Changes in Sexually Transmitted Infections among Gay and Bisexual Men after Enrolling in the PrEPX Implementation Study

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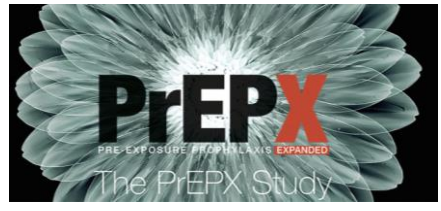
Australasian HIV & AIDS Conference, Sydney, September 2018

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
  2000 enrolled in first 10 weeks
- **Participants returned every 3 months**
  HIV and comprehensive STI testing
  Electronic behavioural survey

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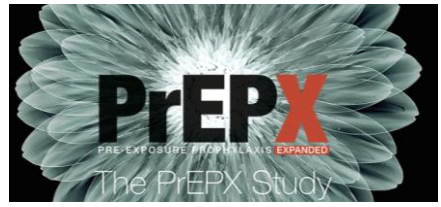

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  HIV and comprehensive STI testing
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- **Primary outcome: Reduction in population-level HIV incidence**
- **Secondary outcome: Sexually transmissible infections among PrEP users**

STIs in PrEP Users

- **Evidence suggests STIs increase among MSM using PrEP**

  Meta-analysis of 8 PrEP studies found increase in STIs, especially rectal infections

  Effect was greatest in more recent studies[1]

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  STIs increasing among Australian GBM since 2010[3]

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- **STI rates were increasing prior to the introduction of PrEP**

  STIs 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]

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

- **Majority of participants enrolled in PrEPX at ACCESS clinics**
  - Track participant movement between clinics
  - Include tests performed between study visits

Participant characteristics

Participants enrolled at ACCESS sites	n=2,981
Age (median, range)	34 (18-72)
Gay or bisexual	2,922 (98%)
Transgender Female	4 (0.1%)
Transgender Male	11 (0.4%)
Used PrEP before enrolment	834 (28%)
CRAI in 3 months prior to baseline	1430 (48%)
STI diagnosed in 3 months prior to enrolment	484 (16%)
STI diagnosed at enrolment	407 (13%)

1. STIs during PrEPX follow-up

STI Incidence

- **Study period July 2016 – March 2018**
- **Total follow-up: 3180 person-years (median, 14.4 months)**
- **Total STIs diagnosed: 2,982**

	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

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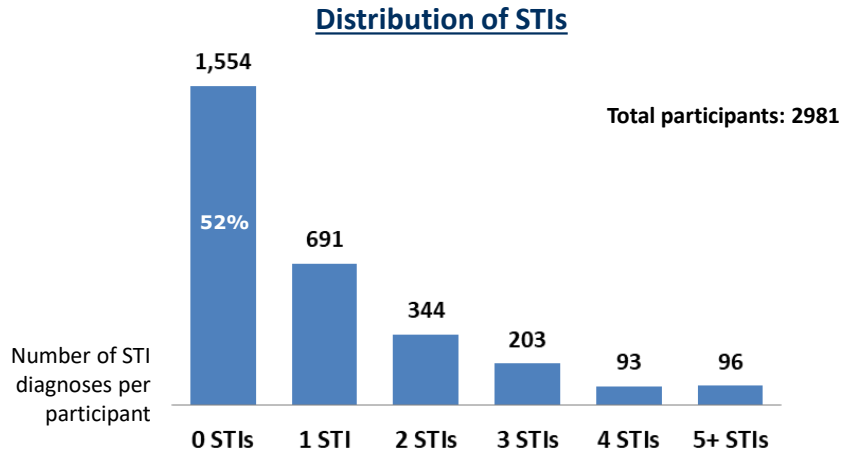

