

Application of simple fertility awareness-based methods of family planning to breastfeeding women

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Objective: To determine the potential efficacy of two simple fertility awareness-based methods of family planning—the Standard Days Method™ and the TwoDay Method™—among breastfeeding women.

Design: Analysis of pre-existing data set, collected in 1986–1990.

Setting: Pre-existing data from Australia, Britain, and Canada.

Patient(s): Seventy-three breastfeeding women in Australia, Britain, and Canada, who were followed starting 42 days postpartum, until they had at least two potentially fertile cycles (defined as cycles with adequate levels of urinary estrogens (E) and pregnanediol glucuronide and a long enough luteal phase to support a pregnancy). We examine this existing data set.

Intervention(s): None.

Main Outcome Measure(s): Probability of pregnancy from intercourse on different days of the cycle relative to ovulation for breastfeeding women following the instructions of the Standard Days Method or the TwoDay Method.

Result(s): These two methods may be appropriate for different groups of breastfeeding women at different times. The Standard Days Method may be appropriate after cycle regularity is established, whereas the TwoDay Method may be a more effective option earlier in the postpartum period.

Conclusion: A need remains for a more appropriate simple fertility awareness-based method during this early period. (Fertil Steril® 2003;80:1241–8. ©2003 by American Society for Reproductive Medicine.)

Key Words: Standard Days Method, TwoDay Method, contraceptive efficacy, fertility awareness, breastfeeding

The potential efficacy of two simple fertility awareness-based methods of family planning—the Standard Days Method™ and the TwoDay Method™—for breastfeeding women were examined. Both methods offer simple but effective guidelines to help women identify their “fertile window”—the days each cycle when they should avoid unprotected intercourse to prevent pregnancy.

Worldwide, significant numbers of women breastfeed their children (1). Many of these women are particularly vulnerable to pregnancy because they often believe that breastfeeding protects them from pregnancy. For the health of the mother and the infant, it is important that she not become pregnant again for at least 2.5–3 years, and recent research suggests that the ideal birth spacing interval is 3–5 years (2). This is particularly important if she is

breastfeeding (3). Fertility awareness-based methods of family planning may be especially useful for breastfeeding women, because they do not affect the nutritional quality or quantity of milk, and do not involve transmission of exogenous hormones to the infant.

The Standard Days Method, based on a fixed formula defining the fertile window as days 8–19 of the menstrual cycle, was shown in a clinical trial to have a failure rate of <5% when used correctly by women who were screened for potential cycle regularity (4). The TwoDay Method involves noticing the presence and absence of cervical secretions. Its theoretical efficacy for non-breastfeeding women has been established (5, 6), and a clinical efficacy trial is ongoing. The use of these methods among breastfeeding women has not yet been tested. Breastfeeding affects factors

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that are central to some fertility-awareness-based methods, including cervical secretions and cycle length and regularity.

The current study is designed to assess the potential efficacy of the Standard Days Method and the TwoDay Method if used by breastfeeding women. The methods are described fully in the Appendix.

Why Focus on Breastfeeding Women?

Breastfeeding alters the normal pattern of hormonal events in the hypothalamus-hypophysis-ovary axis, resulting in suppressed ovarian activity and reduced fertility. There is much evidence that the frequency and duration of breastfeeding episodes are important in suppressing ovulation and lowering the probability of conception (7, 8). Even when ovulation returns, hormonal function often remains disrupted, resulting in continuing reduced probability of fertilization and implantation (9). Yet, fertility eventually returns, and the probability that lactating women will become pregnant if they have unprotected intercourse increases with time. A significant number of women worldwide breastfeed their children (1), and many become pregnant when their babies are still very young, endangering the health and lives of themselves and their children.

Efforts to determine the timing of the postpartum return to fertility and factors influencing it have led to the development of the Lactational Amenorrhea Method of family planning (LAM). LAM is based on three criteria. For a woman to be eligible to use LAM, she should be less than 6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (10). When women are more than 6 months postpartum, when their menstruation returns, or when they are no longer fully breastfeeding, LAM is no longer considered as effective, and they should use another family planning method if they wish to avoid pregnancy (11).

