



A comparison of three daily coital diary designs and a phone-in regimen

Melissa A. Hays*, Belinda Irsula, Susan L. McMullen¹, Paul J. Feldblum

Biostatistics Division and Clinical Research Department, Family Health International, Research Triangle Park, NC 27709 USA

Received 2 November 2000; received in revised form 9 January 2001; accepted 24 January 2001

Abstract

Barrier contraceptive trials and disease intervention studies often utilize coital diaries to measure sexual exposures: dates and frequency of intercourse, product use, additional or alternative contraceptive use, and menstrual bleeding. The validity of these self-reported data is a matter of debate, but if used, better diary designs are sought. We studied 3 different coital diaries, plus a phone-in regimen (none or weekly) in a 3 × 2 factorial design to compare participant ratings and promptness of recording. Our underlying presumption was that ease of and satisfaction with use, and promptness of data collection, are associated with greater accuracy. A self-completed questionnaire at the end of the study collected comparative retrospective data. Diary 1 captured information about a single day on one page and had three columns, for up to three possible acts of intercourse. Diary 2 had the same question format as the first diary, but contained 7 days per page. Diary 3 had 7 days on a page, but instead of a column for each act, participants enumerated the number of acts, the types of contraception used, and condom use details. Half of the women in each diary group phoned in their data weekly. Phone-in improved participants' satisfaction with the diary design as reflected by higher ratings of diary features. Phone-in did not improve recall of data at the end of the study for any of the diaries. There were no differences in the promptness of diary completion. Diaries 1 and 2 showed good concordance with recalled data, and participants expressed a preference for the layout of Diary 2. Women assigned to Diary 3 expressed dissatisfaction with the design and were worse at recalling data at the end of the study, probably due to the complexity of that diary design. © 2001 Elsevier Science Inc. All rights reserved.

Keywords: Coital diaries; Barrier contraceptives; Randomized controlled trial

1. Introduction

Because of their potential for both pregnancy prevention and protection against sexually transmitted infections (STIs), barrier contraceptives now receive considerable scientific scrutiny. Compliance data can aid in the interpretation of barrier contraceptive effectiveness results, whether for pregnancy or STI prevention. Trials may include collection of product use data on coital diaries, with information on dates and frequency of intercourse, product use, correctness of use, additional or alternative contraceptive use, and menstrual bleeding. The advantages and disadvantages of these diaries have recently been summarized [1,2]. In some cases, diaries appear to have collected more valid data on

sexual exposures than recall measures. Negative aspects of diaries include the time, effort, and expense to administer and analyze them, and participant fatigue and reactivity during their use.

While it is infeasible to validate coital data, it is possible to develop study materials and methods that improve participant motivation and satisfaction, thereby reducing the likelihood of erroneous inference. Electronic data collection is a recent innovation, and telephone reporting is used in developed countries. Both approaches allow more precise ascertainment of when events occurred and data were recorded, and allow study staff to track data collection and intervene with additional support in case compliance drops or errors are observed. But these newer methods require substantial financial and/or technological resources. They may not be practical in developing countries, and simpler yet valid approaches should be tested.

Assuming that coital diary data are imperfect but broadly valid [3], there are various aspects of diary design that can enhance accuracy, such as minimizing missing data, mini-

* Corresponding author. Tel.: +1-919-544-7040; fax: +1-919-544-7261.

E-mail address: mhays@fhi.org (M. Hays).

¹Currently at GlaxoWellcome, Research Triangle Park, NC 27709, USA.

