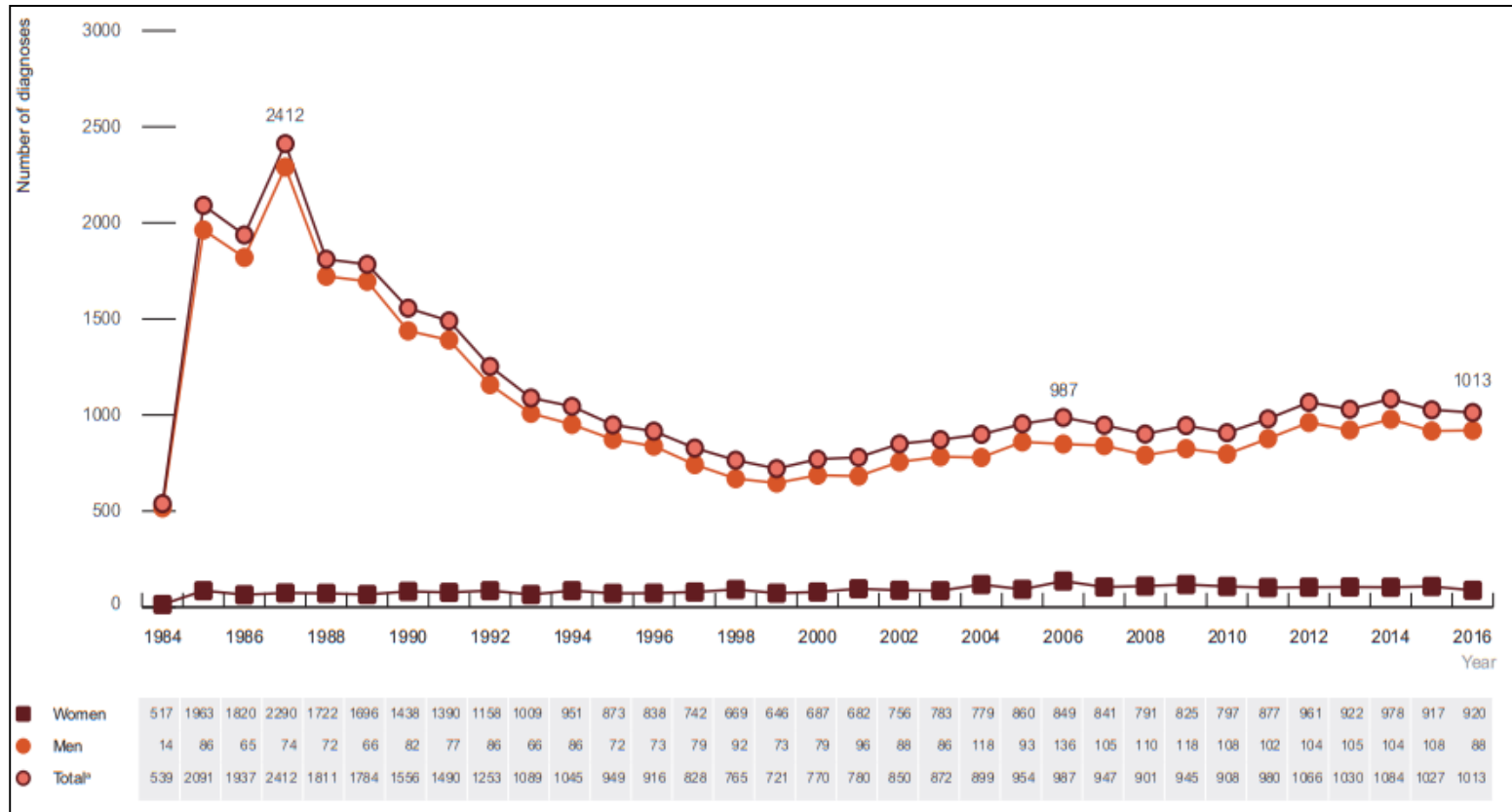




Western Australian pre-exposure prophylaxis for HIV implementation trial (PrEPIT-WA)

