Changes, Patterns and Predictors of Sexually Transmitted Infections in Gay and Bisexual Men Using PrEP

Interim Analysis from the PrEPX Study

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Abstract THAC0502

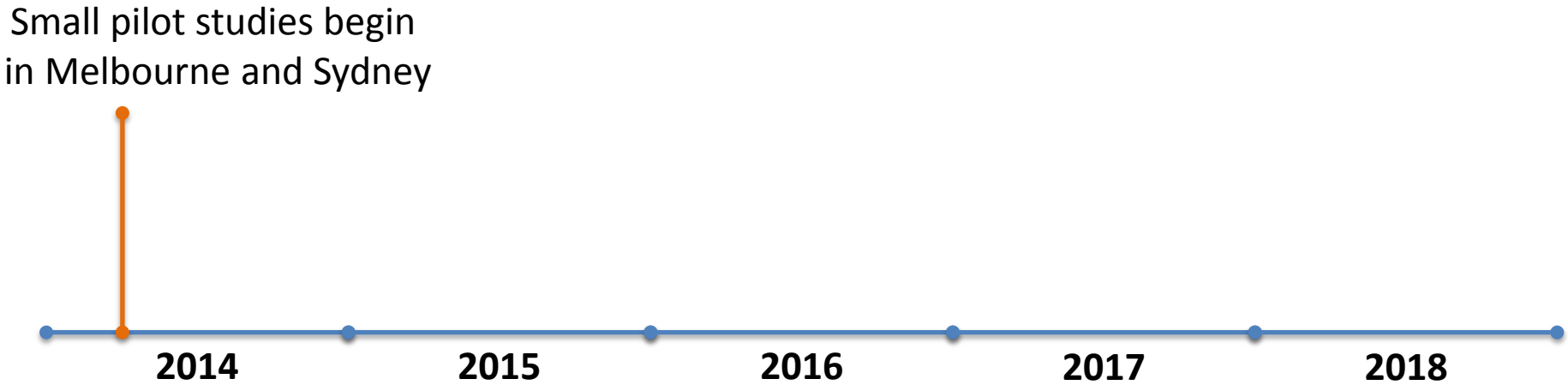
South Australian Sponsor and Research Partner:

Conflicts of interest

Nothing to disclose

Background

PrEP in Australia



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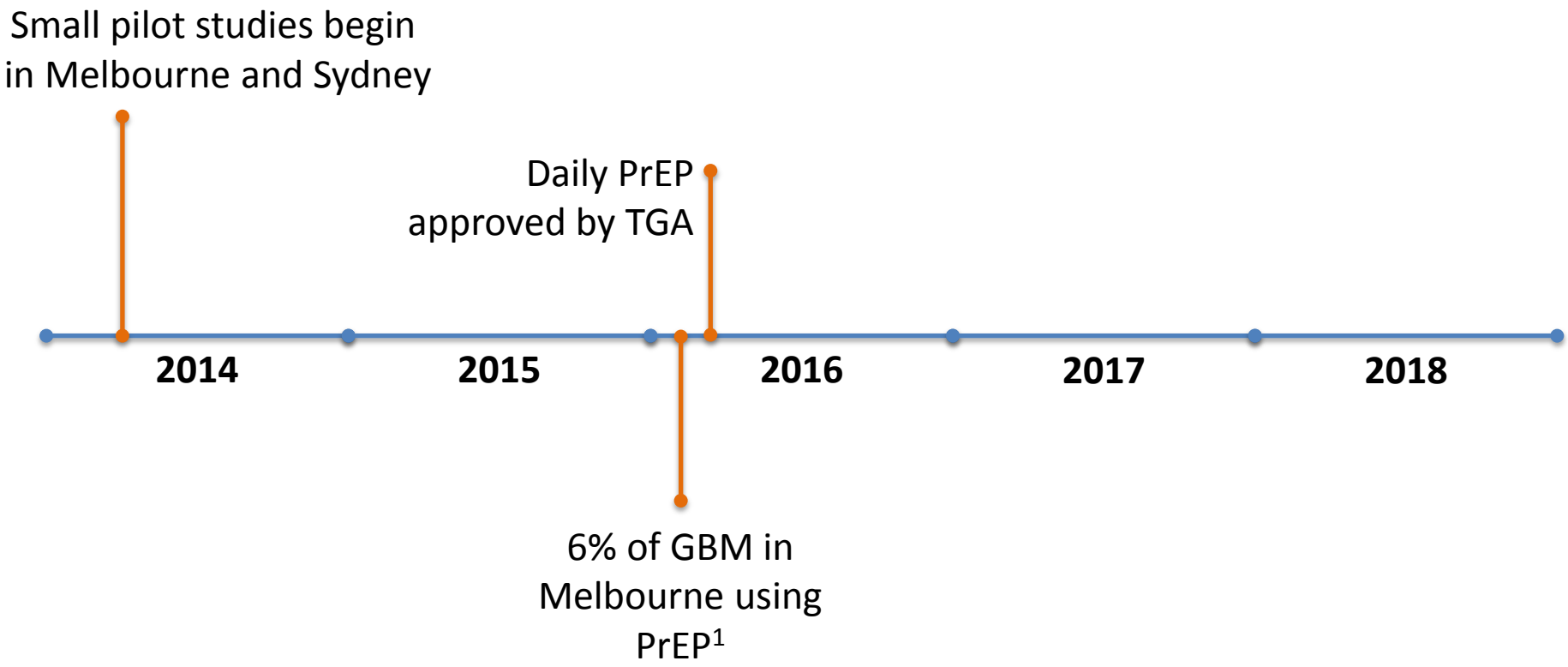

