

CLINICAL VALIDATION OF PATIENT-COLLECTED SWAB SPECIMENS IN DIAGNOSIS OF SEXUALLY-TRANSMITTED INFECTIONS IN CLINICAL SETTING

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Objective

To compare the accuracy of patient-collected specimens (PCS) vs. clinician-collected specimens (CCS) for screening and diagnosis of STIs. Milwaukee Health Department (MHD) recognized a need for patient-collected sampling for clients not needing a complete STI screening exam and to streamline client intake. In order to determine whether PCS are as accurate as CCS in terms of diagnosing STIs, MHD validated the use of nucleic acid amplification test (NAAT) for patient-collect samples and compared with clinician-collected swab both from genital and extra-genital sources. PCS was validated for screening of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) and conventional GC culture.

Introduction

City of Milwaukee, is one of the top 10 U.S. cities with the highest reported STIs (<https://www.innerbody.com/std-testing/std-statistics>). In 2019, 51.8% of all confirmed Gonorrhea (GC) cases reported in Wisconsin were from the City of Milwaukee, for a total of 4,686 cases at a rate of 794.0 cases per 100,000 populations (WI DPH) (www.dhs.wisconsin.gov/std/data.htm). Since 1932, the City of Milwaukee Health Department's Sexual Health Clinic located at the Keenan Health Center (KHC) has been providing sexually transmitted infection (STI). All clients who are either symptomatic, contacts to GC positive cases, NAAT positive, and/or TOC clients, get tested by culture. *N. gonorrhoeae* culture is also required to evaluate treatment and to monitor developing resistance to current treatment regimens. For screening and diagnosis of Gonorrhea infection in clients that prefer setting, use of Patient-collect swabs for GC culture and NAAT was utilized for better patient management at MHD STD clinic

Methods

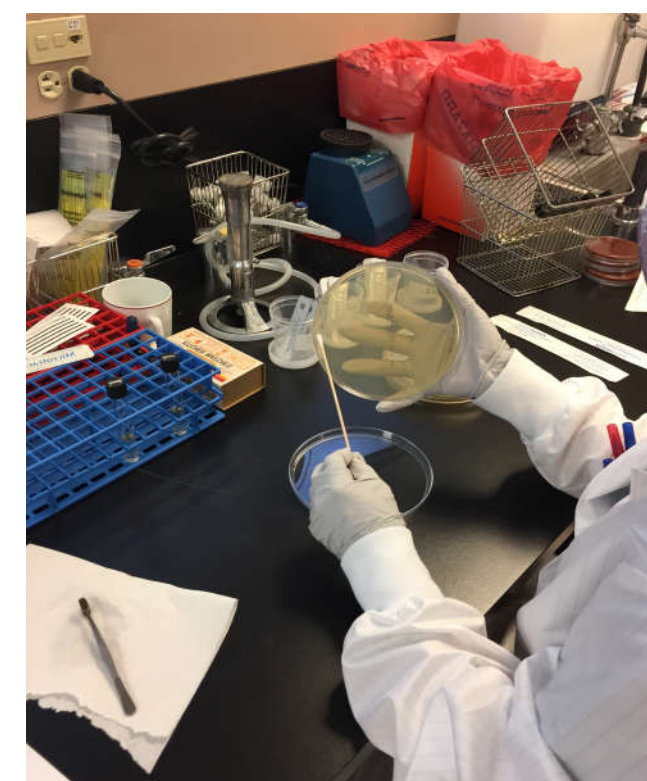
Clinician-collected swab was used as the gold reference standard which assumes 100% accuracy. For *N. gonorrhoeae* culture and antibiotic susceptibility testing, MHD STD Clinic patients obtained PCS from vaginal (CCS: Cervical), penile meatal (CCS: Urethral), pharyngeal, or rectal sites, and providers obtained CCS from the same patient and same site. Ten swab samples sets (PCS and CCS) were collected from each site. Forty blinded pretested patient-collected clinical swab samples were received from partner clinic for NAAT performance verification of patient-collected verses clinician-collected vaginal swab for screening of CT, GC, TV and/or MG using Panther system (Hologic® Inc.). Clients received collection kit manufacturer instructions on how to self-collect vaginal, penile meatal, rectal, and pharyngeal specimens.



CCS and PCS for culture were collected in ESwab™ collection and transport system (Copan Diag., Inc.)



CCS and PCS for NAAT were collected in APTIMA tubes (Hologic Inc.)