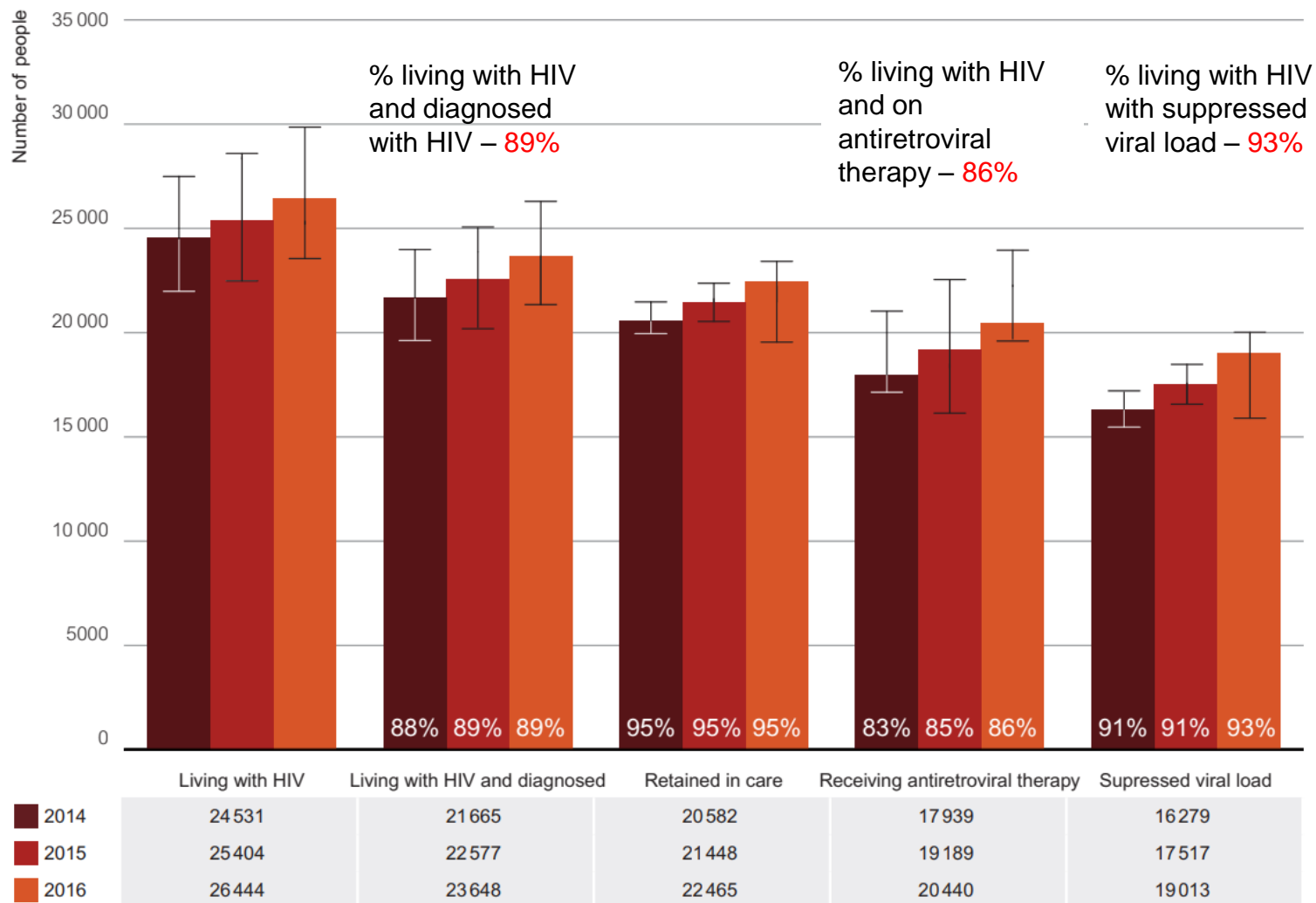
STI & BBV Quarterly Forum - 29 Nov 2018
PrEPIT-WA Project Team