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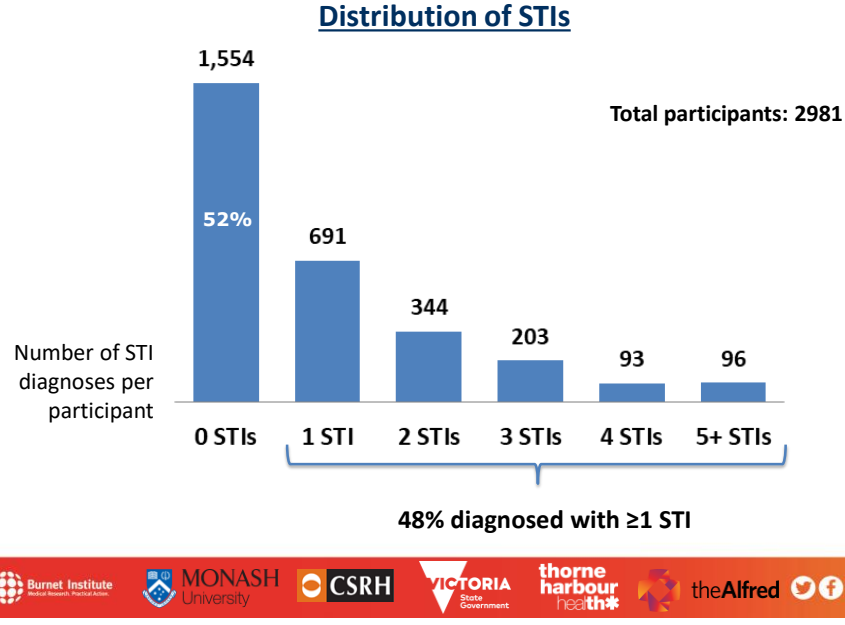

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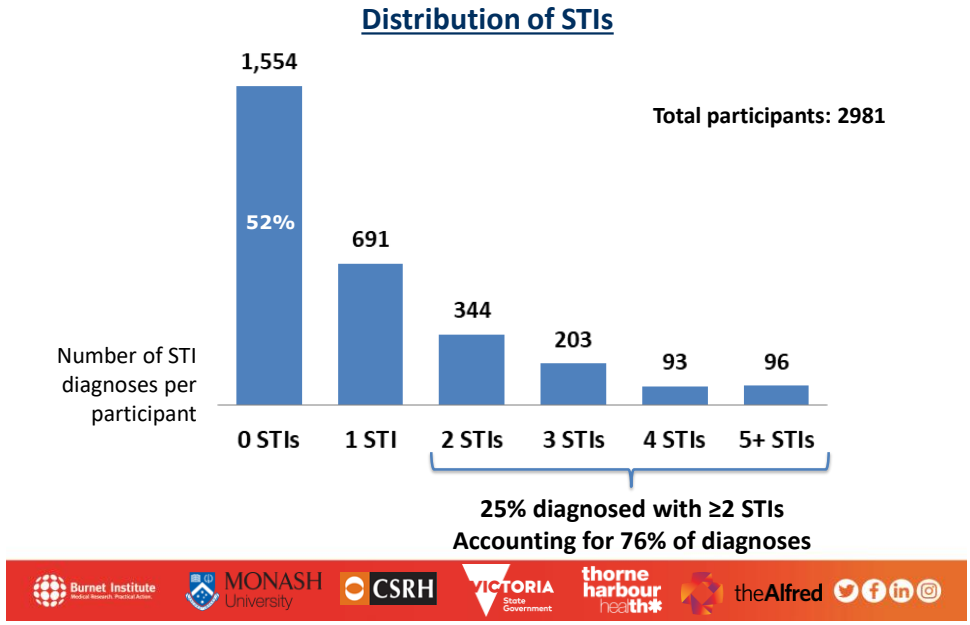

