



Trends in bacterial STI diagnoses among gay and bisexual men before and after emergent doxyPEP guidance

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AT BURNET INSTITUTE, WE PROUDLY ACKNOWLEDGE
THE BOON WURRUNG PEOPLE OF THE KULIN NATIONS
AS THE TRADITIONAL CUSTODIANS OF THE LAND ON
WHICH OUR OFFICE IS LOCATED. WE PAY OUR
RESPECT TO ELDERS PAST AND PRESENT, AND EXTEND
THAT RESPECT TO ALL FIRST NATIONS PEOPLE.

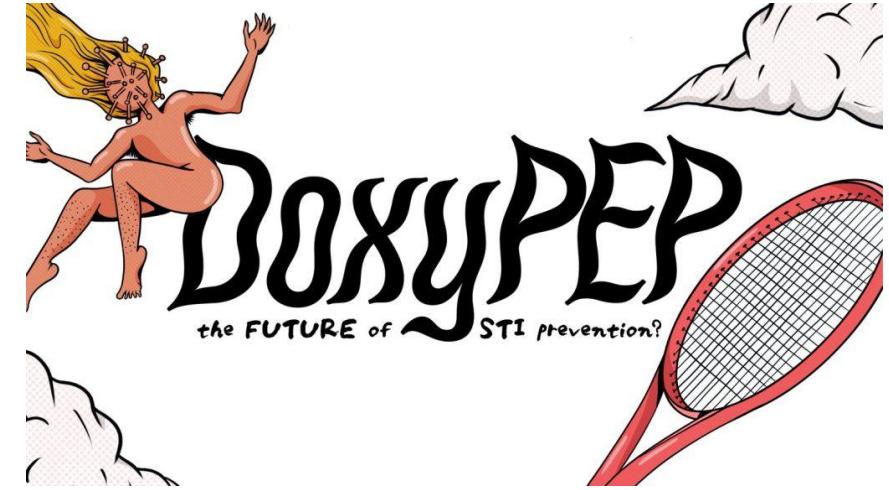


Disclosures

- Honoraria from Gilead Sciences Ltd.

Background

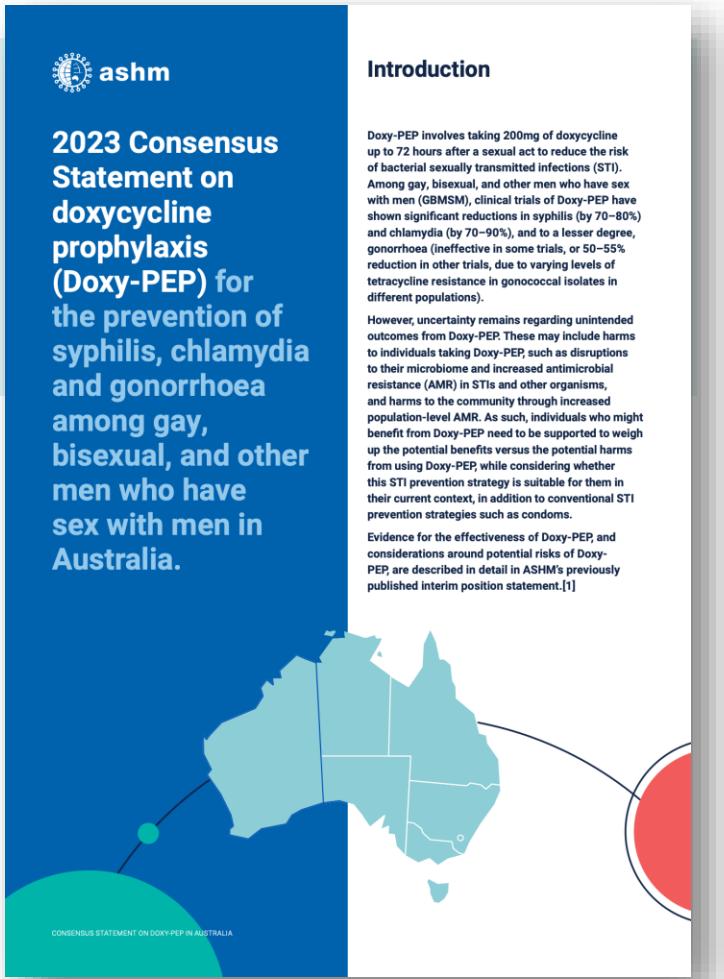
- DoxyPEP reduced syphilis & chlamydia in large RCTs of gay and bisexual men and transgender women^{1,2}
- **DoxyPEP Consensus Statement released in 2023**
- US data suggest doxyPEP implementation is already having a significant population-level effect
- Few data are available on population-level uptake and impact of doxyPEP in Australia



Aim

- Explore population-level changes in bacterial STIs among gay and bisexual men in Australia following the release of emergent doxyPEP guidance

Australian consensus statement



ashm

2023 Consensus Statement on doxycycline prophylaxis (Doxy-PEP) for the prevention of syphilis, chlamydia and gonorrhoea among gay, bisexual, and other men who have sex with men in Australia.

