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# The GIN study

## Incidence and duration of oropharyngeal gonorrhoea and chlamydia infections among men who have sex with men: a prospective cohort study

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# Declaration

The authors declare no conflicts of interest

# Background



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- Gonorrhoea infections have been rising internationally, and men who have sex with men (MSM) are disproportionately affected
- Controlling gonorrhoea among MSM is challenging, with increased use PrEP and a decline in condom use
- Among symptomatic individuals, timely diagnosis and treatment is possible to reduce the rate of ongoing transmissions
  - However extragenital sites of infection are frequently associated with a lack of symptoms and asymptomatic infections may be missed
- Gonorrhoea infection is commonly detected at the oropharynx
  - Both *N. gonorrhoeae* and *Chlamydia trachomatis* can be detected in saliva and may be transmitted during saliva exchange
- However, the natural history and incidence rates of oropharyngeal infections is poorly understood



Source: Photo from Gaymers México

Chow Lancet HIV 2019; Lahra Microbiology Australia 2016; Holt Lancet HIV 2018; Fairley Sex Health 2015; Cornelisse STD 2017; Fairley Lancet ID 2019; Fairley EID 2017; Chow J Clin Micro 2016; Phillips J Clin Microbiol 2019; Chow STI 2019



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- To determine the natural history and incidence of oropharyngeal gonorrhoea and chlamydia among a cohort of MSM over a 12-week period
- To examine risk factors associated with incident oropharyngeal infections





## Study design & Eligibility – build and add assay used

- The **G**onorrhoea **I**ncidence (**GIN**) Study – a prospective cohort study of MSM
- From August to October 2019, 100 MSM were recruited from MSHC
- Eligibility:
  - Sufficient English to understand procedures, and aged  $\geq 18$  years
  - Men at a higher risk of gonorrhoea acquisition were recruited:
    - Diagnosis of oropharyngeal gonorrhoea in the last 3mo
    - OR taking PrEP (aged 18-35)
    - OR had at least one casual partner in prior 3mo if not taking PrEP
- Men provided saliva samples and questionnaires weekly for 12 weeks (reimbursed \$10 per sample)
- All oropharyngeal swabs and saliva samples were tested by NAAT using the Aptima Combo 2 assay (Hologic Panther system)
- The incidence rate was defined as the number of incident cases per 100 person-years
- Poisson regression was performed to examine the risk factors associated with incident oropharyngeal infection, with incident rate ratios (IRR) and corresponding 95% confidence intervals calculated



## Sampling & Study Timeline

**Baseline day 0  
(clinic)**

**Weeks 1-11  
(home/postal sample)**

**Week 12  
(clinic)**



### How to take a saliva sample instruction sheet



**1 What's in each pack?**

- a) A padded bag for reply paid postage
- b) A questionnaire
- c) 1 plastic zip-lock bag
- d) A small yellow topped tube (UriSWAB)
- e) A large yellow topped jar (saliva jar)

**2 To start**

- a) Wash your hands thoroughly with soap and water
- b) Remove the lid from the saliva jar in preparation to spit into the jar

**3 Preparing for the saliva sample**

- a) Accumulate saliva in your mouth for about 30 seconds to get a reasonable saliva sample
- b) Spit as much saliva into the jar as possible

If the sample is small, repeat step a) again to **increase** the saliva sample

**4 Collecting the saliva sample**

- a) Open the small yellow topped tube (UriSWAB) you will see a sponge attached to the lid
- b) Swirl the absorbent sponge in the saliva for 30 seconds. You may need to tilt and rotate the sponge several times into the saliva to ensure maximum coverage of the sponge area. Ensure the sponge is completely saturated with the saliva

**5 Completing the sample collection**

- a) Place the UriSWAB back in the tube and seal firmly
- b) Put the lid back on the saliva jar and discard in the bin.