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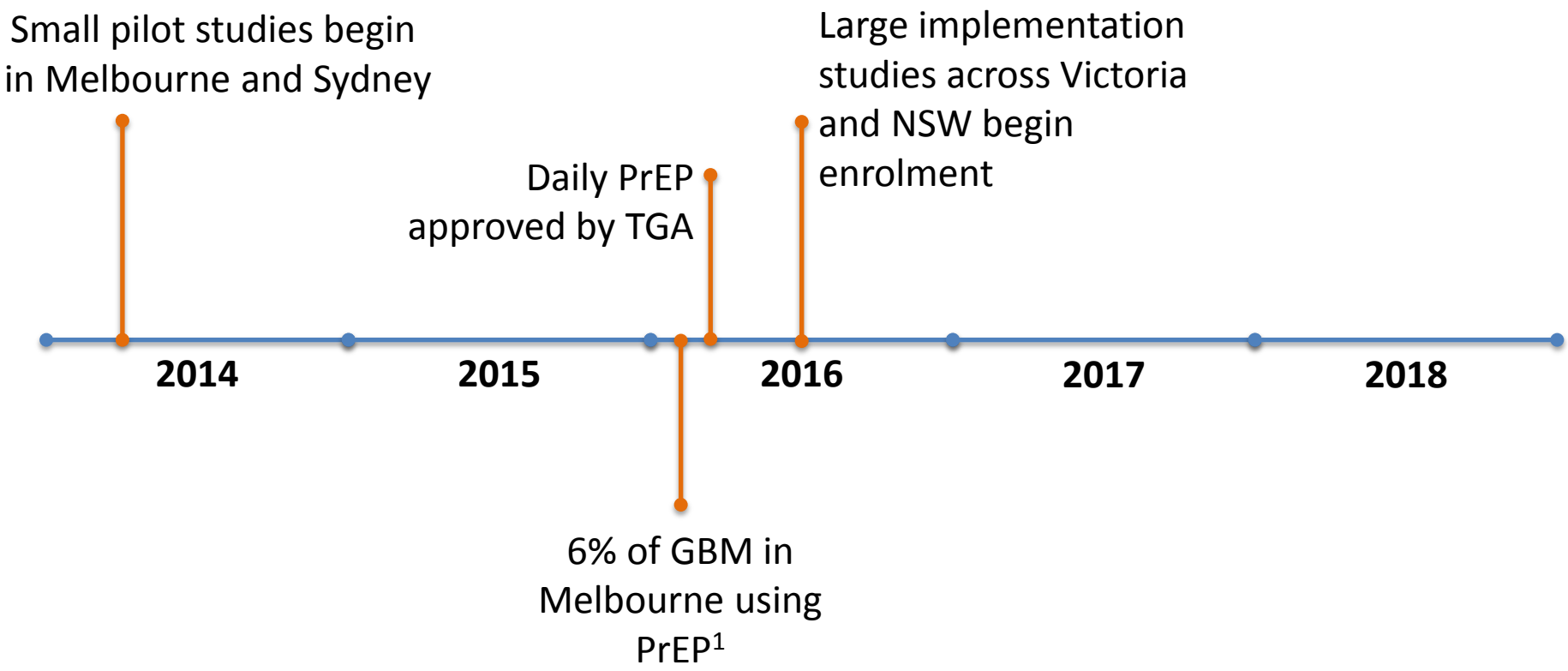

