A Comparison between Self and Clinician-collected Vaginal Swabs for Detection of Bacterial Vaginosis among Women in Kisumu, Kenya

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Abstract

Two tests are available for diagnosis of bacterial Vaginosis (BV), Amsel and Nugent. The latter is considered more sensitive. Laboratory diagnosis for BV requires a vaginal swab specimen. In developing countries, vaginal swabs are only collected by trained health clinicians and use of speculum, examination couch and expensive equipment like autoclave is necessary. In contrast, women in developed countries have a choice of either collecting self swab or allowing a trained health clinician to collect the vaginal swab. This study sought to evaluate the validity and reliability of self collected vaginal swabs for diagnosis of BV by comparing with clinician collected ones. Ten beaches were identified based on convenience along Lake Victoria in Kisumu County from which 105 women volunteers were enrolled. Three vaginal swabs were collected from each woman. The first two swabs were self collected while the third one was collected by a qualified clinician. Smears were prepared, read and interpreted by Nugent method while demographic and clinical data were obtained by use of structured questionnaires and pelvic examination forms respectively. There was high agreement (validity) between the clinician collected and the first self collected swab, Kappa score of K=0.952 ($p<0.001$). The reliability of the clinician and the second self collected swab had a Kappa score of K=0.905 ($p<0.001$). The self collected vaginal swabs (SCVS) were found to be valid and reliable for use in diagnosis of bacterial vaginosis.

Keywords: Clinician collected vaginal swabs, self collected vaginal swab, reliability, validity, bacterial vaginosis.

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Introduction

Bacterial Vaginosis (BV) is the most common vaginal condition among reproductive age women and is associated with a change in vaginal ecology, resulting in overgrowth of certain bacteria such as *Gardnerella vaginalis*, and other anaerobes which replace the hydrogen peroxide producing *Lactobacillus species* that dominates in normal vagina (Spiegel *et al.*, 1980). The prevalence of BV is high, between 20 and 48% in populations in sub Saharan Africa (Bukusi *et al.*, 2006; Demba *et al.*, 2005). However, BV is normally asymptomatic in more than 50% of these women (Koumans *et al.*, 2007). BV is associated with increased risk of STI acquisition including HIV (Cohen *et al.*, 1995). The diagnosis of BV in low resource settings remains a challenge. The Spiegel (Spiegel *et al.*, 1983; Amsel *et al.*, 1983), Nugent (Nugent *et*

al., 1991) and Hay-Ison criteria (Hay & Ison, 2002) require trained technicians and may involve clinician collected samples. The Nugent criterion is currently employed as gold standard (Nugent *et al.*, 1991). More so, BV management cannot be left to syndromic management alone as it is not effective (Vishwanat *et al.*, 2000). Unwillingness to undergo pelvic examination, specimen collection procedures and early STI diagnosis remain a major barrier to healthcare among women (Kissinger *et al.*, 2005). This unwillingness has been associated with fear of discomfort during examination, mistrust of healthcare providers, perceived lack of privacy, perceived lack of vulnerability among women and denial of being at risk (Wiesenfeld *et al.*, 2001). Following standardizing and validating the microscopic image area used for scoring bacterial morphotypes (Larsson *et al.*, 2004), there is a dire need for effective and simplified method of collecting vaginal swabs for BV diagnosis in developing countries. The use of self collected vaginal swabs (SCVS) for BV diagnosis has worked in other countries (Tanksale et al., 2003). The objectives of this study were to determine the validity of SCVS, reliability of SCVS in diagnosis of BV, preference of women on vaginal swab collection method and to assess women's awareness and perceptions on abnormal vaginal discharge.