Study 9617 Center 9999		DIARY 1		
1. Subject Number: <input type="text"/>				
The following responses refer to this date: _____ / _____ / _____ MONTH DAY YEAR				
2. Did you have any vaginal bleeding?..... <input type="text"/> 0 = none 1 = spotting 2 = menses				
3. How many times did you have vaginal sex?..... <input type="text"/> If you had no vaginal sex, go to Question 10.				
4. In the box(es) to the right, write the number that corresponds to the method you used for each time you had sex: 1 = used condom only 2 = used condom with another method* 3 = used another method only* 4 = used no method* * Rhythm and emergency contraceptive pills are not considered methods for this study. If you had sex more than 3 times on this date, continue on a blank form from the back of the diary. If you did not use any condoms for an act, go to question 10.		1st act	2nd act	3rd act
		Circle Y or N in response to each question for each time you had sex.		
5. Was the condom put on before your partner's penis touched your genitals?		Y N	Y N	Y N
6. Was the penis withdrawn from the vagina while still hard?		Y N	Y N	Y N
7. Was the rim of the condom held during withdrawal?		Y N	Y N	Y N
8. Did the condom slip completely off during intercourse or when withdrawing the penis from the vagina?		Y N	Y N	Y N
9. Did the condom break during intercourse or when withdrawing the penis from the vagina?		Y N	Y N	Y N
10. Date you completed this page: _____ / _____ / _____ MONTH DAY YEAR				

Fig. 1. Design of Diary 1.

mizing the interval between coitus and data recording, and balancing the amount of information desired against the participant burden. We conducted a randomized trial to address these issues. The primary objectives of the study were to compare participant ratings of 3 different diary designs, the promptness with which participants recorded information, and the effect of a weekly telephone call-in regimen. The secondary objective was to assess the concordance between retrospective information collected on an end-of-study questionnaire with prospective diary information.

2. Materials and methods

2.1. Study design

This 3 × 2 factorial, randomized design studied the type of diary (Diary 1, 2, and 3) and type of phone-in regimen (none or weekly). After agreeing to enroll, we assigned each participant to one of the six experimental groups formed by all possible combinations of the two factors, using a computer-generated blocked randomization list.

Women between the ages of 18 and 35 who were sexually active and expected to remain so during the 6-week study period were recruited. To be eligible, women had to be using condoms as the primary method of contraception for the past 3 months, and be planning to use condoms as the

only means of contraception during every act of vaginal intercourse for the next 6 weeks. Women with latex allergy, or who were currently pregnant, or who had been diagnosed or were suspected of being infected with human immunodeficiency virus (HIV), or had partners who were HIV-infected or were suspected of being HIV-infected, were excluded.

2.2. Diary and phone-in design

All 3 diaries were designed to collect information for each day of the study, regardless of whether or not coitus occurred. Diary 1 captured information about a single day on one page and had three columns, for up to three possible acts of intercourse (Figure 1). Contraceptive and condom use questions were asked about each act of intercourse. Diary 2 had the same question format as the first diary, but contained 7 days per page (Fig. 2). For both Diaries 1 and 2, if a participant had more than three acts of intercourse in a day, she filled out an additional diary page with the same date. Diary 3 had 7 days on a page, but instead of a column for each act, participants enumerated the number of acts, the types of contraception used, and condom use details (Figure 3). All three diaries asked participants to record the date that entries were made.

Each participant assigned to one of the three "phone-in" groups was given an 800 number to call and answer a set of six automated questions about her menses and coital activity

Study 9617 Center 999										Diary 2														
1. Subject number: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>																								
Answer the following questions for each day of the week	Sunday			Monday			Tuesday			Wednesday			Thursday			Friday			Saturday					
	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /				
	MON	DAY	YEAR	MON	DAY	YEAR	MON	DAY	YEAR	MON	DAY	YEAR	MON	DAY	YEAR	MON	DAY	YEAR	MON	DAY	YEAR			
2. Any vaginal bleeding (e.g. spotting, menses) <small>0 = none 1 = spotting 2 = menses</small>																								
3. Total number of acts of vaginal sex																								
4. Date you filled out the column <small>If you had NO sex, STOP HERE:</small>	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /			
	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year	Mon	Day	Year
There is a space for you to record information about three acts in one day. If you have sex more than three times in one day, continue on a blank form from the back of the diary.																								
	Sunday			Monday			Tuesday			Wednesday			Thursday			Friday			Saturday					
	1st act	2nd act	3rd act	1st act	2nd act	3rd act	1st act	2nd act	3rd act	1st act	2nd act	3rd act	1st act	2nd act	3rd act	1st act	2nd act	3rd act	1st act	2nd act	3rd act			
5. In the box(es) to the right, write the number that corresponds to the method you used each time you had sex: <small>1 = used condom only 2 = used condom with another method* 3 = another method only* 4 = used no method</small>																								
<small>If you didn't use a condom for an act, skip questions 6-10 for that act.</small>	For items 6-10, please respond to the statements by writing a "Y" for YES or an "N" for NO in each box.																							
6. Was condom put on before your partner's penis touched your genitals?																								
7. Was the penis withdrawn from the vagina while still hard?																								
8. Was the rim of the condom held during withdrawal?																								
9. Did the condom slip completely off during intercourse or when withdrawing the penis from the vagina?																								
10. Did the condom break during intercourse or when withdrawing the penis from the vagina?																								