Introduction

Doxy-PEP involves taking 200mg of doxycycline up to 72 hours after a sexual act to reduce the risk of bacterial sexually transmitted infections (STI). Among gay, bisexual, and other men who have sex with men (GBMSM), clinical trials of Doxy-PEP have shown significant reductions in syphilis (by 70–80%) and chlamydia (by 70–90%), and to a lesser degree, gonorrhoea (ineffective in some trials, or 50–55% reduction in other trials, due to varying levels of tetracycline resistance in gonococcal isolates in different populations).

However, uncertainty remains regarding unintended outcomes from Doxy-PEP. These may include harms to individuals taking Doxy-PEP, such as disruptions to their microbiome and increased antimicrobial resistance (AMR) in STIs and other organisms, and harms to community through increased population-level AMR. As such, individuals who might benefit from Doxy-PEP need to be supported to weigh up the potential benefits versus the potential harms from using Doxy-PEP, while considering whether this STI prevention strategy is suitable for them in their current context, in addition to conventional STI prevention strategies such as condoms.

Evidence for the effectiveness of Doxy-PEP, and considerations around potential risks of Doxy-PEP, are described in detail in ASHM's previously published interim position statement.^[1]

CONSENSUS STATEMENT ON DOXY-PEP IN AUSTRALIA

1 Doxy-PEP should be considered primarily for the prevention of syphilis in GBMSM who are at risk of this STI, although for some individuals the reduction in chlamydia, and the lesser reduction of gonorrhoea might be important. Some stakeholders held the view that Doxy-PEP should be considered *only* for the prevention of syphilis in GBMSM, for the reasons listed above.

2 While evidence for appropriate suitability criteria for commencing Doxy-PEP is limited, the following might be appropriate for considering doxy-PEP until further data emerges:

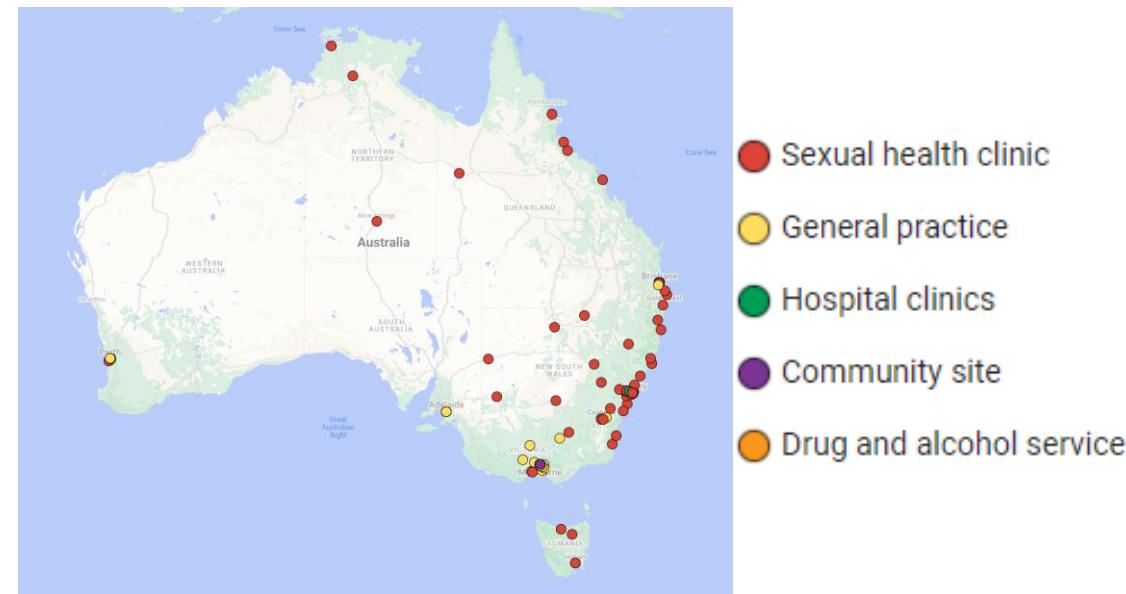
- GBMSM with a recent syphilis diagnosis (e.g., within the previous six or twelve months); or
- GBMSM with two or more recent other (i.e., not syphilis) bacterial STI diagnoses (e.g., within the previous six or twelve months); or
- GBMSM who identify an upcoming period of heightened STI risk, for example, attendance at a sex event, or holiday plans that likely involve sexual activity with multiple casual sexual partners; or
- GBMSM with concurrent male and cisgender female sexual partners or other sexual partners with a uterus, recognising the additional health risks posed by chlamydia, gonorrhoea and syphilis for people with a uterus.
- GBMSM who present for HIV PEP can also consider Doxy-PEP, although the indications for HIV PEP do not necessarily indicate a need for Doxy-PEP.

