPs about PrEP as part of their '*role of advocacy in the community – what can and can't be done either by law or PBS authorisation*'. Though one regional HCP described sensing that most of the GPs they approached were not interested, with one GP stating, '*I don't believe in it, I don't want those people in my waiting room*', further stating that they have also experienced local GPs '*not wanting to prescribe contraception or RU486 [for medical termination of pregnancy]*', but that '*they will keep chipping away*' on behalf of their community.

Some study HCP acknowledged that GPs who had completed S100 training or those with a special interest in HIV and sexual health were probably best placed to take on PrEP care in the generalist PHC context.

'There's a lot of GPs who've done the S100 course, but don't actually practise because they don't have enough caseload to maintain the competence or confidence. But they're ones, I reckon, even if they're not registered in S100, I reckon they're the ones that would be good because they'd had that foundational knowledge.'
'[S100 GP practise nurse]

However, many suggested that all HCP provider education about PrEP and sexual health care more broadly, needed to be increased and ideally commence early within training programs to improve the potential for sustained change:

'It probably does belong more amongst doctors who do have a bit of a special interest, to be honest. Or, if you started educating the medical students as they came through, but then you would have to do--I feel like sexual health is extremely uneducated in medical school. I have medical students sit with me and they are still very confused between HPV and herpes virus. So, that's where--and then you talk about something at much higher level than HIV. So, that would just be way too confusing.' [Urban S100 GP]

Similar to experiences and concerns accessing local community pharmacies in regional areas, with many describing real and perceived fear and experiences of discrimination and breaches of confidentiality, with 'too much talk in a small town' as an ongoing issue for people accessing local GP practices:

'I agree with that [PBS listing allowing any GP to prescribe] I think we really need to have that access, particularly in regional and remote…..I think the issue is around the knowledge of particularly risk and also men who have sex with men and also access…. I think there are lots more problems around shame and stigma, discrimination, lack of knowledge… still significant barriers.' [Region SHS HCP]

Some described how their clients preferred to keep their sexual health separate from their general health care and this was no different with how clients were wishing to access PrEP:

'A lot of people just say, "Look, I don't go to my GP for my sexual health." … They want their GPs looking after their blood pressure. They want their GPs to be looking after other things; and sexual health, they want to be able to be open, be able to ask the questions, and be as… and get as informed information as possible…sexual health centres have the capacity and experience to provide a comprehensive prescribing as well as the overarching support and information about PrEP; and I don't think general practise has that, and I don't think it has the capacity for it in the future.' [Urban SHS nurse]

A mixture of service models and disciplines assessing PrEP eligibility and providing prescriptions was considered essential. Public SHS were deemed well suited to cater for the more marginalised *'chaotic*' client; as opposed to GPs for people '*with their act together'* who have a Medicare card and were able to pay. It was also considered vital for Aboriginal Community Controlled Health Services to be involved with PrEP provision. However, the lack of bulk billing GPs and alternate 'free' primary health care services in most locations were identified as significant barriers for people accessing PrEP in locations other than public SHS and bilk billing GP practices. Some HCP suggested clients were out of pocket by $30-$80 before having to consider paying the private laboratory costs and the PBS dispensing fees.

There was also concern that there had been limited uptake of PrEP related work within local non-S100 GPs and other primary health care facilities, including Aboriginal community controlled health services (ACCHS), despite active engagement with staff. One regional SH specialist suggested funding models incentivising key performance indicators (KPIs) for chronic disease highlighted the lack of similar incentives for sexual health, STI and BBV, noting *'there is no KPI incentive for PrEP*'.

Telehealth was proposed as one method of addressing some of the barriers to access and uptake among regional and remotes populations, especially if a local nurse competent in sexual health and HIV prevention and care was engaged:

'you might have an NO6 who is capable and has got service delivery managed up to be able to do tele health consultations to the doctors at [clinic name], but when they get their script through the fax are they going to be willing to take it to the local community pharmacy? Because the pharmacist will see the code. One plus one equals two… there's too much talk you know.' [Regional SHS nurse]

Consideration also needs to be given to nurse-led models of PrEP assessment and prescription. Nurses positioned in the public SHS and specialist HIV GP study sites were considered to be integral in facilitating rapid PrEP uptake among at-risk Queenslanders. The PBS physician-led model of PrEP provision, restricts nurse input and shifts workload to physicians. Participant reports of inadequate STI testing, refusal to prescribe, discrimination and stigmatisation in generalist settings, raised concerns of generalist nurses and physician preparedness to prescribe PrEP and provide comprehensive sexual health care, and the roll-on associated risk of harm this may hold for at-risk populations:

'I think an idea of having a nurse-led model of care for PrEP and stuff like that would be ideal.' [Urban SHS nurse]

Responsive models of nurse-led PrEP delivery are necessary to ensure equitable access, particularly for those living in regional areas where access to providers with PrEP knowledge is limited. Nursing involvement across a range of practice settings is essential to foster comprehensive HIV prevention pathways for priority populations. Education of generalist nurses and physicians must incorporate clients' broader sexual health and, HIV/STI testing needs in, addition to addressing stigma and discrimination. A significant barrier for this to occur within the generalist GP setting is the inability for nursing activity to be renumerated through Medicare Benefits Schedule (MBS) item codes.

9. Discussion

During the study implementation, the aim of the M&E component was to examine the feasibility and acceptability of the QPrEPd model of PrEP provision, explore barriers to access and uptake, and assess whether access was equitable for priority groups across the state. During the study closure, the aims were to explore the real-life experience of the participants and HCP during the study closure and transition to the PBS model of PrEP delivery. This report has addressed these aims using the following key questions:

1. What were the experiences of participant's uptake of PrEP in urban, regional and remote areas during the trial?

2. Was there equitable access of PrEP by key priority target groups during the trial?

3. Were there any key differences between the original QPrEPd cohort and the QPrEPd-X cohort during the trial?

4. What were the experiences of participant's and service providers during the trial closure period and transition to the PBS model of access?

