Self-collection of vaginal swabs among adolescent girls in a school-setting in East Africa

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**ABSTRACT**

**Background**: Few studies have evaluated the acceptability of self-collected vaginal swabs among young women in sub-Saharan Africa, including in school settings. We evaluated the acceptability of two conditions for the self-collection of swabs in secondary schools in Entebbe, Uganda.

**Methods**: Assenting girls with parental consent from 3 secondary schools were provided instructions for sampling, and randomly allocated to self-collection of vaginal swabs with or without nurse assistance to help with correct placement of the swab. Swabs were tested for bacterial vaginosis (BV) by Gram stain. Participants were followed-up after 1-2 days and 1-2 weeks and invited for a qualitative interview.

**Results**: Overall 96 girls were enrolled (median age 16, interquartile range 15-17). At the first follow-up visit, participants in both arms reported that instructions for sample collection were easy to understand and they felt comfortable with self-collection. Girls in the nurse assistance arm reported feeling less relaxed (27% vs 50%, p=0.02) than those in the arm without nurse assistance, but more confident that they collected the sample correctly (96% vs 83%, p=0.04). About half of participants (47%) agreed that self-sampling was painful, but almost all (94%) would participate in a similar study again. Qualitative data showed that participants preferred self-collection without nurse assistance to preserve privacy. BV prevalence was 14% (95%CI 8-22).

**Conclusion:** In this setting,self-collection of vaginal swabs in secondary schools was acceptable and feasible, and girls preferred self-collection without nurse assistance. Self-collection of swabs is an important tool for the detection, treatment and control of reproductive tract infections in girls and young women.

**Brief summary**

The self-collection of vaginal swabs for the testing of reproductive tract infections is acceptable and feasible in a school setting among adolescent girls in Uganda. This is an important tool for school-based health interventions in this population.

**BACKGROUND**

Self-collected vaginal swabs for detection of sexually transmitted infections (STIs) are broadly acceptable to women, and perform as well as other specimen types for the detection of curable STIs such as *Chlamydia trachomatis* and *Neisseria gonorrhoeae* [1,2]. Self-collected vaginal swabs have also been used successfully for the detection of bacterial vaginosis (BV) by Gram stain [3,4]. However, there are few studies that have evaluated acceptability outside of home or clinic settings. In addition, few studies have evaluated the acceptability of self-collected swabs in low- and middle-income settings (LMIC) [2].

Adolescent girls and young women are at high risk for STIs and BV in East and Southern Africa [5], highlighting a critical need for strategies to detect and control STIs in this setting. STIs/BV can cause serious morbidity, including pregnancy complications, infertility, poor neonatal outcomes and enhanced HIV transmission. Many of these sequelae are preventable if testing and treatment is implemented.

Strategies for combining STI/BV detection with other reproductive and sexual health programmes (e.g. family planning and menstrual hygiene) show promise [6,7]. Yet, clinic-based strategies can be hampered if young people avoid health centres due to perceived stigma, costs and long waiting time [8]. Furthermore, finding young people at home can also be a challenge for population-based strategies [9]. Secondary schools offer a promising platform to deliver reproductive and sexual health programmes that include testing for STIs/BV; however, acceptability of school-based genital sampling has not been evaluated. In addition, in adolescent girls, the level of support needed for self-sampling is unknown.

We conducted an acceptability and feasibility study of self-collected swabs among girls in 3 schools in Entebbe, Uganda as a part of a broader study to develop a menstrual hygiene management (MHM) intervention.

**METHODS**

**Study population and design**

A vaginal swab sub-study was nested within a secondary school-based study developing an MHM intervention in a peri-urban district of Uganda. The goal of the parent study was to conduct formative work prior to a trial to evaluate the effect of the MHM intervention on school attendance in this setting. The parent study was conducted among 352 female students aged 12-17 years in four purposively selected secondary schools from October 2015 to August 2016: 1 public Universal Secondary Education (USE); 1 public non-USE; and 2 private schools (1 high socio-economic status (SES), and low SES) [10]. For the vaginal swab sub-study, the private high SES school was excluded a-priori, as the parent study found that girls attending this school had good menstrual hygiene and private high SES schools would be excluded in a future trial.

