

Published in final edited form as:

Sex Transm Dis. 2012 August ; 39(8): . doi:10.1097/OLQ.0b013e3182515fe4.

Vaginal practices diary: development of a pictorial data collection tool for sensitive behavioural data

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Abstract

Background—Intravaginal practices (IVP) are highly prevalent behaviours among women at increased risk for HIV in sub-Saharan Africa. IVP data collected by face-to-face interviews (FTFI) may be subject to recall or social desirability bias. Daily self-administered diaries may help to decrease bias associated with FTFI. IVP data from a diary and FTFI were compared during a multi-site microbicide feasibility study in Tanzania and Uganda.

Methods—Two hundred women were recruited and given diaries to complete daily for six weeks. Data obtained in the diary were compared to data from the FTFI during clinical visits to assess the consistency of reporting of IVP between the data collection methods.

Results—In Tanzania, proportions of overall vaginal cleansing and insertion were similar for the FTFI and the diary, but the diary indicated higher frequency of cleansing and use of a cloth or other applicator. In Uganda, proportions of overall vaginal cleansing were similar for FTFI and the diary, but the diary indicated higher frequency of cleansing, use of soaps and cloths for cleansing, and insertion. Most of the inconsistencies between the two data collection methods were from reported frequency of IVP or IVP related to sexual intercourse.

Conclusions—The comparison of FTFI and the vaginal practice diary suggests that recall of IVP may be improved by a daily self-administered diary, especially for frequency of cleansing and cleansing in proximity to sexual intercourse. The vaginal practices diary can provide a more detailed understanding of IVP and aid in the interpretation of findings from FTFI. Vaginal practices diary: development of a pictorial data collection tool for sensitive behavioural data.

Keywords

Vaginal practices; Diary; HIV; Sexual behaviour; sub-Saharan Africa

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Summary: Diaries can be used to collect sensitive information on vaginal practices among women at high risk for HIV; they may decrease bias and provide a useful addition to face-to-face interviews.

Conflicts of interest: The authors have no conflicts of interest to declare in connection with this work.

Introduction

Around 25 million people are infected with HIV in sub-Saharan Africa – two-thirds of the worldwide total. The greatest burden is shouldered by 13.3 million African women, who make up 60% of the epidemic in this region(1). This inequity may reflect greater biological susceptibility, but also behaviours that stem from social, gender and sexual norms which will differ between populations. There is evidence that some types of intravaginal practices (IVP), such as intravaginal cleansing or insertion (i.e. placing something inside the vagina, such as herbs), may be risk factors for HIV infection; however there have been conflicting results from prospective studies(2-4). Results from a systematic review suggested an association between IVP and incident HIV; however, a high level of heterogeneity was found between studies and this was attributed to different terminology and descriptions of IVP(5). In addition, IVP may interfere with HIV prevention methods such as vaginal microbicides, thus it is important to obtain accurate measures of IVP in microbicide trials. Collecting valid behavioural data in populations of women at increased risk of HIV is critical for designing appropriate interventions for HIV prevention. A systematic review on the collection of sexual behavioural data in developing countries concluded that questionnaire delivery mode affects the reporting of sexual behaviours(6). Most studies use structured face-to-face interviews (FTFI) to collect retrospective data on IVP. This method is inexpensive and relatively easy to administer to large cohorts, but is subject to social desirability and recall bias(7, 8). In addition, data from FTFI may oversimplify IVP use by asking women to summarise their practices over time.

Prospective diaries have been used to collect data on sensitive behaviours among women at high risk for HIV in sub-Saharan Africa since the late 1990s'(9-12). Diaries are daily self-completed data collection tools that can be in written, pictorial(10, 13), electronic(14) or verbal (eg. daily telephone reports(15)) format. In addition to decreasing social desirability bias by being self-completed, diaries have the advantage of collecting daily events near real-time, thereby decreasing recall bias(9, 11, 16).

This paper describes the first vaginal practices diary developed for use in research and its application in a multi-site microbicide feasibility study among women at increased risk for HIV in Uganda and Tanzania. Our aims were to compare the diary data to IVP data obtained by a FTFI, and to investigate the consistency of reporting between methods and within each method over time.

