

# **Self-sampling with oral rinse to detect oropharyngeal *Neisseria gonorrhoeae* among men who have sex with men (SSONG study)**

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## *Introduction*

- Men who have sex with men are disproportionately affected by *N. gonorrhoeae* infections
- Majority of these infections are extra-genital, around 40% are oro-pharyngeal
- Sampling for oro-pharyngeal *N. gonorrhoeae* entails clinician collected swab, which is often uncomfortable
- The use of a patient-collected oral rinse could be experienced as less uncomfortable and used for home-based sampling

## *Objectives*

- **Study objective**

- To assess whether self-collection of an oral rinse is non-inferior to clinician-collected swabs to detect *Neisseria gonorrhoeae* using culture and Nucleic Acid Amplification Tests (NAAT) among MSM

- **Exploratory objective**

- To assess whether *N. gonorrhoeae* may still be detected using NAAT in *N. gonorrhoeae* positive oral rinse samples minimum 5 days after collection

## *Methods*

- **Study design**
  - Open-label study comparing oral rinse versus clinician collected swabs for the detection of oro-pharyngeal *N. gonorrhoeae* in MSM
- **Study population**
  - MSM with a positive *N. gonorrhoeae* test result (oro-pharyngeal swab or pooled sample) detected in routine care at the Institute of Tropical Medicine
- **Study procedures**
  - Clinical collected oro-pharyngeal swab (Eswab, COPAN Diagnostics, Inc., Italy)
  - Oral rinse (sterile water Aqua Sterop - 15 mL)
  - Short questionnaire

### Routine care

MSM with a + Ng test  
(oro-pharyngeal, pool)