Annual HIV diagnoses by sex, Australia, 1984-2016

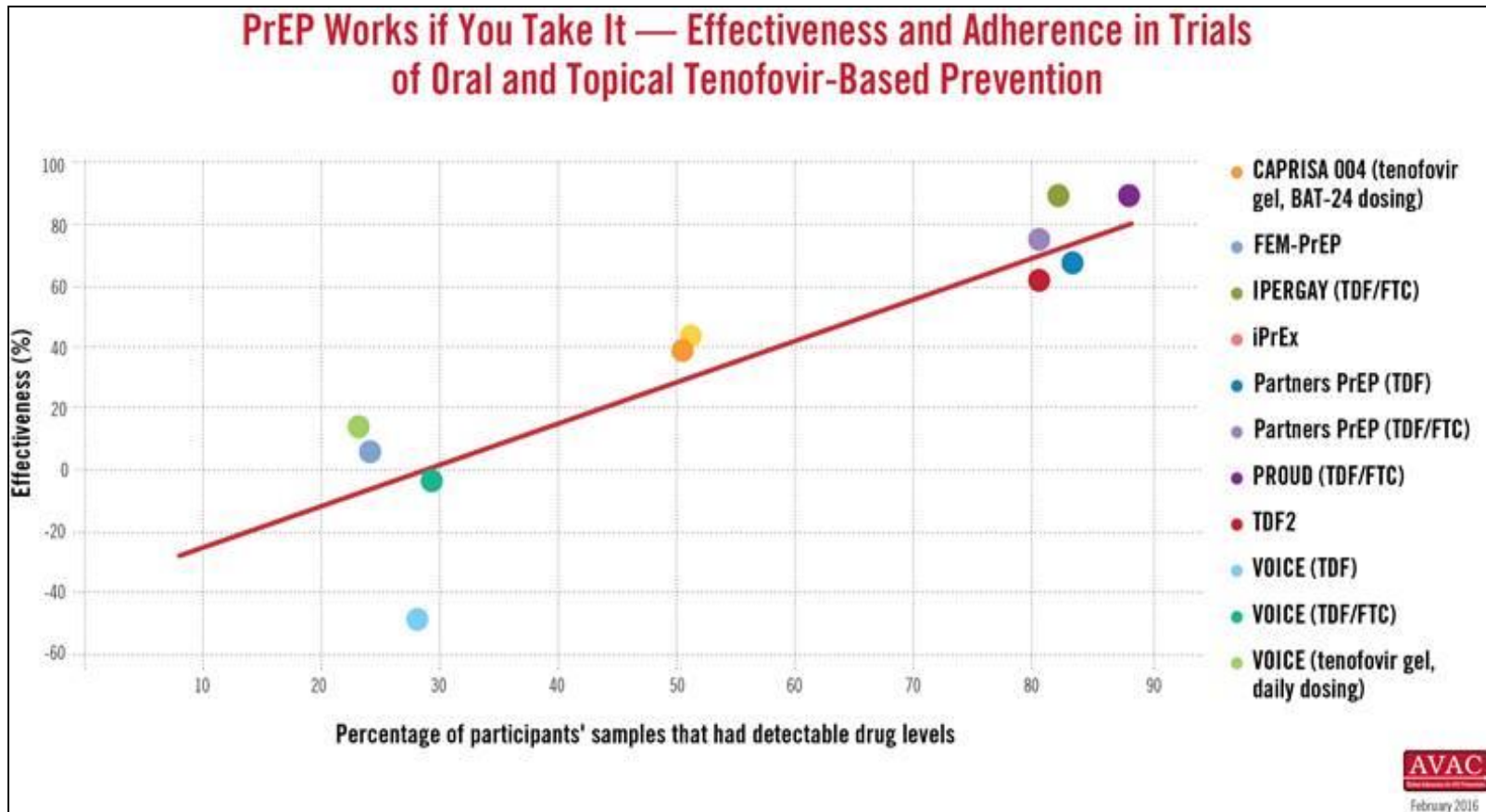


Stable HIV diagnoses

UN targets – approaching 90/90/90



- **Government strategy** (7th National HIV Strategy – 2014 to 2017) works towards ‘**virtual elimination of HIV transmission by 2020**’:
 - Increase HIV testing
 - Increase HIV treatment coverage
 - Maintain levels of safe behaviours and harm reduction approaches
 - “PrEP may be useful in very high risk population groups, and its place in the prevention response needs to be determined”.
- To achieve the goal of virtual elimination of HIV transmission by 2020 pre-exposure prophylaxis is needed.



PrEPIT-WA design based on EPIC-NSW

An implementation research to mimic the conditions that will occur when PrEP is rolled out at the population level at a large scale, and conducted within a clinical trial framework (TDF/FTC not TGA registered) – funded by the WA DOH, a formal collaboration between government, academia, community organisation (WAAIDS), highly informed and enthusiastic sexual health and primary care clinicians.