**Study procedures for the vaginal swab study**

An initial school visit for the vaginal swab-study was scheduled with each headteacher to identify a private space for consenting, interviewing and sampling. This was followed by a meeting with teachers, the school health officer and students to inform them about the study. Of the 352 girls participating in the parent survey, 155 girls were randomly selected, stratified by school and reported sexual intercourse (sexual debut) in the parent survey. Selected girls were given invitations for a parent/guardian information session. If a parent/guardian was unable to attend the information session, the study team conducted a home visit. Written informed consent was required from parents/guardians for girls aged less than 18 years or oral consent for girls aged 18 years or more. We used a thumb print and signature of an independent witness for consenting parents/guardians with literacy challenges. A translated Luganda version of the information sheets and consent forms were available to parents/guardians whenever necessary.

On the day of enrolment, a temporary study clinic was prepared at each school in a pre-agreed location. A screening list of girls with parental consent was generated. Girls were randomised to one of two study arms (within school to self-collect vaginal swabs either with or without nurse assistance) using blocks of 4 and 6 assigned using a random number generator. This was pre-allocated on the screening list. Girls were eligible for the study if they were not menstruating on the day of enrolment. Consenting/assenting girls were enrolled and interviewed to obtain data on socio-demographics, genital hygiene practices, and genital symptoms. All girls were provided information about how to self-collect the vaginal swabs with a prepared script; girls in the arm without nurse assistance were also shown a diagram of how to self-collect a vaginal swab. Three self-administered vaginal swabs were collected: 1 cotton swab for BV and 2 additional Copan® flocked swabs (Copan Diagnostics, USA) for storage for future molecular testing of the microbiota. For the purpose of this study, ‘nurse assistance’ was defined as the nurse providing verbal instruction, visualising correct placement of the swab, and helping to guiding her hand if needed. Self-sampling without nurse assistance meant that the nurse was on the other side of a privacy screen available to provide verbal instruction if needed. Participants with genital symptoms were referred to the Uganda Virus Research Institute (UVRI) adolescent health clinic for free syndromic management by a research study physician (GM). Girls were given a snack while they were waiting and a bar of soap after completion of the visit to compensate them for their time.

Participants were followed-up after 1-2 days (Follow-up 1) and 1-2 weeks (Follow-up 2) to assess the acceptability of taking the swab. Interviews were carried out by a female social science research assistant blinded to study arm. Participants were asked to rate their agreement with 10 statements using a 4-point Likert scale (very easy, easy, difficult, very difficult; strongly agree, agree, disagree, strongly disagree) to assess the ease of understanding of consent for the study and the instructions for collecting the sample, and the experience of sample collection, respectively. At the end of the quantitative interview, girls were invited to discuss their experience using open-ended questions to gain more in-depth qualitative understanding of each girl’s experience. The purpose of Follow-up 2 was to assess the reliability of the Likert-style questions, and to deepen the rapport for the qualitative open-ended questions. In addition, each nurse was interviewed to assess acceptability of the sampling methods from the providers’ perspective.

**Laboratory methods**

Laboratory testing was performed according to standard operating procedures. Laboratory technicians were blinded to the study arm allocation. Vaginal swabs were used to prepare a slide. Slides were air dried at the school and transported to a central laboratory, heat-affixed, Gram stained, and examined for BV using the Nugent score [11]. A Nugent score of 0–3 indicated normal microbiota, 4–6 indicated intermediate microbiota, and 7–10 indicated BV. Laboratory technicians were blinded to study arm. All slides were read by a single technician; 25% of slides were double read by a second technician.

**Quantitative Data Management and Statistical Methods**

Questionnaire data were double-entered into OpenClinica (Akaza Research, USA), and analysed using Stata 14 (College Station, TX, USA). The statistical analysis plan was prepared prior to the statistical analysis, and the analysis was carried out per protocol. Continuous data (age) were categorised into meaningful categories. Categorical data were summarised using frequency counts and percentages. Missing data were not imputed.

Participant characteristics were obtained from the parent study and the vaginal swab sub-study. Characteristics were compared by study arm (i.e. with or without nurse assistance). Socio-demographic, puberty and sexual debut data obtained from the parent survey were compared by study arm of the vaginal swab sub-study. Likert responses were categorised into binary variables: easy/very easy vs difficult/very difficult; or agree/strongly agree vs disagree/strongly disagree. Proportions by arm were compared with Chi-square statistics and p-values. To explore the consistency of responses by follow-up visit, proportions from aggregate data were compared using McNemar’s test for matched binary data, and a Kappa statistic was calculated to measure consistency of reporting for each individual participant. We used the Landis and Koch interpretation for the strength of agreement for the Kappa coefficient: values greater than 0.75 represent excellent agreement; values between 0.40 and 0.75 represent fair to good agreement; and values less than 0.40 represent moderate to poor agreement [12].