A fertility awareness-based method of family planning is one possible choice for women who continue to breastfeed and seek an alternative family planning method that does not affect milk quality or quantity after they no longer meet the LAM criteria. Established fertility awareness-based methods, such as the Billings Ovulation Method and the Symptothermal Method, are applicable, with some modifications, to breastfeeding women (12, 13).

Various studies examined their efficacy, concluding that these methods can be effective in preventing pregnancy in lactating mothers (14). However, the first cycles postpartum present additional difficulties for breastfeeding users, because the normal mucus and temperature patterns may not yet be established even after potentially fertile ovulatory cycles have resumed (15). Users need to learn to recognize the symptoms of changed/increased fertility, and distinguish between them and the usual symptoms of ovulation. This increases the complexity of the methods and can be particularly difficult for women who are new to these methods. Special attention is needed during the interface between

breastfeeding and fertility awareness-based methods, above and beyond the usual requirements of these methods (15, 16).

Clearly, breastfeeding women could benefit from a simple fertility awareness-based method of family planning, provided that the method is effective in helping them avoid unplanned pregnancies while they continue to breastfeed. The purpose of this secondary analysis is to assess the theoretical effectiveness of such methods for breastfeeding women, including those who no longer meet the LAM criteria.

MATERIALS AND METHODS

The original data were collected by Family Health International (FHI) from 1986–1990 in a study of the Symptothermal Method, and are reanalyzed here. Data are available on 73 breastfeeding women in Australia, Britain, and Canada. The mean age of study participants was 29 years, and their average number of live births, 2.3. Education levels were slightly higher in Canada and more of the Canadian women had professional occupations and worked outside the home, but these differences across the centers were not statistically significant (14).

Study participants contributed daily information starting 42 days postpartum, and until they had at least two “normal” cycles (defined as cycles with adequate urinary levels of estrogens (E), pregnanediol glucuronide, and a luteal phase long enough to support a pregnancy) (14). Daily information is available on breastfeeding patterns, appearance and characteristics of cervical secretions, and cycle characteristics such as timing of ovulation, bleeding, and cycle length.

Ovulation was defined as day of maximum urinary E, measured by spectrofluorometry. A cycle was said to have adequate luteinization to support a pregnancy if >9.0 $\mu\text{moles}/24$ hours of pregnanediol were measured and there was a luteal phase, as measured from the E peak to the day before the next menstruation, of at least 10 days. The cycle was considered to have an inadequate luteal phase to support a pregnancy if there were pregnanediol concentrations of between 4.5 and 8.9 $\mu\text{moles}/24$ hours or if the luteal phase was fewer than 10 days. Follicular activity with corresponding pregnanediol concentration of fewer than 4.5 $\mu\text{moles}/24$ hours was considered to be anovulatory (14). This definition of ovulatory cycles was standard when these data were collected (1986–1990) (17, 18). We recognize that other markers of ovulation, such as serum or urinary LH concentration and urinary steroids concentration related to creatinine are the standard today. The literature suggests a high correlation between these markers (19). The definition we use for an adequate luteal phase is widely used (20).

In this assessment we consider a woman to be protected by a method on days when she would avoid unprotected intercourse if she followed the method instructions. Thus, by

definition, a woman is protected by the Standard Days Method on days 8–19 of her menstrual cycle. A woman is protected by the TwoDay Method on any day in which she notices cervical secretions (of any type) on that day or noticed them the day before.

Wilcox et al. (21) identified the probability that unprotected intercourse on specific days (relative to the day of ovulation) resulted in pregnancy (clinically detected at 6 weeks from the first day of last menstrual period). Because of the viability of sperm, intercourse 6 or more days before ovulation rarely results in pregnancy. However, the probability of clinically detected pregnancy increases progressively, from about 4% if intercourse occurs 5 days before ovulation, to 29% 2 days, and 27% 1 day before ovulation, declining to 8% if intercourse occurs on the day of ovulation and zero thereafter. Unprotected intercourse one or more days after ovulation can rarely result in pregnancy.

The FHI data identify the presumptive day of ovulation during each cycle, detected by daily measurement of total E and pregnanediol glucuronide urinary concentrations. Thus, by applying the Wilcox et al. (21) findings, we could determine probability of pregnancy from intercourse on each cycle day in the data. To do so, we applied the methods' rules to the cycles in the data set to identify the days each cycle in which women would avoid unprotected intercourse if they followed the rules of the Standard Days Method or the TwoDay Method.