Methods

This was an experimental study. The study took place at ten fishing beaches along Lake Victoria within Kisumu County, Kenya among women working in the fishing camps, who were considered to be at high risk for Sexually Transmitted Infections/Human Immuno-Deficiency Virus (STI/HIV). These women visit the fishing beaches to buy fish which they later retail in urban and residential areas. Approval for this study was given by Kenya Medical Research Institute Scientific Steering Committee, Maseno University and ethical clearance by the National Ethical Review Committee (NERC). The sample size that had adequate power (90%) to detect a high rate of agreement (Kappa = 0.90) for a two-sided, alpha = 0.05 test was determined using the following formula which calculates comparative samples:

$$n = \frac{D\left(z_\alpha \sqrt{2\bar{p}(1-\bar{p})} + z_\beta \sqrt{p_1(1-p_1) + p_2(1-p_2)}\right)^2}{(p_1 - p_2)^2}$$

(See Appendix)

One hundred and five women participants aged 18-49 years, involved in the fishing industry that is, selling, buying or processing fish on the beaches located on the Kenyan shores of Lake Victoria and were able and willing to give informed consent, were recruited and enrolled in the study. Those on menses were requested to return after one week while those who cook for fishermen but do not trade in fish were not eligible. The first structured questionnaire was administered to the volunteers to collect information on participant's demographic and hygiene behaviour. After completion of the first structured questionnaire volunteers were sent to a clinic room where they were requested to self-collect the first and second Self Collected Vaginal Swabs (SCVS), for BV diagnosis. Subsequently, the Clinician Collected Vaginal Swabs (CCVS) was collected. The clinician filled-in the history and clinical form for the participants. Following this, the second questionnaire, which collected information on both SCVS and CCVS methods, was administered to the volunteers by trained community health workers. Bacterial Vaginosis (BV) vaginal smears were made from the three swabs collected, stained and read using Nugent criteria. This test was performed as described by Nugent (Nugent *et al.*, 1991). The laboratory technologists were blinded from clinical criteria to prevent observer bias. The three sets of smears from each participant were read independently. Any difference in reading the Gram stained smears between the two medical laboratory technologists was noted

and discussed by the first and second medical laboratory technologist. A final diagnosis was reached by consensus after observing the slides in question together.

The study questionnaire had been formatted into TeleForm version 8.1.0 (Cardiff™, Vista, California) for the collection of all quantitative survey data. TeleForm Data Collection Instruments (TDCIs) were filled at Nyalenda Health Centre during the volunteers' visits. TDCIs were scanned in computer. These data were exported to SPSS 12.0 (SPSS Inc, Chicago, IL) programme. BV results were entered into worksheet in Micro-Soft (MS) Excel software before being exported to Statistical Package for Social Scientists (SPSS) programme and MS Excel 2003 for analysis. These data were quality controlled and checked for validity through data cleaning and coding. Data were analyzed using MS Excel 2003 by simple descriptive statistics for demographic variables, while the Kappa score was used as a measure of correlation of diagnosis of BV. The scores of the first SCVS and the CCVS gram smears were compared to give the validity of the first SCVS. A comparison of scores of the first SCVS and the scores of the second SCVS gave the reliability of the vaginal swabs by participants. Scores of the CCVS and the second SCVS yielded validity of second SCVS. The proportion of participants with positive and negative preferences to SCVS was also assessed.

Results

One hundred and five women volunteered to participate in this study. CCVS was used as standard method of collecting vaginal specimen for BV diagnosis. The validity of first SCVS in diagnosis of BV was 0.952 (p-value < 0.001). The validity of second SCVS was 0.905 (p-value < 0.001). The comparisons of first and second SCVS gave the reliability of the clients in collecting self specimens. The Kappa score for the reliability was k=0.857 (p value=0.001) which is highly significant and therefore highly reliable. The BV prevalence among these women was 50.48% by CCVS, 49.53% by first SCVS and 51.43% by second SCVS (Table 1a, b, c & d).

