UK Health Security Agency

PrEP Impact Trial

NHS Chelsea and Westminster Hospital NHS Foundation Trust

Public Health England

NHS England

STI incidence and PrEP uptake in participants from underserved populations in the HIV Pre-Exposure Prophylaxis (PrEP) Impact Trial

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1 Background

- PrEP and STIs
- PrEP Impact Trial
- Underserved populations

2 Analysis methods

- PrEP uptake
- STI incidence

3 Results

- PrEP uptake in women and other populations
- STI incidence in women and other populations

4 Key messages

- Limitations
- Implications

High incidence of **bacterial sexually transmitted infections (STIs)** among PrEP users[1]

Limited assessment in **women and other populations** outside of low resource settings[2]

To enable routine commissioning of HIV PrEP in England in 2017,

the **PrEP Impact Trial** was undertaken to assess **outstanding implementation questions**

We utilise data from the PrEP Impact Trial to assess PrEP uptake and STI incidence in typically underserved populations in PrEP programmes who accessed sexual health services (SHS) in England

[1] Traeger MW et al. JAMA. 2019 Apr 9;321(14):1380-1390. [2] Stewart J et al. AIDS. 2020 Apr 1;34(5):651-658

PrEP Impact Trial

PrEP Impact Trial

Prospective, **non-interventional**, non-randomised, open-label trial

Open to **all specialist sexual health services (SHS)** in England

Attendees underwent **clinical risk assessment** to determine **PrEP eligibility**

Trial data **linked** to **GUMCAD STI Surveillance System**

Protocol, eligibility found at:

www.prepimpacttrial.org.uk

Of 26,000 trial places, 1,000 places were ringfenced for underserved populations

Underserved populations in the PrEP Impact Trial

Women and other populations (WP)

Women

Cisgender (cis women)

Transgender (trans women)

Other populations

Men

Cisgender, heterosexual (cis het men)

Transgender (trans men)

Other populations

Non-binary people

(non-binary)

PrEP Impact Trial

PrEP Impact Trial Objectives

i.

To measure **PrEP-eligibility, PrEP-uptake, duration of PrEP-eligibility and duration of PrEP-use** (PrEP prevention care continuum) among SHS attendees in England

ii.

To determine whether or not incident **HIV infections** in trial participants are due to **non-adherence or biological failure**

iii.

To measure change over time in **HIV diagnoses and incidence rate** in those at high HIV risk

iv.

To measure change over time in **bacterial STI diagnoses and incidence rate** in those at high HIV risk

v.

To measure the **PrEP prevention care continuum by clinic throughput** and in different regions

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PrEP uptake in women other populations

Attendees clinically assessed as **eligible for PrEP** who joined the Impact Trial from trial start in **October 2017 through February 2020**
(i.e. prior to COVID-19 related restrictions)

PrEP Eligibility:

Recorded clinical coding:

- PrEP eligibility
- PrEP prescription
- PrEP offer and decline

% Uptake:

$$\frac{\text{No. of attendees taking up PrEP offer during analysis period (i.e. trial participants)}}{\text{No. of attendees defined as eligible during the analysis period}}$$

PrEP Impact Trial

STI incidence in women and other populations

No. of bacterial STI diagnoses in follow-up period

- Chlamydia (CT)*
- Gonorrhoea (GC)*
- Syphilis (Syph)*
- **Any STI**

*One respective diagnosis per 30-day window period

Follow-up through

- First positive HIV test, or
- Recorded trial discontinuation, or
- Last SHS visit

In trial participants, restricted to those with **at least 1 visit after enrolment**

In non-trial attendees, restricted to those with **at least 2 visits from start of SHS recruitment and no known outside sourcing of PrEP**

PrEP Impact Trial

STI incidence in women and other populations

Mean incidence rates per 100 person-years, 95% confidence intervals (Poisson regression)

Excludes diagnoses at enrolment (trial participant) or first SHS attendance (non-trial attendee)

Potential differences in service provision were accounted for by estimating a cluster-based variance–covariance matrix to account for **within-clinic correlation**

