CONTEMPORARY OB/GYN

Translating science into sound clinical practice

Explaining ovulation awareness-based family planning methods

By Victoria H. Jennings, PhD, and Helain J. Landy, MD

These easily taught birth control methods may be just what some patients are looking for. Nonhormonal approaches like the Standard Days and the TwoDay Methods hinge on identifying a woman's fertile window: the days during her cycle when pregnancy is likely.

uality of care in family planning demands that obstetrician/gynecologists be knowledgeable about every birth control method in order to educate a patient about all her options. An important component in helping a patient choose an appropriate contraceptive method is to consider her preferences as well as medical eligibility criteria.

The many patients who prefer nonhormonal or nonsurgical methods may be interested in approaches that involve understanding their natural fertility. [Fertility Awareness-Based (FAB) methods of family planning are based on a patient's observations of the fertile and infertile phases of her menstrual cycle.] Women who use this method avoid unprotected intercourse on fertile days, by abstaining or using a barrier method, to prevent pregnancy. Succeeding at a given method depends on three things: the method's accuracy in identifying the fertile days, the woman's ability to follow the method instructions to determine when she is fertile, and the couple's ability to avoid unprotected intercourse on the woman's fertile days.

As is true for many other contraceptive methods, FAB methods are very effective when used correctly (Table 1).¹⁻⁴ Moreover, they pose no threat to either the woman or—

should pregnancy occur—to the developing fetus.^{5,6} Some FAB methods (e.g., Ovulation Method, Symptothermal Method) require patients to attend several instruction sessions lasting a few hours or more.¹⁻⁴ In contrast, you can teach patients about two more recent methods, the Standard Days Method (SDM) and the TwoDay Method, in one brief session (Table 2).

Safe, effective, and practical, these newer methods were studied and field tested by the Institute for Reproductive Health at Georgetown University with support from the U.S. Agency for International Development.

Most likely, FAB methods were not stressed in your medical school or residency training in obstetrics and gynecology. Our goal is to bring you up-to-speed in educating patients about these options by summarizing the currently available FAB methods to make it easier for you to incorporate them into a typical ob/gyn practice. Although we'll focus on the SDM and the TwoDay Method because their simplicity makes them much easier to teach to patients, we'll also refer readers to other sources for more detailed information on the Ovulation and Symptothermal Methods.

FAB methods

Not surprisingly, effectiveness is

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Comparative failure rates of various methods: Percentage of women experiencing unplanned pregnancy during first year of use

Method	Correct use (%)	Typical use (%)	
No method	85	85	
Spermicides	18	29	
Diaphragm	6	16	
Condom	2	15	
Oral contraceptives	0.3	8	
Ovulation Method	3	22	
Symptothermal Method	2	13 to 20	
Standard Days Method	5	12	
TwoDay Method	4	14	

used correctly. But your patients can achieve correct use with appropriate instruction and support. Since incorrect use involves having unprotected intercourse during a woman's fertile time, pregnancy rates may be high depending on when-and how often—during the fertile time she unprotected intercourse (with estimates of pregnancy rates with incorrect use higher than 22%, according to some studies). It's important to consider the efficacy of FAB methods in the context of other userdirected methods. Table 1 compares both the correct and typical use failure rates of FAB methods to other user-directed methods. Women who've chosen the FAB method who use barrier methods

on fertile days have a somewhat

higher risk of pregnancy than do

those who abstain, because of the

highest when FAB methods are

inherent failure rate of barrier methods.

Ovulation Method

[The Billings Ovulation Method focuses on the cervical secretions produced in response to rising levels of estrogen during the late follicular phase of the menstrual cycle.⁷ Women who use this method (developed in the 1960s by Drs. John and Evelyn Billings) are advised to observe their secretions many times daily throughout their cycle, to assess their quantity and quality (i.e., appearance, viscosity, and texture), to record their observations on a chart, and to avoid unprotected intercourse on all fertile days that the method has identified. They are taught to recognize the pattern of cervical secretions usually seen in a typical menstrual cycle—absence of secretions right after menses; scanty, sticky secretions for the next few days; abundant and wet secretions immediately before,

during, and after ovulation; then absence of secretions again until after the next menses. Techniques for observing these secretions include noting their presence on toilet paper or underwear and simply being aware of a feeling of wetness at the vulva. Women using the Ovulation Method avoid unprotected intercourse during menses, on preovulatory days following days with intercourse, and on all days with secretions until the fourth day after the "peak" secretions day (i.e., the last day with watery, viscous secretions). Additional information about the Ovulation Method, including guidance for offering it to patients, is available from several sources, including http://www.woomb.org.