Data source



*Australian Collaboration for Coordinated Enhanced
Sentinel Surveillance of Blood-borne Viruses and
Sexually Transmitted Infections*

- Surveillance network established >10 years ago
- >100 services with national representation
- High coverage of PrEP users and PLWHIV
- Specialised data extraction software GRHANITE
- Linkage allows for individual-level, longitudinal monitoring over time and across clinics
- Line-listed data for HIV, STIs, viral hep, Rx, Dx, visits



Data source



Limitation:

- While doxycycline prescriptions are captured, data on **prescription reason** not well recorded
- DoxyPEP often **prescribed off-label**, with clinicians **not recording intended use** in EMS
- **High variability** in the amount prescribed and number of refills (no formal clinical guidelines)
- High levels of **informal use** (i.e., doxycycline not prescribed by a doctor)

Unable to classify individuals
in ACCESS as doxyPEP users

Ecological analysis
(with sensitivity analyses)



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graph LR; A[Unable to classify individuals in ACCESS as doxyPEP users] --> B[Ecological analysis (with sensitivity analyses)]
```

Methods *Interrupted time series*

Cohort: Gay and bisexual men attending ACCESS clinics

Data: All positive diagnoses of

- Syphilis (newly identified case of infectious syphilis)
- Chlamydia (positive NAAT)
- Gonorrhoea (positive NAAT)



Study period: 1st January 2022 - 31st December 2024 (3 years)

Interrupted time series: Segmented linear regression

- Number of new STI diagnoses per calendar month
- Estimated relative change in diagnoses at **December 2024** (last time point)
 - Compared **fitted value of observed data** vs **expected value under counterfactual scenario** of no doxyPEP guidance

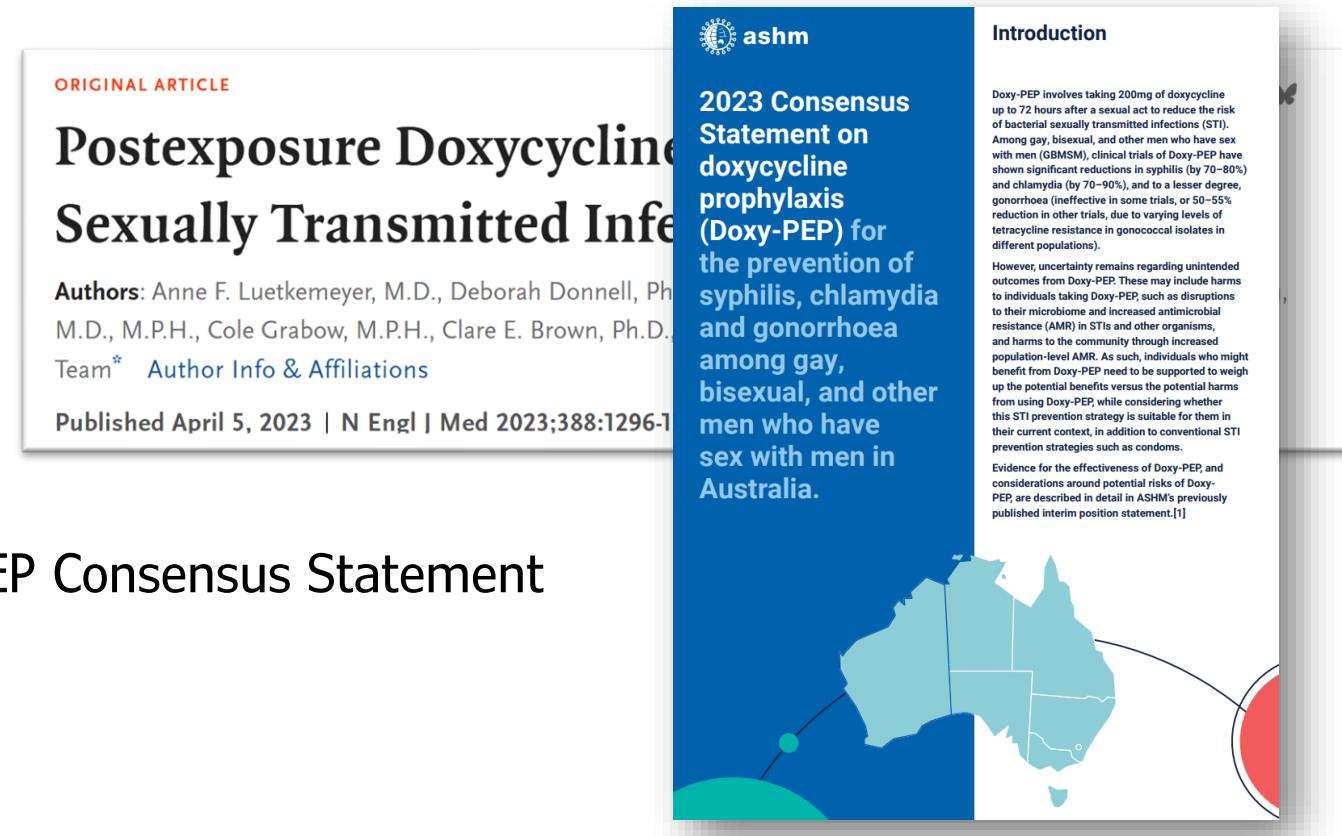
Methods *Interruptions*

Interruption 1: Publication of US DOXYPEP study in NEJM (Leutkemeyer et al)

Coincided with community health promotion about doxyPEP in US & Australia

Published April 5th 2023

Interruption set at **April 2023**