Materials and Methods

Vaginal practice diary development

The purpose of the vaginal practice diary was to collect data on the frequency and types of vaginal practices performed by a woman each day and to capture key associated behaviours. The diary was first developed in Tanzania and then adapted to the local study population in Uganda. Initial diary designs and drawings were developed by a team of investigators including social scientists, reproductive health experts, HIV epidemiologists, and a local artist. A self-completed, pictorial diary was designed to be administered to low-literacy populations by showing pictures of vaginal practice acts. The diary was revised after six focus group discussions (FGDs) and two pilots with the study population. A final design was based on the acceptability and understandability of the design as rated by the pilot participants (see Figure 1a). The diary was adapted by a local artist and piloted in Uganda (Figure 1b). The diary text, instructions and interviews were in Swahili (Tanzania) or Luganda (Uganda). Although this diary was adapted from a coital diary that was administered for four weeks, the vaginal practices diary was designed to be administered for six weeks to capture at least one complete menstrual cycle.

Main cohort studies

In Tanzania, the main cohort enrolled 970 HIV-negative women at high risk of HIV from three towns located close to gold or diamond mines in North-West Tanzania. All participants were employed in bars, guesthouses, or other food and recreational facilities, and enrolled between August 2008 and August 2009. In Uganda, the main cohort consisted of 1027 women (645 HIV negative and 382 HIV positive) living in the capital city, Kampala. Participants were either self-identified sex workers or employed in entertainment facilities such as bars, nightclubs, and lodges, and enrolled between April 2008 and April 2009. In both settings, participants were seen every three months. At each visit, the participant had a FTFI conducted by a research nurse, which included retrospective questions on sexual behaviour and IVP over the preceding three months. The IVP questions from the FTFI are presented in Figure 2.

Diary Study: Comparison of diary with FTFI in the main cohort

In Tanzania, 100 participants were randomly selected from participants enrolled in the main cohort at two of the three sites (N=663) between the months of September 2008 and June 2009. Participants were invited to participate in the Diary Study at the end of their main cohort enrolment visit. Each consenting participant was asked to fill out the diary every day for six weeks (42 days) to ensure that at least one menstrual period was captured. A female research assistant (RA) taught participants how to use the diary during the enrolment visit, and then visited the participant two days later to support learning for how to use the diary. Each participant was visited every week by the same RA to collect the diary, carry out a quality check, issue a new diary, and answer questions about the study. Participants were encouraged to fill in the diary every day and not just before the RA visit. In the Tanzanian cohort, the enrolment and three month follow-up FTFI were compared with the diary, representing the visit prior to and after Diary Study enrolment (see Figure 3). A sample size of one hundred, or approximately 10% of the main study, was expected to be sufficient to describe the vaginal practices of the cohort with reasonable precision while remaining logistically feasible; for example, if a practice was reported by 80% of women, the 95% CI would be 0.71 to 0.87.

In Uganda, between July and September 2009, 100 women were enrolled into the Diary Study by selecting every fourth participant at any follow up visit for the main cohort study. All consenting participants for the Diary Study were asked to follow the same protocol as described above for the Tanzania cohort. In the Ugandan site, the diary data were compared with the three-monthly FTFI prior to and after Diary Study enrolment (see Figure 3).

Ethical considerations

This study was approved by the ethics committees of the London School of Hygiene and Tropical Medicine, the Tanzanian National Institute for Medical Research, the Science and Ethics Committee of the Uganda Virus Research Institute, and the Uganda National Council for Science and Technology. Informed consent was obtained from all participants prior to enrolment.

Statistical analysis

Diary and FTFI data were double-entered. All analyses were performed using Stata, version 11 (StataCorp, College Station, Texas, USA). Three analyses were carried out: a comparison of the second FTFI with the diary data, as the reporting period of this FTFI would overlap with the six weeks of the Diary Study; a comparison of the first FTFI to the second FTFI to examine the consistency over time of practices reported in the FTFI; and a comparison of the first three weeks to the last three weeks of the diary data to assess the consistency over

time of practices reported in the diary. The first two analyses were restricted to participants who provided a second FTFI. The third analysis was restricted to participants with complete data for the six week study period.

Diary data were summarized on a per-woman basis. On days when participants reported cleansing more than four times, or insertion more than twice, it was assumed that they cleansed five times or inserted three times. Cleansing frequency was calculated as the total number of cleansing acts recorded in diaries by each woman, divided by the total number of days with diary data, and rounded to the nearest whole number. Substance used for cleansing was categorised as “water only” or “other” if a substance other than water was used at least once during the six week study. Application method for cleansing was categorised as “fingers only” or “cloth” if a cloth was used at least once during the study period, or “other” if another applicator was used at least once during the study period.