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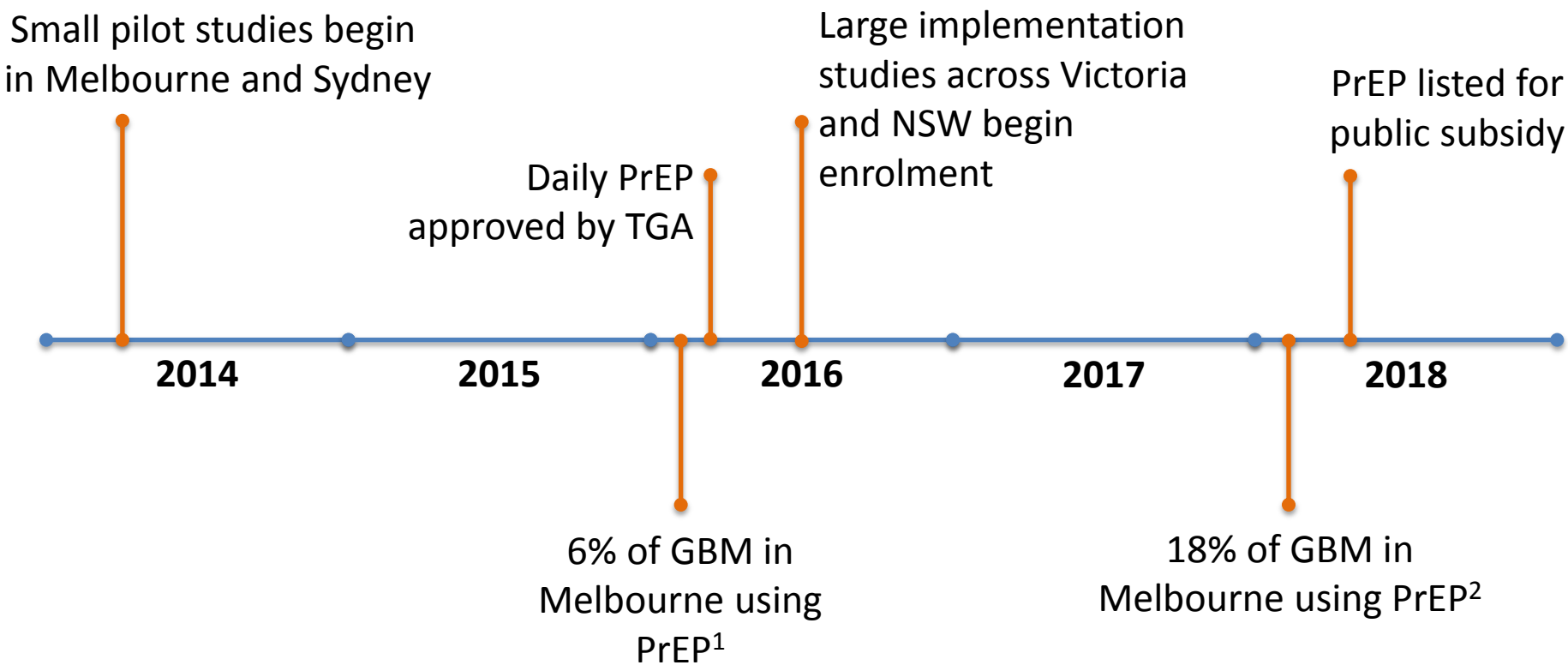

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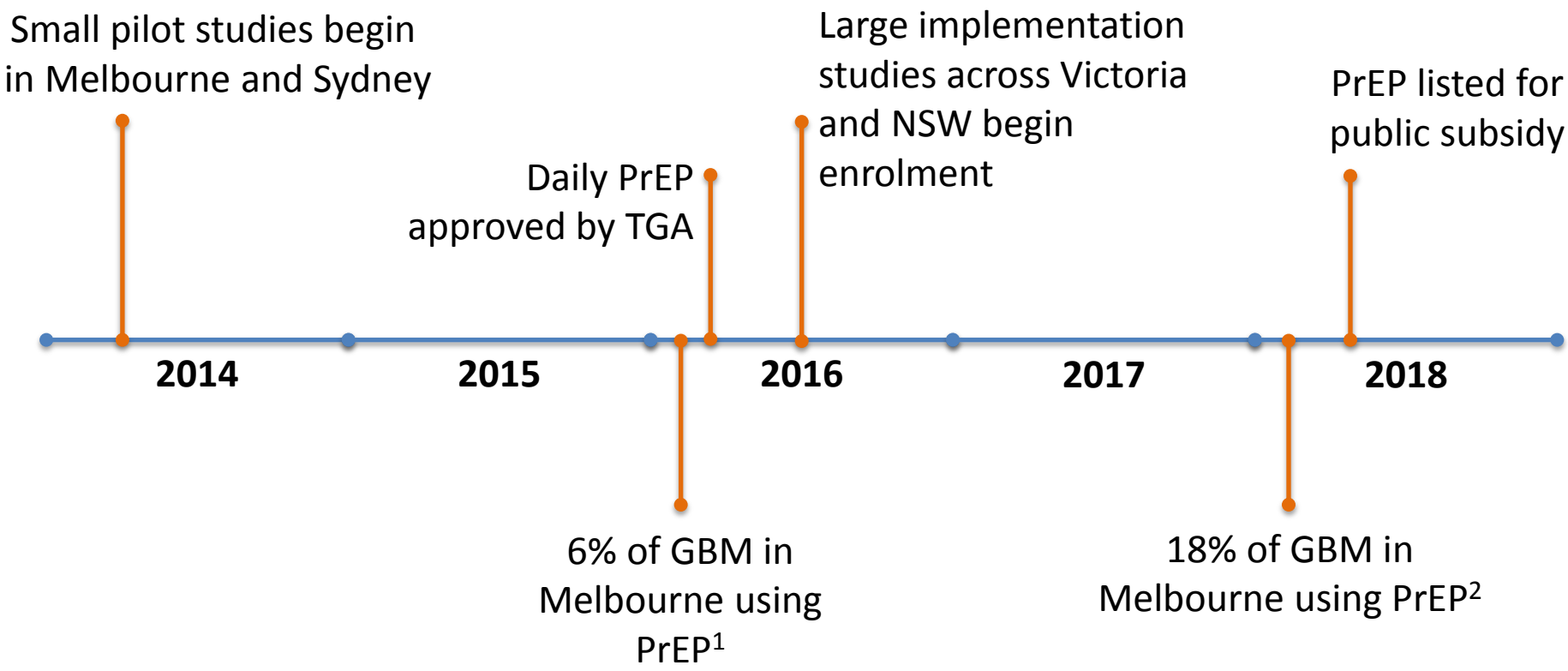

