Measuring Compliance Among Oral Contraceptive Users

By Linda Potter, Deborah Oakley, Emelita de Leon-Wong and Ruth Cañamar

Irregular use of the pill compromises the effectiveness of this highly reliable method. The consistency of pill-taking has traditionally been estimated through women's own reports of their patterns of pill use. In this study, self-reported data on pill-taking were compared with data from an electronic device measuring compliance among 103 women attending university health services and publicly funded family planning clinics. In three months of pill use, the electronic and self-reported data agreed on the number of days when pills were missed only 45% of the time; the level of agreement dropped from 55% in the first month to 38% in the third month. In each month, the proportion of women reporting no missed pills was much higher than the proportion recorded electronically (53–59% compared with 19–33%), and the proportion missing at least three pills according to the electronic data was triple that derived from the women's reports (30–51% vs. 10–14%). In addition, the electronic data recorded substantially more episodes in which women missed pills on two or more consecutive days (88 vs. 30). (Family Planning Perspectives, **28:**154–158, 1996)

Oral contraceptives are the most effective reversible method of contraception available; the first-year pregnancy rate is less than 0.5% among perfect users and 3% among typical (married) users.[1] However, pregnancy rates as high as 16% and 40% have been reported in certain subgroups of women attending family planning clinics.[2] Pregnancies among pill users may be due to any combination of high fecundity, other physiological factors (such as the effects of countervailing medications or extreme gastrointestinal upset)[3] and irregular pill-taking without compensatory measures to provide contraceptive protection.

At the time this article was written, Linda Potter was principal scientist, Contraceptive Use and Epidemiology Division, Family Health International (FHI), Research Triangle Park, N.C. Deborah Oakley is professor, School of Nursing, University of Michigan, Ann Arbor; Emelita de Leon-Wong is senior biostatistician, FHI; Ruth Cañamar is research associate, Public Policy Research Institute, Texas A&M University, College Station. This study was supported in part by the Office of Population, U.S. Agency for International Development, and by the Office of the Vice-President for Research, University of Michigan. The oral contraceptives were donated by Ortho-McNeil Pharmaceuticals, and staff time was donated by the University of North Carolina and the University of Michigan student health services, Planned Parenthood of West Michigan and the Wake County, North Carolina, Health Department. The authors thank Vicky Brennan, Joyce Cramer, Michael Kafrissen, Douglas Nichols, Elizabeth Raymond and John Urquhart for their comments on early drafts. A detailed statistical report on this study is available from FHI: E. Wong, S. Moeng and A. Johnson, "Do Self-Reports of Oral Contraceptive Compliance Agree with Electronic Reports? Tables and Statistical Report," Biostatistics and Information Technology Office, FHI, Research Triangle Park, N.C., 1995.

Irregular pill-taking may be an important factor in the pregnancy rate among users,[4] and in studies around the world, as many as 60% of women relying on the pill have reported irregular use.[5] Yet, family planning researchers studying women's use of the method have depended primarily on users' reports of a small number of variables that may or may not be related to pill-taking patterns. These variables have included such broad measures as contraceptive use at first or most recent intercourse, current method, and starting and ending dates for each method used during a retrospective period; the data have been based on global reports of the regularity of use, more specific self-reported numbers of pills missed in any month and, in clinical trials, daily diaries. The daily diary remains the standard technique for measuring oral contraceptive use in rigorous clinical trials.

Compliance with drug regimens prescribed to treat infertility, epilepsy, hypertension and diabetes has been assessed through pill counts and measurements of serum concentration of the medication. Pill counts may substantially overestimate compliance,[6] because patients may remove unused medication from the package at any time and thus can "dump" pills just before making a physician visit. In addition, estimates of compliance based on pill counts are vulnerable to missing data because many patients do not bring their medication container to follow-up visits, even when considerable effort is devoted to reminding them.[7] Further, the timing of pill-taking cannot be determined from pill counts.[8]

Serum concentrations are somewhat more accurate as indicators of compliance, but their utility depends on the pharmacokinetics and pharmacodynamics of the medication and the interval between blood, urine or saliva tests.[9] Because use generally improves just prior to a medical visit,[10] and most medications have relatively short half-lives, most physiological tests reflect medication-taking only for the most recent days, and results are not representative of an entire month or a longer period.

