New Approaches to Fertility Awareness-Based Methods: Incorporating the Standard Days and TwoDay Methods into Practice

Elaine Germano, CNM, DrPH, and Victoria Jennings, PhD

Helping clients select and use appropriate family planning methods is a basic component of midwifery care. Many women prefer nonhormonal, nondevice methods, and may be interested in methods that involve understanding their natural fertility. Two new fertility awareness—based methods, the Standard Days Method and the TwoDay Method, meet the need for effective, easy-to-provide, easy-to-use approaches. The Standard Days Method is appropriate for women with most menstrual cycles between 26 and 32 days long. Women using this method are taught to avoid unprotected intercourse on potentially fertile days 8 through 19 of their cycles to prevent pregnancy. They use CycleBeads, a color-coded string of beads representing the menstrual cycle, to monitor their cycle days and cycle lengths. The Standard Days Method is more than 95% effective with correct use. The TwoDay Method is based on the presence or absence of cervical secretions to identify fertile days. To use this method, women are taught to note everyday whether they have secretions. If they had secretions on the current day or the previous day, they consider themselves fertile. The TwoDay Method is 96% effective with correct use. Both methods fit well into midwifery practice. J Midwifery Womens Health 2006;51:471–477 © 2006 by the American College of Nurse-Midwives.

keywords: CycleBeads, family planning, fertility awareness, midwifery, Standard Days Method, TwoDay Method

INTRODUCTION

Well-established fertility-based awareness methods, such as the Billings ovulation method and the symptothermal method (and their variants), have been carefully studied to determine their effectiveness in helping couples avoid pregnancy. When used correctly, these methods have a reported efficacy between 95% and 98%.^{1,2} Furthermore, their use poses no potential harm to either the woman³ or, should pregnancy occur, to the developing fetus.⁴ Despite their efficacy and safety, the acceptance and use of these methods is limited. According to the 2002 National Survey of Family Growth,⁵ fewer than 1% of women in the United States currently use them. Reasons for this include the time and effort required to train providers (some training programs involve a few weeks of training, others involve several months); the time required to teach a couple to use these methods (ranging from several hours to several days over a period of 3 to 6 months); and the complexity of using the methods.⁶ In the early 1990s, a survey of 484 randomly selected women in Missouri found that only 2.8% of women were using fertility awareness-based methods to avoid pregnancy, and many women believed the methods to be unreliable (36.6%) and not easy or convenient to use (30%). However, when given information about the methods, 22.5% reported that they would be likely to use such methods in the future.⁷ Another study found no users of fertility awareness-based methods among female clients of

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a family medicine clinic in Utah, although after receiving information about the methods, 22% of the women reported they were likely to use them in the future.⁸

For a variety of reasons, fertility awareness—based methods have been under-represented among the methods offered to women by many family planning providers. Studies have shown that many providers believe these methods to be ineffective and difficult to provide and use.⁶ A study among Missouri physicians found that physicians were more likely to mention these methods if they were aware of qualified instructors in their area, and that only 47% mentioned it as a viable option to selected women.⁹ A survey of CNMs found that although most indicated that they had some preparation to prescribe and educate clients in the use of natural family planning methods, only 22% would mention them as a viable option to all clients, while 63% would offer them to selected clients. 10 A recent study of nurse-midwife and nurse practitioner perceptions of the Standard Days Method, a new fertility awareness-based method, showed a positive response to the prospect of providing this method to their clients.¹¹

The Standard Days Method and the TwoDay Method are two new fertility awareness—based methods developed by researchers at the Georgetown University Institute for Reproductive Health. They are effective, easy for women and couples to use, and easy for health care providers to offer.

THE METHODS

Fertility awareness-based methods are based on the observation of fertile and infertile periods of the menstrual cycle. Figure 1 provides an overview of the menstrual cycle, correlating days of the cycle with the presence of the relevant hormones, and the symptoms

that are observable by women to determine their fertile and infertile days.

The dominant sign of the cycle is the menses. Other symptoms that can assist a woman in monitoring her fertile days are: (1) a change in secretions from the cervix that can be felt or observed at the vaginal opening—typically, these secretions go from being none right after menses to being abundant and wet right before and during ovulation, then disappearing again until after the next menses; (2) a change in basal body temperature that increases around the time of ovulation; and (3) a change in the position and feel of the cervix.