Visit for treatment

Study proposed

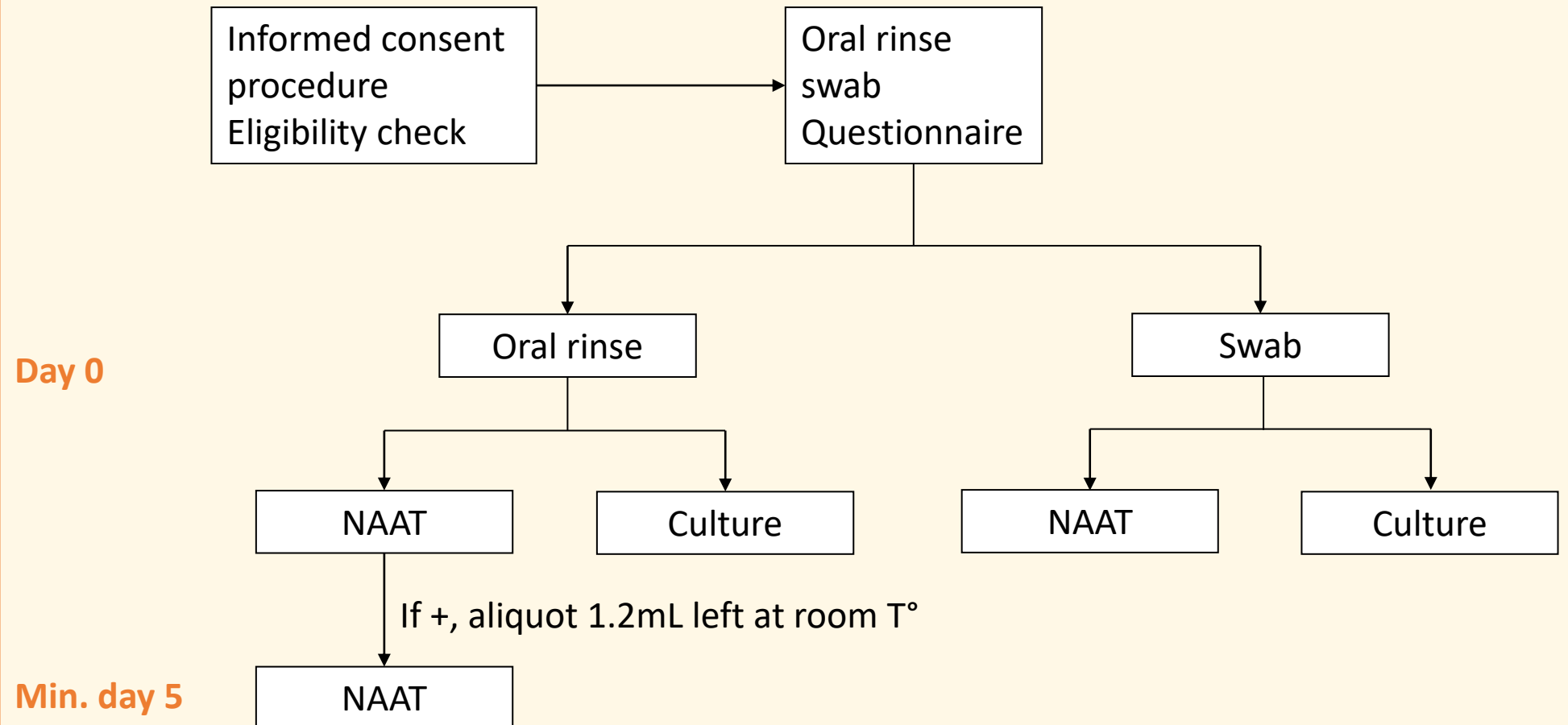
Treatment

### Study procedures

Informed consent  
procedure  
Eligibility check

Oral rinse  
swab  
Questionnaire

## Study procedures



**NAAT:** Abbott CT/NG m2000 RealTime System and in-house PCR

**Culture:** GC-Lect

## How to use the oral rinse? – SSONG Study

1



- Take the recipient containing the oral rinse
- Pour the entirety of the oral rinse in your mouth

2



- Gargle with the oral rinse at the back of your mouth for 20 seconds

3



- Spit the entirety of the rinse in the sterile recipient provided by the clinician

