



PRACTICE

CLINICAL UPDATES

Fertility awareness based methods for pregnancy prevention

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What you need to know

Best available estimates of the effectiveness of fertility awareness based methods for contraception come from a small number of moderate quality studies, and should be interpreted with caution

People using fertility awareness based methods for contraception should know that they may prove less effective if and when assessed in higher quality studies or diverse populations

Offering a range of acceptable family planning methods is essential to help people achieve their reproductive goals in a patient centred manner

Providing clear information about all contraceptive options requires high quality scientific evidence. Some fertility awareness based methods have (moderate quality) effectiveness data available; others do not

Online and in-person educational resources are available to help potential users learn more about fertility awareness based method options and how to use them correctly

Fertility awareness based methods of contraception are increasingly being used for pregnancy prevention.¹ In the US, the proportion of contraceptive users who choose such methods has grown from 1% in 2008 to approximately 3% in 2014.^{1,2} Relative to other methods of pregnancy prevention, however, substantial misinformation exists around fertility awareness based methods of contraception, particularly about the effectiveness of specific methods and how to use them. Providers who offer family planning counselling can promote correct and consistent use of the chosen method by helping people find a method that best fits their individual lifestyle, preferences, and goals.³ This article aims to help clinicians counsel people about fertility awareness based methods for pregnancy prevention by explaining the different methods, the evidence base for their effectiveness, and practical considerations for use.

What are fertility awareness based methods of contraception?

Fertility awareness based methods are devised on the premise that sexual intercourse can only lead to pregnancy during approximately 6-9 days of the menstrual cycle, commonly referred to as the “fertile window” (or fecund window, [box 1](#)).⁵⁻⁷ Timing of ovulation varies among and between women, therefore so does the timing of the “fertile window.”⁷ Users of fertility awareness based methods track changes in one or more biomarkers of cyclical fecundability (menstrual dates, basal

body temperature, cervical mucus or position, and urinary hormone metabolites). These are used to predict days of high and low fecundability during each menstrual cycle. Each method uses a specific set of biomarkers and interpretation rules and/or algorithms to approximate the start and end of the “fertile window”. Given the difficulty of determining ahead of time exactly when ovulation will happen, the length of time approximated by most methods as potentially fecund is generally at least several days longer than the (6-9 day) span of actual fecundability. To avoid pregnancy, people using fertility awareness based methods can either remain abstinent or use an additional method (eg, male condoms or other barrier methods), during the approximated “fertile window.”²

Box 1: The fertile or fecund window?

Although “fertile window” is often used, the term “fecund window” may be more accurate. English speaking demographers generally use the term “fecundity” to describe the physiological ability to reproduce, “fecundability” to describe the probability of conceiving during a normal menstrual cycle given unprotected intercourse, and “fertility” to describe the number of offspring. However, the terms have different meanings across various disciplines and languages⁶ and these terms are poorly distinguished in common parlance. For this reason, we use quotation marks around the phrase “fertile window” in this paper, since this term is widely used.⁷ The name of this category of methods itself (fertility awareness based methods) might be more accurately termed “fecundability awareness based methods.”

What are the different methods?

To our knowledge, 14 fertility awareness based methods have been subject to clinical trials.⁸ Many more are being promoted without evidence from prospective studies to estimate their effectiveness. Methods can be classified as

- **Calendar based methods** which rely on tracking menstrual cycle dates
- **Mucus based methods** which rely on tracking changes in cervical mucus
- **Basal body temperature based methods** which rely on tracking changes in basal body temperature as well as a calendar calculation

- **Symptothermal methods** which rely on tracking changes in multiple biomarkers (generally including cervical mucus and basal body temperature)
- **Urinary hormone based methods** which rely primarily on tracking changes in metabolites of oestradiol and luteinising hormone in the urine.

Most methods rely on the user making their own interpretation of biomarkers to attempt to predict the “fertile window.” Some rely on use of an app or device implementing an algorithm (based on inputs provided by the user) to attempt to predict the “fertile window” for users. Further details about individual methods are described in the infographic.

What is the evidence that fertility awareness based methods are effective?

In our systematic review, we found no high quality prospective studies of the effectiveness of fertility awareness based methods for pregnancy prevention.⁸ We found 12 distinct methods with moderate quality evidence estimating effectiveness for pregnancy prevention (infographic). Given the lack of high quality studies and the relatively small number of studies for each method, we suggest that current estimates of the effectiveness of each method be interpreted with caution. When attempting to interpret this research, one important caveat is that participants who complete prospective studies are often not reflective of the general population (because of study eligibility requirements, personal characteristics associated with adhering to potentially burdensome trial requirements, and frequent interaction with study staff). Therefore, the estimates in our systematic review, which are derived from prospective studies, should be viewed as “best case scenarios.” For most other contraceptive methods, estimates from prospective studies can be triangulated with those from population based retrospective surveys (eg, the National Survey of Family Growth in the US), which can produce more generalisable estimates. This type of triangulation is impossible for individual fertility awareness based methods, since at present the number of users of each of these methods is not large enough in population based surveys to calculate effectiveness estimates for individual methods. Moreover, in addition to those fertility awareness based methods identified in the published literature, there are others being promoted directly to users without appropriate studies estimating the effectiveness of these options for pregnancy prevention, sometimes accompanied by a lack of sufficient regulatory oversight regarding misleading marketing claims.^{9 10}

How effective are these methods in preventing pregnancy with typical use?