Proportions from aggregate data were compared using McNemar’s test for matched binary data and a marginal homogeneity test for data with more than two categories between the first and second FTFI, the second FTFI and the diary, and the first and last three weeks of the Diary Study. 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(17).

Results

Comparison of FTFI and diary data

Participants in Tanzania were young (65% <30 years old), worked in bars or guesthouses (60%), and over half completed primary school education (data not shown). Of the 100 participants who enrolled in the Diary Study in Tanzania, 78 had a second FTFI at the three month follow-up visit. Of the 22 women who did not follow up at three months, there was evidence that they were younger, more likely to have worked in a bar, more likely to have taken part in transactional sex, and cleansed with less frequency than attenders. In addition, being a participant in the Diary sub-study was not associated with missing the second FTFI in the main study. Table 1a shows that the aggregate data collected in second FTFI and the diary were similar except for reporting cleansing frequency ($p<0.01$) and reporting the use of a cloth or other applicator ($p<0.01$). The diary data reported a higher frequency of daily cleansing, with more than two-thirds of the cohort cleansing four or more times a day, while in the FTFI most participants reported usually cleansing two to three times a day. The diary reported that 34.7% of participants used a cloth at least once; yet the FTFI reported that only 4.1% of women reported usually using cloth when they cleanse. However, the comparison of applicators was limited as the diary provided data on ever used, while the FTFI summarised data by asking about “usual” practice. Kappa statistics revealed almost perfect agreement for overall cleansing, but only fair agreement for cleansing substance and only slight agreement for cleansing by application, cleansing frequency, cleansing before and after sex and insertion.

Participants in Uganda were also young (75% <30 years old), 43% worked as bar workers and 43% as commercial sex workers, and 42% had not completed primary school while 31% had commenced secondary school (data not shown). Of the 100 participants who enrolled in the Diary Study in Uganda, 93 participants had a second FTFI at the next three month visit. Table 1b shows that the aggregate data collected from the second FTFI and the diary differed for most variables. The frequency of daily cleansing was higher in the diary data, with more than 95% of the participants cleansing four or more times a day, while in the FTFI, only 49% of the participants reported usually cleansing four or more times a day. The diary reported a higher frequency of using a substance other than water (79.6% vs. 56.5%,

$p < 0.01$). In the diary 48.4% of participants reported using cloth at least once, while only 17.4% of participants reported usually using cloth in the FTFI ($p < 0.01$). The diary reported high percentages of participants cleansing before (94.6%) or after (95.7%) sex at least once. In contrast, in the FTFI, only 48.9% of the participants reported cleansing to prepare for sex ($p < 0.01$), and 88.0% reported cleansing after sex ($p < 0.01$). In the diary, 48.4% of participants reported inserting at least once compared with only 31.2% in the FTFI ($p < 0.01$). Kappa statistics for these comparisons revealed fair agreement for reporting substance and insertion, but only slight consistency for application, frequency of cleansing, and cleansing related to sex.

Consistency of FTFI data

In Tanzania, there were few statistically significant differences in the aggregate data between the first and second FTFI (Table 1a). Kappa statistics for these comparisons revealed fair to moderate consistency of participant reporting for cleansing, substance, and application and insertion, but only slight consistency for frequency of cleansing and poor consistency for cleansing related to sex. In Uganda, there were few differences in the aggregate data reported in the first and second FTFI (Table 1b). During the second FTFI, there was an increase in number of participants who reported cleansing to prepare for sex as one of the reasons why they cleansed, 34.1% to 48.9% ($p = 0.02$). Kappa statistics for the comparison of individual participant consistency between the two FTFI revealed substantial agreement for insertion; moderate agreement in participant reporting for cleansing and substance; fair agreement for cleansing application, frequency of cleansing, and cleansing to prepare for sex; and only slight agreement for cleansing after sex.

Consistency of diary data

The diary data from the first and last three weeks were compared to see how consistent reporting was over the six week period (Table 2). In general, the consistency over the six week period was better than between the two FTFI or between the second FTFI and diary data. The agreement for intravaginal cleansing for Tanzania was perfect ($\kappa = 1.0$, $p < 0.01$), and in Uganda, both methods recorded all the women as engaging in intravaginal cleansing. Both cohorts also had perfect agreement for insertion.