The image shows a screenshot of a NEJM article. At the top left is the 'ashm' logo. The title is '2023 Consensus Statement on doxycycline prophylaxis (Doxy-PEP) for the prevention of syphilis, chlamydia and gonorrhoea among gay, bisexual, and other men who have sex with men in Australia'. The text discusses Doxy-PEP and its effectiveness. The abstract begins with 'Doxo-PEP involves taking 200mg of doxycycline up to 72 hours after a sexual act to reduce the risk of bacterial sexually transmitted infections (STI)...'. The introduction continues with 'However, uncertainty remains regarding unintended outcomes from Doxy-PEP. These may include harms to individuals taking Doxy-PEP, such as disruptions to their microbiome and increased antimicrobial resistance (AMR) in STIs and other organisms, and harms to the community through increased population-level AMR. As such, individuals who might benefit from Doxy-PEP need to be supported to weigh up the potential benefits versus the potential harms from using Doxy-PEP, while considering whether this STI prevention strategy is suitable for them in their current context, in addition to conventional STI prevention strategies such as condoms.' The abstract concludes with 'Evidence for the effectiveness of Doxy-PEP, and considerations around potential risks of Doxy-PEP, are described in detail in ASHM's previously published interim position statement.[1]' At the bottom right is a stylized map of Australia with a red circle in the bottom right corner.

Interruption 2: Release of Australian DoxyPEP Consensus Statement

Published September 27th 2023

Interruption set at **October 2023**

Methods *Sensitivity analyses*

Main analysis :

- All STI diagnoses among GBM attending an ACCESS clinic

Sensitivity analysis 1:

- Only include diagnoses among GBM with a recent (past 24 months) STI
- **-> Proxy for doxyPEP eligibility criteria**

Sensitivity analysis 2:

- Only include diagnoses among GBM with any doxycycline prescription during the study period
- **-> Closer to cohort of GBM prescribed doxyPEP at an ACCESS clinic**

Results

STI diagnoses



8,075 syphilis diagnoses
40,773 chlamydia diagnoses
36,074 gonorrhoea diagnoses

Cohort



36,027 GBM
with at least one
STI diagnosis

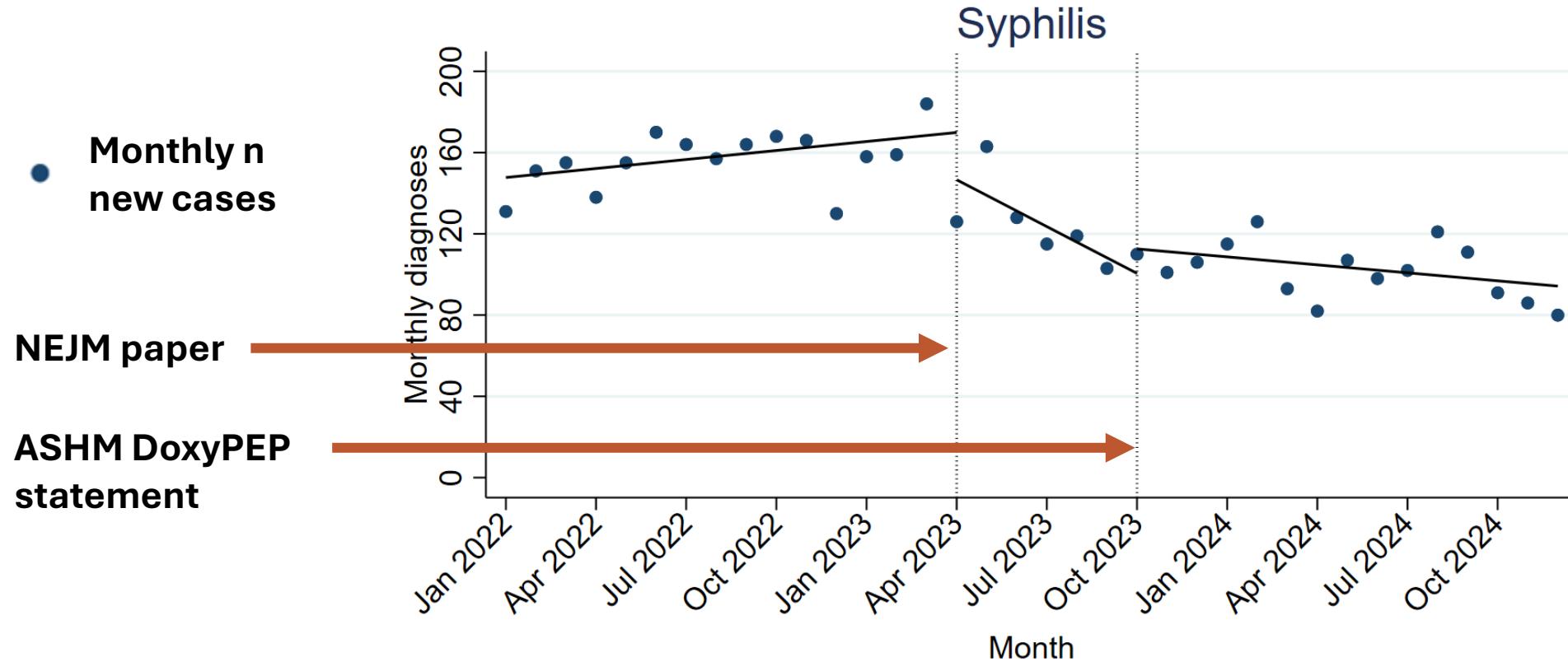
Clinics



27 services
58% SHCs
42% GPs

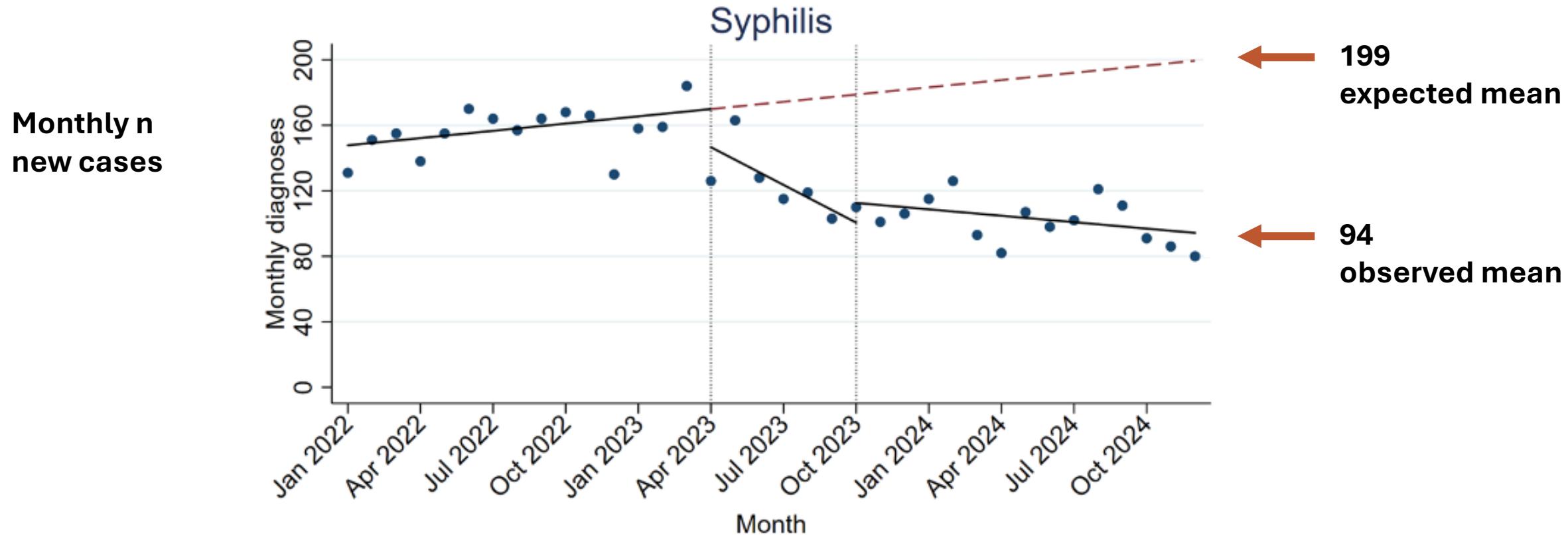
Results

