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Ease and Comfort of Cervical and Vaginal Sampling for *Chlamydia trachomatis* and *Trichomonas vaginalis* with a New Aptima Specimen Collection and Transportation Kit

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Use of a new collection kit for vaginal and cervical sampling was reported as easy by the majority of 692 women and not uncomfortable (by 87.4% of those ≥25 years old and 78.8% of those <25 years old). By Aptima testing, patient- and physician-collected samples agreed strongly for *Chlamydia trachomatis* (99.6% to 99.3%; κ = 0.93 to 0.89) and *T. vaginalis* (99.6% to 98.9%; κ = 0.97 to 0.78).

Chlamydia trachomatis and *Trichomonas vaginalis* are common sexually transmitted infections (STI) of the lower genital tract. Control programs require screening to detect and treat asymptomatic infections to prevent upper tract complications due to *C. trachomatis* and persistent *T. vaginalis* infections and related sequelae.

Detection of infections requires the collection of endocervical or vaginal samples during a pelvic examination or self-collection of first-void urine or vaginal samples. If self-swabbing is to be used for screening, the procedure and collection device will be more acceptable if the device is easy to use and is not uncomfortable.

A new specimen collection and transportation (SCT) kit (Hologic/Gen-Probe Incorporated) was developed for sampling the cervix and vagina for STIs and transporting the specimens to the laboratory to be tested by Aptima transcription-mediated amplification assays. The collection device is a tapered brush similar in appearance to collection brushes used for collecting cervical cells for human papillomavirus testing (1, 2). The objective was to determine the ease and comfort of using the SCT when women self-collected a vaginal sample and to compare the new SCT kit for detection of *C. trachomatis* and *T. vaginalis* from self-collected vaginal SCT (S-VSCT) and physician-collected vaginal and cervical samples.

A total of 708 women (580 attending a gynecology clinic and 128 attending a street youth health clinic) signed consent for the collection of 2 vaginal and 3 cervical samples as outlined in the consent form, which was approved by St. Joseph's Healthcare and Juravinski Hospital Research Ethics Boards in Hamilton, Ontario, Canada. Each patient self-collected a vaginal sample and then answered a questionnaire concerning ease and comfort of collection using the new SCT kit. The physician then collected a vaginal sample (P-VSCT) and, after insertion of a speculum, collected PreservCyt (PC) L-Pap, cervical SCT (CSCT), and SurePath (SP) L-Pap endocervical samples. The PC L-Pap sample was always collected first as the standard of care for cervical cytology. L-Pap samples were collected with a cervix broom placed into the manufacturer's medium. The PC L-Pap sample was processed for cytology, and the remainder of the sample was sent with the other samples to the Infections Research Laboratory (IRL) at St. Joseph's Healthcare, where they were tested within 72 h by Aptima Combo 2 (AC2) for *C. trachomatis* and Aptima *T. vaginalis* (ATV) for *T. vaginalis* on a TIGRIS DTS instrument (Hologic/Gen-Probe Incorporated).

Each patient was asked to complete a 5-point Likert scale questionnaire indicating whether it was very easy, easy, neither easy nor difficult, difficult, or very difficult to open the package and take out the tube and collection device, collect the sample, uncap the tube, elute the sample, and recap the tube. They were also asked whether collection was comfortable or uncomfortable.

Agreement between sample types was assessed as raw agreement and as agreement beyond chance (using the kappa statistic [κ]) along with 95% confidence intervals.

The responses to the ease and comfort of collection with the new SCT kit were very favorable (Fig. 1). The survey was completed by 692 women. One of the strengths of the study was the number of women from 2 different clinics who were able to assess the ease and comfort of self-collecting vaginal samples with the new SCT kit. Although almost all reported that opening the package (99.7%), collecting the sample (93.9%), uncapping the tube (99.3%), eluting the sample from the brush (99.9%), and recapping the tube (99.7%) were very easy, easy, or neither easy nor difficult, 6.1% experienced some difficulty in self-collecting the sample, and this was not related to age. Collection was not uncomfortable for 84.3% of the women, and a subanalysis of the question according to age showed that 87.4% of women 25 years or older ($n = 480$) and 78.8% of those <25 years of age ($n = 212$) reported that the collection process was not uncomfortable ($P = 0.005$). These observations are similar to other studies assessing self-collection of vaginal samples using swabs (3–6). Other studies have reported that self-collection of vaginal samples was not preferred over collection by health care workers (7–10) but was acceptable. The reasons for not preferring self-collection of vaginal samples

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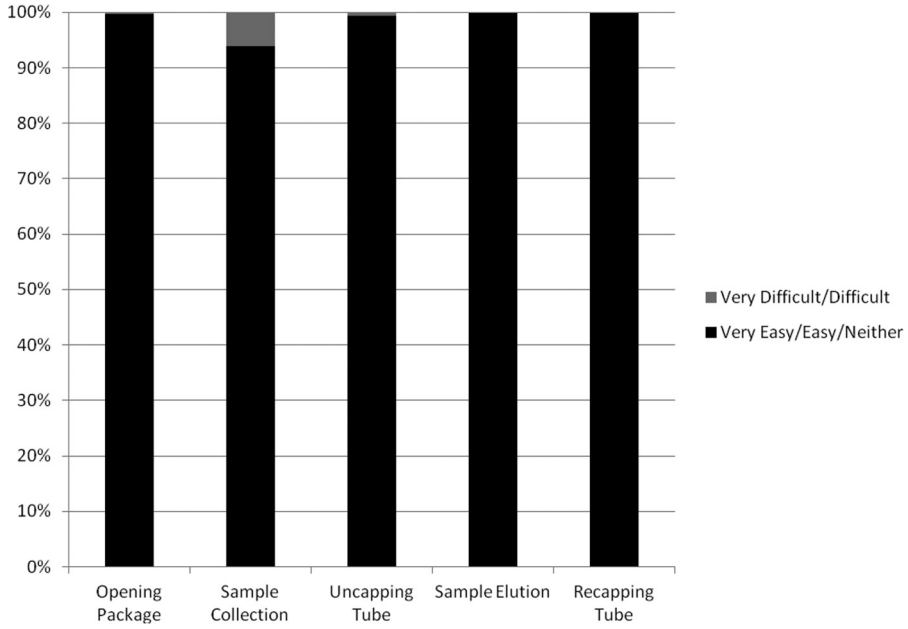