- More than 15,000 enrolled in PrEP studies nationwide
- PrEP currently available for $39.90 / month
- PrEP can be prescribed by any doctor or nurse practitioner

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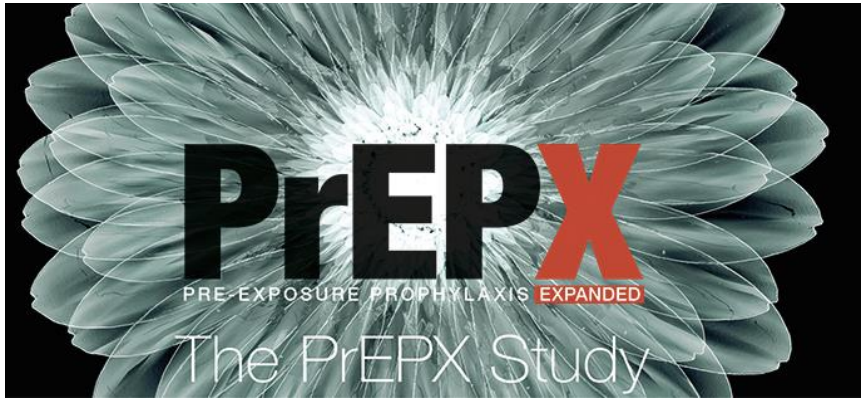
The PrEPX Study



Victoria, Australia

- **Multi-site implementation study**

  More than 10 metropolitan, regional and rural clinics

- **Study duration July 2016 – March 2018**

  4,275 participants, mostly gay and bisexual men

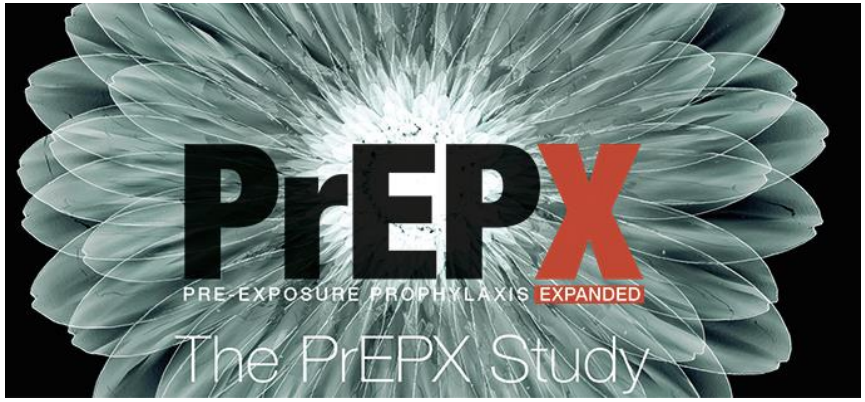
  1000 enrolled in first 3 weeks

- **Participants returned every 3 months**

  HIV and STI testing

  Behavioural survey

The PrEPX Study



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- **Primary outcome: Reduction in population-level HIV incidence**

- **Secondary outcome: Sexually transmissible infections among PrEP users**

STIs in PrEP Users

- **Evidence suggests STIs increase among PrEP users[1,2]**

1. Traeger et al. 2018
2. Lal et al. 2017
3. Kirby Institute 2017
4. Holt et al. 2017

STIs in PrEP Users

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STIs in PrEP Users

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- **High screening in PrEP users introduces detection bias**

  Australian PrEP guidelines recommend quarterly STI screening

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STIs in PrEP Users

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- **Many studies lack pre-PrEP STI incidence data**
- **High screening in PrEP users introduces detection bias**

  Australian PrEP guidelines recommend quarterly STI screening
- **STI rates were increasing prior to the introduction of PrEP**

  Gonorrhea, chlamydia and syphilis increasing among Australian GBM since 2010[3]
- **Consistent condom use has been decreasing**

  Condomless sex among Australian GBM increased from 27% to 39%, 2000 to 2015[4]