Incidence rates (IRs) adjusted for testing frequency

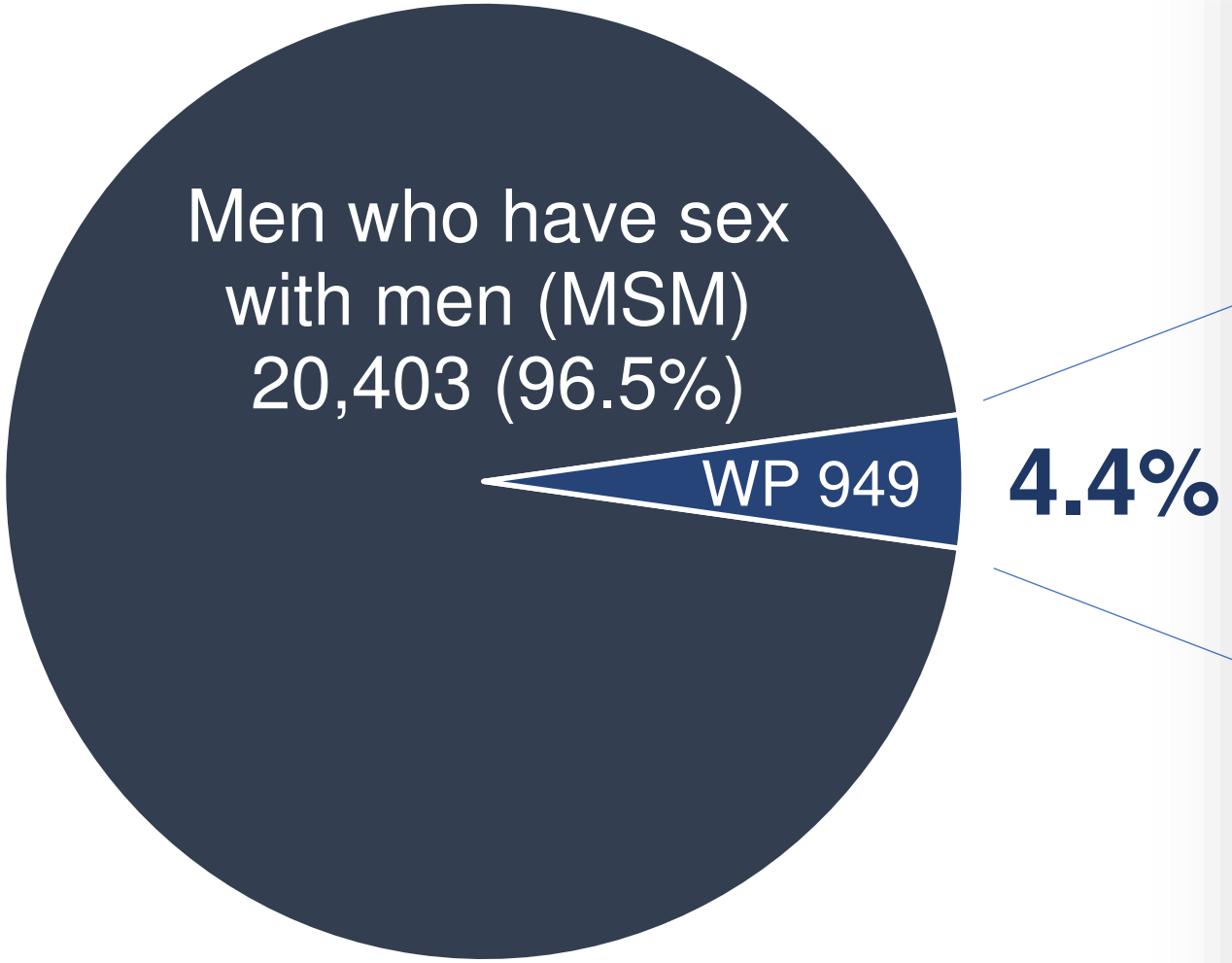
PrEP Impact Trial

4.4%

There were 21,356* trial participants recruited through February 2020

157 SHS across all regions of England
(80% of all SHS activity)

*Total includes 4 cisgender men with unknown sexual orientation



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Women and other populations

Participants	Cis women	Trans women	Cis het men	Trans men	Non-binary	MSM
Total	309	319	137	141	43	20,403

Women and other populations

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Total	**309**	**319**	**137**	**141**	**43**	**20,403**
Median age (IQR)	33 (27-42)	31 (26-41)	39 (31-51)	28 (24-38)	27 (23-32)	33 (27-42)
White ethnicity	58.9%	59.6%	48.9%	70.2%	58.1%	76.2%
UK born	53.4%	47.3%	52.6%	65.3%	62.8%	61.3%
Living in London	46.0%	59.3%	35.8%	52.5%	41.9%	53.1%
Most deprived IMD	30.7%	21.0%	19.7%	24.1%	23.3%	20.6%

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PrEP Uptake

	Attendees	Eligible	Enrolled*	Uptake
MSM	144,921	34,880	20,349	58.3%
Women and other populations	1,325,200	2,111	939	▼ 44.5%

*Excludes trial participants with no record of receiving a PrEP prescription during the analysis period (54 total,10 WP) **No surveillance identifier available

PrEP Uptake

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MSM		**144,921**	**34,880**	**20,349**	**58.3%**
Women and other populations		**1,325,200**	**2,111**	**939**	▼ **44.5%**
Women	Cis women	762,092	603	305	▼ 50.6%
	Trans women	462	359	318	▲ 88.6%
Men	Cis het men	562,354	942	135	▼ 14.3%
	Trans men	249	164	138	▲ 84.1%
Non-binary people**		N/A	N/A	43	N/A