Both cohorts had substantial agreement for substance used to cleanse, and moderate agreement for method of application. However, in both cohorts, there was an increase over time in the proportion of participants that reported use of water only for cleansing (Tanzania: from 35% to 52%, $p < 0.01$; Uganda: from 24% to 32%, $p = 0.02$), and a corresponding decline of the proportion of participants that reported the use of other substances. In Uganda there was also an increase in the proportion of participants reporting using fingers only (from 44% to 56%, $p = 0.01$). There was also high agreement for frequency of cleansing in both cohorts. In Tanzania, there was substantial agreement for cleansing related to sex, while only moderate to fair agreement for these variables in Uganda.

Discussion

A daily vaginal practices diary was developed and tested to quantitatively measure IVP and, to our knowledge, this was the first reported use of a vaginal practices diary. Our aims were to compare the consistency of IVP data obtained in the diary to FTFI, and to report the consistency of the IVP data over time within each method. Overall, we found that participants reported more IVP in the diary than in the FTFI, and over time, the diary data were more internally consistent than the FTFI. In addition, most of the inconsistencies between the two FTFIs, and between the FTFI and diary, were from reported frequency of IVP or IVP related to sexual intercourse.

In Uganda, the proportions of women reporting IVP were higher in the diary than in the FTFI, and in both sites, a greater proportion of women reported insertion in the diary and a higher frequency of daily cleansing. This latter finding is congruous with results from a coital diary study among female sex workers in South Africa that found higher reported frequency of sex in the diaries than in the FTFI(10), and with a coital diary study among women at increased risk for HIV in Mwanza City, Tanzania that found that twice as many sex acts were recorded in a diary compared with the FTFI(11). An advantage of the diary was that interval of memory recall was short and closer to direct counts of the behaviour, while FTFI required the participant to average or summarise a practice over a longer time period. However, these results should be interpreted with caution as the FTFI explicitly used summary questions for cleansing application, timing and frequency (e.g. “About how often do you cleanse inside the vagina?” “When do you usually cleanse inside the vagina?”). In addition, our capacity to compare direct counts of IVP was limited as the Diary Study period was for six weeks, while the length of recall for the FTFI was three months.

There was more consistency of IVP over time in the diary than in the FTFI. While the comparison between the first and second FTFI showed similar proportions of reported IVP over a three month time period, there were considerable differences in IVP related to sex. These differences may be related to bias, as it may have been more sensitive to discuss IVP in relation to sex than routine hygiene. Comparison between IVP in the first and last three weeks of the diary showed few differences with the exception of cleansing by substance in both cohorts, in which there was greater use of other substances (e.g. soaps) in the first three weeks. It is possible that weekly visits from the same RA may have encouraged participants to either change their practice or to report in a more socially desirable way; although study staff were trained to respond neutrally to reports of any type of IVP. Investigating IVP use over time within each data collection mode revealed which method was more reliable; nevertheless, it is possible that the diary appeared to be more reliable because of a shorter reporting period of six weeks versus three months for the FTFI. The apparent reliability of the diary may also suggest that there was little participant fatigue associated with filling out a daily diary. In addition, although this is the first time that a diary data collection tool of this type has been administered for longer than four weeks, there was only a small drop off in retention between weeks four and five, and no change between weeks five and six in both cohorts, suggesting that longer time periods of diary data collection may be feasible.

The comparison of the diary to the FTFI data highlights two limitations of FTFI: most inconsistencies between the methods were found in the reports of IVP frequency and IVP related to sex. The former was likely to be an indicator of poor memory recall, and the latter may have demonstrated a degree of social desirability bias. This finding is especially important in the context of future microbicides research where IVP may interfere with a product used before or after sexual intercourse. Reporting from the MDP 301 PRO2000 Trial, Pool and colleagues strongly suggested the use of diaries as part of a mixed methods approach to better understand complex behaviour within microbicide trials(13). After analysing the data from the diary, we noted several limitations with the diary design. The original design was developed in Tanzania, where there was evidence from past studies of cleansing two to three times a day, and rare insertion(9); thus the decision to record up to four acts of cleansing and two acts of insertion was justified. However, in Uganda, where we had less information on IVP frequencies, we underestimated the higher frequencies of IVP and this limited our ability to obtain detailed data in women for all IVP acts. This limitation highlights the necessity of documenting specific practices in different populations for future studies.

In conclusion, our study suggests that the reporting of IVP may be improved by a daily, self-administered diary, especially for frequency of cleansing and cleansing in proximity to

sexual intercourse. Given the importance of understanding IVP in the context of clinical trials for vaginal products, such as vaginal microbicides, the vaginal practices diary should be used as part of a mixed methods approach to understanding these sensitive behaviours in future clinical trials.