Table 1a: Comparison of first self collected vaginal swabs (SCVS) with clinician collected vaginal swab (SCVS) for diagnosis of Bacterial Vaginosis

BV Status by First SCVS			Normal	Inter	BV	Total
BV Status by CCVS	Normal	Frequency	37	0	0	37
		%	94.9	0.0	0.0	35.2
	Intermediate	Frequency	2	13	0	15
		%	5.1	92.9	0.0	14.3
	Bacterial Vaginosis	Frequency	0	1	52	53
		%	0.0	7.1	100.0	50.5
	Total	Frequency	39	14	52	105
		%	100	100	100	100

P-value: 0.001
Kappa Score: 0.952

Table 1b: Comparison of second self collected vaginal swabs (SCVS) with clinician collected vaginal swab (CCVS) for diagnosis of Bacterial Vaginosis

BV Status by Second SCVS						
			Normal	Inter	BV	Total
BV Status by CCVS	Normal	Frequency	36	1	0	37
		%	100.0	6.7	0.0	35.2
	Intermediate	Frequency	0	12	3	15
		%	0.0	80.0	5.6	14.3
	Bacterial Vaginosis	Frequency	0	2	51	53
		%	0.0	13.3	94.4	50.5
	Total	Frequency	36	15	54	105
		%	100	100	100	100

P-value: 0.001
Kappa Score: 0.905

Table 1c: Comparison of first self collected vaginal swabs (SCVS) with second self collected vaginal swab (SCVS) for diagnosis of Bacterial Vaginosis

BV Status by First SCVS						
			Normal	Inter	BV	Total
BV Status by 2nd SCVS	Normal	Frequency	36	3	0	39
		%	1.0	0.2	0.0	37.1
	Intermediate	Frequency	0	10	4	14
		%	0.0	0.7	7.4	13.3
	Bacterial Vaginosis	Frequency	0	2	50	52
		%	0.0	0.1	92.6	49.5
	Total	Frequency	36	15	54	105
		%	100	100	100	100

P-value: 0.001
Kappa Score: 0.857

Table 1d: Summary of diagnosis by Nugent criteria obtained from the three vaginal swabs/smears namely CCVS, first SCVS and second SCVS

	CCVS		First SCVS		Second SCVS	
	Frequency	%	Frequency	%	Frequency	%
Normal	37	35.2381	39	37.1429	36	34.2857
Inter	15	14.2857	14	13.3333	15	14.2857
BV	53	50.4762	52	49.5238	54	51.4286
Total	105	100	105	100	105	100

About 15% (15/105) of the participants said they preferred SCVS while 61.9% (65/105) said they preferred the CCVS method. About 23.81% (25/105) had no preference on method of swab collection (Figure 1). More than 93.3% (n=15) of those who preferred SCVS did so because it was easy, they could do it; it was a less painful procedure and more private. More than 90% of (n=65) who preferred CCVS liked it because it was easy, safer, less painful procedure, done by clinician, and one need not to know how to do it (Table 2). Twenty two percent (23/105) women participants said they did not know what abnormal vaginal discharge was. Most of the women (92.38) said that they had not experienced abnormal vaginal discharge. All of them said they would seek treatment if they had abnormality of vaginal discharge. Whereas 98% would do it in a health institution, only 2% would seek help from herbal or witch doctor. Sixty eight percent (71/105) thought their friends would suspect that they were HIV positive if they sought treatment on vaginal related health services. Only 12% (13/105) of their friends thought it was a good idea. These friends further associated abnormal vaginal discharge with infection while 35% (37) said they did not know it (See Table 3).