Monthly syphilis diagnoses



Results

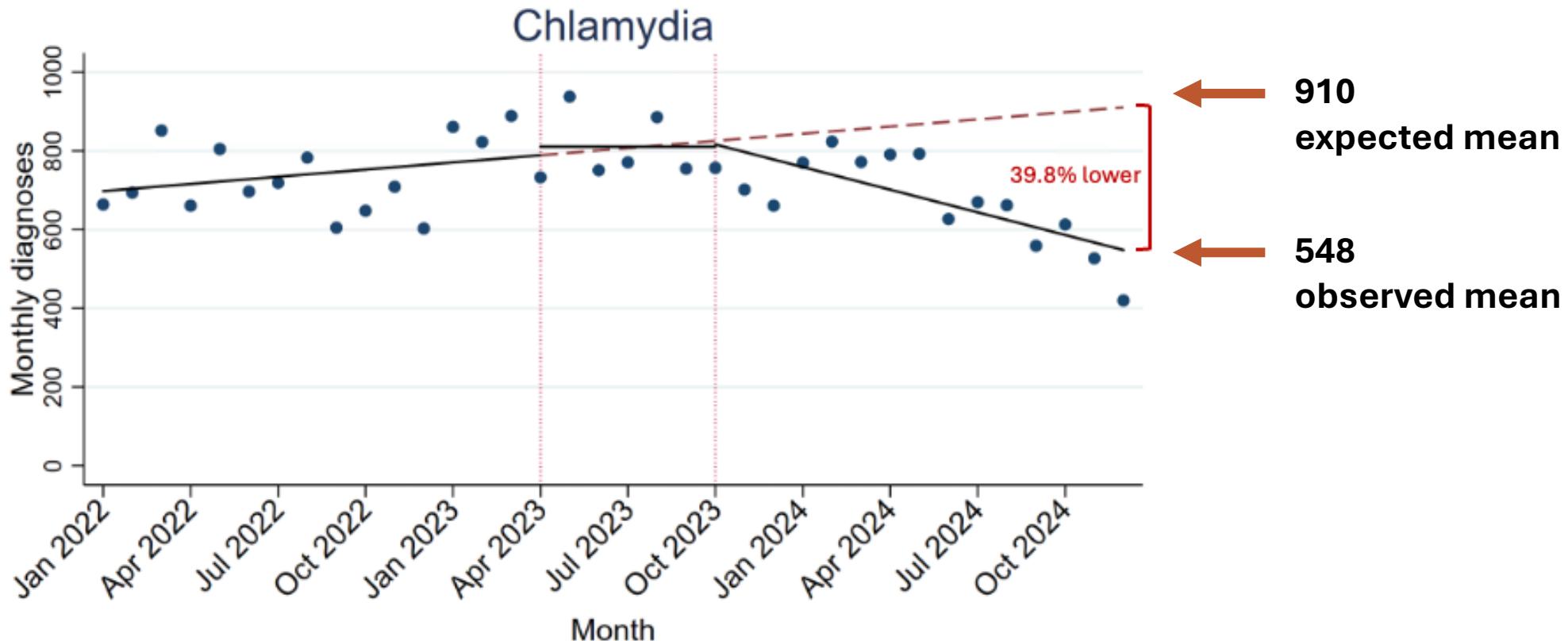
Monthly syphilis diagnoses



Results

Monthly chlamydia diagnoses

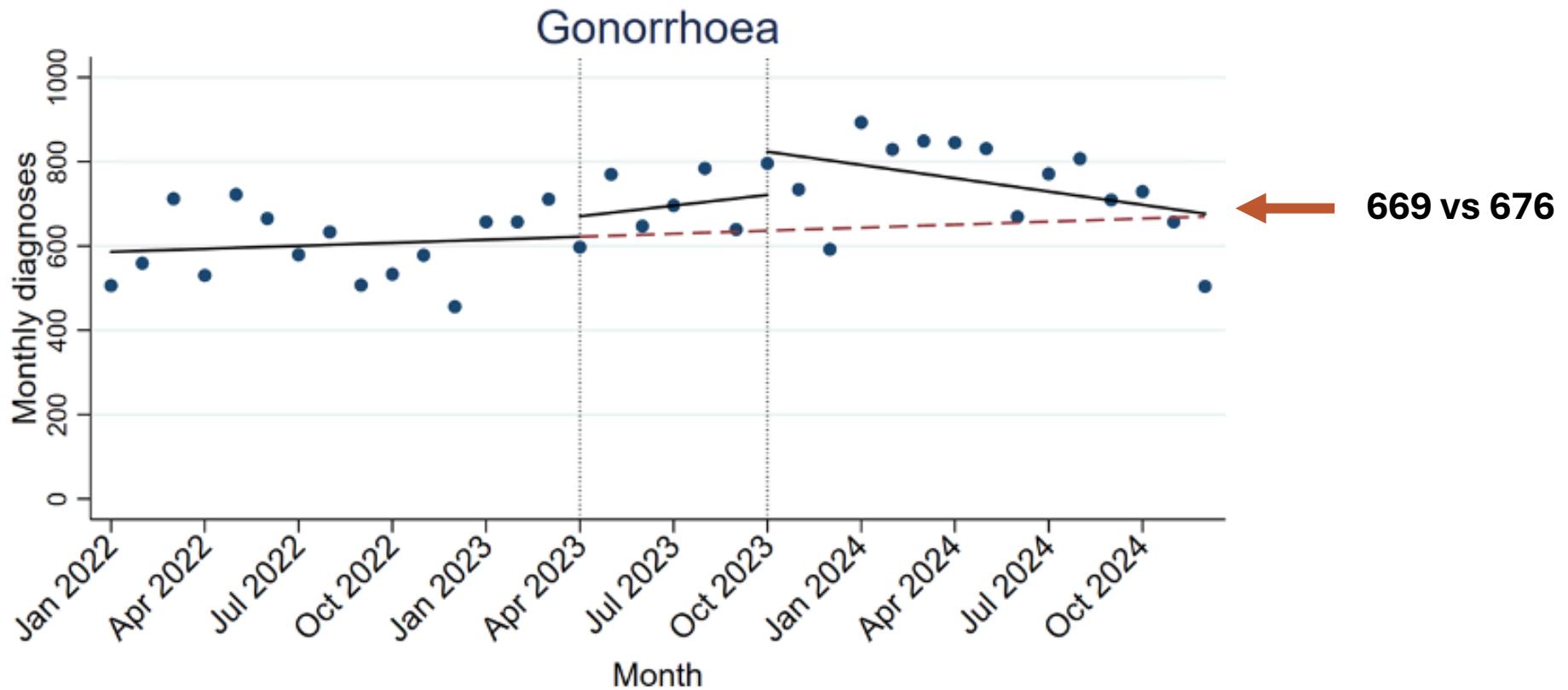
Monthly n
new cases



Results

Monthly gonorrhoea diagnoses

Monthly n
new cases



Results *Sensitivity analyses*

**Counterfactual vs observed (relative reduction)
at December 2024**

	Syphilis	Chlamydia	Gonorrhoea
Main analysis	199 vs 94 (-52.7%)	910 vs 548 (-39.8%)	669 vs 676 (+1.0%)

Results *Sensitivity analyses*

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Sensitivity 1: GBM with >1 STI in past 24 months	104 vs 44 (-57.7%)	458 vs 293 (-36.0%)	312 vs 334 (+7.1%)

Results *Sensitivity analyses*

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Sensitivity 1: GBM with >1 STI in past 24 months	104 vs 44 (-57.7%)	458 vs 293 (-36.0%)	312 vs 334 (+7.1%)
Sensitivity 2: GBM with >1 doxycycline prescription (any indication) in study period	127 vs 54 (-57.5%)	888 vs 509 (-42.7%)	494 vs 454 (-8.4%)

Discussion

Syphilis & chlamydia among gay and bi men have curtailed following doxyPEP guidance