Symptothermal Method

The Symptothermal Method involves daily observation of cervical secretions as well as taking basal body temperature (BBT) readings.8 I Under the influence of progesterone, BBT rises at least 0.4°F around the time of ovulation and remains elevated until the end of the cycle. Women using the Symptothermal Method are told to observe their cervical secretions and BBT daily, record them on a chart, and apply the rules governing method use to avoid pregnancy. They're also advised to identify when they've had 3 days of higher temperatures following 6 days with lower temperatures as confirmation that they have in fact ovulated. Further information is available at www.fertilityuk.org.

Standard Days Method

The SDM, like other FAB methods, is based on the physiology of the menstrual cycle and the functional

Standard Days Method: works best if cycle's between 26 and 32 days . . . Means avoiding unprotected sex on Days 8 to 19 . . . Symptothermal: observe secretions; take temps . . .

TABLE 2 FAB method protocols

Method	Observations	Days to avoid unprotected intercourse
Ovulation Method	■ Monitor cervical secretions daily	■ Menses
	■ Assess quality and quantity of secretions	■ All days with secretions
	■ Record observations on chart	■ The next preovulatory day after having intercours
		on a preovulatory day
		■ Until 4 days past "peak" day
Symptothermal Method	■ Monitor cervical secretions daily	■ Menses
	■ Assess quantity and quality of secretions	■ All days with secretion
	■ Take basal body temperature daily	■ The next preovulatory day after having intercours
	■ Record observations on chart	on a preovulatory day
		■ Until 3 days of higher temperatures following
		6 days of lower temperatures or 4 days past peak
Standard Days Method	Track cycle days beginning with first dayNote days 8 to 19 of cycle	■ Days 8 to 19 of cycle
TwoDay Method	■ Note presence or absence of cervical secretions	■ All days with secretions
	■ Record on chart	■ One day following days with secretions
Source: Used with permission of	Institute for Reproductive Health.	

life span of the sperm and the ovum. This method is appropriate for women whose menstrual cycles are usually between 26 and 32 days long (roughly 78% of cycles are within this range). In developing the SDM, researchers considered two sets of 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.

With regard to the first probability, hormonal and ultrasound studies tell us that a woman is fertile up to a total of 6 days during each cycle—5 days before ovulation plus the 24 hours after ovulation. There is approximately a 4% probability of pregnancy from intercourse 5 days before ovulation. The highest probability of pregnancy (between 25% and 28%) occurs on the 2 days preceding ovu-

lation. The probability of conception drops to 8% to 10% during the 24 hours after ovulation. Fertility subsequently decreases, with a 0% probability of conception by the day after ovulation (Figure 1). These probabilities are due to the limited viable life span of the sperm inside the woman's reproductive tract (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.

To determine when ovulation occurs, and thus when during the cycle the 6-day fertile window occurs, researchers again considered probabilities. In the great majority of cycles, ovulation occurs very close to the middle of the cycle, particularly in those lasting between 26

and 32 days. In roughly 30% of cycles, ovulation occurs at the midpoint (for example, on day 14 in a 28-day cycle, or day 16 in a 32-day cycle). By 4 days before or after midpoint, 94% of ovulations have occurred (Figure 2).9

Investigators applied a computer model that combined the probability of pregnancy on different cycle days related to ovulation, and the probability of the timing of ovulation, to a large data set of more than 7,500 menstrual cycles. Analysis showed that, for women with menstrual cycles between 26 and 32 days, pregnancy is likely only on days 8 through 19.9

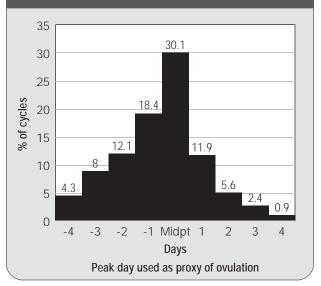
A clinical trial has confirmed that the SDM is useful in avoiding pregnancy. After 478 women were taught the method, they were followed prospectively for up to 13

Day after ovulation chances of getting pregnant drop to 0% . . . 94% of ovulations occur by 4 days before or after cycle midpoint . . . CycleBeads critical to Standard Days Method . . .