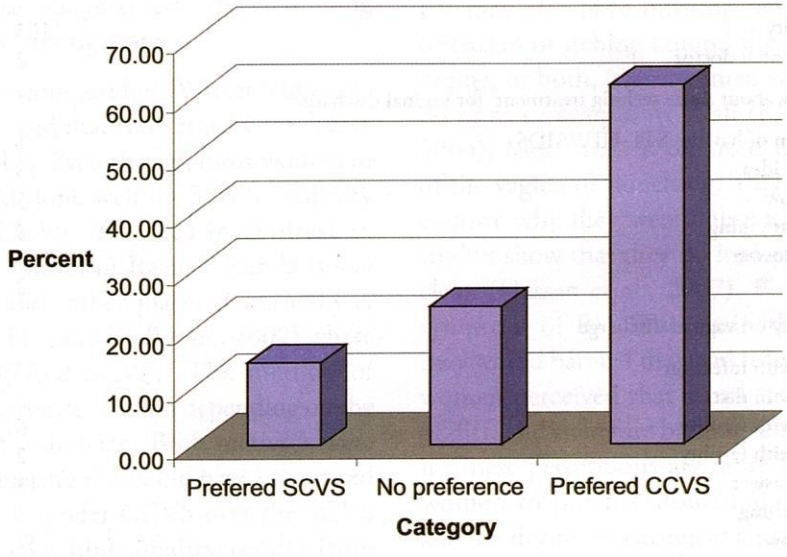

Figure 1: Preferences on method of vaginal collection for BV diagnosis

Table 2: Reasons for the choice of method of collecting a vaginal swab

Why they preferred CCVS n=65	
Easy to perform	59 (90.77%)
A less painful procedure	59 (90.77%)
Procedure done by a clinician	64 (98.46%)
They do not need to know how to do it	65 (100%)
It is safer	64 (98.46%)
Why they preferred SCVS n=15	
Easy to perform	14 (93.33%)
A less painful procedure	14 (93.33%)
It's more private	14 (93.33%)
They can do it themselves	15 (100%)

Table 3: Understanding of women participants on aspects of BV

	N	%
Understanding of abdominal vaginal discharge		
Dirt	10	9.52
Ovulation	7	6.67
Seminal fluid	12	11.43
An infection	8	7.62
Flow from uterus	34	32.38
Lubricant	3	2.86
I do not know	23	21.9
Unpleasant discharge	6	5.71
menses	2	1.9
Would seek cure		
Yes	105	100
Where would you seek cure?		
Health facility	103	98.1
Herbalist / witch doctor	2	1.9
What friend say about those seeking treatment for vaginal discharge		
Suspect them of having STI, HIV/AIDS	71	67.62
A very good idea	13	12.38
I do not know	5	4.76
Do not say anything	7	6.67
Decline to answer	7	6.67
It is not ok	2	1.9
What friends say on vaginal discharge		
Associated with infection	23	21.9
Associated with dirt	3	2.86
Associated with fertility	6	5.71
Associated with fertility	2	1.9
Decline to answer	13	12.38
They say nothing	3	2.86
I do not know	37	35.24
Pre-menses sign	1	0.95
Its normal	2	1.9
It shows maturity	2	1.9
Unpleasant discharge	6	5.71
Post coital discharge	7	6.67
If you had a bad smell, what would you think it is?		
Do not know well	8	7.62
An infection	65	61.9
Could be blood	1	0.95
Dirt	30	28.57
It is a discharge	1	0.95
What would you do to clear the smell?		
Seek hospital treatment	55	52.38
Take a bath	47	44.76
Take herbal medicine	2	1.9
Do not know what to do	1	0.95

Discussion

This study sought to determine the validity and reliability of SCVS. Similar studies in developed countries have shown strong validity and reliability (Tanksale *et al.*, 2003 and Nelson *et al.*, 2003) that are comparable to the results of this study. Women in Africa can equally collect valid and reliable vaginal specimens as it was revealed in this study. SCVS was found to have a high degree of accuracy in diagnosis of BV and women performed it themselves well. These data demonstrate that with specific instructions, SCVS can perfectly approximate BV status in women. This method therefore can be used in place of clinician obtained swabs in determining BV prevalence among women.

As in a previous studies (Wiesenfeld *et al.*, 2001) women said that collecting SCVS is easy and comfortable. Even though most women in this study had done well on SCVS, majority preferred a CCVS. This was in contrast to other similar studies in Rakai, Uganda (Gray *et al.*, 1998) and other places (Chernesky *et al.*, 2005 and Holland-Hall *et al.*, 2002) where majority preferred SCVS. The method of choice used can be decided on depending on the availability of a clinician. Both methods were readily available and this could have influenced these women to prefer CCVS over the SCVS due to perceived high quality results from CCVS. Women who participated in this study were from homogeneous background. Similar studies can be performed on women of diverse background and regions as opposed to the study at hand which dealt with women trading in fish. Randomization can also be done when enrolling volunteers as opposed to this study where only those who 'wanted' to participate were enrolled ('first come first served basis'). The results on preference may not therefore be generalizable to all women in Kenya.

