Feasibility and Acceptability of a Novel Cervicovaginal Lavage Self-Sampling Device Among Women in Kigali, Rwanda

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Abstract: The Delphi Screener is a novel cervicovaginal lavage self-sampling device. Sixty women in Kigali (Rwanda) assessed the Screener at 2 consecutive visits. Between the visits, ease of use improved, reported difficulties decreased, and the collected sample weight increased. Most women preferred self-collection over a speculum examination.

To stop the spread of sexually transmitted infections (STIs), early diagnosis and timely treatment are essential. However, many STI cases are diagnosed late or not at all for a variety of reasons: infections are often asymptomatic, many patients are reluctant to get tested, and access to clinics, trained health care workers, and/or laboratory testing is often poor.[1] Some of these barriers can be addressed by encouraging at-risk populations to sample and/or test themselves with the use of self-sampling devices.[1–5]

The Delphi Screener, developed by gynecologists in the Netherlands, received Conformité Européenne marking in 2011 and is marketed by Delphi Bioscience BV (Scherpenzeel, the Netherlands). More than 10,000 European and American women have used the Screener in cervical cancer screening programs to collect samples for subsequent liquid cytology and/or human papillomavirus testing.[6–12] Some studies showed that adding the possibility of self-sampling increased participation rates in cervical cancer screening programs,[6,10,11,13] and 2 studies found good test result concordance with samples obtained by gynecologists.[12,14] Self-sampling has also been successfully used for the diagnosis of other STIs and vaginal infections in a variety of settings including African settings.[3,15–18] However, thus far, the Delphi Screener has not yet been used in African settings or to test for STIs or vaginal infections. We therefore conducted a pilot study in Kigali, Rwanda, to determine the feasibility and acceptability of the Delphi Screener among Rwandan women.

The study population consisted of a subsample of 60 Rwandan women participating in a multicountry, observational, prospective cohort study to establish baseline ranges of vaginal microbiome and immunology biomarkers: 30 HIV-negative female sex workers (referred to as the FSW group) and 30 HIV-positive women attending an HIV clinic at Muhima Hospital (referred to as the clinic group). All participants were sexually active, not pregnant, and between 22 and 35 years old. All clinic group participants were asymptomatic, on antiretroviral treatment for at least 6 months, and had a CD4+ count of at least 350 cells/μL. Participants provided written informed consent for the main study and the self-sampling substudy separately. The study was approved by the Rwanda National Ethics Committee and the Ethics Committee of Ghent University Hospital in Ghent, Belgium.

The main study consisted of 7 study visits: visits 1 to 5 at various time points over 2 menstrual cycles and visits 6 and 7 at 3-monthly intervals thereafter. The self-sampling visits were scheduled between visits 5 and 7, with a minimum of 1 week between any 2 main or substudy visits. Participants were shown how to use the Screener, and posters with user instructions in the local language (Kinyarwanda) were available in the clinic room. At the first self-sampling visit, the study clinician was present in the room unless the participant asked her to leave (opt-out), and during the second self-sampling visit, the participant was asked whether she preferred the clinician to be in the room (opt-in). The self-sampling procedures consisted of washing hands, unscrewing a test tube, opening the plastic pouch containing the Screener, inserting the Screener in the vagina in supine or squatting position, pushing a button to release its 3 mL liquid

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contents (buffered saline) into the vagina, counting to 3, releasing the button to collect the fluid sample back into the screener, removing the Screener from the vagina, transferring the content in the test tube, closing the test tube, discarding the Screener, and washing the hands again. Participants were interviewed at each visit. In addition, the clinician recorded her observations when present in the room. The duration of self-sampling was measured, and the collected samples were weighed.

Data analysis was performed using SPSS.[19] Comparisons between groups at the same visit were made by Pearson χ^2 test for proportions and Mann-Whitney U test for medians. Comparisons between visits were made by McNemar test for proportions and Wilcoxon paired signed rank test for medians. Multivariable logistic regression models included age and variables that were statistically significantly associated with the outcome of interest in bivariable models; 90% confidence intervals were calculated owing to small sample sizes.

All participants completed both self-sampling visits, except for 1 woman in the clinic group. The median age was 26.5 years (range, 22–33) years in the FSW group and 30.5 (22–35) years in the clinic group. Fifty-seven percent of the women in the clinic group had attended secondary school, but only 13% of the FSWs had. None of the participants had ever used tampons or self-sampling devices, but 13% of the FSW group and 37% of the clinic group had ever inserted vaginal medications. All of these differences reached statistical significance ($P < 0.05$).