Study population:

- 2,000 participants at high-risk of HIV infection as rapidly as feasible & FU for up to 20 months.
- Mainly gay and bisexual men & a small number of heterosexuals, PWIDs, and transgender people.

Eligibility:

- Eligibility for PrEP: 4 sets of behavioural risk criteria (**HIGH RISK**) as per ASHM Guidelines (MSM, trans & gender diverse people, heterosexual people, PWID)
- Study specific criteria: inclusion & exclusion criteria as per Study Protocol

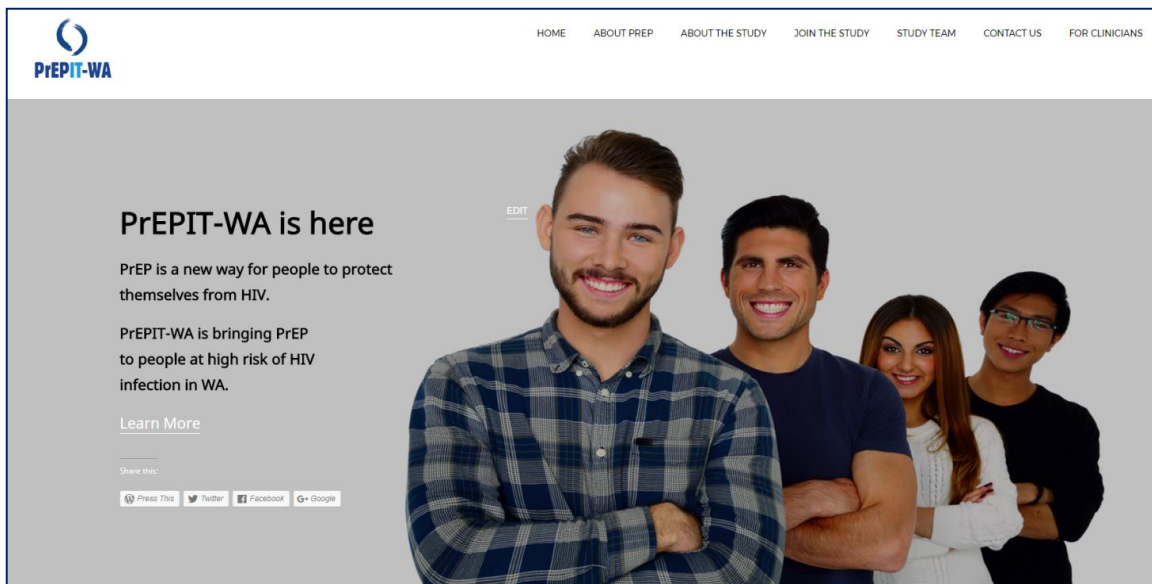
Primary outcomes:

- HIV incidence in the cohort and
- HIV diagnoses in the State

Simple for clinics: HIV/STI outcomes are collected electronically

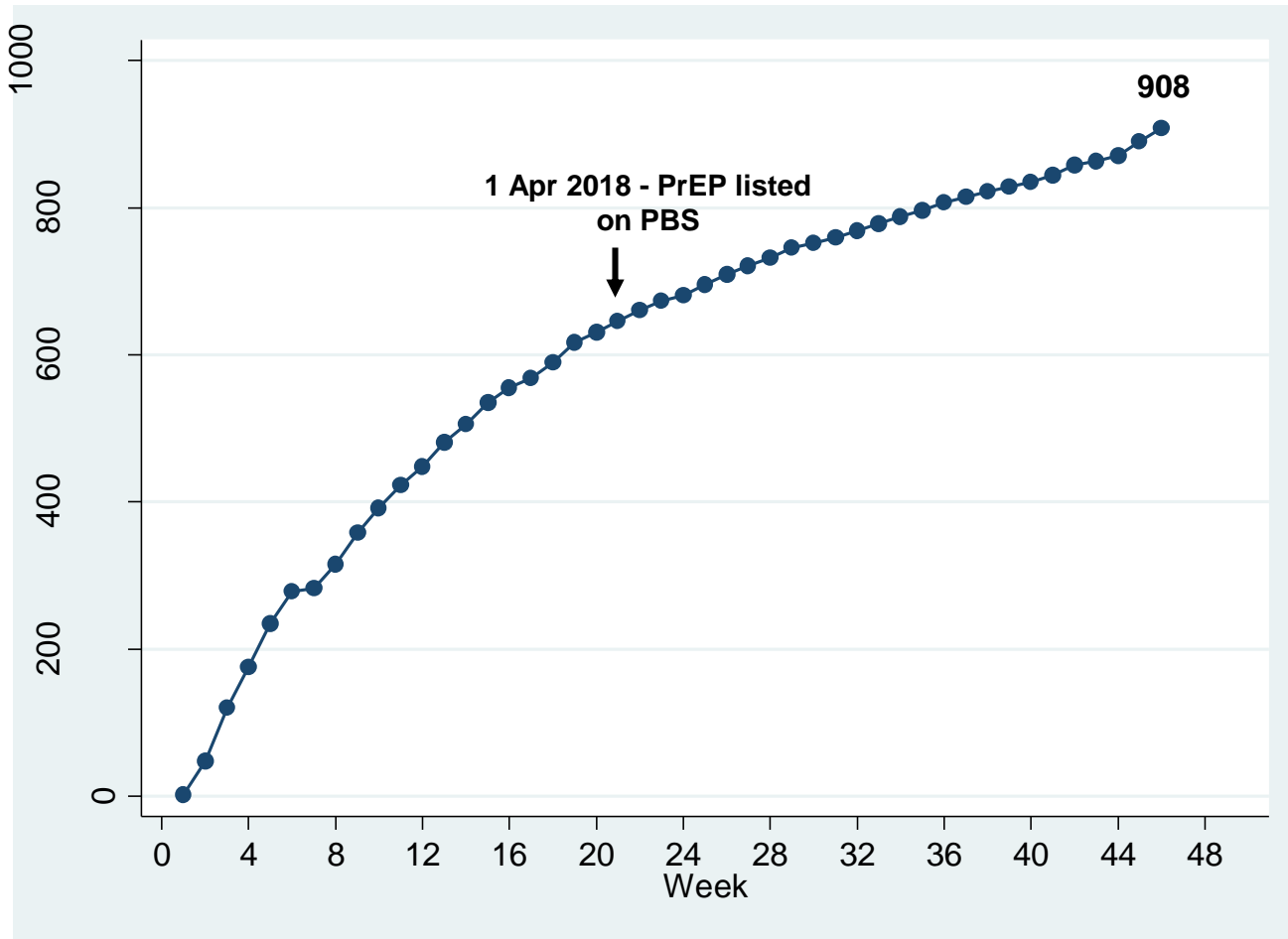


Recruitment commenced in Nov 2017



Site	Principal Investigator
South Terrace Sexual Health Clinic, Fremantle	A/Prof Lewis Marshall
Royal Perth Hospital Sexual Health Clinic, Perth	Dr Christine Dykstra
M Clinic, Perth	Dr Haipeng Wang
GP on Beaufort, Perth	Dr Goran Pervan

Enrolment of PrEPIT-WA participants from 13 Nov 2017 to 30 Sept 2018



Study transition started from 1 Nov 2018, last dispensing to complete by 31 Jan 2019 & last study FU visit by 30 Apr 2019

Reason for screen failure	N
eGFR <60 at baseline	2
They were diagnosed with HIV at baseline	2
Other	3
Total individuals	7