Need to disseminate information on BV

The overall BV prevalence among three sets of vaginal specimens for BV diagnosis compared relatively well with a 50.5%, 49.5% and 51.4% in Clinician, first self and second self collected vaginal swab respectively. This is yet another confirmation that SCVS is as good as CCVS.

Women with BV may have an abnormal vaginal discharge with an unpleasant odour. Some women report a strong fish-like odour, especially after intercourse (Soper *et al.*, 1999). Discharge, if present, is usually white or grey and it can be thin (homogeneous). Women with BV may also have burning sensation during urination or itching around the outside of the vagina, or both. Some women with BV report no signs or symptoms at all (Klebanoff *et al.*, 2004). Most women reported washing inside of the vagina or douching. This study did not enquire why they were doing it, but previous studies show that they do it to ensure they are clean (Hassan et al., 2007). Fishy odour is a symptom of BV. Women in this study said they would bathe if they had fishy odour. These women perceived that a bad smell was a sign of dirt, and therefore bathing alone could clear it. These perceptions are more likely to cause women to practice douching. Others bathe and use drying or astringent agents to make the vagina dry for dry sex claiming their sex partners prefer it to normal (lubricated) sex (Runganga *et al.*, 1992). However, douching is known to increase chance of one developing BV due to clearing/killing *Lactobacillus* species which are responsible for a healthy vagina (Hassan et al., 2007). Increasing frequency of vaginal washing is associated with a higher likelihood of BV (Hassan *et al.*, 2007). Women should not practice douching because of fishy smell, but rather seek health services. There is need to disseminate information on BV to women.

The study further sought to determine the reaction of women if they discovered they had fishy vaginal odour. Sixty two percent (65/105) said they would suspect infection while twenty eight percent (30/105) would think they were unclean (dirty). Women in the fishing industry in Kisumu do not fully understand what fishy smell in vagina is all about. A good number said they would seek hospital treatment in case of fishy smell but it is unfortunate that sixty eight percent (71/105) of their friends would suspect that they are HIV positive, an indication that HIV stigma is still high among women who trade in fish in Kisumu District. Inaccurate perceptions on BV cause an unfounded fear (stigma) and therefore high prevalence of STI as many women do not seek health services.

Conclusions

The SCVS for diagnosis of BV was found to be both significantly valid and reliable. Women preferred CCVS over SCVS for diagnosis of BV. However, participants were willing to obtain their own vaginal swab specimens for BV diagnosis. No participant declined to obtain one or reported difficulty in obtaining SCVS. Women's awareness and perceptions of vaginal discharge and STI/HIV/AIDS was found to be inaccurate and misleading.

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References

Amsel, R., Totten, P., Spiegel, C., Chen, K., Eschenbach, D., Holmes, k. (1983). Nonspecific vaginits: Diagnostic criteria and microbial and epidemiologic association. *American Journal of Medicine,* 74(1), 14–22. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/6600371.

Bukusi, E., Cohen, C., Meier, A., Waiyaki, P., Nguti, R., Njeri, J., and Holmes, K. (2006). Bacterial vaginosis: risk factors among Kenyan women and their male partners. *Sexually Transmitted Infections.* vol. 33, No. 6, p361-367. doi: 10.1097/01.olq.0000200551.07573.df.

Chernesky, M., Hook, E. 3rd, Martin, D., Lane, J., Johnson, R., Jordan, J., Fuller, D., Willis, D., Fine, P., Janda, W., Schachter, J. (2005). Women Find it Easy and Prefer to Collect their Own Vaginal Swabs to Diagnose *Chlamydia trichomatis* or *Neisseria gonorrhoeae* Infections. *Sexually Transmitted Diseases,* 32(12) 729–733. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/16314768.