Fig. 2. Design of Diary 2.

over the previous week. Participants in the phone-in groups were asked to call each Sunday (but were permitted to call in at any time). Responses were audiotaped and transcribed the following week.

2.3. Study procedures

Prior to study initiation, the protocol and advertisements were approved by the Protection of Human Subjects Committee of Family Health International (FHI). Women were recruited through newspaper advertisements and flyers at local colleges and Planned Parenthood offices. Each volunteer was counseled and informed about study procedures, risks and benefits, and signed the informed consent form. She was then instructed in the proper completion of her coital diary (including a demonstration of recording hypothetical data) and asked to demonstrate her understanding of the correct use of the diary. Each participant was asked to complete her assigned diary daily for 6 weeks.

Each woman was offered 30 free latex condoms and given the option of using the study condoms or purchasing a brand of her own choosing. She was instructed on proper storage and use of condoms, given an instruction sheet with the same information, and asked to repeat the instructions in order to confirm her understanding. Participants were instructed to contact the study coordinator to obtain additional condoms if needed.

Every participant was scheduled for an end-of-study visit from 6-8 weeks post-admission. At this visit, the participant turned in her diary and was asked to rate her diary on a rating form. She was also given a questionnaire covering coital frequency, condom use, and diary promptness and accuracy. Near the end of this study, women who were making their end-of-study visit were also shown the other two diaries in the study and asked to express their preference were they to continue completing a diary for the next several weeks.

Subject number:

DIARY 3

SUN	MON	TUES	WED	THURS	FRI	SAT
Mon Day Year						
1. Bleeding: <input type="checkbox"/> (0) none (1) spotting (2) menses						
2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here	2. Sex _____ If '0', complete #3 and STOP here
3. Date complete: _____ Month Day Year						
4. Only condoms: _____						
5. Condoms and another method: _____						
6. Only another: _____						
7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.	7. No method: _____ If no condoms used, STOP HERE.
8. # of condoms: _____						
9. On before: _____						
10. Withdrawn hard: _____						
11. Held by rim: _____						
12. Broke: _____						
13. Slipped off: _____						
14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?	14. Ejaculation: <input type="checkbox"/> (0) No <input type="checkbox"/> (1) Yes <input type="checkbox"/> If YES, how many?

Fig. 3. Design of Diary 3.

2.4. Analysis

Primary objectives were to compare participant ratings of different diary types, and to compare the percentage of times that each diary type was completed daily by participants. Ratings of the diaries were based on responses to 22 five-point scale questions (1 = strongly disagree, 5 = strongly agree). In addition to the overall rating, 3 subscales were constructed prior to examining the data: five questions on the features of each regimen (diary size, preference for phone-in to a recording or a person); eight questions on the task of filling out the diary (diary ease and clarity, the burdensomeness of recording and phone-in); and nine questions on opinions regarding coital diaries (comfort with questions, privacy, embarrassment, social desirability). The percentage of times that the diary was reportedly completed daily was defined as the number of times that the participant reported completing the diary on the same day divided by the total number of days for which diary data were reported by that participant. Diary data for participants

who had more than 6 weeks of data were truncated at 42 days to avoid biasing this completion outcome variable. Unless otherwise stated, a p-value of 0.05 was considered statistically significant for all tests.

