

Ease, Comfort and Performance of a Novel HerSwab Vaginal Self-Sampling Device for the Detection of *C. trachomatis* and *N. gonorrhoeae*

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REVISED ABSTRACT

Many sexually transmitted infections (STI) are asymptomatic in the lower genital tract of women, and if undiagnosed and untreated may cause upper tract complications. Lack of intervention is strongly associated with repeat infections with *C. trachomatis* (CT) and *N. gonorrhoeae* (NG). Although control programs require screening to treat and detect asymptomatic infections, commonly reported barriers to STI screening include embarrassment, fear of pain, lack of comfort with pelvic examinations, the invasiveness of physician sampling, concerns about confidentiality and denial of STI risk. Self-collected vaginal (SCV) swabs enable accurate detection of many sexually transmitted infections. We compared SCV samples collected using a novel HerSwab™ device and transported dry to physician-collected vaginal (PCV) Aptima swabs for the detection of CT and NG, and measured patients' ease and comfort with self-collection. A total of 189 women aged 16-41 were recruited from a street youth clinic and a therapeutic abortion clinic. Using a standardized anonymized questionnaire, significantly more women reported self-collection with HerSwab to be easy and comfortable. They preferred self-collection over physician collection (80.9%), and would consider using HerSwab for self-collection at home (79.7%). SCV and PCV samples showed good agreement for CT (90.2%-97.3%, 0.47-0.81 κ) and NG (95.1%-99.6%, 0.12-1 κ), and the HerSwab collection detected slightly more positive patients. Overall prevalence of infection was 10.6% for CT and 2.6% for NG. HerSwab enables accurate home-based vaginal self-collection and dry transport for the detection of common STIs.

OBJECTIVE

To survey opinions on ease and comfort from young sexually active women self-collecting vaginal samples with HerSwab, and to compare agreements between SCV and PCV samples for the detection of CT and NG with a transcription-mediated amplification (TMA) RNA-based assay, Aptima Combo 2 (AC2; Hologic Inc., San Diego, CA, USA).

METHODS

Study Design & Clinic Instructions:

- A total of 189 women aged 16-41 participated in the study. 110 women were recruited from a street youth clinic and 79 women were recruited from a therapeutic abortion clinic.
- Women consented for the collection of a physician-collected vaginal (PCV) Aptima swab and a self-collected vaginal (SCV) sample using HerSwab. The Study received approval from the Hamilton Integrated Research Ethics Board (HiREB)
- The research coordinator demonstrated steps for proper self-collection using HerSwab, provided participants with illustrated instructions (Figure 1), clarified any outstanding questions, and recorded previous STI history and symptomology (dysuria, pelvic pain, discharge).