To calculate the theoretical efficacy of the Standard Days Method, we assume that on days 8–19 of the cycle the probability of pregnancy is zero, regardless of the proximity of these days to ovulation, because the woman follows the methods' rules. (To follow the method rules the woman may have no intercourse, or she may use a barrier method, on the days the methods identify as fertile. In our analysis we assume no intercourse. We recognize that our results may show somewhat higher pregnancy rates if the woman had intercourse on these days but used a barrier method, depending on the effectiveness of the method she uses. In cycle days other than days 8–19, the probability of pregnancy is the one suggested by Wilcox et al. (21) for each day relative to ovulation.

We repeated this analysis for subsets of cycles. First we explored the theoretical probability of pregnancy for women using the method by frequency of breastfeeding. To do this we calculated the mean number of breastfeeding episodes per day (24 hours from morning to the next morning) across each cycle, and compared cycles with mean low frequency to cycles with a mean high frequency of breastfeeding episodes. We chose six breastfeeding episodes in a 24-hour period as the cutoff point because this allowed us to compare two groups of women of approximately the same size.

Next, we explored changes in the probability of pregnancy over time. We compared the probabilities for the first

cycle postpartum (cycle beginning with the first postpartum menstruation) to those of the second and third cycles (numbers were too small to analyze these separately), and those of fourth and higher postpartum cycles. Finally, because previous studies have shown that the Standard Days Method is most appropriate for women with cycles that regularly range between 26 and 32 days (4, 22), we calculated probabilities of pregnancy for women using the Standard Days Method, but analyzing only cycles that fall within this range.

We calculated the theoretical efficacy of the TwoDay Method similarly: if the woman notices secretions of any type on any day or the day before, her probability of pregnancy on that day is set to zero, assuming that she follows the method rules. On all other cycle days the probability of pregnancy is the one suggested by Wilcox et al. (21) for each day relative to ovulation. Again, we calculated the probabilities for subsets of cycles—low and high frequency of breastfeeding episodes. We also compared the probabilities for the first postpartum cycle to those of the second and third cycles, and those of fourth and higher postpartum cycles.

Note that our results of the theoretical effectiveness of the TwoDay Method are conservative, because we treat days as fertile when they are near ovulation, even if there are no cervical secretions. The likelihood of pregnancy from intercourse on days where there are no cervical secretions is greatly reduced (6, 23), but this is not accounted for in our model as we cannot quantify the difference.

Not all cycles are ovulatory. Anovulatory cycles have a zero probability of pregnancy from unprotected intercourse on all days. Similarly, ovulatory cycles with a luteal phase that is too short to allow for implantation also have a zero probability of pregnancy from unprotected intercourse on all days. In our analysis we set the probability of pregnancy in these cycles to zero in all days of the cycle, because a woman cannot become pregnant from intercourse in anovulatory cycles.

Study participants contributed up to 13 cycles (with a mean 4 cycles). This resulted in information on 359 cycles. Because some women did not have two "normal" cycles until after they weaned their babies, women were breastfeeding in only 274 of these cycles. We include in our analysis only cycles in which the woman was fully or partially breastfeeding (for definitions of breastfeeding levels, see Labbok and Krasovec (24)).

We define cycle zero as the time before the first postpartum menstruation. (We use the term menstruation to refer to vaginal bleeding lasting several days [although in gynecology, menstruation is sometimes restricted to mean such bleeding if it is preceded by ovulation]). Previous studies on fertility while breastfeeding show that many, but not all, of cycle zero are either anovulatory or cannot sustain a pregnancy. Campbell and Gray (9), for example, followed 60 breastfeeding women in the United States, and discovered

TABLE 1

Characteristics of cycles.

Cycle number ^a	Mean number of days	Range of cycle length (days)	Ovulatory	Normal ^b	Total
0	215.9	65–469	67.1%	32.9%	73
1	34.6	15–115	90.2%	57.4%	61
2	30.4	14–45	89.1%	63.0%	46
3	31.2	21–58	87.9%	69.7%	33
4	30.9	22–59	90.9%	81.8%	22
5+	28.6	22–35	97.6%	69.0%	42

^a Cycle 0 is the cycle before the first postpartum menstruation.