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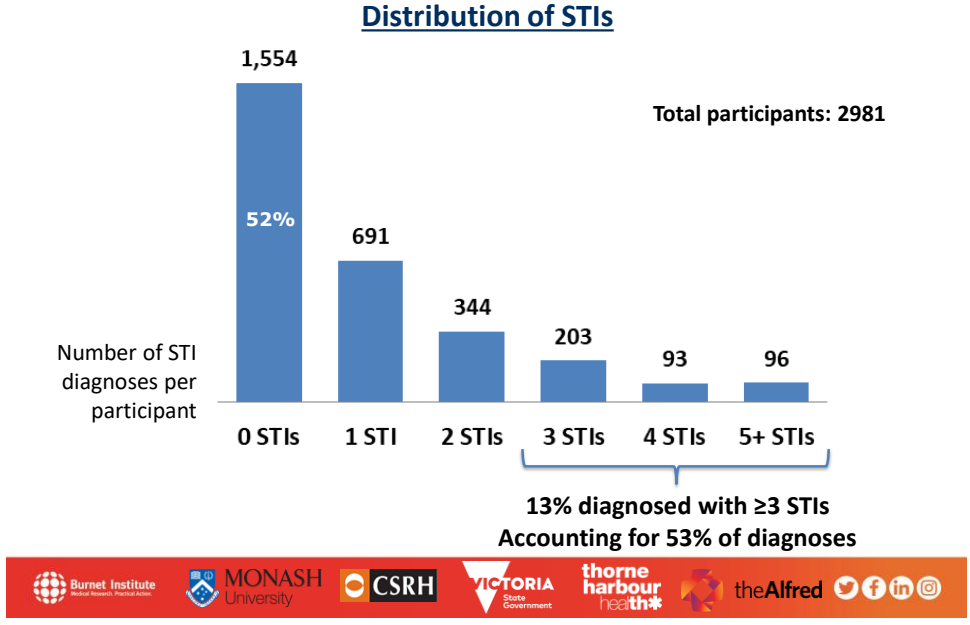

2. Behavioural predictors of STIs

Methods

- **Behavioural survey completed at baseline and every three months**

  Condom use, number of partners, drug use, participation in group sex

- **Cox proportional hazards regression model**

  Demographic and behavioural covariates

  Time-varying behavioural covariates 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
Reporting PrEP use before PrEPX	1.10 (0.96 – 1.27)	0.161
GHB use during sex in last 6 months	1.24 (1.02 – 1.51)	0.027

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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
  ≥1 STI test at least 6 months before PrEPX enrolment

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- **Disaggregated by previous PrEP use**
  541 previous PrEP-users (39%)
  837 PrEP-naïve participants (61%)

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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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

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Change in testing rate

	Mean number of visits			Mean number of tests		
	1 year before PrEPX	During PrEPX	Change	1 year before PrEPX	During PrEPX	Change
Previous PrEP users	4.4	4.7	+7%	11.7	13.0	+10%
PrEP-naïve participants	3.2	4.7	+48%	8.5	12.9	+51%

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Adjusted negative binomial model

	Unadjusted		Adjusted*	
	IRR (95% CI)	p-value	aIRR (95% CI)	p-value
Previous PrEP users				
Any STI	1.13 (0.99 – 1.28)	0.072	1.05 (0.92 – 1.19)	0.490

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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

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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

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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
  - Modeling indicates that increased screening among PrEP users may lead to an overall decrease in population-level STI incidence[5]

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- **Strategies targeted towards PrEP users experiencing high rates of reinfection could have a significant community-level impact**
- **Community involvement critical to success of future measures to reduce STIs**

Acknowledgements

PrEPX Study Team

Edwina Wright – Principal Investigator
Brian Price
Anne Mak
Luxi Lal
Dean Murphy
Jude Armishaw
Timmy Lockwood
Olga Vujovic
Christina Chang
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Study Clinics

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

Pharmacies

John Silverii's Pharmacy: John Silverii
Newton and Leung Pharmacy: Johnny Phu
Melbourne Sexual Health: Anne Mak
Alfred Clinical Trials Pharmacy: Anne Mak
Healthsmart: Joseph Tesoriero
Central Pharmacy: Manoj Vassan, Kie Lim
Russell Frajman Pharmacy: Russell Frajman

ACCESS

Burnet Institute, Kirby Institute & NRL

Community Organisations

VAC: Simon Ruth, Colin Batrouney, Jeremy Wiggins
PrEP'DForChange: Chris Williams
PrEPaccessNOW: Jeff Montgomery & Michael Whelan
Living Positive Victoria: Brent Allen
Victorian Aboriginal Controlled Community Health Organisation: Kat Byron
Centre for Culture Ethnicity and Health: Alison Coelho
Harm Reduction Victoria: Jenny Kelsall

Funding Bodies

Victorian Department of Health and Human Services: Michael West
Alfred Health (Study sponsor): Andrew Way
Victorian AIDS Council*: Simon Ruth

Research Participants

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

References

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