**Qualitative Data Management and Analysis**

A thematic content analysis was conducted by a research assistant and a senior social scientist. Key themes and subthemes emerging from the data were classified in a matrix, capturing participant narratives to illustrate each theme.

**Ethics**

The study was approved by the Ethics Committees of the Uganda Virus Research Institute (GC/127/15/04/508), the Uganda National Council for Science and Technology (HS/1810), and the London School of Hygiene and Tropical Medicine (Ref 9682).

**RESULTS**

Participants were recruited and followed from 7 April 2016 to 10 May 2016. Of the 155 girls screened for the vaginal swab study, 104(80%) parents/guardians consented, and 96(62%) girls consented to enrol in the study. Of these, 49(51%) were allocated to nurse assisted arm. Two participants in the arm without nurse assistance, asked for nurse assistance during sampling; however, the data for these participants was analysed per protocol.

The median age of girls was 16 years (interquartile range [IQR]: 15-17). Two-thirds of girls were from low SES (government and private) schools (Table 1). Sociodemographic characteristics were similar by arm, but maternal education was higher in the sub-study (36%) than in the parent study (28%). In the sub-study, all but one girl reported passing menarche. Only 5% reported having passed sexual debut. In the sub-study, more participants with nurse assistance vs without nurse assistance reported having ever had a genital examination (39% vs 4%) or having ever looked at their genitals (75% vs 32%).

**Acceptability of self-collected vaginal swabs**

Both study arms reported that the study and the instructions for the sampling were easy to understand, and that the swab was easy to collect (Table 2). During Follow-up 1, most girls agreed that they felt comfortable with self-collection (56% with nurse assistance and 61% without nurse assistance; p=0.51). Among girls with nurse assistance, fewer agreed that they were in control (48% vs 67%, p=0.06) and relaxed (27% vs 50%, p=0.02). However, more girls with nurse assistance felt confident of their ability to collect the sample correctly (96% vs 83%, p=0.04), and fewer were worried that they might not be doing the test correctly (27% vs 48%, p=0.04) compared to girls without nurse assistance. There was some evidence that girls with nurse assistance were more embarrassed than those without nurse assistance (56% vs 37%, p=0.06). Overall, 45(47%) participants agreed that self-sampling was painful. Few girls felt offended by self-sampling, and most girls would be willing to be in a study like this again (94%) or recommend the study to a friend (94%). Girls reported the maximum number of swabs they were comfortable self-collecting in the future: 1 swab (20%); 2-3 swabs (64%); 4-5 swabs (12%); and >5 swabs (4%).

Between the first and second follow-up visits, there was no evidence for a difference between the responses overall with a few exceptions (Table 2). In the arm without nurse assistance, there was an increase in proportion of girls who agreed that they felt relaxed during the sampling (p=0.02), and in the arm with nurse assistance there was a decrease in the proportion of girls who trusted that they were doing the test correctly (p=0.01). There was some evidence of a decrease in proportion of girls who agreed that sampling was painful in the second follow-up visit among those in the arm with nurse assistance (p=0.07). Kappa statistics for these comparisons revealed fair to moderate consistency of participant reporting between the first and second follow-up visits – highest consistency for feeling pain (κ=0.70) and lowest for feeling offended during sampling (κ=0.40).

Qualitative results

83 of the 96(86%) girls provided qualitative data for analysis. Of these, 42(49%) and 41(51%) were from the arms with and without nurse assistance, respectively. The median age was 16 (IQR:15-17).

*Embarrassment*

Qualitative data from girls with nurse assistance reported feeling embarrassed to be undressed in front of the female nurse, and stated preferences for self-collection without the assistance of the nurse.

*I was in fear and felt shy of the nurse seeing my private parts since collecting the swab involved removing of the knickers*. (17 years; with nurse assistance)

*It was a good experience, but I suggest that the nurse just gives information and lets me collect the swabs myself.* (17 years; with nurse assistance)

This was corroborated by the two nurses who remarked that girls preferred to self-collect on their own, and that “in Africa, showing private parts to another person is embarrassing.” Some girls overcame their sense of embarrassment by the encouragement of a nurse or friends who had gone through the same procedure.