Cohen, C., Duerr, A., Pruithithada, N., Rugpao, S., Hillier, S., Garcia, P., and Nelson, K. (1995). Bacterial vaginosis and HIV seroprevalence among female commercial sex workers in Chaing Mai, Thailand. *Journal of International AIDS Society,* 9(9), 1093–1097. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8527084.

Demba, E., Linda, M., van der Loeff, M., Akum, A., Gooding, E., Bailey, R., *et al.* (2005). Bacterial vaginosis, vaginal flora patterns and vaginal hygiene practices in patients presenting with vaginal discharge syndrome in The Gambia, West Africa. *BMC Infectious Disease.* 5:12, doi:10.1186/1471-2334-5-12.

Gray, R., Wawer MJ, Girdner, J., Sewankambo, N., Serwadda, D., Meehan, M., Gaydos, C., li, C., and Quinn T. (1998). Use of SCVS for Detection of Chlamydia trachomatis Infection. *Sexually Transmitted Diseases,* 25(8), 450. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9773442.

Hassan, W., Lavreys, L., Chohan, V., Richardson, B., Mandaliya, K., Ndinya-Achola, J., Kiarie, J., Jaoko W., Holmes, K., McClelland, R. (2007). Associations between intravaginal practices and bacterial vaginosis in Kenyan female sex workers without symptoms of vaginal infections. *Sexually Transmitted Disease,* 34(6), 384-388. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17065846.

Hay, E. and Ison, C. (2002). Validation of a simplified grading of Gram stained vaginal smears for use in genitourinary medicine clinics. *Sexually*

Transmitted Infections, 78, 413-415. doi:10.1136/sti.78.6.413.

Holland-Hall, C., Wiesenfeld, H., and Murray P. (2002). SCVS for the detection of multiple sexually transmitted infections in adolescent girls. *Journal of Pediatric Adolescent Gynecology,* 15(5), 307-313. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12547662.

Kissinger, P., Dumestre, J., Clark, R., Wenthold, L., Mohammed, H., Hagensee, M., and Martin D. (2005). Vaginal Swabs Versus Lavage for Detection of *Trichomonas vaginalis* and Bacterial Vaginosis among HIV-Positive Women. *Sexually Transmitted Diseases,* 32(4), 227–230. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15788920.

Klebanoff, M., Schwebke, J., Jun, Z., Tonja, R., Nansel, K., & William, A. (2004). Vulvovaginal symptoms in women with bacterial vaginosis. *Obstetrics and Gynecology,* 104(2), 267-272. doi: 10.1097/01.AOG.0000134783.98382.b0.

Koumans, E., Sternberg, M., Bruce, C., McQuillan, G., Kendrick, J., Sutton, M., and Markowitz, L.. (2007). The Prevalence of Bacterial Vaginosis in the United States, 2001-2004; Associations with symptoms, sexual behaviours, and reproductive health. *Sexually Transmitted Diseases,* 34(11), 864-869. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17621244.

Larsson, P., Carlsson, B., Fåhraeus, L., Jakobsson, T. and Forsum, U. (2004). Diagnosis of bacterial vaginosis: need for validation of microscopic image area used for scoring bacterial morphotypes. *Sexually Transmitted Infections,* 80(1), 63-67. doi:10.1136/sti.2003.006106.

Nelson, D., Scarlett, B., Terri, S., and Graya, I. (2003). Self-collected versus provider-collected vaginal swabs for the diagnosis of bacterial vaginosis: An assessment of validity and reliability. *Journal of Clinical Epidemiology,* 56(9), 862–866. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/14505771.

Nugent, R., Krohn, M., and Hillier, S. (1991). Reliability of diagnosing bacterial vaginosis is improved by a standardized method of Gram stain interpretation. *Journal of Clinical Microbiology,* 29(2), 297–301. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC269757/.