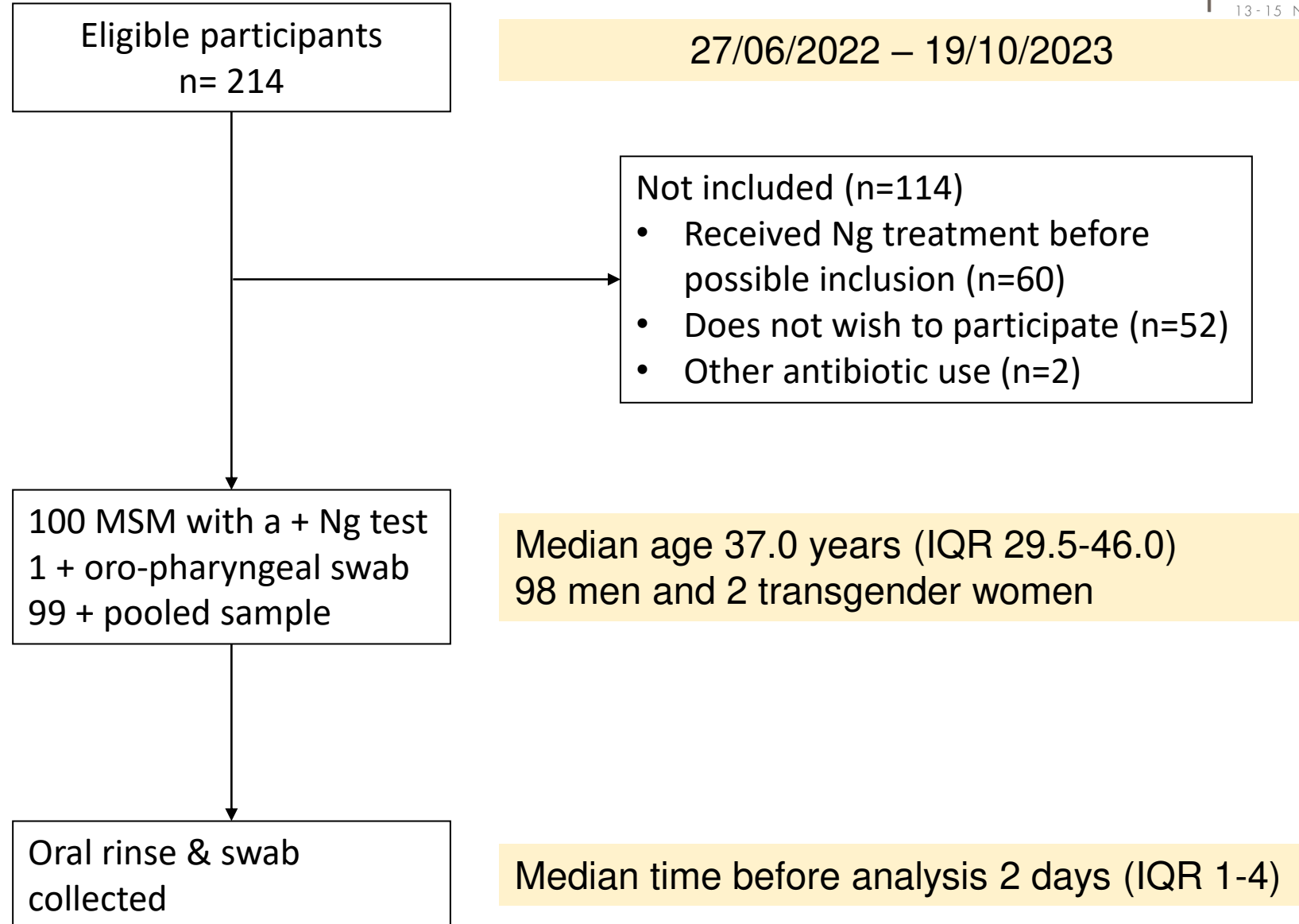
## *Methods*

- **Study outcomes**

- Agreement using Cohen's kappa statistic for *N. gonorrhoeae* (NAAT)
- Diagnostic accuracy (sensitivity, specificity, PPV, NPV) for *N. gonorrhoeae* (NAAT)
- Positivity in *N. gonorrhoeae* NAAT on oral rinse min. 5d after collection and storage at room temperature
- Participants' perceptions and preferences



## Results



100 MSM with a + Ng test

Oral rinse & swab  
collected

## Results

NAAT

78 + Ng samples in 45  
individuals (45%)

42 + in oral rinse (93%)

36 + in swab (80%)

37 still + after min. 5d  
(88%)

Median time before analysis  
8.5 days (IQR 7-11)

Culture

24 + Ng samples in 18  
individuals (18%)

8 + in oral rinse (44%)

16 + in swab (88%)

## Results

- NAAT

		Oral rinse		
		+	-	
Swab	+	33	3	36
	-	9	55	64
		42	58	100

- Agreement between both techniques is good ( $\kappa = 0.75$ ,  $p\text{-value} < 0.001$ )
- Gold standard for diagnostic accuracy calculations: sample + for Ng either on oral rinse, or on swab