Fertility awareness-based methods usually rely on the identification of more than one of these symptoms; hence the difficulty in their use and in the increased time required for health care providers to effectively teach these methods. The ovulation method, also known as the cervical mucus method or the Billings method, requires that a woman monitor the character of her cervical mucus and the sensation of wetness at her vulva, with a dry vagina or sticky mucus correlated with infertile days and wet or slippery mucus correlated with fertile days. The symptothermal method requires the woman to monitor her cervical secretions, record her basal body temperature daily, and monitor other bodily changes during the cycle, such as breast tenderness, mittelschmerz, increase in libido, and mood changes. In a limited number of settings, commercially available fertility monitoring devices (e.g., Persona and Clearblue [both from Unipath Diagnostics, Inc., Waltham, MA]), are used in conjunction with other symptoms to identify hormonal changes associated with fertility.12 The two methods described below aim to simplify the techniques used by women to identify their fertile days and by providers to teach the methods.

THE STANDARD DAYS METHOD

The Standard Days Method is based on the physiology of the menstrual cycle and the functional life span of the sperm and the ovum. It is appropriate for women whose menstrual cycles are usually between 26 and 32 days long. Approximately 80% of cycles are within this range; however, the percent of women with cycles in this range depends on the characteristics of the population, including age, breastfeeding status, and recent use of hormonal contraception. Couples using the Standard Days Method are advised that the woman should be considered fertile on days 8 through 19 of her cycle. They need not

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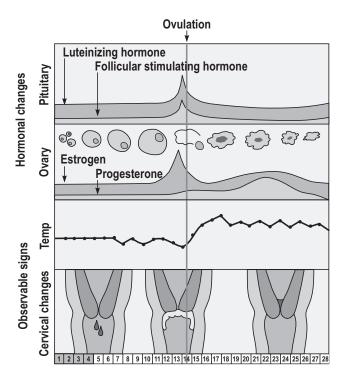


Figure 1. Hormonal, follicular, temperature, secretions, and cervical changes during the menstrual cycle. Created by Elaine Germano.

monitor temperature, cervical secretions, or any other bodily symptoms to use the Standard Days Method.

In developing the Standard Days Method, researchers considered two probabilities: the probability of pregnancy vis-à-vis ovulation, and the probability of the timing of ovulation vis-à-vis the midpoint of the cycle. Hormonal and ultrasound studies have shown that a woman is fertile up to a total of 6 days each cycle; 5 days before ovulation plus the 24 hours after ovulation.¹⁴ There is approximately a 4% probability of pregnancy if intercourse occurs 5 days before ovulation. The probability of pregnancy increases to 15% if intercourse occurs 4 days before ovulation, and increases to between 25% and 28% if intercourse occurs 1 to 2 days before ovulation. After ovulation, there is an 8% to 10% probability of pregnancy if intercourse occurs within 24 hours. Fertility then decreases, and there is no probability of pregnancy by the day after ovulation (Figure 2).

These probabilities are determined by the limited viable life span of the sperm after ejaculation (not more than 5 days) and to the very limited viable life span of the egg following ovulation (less than 24 hours). Together, these result in an actual fertile window of no more than 6 days during the woman's cycle.

In determining when ovulation occurs, and thus when during the cycle the 6-day fertile window occurs, data have shown that in the great majority of cycles, ovulation occurs very close to the middle of the cycle, particularly in cycles between 26 and 32 days long.¹³ In approxi-

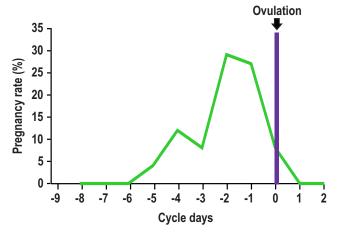


Figure 2. Probability of pregnancy from intercourse on days relative to ovulation. Data from Wilcox et al. 14 and the Institute for Reproductive Health. 22

mately 30% of cycles, ovulation occurs at the midpoint (for example, on or very close to day 14 in a 28-day cycle, or day 15 in a 30-day cycle). In approximately 60% of cycles, ovulation occurs within 1 day before or after midcycle. In approximately 78% of cycles, ovulation occurs within 2 days before or after the midpoint. By 4 days before or after midpoint, 95% of ovulations have occurred (Figure 3). Note that "peak day" refers to the last day of fertile-type cervical secretions and serves as a proxy for ovulation.