In recent years, electronic monitoring devices installed in a variety of medication dispensers (bottles, pill packs, droppers and nebulizers)[11] have been widely used to record the presumptive taking of cardiac, epilepsy and other medications.[12] Typically, a battery, clock and microchip are incorporated into circuitry attached to the dispenser, and when a dose of the medication is dispensed, the microchip records the date and time. At the completion of the study, or at specified intervals, the dispenser is attached to a communication device and the data are downloaded to a computer.

The most widely used electronic device is the Medication Event Monitoring System (MEMS). Its clock is of proven accuracy, and the device records fewer false positives or false negatives than are reported through visual observations.[13] Although electronic monitoring devices cannot document that a pill has been ingested, presumptive pill-taking is broadly viewed as a valid measure of actual pill-taking.[14] The validity of electronic records has also been substantiated by the reappearance of symptoms (for example, clinical episodes of seizures or increased blood pressure) among patients who were shown by the electronic data to have missed or delayed doses of other medications.[15] In addition, when blood levels of the drug have been measured, the results have generally been in accord with those predicted by the electronic records.[16]

Given the discrepancies between electronic data and self-reports that have been recorded for medications other than oral contraceptives, it is reasonable to ask whether irregular pill use is more com-

mon than reported by users themselves. The purpose of this article is twofold: to examine the extent of agreement between users' daily diary reports and data from electronically augmented pill packs, and to estimate the degree of compliance with the instructions for effective use typically provided in clinical practice. Documenting the extent of agreement between users' reports and electronic reports of compliance is important to understand any biases in the use of self-reports.

Methods

Data Collection

Data for this study were collected at a university health service and a publicly funded clinic in each of two states, North Carolina and Michigan, in 1993–1994. All patients aged 18 or older who voluntarily chose the pill as their method of birth control, whether they were electing to use oral contraceptives for the first time or were resuming use six months or more after discontinuation, were asked if they wished to participate in the study. They were told that this was a study of how women take the pill, and that they would be given a dispenser with an electronic device that monitors when they take their pills.

After giving their informed consent, 168 women enrolled in the study (68 in North Carolina and 100 in Michigan). Participants completed a baseline questionnaire and received a free cycle of pills. They returned to the clinic at the end of each of the next two pill cycles to complete another questionnaire and obtain another free cycle of pills. At the end of the third cycle, they completed a fourth questionnaire and were given three more free pill packages in appreciation for completing the study.

In addition to using the electronic dispensers, the women were asked to keep a diary of their daily pill-taking, when they started each pill pack, days of menstrual bleeding, side effects, days when sexual intercourse occurred and what backup method of contraception they used, if any. At each visit, the woman received a monthly diary card (formatted as a calendar page, with space for daily entries) on which to record this information. Careful instructions were given, and examples provided, to facilitate consistent and correct completion of the diary cards.

The pill formulation the women received was a commercially available brand, in its normal packaging, with the addition of a thin casing on the bottom that held the monitoring device.* Each time the pill dispenser was opened, the battery was activated, switching on a light beam across the dispenser's opening. When the pill was removed, it broke the light beam, causing the random-access microchip to record the exact time and date of removal.

Each woman received a precoded dispenser that she used throughout the study; each month, clinic or study personnel installed a new cycle of pills. Upon completion of participation in the study, the women were asked to return the dispenser to the clinic. Thirty women (most of whom did not complete the study) did not return them, despite study personnel's repeated requests. The 138 devices that were returned were sent to the manufacturer, who used proprietary software to download the data onto a diskette.

The electronic data were valid for 110 of the women who returned the device. (The pill pack did not have an automatic closure, so if it was left open, the battery drained and all data were deleted; data were also lost for other, unknown reasons.) Of these women, 103 also had at least one cycle of diary data and had completed the baseline questionnaire. Both electronic and diary card data were available for all 103 women for cycle 1, for 95 women for cycle 2 and for 89 women for cycle 3; data for all three cycles were available for 87 women.

As in other studies using electronically augmented pill bottles, the operational definition of a pill-taking day is the period between 3:00 A.M. and 2:59 A.M. This time frame is more realistic than the standard midnight-to-midnight definition, as it allows for late-night schedules, which are an issue especially on weekends. With this scheme, a consistent oral contraceptive user who takes her pill at 11:00 on Thursday night, then 1:00 on Saturday morning and 11:00 Saturday night is appropriately credited with taking one pill each day, rather than one on Thursday, none on Friday and two on Saturday.