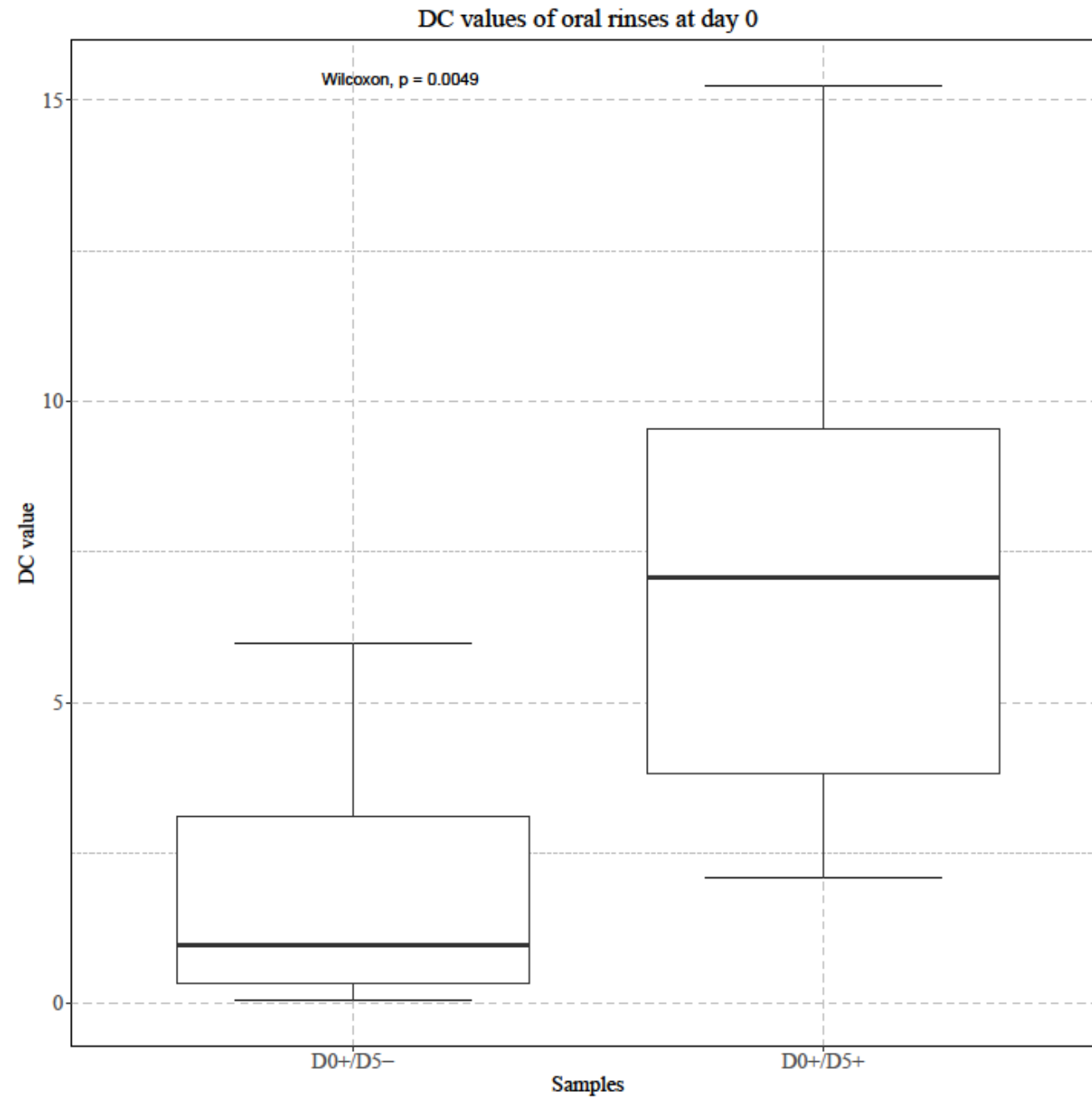
## *Results*

- Diagnostic accuracy for NAAT

	<b>Oral rinse</b>	<b>Eswab</b>
Sensitivity	93.3% (86.1 - 100)	80.0% (68.3 – 91.7)
Specificity	100% (100 – 100)	100% (100 – 100)
PPV	100% (100 – 100)	100% (100 – 100)
NPV	94.5% (89.1 - 100)	85.9% (77.4 – 94.5)