Researchers then created a computer model based on the combination of these two probabilities; the probability of pregnancy on different cycle days related to ovulation, and the probability of the timing of ovulation. They applied this model to a large data set provided by the World Health Organization, which included more than 7500 menstrual cycles, and found that for women with menstrual cycles between 26 and 32 days long, pregnancy is likely only on days 8 through 19 of the cycle. On all other days, pregnancy is very unlikely. Therefore, to use the Standard Days Method to prevent pregnancy, couples avoid intercourse from day 8 through day 19 of each cycle. On all the other cycle days, they can have intercourse without concern of pregnancy. 13

The efficacy of the Standard Days Method has been described elsewhere. 12,15 With correct use, the failure rate with the Standard Days Method is 4.8%, based on life table analysis, which means that fewer than five women out of 100 using the method for one year will get pregnant in the first year of use. In the actual study, 43 out of the 478 (9%) became pregnant. Typical use, which includes those months when couples did have unprotected sex on days 8 through 19, resulted in a failure rate of 12 per 100 women. It is important to put this information about efficacy in the context of other user-directed methods. Of 100 women using no method of family planning for one year, 85 will become pregnant.

Of 100 women who use spermicides, a diaphragm, or condoms correctly every time they have sex, ¹⁶ 6, and 2, respectively, will become pregnant during the first year of use. Oral contraceptives, used correctly, are more effective; fewer than one woman out of 100 who use the method correctly for one year will get pregnant. ¹⁶ Thus, the Standard Days Method is as effective or more effective than most other user-directed methods, with correct and typical use (Table 1).

Offering the Standard Days Method to Your Clients

Additional studies of the Standard Days Method have demonstrated that CycleBeads (available from Cycle Technologies, at *www.Cyclebeads.com*) are an essential component of teaching and use of the method.¹⁷

CycleBeads are a color-coded string of beads that help a woman keep track of her cycle days, know which days she can get pregnant (days 8 through 19), and monitor her cycle lengths to be sure they are between 26 and 32 days long. To use CycleBeads, she moves a rubber ring over one bead every day to visibly track where she is in her menstrual cycle. The colors of the beads indicate whether she is on a fertile or infertile day. Couples are counseled to avoid intercourse when the rubber ring is on a white bead, representing a fertile day. Figure 4 describes how to use CycleBeads.

The following list includes additional findings that are helpful to midwives who want to include the Standard Days Method in their services.

(1) It is very important for a woman to be screened before she begins using the Standard Days Method to assess whether her cycles are likely to be between 26 and 32 days long. While it is not necessary for her to know her exact cycle length, her responses to two questions ("Do your periods usually come about a month apart?" and "Do your periods usually come when you expect them?") are sufficient for this assessment.¹⁸

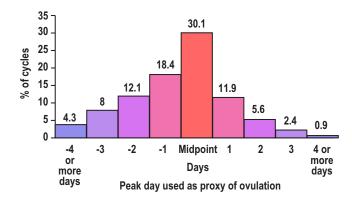


Figure 3. Probability of ovulation relative to midpoint of the cycle. "Peak day" refers to the last day of fertile-type cervical secretions and serves as a proxy for ovulation. Data from the Institute for Reproductive Health²² and Arevalo et al.¹³

Table 1. Contraceptive Failure Rates for User-directed Methods

Women Experiencing an Unintended
Pregnancy Within the First Year
of Use (%)

Method	Correct Use	Typical Use
None	85	85
Spermicides alone	15	29
Diaphragm	6	16
Condom	2	15
Oral contraceptives	0.3	8
Standard Days Method	5	12
TwoDay Method	4	14

Data from the Institute for Hatcher et al. 16 and Reproductive Health. 22

- (2) Women who know when their last period started can begin using the Standard Days Method immediately; those who do not should wait until their next period begins.
- (3) Women who are breastfeeding or have recently used long-acting hormonal contraception require further screening to assess whether their cycle regularity is re-established before determining whether the Standard Days Method is appropriate for them.
- (4) Ongoing monitoring of cycle length is important, as some women have less regular cycles than they initially believe. CycleBeads help women monitor their cycle lengths. The Standard Days Method is not as effective for women with cycles outside the 26 to 32 day range. Therefore, women who have more than one cycle longer than 32 days or shorter than 26 days in a 12-month period should return to their provider to consider another method.
- (5) The Standard Days Method can be used successfully by both low-literacy and high-literacy women. 19,20
- (6) The Standard Days Method is easy for providers to teach and clients to learn; counseling takes 20 to 30 minutes on average.²¹
- (7) Most people who choose the Standard Days Method do so because it is natural and has no side effects. Religion appears to be a very minor factor in choosing this method.¹⁷

The Standard Days Method is now being used in more than 25 countries around the world. Ministries of health, nongovernmental organizations, international private voluntary organizations, and community development groups are including it in their policies, norms, and services. The method is included in international guidance documents, such as the World Health Organization's Medical Eligibility Criteria for Contraceptive Use, the US Agency for International Development's Global Health Technical Briefs, and Contraceptive Technology, 18th edition. Materials for training and service provision, including online training for providers, are available from the Institute for Reproductive Health

at Georgetown University.²² Support materials include screening and follow-up checklists, a reference guide for counseling clients, an informational Standard Days Method video, a counselor training video, a provider training manual, and brochures and pamphlets for clients.