Unadjusted means for each of the primary outcomes (any differences by diary type and/or any difference due to phone-in regimen) were calculated. An analysis of variance compared the six groups, plus the two main effects. In addition, tests for homogeneity [4,5] and for interactions were performed and considered significant at the 0.10 level.

The secondary objective of this study was to compare the level of agreement between questionnaire results collected at the end-of-study visit with information reported on the daily diaries. The frequencies of coital acts, condom uses, and acts with correct condom use were calculated for each diary type. Correct condom use was defined as an act for which the condom was donned before the penis touched the vagina; the penis was withdrawn while still erect; and the rim of the condom was held during withdrawal. The same analysis of variance approach used for the primary objec-

Table 1
Demographic features of enrolled population (n = 90)

Characteristic	N	(%)
Age (in years)		
18–25	51	(56.7)
26–30	27	(30.0)
31–35	12	(13.3)
Mean (SD)	24.9 ± 4.30	
Median	24.5	
Range	18–35	
Race		
Caucasian	73	(81.1)
Black	12	(13.3)
Hispanic	1	(1.1)
Asian	2	(2.2)
Other	2	(2.2)
Education (years completed)		
<7	1	(1.1)
7–12	7	(7.8)
>12	82	(91.1)
Mean (SD)	15.4 ± 2.57	
Median	16	
Range	3–23	
Marital status		
Married/living with partner	28	(31.1)
Married/not living with partner	2	(2.2)
Unmarried/living with partner	17	(18.9)
Unmarried/not living with partner	43	(47.8)

tives was applied to these diary outcomes. Retrospective summary information on coital acts, condom breakage and

slippage, etc., was collected on the end-of-study questionnaire. The level of agreement between the end-of-study responses and those on the daily diaries was quantified using a concordance statistic, ρ_c [6,7] or a Kappa statistic, κ [8], depending on the question, and bootstrapped 95% confidence intervals were calculated. The level of agreement was assessed for each main effect, diary type and phone regimen, adjusting for the other effect. If an outcome had no variation, i.e. the value of the outcome was the same for all participants, concordance was set at 1.0 with no confidence interval.

3. Results

A total of 90 participants were enrolled in the study. Participants were mainly young, Caucasian, well-educated, and single (Table 1). Women in the Diary 3 group were most likely to be single and not cohabitating (data not shown). Women using Diary 2 were the longest-term condom users (median 22 months) but almost all women were consistent condom users (data not shown). Background characteristics varied less by phone-in regimen. One participant failed to make her final 6-week visit, could not be contacted to reschedule, and was considered lost to follow-up. The 89 women who completed the study recorded at least 6 weeks of diary data.

Ratings of the diaries (Table 2) did not vary significantly by type of diary, but did vary significantly by phone-in

Table 2
Primary outcomes in analysis population (n = 89)

	Overall rating		Rating of features		Rating of tasks		Rating opinion about diaries		Diary days (%) completed within one day ^b	
	Mean ^a	(SD)	Mean ^a	(SD)	Mean ^a	(SD)	Mean ^a	(SD)	Mean ^a	(SD)
Diary 1										
No phone	3.83	(0.28)	1.98	(0.90)	4.02	(0.24)	4.36	(0.53)	66%	(0.36)
Phone	3.76	(0.38)	2.60	(0.48)	3.73	(0.50)	4.44	(0.49)	57%	(0.24)
Overall	3.80	(0.33)	2.27	(0.79)	3.88	(0.40)	4.40	(0.50)	62%	(0.31)
Diary 2										
No phone	3.93	(0.40)	1.98	(0.46)	4.07	(0.37)	4.53	(0.51)	69%	(0.25)
Phone	3.83	(0.49)	2.65	(0.59)	3.93	(0.39)	4.41	(0.76)	56%	(0.38)
Overall	3.88	(0.44)	2.31	(0.62)	4.00	(0.38)	4.47	(0.64)	63%	(0.32)
Diary 3										
No phone	3.76	(0.32)	2.24	(0.77)	3.84	(0.32)	4.27	(0.43)	57%	(0.32)
Phone	3.78	(0.37)	2.59	(0.40)	3.94	(0.27)	4.30	(0.61)	78%	(0.26)
Overall	3.77	(0.34)	2.41	(0.63)	3.89	(0.30)	4.29	(0.52)	67%	(0.31)
Phone-in										
No phone	3.84	(0.34)	2.06	(0.72)	3.98	(0.32)	4.39	(0.50)	64%	(0.31)
Phone	3.79	(0.41)	2.61	(0.49)	3.87	(0.40)	4.38	(0.62)	63%	(0.31)
p-values ^c										
Overall	0.836		0.005		0.137		0.834		0.325	
Diary	0.501		0.743		0.338		0.458		0.757	
Phone	0.560		<0.001		0.149		0.961		0.947	
Interaction	0.840		0.575		0.122		0.770		0.075	