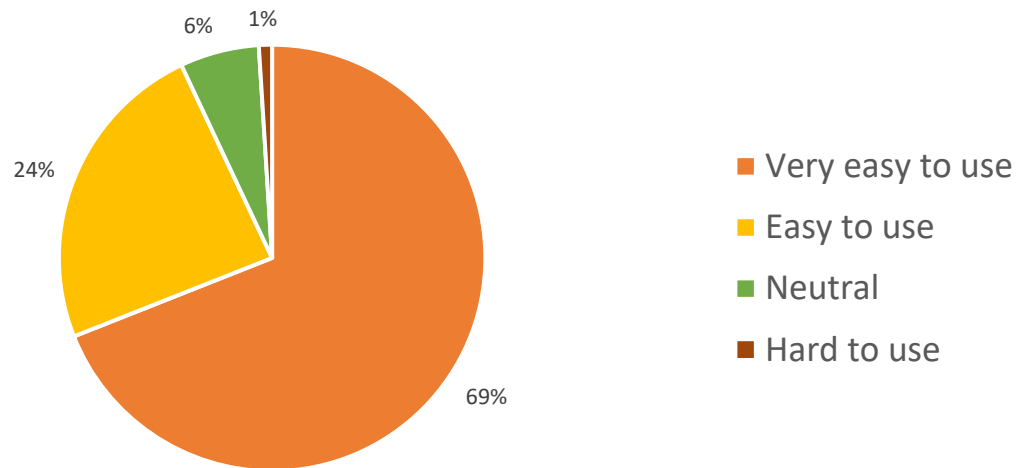
## Results

- DC values

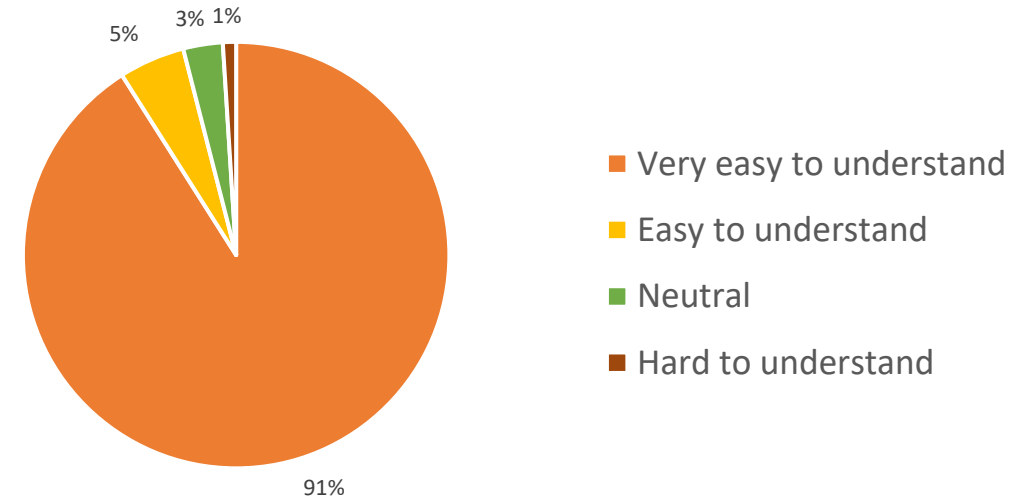


## Results

How easy did you find using the oral rinse for sample collection?

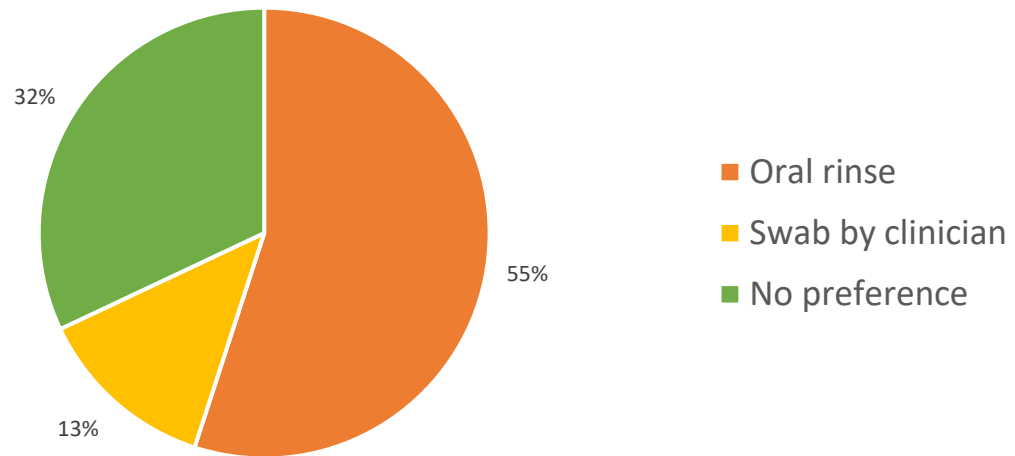


How easy did you find it to understand the collection instructions of the oral rinse?