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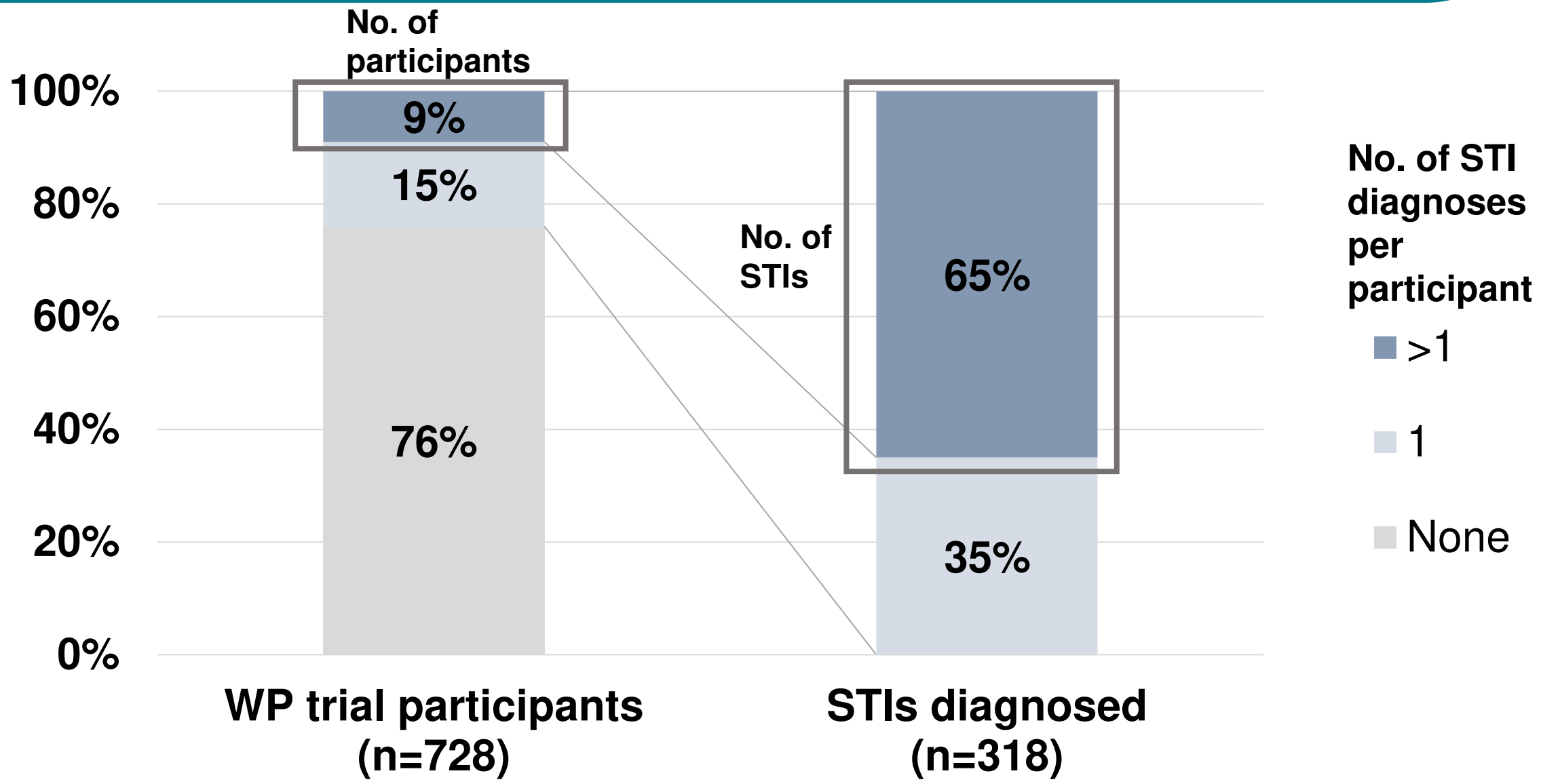

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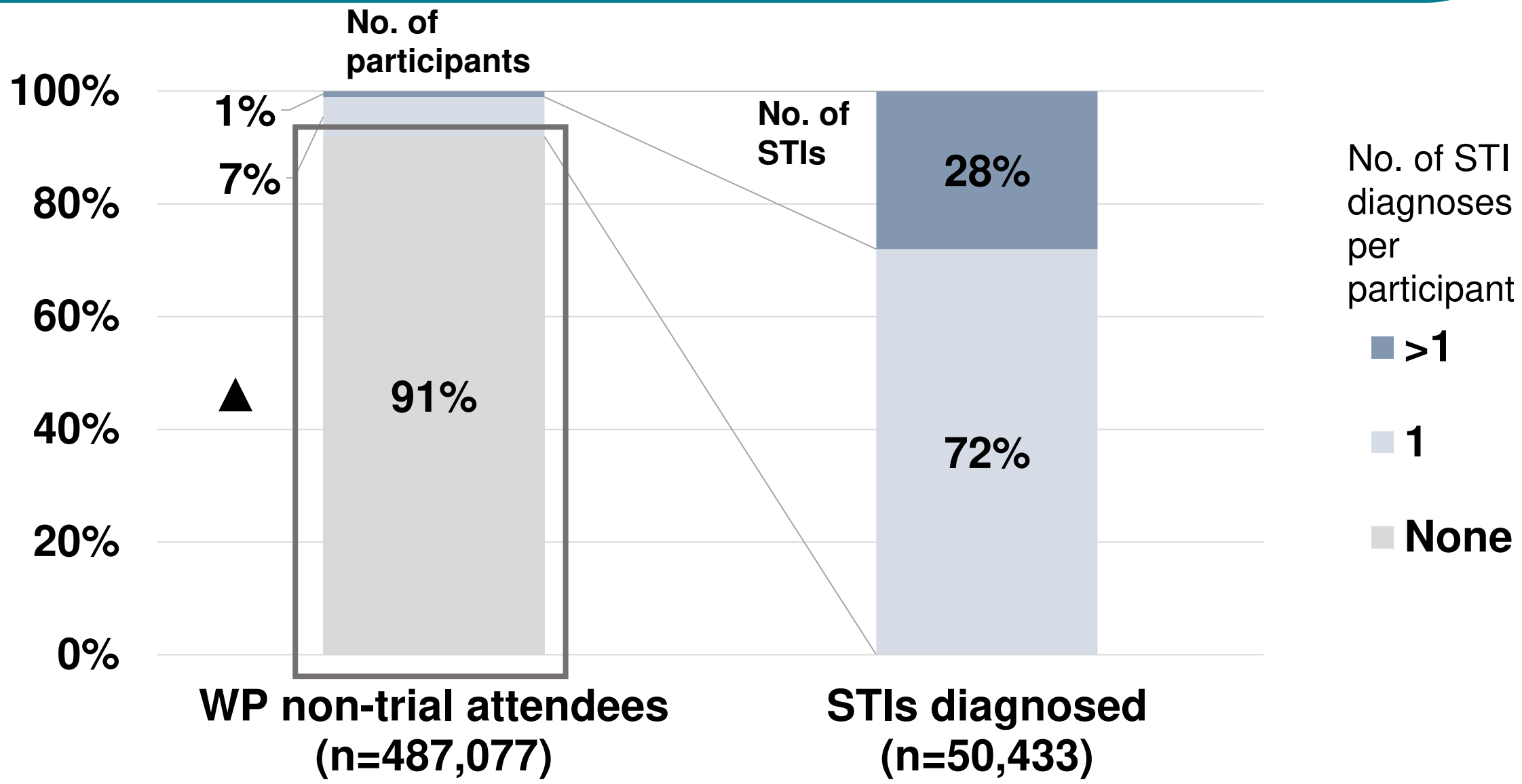