^a Unadjusted means and standard deviations (for Ratings, 1 = strongly disagree; 5 = strongly agree).

^b An entry was considered completed the same day if the date completed matched that day's date.

^c Overall F-test and p-value refer to test of all six groups, e.g., every phone-in and diary combination.

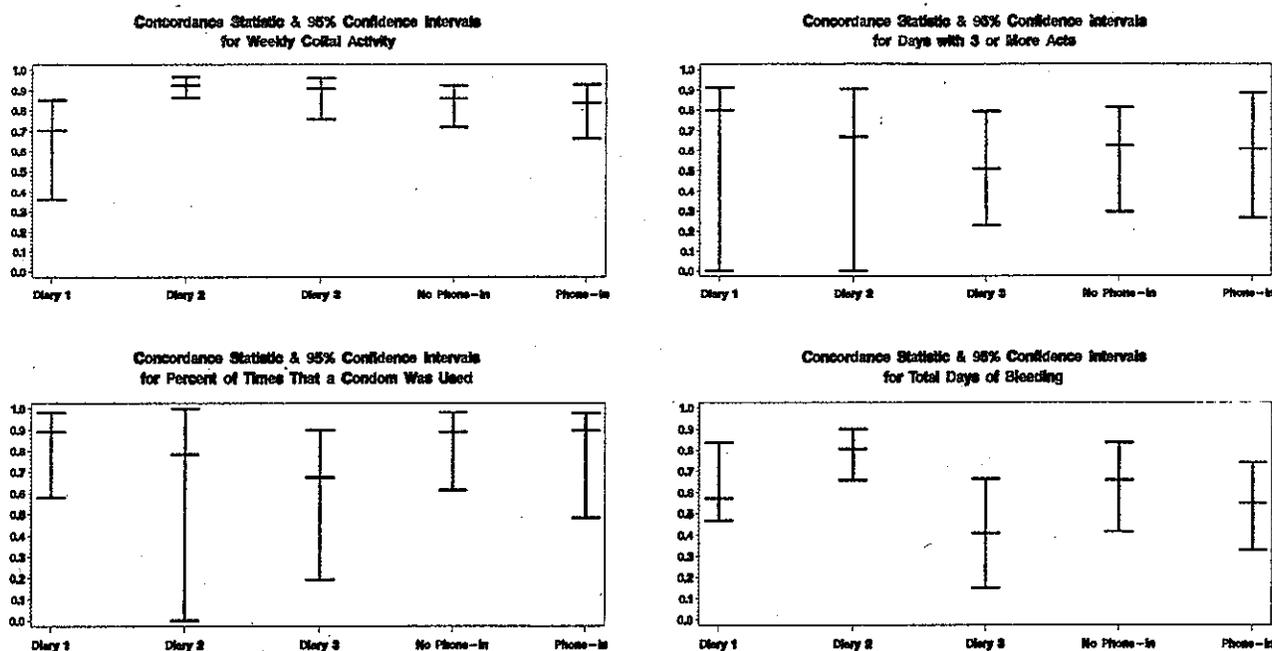


Fig. 4. Concordance between diary information and end-of-study questionnaire items.

regimen. Women assigned to phone-in rated the features of the diaries more positively than women who did not phone in ($p < 0.001$). None of the other rating outcomes was significant. The highest cell means for the other three rating outcomes (overall, task, and opinion) are for the Diary 2 group that did not phone in, however.