^b A normal cycle is an ovulatory cycle with adequate urinary E, pregnanediol glucuronide, and luteal phase of sufficient length that the cycle is considered adequate to support a pregnancy.

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that two-thirds of women ovulated before their first menstruation, but 47% of those cycles had decreased luteal phase pregnanediol excretion. Thus, about one-third of breastfeeding women can theoretically conceive from unprotected intercourse on cycle zero. If they rely on resumption of bleeding as the first sign of the return of fertility, they have no warning of it.

Because cycle days are numbered starting at the first day of menses, the Standard Days Method, by definition, cannot be used before the return of menses after postpartum amenorrhea. However we examine the applicability of the Two-Day method to breastfeeding cycle in cycle zero as well as subsequent cycles.

RESULTS

Women in the study had their first menstrual bleed between days 65 and 469 postpartum (mean day 216, approximately 7 months). Seven women (10%) were still in their cycle zero on their babies' first birthday. Some 67% of cycle zeros in the study were ovulatory, which means that ovulation resumed before any bleeding. But only 49% of ovulatory cycles could sustain a pregnancy (as determined by hormonal levels and length of luteal phase).

Examining the frequency of breastfeeding during the last 30 days of cycle zero confirms the known relationship between intensity of breastfeeding and return to fertility—reduced level of breastfeeding promotes the return of ovulation. Of the 24 women who had an ovulatory cycle zero that could sustain a pregnancy, 75% breastfed a mean of less than five times a day, and all but one woman breastfed a mean of less than eight times a day.

Table 1 shows the characteristics of cycles in the study after the first postpartum menses. Not surprisingly, with increasing number of cycles postpartum, the mean cycle length is progressively closer to the population mean of 29. After five or more menstrual bleeds postpartum, virtually all cycles are ovulatory and most of these cycles have adequate

hormonal levels and a long enough luteal phase to sustain a pregnancy.

The Theoretical Efficacy of the Standard Days Method in Breastfeeding Women

Use of the Standard Days Method is based on counting cycle days, beginning with “day 1”—the first day of menstrual bleeding. Therefore, the Standard Days Method, by definition, cannot be applied to cycle zero.

Table 2 shows the theoretical probability of pregnancy from intercourse on different days relative to ovulation, for breastfeeding women following the Standard Days Method rules—avoiding intercourse on days 8–19 of their menstrual cycle. Results suggest that the method is most effective for cycles ranging between 26 and 32 days for breastfeeding women, and cycle length is more significant in predicting method efficacy than daily number of breastfeeding episodes. When we compared the probabilities of pregnancy in the first cycle to those of the second and third cycles and those of fourth and higher postpartum cycles, we see that the method is clearly more effective in the later cycles.

Comparing this application of the Standard Days Method to breastfeeding women to the results of a similar exercise with nonlactating women (22) suggests that the Standard Days Method is not as effective for breastfeeding women as it is for nonbreastfeeding women. In a theoretical analysis of a data set on nonbreastfeeding women, the highest theoretical probability of pregnancy for nonbreastfeeding users of the method of all cycle lengths, on any given day, was only about 0.0108. As our estimates show (Table 2) this probability is higher for breastfeeding women (0.0529). These results are consistent regardless of frequency of breastfeeding (note that daily probability of pregnancy from intercourse on different days is not additive across days).

However, as Table 2 shows, the method is theoretically quite effective for breastfeeding women with cycles that range 26–32 days in length. The highest theoretical probability of conception on any given day for breastfeeding

TABLE 2

Estimated probabilities of pregnancy from intercourse on different days relative to ovulation, for breastfeeding women using the Standard Days Method.

Cycle day ^a	All cycles n = 204	Mean no. breastfeeds in 24-hour period		Cycle no.			Cycles with length of 26–32 days		
		<6 n = 125	6+ n = 79	Cycle 1 n = 61	Cycles 2 and 3 n = 79	Cycles 4+ n = 64	All n = 111	Cycles 1–3 n = 69	Cycles 4+ n = 42
Ov-5	0.0045	0.0045	0.0046	0.0092	0.0015	0.0038	0.0000	0.0000	0.0000
Ov-4	0.0152	0.0134	0.0182	0.0256	0.0107	0.0113	0.0000	0.0000	0.0000
Ov-3	0.0110	0.0109	0.0111	0.0170	0.0102	0.0062	0.0000	0.0000	0.0000
Ov-2	0.0470	0.0441	0.0513	0.0667	0.0441	0.0316	0.0078	0.0084	0.0070
Ov-1	0.0529	0.0497	0.0581	0.0753	0.0513	0.0338	0.0170	0.0194	0.0130
Ovulation	0.0204	0.0224	0.0172	0.0302	0.0202	0.0111	0.0115	0.0150	0.0057

Note: We assume no intercourse on the days the method considers fertile. Pregnancy was detected clinically 6 weeks after last menstrual period.