FIGURE 1. Probability of pregnancy from intercourse on days relative to ovulation 35% 30% 25% Pregnancy rate 20% Ovulation 15% 10% 5% 0% -8 -7 -6 -5 -4 -3 -2 -1 0 Days

Source: Institute for Reproductive Health. Data taken from Wilcox A, et al. 10

FIGURE 2. Probability of ovulation relative to midpoint of the cycle (%)



Source: Institute for Reproductive Health, analysis of data from World Health Organization.

cycles, with a failure rate of less than 5 per 100 women years with correct usage.³

Offering the SDM to your patients

Most women can learn to use the SDM in about 20 minutes. [CycleBeads (Figure 3) are a string of 32 color-coded 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.] Several SDM studies have confirmed that CycleBeads are a critical component of teaching the method and using it correctly.¹¹

To use CycleBeads, a woman 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 (white bead) or infertile (brown bead) day. Users are counseled to avoid unprotected intercourse when the rubber ring is on a white bead.

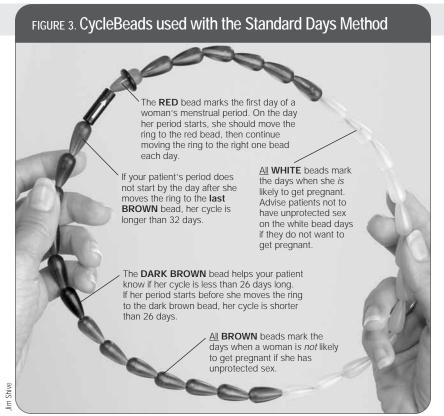
Here are additional important and practical points to cover when offering the SDM.

- It's essential to screen for cycle length before starting the method, because even some women with regular cycles may consistently have quite short or long cycles and thus would be fertile well outside the 8- to 19-day window.¹² While it's unnecessary for a woman to know her exact cycle length, her response 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.¹³
- Women who know when their last period started can begin using the SDM immediately; advise those who do not to wait until their next period begins.
- Women who are breastfeeding, recently gave birth, or recently used long-acting hormonal contraception require special screening to assess whether—or when—the SDM is appropriate for them, as these situations affect cycle regularity and the woman may need to wait until her normal cycling resumes.
- Ongoing monitoring of cycle length is also important, as some

- women have fewer regular cycles than they initially believe. Cycle-Beads help women monitor their cycle lengths. The SDM is not as effective for women with cycles outside the 26- to 32-day range. Therefore, offer another method to women who have more than one cycle that's longer than 32 days or shorter than 26 days in a 12-month period. ¹³
- Assessing whether the woman and her partner will be able to use the method effectively involves discussing with your patient whether she and her partner both want to use the method as well as strategies for avoiding unprotected intercourse on fertile days.

The SDM now is included in international guidance documents, such as the World Health Organization's Medical Eligibility Criteria for Contraceptive Use, the IPPF's third edition of Medical and Service Delivery Guidelines for Sexual and Reproductive Health Services, the 18th edition of Contraceptive Technology, and the eighth edition of A Pocket Guide to Managing Contraception. 5,14-16

White beads for fertile days, brown for infertile . . . Must screen for cycle length before providing SDM . . . TwoDay: based on secretions noted today or yesterday . . .



Source: Adapted with permission of the Institute for Reproductive Health, Georgetown University.

TwoDay Method

[Women using the TwoDay Method monitor the presence or absence of cervical secretions and then consider two questions: Did I notice any secretions *today*? Did I notice any secretions *yesterday*?]

If a woman noticed any secretions today or yesterday (on toilet paper or underwear, or by noticing wetness at the vulva), she is potentially fertile today. If she did not (that is, if she had two consecutive days with no secretions), her probability of becoming pregnant today is very low (Figure 4).