Runganga, A., Pitts, M., and McMaster, J. (1992). The use of herbal and other agents to enhance sexual experience. *Social Sciences and Medicine,* 35, 1037-1042.

Soper D. (1999). Gynecologic Complications of Bacterial Vaginosis: Fact or Fiction? *Current Infectious Disease Reports,* 1(4), 393-397. DOI: 10.1007/s11908-999-0048-9.

Spiegel, C., Amsel, R., and Holmes, K. (1983). Diagnosis of bacterial vaginosis by direct Gram stain of vaginal fluid. *Journal of Clinical Microbiology,* 18(1), 170–177. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC270763/.

Spiegel, C. , Amsel R., Eschenbach, D., Schoenknecht, F. et al. (1980). Anaerobic bacteria in nonspecific vaginitis. *New England Journal of Medicine.* 303, 601–607. Doi: 10.1056/NEJM198009113031102

Tanksale, V., Sahasrabhojanee, M., Patel, V., Nevrekar, P., Menezes, S. and Mabey, D. (2003). The reliability of a structured examination protocol of and self administered vaginal swabs: a pilot study of gynaecological outpatients in Goa, India. *Sexually Transmitted Diseases,* 79(3), 251-253. doi:10.1136/sti.79.3.251.

Vishwanat, S., Talwar, V., Prasad, R., Coyaji, K., Elias, C., and Zoysa I. (2000). Syndromic management of vaginal discharge among women in a reproductive health clinic in India. *Sexually Transmitted Infections,* 76(4), 303-306. doi:10.1136/sti.76.4.303.

Wiesenfeld, H., Lowry, D., Heine, R., Krohn, M., Bittner, H., Kellinger, K., Shultz, M., and Sweet, R. (2001). Self-collection of vaginal swabs for the detection of *Chlamydia,* gonorrhoea, and trichomoniasis: opportunity to encourage sexually transmitted disease testing among adolescents. *Sexually Transmitted Diseases,* 28(6), 321-325. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11403188.

Appendix

Sample size determination

The sample size that had adequate power (90%) to detect a high rate of agreement (Kappa = 0.90) for a two-sided, alpha = 0.05 test was determined by;

$$n = \frac{D\left(z_\alpha \sqrt{2\bar{p}(1-\bar{p})} + z_\beta \sqrt{p_1(1-p_1) + p_2(1-p_2)}\right)^2}{(p_1 - p_2)^2}$$

Where:-

$P = P_1 + P_2$ is mean proportion of success

n is sample size

P represents swabs taken from volunteers

$\mathbf{P_1}$ is the proportion of good clinician collected swabs (specimen) from women

$\mathbf{P_2}$ the proportion of good self collected swabs (specimen) from women

$\underline{(P_1 - P_2)}^2$ is the difference to be detected

D is the design effect. The design effect = 2 because we used clusters (beaches) while sampling.

Z alpha is the critical value for a type 1 error. This is the value of the standard normal distribution corresponding to the significance level of alpha.

Z beta is the critical for a (1-beta) power. This is the value of the standard normal distribution corresponding to the desired level of power.

For the study at hand estimates of P_1 = **99%**; P_2 = **80%** and 90% power **(1.28)** and 5% type 1 error **(1.96)** were used. This was because the study was interested in the convectional alpha of 0.05 and beta level of 0.1, representing a power of 90% to detect the effect of the magnitude if it really existed. The sample size for this study was calculated as follows,

$$n = \frac{2\left(1.96\sqrt{2*0.895(1-0.895)} + 1.28\sqrt{0.99(1-0.99) + 0.8(1-0.8)}\right)^2}{(0.99-0.80)^2}$$

$$n = \frac{2(1.96*0.434 + 1.28*0.412)^2}{(0.19)^2}$$

$$n = \frac{2(0.8497 + 0.5274)^2}{(0.19)^2}$$

$$n = \frac{2(1.3771)^2}{(0.19)^2} = 105.06$$

The final size was **n=105.06.** The study therefore used **105 women volunteers.**