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Aims

1. Calculate STI incidence and distribution among PrEPX participants

2. Explore behavioural characteristics associated with STI risk

3. Identify changes in STI incidence before and after using PrEP

Data Collection

Australian Collaboration for Coordinated Enhanced Sentinel Surveillance

A national STI and BBV sentinel surveillance system

Over 100 sites nationally

- **Most participants enrolled in PrEPX at ACCESS clinics**
  - Track participant movement between clinics
  - Include between-study-visit test events

Participant characteristics

Participants enrolled at ACCESS sites	n=2,981
Age (median, range)	34 (16-72)
Gay or bisexual	2,922 (98%)
Transgender Female	4 (0.1%)
Transgender Male	11 (0.4%)
Used PrEP before enrolment	834 (28%)
STI diagnosed in 3 months prior to / at baseline	775 (26%)
CRAI in 3 months prior to baseline	1430 (48%)

1. STIs during PrEPX follow-up

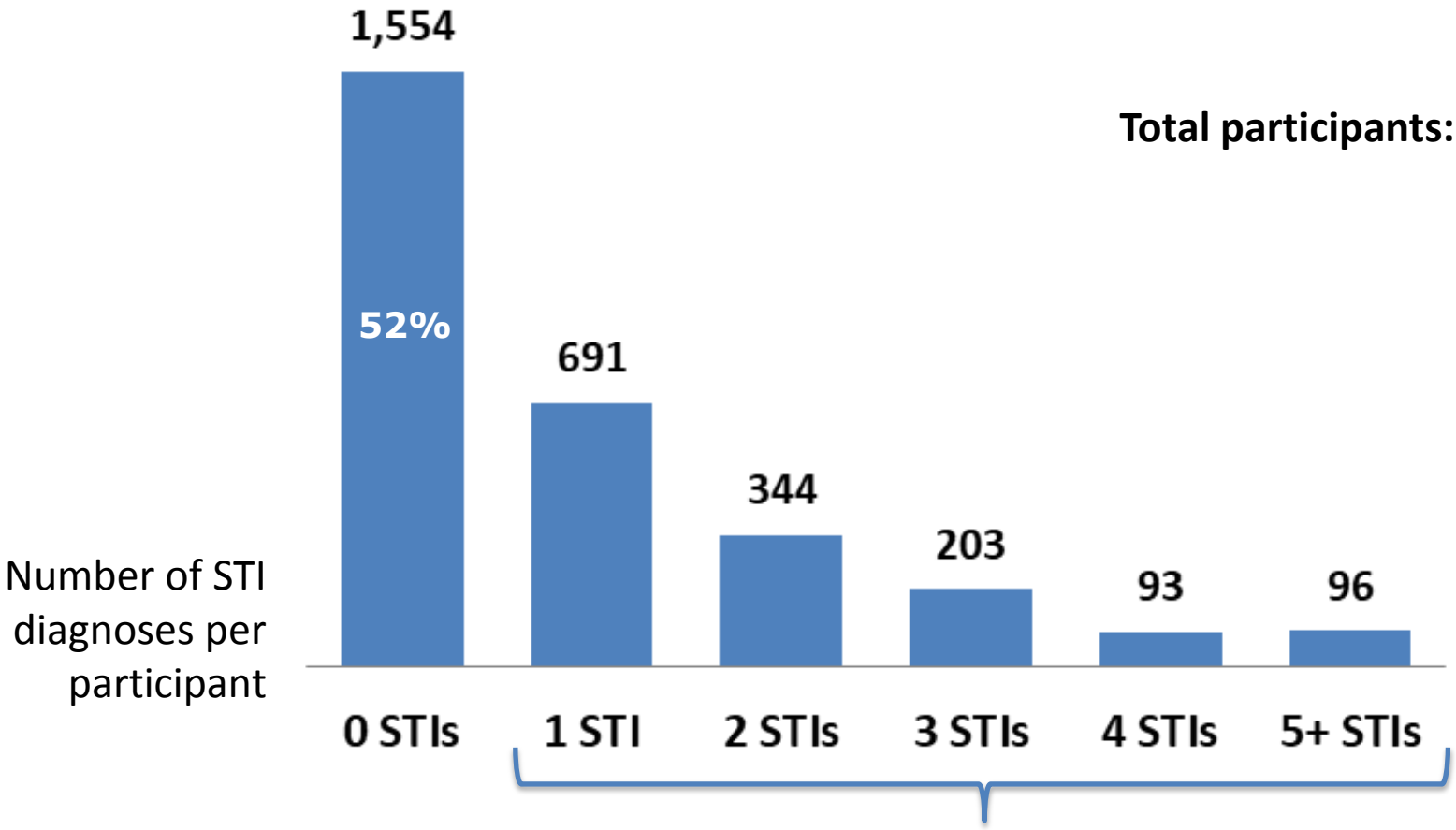
STI Incidence

- Study period July 2016 – March 2018
- Total follow-up: 3180 person-years (median, 14.4 months)

	Incidence rate (per 100 person-years)
Any STI	91.9
Chlamydia	44.8
Gonorrhea	38.6
Syphilis	8.0
Any rectal infection	56.6
Any urethral infection	22.4
Any pharyngeal infection	23.5

