

# High STI Incidence in NZ PrEP study Participants: Implications for real world delivery

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## NZ PrEP: Declarations

- Gilead Sciences is funding the study medications, research associated laboratory costs and a research nurse
- NZAF and PHARMAC provided funding to set up and analyse the on-line behavioural survey

## Background

- NZ PrEP is a demonstration project of HIV pre-exposure prophylaxis in Aotearoa, New Zealand
- **He muka nō te taura whiri- 'Many Strands Make up one Rope'**

It began and continues as a collaboration between:

- Body Positive Inc.
- University of Auckland
- New Zealand AIDS Foundation (NZAF)
- Auckland Regional Sexual Health Service

## NZ PrEP Protocol

- Based on NSW Prelude
  - Open-label single-arm treatment evaluation study
- Duration 24 months
- Sample limited to 150 due to ARSHS operational requirements
- Ethics approval granted by HDEC 15/09/2016 16NTA112

## Aims

- To implement fully-funded PrEP in a sexual health clinic setting to:
- Assess feasibility, retention and duration of use
- Refine clinical protocols to optimise service delivery
- Assess risk behaviours on PrEP including sexual partnering; condom use; **STI and HIV incidence**
- Analysis of factors (socio-demographic and attitudes) associated with PrEP acceptability, retention and sexual behaviours

## Inclusion Criteria

- HIV negative GBM or Trans people were eligible if:
- Aged 18 or over and eligible for funded care in NZ and resident in Auckland during duration of study
- No medical contraindications to taking tenofovir/emtricitabine
- And if they fitted specific behavioural risk criteria

## Protocol

- Participants were tested at enrolment for STI's, HIV, viral hepatitis and renal and liver function
- They were re-tested at 1 month and then were required to attend 3-monthly follow-up for STI testing, repeat serology for HIV and syphilis, renal and liver function testing
- At enrolment participants were required to complete an on-line baseline behavioural survey and after each subsequent 3-monthly visit (modified from VicPrEP)
- Truvada is dispensed at community pharmacies


## Protocol Variation

- Ethnicity quotas-50% of sample were required to be non European
  - To look at possible ethnic disparities in retention and adherence
- Participants had to have had sex with at least 5 CMPs in the previous 3 months or 10 in the previous 6 months to be eligible
- Enrolment began in February 2017 and was completed in December 2017
- PHARMAC made fully-funded PrEP available on 1<sup>st</sup> of March 2018

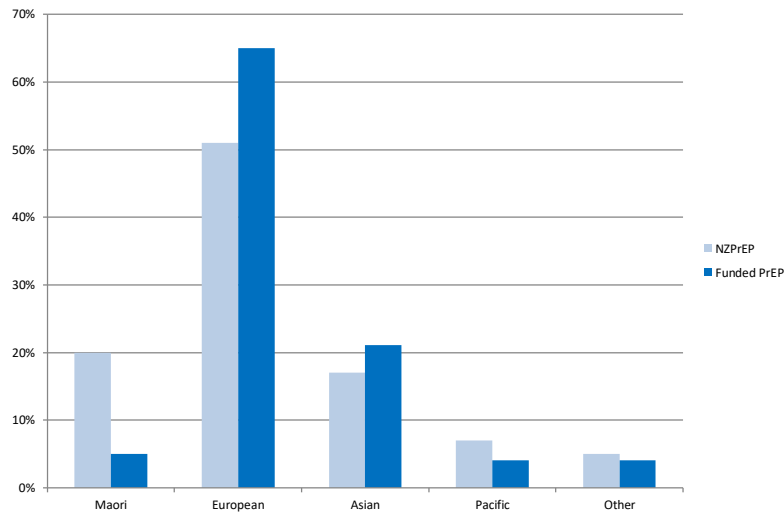
## STI Prevalence and Incidence

- Baseline prevalence defined as STI diagnosis at Visit 0(pre-enrolment)
- Incident STI was defined as a new STI diagnosis at a subsequent visit
- If a participant was diagnosed with an STI between scheduled visits this was counted in the following scheduled visit
- There have been no incident HIV infections
- There were 38 visits made by participants in addition to those scheduled in the protocol
- Results are from 1<sup>st</sup> 6 months of follow-up

## Baseline Characteristics n=150

	n	%	
<30	62	43.3	Range=18-55, median=31
30+	81	56.6	
European only	72	48.0	 52% Non-European (total response method)
Maori	32	21.3	
Pacific	13	8.7	
Asian	29	19.3	
MELAA	10	6.7	
Central Auckland	88	58.7	
Rest of Auckland	62	41.3	
Less than tertiary degree	67	44.7	
Tertiary degree	83	55.3	
Gay	138	92.0	
Bisexual or other	12	8.0	

## Comparison with Funded PrEP



## STI Diagnoses by Study Visit

	Visit 0 Pre-enrolment n=150	Visit 2 1 month n=145	Visit 3 3 months n=139	Visit 4 6 months N=131	Total No. Incident STI's
Gonorrhoea	17 (11.3%)	10 (6.8%)	15 (10.8%)	17 (12.8%)	44
Chlamydia	21 (13%)	10 (6.8%)	24 (17.3%)	21 (16.0%)	58
Syphilis	4 (2.7%)	2 (1.4%)	1 (1.0%)	7 (5.3%)	10
Rectal STI	29 (19%)	11 (7.5%)	22 (15.8%)	16 (12.2%)	
Any STI	35 (24%)	24 (16.5%)	34 (24.5%)	39 (29.8%)	115

## STI Incidence

- Overall incidence of any STI at 6 months was significantly higher among participants who at baseline reported in the previous 3 months:
- More than 10 male partners (61.9%,  $p<0.05$ )
- Group sex (67.7%,  $p<0.01$ )
- And chemsex (81.8%,  $p<0.01$ )
- But was not associated with ethnicity or age.

## Baseline Prevalence of STI's in other Demonstration Projects

Baseline	NZPrEP	PROUD	PRELUDE
Any STI	24%	17%	17%
Rectal gonorrhoea	9.3%	5.0%	2.6%
Rectal chlamydia	12.6%	4.0%	7.8%
Syphilis	2.7%	5.0 %	1.1%

## Summary

- Incident STIs are high in this sample
  - Behavioural risk factors
  - Regular STI testing
- Many participants are making additional visits to their 3 monthly scheduled visits
- PrEP provision has increased clinic workload.
- Costly in terms of clinician time, laboratory testing etc
- Sexual health services will need adequate resourcing to manage demand
- Ethnicity quotas have shown the importance of improving equity and access

## Acknowledgements

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## Steering Group

- ARSHS-Sunita Azariah, Suzanne Werder, Renee Jenkins, Rose Forster, Rick Franklin
- University of Auckland-Peter Saxton
- Body Positive-Mark Fisher, Ron Graham
- NZAF-Whati Te Waake-(Kaiarahi), Jason Myers, Joe Rich