Although a full pill cycle consists of 28 days, active hormonal pills are taken only during the first 21 days; inactive "reminder" pills (placebos) are taken for the last seven days. Only events during the 21 active pill days of a cycle were used in the analysis. Cycle-specific estimates were calculated using SAS, and averages across cycles were calculated using SUDAAN. With SUDAAN, the correlated responses across cycles were considered in the calculation of the variance estimates.[17]

Results

The background and reproductive characteristics of the women included in the analysis did not differ significantly from those excluded. On average, the women in the sample were 20.9 years of age and had had 13.7 years of education. As shown in Table 1, participants were most likely to be white (75%) and not married (93%). Although 89% of the women had no children, 18% had been pregnant.

Table 1. Percentage distribution of women using electronically augmented pill dispensers, by selected characteristics, according to type of clinic site,1993–1994

Characteristic	All (N=103)	Student health (N=77)	Public health (N=26)
Age (yrs.)			
<20	39.8	41.6	34.6
≥20	56.3	55.8	57.7
Unknown	3.9	2.6	7.7
Education**			
<high school	4.9	0.0	19.2
≥high school	93.2	97.4	80.8
Unknown	1.9	2.6	0.0
Race			
White	74.8	77.9	65.4
Nonwhite	24.3	20.8	34.6
Unknown	1.0	1.3	0.0
Marital status*			
Not married	93.2	97.4	80.8
Married	5.8	1.3	19.2
Unknown	1.0	1.3	0.0
Previous method use**			
Used the pill	38.8	31.2	61.5
Used other methods	60.2	67.5	38.5
Unknown	1.0	1.3	0.0
Parity*			
0	89.3	96.1	69.2
≥1	9.7	2.6	30.8
Unknown	1.0	1.3	0.0
Previous pregnancy**			
Ever pregnant	17.5	7.8	46.2
Never pregnant	81.5	90.9	53.8
Unknown	1.0	1.3	0.0
Total	100.0	100.0	100.0

*Difference between sites is significant at p≤.05. **Difference between sites is significant at p≤.01.

Women from the student health and public health centers differed significantly with respect to a number of characteristics. Compared with participants from the public health clinics, the students had a higher mean number of years of education (14.1 vs. 12.5 years—not shown) and were more likely to be unmarried (97% vs. 81%); they were less likely to have previously used the pill (31% vs. 62%), to have children (3% vs. 31%) and to have ever been pregnant (8% vs. 46%).

*In the United States, oral contraceptives are distributed in a variety of blister packs. Thus, the MEMS device that has been installed in the caps of pill bottles had to be adapted to fit the packaging. This experimental version of the device was developed by the APREX Corporation. (See: J. A. Cramer and B. Spilker, 1991, reference 5; and J. A. Cramer et al., 1989, reference 16.)

Table 2. Number and percentage of women whose electronic and diary reports agreed on number of active pills missed, by selected characteristics

Characteristic	N	%	S.E.
Total	**103**	**45.3**	**3.4**
Type of site			
Student health	77	44.1	7.4
Public health	26	45.7	3.8
Age (yrs.)			
<20	41	46.6	5.9
≥20	58	43.8	4.3
Education*			
<high school	5	66.7	10.7
≥high school	96	44.0	3.5
Race			
White	77	45.2	4.1
Nonwhite	25	44.8	6.2
Marital status			
Not married	96	44.6	3.6
Married	6	52.9	10.7
Previous method use			
Used the pill	40	44.5	5.0
Used other methods	62	45.5	4.7
Parity			
0	92	44.8	3.6
≥1	10	48.1	9.8
Previous pregnancy			
Ever pregnant	18	54.2	7.6
Never pregnant	84	43.3	3.8

*Difference between percentages is significant at p<.04. *Note:* S.E.=standard error.

As Table 2 shows, when averaged across cycles, the diary and electronic data agreed on the number of active pills missed for only 45% of the study participants. This figure did not vary significantly by site or by any of the women's background characteristics except education. The result for education, however, may have been unstable because of the small number of participants who had not completed high school.*

In the diary data, women reported having missed 1.0–1.1 pills per cycle. The electronic data showed that overall, participants missed an average of 2.6 pills, and the number increased over time, from 2.2–2.3 in cycles 1 and 2, to 3.5 in cycle 3. Thus, by cycle 3, participants were missing an average of one more pill than they had in cycle 1, and three times as many as they reported in their diary data. Variability around these means, as measured by the standard error, was small and did not increase over time.†