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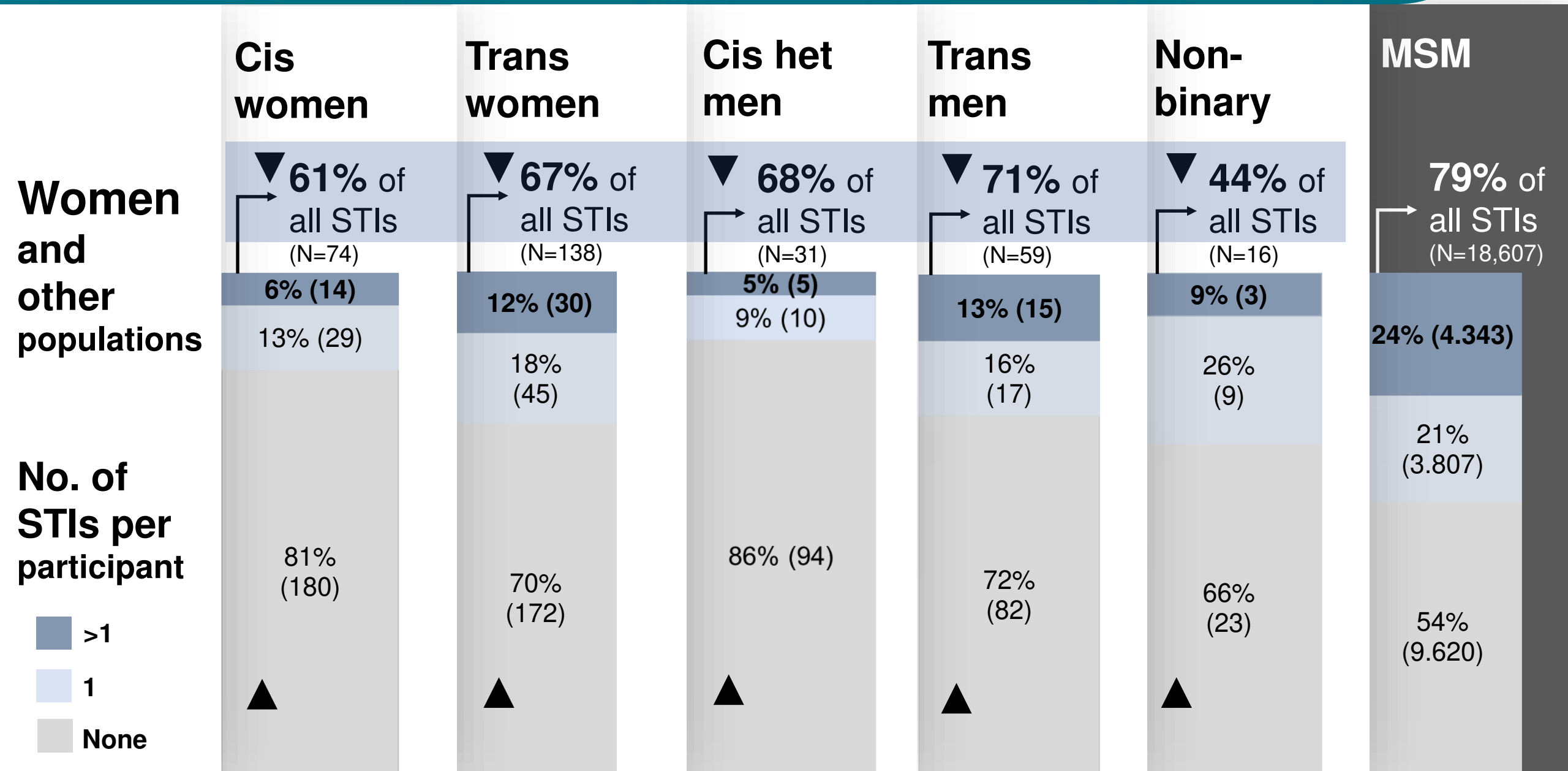
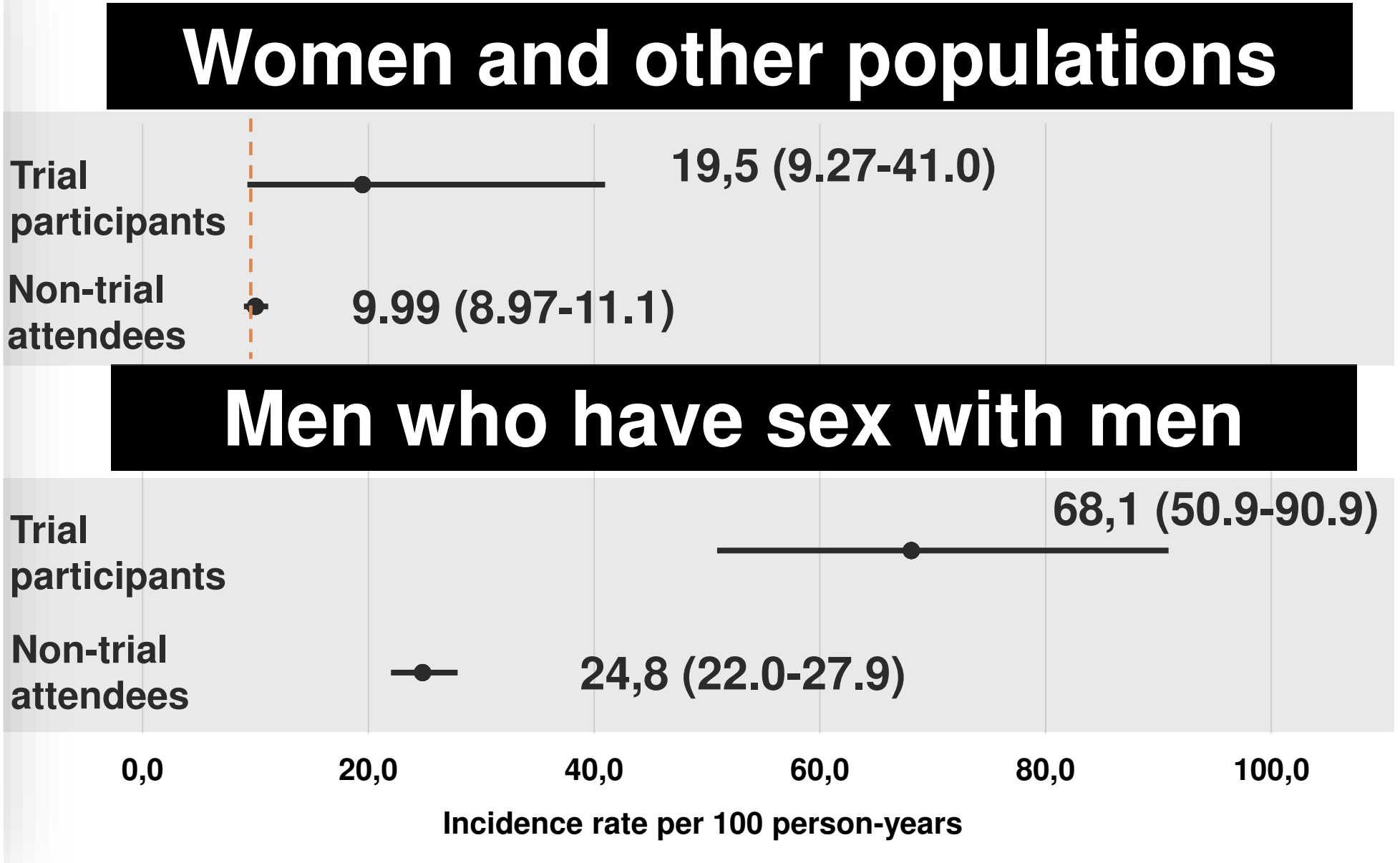