1. STIs during PrEPX follow-up

Distribution of STIs



Total participants: 2981

48% diagnosed with ≥1 STI

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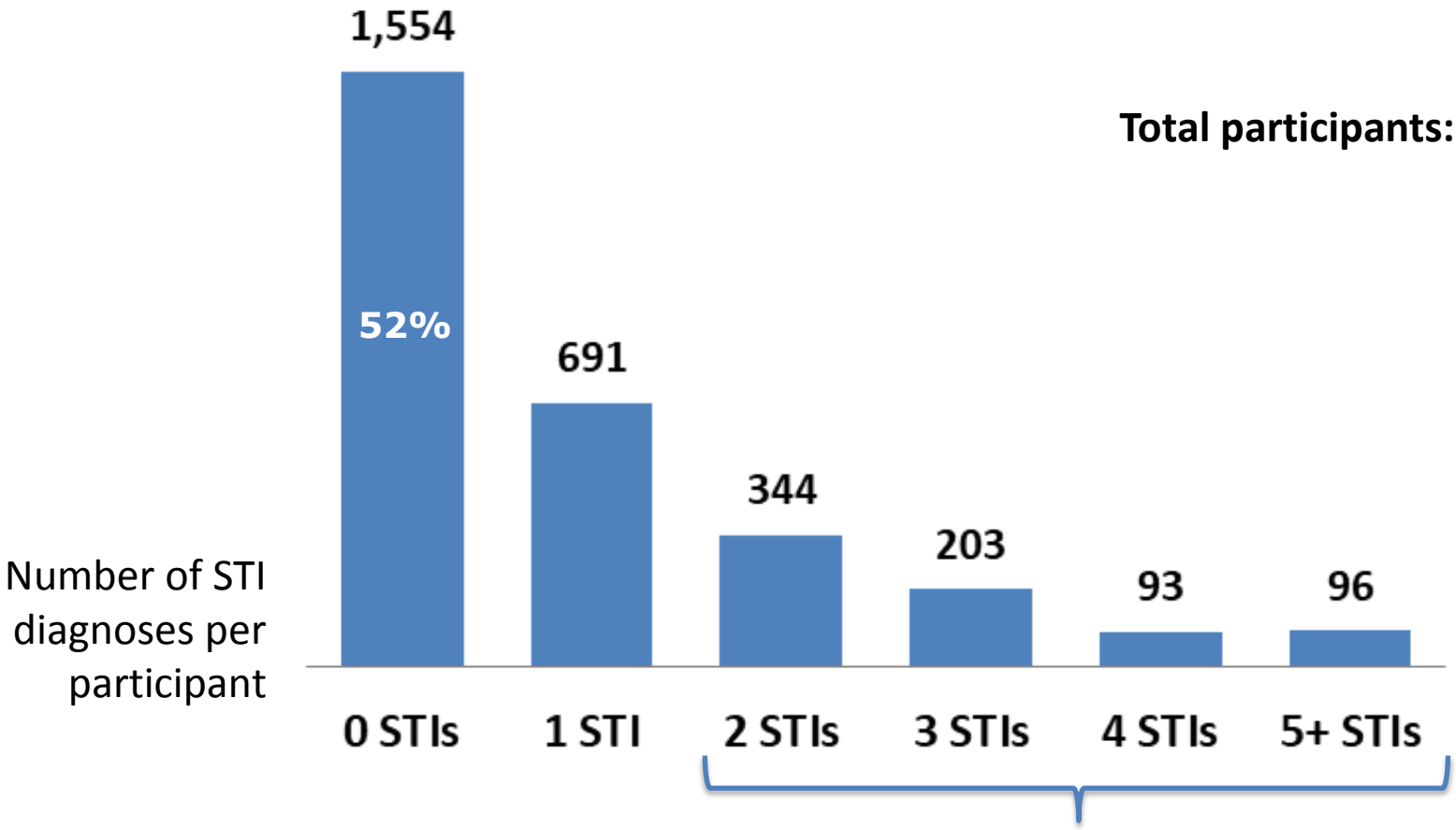
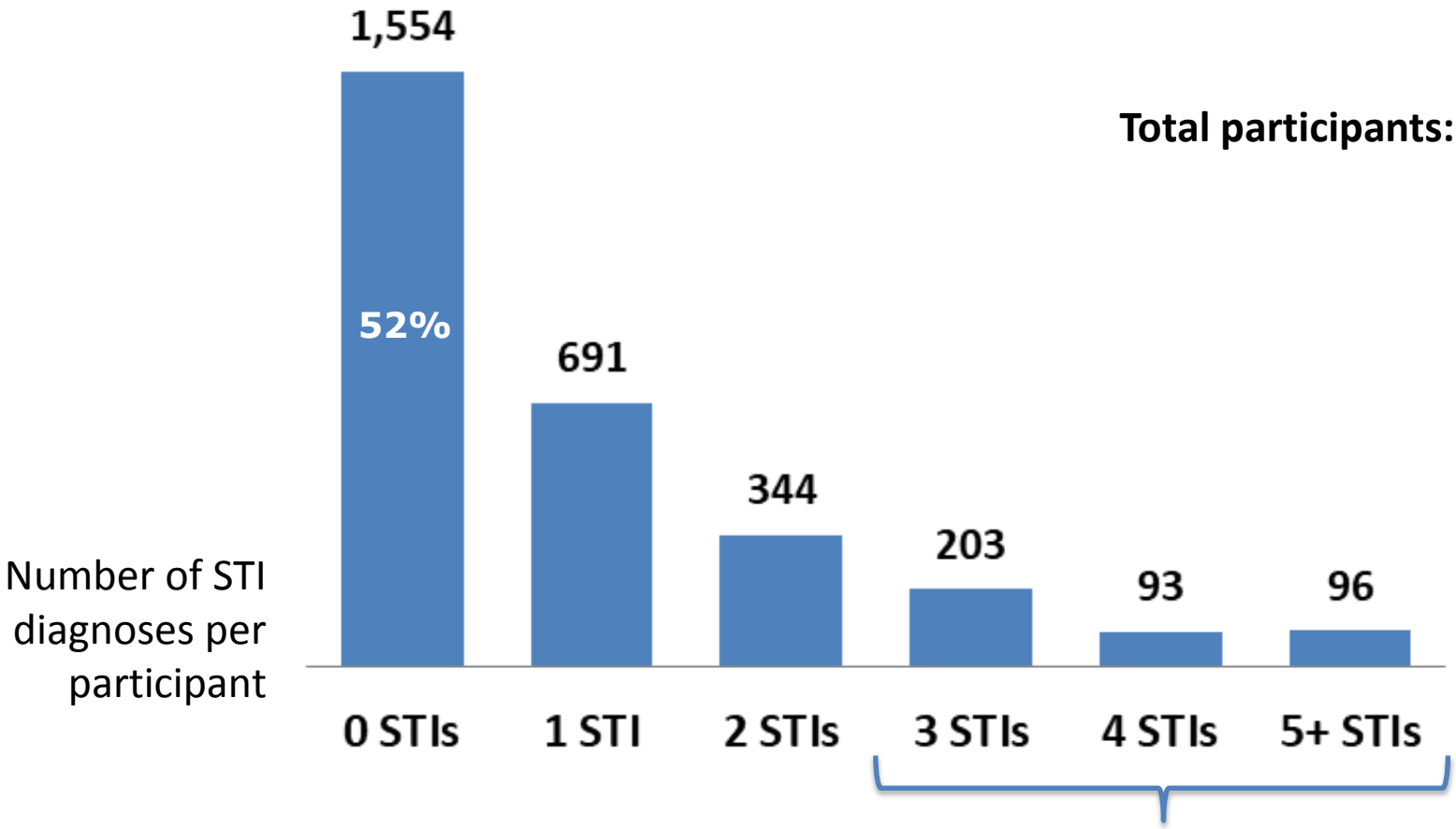