The proportion of women whose diary and electronic data agreed on how many doses were missed declined from 55% in the first cycle to 41% in the second and to 38% in the third cycle. In each cycle, as Figure 1 shows, a much higher proportion of participants reported missing no active pills than missed no pills according to the electronic data (for example, 58% vs. 33% in cycle 1); the proportion missing one or two pills was similar regardless of data source. The most important difference was that the proportion of women whose diaries indicated they had missed three or more pills was much smaller than that recorded electronically. In cycles 1 and 2, 10% of women reported missing three or more pills, whereas the electronic data indicated that 30–34% missed that number. For cycle 3, the proportion was 14% from the diary records and 51% from the electronic data. On the other hand, very few participants overreported their errors; for example, two women did so in cycle 1 (not shown).

The electronic data also present an opportunity to examine pill users, absolute level of compliance. The proportion of women whose electronic data indicated that they missed no pills declined from 33% in cycle 1 to 19% in cycle 3, while the proportion missing three or more pills increased from 30% to 51%.

Data from the electronic devices revealed far more episodes of consecutive days of missed pills than did the self-reports (Table 3). Whereas the diary data recorded 30 episodes of women's missing pills on two, three or more consecutive days, the electronic data reported 88 such instances. Furthermore, the number of such episodes reported by the diary data was fairly stable throughout the study period, increasing only slightly in cycle 3; the electronic data, by contrast, showed the number doubling between the second and third cycles.

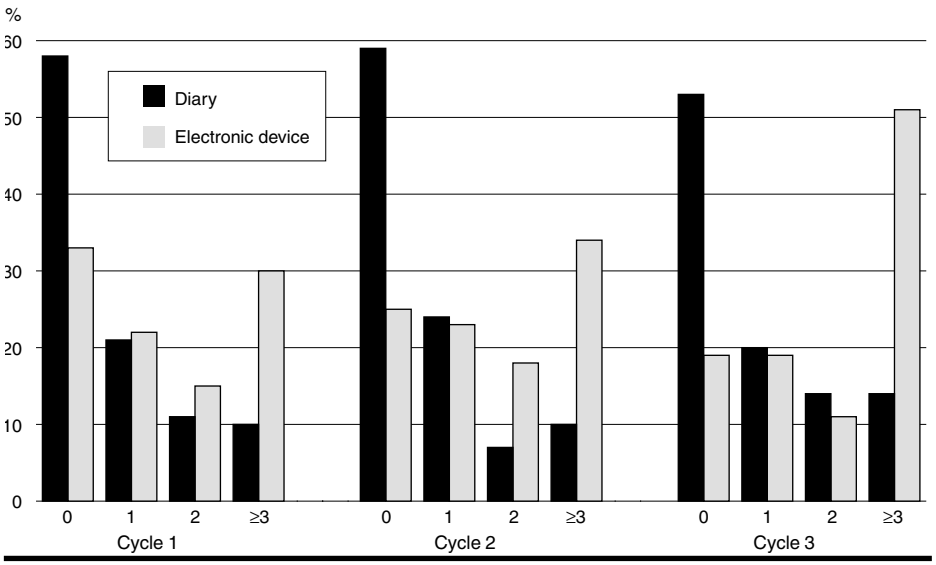
Finally, both sources of data showed that women were most likely to miss pills on Fridays and Saturdays; however, agreement between the diary and electronic data was worst on those two days and deteriorated slightly from cycle 1 to cycle 3. In 98% of cases, both data sources agreed that each new pill pack was started on a Sunday, as instructed at all four clinics.

Discussion

As has been found for other medications, diary cards overreport the consistency with which women take oral contraceptives. In some cases, this problem may be due to conscious misreporting of daily data. However, delayed recording may be a greater problem. Some of the women may have completed their diary cards weekly or less often, at least part of the time. Since pill-taking is likely to trigger the recording of the diary entry, women who miss the most pills are probably the most likely to enter their diary data intermittently.

If women did not record their pill-taking daily, but did it at a later time in a mechanical way, much as office workers or clinic staff may complete daily time sheets or expense reports, their diary data might be influenced by memory errors and response bias. In other words, discrepancies between diary cards and electronic data were not necessarily due to deliberate concealment of "incorrect" behavior. Instead, the diary

Figure 1. Percentage of women by number of active pills missed, according to data source and cycle



*Kappa statistics were calculated for each subgroup comparison. The kappa for education was close to zero, indicating the relationship was random. Because none of the other differences were statistically significant across cycles, their kappas are not reported here.