5. Were there any negatives or positives of the early closure?

6. Were there any unmet needs or barriers to uptake, access, continuance, or adherence of PrEP after closure of the trial?

This section summarises the key findings and presents a range of points for consideration in relation to practice, policy and future research.

9.1 QPrEPd experience and impact

The majority of HCP and participants interviewed at entry to QPrEPd and after the closure described QPrEPd with optimism, having achieved the intended goal of increasing access to PrEP for Queenslanders. The positive impact of the QPrEPd study and broader PrEP availability on individual participants was strongly illustrated in the interviews and survey data, with people stating it 'changed their life' by making them confident and comfortable to enjoy sex for the first time. HCP and PrEP users alike believe that increased availability of PrEP has been one of the strongest steps towards eradicating HIV in Australia.

For the study site HCPs there were also a number of benefits associated with being a study site which they hoped would continue post study closure. QPrEPd was attributed with increasing their service engagement and credibility within their local community, attracting new clients including those from previously hard-to-reach priority populations, and contributed to increased rates of STI and HIV testing among never and infrequent testers.

There was however a strong sense of pressure to become a "PrEP factory" among some HCP and this had significant roll-on effects on some services capacity to meet needs of other clients[25]. HCP highlighted the need for careful consideration of workloads and clinic capacity when rapidly rolling out new services or large scale research projects, such as QPrEPd, where there was no additional financial compensation or clinical or administrative support to assist this process. There appears to be conflict between these two outcomes for services. On the one hand many being encouraged that people with previously suboptimal service engagement were now attending, but, on the other, being displeased with the added strain on service capacity from the increased pressure on clinical workload, raised pathology costs and service reorientation.

9.2 Experiences and access for key priority target groups during the study

Enrolment numbers fluctuated throughout the study duration as people withdrew and new participants enrolled. The total highest number of participants enrolled in QPrEPd was 2,331 and for the QPrEPd-X arm was 598 (n = 2,929).

Again, the majority of participants identified as gay (68.2%, 1,988) or bisexual (10.1%, 295) cis-males (76.2%, 2,220), aged between 20 and 39 years of age (62.6%, 1,823). Most were born in Australia (76.9 %, 1,754), and living in a major city in South East Queensland (SEQ) (77.8%, 1,763).

These characteristics of the total QPrEPd cohort are very similar to those of the participants that enrolled within the first seven months of QPrEPd implementation, '*the early adopters'*, outlined in the first annual report[1].

These results suggest that QPrEPd and QPrEPd-X engaged and continued to recruit people who would most benefit from the use of PrEP from among the priority populations identified as at high risk of HIV in both the national[26] and Queensland [27] strategies, and in 2018 surveillance data[21]. QPrEPd and QPrEPd-X also continued to provide a platform for engaging people into sexual health care and increasing HIV and STI testing rates among never (15.6% of total enrolled) and sub-optimal testers.

There were no significant noticeable differences between the QPrEPd and QPrEPd-X participant profiles, so for the purposes of this final discussion, all participants will be referred to under the overarching QPrEPd study title.

It is also important to note that demographic marker details collected at screening and enrolment of participants were minimal and included no behavioural items. This meant we were unable to report the profile of all 2,929 participants enrolled in QPrEPd, and the correlation of demographic markers with patterns of behaviour. PrEP use and clinical case report data is only available for those participants who voluntarily completed the entry survey (n = 2280).

9.2.1 Age distributions of people accessing PrEP

The spread of QPrEPd participants screened across the age groups and those who are actively enrolled in the QPrEPd study is reflective of the age groups represented in the notification data extracted from the Queensland NOCS data on 4 June 2019[17].

Notifications of newly diagnosed HIV cases in Queensland in people aged 30 years or older have declined in these figures, however, among people aged 20 to 29 years notifications have remained relatively stable.

Just over one third (32.5%, 946) of QPrEPd participants were aged between 20 to 29 years of age. However, the notification trends suggest that promoting access and uptake of PrEP among this age group should continue to be a focus of PrEP campaigns.

While the demand for PrEP among people under 18 years of age is unknown, sustained notification in the 20 to 29 year old age group warrants further exploration of the HIV risk and need for PrEP along with barriers to access and uptake among young people under 29 years of age.

9.2.2 Regional and remote populations access, uptake and barriers

The majority of participants (77.8%) resided in a major city of SEQ and had to travel less than 10km to their study site. The distribution across areas of remoteness is similar to those reported in the 2017 Annual Report (Table 64) and is reflective of the Queensland population distribution whereby approximately 70% of Queensland's population live in the SEQ area.[19, 20]

Table 64: Percentage of Participants by ABS Area of Remoteness (%)

	% of Participants	
ABS Area of Remoteness	**2017 Report (n=1421)**	**Final Report (n=2266)**
Major Cities of Australia	78.9%	77.8%
Inner Regional Australia	8.3%	9.0%
Outer Regional Australia	12.5%	13.0%
Remote Australia	0.1%	0.1%
Very Remote Australia	0.07%	0.1%
Total	100.0%	100.0%

Participants living in regional and remote areas of Queensland continued to demonstrate a willingness to travel considerable distances to access PrEP with 5.9% (133) travelling more than 50km to their study site. This suggested a highly motivated group of health literate people aware of their HIV risk with the resources to travel these distances. However, with the majority of study sites located in inner regional and major city locations, travelling these distances was the only option for people wanting to access PrEP under a demonstration model. This raises concern for those who did not have the resources or health literacy needed to seek out and travel to these locations.