**6 Seal and bag sample**

- a) Write the date you collected the saliva sample on the UriSWAB
- b) Place the UriSWAB into the small plastic bag and seal

**7 Questionnaire**

- a) Wash your hands with soap and water
- b) Complete the corresponding questionnaire provided

**8 Postage**

- a) Place both the plastic bag with the UriSWAB and the completed questionnaire into the reply paid envelope
- b) Seal the envelope
- c) Deposit the reply paid envelope in any Australia Post box. There is no cost for postage

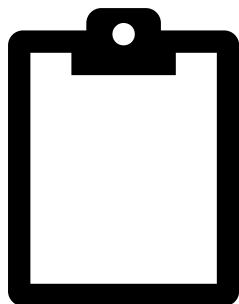


## Sampling & Study Timeline





## Baseline demographic and sexual practices data



Median age = 30 years (IQR=26-33 years)



HIV-negative taking PrEP n=89 (89%); HIV-negative not taking PrEP (n=9); living with HIV (n=2)



Oropharyngeal gonorrhoea detected in the 3 months prior to enrolment n=78 (78%)

Sexual practices in the 3 months prior to enrolment:



- Median number of male partners = 9 (IQR: 5-15)



- Median tongue-kissing partners = 8 (IQR: 4-15)



- Median penile-oral sex partners = 5 (IQR: 3-10)



- Median insertive rimming partners = 2 (IQR: 2-6)



## Oropharyngeal *N.gonorrhoeae* detected



12 men had oropharyngeal gonorrhoea detected

4 men had transient oropharyngeal gonorrhoea detected, which was then undetectable in the following 2+ weeks

2/4 had oropharyngeal gonorrhoea detected again at study endpoint

	Week												
ID	0	1	2	3	4	5	6	7	8	9	10	11	12
1					S	S	S, O	S*					
2											S	S	S, O
3													O
4							S	S	S	S			
5					S	S	S	S	S	S	S		O
6												S	S, O
7													O
8								S					O, A
9						S	S		S				O, A
10													O, A, U
11			S	S									O
12								S	S	S	S	S, O	*

	Negative NAAT result	S=saliva sample
	Positive NAAT result	O=oropharyngeal swab
	Equivocal NAAT result	A=anal sample
	Invalid NAAT result	U=urethral sample
	No sample	