†The extent of agreement between diary and electronic data on when pills were missed and on whether or not missed pills were made up the following day remains to be analyzed.

Table 3. Number of episodes of consecutive days of missed pills, by data source, according to cycle and type of clinic site

Cycle and type of site	2 missed pills		≥3 missed pills	
	Diary	Electronic	Diary	Electronic
All cycles	**12**	**46**	**18**	**42**
Student health	8	31	11	28
Public health	4	15	7	14
Cycle 1	**4**	**12**	**6**	**10**
Student health	3	8	3	5
Public health	1	4	3	5
Cycle 2	**2**	**10**	**6**	**10**
Student health	2	8	4	8
Public health	0	2	2	2
Cycle 3	**6**	**24**	**6**	**22**
Student health	3	15	4	15
Public health	3	9	2	7

card may not be the best technology for accurate record-keeping of daily events.

Our finding that the discrepancy between self-reported and electronic data does not seem to differ by personal characteristics is a new one and could be due to the relative homogeneity of the study population. However, if this finding can be generalized, the amount of error introduced by self-reports in previous studies would not differ by the background characteristics investigated here, except possibly education. For clinicians, this finding means that self-reports of pill-taking need to be followed by further assessment of all users, depending on indirect clinical indicators, including side effects, not demographic characteristics or reproductive history. The most telling indicator may be irregular bleeding, including spotting.[18]

The increase between cycles 1 and 3 in the proportion of women who missed three or more pills shows that the women in this sample became less careful about their pill-taking behavior over time. This change may reflect women's learning to make up for occasional missed pills and setting a personalized schedule of use that they consider "effective enough." Or it could signal "fatigue" in conscientious use. Some studies have found that visits to the doctor or clinic serve as a memory jog, increasing correct pill-taking near times of visits.[19] A third hypothesis is that each time an oral contraceptive user makes an error in pill-taking but does not become pregnant, her sense that she can "get away" with irregular use increases.[20]

In our study, participants returned to the clinic each month for a supply visit, yet their daily pill-taking compliance, as well as the extent of agreement between diary and electronic data, deteriorated over the three cycles. Thus, it seems that a follow-up appointment does not necessarily act as a memory jog; if it did, compliance would decline even more over time in routine clinical care, when monthly return visits are not required. Rather, compliance "fatigue" may be due to the characteristics of women who continued in the study, as compared with the characteristics of those who dropped out. While one might expect study dropouts to be the ones with the most difficulty in following directions for use, data on pill-taking from Colombia and on continuation among North Carolina women using an injectable contraceptive revealed that compliance was no worse among women discontinuing the method than among ongoing users.[21]

It is difficult to speculate about the precise reasons for the downward trend in daily pill-taking; boredom, overconfidence and self-selection, among other factors, all may play a role. Clearly, this issue should be studied in order to determine how women's attitudes change over time. In addition, longer studies are needed to determine if compliance plateaus, continues to worsen or improves over extended periods of time.

Our analysis addresses the total number of pills missed in a cycle and the number of episodes in which pills are missed on two or more consecutive days, which would increase the risk of pregnancy unless a backup method of contraception was used. It does not, however, consider how the timing of pill-taking or repeated brief episodes of missed pills affect the risk of pregnancy. Analysis is under way to identify the timing of missed pills and related events, such as the use of a backup method. Only with this information can we understand the magnitude of the effect of various patterns of irregular pill-taking, as well as the number of missed pills, on the risk of pregnancy.

More research is needed, with larger samples and over longer periods of time, to determine whether the findings of this small exploratory study can be replicated and whether the pill-taking patterns found here change with long-term use. Unfortunately, the electronic device used for this study was experimental and is no longer being manufactured. Until suitable electronic monitors become available, we recommend that research efforts be devoted to other measures that can provide an important quality of the electronic device: recording that is not triggered by pill-taking. Telephone diaries, time-stamped computerized diaries, two-way beepers and similar measurement techniques have been suggested.[22] These techniques should encourage contemporaneous recording of the event of interest; in any case, the time and date of recording could be included in data analysis.