Access through local GP services and community pharmacies under the PBS access model may address this need to travel. However, MSM and other marginalised populations and communities, living in regional remote areas may be reluctant to access these services locally due to perceived and enacted experiences of stigma and discrimination.[28]

It also remains unknown if there are services and/or HCP in these areas that have the skill and/or willingness to provide access to PrEP and appropriate safe sexual health care.[29-31] More understanding of the barriers for accessing PrEP for regional remote living people is needed, and consideration also needs to be given to innovative models of care to improve access.

9.2.3 Aboriginal and Torres Strait Islander peoples access, uptake and barriers

In total, 78 (3.4%) participants identified as Aboriginal and Torres Strait Islander peoples. This number had risen from the first annual report when there were only 42 (2.9%) Aboriginal and Torres Strait Islander peoples among the 1,674 active participants[1]. As stated in section 8.1, the total numbers of Aboriginal and Torres Strait Islander people screened or enrolled into QPrEPd is unknown as Aboriginal and Torres Strait Islander status was only collected on the entry survey, and not as a required demographic marker on the CRF data collected at the screening or enrolment clinical visit by clinicians.

Nonetheless, and consistent with the first annual report[1], the last available enrolment figures of 3.4% (QPrEPd) and 3.8% (QPrEPd-X) suggest the proportion of Aboriginal and Torres Strait Islander peoples is similar to the 2016 Census data which reported that 4% of the Queensland population identified as Aboriginal and/or Torres Strait Islander peoples.[32]

However, in both QPrEPd and QPrEPd-X cohorts, Torres Strait Islander peoples remain noticeably underrepresented (5.1% of total Aboriginal and Torres Strait Islander people sample), as compared with 11.3% of the 186,482 people who identified as being of Aboriginal and/or Torres Strait Islander origin in the 2016 Census.

The total proportion of Aboriginal and Torres Strait Islander people who identified as one of the HIV priority target groups such as gay, MSM and/or as Two Spirits is unknown, due to the data limitations stated previously. Nonetheless, gay, bisexual and two spirits Aboriginal and Torres Strait Islander peoples, were represented among the QPrEPd cohort. These were, however, primarily urban living Aboriginal and Torres Strait Islander peoples who were aware of PrEP, perceived themselves to be at increased risk of HIV, and were either self-motivated to seek out a study site and access PrEP or were already accessing sexual health care at one of the study sites.

This suggests barriers to access and uptake continue to exist for Aboriginal and Torres Strait Islander peoples, particularly those living in regional areas and who might not have access to appropriate and accessible health information and or services offering PrEP. HCP interview questioned whether these barriers have been addressed by PBS listing for some. One study site CI from a regional public SHS reported that a considerable proportion of their clinical consultations were with Aboriginal and Torres Strait Islander peoples. However at the time of the interview, no Aboriginal or Torres Strait Islander person accessing the service was taking PrEP, even amongst those at risk of HIV.

Further exploration of the barriers and facilitators for PrEP access and uptake experienced by Aboriginal and Torres Strait Islander peoples at risk of HIV, particularly those living in regional and remote areas of Queensland, is still needed to ensure equitable and appropriate access is achieved and maintained.

The first Annual QPrEPd Report identified that PrEP access for Aboriginal and Torres Strait Islander peoples was inequitable. A significant amount of work is still required to identify and address barriers to accessing PrEP and to understand how to implement and promote PrEP uptake in a culturally safe and effective manner that does not undermine the longstanding embedded harm minimisation and safer sex prevention messaging.

Considerable work is being conducted in north Queensland under the North Queensland Aboriginal and Torres Strait Islander sexually transmissible infections action plan 2016−2021[33]. However, further understanding of Aboriginal and Torres Strait Islander peoples HIV vulnerability beyond the epidemiological data and new HIV diagnosis notifications rates is warranted across the state.

This must include:

1. understanding of the social determinants of health influencing their vulnerability and the realities of their personal community including their gender and sexuality identities and fluidities
2. exploration of how more Aboriginal Community Controlled Health Services (ACCHSs) and other AMS could be supported to provide access to PrEP and expanded sexual health HIV services, particularly, given the current trending upward of new HIV diagnosis among Aboriginal and Torres Strait Islander peoples
3. exploring the awareness and understanding of ACCHSs staff and other Aboriginal and Islander health care workers (HCW) in regard to PrEP along with their perspective on how best to promote and implement PrEP into their communities and existing practice.

Concerted and sustained efforts at local, state and national levels is required to understand and address the complex interplay of factors influencing PrEP use within the HIV and sexual health work currently being undertaken with Aboriginal and Torres Strait Islander peoples and communities.

This includes:

1. education and support for Aboriginal Health Workers and staff at ACCHSs

2. whole of community sexual health, HIV and PrEP awareness and education

3. the integration of PrEP with broader sexual health HIV messaging and alcohol and other drugs work and

4. the need to build onto existing services, particularly those using peer educator/recruiters and community development models.

9.2.4 People born overseas and Medicare ineligibles access, uptake and barriers

HIV notification rates among Australian-born people has remained relatively stable over the last decade (2008 to 2017).[21] However, with almost half (46.6%) of all National HIV notifications in 2018 among people born overseas,[16] and the proportion of notifications among MSM who were born in Asia (Southeast Asia, Northeast Asia, and Southern and Central Asia) has continued to increase over the past 10 years (28% in 2008 to 52% in 2017[21]). It is therefore increasingly important to target PrEP education and access for people born overseas in these and other high prevalence countries.

