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### Title
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# Self-obtained vaginal swabs are not inferior to provider-performed endocervical sampling for Emergency Department diagnosis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*

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## Background

- *Neisseria gonorrhaeae* (NG) and *Chlamydia trachomatis* (CT) are the two most common sexually transmitted infections (STIs) in the United States and increasing steadily with over 500,000 and 1.7 million cases in 2018, respectively.
- Standard of care for NG/CT diagnosis is testing with a nucleic acid amplification test (NAAT) and sample collection via provider-performed endocervical sampling (PPES).
- PPES can add significant delay in a busy emergency department (ED) setting in which exam room and/or provider availability is limited.
- Prior research in non-emergency department settings on self-obtained vaginal swabs (SOVS), where the patient collects their own vaginal sample using the NAAT swab, has shown favorable results. However, another study has shown a patient preference for PPES over VSS.
- If VSS was found to have noninferior sensitivity compared to PPES in the ED, with good patient acceptability, this would allow for earlier collection of samples and another diagnostic option for patients where a pelvic exam cannot be performed.

## Objectives & Methods

- This was a prospective observational cohort study comparing two methods of NG/CT collection in an academic urban emergency department serving a largely underserved population in Fresno, CA from 2018 to 2020.
- A convenience sample of English and Spanish speaking females over 18 were included in the study where each patient had both PPES and SOVS performed.
- Testing of NG/CT was performed using a rapid 90-minute runtime NAAT assay (Cepheid® Xpert® CT/NG).
- Patients completed a one-page survey regarding acceptability of SOVS regardless of whether they enrolled. If participating, they also answered questions on current symptoms, demographics, and history of STI.
- A minimum sensitivity of 90% for SOVS was established to be considered clinically noninferior to standard PPES, based on prior research.

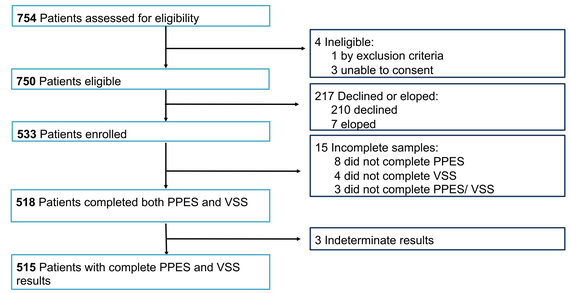
## Results & Discussion

| Characteristic | % (n)) |
|---|---|
| **Age (years)** | |
| 18-24 | 32 (171) |
| 25-34 | 39 (209) |
| 35-44 | 16 (87) |
| 45-54 | 10 (52) |
| 55+ | 3 (14) |
| **Age mean (SD)** | 30.7 (9.9) |
| **Ethnicity** | |
| Asian | 5 (25) |
| Black/African American | 19 (100) |
| Hispanic | 52 (276) |
| Non-Hispanic White | 13 (69) |
| Native American | 2 (13) |
| Multiple ethnicities | 8 (41) |
| Declined to answer | 1 (4) |
| **Primary Language** | |
| English | 88 (469) |
| Spanish | 9 (50) |
| **Pregnant** | 20 (106) |
| **History of STI** | 45 (238) |
| **Trichomonas infection** | 7 (38) |
| **Symptoms** | |
| Vaginal bleeding | 34 (183) |
| Vaginal discharge | 52 (277) |
| Dysuria | 46 (244) |
| Pelvic pain | 76 (406) |

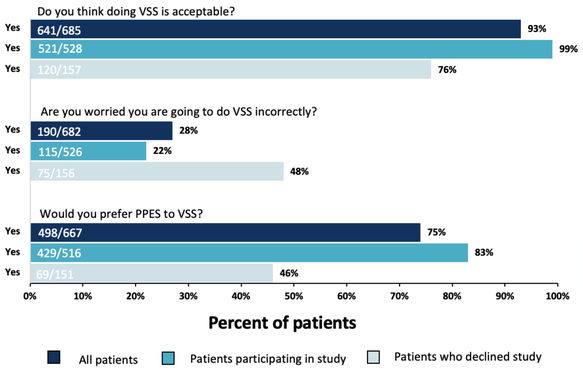
**Table 1:** Characteristics of patients enrolled in study.