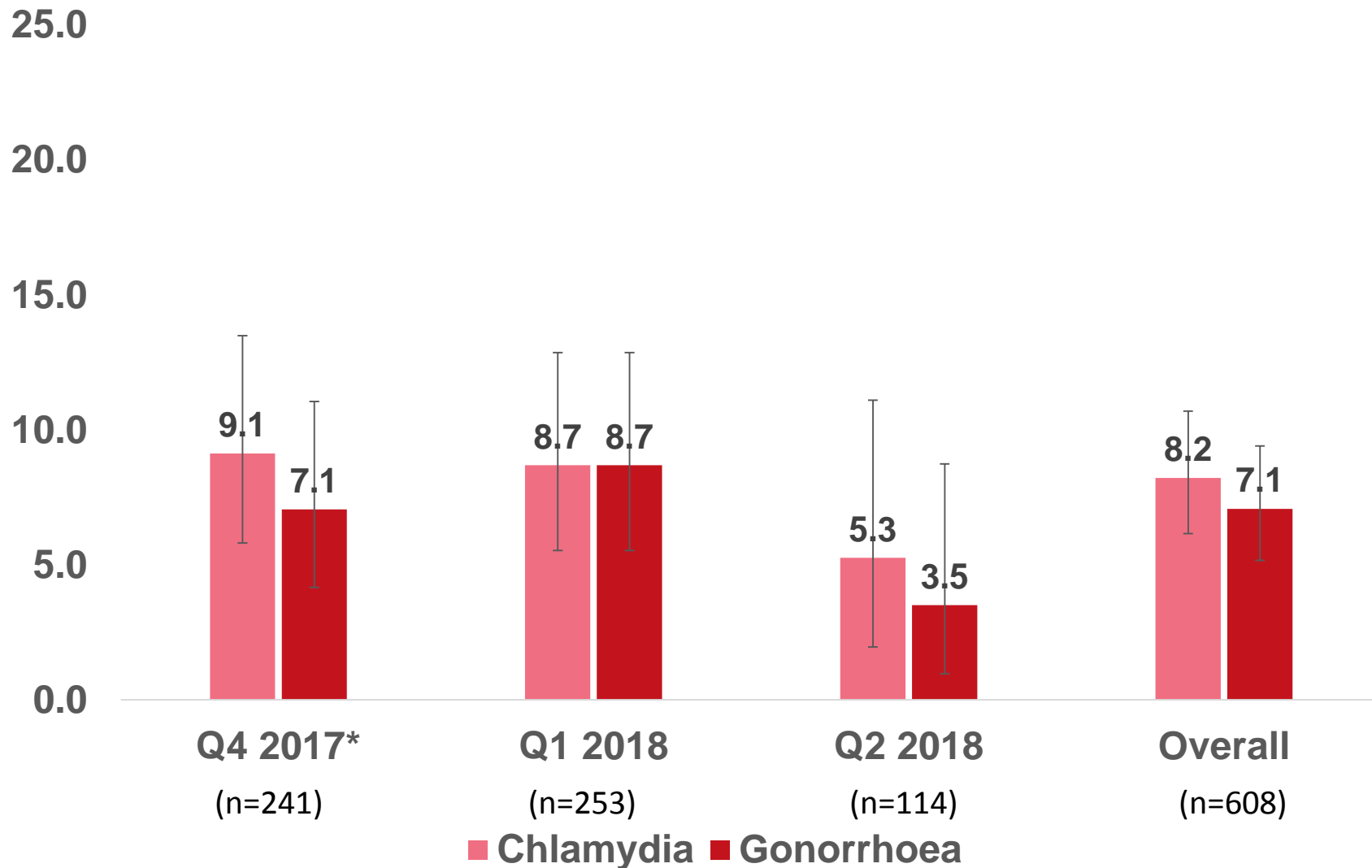
Reason for withdrawal from study	N
Moved interstate/overseas	4
Side effects	2
Tired of or found it too difficult to take pills every day	1
Other	1
Total individuals	8

Characteristics	N	%
Gender		
Male	890	98.0
Female	2	0.2
Transgender, male-to-female	10	1.1
Transgender, female-to-male	0	0
Other	6	0.7
Total	908	100.0
Sexual identity		
Gay/Homosexual	827	91.1
Bisexual	70	7.7
Heterosexual	6	0.7
Other	5	0.6
Total	908	100.0