None of the women asked the clinician to leave the room during self-sampling at the first visit; during the second visit, 30 women (33% of the FSW group and 69% of the clinic group, $P = 0.006$) asked for the clinician to be present. One woman in each group chose to collect the sample while squatting; all other women chose the supine position. The median duration of self-sampling at both visits was 4 minutes, but the range decreased from 2 to 14 minutes at visit 1 to 2 to 6 minutes at visit 2 (Table 1). The median amount of fluid collected improved significantly, from 1,716 mg at visit 1 to 2322 mg at visit 2 ($P < 0.001$). Fluid leakage from the vagina after self-sampling was observed by the clinicians 10 times (10/60) at visit 1 and 5 times (5/30) at visit 2 ($P = 1.000$). The clinicians also observed that 6 women (6/60) at visit 1 and 4 women (4/30) at visit 2 were trembling during self-sampling ($P = 0.625$). Four women at visit 1 and none at visit 2 asked for the instructions to be repeated.

At the first and second visits, 63% and 71% of the participants, respectively, deemed the Screener to be both very easy to use and very comfortable ($P = 0.267$). Only 1 participant

TABLE 1. Feasibility and Acceptability of Delphi Screener Use

Feasibility	**Visit 1 (n = 60)**	**Visit 2 (n = 59)***	**OR (95% CI)**	**Wilcoxon or McNemar, $P^{\dagger}$**
Refused nurse at visit 1[‡]	0/60 (0%)	NA	NA	NA
Preferred nurse at visit 2[‡]	NA	30/59 (50.8%)	NA	NA
Median duration of self-sampling (range), min	4 (2–14)	4 (2–6)	NA	0.397
Median weight of Screener fluid collected (range), mg	1716 (308–3721)	2322 (245–3822)	NA	<0.001
Participants that collected at least 1500 mg	33/60 (55.0%)	37/59 (62.7%)	1.38 (0.66–2.86)	0.332
Participant asked at least 1 question before or during the self-sampling[§]	6/60 (10.0%)	2/59 (3.4%)	0.32 (0.61–1.63)	0.219
Participant had at least 1 difficulty with procedure (clinician-reported)[¶]	11/60 (18.3%)	6/59 (10.2%)	0.50 (0.17–1.47)	0.227
Participant had at least 1 difficulty with the procedure (self-reported)[‖]	11/60 (18.3%)	4/59 (6.8%)	0.32 (0.10–1.08)	0.065
Acceptability	**Visit 1**	**Visit 2**	**OR (95% CI)**	McNemar, **P**
Ease of use: very easy	39/60 (65.0%)	46/59 (78%)	1.92 (0.85–4.29)	0.077
Comfort of use: very comfortable	47/60 (78.3%)	48/59 (81.4%)	1.21 (0.49–2.96)	0.754
Screener deemed both very easy to use and very comfortable	38/60 (63.3%)	42/59 (71.2%)	1.43 (0.66–3.09)	0.267
Comfort of last speculum examination: very comfortable	46/60 (76.7%)	50/59 (84.7%)	1.69 (0.67–4.28)	0.332
What method would you prefer: self-sampler**	42/60 (70.0%)	37/59 (62.7%)	0.72 (0.33–1.55)	0.344
What method would you prefer: speculum examination by clinician[††]	18/60 (30.0%)	22/59 (37.3%)	1.38 (0.65–2.98)	0.344

*One participant in the clinic group was lost to follow-up after visit 1.

[†]Wilcoxon paired signed rank test for medians and McNemar test for proportions.

[‡]An opt-out procedure was used at visit 1 and an opt-in procedure at visit 2.

[§]Questions asked were as follows: "Can you help me?" (0.8% of the participants); "Can you repeat the instructions?" (3.4%); and "How can I open the Screener?" (2.5%).

[¶]Clinician-observed difficulties included those with preparing the Screener (3.4% of the participants), inserting the Screener (6.7%), withdrawing the Screener (7.6%), and processing the collected sample (4.2%).

[‖]Participant-reported difficulties included those with preparing the Screener (3.7% of the participants), inserting the Screener (6.7%), withdrawing the Screener (5.9%), and processing the collected sample (3.4%).

**Reasons for preferring self-sampling: it is easy to use (57.0%), it is quick (24.1%), it is not painful (41.8%), and dislike pelvic examination (20.3%).

[††]Reasons for preferring speculum examination: a physician can assess for abnormalities (62.5%), the Screener is difficult to use (5.0%), feeling too inexperienced with self-sampling (25.0%), or feeling insecure about self-sampling (7.5%).

OR indicates odds ratio; CI, confidence interval; NA, not applicable.