## Oropharyngeal *N.gonorrhoeae* detected

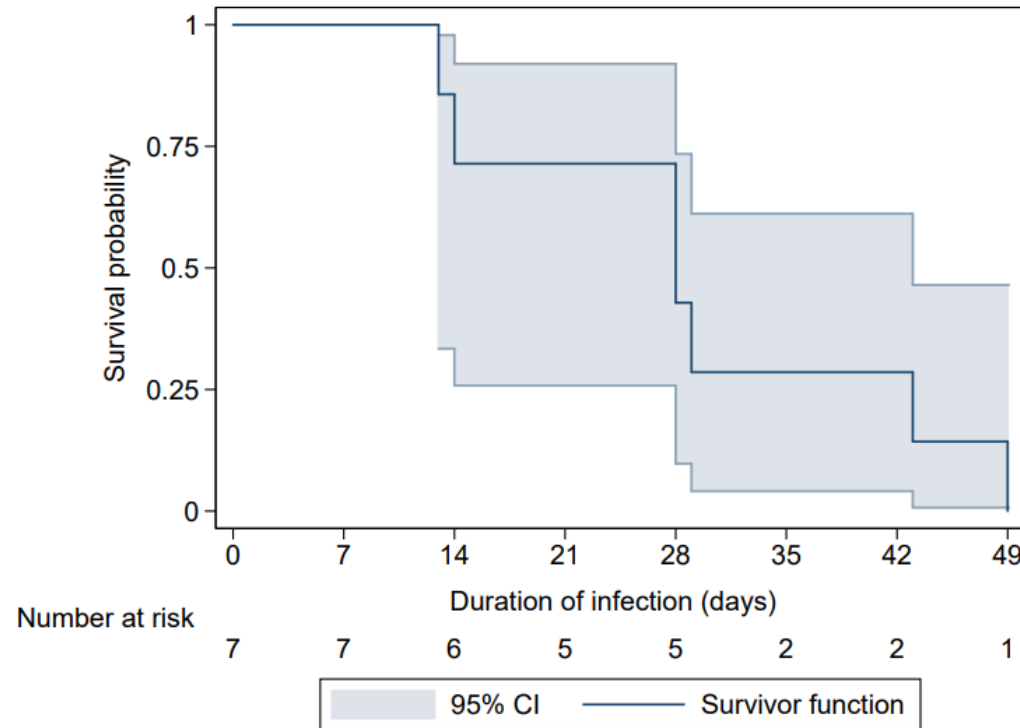


Overall incidence of  
oropharyngeal gonorrhoea:  
62 (95%CI:37-105)  
per 100 person-years

	Week												
ID	0	1	2	3	4	5	6	7	8	9	10	11	12
1					S	S	S, O	S*					
2											S	S	S, O
3													O
4							S	S	S	S			
5					S	S	S	S	S	S	S		O
6												S	S, O
7													O
8								S					O, A
9						S	S		S				O, A
10													O, A, U
11			S	S									O
12								S	S	S	S	S, O	*

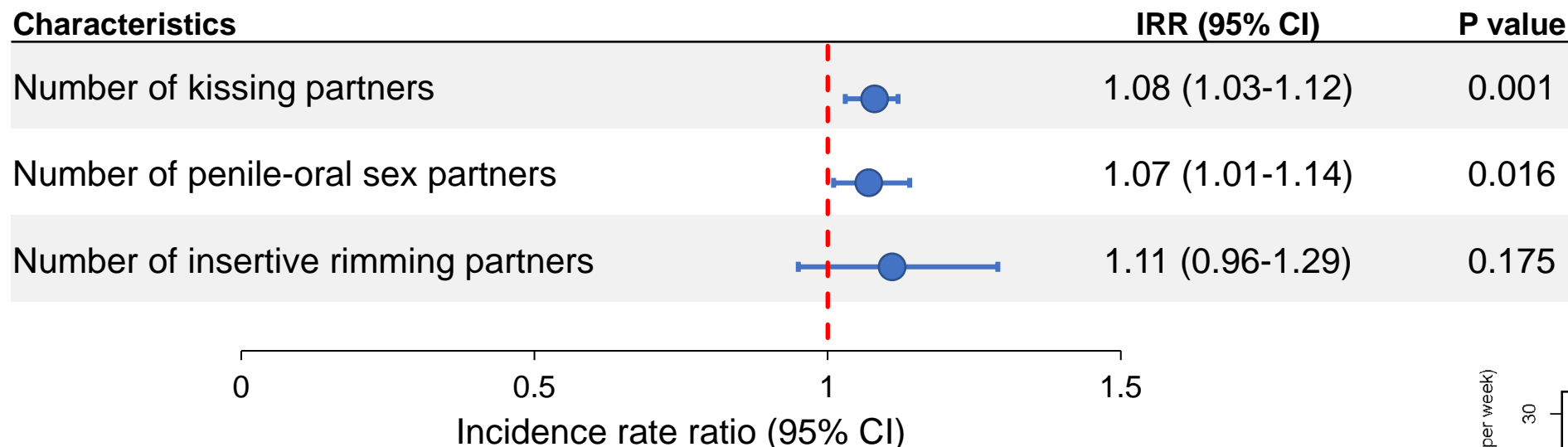
	Negative NAAT result	S=saliva sample
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## Oropharyngeal *N.gonorrhoeae* duration of infection