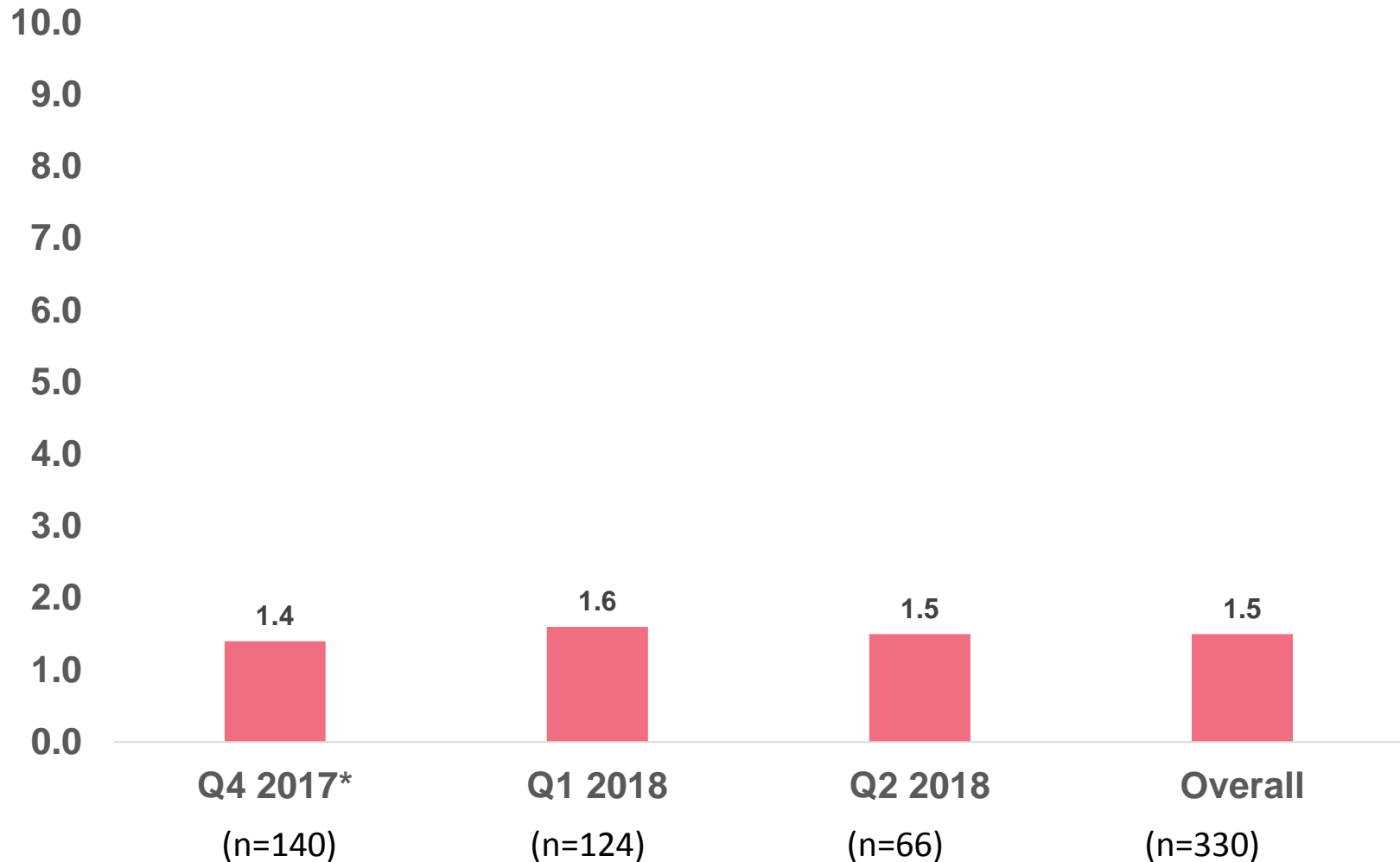
Characteristics	N	%
Age at enrolment (years)		
Median (Inter-quartile range)	37 (27 to 44)	
Age group		
< 20	10	1.1
20-29	304	33.5
30-39	294	32.4
40-49	151	16.6
≥50	149	16.4
Total	908	100.0
Aboriginal and/or Torres Strait Islander status		
Non-Indigenous	892	98.2
Aboriginal and/or Torres Strait Islander	16	1.8
Total	908	100.0

Characteristics	N	%
Country/Region of birth		
Australia	551	60.7
Oceania	38	4.2
Asia	121	13.3
Northern America	12	1.3
South America, Central America & the Caribbean	24	2.6
Europe	123	13.6
Middle East	3	0.3
Africa	36	4.0
Total	908	100.0
Area of residence		
Major cities	884	97.4
Inner Regional	11	1.2
Outer Regional	5	0.6
Remote	8	0.9
Total	908	100.0

Proportion of individuals tested for chlamydia and gonorrhoea at baseline with a positive result, by quarter, 13 November 2017 to 30 June 2018



Proportion of individuals with infectious syphilis at baseline, by quarter, 13 November 2017 to 30 June 2018



What's next?

- Study follow-up is on-going
- HIV incidence throughout the study to be reported in 2019
 - No HIV diagnoses in the enrolled cohort to date
- Longitudinal STI positivity to be reported in 2019
 - Installation of ACCESS still ongoing at clinics