**Figure 1:** Survey responses for study participants and those who declined participation ( when asked about their views regarding vaginal self–sampling (VSS) and provider–performed endocervical sampling (PPES).

### Patient eligibility and enrollment




### Patient views on SOVS




### Characteristics of SOVS compared to PPES

| Composite NG/CT* | | PPES Positive | PPES Negative | Total |
|---|---|---|---|---|
| SOVS | Positive | 77 | 5 | 82 |
| | Negative | 4 | 429 | 433 |
| | Total | 81 | 434 | 515 |

**Sensitivity** (95% CI): 95% (88% - 99%)
**Specificity** (95% CI): 99% (97% - 100%)
**Positive LR** (95% CI): 83 (34–198)
**Negative LR** (95% CI): 0.05 (0.02–0.13)
**Kappa** (95% CI): 0.93 (0.89 - 0.98)

| NG | | PPES Positive | PPES Negative | Total |
|---|---|---|---|---|
| SOVS | Positive | 38 | 1 | 39 |
| | Negative | 1 | 475 | 476 |
| | Total | 39 | 476 | 515 |

**Sensitivity** (95% CI): 97% (87% - 100%)
**Specificity** (95% CI): 100% (99% - 100%)
**Positive LR** (95% CI): 464 (65–3288)
**Negative LR** (95% CI): 0.03 (0.00–0.18)
**Kappa** (95% CI): 0.97 (0.93 - 1.00)

| CT | | PPES Positive | PPES Negative | Total |
|---|---|---|---|---|
| SOVS | Positive | 50 | 5 | 55 |
| | Negative | 3 | 457 | 460 |
| | Total | 53 | 462 | 515 |

**Sensitivity** (95% CI): 94% (84% - 99%)
**Specificity** (95% CI): 99% (98% - 100%)
**Positive LR** (95% CI): 87 (36–209)
**Negative LR** (95% CI): 0.06 (0.02–0.17)
**Kappa** (95% CI): 0.92 (0.86 - 0.97)

*Represents patient–specific composite results. "Positive" indicates patient positive for NG, CT, or both
NG, *Neisseria gonorrhoea*; CT, *Chlamydia trachomatis; LR, likelihood ratio*
SOVS, self–obtained vaginal swab; PPES, provider performed endocervical sampling

- Data for 515 individuals with SOVS and PPES results was analyzed.
- Calculation of sensitivity, specificity, positive and negative likelihood ratio was done using calculators at:http://araw.mede.uic.edu/cgi-bin/testcalc.pl
- Calculations of kappa between the two measurements, was done using the calculator at https://www.graphpad.com/quickcalcs/kappa1/
- Limitations: Language, population generalizability, acceptability survey done prior to SOVS.

## Conclusions & Summary

- SOVS has a high sensitivity for NG/CT compared to PPES, with strong concordance between the two methods, making it a reliable option for STI sample collection without a pelvic exam. This provides an important ED diagnostic alternative to PPES in patients in whom a pelvic examination is not possible or declined. It can also provide a foundation for future ED implementation research to determine if early SOVS with rapid NAAT can decrease under- and overtreatment rates of NG/CT.
- Survey results in participants and non-participants showed a high percentage of individuals who believed that SOVS is acceptable. Of those enrolled, 17% preferred PPES to SOVS and many reported fears of performing SOVS incorrectly and preferred PPES. We hypothesize that this preference might be due to the belief that PPES is more accurate or fear of improper sample collection. This highlights the importance of reassuring patients that, as this study has shown, almost all self-collected samples are adequate.

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