*At first I was so shy about the nurse seeing me but later got comfortable because the nurse was so open and friendly with me.* (16 years; with nurse assistance).

*Concerns about performing the procedure*

Participants worried whether they would collect the swabs correctly. Girls were worried about knowing where to collect the swab, and if they would harm themselves while carrying out the procedure.

*I thought I would not do the test correctly I thought I would place the swab in a wrong place and then get a problem.* (15 years; with nurse assistance).

*Collecting the swab was easy, but I was not comfortable. I was really scared because I thought I would hurt myself with the swab.* (15 years; without nurse assistance).

*Concerns related to the loss of virginity*

There were several issues related to self-collection of the swab and virginity. During the consenting process, girls were informed that the swabs would not break or tear skin near the opening of the vagina, even if they had never had sexual intercourse. Yet, some girls worried that the swabbing may jeopardise their virginity. Other girls were worried that the nurse would notice that they were no longer virgins.

*I was anxious because I thought I would lose my virginity.* (18 years; with nurse assistance).

*I felt shy being seen in the private parts by the midwife and some girls fear being examined in the private parts because some of them are no longer virgins.* (16 years; with nurse assistance).

Lastly, some girls ascribed the pain during the procedure to their virginity.

*The swab pained me because am still a virgin.* (17 years; without nurse assistance).

*Pain*

Many girls mentioned having pain as a result of inserting the vaginal swab. This was often with the first swab only, and it lasted for a short duration.

*I got the information which helped me understand the study and collecting the swab was easy however, I felt some pain though it did not last for long.* (15 years; without nurse assistance).

*I was earlier worried that maybe collecting the swab would be painful and indeed it was painful during the time of collecting the swab however the pain disappeared immediately after collecting the swab.* (18 years; with nurse assistance).

Notably, a few participants mentioned having felt no pain during collection of the swab.

*I did not feel any pain even after collecting the swab it felt normal.* (17 years; without nurse assistance).

*It was not painful at all because all the instruments used were soft and the swab itself was cotton, am happy that I got to be part of the study.* (17 years with nurse assistance).

*Positive impact*

Overall, girls generally appreciated the benefits of having participated in the study, including learning about their reproductive health and receiving treatment for STI symptoms.

*It was a great experience and the way in which the team explained that when one is found with symptoms, she would be given treatment the study has made the girls confident and now feel they belong somewhere in the community*. (18 years; without nurse assistance).

*I learnt how to manage my body hygiene and also got more knowledge on my body parts and the way they are developed since I got a chance to see my private parts and learnt about the different body parts.* (17 years; without nurse assistance).

**Prevalence of genital symptoms and BV**

All slides for BV testing had adequate numbers of bacteria for Nugent scoring. The overall prevalence of BV was 14% (95%CI 8-22): 10% (95%CI 4-23) with nurse assistance; and 17% (95%CI 9-31) without nurse assistance (p=0.192). All cases of BV were in girls who reported not ever having sex.

**DISCUSSION**

To our knowledge, this is the first study to evaluate self-collection of vaginal swabs in a school setting in East or Southern Africa, a region where prevalence of STI, BV and HIV are high. Overall, there was good acceptability and feasibility for self-collecting of vaginal swabs in a school setting. Girls were able to understand instructions, and self-collected high-quality samples that were tested for BV by Gram stain. Most of the girls stated that they would join a similar study again and recommend it to a friend. Girls preferred self-collection without nurse assistance. Privacy was an important factor – girls with nurse assistance felt less relaxed and more embarrassed. Girls also reported satisfaction with learning about their bodies and reproductive health through taking part in the study.