The percentage of diary days with data recorded within one day did not differ meaningfully among the six groups. Examining the individual cell means, however, suggested an interaction of diary type and phone-in regimen. Women who were assigned to Diary 3 and the phone-in regimen tended to complete more days promptly (78%) than phone-in subjects with Diaries 1 and 2 (57% and 56%, respectively). Women assigned to Diaries 1 and 2 who did not phone-in had a higher percentage of days with diary completion on the same day (66% and 69%, respectively) than the Diary 3 women (57%).

Coital activity during the study was similar across all six groups (data not shown). Study participants reported a mean of 17.4 coital acts during the study, used condoms for about 90% of all acts, and reported correct condom use for about 40% of these acts. There was no statistically significant difference for any coital outcome by any main or simple effect (i.e., by phone, by diary, or across all six groups). One percent of condoms broke, as reported on the diaries, although fewer breaks were reported on the end-of-study questionnaire.

In addition, about 3% of the participants reported on the questionnaires that they had recorded correct condom use in the diary but had, in fact, not followed the condom use directions. From 6–20% indicated that they had reported

correct condom use on a diary, but did not truly remember whether use was in fact correct.

Concordance between diary information and the end-of-study questionnaire was assessed for 8 end-points (Figs. 4 and 5). For most of the end-points, the point estimates and confidence intervals for the 2 phone-in regimens are similar across type of diary or phone-in regimen. Among the diaries, both Diaries 1 and 2 had good to excellent concordance ($\rho_c, \kappa > 0.60$), except for recall of 'number of acts where a method other than condoms were used' (Fig. 5; $\rho_c < 0.20$). For 5 of the outcomes, Diary 1 has the highest point estimates, i.e., best concordance, and Diary 2 has the highest point estimates for the other three. For four of the outcomes, Diary 2 has the narrowest confidence intervals, and for two other outcomes, Diary 1 has the narrowest intervals. In general, agreement between diary information and final questionnaire for Diary 3 was lower, but no test for differences in concordance between the six groups was done.

Of the participants who were shown the other two diaries at the end-of-study visit, most preferred Diary 2. Participants generally felt that having only one day per page (Diary 1) was cumbersome, while Diary 3 appeared cluttered and difficult to follow. For analytical purposes, the designs of Diaries 1 and 2 allow for reporting correct condom use by act rather than by day. The design of Diary 3 might be expected to be easier to complete, but in fact seemed to confuse participants. Also, participants who used Diaries 1 and 2 indicated that they were willing to fill out diaries for a longer period of time (mean 6 months) than participants who were assigned to Diary 3 (3.5 months).