- We estimated a relative reduction of 57% for syphilis and 40% for chlamydia
- Impact may have been earlier for syphilis than for chlamydia
- Similar to population-level data from San Francisco showing similar trends¹

DoxyPEP use increased over the study period

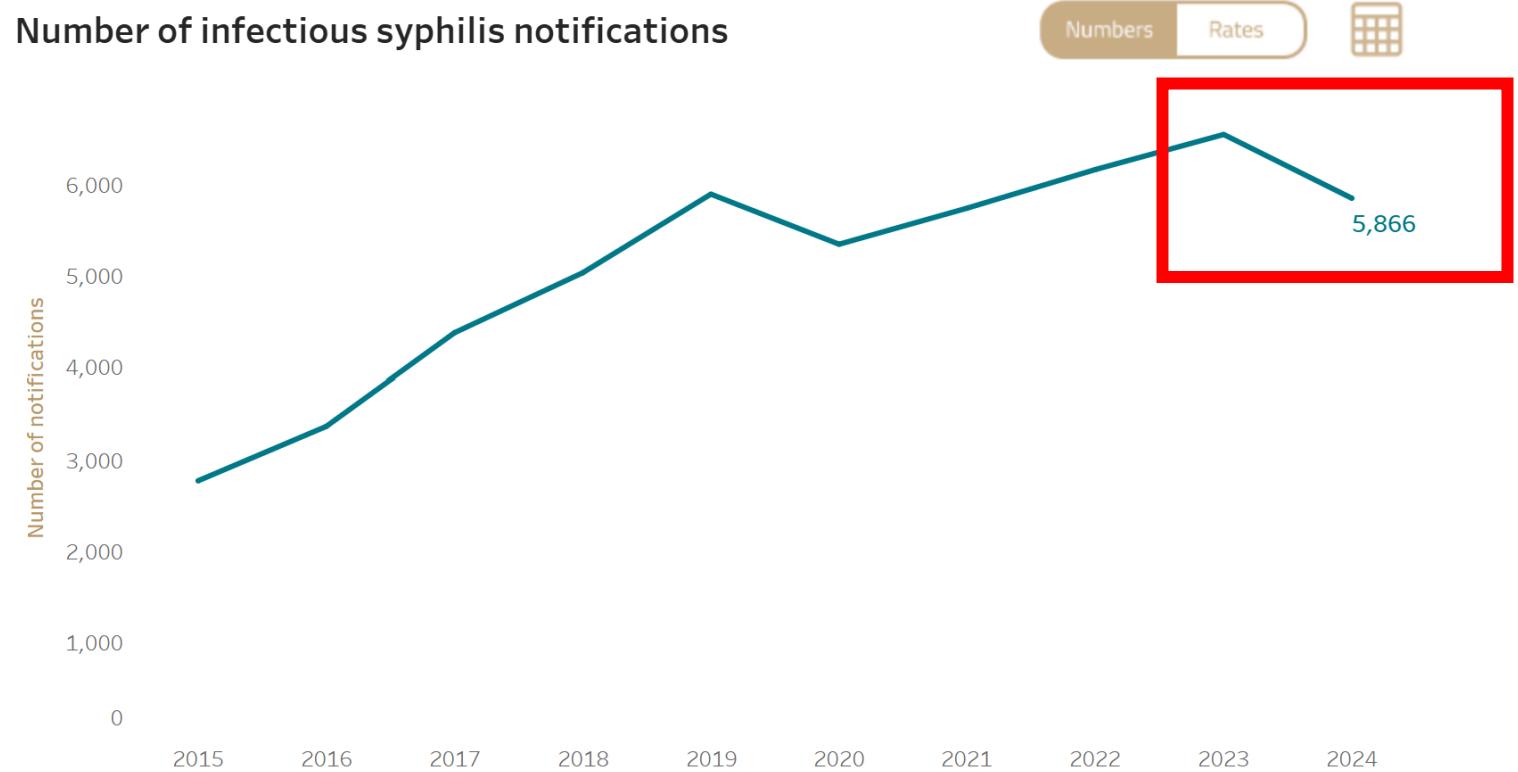
- GBQ+ Periodic Survey in 2025² - 13% of GBM in Melbourne had used doxyPEP in past 6m
- Survey of 2,095 GBM in Australia in July-November 2024 found that (Latt et al)
15.4% had ever used doxyPEP and 14.6% had used doxyPEP in the past year

Data suggest doxyPEP may already be having an impact on population-level STIs

Need for ongoing surveillance including changes in gonorrhoea AMR

Next steps

- Larger model incorporating testing rates
- Compare to trends in non-GBM populations
- Explore trends in NNDSS notification data
- Work with ACCESS sites to capture self-reported doxyPEP use



Acknowledgements

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Jason Asselin
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Burnet
reach for the many

Thank you

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