FIG 1 Summary of ease of self-collecting vaginal samples using a new specimen collection and transportation (SCT) kit.

have included concerns about collecting an inadequate sample (10–13) and that self-collection was not as comfortable as collection by health care workers (12).

Prevalences of *C. trachomatis* and *T. vaginalis* infections were 12.5% and 13.4% in the youth health clinic and 1.0% and 0.3% in the gynecology clinic. The prevalences of *C. trachomatis* and *T. vaginalis* in our younger sexually active women are proportionately similar to 8.7% and 6.7%, respectively, reported in a previous study using the Aptima assay (14).

Strong overall agreements of *C. trachomatis* positives and negatives were observed between S-VSCT and the physician-collected P-VSCT (99.6%; $\kappa = 0.93$), CSCT (99.4%; $\kappa = 0.91$), PC L-Pap (99.4%; $\kappa = 0.91$), and SP L-Pap (99.3%; $\kappa = 0.88$) samples (Table 1). Similarly, strong overall agreements were calculated for *T. vaginalis* between self-collected vaginal samples and physician-collected vaginal and cervical samples: S-VSCT to P-VSCT (99.9%; $\kappa = 0.97$), CSCT (99.7%; $\kappa = 0.94$), PC L-Pap (99.6%; $\kappa = 0.91$), and SP L-Pap (98.8%; $\kappa = 0.78$) (Table 2).

Although there was good agreement in the current study between S-VSCT and SP L-Pap samples (99.3% for *C. trachomatis* and 98.9% for *T. vaginalis*), the kappa values were 0.89 for *C. trachomatis* and 0.78 for *T. vaginalis*. Fewer *C. trachomatis* and *T. vaginalis* infections were detected in SP L-Pap samples than in PC L-Pap samples, as reported in 3 previous studies (15–17). Differences between PC and SP L-Pap sensitivity values may be due to order of collection in the study or due to different ingredients in the two L-Pap transportation fluids. SP L-Pap contains chemicals which can induce nucleic acid cross-linking and effect RNA integrity, causing false-negative results with time (18, 19). This phenomenon can be reversed to some extent by proteinase K and heat treatment of the SP L-Pap samples (20), although this was not attempted in this study.

In conclusion, the high level of acceptability of the new SCT collection kit for vaginal self-sampling, including ease of collection and comfort, plus the strong agreement of self-collected vaginal sampling with physician-collected cervical and vaginal

TABLE 1 Overall agreement of S-VSCT samples with P-VSCT, CSCT, PC, and SP samples for *C. trachomatis*[a]

Sample	Result	No. of S-VSCT samples			% overall agreement (95% CI)	Kappa (95% CI)
		+	−	Total		
P-VSCT	+	21	0	21	99.6 (98.8–99.9)	0.93 (0.85–1.0)
	−	3	681	684		
CSCT	+	22	2	24	99.4 (98.6–99.8)	0.91 (0.83–1.0)
	−	2	680	682		
PC L-Pap	+	22	2	24	99.4 (98.5–99.8)	0.91 (0.83–1.0)
	−	2	669	671		
SP L-Pap	+	16	0	16	99.3 (98.1–99.7)	0.89 (0.77–1.0)
	−	4	518	522		

[a] S-VSCT, self-collected vaginal specimen collection and transportation sample; P-VSCT, physician-collected vaginal specimen collection and transportation sample; CSCT, cervical specimen collection and transportation sample; PC, PerservCyt sample; SP, SurePath sample. +, positive; −, negative.

TABLE 2 Overall Agreement of S-VSCT samples with P-VSCT, CSCT, PC, and SP samples for *T. vaginalis*[a]

Sample	Result	No. of S-VSCT samples			% overall agreement (95% CI)	Kappa (95% CI)
		+	−	Total		
P-VSCT	+	19	1	20	99.6 (98.8–99.9)	0.93 (0.85–1.0)
	−	0	676	676		
CSCT	+	17	0	17	99.6 (99.2–100)	0.97 (0.92–1.0)
	−	2	675	677		
PC L-Pap	+	16	0	16	99.6 (98.5–99.8)	0.91 (0.81–1.0)
	−	3	668	671		
SP L-Pap	+	11	0	11	98.9 (97.6–99.5)	0.78 (0.61–0.96)
	−	6	517	523		

[a] S-VSCT, self-collected vaginal specimen collection and transportation sample; P-VSCT, physician-collected vaginal specimen collection and transportation sample; CSCT, cervical specimen collection and transportation sample; PC, PerservCyt sample; SP, SurePath sample. +, positive; −, negative.

samples, provides good evidence for its use in testing for *C. trachomatis* and *T. vaginalis* from these sample types.

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