Women and other populations
No. of STIs per participant
>1
1
None
Cis women
61% of all STIs
(N=74)
6% (14)
13% (29)
81% (180)
Trans women
67% of all STIs
(N=138)
12% (30)
18% (45)
70% (172)
Cis het men
68% of all STIs
(N=31)
5% (5)
9% (10)
86% (94)
Trans men
71% of all STIs
(N=59)
13% (15)
16% (17)
72% (82)
Non-binary
44% of all STIs
(N=16)
9% (3)
26% (9)
66% (23)
MSM
79% of all STIs
(N=18,607)
24% (4.343)
21% (3.807)
54% (9.620)

Any STI incidence

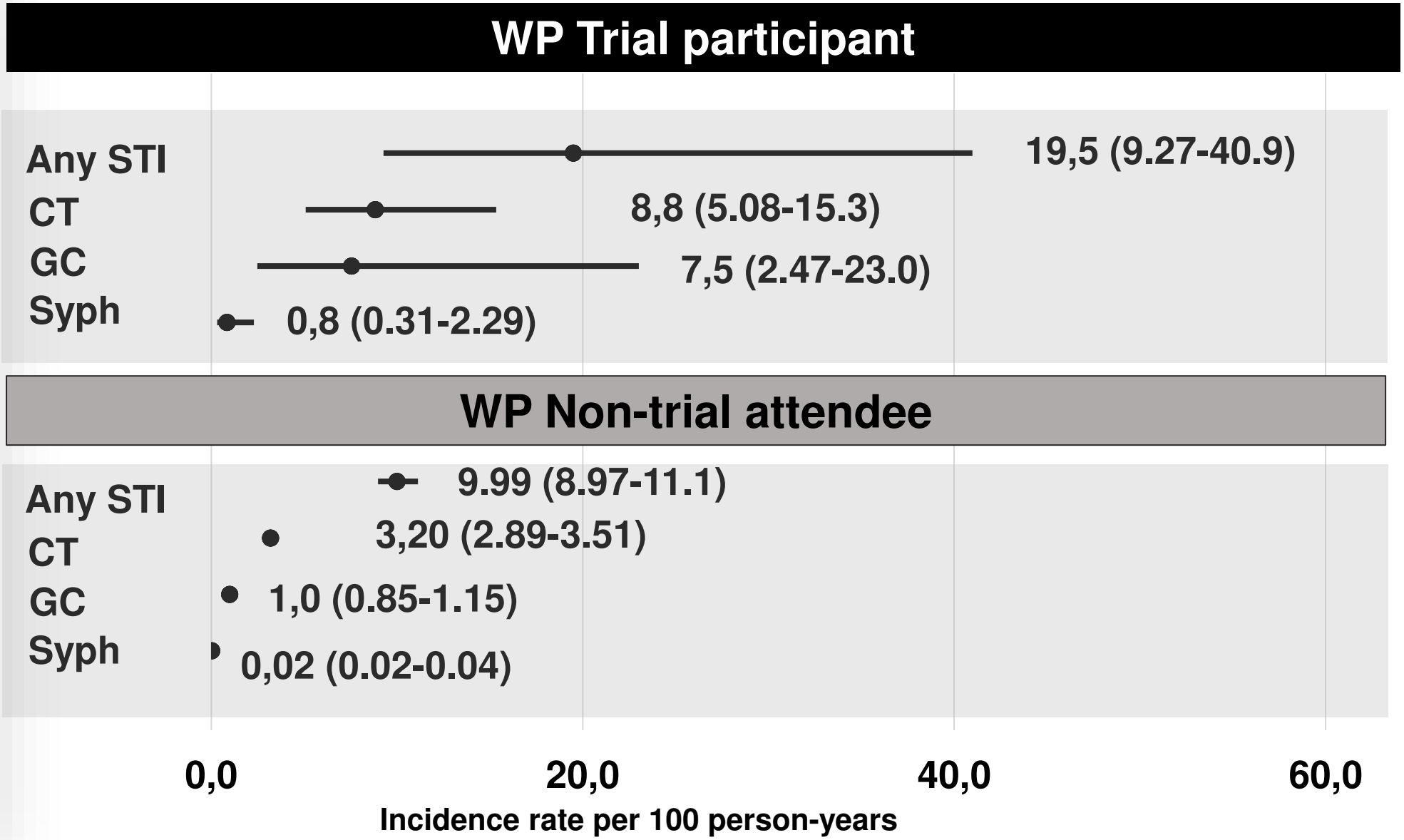
adjusted by test frequency



STI incidence

in women and other populations

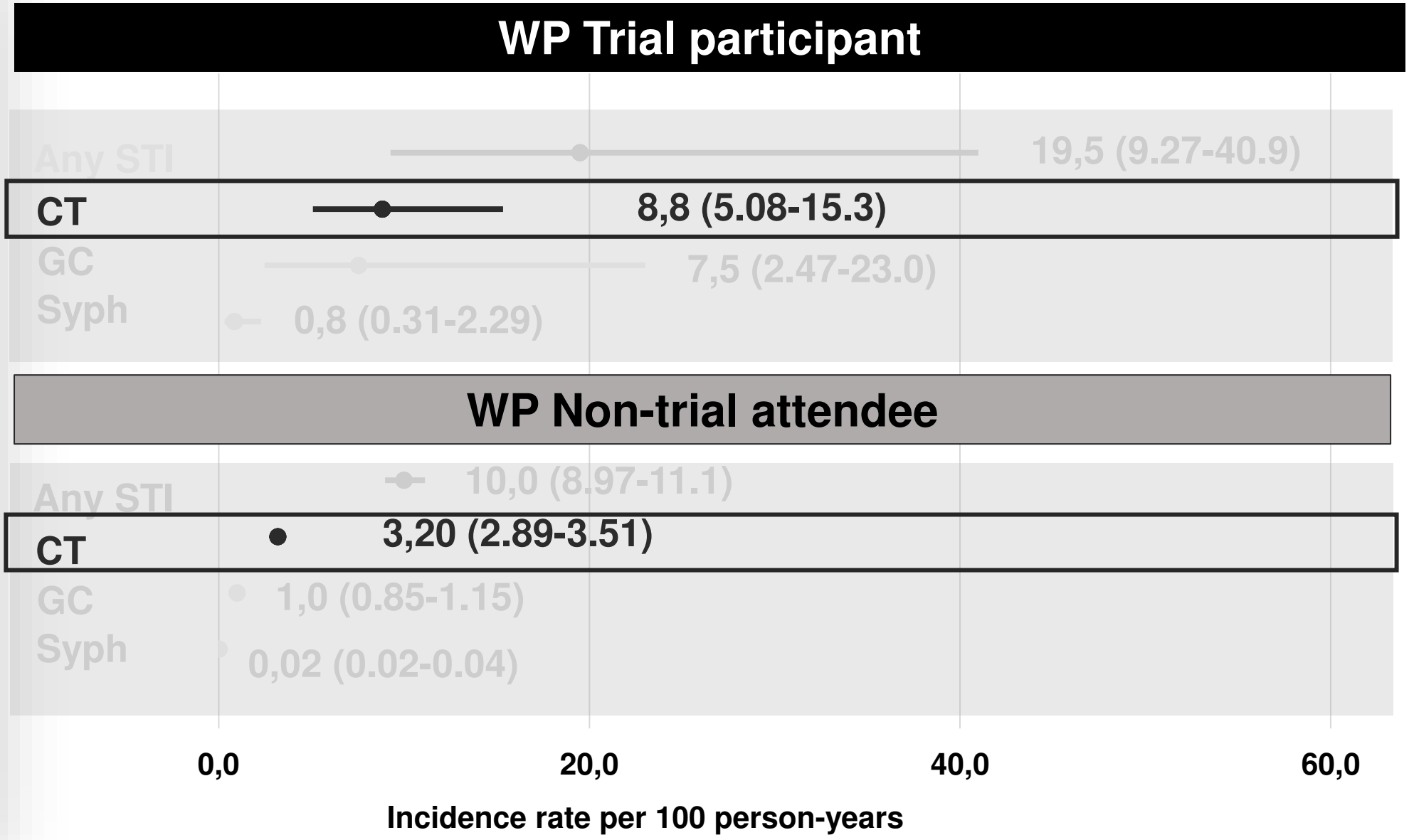
adjusted by test frequency



STI incidence

in women and other populations

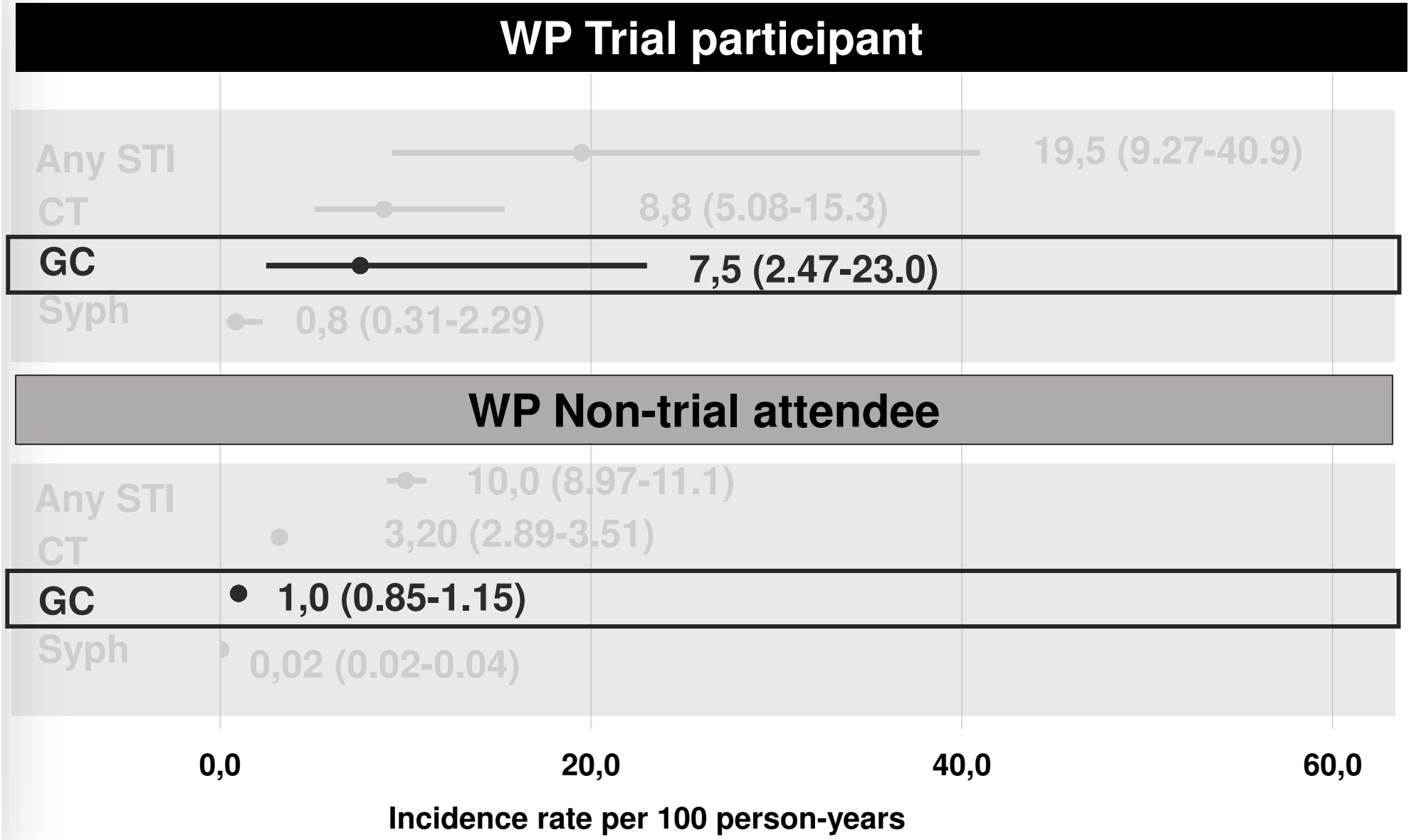
adjusted by test frequency



STI incidence

in women and other populations

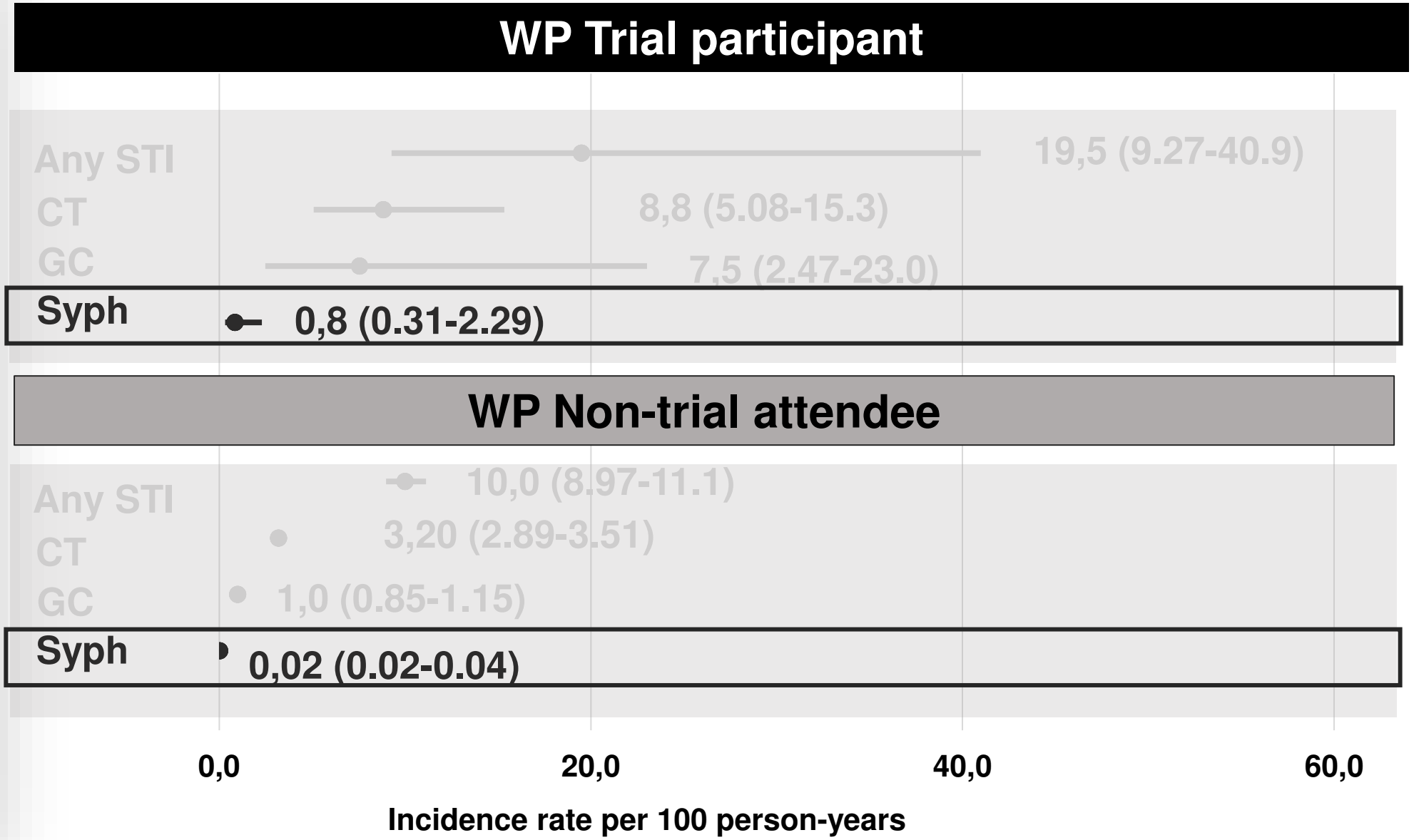
adjusted by test frequency



STI Incidence

in women and other populations

adjusted by test frequency



Key messages

Women and other populations

PrEP uptake