^a Ov denotes ovulation.

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women with cycles in this range following the Standard Days Method instructions is only 0.017 (compared to 0.007 for nonbreastfeeding women with cycles in this range). After women have had four or more menstrual periods this probability is only 0.013.

These results suggest that breastfeeding introduces more variability in the day of ovulation, therefore increasing the variability of the fertile window, even if cycle length is within the 26- to 32-day range. This is confirmed when we examine the mean day of ovulation. In the first cycle postpartum, the mean day of ovulation for breastfeeding women (regardless of cycle length) is 22.4 (SD 7.743), in the second cycle the mean is 19.1 (SD 3.288), and in the third cycle it is 18.4 (SD 3.577). For cycles ranging 26–32 days (in cycles 1–3) the mean ovulation day is 17.8 (SD 2.192).

Yet the Standard Days Method can be an effective family planning method for breastfeeding women, after they have had four or more menstruations postpartum. Waiting for the fourth cycle would have two advantages. First, as we have shown, the theoretical effectiveness of the method increases with time postpartum. Second, because women cannot predict their cycle length in advance, these first three cycles would allow the woman to monitor the lengths of her cycles and establish the fact that they generally fall within the 26- to 32-day range (the method would still be effective if the woman had an occasional cycle out of range).

We calculated that 20 women in the study (27%) had cycle lengths ranging 26–32 days in their second and third cycle postpartum, therefore the Standard Days Method would be very effective for them beginning in cycle four. The fact that 73% of breastfeeding women would not be able to use the Standard Days Method this early in the postpartum period is an important limitation of the application of this method to breastfeeding women.

The Theoretical Effectiveness of the TwoDay Method in Breastfeeding Women

The TwoDay Method can theoretically be used by women in cycle zero because if they ovulate they should notice secretions. However, although some women experience no cervical secretions in cycle zero unless they ovulate, others notice secretions for many consecutive days even if they are not fertile at the time. Billings and Westmore (12) call this phenomenon “basic infertile pattern.”

In our data women experienced on cycle zero a mean of 77 days with secretions (median 32 days, range 0–362 days, and highly correlated with the length of cycle zero). Half of the 42 women whose cycle zero was longer than 6 months (so that after month 6 they were no longer eligible to use LAM) experienced extensive mucus patches, so that they noticed secretions in 80% or more of days in the later part of their cycle zero. Although they may have been fertile for some of these days, we assume they were not fertile in all of them. We conclude, therefore, that the TwoDay Method may not be acceptable to use in cycle zero, because for many women it would require a period of avoiding unprotected intercourse that may be too long to be acceptable.

Table 3 shows the theoretical probability of pregnancy from intercourse on different days relative to ovulation in cycles after the first menses postpartum, for breastfeeding women following the TwoDay Method instructions—avoiding intercourse on each day in which they noticed cervical secretions on that day or the day before.

As Table 3 indicates, the TwoDay Method may be a very effective option for breastfeeding women, regardless of daily number of breastfeeding episodes and in which cycle postpartum they are. It is interesting to note that the probabilities of pregnancy are higher for women who breastfeed more. This may be explained by the fact that increased breastfeed-

TABLE 3

Estimated probabilities of pregnancy from intercourse on different days relative to ovulation, for women using the TwoDay method.