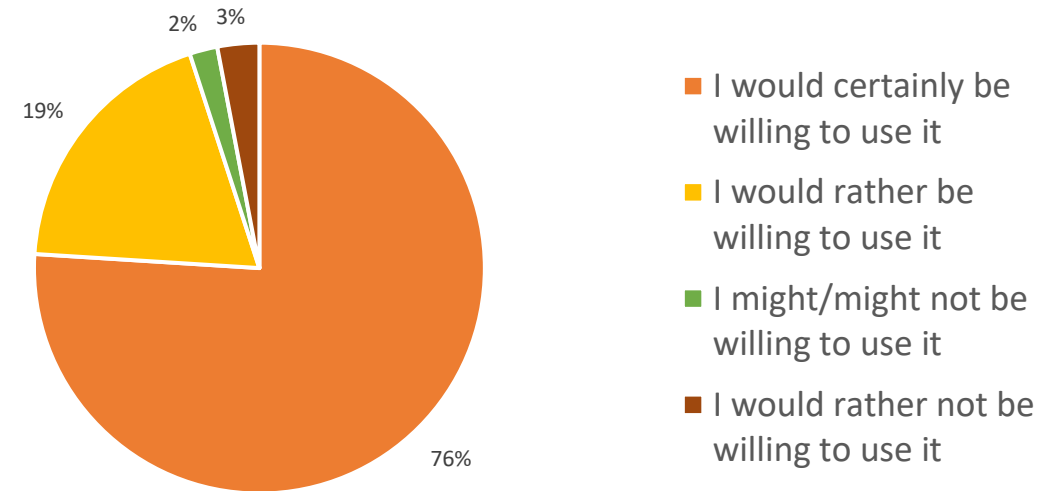


## Results

If both are equally good at diagnosing STIs which sampling method would you prefer **AT THE CLINIC** in the future?



To what extent would you be willing to use this oral rinse for sample collection **AT HOME** in the future?



## *Results*

- Most reported disadvantages of oral rinse:
  - Gargling time too long (14 participants)
  - Recipient too small (8 participants)



## *Conclusions*

- Oral rinse performs better than clinician-collected swab for the detection of oro-pharyngeal *N. gonorrhoeae* using **NAAT**
- Results for *N. gonorrhoeae* **culture** are less encouraging
- Most patients found it **easy** to use and would be **willing** to use it both at the clinic and at home
- Oral rinse might be an option for **home-based sampling**

*Thank you for your attention!*

*Thank you to the SSONG study team:*

Irith de Baetselier

Dorien Van den Bossche

Maartje van Frankenhuijsen

Vicky Cuylaerts

Lida van Petersen

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## *Results*

- 100 patients included between 27/06/2022 and 19/10/2023
- Median age 37.0 years (IQR 29.5-46.0)
- 98 men and 2 transgender women

## Results

- NAAT

		Oral rinse		
		+	-	
Gold standard	+	42	3	45
	-	0	55	55
		42	58	100

		Eswab		
		+	-	
Gold standard	+	36	9	45
	-	0	55	55
		36	64	100

## Results

- Culture ( $kappa = 0.44$   $p\text{-value} < 0.001$ )

		Oral rinse		
		+	-	
Gold standard	+	8	37	45
	-	0	55	55
		8	92	100

		Eswab		
		+	-	
Gold standard	+	16	29	45
	-	0	55	55
		16	84	100

## *Results*

- Diagnostic accuracy for culture

	<b>Oral rinse</b>	<b>Eswab</b>
Sensitivity	17,7% (6,6 – 28,9)	35,5% (21,6 – 49,5)
Specificity	100% (100 – 100)	100% (100 – 100)
PPV	100% (100 – 100)	100% (100 – 100)
NPV	59,8% (49,7 – 69,8)	65,5% (55,3 – 75,6)

## Results

- Diagnostic accuracy for NAAT at day 7 assuming that all negative swabs would have tested negative

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	<b>Oral rinse</b>
Sensitivity	82,2% (71,1 – 93,4)
Specificity	100% (100 – 100)
PPV	100% (100 – 100)
NPV	87,3% (79,1 – 95,5)