Of the 526 participants who reported that they were born overseas on their completed entry survey, 24.5% (129) were from Asia (South, East or South-East), 13.1% (69) the Americas (Latin, Caribbean and North), and only 4.4% (23) were from the Sub-Saharan Africa region, the three regions with the highest HIV notification rates in Australia's 2017 National surveillance data.[21]

The proportion of participants born in Asian regions and the Americas enrolling into QPrEPd remained similar across the 24-month duration of the study to those reported in the 2017 first Annual Report; 22.4% (74/329) and 12.7% (42/329) respectively. However, the proportion of people born in Sub-Saharan Africa dropped from 5.7% (19/329)[1] to 4.4%, suggesting that while the QPrEPd model of PrEP dissemination continued to facilitate access and uptake for some overseas born populations, consideration needs to be given to the nuanced sociocultural and structural barriers and the geographical and service context where people are living and are able to access PrEP.

It is well recognised that people born overseas face a range of complex and intersected barriers to access HIV testing and health care in general in Australia[34, 35], particularly those who are Medicare ineligible.[36, 37] The proportion reporting they had no Medicare Card was up slightly from the 2.4% noted in the 2017 Annual Report[1] to 3% (69).

While a promising trend, the closure of QPrEPd, Medicare ineligible people seeking PrEP will now be faced with additional barriers to access. They may be seen at some of the public SHS, but they will be unable to access PBS subsidised PrEP, thus being forced to pay full price, import from overseas, or cease taking PrEP.

Only 72 (2.5%) of participants reported they were on a student scholarship or allowance, suggesting international students studying in Australia may also be experiencing financial barriers to PrEP access and uptake. Studies have been found to have limited sexual health/HIV/PrEP knowledge, misconceptions about HIV prevalence and risk, engaging in frequent travel back and forth to countries of high prevalence, and low STI/HIV testing rates among international students studying in Australia. This, often combined with sexual initiation and freedom to explore sexual orientation in Australia, which has the potential for transmission and later diagnosis of HIV and other STI within this population.[38-41]

It is therefore imperative barriers to PrEP access and uptake among people born overseas who are at risk of HIV are identified, are understood and addressed as we move forward under the PBS model of PrEP delivery. Achieving equity of access for all people at risk of HIV in Australia will require continued discussion, surveillance and implementation of innovative targeted strategies and solutions that address the needs of people born overseas at risk of HIV.[42]

9.3 Relationship diversity, condomless sex, and STIs

During the study there was a significant increase in the number of self-reported sexual partners people had in the previous six month period (P <0.001). Consistent with other Australian[43, 44] and international studies[44], there was also an overall significant increase in condomless anal intercourse (CLAI) with regular, 'fuck buddies' and casual sexual partners between enrolment and 12-months (*P* <0.001).

9.3.1 Gender diversity of sexual partner/s

The majority of QPrEPd participants identified as gay males having sex with other men. This report however also highlighted the gender diversity of sexual partners reported by the gay, bisexual and heterosexual identifying participants. Bisexual identifying men have gender diversity among their sexual partners, but experiences of heteronormativity, homophobia and judgement may prevent disclosure of the gender diversity and the full nature of their sexual behaviours and relationships [45-47]. Without further discussions between HCP and clients, there may be the assumption that 'a man with a regular female partner' in Australia is at low risk of HIV. However, the additional sexual identity and 'activity' data outlined in this report suggests further consideration of anatomical site specific STI testing, and access to PrEP for them and their partner/s is required. Given the known reticence of non-sexual health specialist HCP to initiate discussions about sex with clients,[48, 49] this diversity and potential for HIV exposure will remain unknown, resulting in missed opportunities for discussing PrEP eligibility, adequate and appropriate testing, and provision of health information unless additional training is in place.

9.3.2 STI risk and rates

Increasing CLAI results in increased risk of transmission of STIs with some studies reporting an association between PrEP and increased rates of STI, particularly around commencement and in the early stages of using PrEP[7, 8].

Among QPrEPd participants there was a noted gradual deceasing trend in STI prevalence over time. However, an increasing STI positivity was associated with CLAI with a casual partner (aOR 1.19 95% CI 1.10, 1.28; *P* <0.001) and group sex involving two or more other people (aOR 1.20 95% CI 1.11, 1.30; *P* <0.001) [3, 4]. Increased STI risk was also associated with being younger (aOR 0.99 95% CI 0.98, 1.00; *P* 0.01) suggesting STI risk is different for subsets of PrEP users.

HIV prevention campaigns need to take into consideration these differences and tailor the communication strategies accordingly to include PrEP as an adjunct to the existing portfolio of STI / HIV prevention strategies. This is particularly important given the rising rates of infectious syphilis, gonorrhoea and Lymphogranuloma venereum in Queensland,[50, 51] the rising rates of antimicrobial resistant gonorrhoea rendering treatment increasingly challenging[52], and the potential lack of GP awareness to treat rectal chlamydia and pharyngeal gonorrhoea infections differently to genital infections due to reduced drug penetration [53].

Post study closure, 28.2% (n=67) of the 6-month follow-up survey respondents continuing to use PrEP reported having been diagnosed with an STI following QPrEPd closure, indicating an incidence of 15.3% for both chlamydia and gonorrhoea and 9.2% for infectious syphilis in the cohort of current PrEP users. This suggests people are being diagnosed with STI at similar rates as during the study.

It is important to note that 63.0% of the people who had stopped taking PrEP 6-months post study closure had engaged in condomless vaginal and/or anal sex with at least one partner but only one third had been tested for HIV and other STIs. With one in five (22.2%) non-PrEP users reporting an STI diagnosis since exiting the study, this indicates non-PrEP users are reducing their testing frequency but still engaging in risk behaviours for acquiring STIs including HIV. Entering into a monogamous relationship was cited as the reason for stopping PrEP by 13 of the 27 participants who had ceased PrEP, with a further 8 of the 27 no longer being sexually active. However, the timing of ceasing PrEP and the most recent STI test were not explored.