In a systematic review of 45 studies evaluating self-sampling, 28 evaluated self-collected swabs[2]. Of these, only 6 were conducted in LMIC - 3 were in sub-Saharan Africa (2 from South Africa and 1 from Kenya)[13–15]. Only 1 US study evaluated self-collection from a school setting [16]. There were 9 studies that assessed acceptability in adolescents and young people only, while many more included adolescents and young people in the study [2]. Similar to our study, most studies in the review reported that self-collection of vaginal swabs was feasible and acceptable. Most studies also reported that women preferred self-sampling to clinician sampling, and several studies showed that self-sampling was more acceptable by younger participants [14,17]. Also similar to our study, 2 US studies of young people aged 14-22 years reported lower trust in self-collection compared to clinician collection at baseline; however, trust in self-sampling increased after sampling experience [18,19]. These findings mirror the results in our study in which girls were less confident about carrying out the procedure without nurse assistance but suggest that confidence could improve in a longitudinal design with repeat sampling. Privacy and safety regarding self-collection of samples were the most common issues of concern reported in systematic review [2], and this is also reflected by the qualitative data from our study illustrating embarrassment at being seen by the nurse and anxiety about injuring oneself during sampling.

Of the 28 studies evaluating self-collected swabs in the systematic review, only 10 asked about pain or discomfort[2]. While there was more pain reported in our study (almost 50%) than studies in the review (pooled prevalence of 13%) – qualitative data revealed that the pain was of short duration. Pain is often reported in the literature as a comparison; e.g. self-collected swabs were more painful than urine collection in one study [20], but less painful than a gynaecological speculum examination in another [21]. Interestingly, in a South African randomised controlled trial among young people aged 14-25 participants felt more pain self-sampling at home (17%) when compared to self-sampling in a clinic (12%) despite using the same sampling method [13]. This study suggests the subjective nature of pain, in which less confidence and higher anxiety may lead to the perception of more pain. In our study, girls reported being initially scared of sampling due to not knowing their own anatomy and anxiety that they may injure themselves. In the surgical literature, it has been shown that providing information that includes both sensory (sensations that will be experienced) and procedural (the sequence of events) aspects of the procedure reduces anxiety and pain [22]. Thus, providing better anticipatory guidance and information about the self-collection procedure may decrease perception of pain for girls carrying out self-collected vaginal swabs.

BV prevalence was moderately high (14%), though lower than in a study among school girls in Tanzania, aged 17-18 years (25% prevalence) and a population-based study in South Africa among girls aged 15-19 years (40% prevalence)[9,23]. The proportion of girls who report passing sexual debut was higher in both the later studies. BV is associated with sexual intercourse and several studies have shown that BV is rare in sexually naïve girls [24,25], though other studies report BV among sexually naïve girls [26,27]. In our study, all cases of BV were among girls who denied having had penile-vaginal sex. It is unclear if this is due to underreporting of sex or the true prevalence among sexually naive girls in this population. Underreporting of sexual behaviour is common in this population and may be exacerbated in a school setting [23,28]. Although the study staff emphasised confidentiality of results to both parents and participants, students may have feared stigmatization, school expulsion and physical punishment [28].

This study had several strengths, including randomisation of the study arms to investigate the level of support needed for self-collection in school girls. Interviews about acceptability were conducted by blinded social science research assistants and not the nurse who carried out the sampling. Additionally, acceptability was measured by a common set of questions used in the field; this was extended by a second follow-up visit that showed that these questions were broadly reliable, as well as collecting qualitative data to further illustrate and clarify the quantitative data.

There are some limitations to this study. There was imbalance between the study arms regarding previous genital examinations and having ever looked at one’s own genitals – both were more prevalent among girls without nurse assistance and could explain why this group was more relaxed and less embarrassed. In addition, there was no comparison between venues (school vs home vs clinic) or to clinician-collected vaginal swabs which is common in other published research evaluation self-collection of vaginal swabs. However, the study question was to investigate acceptability in a school setting, and operationally, it would be difficult for there to be clinician-collected swabs in school-based interventions in crowded school settings in Uganda.

In conclusion, self-collection of vaginal swabs is acceptable in a school setting, and can provide an important tool for the detection, treatment and control of reproductive tract infections in girls and young women. Engagement with the school, parents/guardians and students provides an important foundation for acceptability and feasibility, and the development of culturally and age appropriate information and instructions is essential, including information on basic anatomy, anticipated discomfort and concerns about virginity. Well-planned school-based reproductive health programmes that include self-sampling can simultaneously provide diagnosis of infections and better awareness of reproductive health for girls and young women.

**Authors' contributions**

The study was designed by GM, RR, JNM, SCF, BT, DAR and HAW. Data were collected by GM, RR, JNM, KN, SM and JN. Data were analysed by JNM, GN, SCF, RR and KN. The manuscript was drafted by SCF. All authors read and approved the final manuscript.

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