Cycle day ^a	All cycles n = 204	Mean no. breastfeeds in 24-hour period		Cycle no.		
		<6 n = 100	6+ n = 104	Cycle 1 n = 61	Cycles 2 and 3 n = 79	Cycles 4+ n = 64
Ov-5	0.0039	0.0035	0.0046	0.0026	0.0046	0.0044
Ov-4	0.0089	0.0067	0.0121	0.0040	0.0091	0.0131
Ov-3	0.0027	0.0026	0.0030	0.0026	0.0010	0.0050
Ov-2	0.0073	0.0070	0.0073	0.0142	0.0038	0.0046
Ov-1	0.0078	0.0065	0.0103	0.0089	0.0068	0.0084
Ovulation	0.0023	0.0019	0.0030	0.0026	0.0020	0.0025

Note: We assume no intercourse on the days the method considers fertile. Pregnancy was detected clinically 6 weeks after last menstrual period.

^a Ov denotes ovulation.

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ing may induce vaginal dryness, which could potentially make it less likely for women to notice cervical secretions on fertile days. This speculation is confirmed when we looked at the percentage of women who noticed secretions on the day of ovulation and the day before, by frequency of breastfeeding. Almost 97% of women who had less than six breastfeeding episodes in a 24-hour period noticed secretions on the day of ovulation and the day before, compared to only 93% of women who breastfed six or more times and 91% of women who breastfed eight or more times.

It appears, then, that the TwoDay Method also could be an effective family planning method for breastfeeding women. The highest probability of pregnancy on any given day relative to ovulation for a breastfeeding woman using the TwoDay Method is only 0.009.

The average actual daily probability of pregnancy for TwoDay method users would be lower, because a woman who is not protected by following the method instructions on a given day (and therefore considered fertile in our analysis) does not have cervical secretions on that day. And unprotected intercourse on days with no noticeable secretions is unlikely to result in pregnancy, even if it occurs in the days just before ovulation (6, 23).

Length of the Identified Fertile Window

Another issue to consider is how long a breastfeeding woman would be required to avoid unprotected intercourse when she uses the Standard Days Method or the TwoDay Method. Breastfeeding women using the Standard Days Method would avoid unprotected intercourse for 12 days each cycle. For breastfeeding women using the TwoDay method the number of days is variable, because the number of days with secretions varies among women and across cycles.

We calculated the mean number of days that breastfeeding users of the TwoDay Method would have to avoid

unprotected intercourse. It ranges from 3–84 days (mean 18.7, median 19). The results are shown in Table 4. When excluding cycles longer than 50 days, the mean period to avoid unprotected intercourse is about 17 days per cycle. For most women it is about a day longer in the first cycle postpartum than it is in subsequent cycles and gets shorter with time postpartum.

When calculating the number of days to avoid unprotected intercourse as a proportion of the total number of days in the cycle, the mean is 52.9%. That is, on average, breastfeeding women using the TwoDay Method (other than on cycle zero), would avoid unprotected intercourse in about half of cycle days. Kennedy et al. (14) analyzed these same data and established that breastfeeding women following the Symptothermal Method would abstain a mean of 79% of the days of each cycle (not including cycle 0). (These data were collected in cycles where women used the Symptothermal Method.)

DISCUSSION

We presented two simple fertility awareness–based methods, and assessed their theoretical efficacy among breastfeeding women using a pre-existing data set. The Standard Days Method requires that women avoid unprotected intercourse on days 8–19 of their menstrual cycle. The TwoDay Method relies on monitoring cervical secretions; users avoid unprotected intercourse on any given day if they notice secretions on that day or the day before. As our results show, both methods appear to be effective for breastfeeding women, although each requires special consideration. Their advantage over the Billings Ovulation Method and the Symptothermal Method is their simplicity—they are simple to teach, learn, and use.

The Standard Days Method requires only 12 days of no unprotected intercourse each cycle. However, it is more

TABLE 4

Mean number of days per cycle that users of the TwoDay method would be required to avoid unprotected intercourse to prevent pregnancy.

	All cycles	Mean no. breastfeeds in 24-hour period		Cycle no.		
		<6	6+	Cycle 1	Cycles 2 and 3	Cycles 4+
All cycles (Standard deviation of mean for all cycles is 9.9)	18.72 (n = 138)	17.87	20.04	21.18	17.29	17.54
Excluding cycles longer than 50 days	17.62 (n = 133)	17.49	17.84	18.07	17.29	17.54

Note: Range for all cycles is 3–84 days. Range excluding cycles longer than 50 days is 3–36 days. Range excluding cycle 1 is 4–31 days.