Study designs requiring interviews at one- or two-week intervals and including carefully constructed self-report measures on specific use behavior may also provide more adequate data about the quality of pill-taking and about how much compliance is "enough."[23]

A woman's success in avoiding unintended pregnancy depends on her fecundity, her frequency and timing of intercourse, the contraceptive method she uses and the quality of her use of that method.[24] Accurate measurement of the quality of use is critical to progress toward understanding the impact that use behavior has on implementing a woman's intention to avoid pregnancy once she has chosen her contraceptive method.

References

1. R. A. Hatcher et al., *Contraceptive Technology,* 16th rev. ed., Irvington Publishers, New York, 1994.

2. S. J. Emans et al., "Adolescents' Compliance with the Use of Oral Contraceptives," *Journal of the American Medical Association,* **257:**3377–3381, 1987; and M. Polaneczky et al., "The Use of Levonorgestrel Implants (Norplant) for Contraception in Adolescent Mothers," *New England Journal of Medicine,* **331:**1201–1206, 1994.

3. R. A. Hatcher et al., 1994, op. cit. (see reference 1); and G. T. Kovacs et al., "Inadvertent Pregnancies in Oral Contraceptive Users," *Medical Journal of Australia,* **150:**549–551, 1989.

4. J. Guillebaud, "The Forgotten Pill—and the Paramount Importance of the Pill-Free Week," *British Journal of Family Planning,* **12:**35–43, 1987; S. R. Killick et al., "Extending the Duration of the Pill-Free Interval During Combined Oral Contraception," *Advances in Contraception,* **6:**33–40, 1990; B. M. Landgren and E. Diczfalusy, "Hormonal Consequences of Missing the Pill During the First Two Days of Three Consecutive Artificial Cycles," *Contraception,* **29:**437–445, 1984; G. S. Letterie and G. E. Chow, "Effect of 'Missed' Pills on Oral Contraceptive Effectiveness," *Obstetrics and Gynecology,* **79:**979–982, 1992; and B. G. Molloy, "'Missed Pill' Conception: Fact or Fiction?" *British Medical Journal,* **290:**1474–1475, 1985.

5. L. Potter, "Oral Contraceptive Compliance and Its Role in the Effectiveness of the Method," in J. A. Cramer and B. Spilker, eds., *Patient Compliance in Medical Practice and Clinical Trials,* Raven Press, New York, 1991, pp. 195–207.

6. M. B. DuBard et al., "Are Pill Counts Valid Measures of Compliance in Clinical Obstetric Trials?" *American Journal of Obstetrics and Gynecology,* **69:**1181–1189, 1993; L. A. Gonder-Frederick et al., "Self-Measurement of Blood Glucose: Accuracy of Self-Reported Data and Adherence to Recommended Regimen," *Diabetes Care,* **11:**579–585, 1988; D. Guerrero et al., "Antihypertensive Medication-Taking: Investigation of a Simple Regimen," *American Journal of Hypertension,* **6:**586–592, 1993; T. Pullar et al., "Time to Stop Counting the Tablets?" *Clinical Pharmacology and Therapeutics,* **46:**163–168, 1989; P. Rudd et al., "Gaps in Cardiovascular Medication Taking: The Tip of the Iceberg," *Journal of General Internal Medicine,* **8:**659–666, 1993; and D. M. Waterhouse et al., "Adherence to Oral Tamoxifen: A Comparison of Patient Self-Report, Pill Counts and Mi-

croelectronic Monitoring," *Journal of Clinical Oncology,* **11:**1189–1197, 1993.

7. S. W. Fletcher, E. M. Pappius and S. J. Harper, "Measurement of Medication Compliance in a Clinical Setting," *Archives of Internal Medicine,* **139:**635–638, 1979; and T. Pullar et al., 1989, op. cit. (see reference 6).

8. S. E. Norell, "Methods in Assessing Drug Compliance," *Acta Medica Scandinavica,* **683(Supplement):**35–40, 1984; B. Spilker, "Methods of Assessing and Improving Patient Compliance in Clinical Trials," in J. A. Cramer and B. Spilker, 1991, op. cit. (see reference 5), pp. 37–56; and T. Pullar and M. Feely, "Problems with Compliance with Drug Treatment: New Solutions," *Pharmacy Journal,* **245:**213–215, 1990.

9. M. B. DuBard et al., 1993, op. cit. (see reference 6); B. Spilker, 1991, op. cit. (see reference 8); and A. R. Feinstein, "On White Coat Effects and the Electronic Monitoring of Compliance," *Archives of Internal Medicine,* **150:-**1377–1378, 1990.