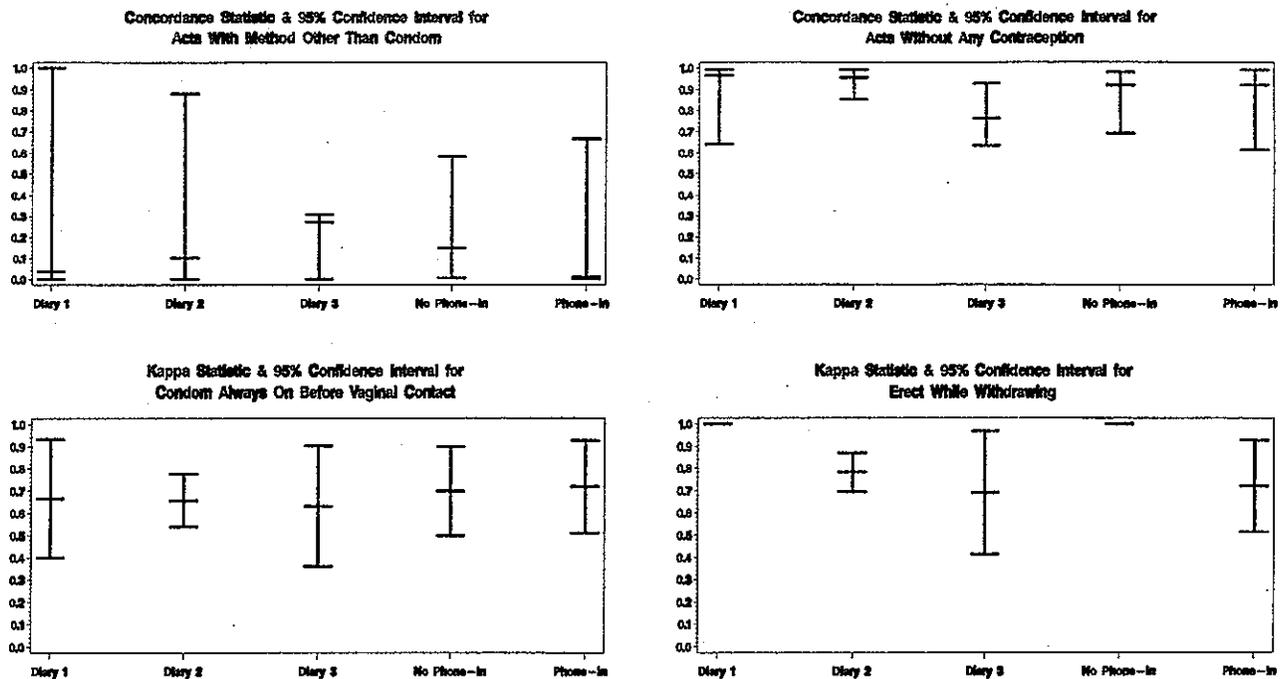


Fig. 5. Concordance between diary information and end-of-study questionnaire items.

4. Discussion

The broad accuracy of coital diary data are asserted by many researchers [1–3], but confirmation is scant. At the very least, important caveats for the use of diaries must be adduced. Agreement between prospective (diary) and retrospective (questionnaire) reports is variable: some studies find higher retrospective frequencies [9,10], and some roughly equal frequencies [2]. Accuracy of coital data may vary dramatically according to features of the participants such as age [2] or educational/literacy status. Accuracy also can vary with the taboo nature of the acts [1], the rarity of the acts [10], and the type of sexual partner (paying versus non-paying) [11]. In the absence of reasonable alternatives, coital diaries provide the sole option for collecting relatively detailed information on sexual activities in a longitudinal research context, and better diaries are of interest.

In our study, which did not attempt to measure validity directly, we made two fundamental assumptions. First, we assumed that the sooner a participant completes a diary entry, the more accurate the information is likely to be. Thus, we tried to motivate participants to make prompt diary entries by collecting information on when each entry is made, or asking women to regularly call an automated 800 number to report their coital activity. But the only means we had to determine promptness were by self-report, and so were subject to bias. Second, we assumed that higher concordance between prospective diary information and retrospective questionnaire information is an indicator of va-

lidity of the data. Again, both sources of data were by self-report, and this assumption is not testable in our study.

Other practical considerations relevant to data quality are worth noting. Coital diaries should be designed to eliminate confusion between acts not recorded (missing data) and dates with no intercourse (no data). Also, although it may be tempting to collect as much data as possible about product use (e.g., whether instructions for use were followed), increased participant burden may lead to non-response, dilatory recording, and/or concocted data, especially as follow-up lengthens.

We found that participants' overall ratings of the three diaries did not vary. Ratings of features varied significantly by phone-in regimen, with women in the phone-in groups having more positive responses. Yet the no-phone group who used Diary 2 had the highest means for overall, task and opinion rating. This fact, which agrees with the retrospective survey, suggests women may prefer a week per page diary format rather than one day per page.

Although there were no significant differences for the outcome "percentage of diary days completed within one day," the phone-in group using Diary 3 had the highest percentage of completion within one day, and the no-phone group in Diary 3 had the lowest percentage of completion within one day. It should be noted that our measure of promptness of recording is also by self-report, and is subject to over-report.