Total participants: 2981

25% diagnosed with ≥2 STIs
Accounting for 76% of diagnoses

1. STIs during PrEPX follow-up

Distribution of STIs



Total participants: 2981

13% diagnosed with ≥3 STIs
Accounting for 53% of diagnoses

2. Behavioural predictors of STIs

Methods

- **Behavioural survey completed at baseline and every three months**
- **Cox proportional hazards regression model**

  Time-varying behaviours were updated at each visit

  Outcome was diagnosis of chlamydia, gonorrhea or syphilis

  Allowed for multiple diagnoses

2. Behavioural predictors of STIs

Cox proportional hazards model

	Adjusted Hazard Ratio (95% CI)	p
Age (5 year increase)	0.94 (0.90 – 0.97)	0.001
Diagnosed with an STI 3 months prior to enrolment	1.24 (1.05 – 1.45)	0.010
CRAI w/ casual partner 3 months prior to enrolment	1.15 (1.01 – 1.32)	0.039
GHB use during sex in last 6 months	1.24 (1.02 – 1.51)	0.027

2. Behavioural predictors of STIs

Cox proportional hazards model

	Adjusted hazard ratio (95% CI)	p
Number of anal sex partners in last 6 months		
2-5	-reference-	
6-10	1.27 (1.04 – 1.57)	0.020
11-20	1.88 (1.46 – 2.41)	<0.001
21 - 50	2.13 (1.54 – 2.95)	<0.001
more than 50	2.55 (1.59 – 4.09)	<0.001
Group sex in last 6 months		
None	-reference-	
Once / a few times	1.28 (1.10 – 1.50)	0.002
At least monthly	1.47 (1.16 – 1.85)	0.001
At least weekly	1.67 (1.16 – 2.41)	0.006
Condom use with casual partners in last 6 months		
Always	-reference-	
Usually (>50%)	1.38 (0.96 - 1.97)	0.081
Sometimes (<50%)	1.38 (0.96 - 1.99)	0.080
Never	1.31 (0.88 - 1.97)	0.183