There are limitations to both the post closure self-reported STI rates and those reported above from the QPrEPd clinical case reporting data that may suggest under or incomplete reporting of STI diagnosis rates. Firstly, there may be recall and reporting bias with the post closure survey figures and secondly during the study duration there was no mechanism for recording or identifying if QPrEPd participants had been diagnosed with an STI outside of the 3-monthly study clinical case reporting at another health service. Additionally, people not engaging in any sexual activity may not require further STI testing, as long as appropriate window periods were observed at the time of their last test. The subtleties of timing of last STI tests with times of most recent sexual encounter were not explored.

Nonetheless, with all physicians now authorised to prescribe prophylactic ART following the change to the Australian government-subsidised PBS, on 1 April 2018, consideration needs to be given to improving generalist GP knowledge and awareness of the changing local and national STI notification trends and emerging treatment challenges.

Research has shown a reluctance among some GPs and practice nurses to discuss sexual health with clients[49, 54]. This finding is supported by the experiences and challenges reported by both QPrEPd exiting participants and HCP with regard to accessing PrEP and adequate STI testing during the transition of PrEP access from the demonstration study model into PHC settings.

It is essential that PrEP education for GP and supporting PHC staff includes comprehensive sexual health and STI testing education and clinical upskilling. Such training has been shown to increase willingness to engage in appropriate sexual health conversations and care with patients[55].

9.4 PrEP dosing practices and preferences

9.4.1 Adherence to daily dosing

Given the proven efficacy of PrEP,[56, 57], decreasing rates of consistent condom use may not pose a problem for the onward transmission of HIV.[58] The efficacy of PrEP is however dependent on adherence. Adherence to the recommended daily dosing was high among QPrEPd participants [3, 4] consistent with other PrEP studies [59, 60] and the majority of respondents continuing to take PrEP during the six months post study closure did so on a daily basis (92.4%) as opposed to on demand or event driven dosing (7.6%).

9.4.2 Increasing interest and use of on-demand/event based/intermittent PrEP

There is increasing interest in and use of on-demand PrEP dosing, also referred to as event based or intermittent dosing, reported by the participants and HCP in this study, and among interstate demonstration study participants [10, 61]. This highlights the need for PrEP prescribers and users and associated community organisations, along with other HCP engaged with sexual health, HIV and PrEP campaigns, to gain knowledge and understanding of these alternate dosing regimens to ensure dosing and adherence is sufficient to sustain the efficacy of PrEP in preventing onward HIV transmission.

There is growing evidence on the safety and efficacy on-demand PrEP for MSM.[57] In July 2019, Global WHO PrEP guidelines were updated to include the 2+1+1 event-driven regimens for MSM.[24] On-demand PrEP is included in the current Australian guidelines for cis-gender men who have sex with men,[62] however, caution is currently recommended prescribing on-demand or other alternate regimens for other at-risk populations due to a lack of efficacy data for cis-gender women or heterosexual men.[62, 63]

Facilitating wider distribution of these changing preferences, guidelines and eligibility criteria is particularly important, as PrEP prescription increasingly moves into the generalist GP realm away from the specialist settings.

9.4.3 Reasons for stopping PrEP and or withdrawing before study closure

A number of participants stopped taking PrEP or withdrew from QPrEPd prior to October 1, 2018 when the approved Early Closure Plan was executed, and the transition/exit of the remaining participants commenced. Side effects such as nausea and vomiting, abdominal pain, constipation and/or diarrhoea, decreased libido, muscular aches, headaches and dizziness, peripheral neuropathy in the lower limbs, insomnia, extreme fatigue, tiredness, dreams, worsening dermatitis, paraesthesia in extremities and increased anxiety, and feelings of depression were all noted as common clinical indications for participants ceasing PrEP or withdrawing from the study.

However, relocation interstate or overseas, entering into a monogamous relationship, confidence my sex partner was not HIV positive, and sexual inactivity were equally common reasons for ceasing PrEP and withdrawing before study closure. The rate of intentional pill breaks increased significantly the longer people were taking PrEP, this suggesting people were starting to make informed choices about pill dosing possibly related to their level of sexual activity, relationship status and level of perceived risk. This again suggests the need for both PrEP users and HCP knowledge and understanding about alternate regimens and timeframes for safely stopping PrEP post a potential exposure.

9.4.4 Post Study PrEP usage and issues for consideration

The majority of people who completed the post closure follow-up survey (89.8%) reported they had continued to take PrEP, and did so daily in the 6 month period post study closure. However, it appears that among the 10.2% (27) of survey responders who reported to have ceased taking PrEP at some point following the closure of QPrEPd, then people under 30 years old were more likely to have ceased taking PrEP than those 30 years old and older (χ^2= 12.28, p<0.001). Caution is needed due to the small sample numbers, however, sustained rates of new HIV diagnoses among 20 to 29 year old Queenslanders[17] suggests under 30's are among those at highest risk for acquiring HIV. Further exploration of why this age group are disproportionately ceasing PrEP is required.

At the 6-months post study time point, a greater proportion of respondents living in regional Queensland (18.5%) were no longer using PrEP compared to those living in SE Queensland (11.3%) suggesting those living outside of major cities were more likely to have ceased taking PrEP following the closure of QPrEPd than those living in urban areas. This raises the question - *is there is a regional factor contributing to sustainability of PrEP use?* This question remained unexplained by the interviews with PrEP users from regional centres and HCP providing services to this cohort, highlighting the need to keep monitoring and exploring PrEP access, uptake and patterns use by area of residence.

Among those who have stopped taking PrEP, entering a monogamous relationship was one of the primary reasons for ceasing PrEP. Most of these stated that they were very likely to recommence PrEP should the nature of their relationship change, though for many this was dependant on affordability with people openly discussing taking PrEP less frequently to 'stretch out' their supply. This highlights the cost of medication for users as an ongoing potential barrier to uptake despite PBS listing reducing the cost of medication for users to a maximum of $40 per month.