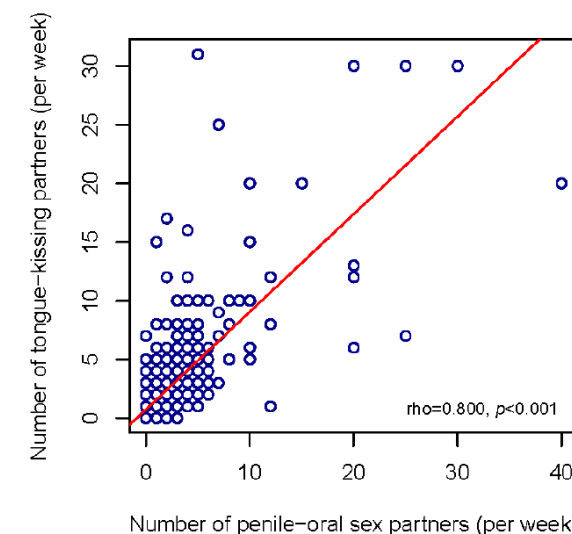
Incident oropharyngeal gonorrhoea  
persisted for a median of  
28 days (IQR=21-36 days)  
n=7

## Risk factors for oropharyngeal *N. gonorrhoeae* infection



Of the 14 incident cases:

- 2 men reported intervals with kissing but NO penile-oral or insertive rimming partners
- 12 men reported intervals with kissing AND penile-oral OR insertive rimming partners








## Oropharyngeal chlamydia detection



- Only 2 incident oropharyngeal chlamydia diagnoses in 2 men

	Week												
ID	0	1	2	3	4	5	6	7	8	9	10	11	12
1	S, O	S*			S								
2											S	S	S, O

 Negative NAAT result  
 Positive NAAT result  
 No sample  
 S=saliva sample  
 O=oropharyngeal swab

Overall incidence of oropharyngeal  
chlamydia: 9 (95%CI: 2-35)  
per 100 person-years

Duration of infection and factors associated with incident infection could not be assessed

# Strengths & Limitations



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- Saliva samples sent via the post resulted in a very high return rate (95%)
- We may have underestimated the true incidence and duration of infection for oropharyngeal gonorrhoea
  - saliva was less sensitive than a throat swab for oropharyngeal gonorrhoea using the Aptima combo assay [7/10 men were swab positive, saliva negative at week 12]
  - STIs and sexual practices vary seasonally, STI cases peak around summer

**Poster 138** A/Prof Eric Chow: Seasonal variations in kissing and sexual activities among men who have sex with men in Melbourne, Australia: implications for seasonal STI preventions and interventions



- We specifically choose men who were likely to have a high incidence of oropharyngeal gonorrhoea and so our estimate may not be generalisable
- Few oropharyngeal chlamydia positive results limited further analyses



# Summary of findings



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- The incidence of oropharyngeal gonorrhoea infection in this cohort was 60% per year
- Half of the cases were detected first on saliva samples collected at home
- Median duration that gonorrhoea infection persisted for was 28 days
  - ? underestimated as saliva not as sensitive as swab samples
  - Barbee *et al* estimated that the median duration of oropharyngeal gonorrhoea infection was 9 weeks (95%CI: 3-19)
- Incident oropharyngeal gonorrhoea was associated with exposure to a partners mouth (i.e. kissing) and/or penis (i.e. penile-oral sex) but not their partner's anus (i.e. rimming) in the previous week
  - Separating the independent contribution of these acts is challenging
- 2 incident oropharyngeal gonorrhoea cases were in men who reported kissing-only partners in the week prior to infection being detected



- Our study implicates the oropharynx as a site for gonorrhoea transmission
- The incidence of oropharyngeal gonorrhoea was relatively high among MSM predominately taking PrEP and the duration of infection was short, with some persisting for only a few weeks
- The current 3-monthly screening approach may not be sufficient to control gonorrhoea
  - Short duration of infection implies screening would need to be very frequent
  - Further studies are required to assess the harms, benefits, cost-effectiveness and adherence to more frequent screening
  - Other novel strategies may be required





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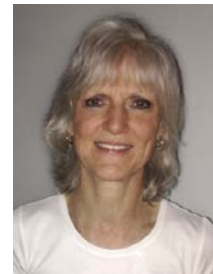
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# Thank you



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