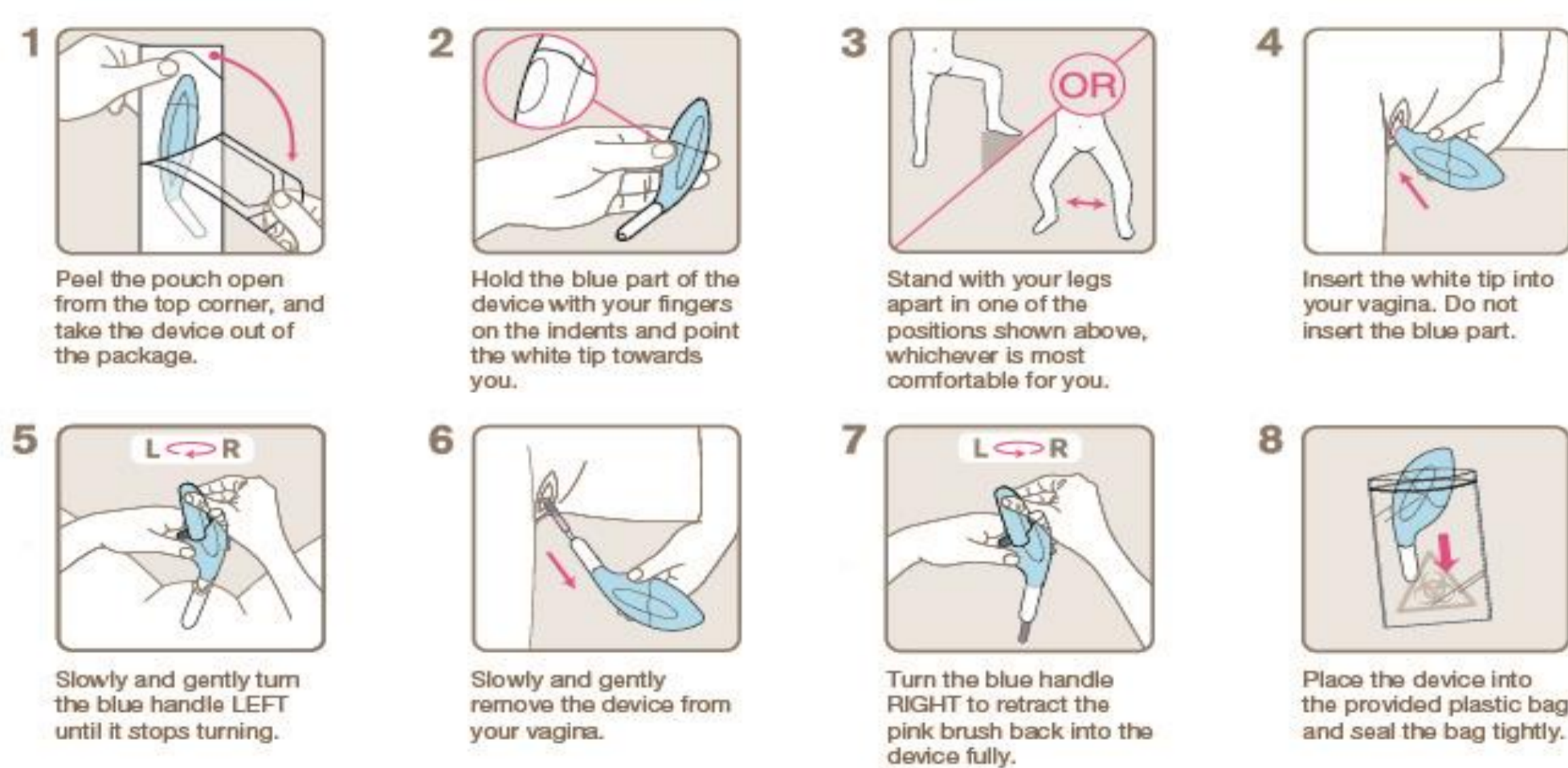


Figure 1: Procedure for vaginal self-sampling using the HerSwab device

Questionnaire:

- Following collection, participants completed a two-page written questionnaire. The first section consisted of a 5-point Likert scale questionnaire where participants indicated ease (for steps 2-7 in Figure 1) and comfort (for steps 3-6) of self-collection using HerSwab.
- Questionnaire responses were recorded such that 4-5 meant 'easy/comfortable-very easy/comfortable', 3 meant 'neutral' and 1-2 meant 'very difficult/ uncomfortable-difficult/uncomfortable' (Table 1).
- Additional open-ended items on the questionnaire included: whether the instructions were easy to follow; whether participants preferred physician or self-collection; participants' reasons for preferring self or physician collection; whether participants would consider self-sampling at home; and whether there was anything that participants would change about the device to facilitate ease and/ or comfort.

Laboratory Testing:

- SCV samples were transported dry in their original packaging, while PCV samples were transported in Aptima Specimen Transport Media (STM). SCV samples were transferred into Aptima STM in the laboratory.
- All samples were tested for CT and NG using the AC2 assay on the Panther automated system within 72 hours of collection, as per the manufacturer's instructions.
- After testing all SCV and PCV samples by AC2, a subset of 6 discordant and 6 concordant specimen pairs were further tested for beta-actin DNA as a quantitative internal control for the amount of specimen collected. DNA from 250 μ L of the samples preserved in Aptima STM was extracted with Qiagen MinElute spin columns using a protocol based on the AmpliLute Liquid Media Extraction Kit (Roche), followed by qPCR using previously published beta-actin primers (Jobin et al, 1997).

RESULTS

Demographics:

- Participants from the street youth clinic ranged in age from 16 to 26 (mean=23.5, SD=4.7), with 24.5% (27/110) presenting with STI symptoms and 43.6% (48/110) having previous history of an STI. Participants from the therapeutic abortion clinic ranged in age from 16 to 41 (mean=24.2, SD=5.3), with none experiencing STI symptoms and 31.6% (25/79) having previous history of an STI.