PBS PrEP monitoring data compiled by the Kirby Institute (Issue #1 June 2019) indicates a steadily increasing cumulative number of people in Queensland who have had one or more PBS-subsidised PrEP dispenses, from around the 220 people in April 2018 when PrEP was listed as a subsidised PBS medicine[14]. By the end of September when QPrEPd closure was announced this had risen to 1,280 people; supporting the QPrEPd finding of a natural attrition of QPrEPd participants following PrEP PBS listing on 1 April 2018.

Between October 2018 to December 2018, a period during which all 1,195 remaining active QPrEPd participants were transitioned/exited out and the study closed (30 November 2018), the cumulative number of Queenslanders who had one or more PBS-subsidised PrEP dispenses rose from 1,580 to 2,610.[14] This suggests, coinciding with the execution of QPrEPd closure, that 1,030 people commenced accessing PrEP via PBS subsidy.

It is worth noting these figures do not include people accessing PrEP via Australian or overseas online pharmacies, nor is it possible to ascertain if the people accessing PBS subsidised PrEP are ex-QPrEPd participants or people initiating PrEP for the first time. However, the data does indicate the number of people receiving PrEP through PBS mechanisms is similar to the number of participants accessing PrEP during the demonstration study.

9.5 Experiences of participant's and service providers during the trial closure period and transition to PBS model of access

9.5.1 PrEP access following closure

The majority (96.8%, 241/249) of participants reported they had not experienced difficulties in accessing PrEP prescriptions following closure of the study. This is not surprising as the majority of survey respondents (75.1%; 187/249) continued to access their previous Study Site to obtain their PrEP prescription, stating they chose to remain with care at the study site after the study closed because they were confident and happy with the knowledge (84.4%) and non-judgemental attitude (72.3%) of the staff. Many had been existing clients of the service for more than one year prior to screening for QPrEPd[1].

A small number (33, 13%) reported that they had transferred care from their study site back to their regular GP, and nearly 1 in 10 participants (9.2%) reported transferring care to a service they had not used before QPrEPd. Distance and time to travel to the study site (41.0%) and out-of-pocket expenses (23.1%) were the two most common reasons given for changing service.

Disturbingly given the recommendation to conduct 3-monthly STI testing as part of PrEP prescription guidelines,[63] concern about not getting comprehensive STI testing, including rectal, oral and urine tests for chlamydia and gonorrhoea at each PrEP appointment, was a common reason for returning to their study site after seeking an alternate local GPs willing to prescribe PrEP.

9.5.2 Prescription dispending

A significant number of follow-up survey respondents (17.9%) had imported PrEP from overseas via an online pharmacy, reporting, in a similar fashion to the participants and HCP interviewed post closure, they reported it was cheaper and they could purchase the full 3-month supply, thereby limiting the need for multiple visits to local pharmacies where only one month of PrEP is supplied at a time. This pathway was cited as being a viable option for people who lived long distance from services, travelled frequently and were Medicare ineligible. However, it was also dependent on people having the health and computer literacy, lifestyle, and resources, necessary to plan ordering to allow time for postage to minimise the risk of unintentional pill breaks.

The vast majority (86.6%) of people still accessing PrEP attended local community pharmacies to get their PrEP prescription dispensed. However, this had not been a smooth transition for some participants with approximately 1 in 5 (21.7%) respondents reporting difficulties getting their PrEP prescription dispensed / filled. The majority of those (90.7%) reporting issues with a lack of PrEP stock held by pharmacies, with some having to wait up to 5 to 7 days.

Of the 249 follow-up survey responders, 2 (0.8%) reported issues of stigma and discrimination. It is not clear if the discrimination related to the pharmacy staff association of the medication with HIV or their perception of why PrEP would be required, such as engaging in MSM behaviours. Some HHS public pharmacies had actively advised public SHS staff and clients that PrEP would not be stocked or dispensed. Generally, this had not been an issue, however for some, particularly people living in small regional towns, the anonymity of the large public HHS pharmacy was preferred to going to local community pharmacies.

The incidence of these negative experiences appeared to be reducing over time as community pharmacies gained awareness and PrEP users and local prescribers were identifying ‘safe and willing’ community pharmacies to use.

9.6 Unmet need or barriers to uptake, access, continuance, or adherence of PrEP after closure of the trial

The majority of participants and HCP involved with QPrEPd believed that the addition of PrEP in the Pharmaceutical Benefit Scheme (PBS) has resulted in more people accessing PrEP. Ideally any physician being able to prescribe PrEP should facilitate wider access and increased uptake, however, many were unsure if this would actually eventuate given the ongoing structural barriers of stigma, pharmacy availability and financial constraints.

Follow-up survey respondents and HCP felt awareness of PrEP was insufficient, with community and government organisations undertaking insufficient activities to promote PrEP use and reduce known barriers to access, particularly within the generalist GP setting.

Those that had experienced difficulties having PrEP prescribed, reported GPs lack of knowledge about PrEP, incorrect PrEP prescriptions and poor availability of appointments.

Given that the majority of follow-up survey responders have so far remained at their study site, the true extent of potential barriers to accessing PrEP within the generalist primary health care setting has not, as yet, been tested. However, as has been voiced by many public SHS HCP, and evidenced by action at one public SHS, the demands being placed on public services could result in a directive from HHS executive to actively encourage those seeking PrEP prescriptions away from SHS to allow for other potential service users improved access. As such, it is imperative for generalist primary health care services to be upskilled and able to meet and respond to all the needs of those requesting PrEP appropriately.

Further education of non-S100 prescriber GPs, Practice Nurses, Nurse Practitioners and other health care providers involved with PrEP provision in primary health care and community controlled organisations is needed and must include information on alternative PrEP dosing regimens and comprehensive sexual health and STI testing education and clinical upskilling.