Validation Study Design:

Phase I: Patient-collect swab for GC culture

- Urethral swab clinician-collect culture = Penile meatal (urethral discharge) swab patient-collect culture
- Endocervical/Vaginal swab clinician-collect culture = Vaginal swab patient-collect culture
- Pharyngeal/Throat swab clinician-collect culture = Throat swab patient-collect culture
- Rectal swab clinician-collect culture = Rectal swab patient-collect culture

N = 10 per category above clinician-collect followed by patient-collect, if agreement ≥ 90%
N = 20 per category above patient-collect followed by clinician-collect, if agreement < 90%

Phase II: Patient-collect swab for NAAT

- Urethral/Urine NAAT = Penile meatal (urethral discharge) self-collect swab NAAT
- Pharyngeal/Throat swab clinician-collect NAAT = Throat swab patient-collect NAAT
- Rectal swab clinician-collect NAAT = Rectal swab patient-collect NAAT

N = 10 per category above clinician-collect followed by patient-collect, if agreement ≥ 95%
N = 20 per category above patient-collect followed by clinician-collect, if agreement < 95%

Results

True positive (TP), False positive (FP), True negative (TN), and False negative (FN) results from each study were extracted to construct two-by-two tables and calculate test sensitivity and specificity. There was 100% agreement between results of GC culture for CCS and PCS, indicating patient-collected screening would be a valid alternative (Table 1). All vaginal samples for NAAT assays except one negative for TV which turned out to be invalid at MHD (insufficient sample for repeat) showed comparable results between the performing laboratories (Table 2). Concordance with the expected result was 97.5% overall.

Table 1. Comparison of GC culture results obtained using clinician-collected and patient-collected swabs collected from different sources (throat, rectal, vaginal, and urethral) in clinical setting.

GC culture results		Clinician-collected rectal swab (CCRS)			GC culture results		Clinician-collected throat swab (CCTS)		
		Positive	Negative	Total			Positive	Negative	Total
Patient-collected rectal swab (PCRS)	Positive	2	0	2	Patient-collected throat swab (PCTS)	Positive	3	0	3
	Negative	0	8	8		Negative	0	7	7
% agreement: 100 %				% agreement: 100 %					
GC culture results		Clinician-collected vaginal swab (CCVS)			GC culture results		Clinician-collected urethral swab (CCUS)		
		Positive	Negative	Total			Positive	Negative	Total
Patient-collected vaginal swab (PCVS)	Positive	5	0	5	Patient-collected penile swab (PCPS)	Positive	7	0	7
	Negative	0	5	5		Negative	0	3	3
% agreement: 100 %				% agreement: 100 %					

Table 2. Comparison of NAAT results obtained using patient-collected swabs for various targets (CT/GC/TV/MG) at two different testing sites.

NAAT results		Patient-collected (non-MHD)		
		Positive	Negative	Total
Patient-collected (MHD)	Positive	20	0	20
	Negative	0	19	19
	Invalid	0	1*	1
% agreement: 97.5%				

Findings

- Due to acceptable diagnostic accuracy in our validation study, self-collected specimens collection option was introduced in STI control programs (STD clinic or non-STD clinic) for patients that are hard to reach, who refuse to go for clinician-based testing, or who decline an examination.
- Vaginal swab NAAT (CT/GC/TV/MG): Collected during June 2019 (97.5% agreement). Since then we have observed the following: (% Positivity, n) CT: 17.5%, n = 975; GC: 7.9%, n = 1170; TV: 15.4%, n = 951; MG: 59.4%, n = 32
- Vaginal swab GC culture: Collected between Dec 2019 till March 2020 (100% agreement). Since then we have received 71 requests (36.6% positivity)
- Penile meatal swab GC culture: Collected between Jan 2020 to May 2020 (100% agreement).
- Throat swab GC culture: Collected between June 2020 to October 2020 (100% agreement).
- Rectal swab GC culture: June 2020 to Dec, 2020 (100% agreement).

Conclusion

Overall more than 95% agreement between expected results and results obtained for STI NAATs and GC culture seen. This study indicates self-collection is as sensitive and accurate as clinician collection to accurately diagnose STDs and improve operational efficiency by allowing MHD staff to detect and prevent more cases of STDs. In the future more innovative interventions such as internet-based or mail-in home and community service testing for patients that are hard to reach, who refuse to go for clinician-based testing, or who decline an examination are required that would eliminate barriers to STI testing.

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