Acknowledgments

We would like to thank the women who participated in these studies from Kampala, Uganda and Geita and Kahama, Tanzania. Many thanks to Professor Janet Seeley for her input on the initial design of the study, support throughout the study period and review of the manuscript. We would also like to thank Dr. Deborah Watson-Jones, Dr. Janneke van de Wijgert, Dr. Adriane Martin Hilber for input on the initial design of the diary, and the local artists for drawing and adapting pictures for the Diary, Mr. David Tibasima in Tanzania and Mr. Joseph Ssembatya in Uganda. We would also like to thank the study teams in both sites: research assistants Flora Madaha (Tanzania), Florence Nago (Tanzania), Sarah Nakamanya (Uganda), Ruth Nalugya (Uganda), and Betty Nalusiba (Uganda); the support of Martin Mbonye (Uganda); transcriber, Happy Ng'Habi (Tanzania); translator, Stanilas Shitindi (Tanzania); data managers, Clemens Masesa (Tanzania) and Catherine Kansime (Uganda). MDP 301 team members in Mwanza aided in the initial FGD and pilots for which we are grateful: Cecelia Yona, Amina Sufiana, Christina Sungita, and Concilia John. Finally, we would like to thank the coordinators and team members of the main cohorts, who accommodated the Diary Study: Dr. Joseph Chilongani, Dr. Amos Mtoka, and Dr. Mucho Mizinduko in Tanzania; and Dr. Justine Bukenya in Uganda.

Financial support for the Intravaginal Practices Project was provided by the UK Medical Research Council.

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First day of the week ___/___/___ Today's date ___/___/___

C1						
C2						
C3						
C4						

EDS

Day of the week _____

I1						
I2						

	Cleanse more than 4 times? ✓ <input type="checkbox"/> ✗ <input type="checkbox"/>		Insert more than 2 times? ✓ <input type="checkbox"/> ✗ <input type="checkbox"/>		How many times did you have sex today? 0 1 2 3 4 +
	Are you menstruating today? ✓ <input type="checkbox"/> ✗ <input type="checkbox"/>		Do you have any abnormal vaginal discharge, smell, itching or irritation today? ✓ <input type="checkbox"/> ✗ <input type="checkbox"/>		

EDS

Figure 1a.

The vaginal practice diary in Tanzania. Each diary booklet consists of 14 printed pages representing one week; one day is represented by two facing pages. On the first page, there are four rows for cleansing acts and each row has a picture depicting cleansing (yes/no), substance used (water/commercial products, such as soap or antiseptic/traditional substances such as herbs), how the substance was applied (“applicator”) (fingers/cloth/other), use in preparation for sex (yes/no), use after sex (yes/no), and condom use during sex (yes/no). On the second page there are two rows for insertion practices, each row with a picture depicting insertion (yes/no), substance used (commercial product/traditional substance), applicator used (fingers/cloth/other), use in preparation for sex (yes/no), use after sex (yes/no), and condom use (yes/no). Page two also has five boxes denoting that a participant had more than four cleansing acts (yes/no), had more than two insertion acts (yes/no), was menstruating (yes/no), had vaginal discomfort (yes/no), and a count of sex acts (1, 2, 3, 4+) on that day.

First day of the week _____ Today's date _____

C1						
C2						
C3						
C4						

Page 1

Day _____

	Cleansing more than 4 times? ✓ ✗		Insert more than 2 times? ✓ ✗		How many times did you have sex today? 0 1 2 3 4 +
	Are you menstruating today? ✓ ✗		Do you have any abnormal vaginal discharge, smell, itching or irritation today? ✓ ✗		

Page 2

GHWP-DS □□□□□□

Figure 1b.
The vaginal practice diary in Uganda. This diary is identical to the Tanzania diary except the pictures have been redrawn by a local Ugandan artist.

Question on cleansing: Participants were read the following instructions, “Some women cleanse inside the vagina. Cleansing is defined as cleaning inside the vagina with water or another substance”

1. In the past three months, have you cleansed inside the vagina? No/Yes
 - 1a) If YES, have you cleansed with the following substances? **Prompt:** Plain water; soap or soap and water; other, specify. (Participants could answer yes/no in response to each option)
 - 1b) In the past three months, about how often have you cleansed inside the vagina? (Participant could state frequency)
 - 1c) When do you usually cleanse inside the vagina? **Prompt:** during daily hygiene or toileting; during menses; to prepare for sex; immediately after sex; when you have a vaginal irritation or bad smell; other, specify. (Participants could answer yes/no in response to each option)
 - 1d) How do you usually cleanse inside the vaginal? **Prompt:** fingers; cloth, including handkerchief; cotton wool; paper, including newspaper; other, specify ((Participants could answer yes/no in response to each option)