Exploration of the barriers to uptake of non-S100 prescriber GPs, Nurse Practitioners, Pharmacists and other service providers involved with PrEP prescribing and provision is warranted.

Development of alternate models of PrEP service delivery including telehealth is needed.

10. Conclusion

A reduction in new HIV notifications, as the direct result of PrEP is now proven.[56, 57] However, the introduction of any new technology including pharmaceuticals, such as PrEP, initially through the QPrEPd study and ongoing via ARTG and PBS mechanisms, must be carefully monitored and evaluated on a continuing basis.

Reduced notifications of new HIV diagnoses is only one measure of PrEP impact. Indicators measuring impact on the broader social and economic circumstances of individuals, communities and organisations supporting such an important public health outcome are also essential. Ongoing close examination of STI testing patterns along with notifications is also warranted.

In a split-funded health service delivery model, such as between the state and federal governments in Australia, monitoring is especially important where the actions of one party may have potentially unwelcome ramifications for the other.

Whilst some additional burden to services was attributable to participation as a QPrEPd study site, such as REDCap documentation, other pressures will remain now that PrEP is available on the PBS, including increased patient numbers and resulting pressure on clinical time and space, increased pathology and pharmacological costs, and redistribution of medical and nursing workload. The negative consequences would appear to have greater impact on public SHS than private GPs, in part due to differing funding and operating models. The off-set burden through the provision of PrEP through non S100 GP is yet to be seen.

It is often those already at the greatest disadvantage who risk being 'left behind' as systems move forward. The Hon Greg Hunt MP stated in a media release (March 2018)[64]:

'*Access to PrEP will not only benefit gay and bisexual men but will also drive down rates of HIV in Aboriginal and Torres Strait Islander peoples, migrant communities and other population groups which have seen increased transmission rates over recent years.'*

Now that PrEP is available and subsidised within Australia, access to PrEP could be considered 'readily-available' to populations most at risk of HIV. However, equitable access to PrEP, as seen within this report, is more than a medication being available through the PBS mechanisms. Consideration must be directed to populations and communities for whom additional barriers exist, such as young people under 29 years of age and people from marginalised populations and communities, including Aboriginal and Torres Strait Islander peoples, those living in regional and remote areas of residence or not born in Australia, Trans and Gender diverse people, individuals on lower incomes, and persons who experience or fear discrimination and stigmatisation.

The impact of PrEP cannot be underestimated. Without the availability of a vaccine to prevent HIV, PrEP is our most significant new pharmaceutical tool available to assist those at risk from acquiring HIV. Additionally, PrEP assists individuals to proactively reduce their own risk of acquiring HIV, without the need for relying on partners and sometimes inaccurate self-report of HIV status or viral load, as has occurred to date. But arguably and most importantly, the availability and use of PrEP has provided people with the opportunity, often for the first time in their lives, to engage in healthy sexual relationships without the fear of HIV. It is important to underscore this liberation is not at the cost of reduced condom use by all.

Ongoing partnerships between communities and government to ameliorate barriers, which contribute to suboptimal uptake and unsustained PrEP use, now and into the future, as stated in the Eighth National HIV Strategy 2018-2022, are a priority if Queensland and Australia as a whole is to achieve the virtual elimination of HIV.

11. M&E reporting and dissemination plan and requirements

The M&E reporting and dissemination plan is guided by Schedule 3 of the Secondary Funding Agreement (SFA) between State of Queensland, acting through Queensland Health (QH), and The University of Queensland dated on 19 October 2016. All M&E reports to the State were provided in writing (in electronic form) to the contact in Schedule 5 of the SFA via CommunityFunding@health.qld.gov.au

11.1 UQ M&E Team Presentations and Publications

11.1.1 Reports

1. Dean, J., & Warner, M. (2017). Queensland Pre-exposure Prophylaxis Demonstration Project Expansion (QPrEPd) Monitoring and Evaluation Annual Report Number 1. Brisbane: Queensland Health and the University of Queensland. Retrieved from http://www.comeprepd.info/wp-content/uploads/2018/04/qprepd-first-report.pdf

11.1.2 Publications

1. Lazarou, Mattea[1], Fitzgerald, Lisa[1], Warner, Melissa [2], Downing, Sandra [3], Williams, Owain D[1], Gilks, Charles F[1], Russell, Darren[4] and Dean, Judith[1#]. HIV in Australia Today: Healthcare provider thoughts on how broader access to PrEP affects uptake and service delivery. (Submitted under review).

2. Rolley, Adam[1,5], Waller, Michael[1], Downing, Sandra[3], Fitzgerald, Lisa[1], Williams, Owain D[1], Gilks, Charles F[1], Russell, Darren [4] and Dean, Judith[1#]. Queensland, Australia PrEP demonstration study: Risk compensation, STI rates and adherence. (Under final review by Authors).

3. Rhoades, Celeste[1,] Waller, Michael[1], Fitzgerald, Lisa[1], Williams, Owain D[1], Gilks, Charles F[1], Russell, Darren [4] and Dean, Judith[1#]. Determinants of intended patterns of pre-exposure prophylaxis (PrEP) use, cessation, or deviation from prescribed HIV PrEP treatment post cessation of Queensland PrEP implementation trial (QPrEPd). (Under final review by Authors).

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[5]School of Clinical Sciences, Queensland University of Technology, Brisbane, Australia.

11.1.3 Presentations

1. 2019 Dean J, Bell, S, Doyle-Adams S, Fitzgerald L, Williams OD, Gilks CF, Russell D and the QPrEPd Operational Management Team. *HIV Pre-exposure prophylaxis provision in Australia: Nurses are key to increasing access and uptake*. American Association of Nurses in AIDS Care. 32nd Annual Conference, ANAC2019: November 7-9, 2019 Portland, Oregon.