Table 1: Summary of ease and comfort of vaginal self-collection using the HerSwab device

	EASE (% rated)				COMFORT (% rated)			
	difficult-very difficult (1-2)	neutral (3)	easy-very easy (4-5)	Mean Response, SD	uncomfortable-very uncomfortable (1-2)	as neutral (3)	comfortable-very comfortable (4-5)	Mean Response, SD
Step 2	0.5 (1/184)	2.2 (179/184)	97.3 (179/184)	4.83; 0.50	N/A	N/A	N/A	N/A
Steps 3-4	1.1 (2/184)	2.7 (5/184)	96.2 (177/184)	4.77; 0.575	10.8 (18/166)	21.7 (36/166)	67.5 (112/166)	3.86; 1.138
Step 5	6.6 (12/183)	8.7 (16/183)	84.7 (155/183)	4.41; 0.953	13.3 (23/173)	23.7 (41/173)	63.0 (109/173)	3.80; 1.165
Step 6	3.8 (7/183)	6.6 (12/183)	89.6 (164/183)	4.62; 0.795	11.0 (19/173)	18.5 (32/173)	70.5 (122/173)	4.03; 1.146
Step 7	2.7 (5/184)	3.3 (6/184)	94.0 (173/184)	4.77; 0.689	N/A	N/A	N/A	N/A

Questionnaire Results:

- Instructions were easy to follow for 97.1% (169/175) of respondents; 80.9% (140/173) preferred self-collection over physician collection; and 79.7% (137/172) would consider self-collection at home.
- 96.2% found the insertion of the device into the vagina to be easy or very easy, and 93.4% found the turning of the device handle while inside the vagina to be easy, very easy, or neither easy nor difficult. Withdrawing the device from the vagina was easy or very easy for 89.6% of respondents (Table 1).
- A previous history of an STI ($\chi^2=1.489$, $p=0.22$) or the presence of symptoms ($\chi^2=0.519$, $p=0.47$) were not significantly related to a preference for self-collection versus physician collection, or to whether participants would consider self-collection at home ($\chi^2=0.807$, $p=0.37$; $\chi^2=0$, $p=1$, respectively).
- Frequently cited reasons for preferring self-collection included **increased comfort** (n=50), **privacy** (n=38) and **convenience** (n=21).

Testing Comparison of Sample Types:

- Overall prevalence of infection was 10.6% (20/189) for CT and 2.6% (5/189) for NG. Overall agreement between PCV and SCV samples tested using AC2 was 94.7% (90.2-97.3), 0.64 κ (0.47-0.81) for CT and 98.4% (95.1-99.6), 0.56 κ (0.12-1) for NG (Table 2).

Table 2: Agreement of *C. trachomatis* and *N. gonorrhoeae* infections by method of collection

	Physician-Collected Vaginal			TOTAL
	CT +	CT -		
Self-collected HerSwab	CT +	10	7	17
	CT -	3	169	172
	TOTAL	13	176	189
	NG +	2	3	5
	NG -	0	184	184
	TOTAL	2	187	189

CT Overall Agreement= 94.7% (90.2-97.3); $\kappa = 0.64$ (0.47-0.81)
 NG Overall Agreement= 98.4% (95.1-99.6); $\kappa = 0.56$ (0.12-1)

- HerSwab detected 4 more CT and 3 more NG infections than PCV samples collected with conventional Aptima vaginal swabs.
- Quantity of beta-actin DNA was not significantly different between SCV and PCV samples ($t=-0.105$, $p=0.918$), or when comparing groups of CT-concordant and CT-discordant specimen pairs.

CONCLUSIONS

- Most women found vaginal self-sampling with the HerSwab device to be easy or very easy, and most found the process to be comfortable, very comfortable or neutral. A majority would consider self-collection using HerSwab at home.
- AC2 testing showed good agreement between SCV and PCV samples for the detection of CT and NG
- HerSwab identified as many or more positives than the traditional Aptima swab.
- These findings demonstrate the feasibility of accurate home-based vaginal self-collection and dry transport using HerSwab

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