Question on insertion: Women were read the following instructions, “Some women insert substances inside the vagina to tighten or close the vagina, dry the vagina, to increase lubrication, as love potions, or to treat vaginal irritations. The following questions will ask you about different substances used for these or other purposes:”

2. In the past 3 months, have you inserted herbs, leaves, roots, or other traditional substances? **Probe with powders from traditional healers, teas, or pulverized sea shell** (Yes/No)
 - 2a) If yes, what have you used? **Probe** (spaces for up to three substances)
 - 2b) If yes, in the past 3 months, about how often have you inserted herbs or other traditional substances? (Participant could state frequency)

Figure 2.

The intravaginal questions from the Tanzanian and Ugandan questionnaires. These questions were identical, except for types of insertion. In Tanzania, participants were asked about traditional medicines, detergent, lemon or lime juice, petroleum-based gels, saliva, and “other.” In Uganda, participants were asked about Coca-Cola or other commercial beverage instead of lemon or lime juice.

(a) Tanzania: All participants were enrolled in the Diary Study at the main cohort enrolment



(b) Uganda: An example of a participant who enrolled in the Diary study at the cohort six month clinical follow up visit

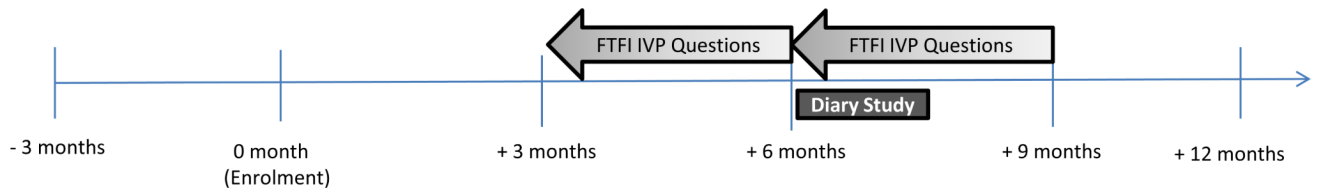


Figure 3.

In Tanzania, participants were invited to participate in the Diary Study at the end of their main cohort enrolment visit. Each consenting participant for the Diary Study was asked to fill out the diary every day for six weeks which corresponds to the period assessed by the second FTFI at the three month visit. In Uganda, women were invited to enrol into the Diary Study at any follow up visit for the main cohort study. The example provided above is for participant who was invited to enrol in the Diary Study at her 6 month visit, in which the Diary Study period would correspond to the period assessed by the FTFI at her nine month visit.

Table 1a

Comparison of intravaginal practices in the **Tanzanian** cohort between the face-to-face interviews (FTFI) and diary data in participants who came to both visits (N=78)

	FTFI 1 (prior to Diary Study enrolment) ^a	FTFI 2 (after the Diary Study enrolment) ^a	p-value ^b for difference in proportions (FTFI 1 and FTFI 2)	Kappa statistic (FTFI 1 and FTFI 2)	Diary data ^c	p-value ^b for difference in proportions FTFI 2 and diary)	Kappa statistic ^d (FTFI vs. diary)
Intravaginal Cleansing	n=78	n=78		0.28	n=78		0.85
No	8 (10.3%)	4 (5.1%)	p=0.29	p<0.01	3 (3.9%)	p=1.00	p<0.01
Yes	70 (89.7%)	74 (94.9%)			75 (96.2%)		
Cleansing by substance	n=69 ^e	n=74		0.44	n=75		0.28
Water only	18 (26.1%)	24 (32.4%)	p=1.00	p<0.01	27 (36.0%)	p=0.83	p=0.01
Other	51 (73.9%)	50 (67.6%)			48 (64.0%)		
Cleansing by application	n=69 ^e	n=74		0.22	n=75		0.13
Fingers only	62 (89.9%)	70 (94.6%)	p=0.69	p=0.01	43 (57.3%)	p=<0.01	p=0.01
Cloth	6 (8.7%)	3 (4.1%)			26 (34.7%)		
Other (Cotton, paper, etc.)	1 (1.5%)	1 (1.4%)			6 (8.0%)		
Cleansing frequency^f	n=70	n=74		0.19 ^g	n=75		0.14 ^g
Less than once a day	2 (2.9%)	3 (4.1%)	p=0.42	p<0.01	0 (0%)	p=<0.01	p<0.01
1 time per day	5 (7.1%)	0 (0%)			4 (5.3%)		
2 times per day	19 (27.1%)	19 (25.7%)			7 (9.3%)		
3 times per day	33 (47.1%)	39 (52.7%)			11 (14.7%)		
4 times per day	7 (10.0%)	12 (16.2%)			30 (40.0%)		
5 times or more per day	4 (5.7%)	1 (1.4%)			23 (30.7%)		
Cleansing to prepare for sex	n=70	n=74		-0.11	n=75		0.12
No	14 (20.0%)	14 (18.9%)	p=1.00	p=0.83	14 (18.7%)	p=1.00	p=0.15
Yes	56 (80.0%)	60 (81.1%)			61 (81.3%)		
Cleansing after sex	n=70	n=74		-0.06	n=75		.03
No	4 (5.7%)	5 (6.8%)	p=0.73	p=0.69	12 (16.0%)	p=0.12	p=0.41
Yes	66 (94.3%)	69 (93.2%)			63 (84.0%)		
Any intravaginal insertion	n=78	n=78		0.49	n=78		0.23
No	68 (87.2%)	73 (93.6%)	p=0.13	p<0.01	70 (89.7%)	p=0.51	p=0.01
Yes	10 (12.8%)	5 (6.4%)			8 (10.3%)		