In addition to screening for cycle length, it is important for the midwife to assess whether or not the woman and her partner will be able to use the method effectively. Men must understand and abide by the maxim that they will need to use a barrier method or not have intercourse on days 8 through 19 of each cycle. Questions to assess the woman's current situation with her partner are included in the support materials.

THE TWODAY METHOD

The TwoDay Method addresses the major limitation of the Standard Days Method, which is that only women with regular cycles between 26 and 32 days long can use the method. The TwoDay Method uses cervical secretions as the indicator of fertility. However, unlike other methods that rely on this indicator, it does not involve analyzing the characteristics of the secretions (e.g., amount, color, consistency, slipperiness, stretchability, or viscosity), and the method rules are quite simple. To use the TwoDay Method, women monitor themselves each day to determine whether or not they have any secretions that day. Then they ask themselves two questions: "Did I notice any secretions today?" and "Did I notice any secretions yesterday?"

If she noticed any secretions yesterday and today, she

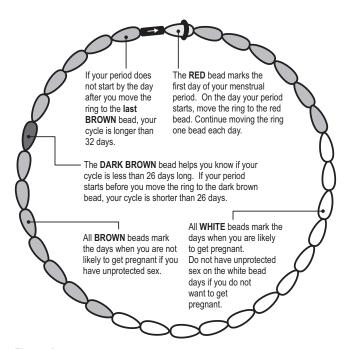


Figure 4. How to use CycleBeads. Band is moved clockwise over the beads. Diagram courtesy of the Institute for Reproductive Health.²²

is potentially fertile today. If she did not notice any secretions either yesterday or today (two consecutive days with no secretions), her probability of becoming pregnant today is very low. Couples using the TwoDay Method should avoid unprotected intercourse on days when the woman is potentially fertile.

As with the Standard Days Method, researchers first determined the theoretical efficacy of the TwoDay Method by applying the algorithm described above to existing data sets, which included detailed information about cervical secretions. Results of this analysis indicated that the theoretical efficacy of the TwoDay Method was at least as high as that of the Standard Days Method.²⁴ Subsequent analyses confirmed these results.²⁵

A prospective, multicenter study tested the efficacy of the TwoDay Method. The method was offered through existing health care programs. The participants included 450 women aged 18 to 39 years, who had at least one previous child, had not used hormonal contraception during the previous 2 months, and were assessed to be at low risk for sexually transmitted diseases and pregnancy complications. In addition, all participants and their partners wanted to delay pregnancy for at least 1 year and were willing to avoid unprotected intercourse on days the TwoDay Method identified as fertile.

After training, providers screened and counseled participants in the TwoDay Method, and collected data about their use of the method and their pregnancy status. Participants were first taught how to monitor their cervical secretions. Providers explained that the secretions might look or feel different on different days of the cycle, and that amounts of secretions vary, but that the woman should consider herself fertile if she noticed secretions of any type, regardless of characteristics or amount. Women were taught to distinguish between cervical secretions and vaginal secretions or semen, and were advised to wait several hours after intercourse to assess the presence or absence of secretions. The TwoDay Method counseling protocol is available from the Institute for Reproductive Health at Georgetown University.²² Women were interviewed every cycle. However, instruction in the TwoDay Method was limited to the initial counseling session and a single follow-up session.

Of the 450 participants who entered the study, more than half completed 13 cycles of method use. Using life table analysis, the first-year pregnancy rate with correct use of the method was 3.5 (95% CI 1.44–5.52). When all cycles and pregnancies were included in the analysis, the pregnancy rate was 13.7 (95% CI 9.93–17.34).

Incorrect method use was reported in approximately 4% of the 3920 cycles in this study. Incorrect use had three potential sources: inaccurate observations of the presence or absence of cervical secretions, inaccurate application of the two-question algorithm, and having unprotected intercourse on a day identified as fertile by

the method rules. Of the 47 pregnancies reported, most occurred during the first few cycles of use and during cycles in which couples had intercourse on days identified by the method as fertile.²⁶

Offering the TwoDay Method to Your Clients

The efficacy study provided important information that can help midwives offer the TwoDay Method to clients. In addition to the finding that women were able to identify the presence or absence of cervical secretions and to apply the two-question algorithm, several additional findings are of interest. First, users of the TwoDay Method gained confidence in their ability to use the method over time. ²⁶ Second, counseling women to note the presence or absence of cervical secretions "after noon" and "just before going to bed at night" is adequate for identifying fertile days, and reduces the potential for confusing semen and cervical secretions.