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3. Change in STIs before and after PrEPX

Methods

- **Subgroup analysis (n=1,378)**

  Participants who had been visiting ACCESS clinics before enrolment

- **Calculated STI incidence before and after enrolment**

  Comparison: 12 months before enrolment vs During PrEPX follow-up

- **Negative binomial regression model**

  Adjusted for change in testing frequency

  Included individual testing rate before and after as a confounding variable

3. Change in STIs before and after PrEPX

Incidence rates before and after PrEPX

Incidence rate (per 100 person-years)				
	1 year before PrEPX	During PrEPX	IRR (95% CI)	P-value
Any STI	69.5	98.4	1.42 (1.29 – 1.56)	<0.001

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Chlamydia	33.3	49.0	1.47 (1.30 – 1.66)	<0.001
Gonorrhea	30.1	42.3	1.38 (1.21 – 1.57)	0.003
Syphilis	6.8	8.7	1.28 (0.98 – 1.68)	0.065

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Rectal Infections	45.0	62.3	1.39 (1.22 – 1.57)	<0.001
Pharyngeal Infections	16.3	23.3	1.43 (1.20 – 1.70)	<0.001
Urethral Infections	17.6	25.9	1.47 (1.21 – 1.77)	<0.001

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Urethral Infections	17.6	25.9	1.47 (1.21 – 1.77)	<0.001
Previous PrEP users	92.4	104.1	1.13 (0.98 – 1.28)	0.072
PrEP naïve participants	55.1	94.2	1.71 (1.49 – 1.98)	<0.001

3. Change in STIs before and after PrEPX

Overall testing rate increased by 48% in PrEP-naïve participants

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Adjusted negative binomial model

	Unadjusted		Adjusted*	
	IRR (95% CI)	p-value	aIRR (95% CI)	p-value
PrEP naïve participants				
Any STI	1.71 (1.49 – 1.98)	<0.001	**1.21 (1.06 – 1.39)**	**0.006**

***Adjusted for differential testing frequency**

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PrEP naïve participants				
Any STI	1.71 (1.49 – 1.98)	<0.001	**1.21 (1.06 – 1.39)**	**0.006**
Chlamydia	1.84 (1.55 – 2.20)	<0.001	**1.38 (1.13 – 1.66)**	**0.001**
Gonorrhea	1.69 (1.42 – 2.01)	0.003	1.11 (0.92 – 1.34)	0.263
Syphilis	1.24 (0.87 – 1.78)	0.065	0.93 (0.62 – 1.40)	0.744

***Adjusted for differential testing frequency**

Summary

1. **STIs during PrEPX follow-up**
   - Overall STI incidence of 91/100 person-years
   - Over half of participants (52%) were not diagnosed with an STI
   - STIs were highly concentrated among PrEP users experiencing repeat infections

Summary

1. **STIs during PrEPX follow-up**
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2. **Behavioural predictors of STI risk**
   - STI risk among PrEPX participants was driven more by numbers of partners and participation in group sex rather than condom use

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2. **Behavioural predictors of STI risk**
   - STI risk among PrEPX participants was driven more by numbers of partners and participation in group sex rather than condom use

3. **Before and after PrEP**
   - STI incidence increased among GBM after enrolling in PrEPX, especially among those starting PrEP for the first time
   - Partly explained by increase in testing frequency
   - After adjusting for testing frequency, GBM using PrEP for the first time experienced a moderate but significant increase for any STI diagnosis and chlamydia infection

Implications

- **STIs increased at the individual-level after initiating PrEP**
  - However, high screening rates reduce duration of infection
  - Models indicate that increased screening among PrEP users may lead to an overall decrease in population-level STI incidence[1]
  - Monitor behavioural change at both individual and population-level

1. Jenness et al. 2017

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  Supports current Australian guidelines for 3 monthly STI testing

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- **Strategies can be targeted towards PrEP users experiencing high rates of reinfection**

- **Community involvement critical to success of future measures to reduce STIs**

1. Jenness et al. 2017

Acknowledgements

PrEPX Study Team

Edwina Wright – Principal Investigator

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Dean Murphy
Jude Armishaw
Timmy Lockwood
Olga Vujovic
Christina Chang
Vincent Cornelisse

Burnet Institute

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Study Clinics

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Northside Clinic: Jeff Wilcox
MSHC: Kit Fairley
PRONTO!: Matt Penn
Centre Clinic: BK Tee
ERA Health: George Forgan-Smith
Alfred HIP Clinic and Nurse Led Clinics

Pharmacies

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Newton and Leung Pharmacy: Johnny Phu
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Alfred Clinical Trials Pharmacy: Anne Mak
Healthsmart: Joseph Tesoriero
Central Pharmacy: Manoj Vassan, Kie Lim
Russell Frajman Pharmacy: Russell Frajman

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Research Participants

PrEPX participants
Participants in previous PrEP research
Animals in PrEP efficacy studies

References

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