^a = Participants were asked if they ever engaged in a practice in the last three months;

^b = McNemar's test was used for binary variables and marginal homogeneity test for data with more than two categories;

^c = Diaries obtained data for 6 weeks;

d = The kappa statistic is comparing the consistency of reporting between the second FTFI and the diary data;

e = The difference from expected numbers represents missing data;

f = For diary data: mean frequency per day, rounded, e.g. 4 corresponds to 3.5 to 4.4 times per day;

g = A weighted Kappa was used for an ordinal categorical variable.

Table 1b

Comparison of intravaginal practices in the **Ugandan** cohort between the face-to-face interviews (FTFI) and diary data in participants who came to both visits (N=92)

	FTFI 1 (prior to Diary Study enrolment) ^a	FTFI 2 (after the Diary Study enrolment) ^a	p-value ^b for difference in proportions (FTFI 1 and FTFI 2)	Kappa statistic (FTFI 1 and FTFI 2)	Diary data ^c	p-value ^b for difference in proportions FTFI 2 and diary)	Kappa statistic (FTFI ^d vs. diary)
Intravaginal Cleansing	n=92	n=93		0.49	n=93		
No	3 (3.3%)	1 (1.1%)	p=0.50	p<0.01	0 (0.0%)	p=1.00	--
Yes	89 (96.7%)	92 (98.9%)			93 (100.0%)		
Cleansing by substance	n=89	n=92		0.48	n=93		0.34
Water only	41 (46.1%)	40 (43.5%)	p=1.00	p<0.01	19 (20.4%)	p=<0.01	p<0.01
Other	48 (53.9%)	52 (56.5%)			74 (79.6%)		
Cleansing by application	n=89	n=92		0.28	n=93		0.17
Fingers only	77 (86.5%)	74 (80.4%)	p=0.57	p<0.01	35 (37.6%)	p=<0.01	p<0.01
Cloth	10 (11.2%)	16 (17.4%)			45 (48.4%)		
Other (Cotton, paper, etc.)	2 (2.3%)	2 (2.2%)			13 (14.0%)		
Cleansing frequency^e	n=89	n=92		0.23 ^f	n=93		0.08 ^f
Less than once a day	1 (1.1%)	1 (1.1%)	p=0.08	p<0.01	0 (0.0%)	p=<0.01	p<0.01
1 time per day	2 (2.3%)	0 (0.0%)			0 (0.0%)		
2 times per day	10 (11.2%)	10 (10.9%)			0 (0.0%)		
3 times per day	43 (48.3%)	36 (39.1%)			4 (4.3%)		
4 times per day	22 (24.7%)	36 (39.1%)			34 (36.6%)		
5 times or more per day	11 (12.4%)	9 (9.8%)			55 (59.7%)		
Cleansing to prepare for sex	n=88 ^g	n=92		0.34	n=93		0.02
No	58 (65.9%)	47 (51.1%)	p=0.02	p<0.01	5 (5.4%)	p=<0.01	p=0.34
Yes	30 (34.1%)	45 (48.9%)			88 (94.6%)		
Cleansing after sex	n=88 ^g	n=92		0.10	n=93		0.07
No	10 (11.4%)	11 (12.0%)	p=1.00	p=0.18	4 (4.3%)	p=0.09	p=0.21
Yes	78 (88.6%)	81 (88.0%)			89 (95.7%)		
Any intravaginal insertion	n=91 ^g	n=92		0.62	n=93		0.39
No	67 (73.6%)	64 (68.8%)	p=0.42	p<0.01	48 (51.6%)	p<0.01	p<0.01
Yes	24 (26.4%)	29 (31.2%)			45 (48.4%)		