Women and other populations were significantly under-represented within the PrEP Impact Trial

Likely due to **low PrEP awareness** and **under-recognition of risk** by both clinicians and clinic attendees

STI incidence

WP trial participants had **higher individual STI incidence rates** compared to non-trial attendees when **adjusted for test frequency**

Compared with non-trial attendees, trial participants had higher:

- CT and syphilis incidence among cis women
- GC incidence among trans women
- Syph incidence among trans men

PrEP Impact Trial

Analysis limitations

Women and other populations

STI incidence

STI incidence rates in trial participants limited by **small subgroup numbers**
low number of events

No evidence of difference in 'Any STI' incidence between WP trial participants and non-trial attendees

WP comparators

Only **one-third of non-trial attendees** were included in incidence calculations

There was **differential follow-up** between trial participants and non-trial attendees

Trans groups likely **underreported**

Cis het men **misclassification**, unmet need

PrEP Impact Trial

Implications

Women and other populations

There is a clear need to increase **awareness and access** to cis women, trans men and women, cis heterosexual men and non-binary people **who could benefit from PrEP**

We must continue to identify the most effective strategies to reach WP across settings

PrEP Impact Trial

Implications

Women and other populations

Monitoring, evaluation and knowledge mobilisation:

- ✓ Current PrEP programmes
  (e.g. uncapped routing commissioning in UK)
- ✓ Increased integration of PrEP services into routine care
  (e.g. general practice, pharmacy)
- ✓ Tailored targeting for specific populations
  (e.g. Black African women, trans men and women)

PrEP Impact Trial

Thanks to

Principal investigators

Clinic staff

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PrEP Impact Trial

Thank you.

Questions?

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