TABLE 2. Determinants of Feasibility and Acceptability of Delphi Screener Use at Visit 2

	Successful Feasibility*†	Less Successful Feasibility*†	Bivariable OR (90% CI)	Multivariable OR (90% CI)‡
Median age (range), y	29 (22–34)	28 (22–35)	1.04 (0.92–1.18)	1.04 (0.90–1.20)
Mean educational level§	3.36	2.69	1.52 (1.04–2.21)	1.19 (0.77–1.85)
Screener reported to be very easy and very comfortable	31/36 (86.1%)	11/23 (47.8%)	6.77 (2.37–19.30)	5.93 (1.89–18.65)
	Preference for Screener†	**Preference for pelvic examination†**	**Bivariable OR (90% CI)**	**Multivariable OR (90% CI)‡**
Median age (range), y	27 (22–35)	30 (22–34)	1.00 (0.89–1.12)	1.00 (0.86–1.16)
Mean educational level§	3.35	2.68	1.53 (1.04–2.24)	1.17 (0.74–1.87)
Screener reported to be very easy and very comfortable	33/37 (89.2%)	9/22 (40.9%)	11.92 (3.87–36.72)	10.30 (3.06–34.67)

*Successful feasibility was defined as having collected at least 1.5 g with the Screener combined with no participant- or clinician-reported difficulties.

†At this visit, 36 of 59 women achieved successful feasibility and 37 of 59 women preferred the Screener over a pelvic examination.

‡Multivariable logistic regression models with successful feasibility and Screener preference as outcome. All 3 predictors were included in each model simultaneously.

§Educational level categories were considered ordinal as follows: 1, no schooling; 2, some primary school but not completed; 3, completed primary school; 4, some secondary school but not completed; 5, completed secondary school; and 6, postsecondary school.

OR indicates odds ratio; CI, confidence interval.

throughout the study reported a physical complaint ("pain") after self-sampling. At the first visit, 42 (70%) of the participants stated that they preferred the Screener, whereas 18 (30%) preferred the pelvic examination performed by a clinician (Table 1). At the second visit, 37 preferred the Screener (63%), whereas 22 preferred the pelvic examination (37%). Of those preferring a pelvic examination, 77% reported as the main reason that pelvic exams allow for internal inspection by a clinician.

Good feasibility (defined as having collected at least 1.5 g of fluid, which is 50% of the volume inserted, combined with no self- or clinician-reported problems), was achieved by 51% of participants at visit 1 and 61% at visit 2 ($P = 0.238$). In bivariable analyses using data from visit 2, good feasibility and good acceptability (defined as participants preferring the Screener over a pelvic examination performed by clinicians) were statistically significantly associated with a higher educational level and reporting self-sampling to be both very easy and very comfortable. In multivariable models, only the latter was statistically significantly associated with good feasibility and acceptability (Table 2). Study group, physical complaints before and after Screener use, self-reported difficulties, and ever use of vaginal medication were not associated with good feasibility or good acceptability ($P > 0.100$).

This study showed reasonable feasibility and good acceptability of the Delphi Screener among Rwandan women. Approximately two thirds of the women preferred the Screener over a pelvic examination, which is slightly lower than reports from the Netherlands (75%), the United States (79%), and Italy (78%).[7–9] Some study participants were visibly nervous during self-sampling, or reported to feel too inexperienced or too insecure for self-sampling, but this improved with practice. Others said that they prefer speculum examinations because internal inspection by a clinician may identify abnormalities that would otherwise not be detected. This was also reported in other African self-sampling studies, probably because most African women rarely have the opportunity to be examined by a clinician.[2,4] Therefore, we think that feasibility and acceptability could be maximized by allowing women to practice with self-sampling in the presence of a clinician and by reassuring women that self-sampling should be considered an addition to, and not a replacement of, pelvic examinations.

The limitations of our study include a limited generalizability (self-sampling was only performed in women of reproductive age in an urban clinic setting), selection bias (all women were already participating in a research study), and social desirability bias. The strengths of our study are that we only included women who had experience with pelvic examinations, that we asked each woman to self-sample twice with a median of 7 weeks in between self-sampling visits, and that we used multiple methods to assess feasibility and acceptability. For example, the agreement between participant-reported and clinician-observed findings was excellent (data not shown).

To conclude, we believe that the Screener could be used by Rwandan women within research studies and in urban clinic settings. Widespread use in cervical cancer or other reproductive health screening programs in rural areas or in home settings would require additional pilot testing and evaluation. The fluid collected by the Screener can be used for molecular diagnostics (as is the case with self-sampled swabs) but could also be used for cytology and to test for soluble molecules, such as antibodies and other immune mediators. However, the performance of the Screener in combination with each of these tests would have to be evaluated.

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