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effective for women with relatively regular cycles, ranging 26–32 days, and does not seem appropriate during the first postpartum cycles, as women have not yet established cycle regularity. About a quarter of breastfeeding women would be able to begin using this method on their fourth cycle postpartum. Other women would have to wait longer to establish cycle regularity. The TwoDay Method is effective even during the first postpartum cycle, regardless of cycle length and regularity. However, it may require many days without unprotected intercourse and is only useful for couples for whom this is feasible.

Although each of these methods present certain issues for breastfeeding women, they may be appropriate for different groups of women at different times. The Standard Days Method may be useful once cycle regularity is established, whereas the TwoDay Method may be a more effective option earlier in the postpartum period and for women whose cycles are not usually 26–32 days long. Field research is needed to establish actual efficacy of the methods in breastfeeding women and to determine an appropriate counseling approach, while maintaining the simplicity of these methods.

Future research may also include a third method that will better address the need of many breastfeeding women. One possibility is a fixed rule that will require avoiding unprotected intercourse for longer than 12 days, and thus protect women from pregnancy better than the Standard Days Method in the first cycles postpartum, until cycle regularity is established. Another option is a combination of elements from both the Standard Days Method and the TwoDay Method. Analyses are underway to assess the potential of these approaches.

APPENDIX

The Standard Days Method and the TwoDay Method were developed by the Institute for Reproductive Health,

Georgetown University, to meet the needs of many women for simple, accurate instructions to help them identify the days when they should avoid unprotected intercourse to prevent pregnancy.

Both methods offer guidelines for identifying the fertile days of the menstrual cycle in a manner that is easy for providers to teach and for clients to learn and use, making it feasible for a wide range of programs to incorporate these methods into their services. With these methods, reproductive health programs are able to meet the needs of more women who prefer to use a fertility awareness–based method or have contraindications to other methods, as well as women in underserved populations.

The Standard Days Method

The Standard Days Method is based on a fixed formula for defining the fertile window. The method counsels women with menstrual cycles usually ranging 26–32 days to avoid unprotected sexual intercourse on days 8–19 (inclusive) of every menstrual cycle to avoid pregnancy. Unlike calendar approaches to fertility awareness, such as the calendar rhythm method, the Standard Days Method does not require arithmetic calculations.

A multicountry prospective trial of the Standard Days Method designed to establish its efficacy in diverse settings, showed a 1-year failure rate of 4.8 with correct use (pregnancies that occurred in cycles in which participants reported no intercourse on days 8–19). When all cycles and all pregnancies were included in the analysis, the first year pregnancy rate was 12.0, similar to or better than the rates of several other user-dependent methods such as male and female condoms and the diaphragm (4).

About 29% of women in the field trial were breastfeeding when they started using the Standard Days Method. The mean age of their babies was 1.1 (median 1 year). All of

them had re-established cycle regularity (cycles between 26–32 days long), and had menstruated at least four times postpartum. This was a requirement of the study to reduce the likelihood of study participants being subfertile. The number of breastfeeding women who became pregnant in the efficacy trial is too small to allow for statistical significance. However, it is interesting to note that they account for only 21% of pregnancies in the study.

The TwoDay Method

The TwoDay Method is another simple approach to identifying the fertile window. TwoDay Method users monitor the presence or absence of cervical secretions, by sensation or observation, every day.

Unlike other approaches to fertility awareness that rely on monitoring cervical secretions (such as the Billings Ovulation Method and the Symptothermal Method), the TwoDay Method does not require that women distinguish between different types of secretions. They simply note the presence or absence of secretions of any type. They then follow a simple algorithm to determine whether they should consider themselves fertile and avoid unprotected intercourse on any given day. Each day a user asks herself two simple questions: [1] Did I notice secretions today? and [2] Did I notice secretions yesterday? If she answers “Yes” to either of these questions she should consider herself potentially fertile, and avoid unprotected intercourse that day to avoid pregnancy. If she answers “No” to both these questions, she is probably not fertile on that day.

Analysis of the TwoDay Method rules applied to existing data concluded that it is a theoretically very effective method of family planning (5, 6). A multicountry prospective trial of its efficacy is underway. Although some women in this trial are breastfeeding, study guidelines require that they menstruate at least four times postpartum before admission to the study. Again, the purpose of this guideline was to ensure that women in the study were not subfertile due to breastfeeding.

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