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## *Results*

- Diagnostic accuracy for oral rinse NAAT with swab as gold standard

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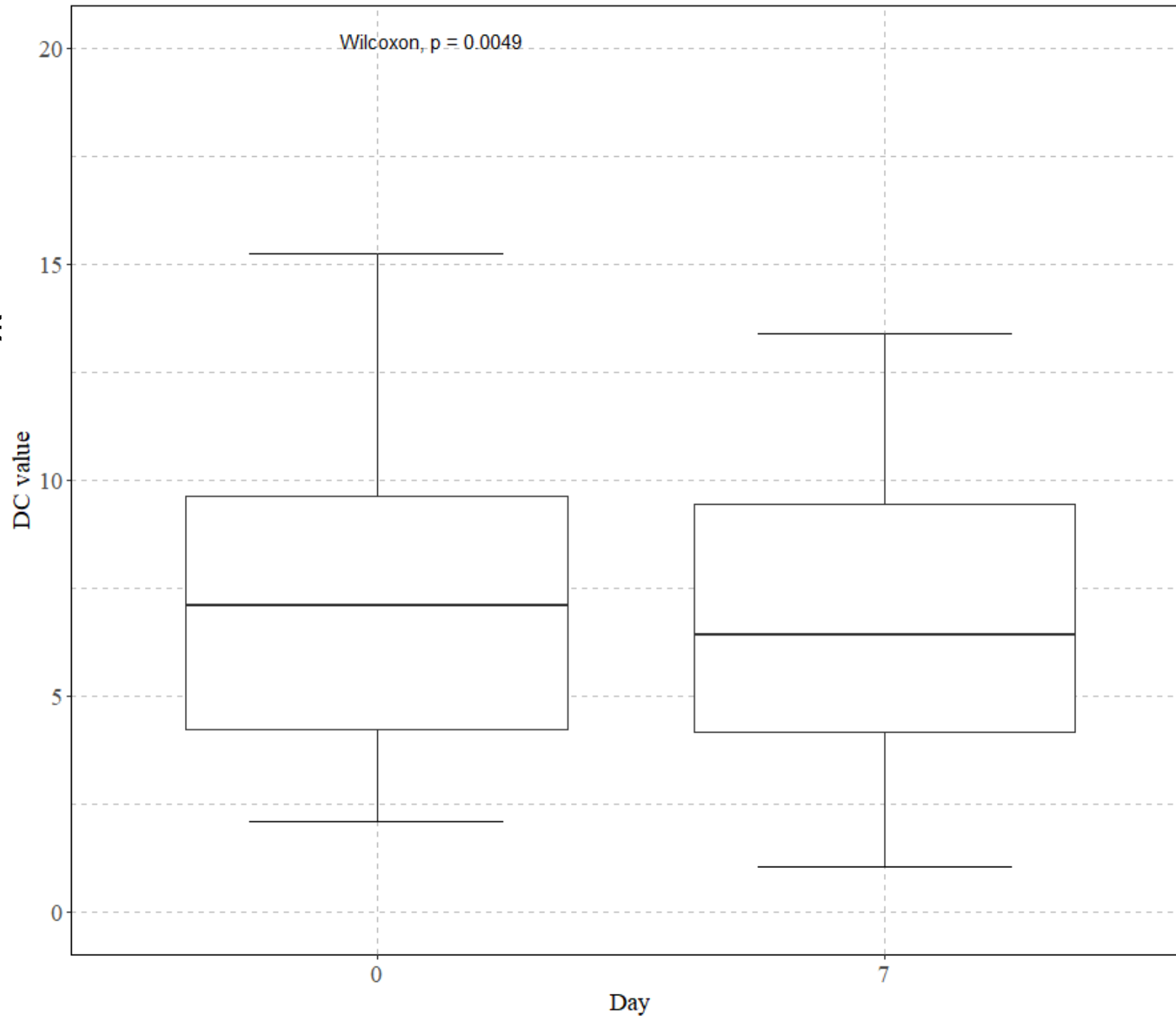
	<b>Oral rinse</b>
Sensitivity	91,7%
Specificity	85,9%
PPV	78,6%
NPV	94,8%

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## Results

- DC value



## Results

- DC value