10. J. A. Cramer, R. D. Scheyer and R. H. Mattson, "Compliance Declines Between Clinic Visits," *Archives of Internal Medicine,* **150:**1509–1510, 1990; and A. R. Feinstein, 1990, op. cit. (see reference 9).

11. J. A. Cramer, "Overview of Methods to Measure and Enhance Patient Compliance," in J. A. Cramer and B. Spilker, 1991, op. cit. (see reference 5), pp. 3–10.

12. J. Urquhart, "Correlates of Variable Patient Compliance in Drug Trials: Relevance in the New Health Care Environment," *Advances in Drug Research,* **26:**237–257, 1995.

13. M. Averbuch, M. Weintraub and D. J. Pollock, "Compliance Assessment in Clinical Trials: The MEMS Device," *Journal of Clinical Research and Pharmacoepidemiology,* **4:**199–204, 1990; and P. Rudd et al., "Improved Compliance Measures: Applications in an Ambulatory Hypertensive Drug Trial," *Clinical Pharmacology and Therapeutics,* **48:**676–685, 1990.

14. M. Averbuch, M. Weintraub and D. J. Pollock, 1990, op. cit. (see reference 13); A. R. Feinstein, 1990, op. cit. (see reference 9); D. Guerrero et al., 1993, op. cit. (see reference 6); T. Pullar and M. Feely, 1990, op. cit. (see reference 8).

15. P. Rudd et al., 1990, op. cit. (see reference 13).

16. J. A. Cramer et al., "How Often Is Medication Taken as Prescribed?" *Journal of the American Medical Association,* **261:**3273–3266, 1989; J. A. Cramer, R. D. Scheyer and R. H. Mattson, 1990, op. cit. (see reference 10); and J. A. Paladino et al., "Clinical and Economic Evaluation of Oral Ciprofloxacin After an Abbreviated Course of Intravenous Antibiotics," *American Journal of Medicine,* **91:**462–470, 1991.

17. E. Wong, S. Moeng and A. Johnson, "Do Self-Reports of Oral Contraceptive Compliance Agree with Electronic Reports? Tables and Statistical Report," Biostatistics and Information Technology Office, Family Health International, Research Triangle Park, N. C., 1995.

18. I. S. Fraser and R. P. S. Jansen, "Why Do Inadvertent Pregnancies Occur in Oral Contraceptive Users? Effectiveness of Oral Contraceptive Regimens and Interfering Factors," *Contraception,* **27:**531–551, 1983; R. A. Hatcher et al., 1994 (see reference 1); and L. Potter et al., "Oral Contraceptive Compliance in Rural Colombia: Knowledge of Users and Providers," *International Family Planning Perspectives,* **14:**27–31, 1988.

19. J. A. Cramer and R. H. Mattson, "Monitoring Compliance with Antiepileptic Drug Therapy," in J. A. Cramer and B. Spilker, 1991, op. cit. (see reference 5), pp. 123–137; and A. R. Feinstein, 1990, op. cit. (see reference 9).

20. S. F. Loza, H. A. A. Sayed and L. Potter, "Oral Contraceptive Compliance and Continuation in Egypt: Complementary Findings of DHS and Focus Group Research," paper presented at the annual meeting of the Population Association of America, Washington, D. C., Mar. 20–24, 1991.

21. L. Potter et al., 1988, op. cit. (see reference 18); and D. B. Dalberth et al., "The First Year of Depo: Who Accepted It and Did They Continue?" Family Health International, Research Triangle Park, N. C., 1996.

22. D. Oakley, "Promising Interventions: The Electronic Monitoring Device," paper presented at the Henry J. Kaiser Family Foundation/National Institute of Child Health and Human Development Forum on Improving Contraceptive Use in the U. S.: Assessing Past Efforts and Setting New Directions, Bethesda, Md., Oct. 6, 1995; and T. Pullar and M. Feely, 1990, op. cit. (see reference 8).

23. D. Oakley, S. Sereika and E.-L. Bogue, "Oral Contraceptive Pill Use After an Initial Family Planning Clinic Visit," *Family Planning Perspectives,* **23:**150–154, 1991; and L. Potter et al., 1988 (see reference 18).

24. D. Oakley, "Rethinking Patient Counseling Techniques for Changing Contraceptive Use-Behavior," *American Journal of Obstetrics and Gynecology,* **170:**1585–1590, 1994; and J. Urquhart, 1995, op. cit. (see reference 12).