Researchers first determined the theoretical efficacy of the TwoDay Method by applying the algorithm described above to existing data sets. This analysis indicated that the theoretical efficacy of the TwoDay Method was high. ¹⁷ Subsequent analyses confirmed these results, and a clinical trial established method efficacy with a

1-year correct use failure rate of less than 4.4%. The TwoDay Method is also included in the WHO's Medical Eligibility Criteria for Contraceptive Use and the eighth edition of A Pocket Guide to Managing Contraception. 5,16

Offering the TwoDay Method to your patients

The efficacy study provided important information for offering the TwoDay Method to patients, confirming that:

- Women are able to identify the presence or absence of cervical secretions and to apply the two-question algorithm following a single counseling session.
- Most women note secretions on toilet paper or underwear, or simply from a sensation of moisture at the vulva. In general, women are comfortable touching their genitals when checking for secretions.
- 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.

Pros and cons of FAB methods

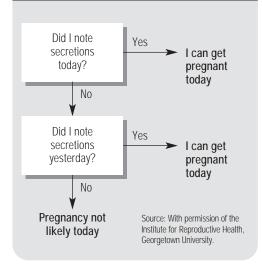
Characteristics of FAB methods that are perceived by some to be advantages may be perceived by others as disadvantages. For example, the importance of the male partner's participation in the method chosen (e.g., by using a condom or not having sex on fertile days, by learning about the chosen method and how to use it) is positive for some couples but difficult to achieve for others. The fact that the woman needs to attend daily to fertility signs is precisely why some women choose FAB methods, while others find this unacceptable. For many women, the lack of side effects of FAB methods offsets their somewhat higher failure rates.

[Certain conditions may make FAB methods more difficult to use and require more extensive counseling and follow-up. These include: recent childbirth, current breastfeeding, recent menarche, recent discontinuation of long-acting hormonal contraceptives, and approaching menopause. FAB methods are not recommended for women with irregular cycles (SDM), inability to interpret their fertility signs correctly (Ovulation, TwoDay, Symptothermal Methods), or persistent reproductive tract infections that affect the signs of fertility (Ovulation Method, TwoDay Method, Symptothermal Method).

[Caution patients for whom getting pregnant is considered high risk that failure rates for FAB methods are higher than for some other methods, and offer alternatives.] For those women who still prefer a FAB

FAB methods not for high-risk women or those with irregular cycles . . . Two-questions for TwoDay Method . . . Failure rates for FAB methods higher than many methods . . .

FIGURE 4. TwoDay Method algorithm



method, we recommend additional counseling and follow-up to ensure correct use. Also, like all family planning methods other than condoms, FAB methods do not prevent STDs.

Who can provide FAB methods?

Highly skilled medical personnel and health educators can be equally successful at providing FAB methods, research shows.⁷ In most settings, the physician's role is restricted to providing general information about FAB methods and referring the patient to an appropriate counselor, such as a nurse practitioner or other trained provider. Even so, it's important for physicians to be well-informed about FAB methods.

Ongoing research

Further ways to improve the effectiveness and adherence to the SDM method are being studied. Investigators are also conducting a study comparing the effect of starting to use the TwoDay Method at various times during the menstrual cycle on accurate understanding and correct use.

Most ovulation prediction kits detect the preovulatory rise in luteinizhormone ing (LH) metabolites, which occurs too close to ovulation to adequately predict this event for avoiding pregnancy. Even those kits such as ClearPlan, which measure both LH and progesterone, have been found to underestimate the onset of the fertile phase, according to a recent study by researchers

at Marquette University. 18 This, combined with their high cost, suggests that ovulation prediction kits may not be a useful tool in routine use of FAB methods, although they may be helpful for women who want to achieve pregnancy.

Conclusions

The Ovulation and Symptothermal Methods are well-established, and guidance for both providers and patients is available through Web sites and in print. You can easily incorporate the newer FAB methods we've discussed in this article into an ob/gyn practice. Materials for training and service provision in the SDM and TwoDay Method, including an on-line training for providers in the SDM, are available from the Institute for Reproductive Health Web site http://www.irh.org. Support materials include screening and follow-up checklists, a refguide for counseling patients, informational videos, a training video, a provider training manual, and patient brochures. \square

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FAB methods don't prevent STDs . . . Be informed about FAB methods, but refer patients to trained counselor . . . Ovulation prediction kits may underestimate fertile phase onset.