^a = Participants were asked if they ever engaged in a practice in the last three months;

^b = McNemar's test was used for binary variables and marginal homogeneity test for data with more than two categories;

^c = Diaries obtained data for 6 weeks;

^d = The kappa statistic is comparing the consistency of reporting between the second FTFI and the diary data;

^e = For the diary data, these are mean frequency per day, rounded, e.g. 4 is actually 3.5 to 4.4 times per day;

f = A weighted Kappa was used for an ordinal categorical variable;

g = The difference from expected numbers represents missing data.

Table 2

Comparison of data from diaries in the first three weeks versus the last three weeks in both cohorts.

	Tanzania (N=82)				Uganda (N=99)			
	Diary data for weeks 1-3	Diary data for weeks 4-6	p-value ^a for difference in proportions	Kappa statistic (p-value)	Diary data for weeks 1-3	Diary data for weeks 4-6	p-value ^a for difference in proportions	Kappa statistic (p-value)
Intravaginal Cleansing								
No	3(3.7%)	3(3.7%)		1.0	0 (0.0%)	0 (0.0%)	--	--
Yes	79 (96.3%)	79 (96.3%)	p=1.00	p<0.01	99 (100.0%)	99 (100.0%)		
Cleansing by substance								
Water only	28 (35.4%)	41 (51.9%)		0.68	22 (23.7%)	32 (32.3%)		0.60
Other	51 (64.6%)	38 (48.1%)	p<0.01	p<0.01	71 (76.3%)	67 (67.7%)	p=0.02	p<0.01
Cleansing by application								
Fingers only	51 (88.6%)	55 (94.7%)		0.54	44 (44.4%)	55 (55.7%)		0.46
Cloth	24 (8.6%)	20 (3.9%)	p=0.68	p<0.01	45 (45.5%)	31 (31.3%)	p=0.01	p<0.01
Other (Cotton, paper, etc.)	4 (5.1%)	4 (5.1%)			10 (10.1%)	13 (13.1%)		
Cleansing frequency^b								
Less than once a day	0 (0%)	0 (0%)		0.82 ^c	0 (0%)	0 (0%)		0.75 ^c
1 time per day	2 (2.5%)	2 (2.5%)	p=0.26	p<0.01	0 (0%)	0 (0%)	p=0.89	p<0.01
2 times per day	10 (12.7%)	8(10.1%)			0 (0%)	1 (1.0%)		
3 times per day	11 (13.9%)	15 (19.0%)			6 (6.1%)	5 (5.1%)		
4 times per day	30 (38.0%)	33 (41.8%)			33 (33.1%)	35 (36.4%)		
5 times or more per day	26 (32.9%)	21 (26.6%)			60 (60.6%)	58 (58.6%)		
Cleansing to prepare for sex								
No	22 (27.9%)	23 (29.1%)		0.63	13 (13.1%)	11 (11.1%)		0.43
Yes	57 (72.2%)	56 (70.9%)	p=1.00	p<0.01	86 (86.9%)	88 (88.9%)	p=0.77	p<0.01
Cleansing after sex								
No	19 (24.1%)	21 (26.6%)		0.64	9 (9.1%)	14 (14.1%)		0.36
Yes	60 (76.0%)	58 (73.4%)	p=0.77	p<0.01	90 (90.9%)	85 (85.9%)	p=0.27	p<0.01
Any intravaginal insertion								
No	68 (82.9%)	68 (82.9%)		1.0	50 (50.5%)	50 (50.5%)		1.0
Yes	14 (17.1%)	14 (17.1%)	p=1.00	p<0.01	49 (49.5%)	49 (49.5%)	p=1.00	p<0.01

^a = McNemar's test was used for binary variables and marginal homogeneity test for data with more than two categories;

^b = These are mean frequency per day, rounded, e.g. 4 is actually 3.5 to 4.4 times per day;

^c = A weighted Kappa was used for an ordinal categorical variable.