Concordance between diary information and the end-of-study questionnaire varied slightly among the diaries and between the phone regimens. Concordance was generally

highest and least variable for Diaries 1 and 2, and poorer for Diary 3. Qualitatively, Diary 3 was felt to be more complex than Diaries 1 and 2.

The main strength of this study was that it compared several diary designs, and phone-in vs. no-phone regimens, with random assignment. We also compared prospective vs. retrospective data collection among all participants. Another strength was our consideration of features that other research has found to be associated with diary accuracy. A weakness was the study's small size; the project had to be terminated early. Equally important, this was a highly educated, homogeneous study population, making our results less able to be generalized. In particular, cohorts in developing countries that have a lower educational attainment might well require an entirely different, possibly pictorial, format. Also, our study had a short duration, and additional intervention might be needed to maintain good compliance over a longer period. Finally, as in most diary studies, our diary and telephone data rest squarely on self-reports by the participants with no ability to validate the information.

We believe that prompt recording of coital data on a diary that is clear and easy to use is more likely to collect valid data than other alternatives. Our Diary 2 seems to fulfill these ends, and was liked best by our study participants. But the validity and reliability of coital diaries are little studied, and their use springs from intuition and conjecture, so questions about the accuracy of self-reported coital data will persist. In another FHI study using a diary similar to Diary 2, a participant revealed that she disliked her condoms so much that she removed them from her partner during intercourse. Without the option to report "removal," she recorded the events as "complete slippage." This anecdote points to the futility of fully characterizing all aspects of sexual behavior, even among motivated, educated volunteers. Even if coital diaries are unable to provide accurate data about individuals, however, they can still be suitable to measure and compare behavior between groups, and within groups over time [3].

Acknowledgments

Support for this study was provided with funds from the U.S. Agency of International Development (USAID, Cooperative Agreement # DPE-3041-A-00-0043-00), although the views expressed in this article do not necessarily reflect those of USAID. Family Health International is an international nonprofit organization that conducts research and provides technical assistance in reproductive health, family planning, sexually transmitted diseases and AIDS.

References

- [1] Ramjee G, Weber AE, Morar NS. Recording sexual behavior: comparison of recall questionnaires with a coital diary. *Sex Transm Dis* 1999;26:374–80.
- [2] Leigh BC, Gillmore MR, Morrison DM. Comparison of diary and retrospective measures for recording alcohol consumption and sexual activity. *J Clin Epidemiol* 1998;51:119–27.
- [3] Pequegnat W, Fishbein M, Celentano D, et al. NIMH/APPC Workgroup on behavioral and biological outcomes in HIV/STD prevention studies: a position statement. *Sex Transm Dis* 2000; 27:127–32.
- [4] Levene H. Robust tests for the equality of variances. In: Olkin I, Ghurye SG, Hoefding W, Madow WG, Mann HB, editors. *Contributions to Probability and Statistics*. Palo Alto, CA: Stanford University Press, 1960. p. 278–92.
- [5] Conover WJ, Johnson ME, Johnson MM. A comparative study of tests for homogeneity of variance, with applications to the outer shelf bidding data. *Technometrics* 1981;23:351–61.
- [6] Lin LI. A concordance correlation coefficient to evaluate reproducibility. *Biometrics* 1989;45:255–68.
- [7] Simpson PM, Lensing S, Phillips PR, Hamer R. Reliably assessing reliability with SAS software. *SUGI Proc* 1998:1189–93.
- [8] Fleiss JL. *Statistical Methods for Rates and Proportions*. New York: John Wiley & Sons, Inc, 1981.
- [9] Feldblum PJ, Weir SS. Retrospective versus prospective estimates of number of sexual partners (letter). *AIDS* 1995;9:1294–5.
- [10] Coxon APM. Parallel accounts? Discrepancies between self-report (diary) and recall (questionnaire) measures of the same sexual behaviour. *AIDS Care* 1999;11:221–34.
- [11] Weir SS, Roddy RE, Zekeng L, Ryan KA, Wong EL. Measuring condom use: asking "Do you or don't you" isn't enough. *AIDS Educ Prevent* 1998;10:293–302.