Based on recommendations from efficacy study participants, materials for providers and users of the Two-Day Method were developed and tested. These materials are available from the Institute for Reproductive Health at Georgetown University.²² The TwoDay Method is included in the World Health Organizations' Medical Eligibility for Contraceptive Use.³ Additional studies are underway to compare the effect of starting to use the TwoDay Method at various times in the menstrual cycle on accurate understanding and correct use.

DISCUSSION

The National Survey of Family Growth has shown that one half of all pregnancies in the United States are unintended, and a significant percentage of women have never received a family planning service.⁵ Every health care visit by a woman of reproductive age is potentially a family planning visit, and all sexually active heterosexual women of childbearing age who are not currently planning a pregnancy should be offered information about pregnancy prevention. If information about contraceptive methods, including fertility awareness-based methods, were provided to such women, the percentage of unintended pregnancies could potentially decrease. Studies in the United States have shown that when women are given information about fertility awarenessbased methods, more than 20% respond that they are likely to use such a method in the future to avoid pregnancy.^{7,8} A study among postpartum women in Poland and Germany found a high interest (60%) in future use of fertility awareness-based methods once these methods were described to them and concluded that there is a potential for an increased use of modern fertility awareness-based methods by women in developed countries.²⁷ However, studies have shown that both physicians and nurse-midwives believe that effectiveness rates of fertility awareness-based methods are less than

those reported in the literature, ^{9,10} and that this belief correlates with the infrequency of offering these methods to clients as viable contraceptive options. ⁹

The Standard Days Method and TwoDay Method are fertility awareness-based methods of family planning that are easy to use, easy to teach, effective, and may fill a gap in needed services for the many women who currently are not protecting themselves from unwanted pregnancy. These are methods that teach women about their bodies and empower them to work with their male partners to avoid unwanted pregnancies. Providing these methods to women who can and want to use them fits well with the midwifery philosophy of care and can easily be added to the services offered to midwifery clients. Learning how to provide the Standard Days Method to clients can be accomplished through the online training program at the Institute for Reproductive Health Web site (www.irh.org). Detailed information about special considerations, such as those for postpartum women, women who have recently used hormonal contraceptives, and perimenopausal women, as well as standard protocols for screening and counseling, are described in the training program. Online training in the TwoDay Method will be available soon.

Most research has focused on the use of these methods with nonbreastfeeding women. Breastfeeding affects cycle regularity and length as well as other fertility signs, including cervical secretions. A modified form of the Standard Days Method among women who are still in amenorrhea and those in their early postpartum cycles is being investigated. At this time, however, use of the Standard Days Method by postpartum women should be postponed until they have had 4 menstrual periods, with the most recent cycle between 26 and 32 days long. The TwoDay Method can be used by postpartum women. However, these women frequently have cervical secretions that are not indicative of actual fertility. This may lead to unnecessarily prolonged periods during which women would need to avoid unprotected intercourse. Until further evidence-based guidance is available, women in these circumstances who want to use the Standard Days Method or TwoDay Method should be encouraged to use another nonhormonal method until they return to a normal cycle pattern.²⁸

Nurse-midwifery is known for its holistic approach to the care of pregnant women, especially at the time of labor and birth. Yet 90% of visits to certified nurse-midwives/certified midwives (CNMs/CMs) are for primary, preventive care. This care includes gynecologic care, annual exams, and reproductive health visits, including prenatal care.²⁹ The midwifery model of care embraces a philosophy that governs the provision of care in all settings and for all types of health care services to women. This philosophy includes the belief that all women have the right to complete and accurate information about their bodies and the health care they receive;

the right to make choices and decisions about their care; and the right to care that respects human dignity, individuality, and diversity.³⁰ Thus, a major part of the midwife's role is to share information, to teach, and to listen. The midwifery model of care also includes a respect for normal physiological processes and a focus on the maintenance of health. Fertility awareness-based methods of family planning are in alignment with these beliefs and this model of practice.

In summary, offering the Standard Days Method and TwoDay Method to clients is an appropriate role for CNMs/CMs. These methods are effective; meet the needs of women seeking a nonhormonal, nondevice approach to family planning; and are feasible to offer in the context of routine visits.

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