2. 2019 Dean JA, Bell SFE, Fitzgerald L, Williams OD, Gilks CF, and Russell D. *Intention Verses Reality: PrEP Use In Queensland Following PBS Listing.* 2019 Australasian HIV/AIDS Sexual Health Conference, Perth, WA. 16-19 September. Oral Presentation.

3. 2019 Rolley A, Waller M, Bell SFE, Fitzgerald L, Williams OD, Gilks CF, Russell DB[3, 4] and Dean JA[1] Queensland PrEP Demonstration Study: *Risk Compensation, STI Rates And Adherence.* Combined Australasian HIV/AIDS and Sexual Health Conference, Perth, WA. 16-19 September. Poster.

4. 2018 Dean J, Warner M, Fitzgerald L, Williams OD, Gilks CF, Russell D and the QPrEPd Operational Management Team. *PrEP Factory or Standard Practice? Health Care* Providers Experiences and Expectations of Prescribing PrEP in Queensland. Australasian HIV/AIDS Conference, Sydney, NSW. 24-26 July 2018. Poster.

5. 2017 Dean J, Fitzgerald L, Williams OD, Gilks CF. QPrEPd Monitoring and Evaluation. HIV Foundation Queensland Research Forum.

11.1.4 Students

1. 2019 Master of Epidemiology Dissertation: Celeste Rhoades. Title: Determinants of intended patterns of pre-exposure prophylaxis (PrEP) use, cessation, or deviation from prescribed HIV PrEP treatment post cessation of Queensland PrEP implementation trial (QPrEPd). Supervisors: Dr Judith Dean and Dr Michael Waller

2. 2018 Bachelor of Health Sciences (Honours): Mattea Lazarou. Title: Attitudes and perspectives of service providers towards prescribing PrEP. Supervisors: Dr Judith Dean and Dr Lisa Fitzgerald

3. 2018 Master of Epidemiology Dissertation: Adam Rolley. Title: Queensland, Australia HIV pre-exposure prophylaxis demonstration study: Risk compensation, STI rates and adherence. Supervisors: Dr Judith Dean and Dr Michael Waller

11.1.5 Other PrEP related Research and Presentations not funded by the QPrEPd Secondary Funding Agreement (SFA) between State of Queensland, acting through Queensland Health (QH)

Presentations

1. 2018 Dean J, Garvey S, Scott M, Fitzgerald L, Williams O, Gilks C. ComePrEPd2dine: exploring factors influencing the experiences of PrEP use: an innovative 'dinner party conversation' approach. Australasian HIV/AIDS Conference Sydney, NSW. 24-26 July. (Poster).

2. 2018 Dean J, Lui CW, Scott M, Lemoire J, Howard C, Mutch A, Gilks C, Williams O, and Fitzgerald L. Willingness To Use Prep Among Gay And Bisexual Men In Queensland, Australia: Differences Associated With HIV Risk, Patterns Of Testing And Location Of Residence Australasian HIV/AIDS Conference. Sydney, NSW. 24-26 July. (Poster).

Grants

1. 2016 J Dean (PI), S Garvey (PI), M Scott (PI), L Fitzgerald, O Williams, CF Gilks, P Sariago. #comePrepd to Dine: The Dinner Party Conversation Project. Exploring community attitudes to Pre Exposure Prophylaxis in Queensland. Queensland AIDS Council Grant ($19,750)

11.2 Study Management Team Presentations and Publications

11.2.1 Presentations

1. 2018 Simon Doyle-Adams On behalf of the QPrEPd Operational team. Is it different "Out-Back"? The Queensland Pre-Exposure Prophylaxis Demonstration (QPrEPd) Project and Sexually Transmitted Infections (STI). Australasian HIV/AIDS Conference, Sydney, NSW. 24-26 July 2018. Oral presentation

2. 2018 Yeganeh S, Cashman C, Downing S, Doyle-Adams S, Elliot M, Fischer J, Lukies S, Pratt R, Rodriguez M, Sutcliffe E, Russell D. *From Top to Bottom – QPrEPd and STIs.* Australasian HIV/AIDS Conference, Sydney, NSW. 24-26 July 2018. Poster

3. 2017 Sutcliffe E, Fischer J, Cashman C, Doyle-Adams S, Downing S, Elliot M, Lukies S, Pratt R, Rodriguez M, Yeganeh S, Russell D. *How was it for you? The first three months on the Queensland PrEP Demonstration Trial.* Australasian HIV/AIDS Conference. Canberra, ACT. Poster.

4. 2017 Rodriguez M, Cashman C, Downing, S, Doyle-Adams S, Elliot, M, Fischer, J, Lukies, S, Pratt, R, Sutcliffe, E, Yeganeh, S, Russell D. *When size really does matter! QPrEPd - The Queensland Pre-exposure Prophylaxis Project*. Australasian HIV/AIDS Conference. Canberra, ACT. Poster.

5. 2017 Doyle-Adams S, Cashman C, Downing, S, Elliot, M, Fischer, J, Lukies, S, Pratt, R, Rodriguez M, Sutcliffe, E, Yeganeh, S, Russell, D. PrEP *Sweat and Tears – Challenges of the QPrEPd.* Australasian HIV/AIDS Conference. Canberra, ACT. Poster.

6. 2017 Doyle-Adams S. The QPrEPd Trial. HIV Foundation Queensland Research Forum.

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3. Rolley A, Waller M, Bell SFE, Fitzgerald L, Williams OD, Gilks C, et al. Queensland PrEP demonstration study: risk compensation, STI rates and adherence. Joint Australasian HIV and Sexual Health Conference; Perth, Western Australia2019.

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