Estimates for the effectiveness of contraceptive methods are usually described in *typical use* and *perfect use* estimates.¹¹ *Typical use* refers to how effective a method is for the average person who does not always use that method correctly or consistently. For people interested in using a fertility awareness based method, it is critical to understand that—in contrast with methods like long acting reversible contraceptives—fertility awareness based methods are particularly sensitive to incorrect and inconsistent use.¹² This is in part due to the high degree of user involvement required to track daily biomarkers of fecundability, and also because imperfect use of this method, by definition, involves unprotected intercourse during days of high fecundability.

Estimates from nationally representative retrospective surveys (such as the National Survey of Family Growth in the US) have

been used to describe the effectiveness of fertility awareness based methods, but for statistical reasons have lumped all users of unique fertility awareness based methods together. In the United States, this grouping all users together results in a group comprised largely of calendar rhythm users; thus, the resulting effectiveness estimate (15 pregnancies per 100 women years)¹¹ largely reflects effectiveness of calendar rhythm use, and may not reflect effectiveness of other fertility awareness based methods. In addition, retrospective survey data cannot be used to estimate perfect use effectiveness. For these reasons, our systematic review focused on typical and perfect use estimates for specific fertility awareness based methods calculated in prospective studies, which we emphasise should be viewed as best case scenarios. These are summarised in the infographic.

In moderate quality prospective studies, among new users of most fertility awareness based methods, typical use estimates for unintended pregnancy ranged, across different methods, from 10 to 34 pregnancies per 100 woman years (infographic). These estimates are within a similar range as typical use estimates for some barrier methods, including male and female condoms, sponges, and diaphragms (eg, 13-21% during the first year of use).¹¹ The Sensiplan and Marquette Monitor methods may be the most effective fertility awareness based methods in typical use, with moderate quality studies generating typical use effectiveness estimates of 1.8-6.8 pregnancies per 100 new users in the first year of use. While more data are needed to confirm these estimates, these numbers are in the range of typical use estimates for combined and progestin-only pills, patches, and rings (7% during the first year of use).¹¹ Limited data exist to address the effectiveness of fertility awareness based methods over longer term use.⁸

How effective are they at preventing pregnancy with perfect use?

In our systematic review, only seven fertility awareness based methods had moderate quality studies that used correct methodological approaches to estimate perfect use effectiveness.⁸ Perfect use unintended pregnancy estimates for most fertility awareness based methods ranged from one to five pregnancies per 100 new users in the first year of use, except for Persona (12 pregnancies per 100 woman years). Thus, in currently available studies, most fertility awareness based methods had perfect use estimates in a range similar to male and female condoms (2-5% during the first year of use).¹¹ Similar to typical use, the lowest perfect use pregnancy rates were observed for users of Sensiplan and the Marquette Monitor, with estimates suggesting one or fewer pregnancies per 100 woman years during the first year of use, though again, these estimates require confirmation in additional studies.

Advantages and disadvantages of fertility awareness based methods

Effectiveness is one important factor that people consider when choosing contraceptive options. Others include safety, side effects, mechanism of action, and affordability.¹³⁻¹⁵ These are summarised in table 1.

Special considerations

People who are unable to negotiate the timing of intercourse with their sexual partner will be unable to effectively use fertility awareness based methods to avoid pregnancy. Women with long or irregular cycles should not generally rely on calendar based methods, though methods that rely on tracking changes

in cervical mucus, temperature, and or urinary hormones may still be appropriate for them. Effectiveness data are limited for users in other special reproductive categories (eg, post partum, lactating, after abortion or miscarriage, adolescents with irregular cycles, women at perimenopause).

Where a person has strong personal or medical reasons to avoid pregnancy (eg, chronic treatment with teratogenic medications or a medical condition that would make pregnancy risky), encourage them to consider using a highly effective contraceptive method such as a long acting reversible contraceptive. However, where someone is unwilling to use a more effective method and strongly desires to use a fertility awareness based method, we recommend respecting the individual's choice and offering transparent information about how to use the methods in the most effective manner.

Other people who may experience additional challenges in using fertility awareness based methods include

- Recent users of hormonal contraceptives
- Those with current or frequent reproductive tract infections
- Those who have undergone female genital cutting
- People on medications that may affect cervical mucus tracking (eg, antihistamines or vaginal creams)
- People who have physical or learning limitations
- Those who have an irregular sleep, work, or travel schedule.¹⁶

These individuals may prefer to consider other contraceptive options. If they choose a fertility awareness based method, we would recommend they work with an experienced and certified instructor (box 2), some of whom are available via telehealth options.

Box 2: Additional educational resources

Training resources for clinicians

- Standard days method: online, free 1-2 hours training module (CME). http://archive.irh.org/SDM_Training/index.php
- Two day method: online, free toolkit. <https://www.k4health.org/toolkits/twoday>
- Sensiplan materials and training (available at cost). https://www.sensiplan-im-netz.de/?page_id=910.
- Billings Ovulation Method: religious components, teacher training (available at cost). <https://www.woombinternational.org/global-outreach>
- Marquette Symptohormonal Method: religious components, teacher training available (at cost). https://nfp.marquette.edu/avoiding_pregnancy.php

Overview documents

- Contraceptive Technology 21st Ed (particularly the chapter on fertility awareness based methods, ch 12, 26. <http://www.contraceptivetechnology.org/the-book/>
- World Health Organization's medical eligibility criteria for contraceptive use, Fifth Edition https://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/
- Family Planning Handbook: A Global Handbook for Providers, ch 18, 2018. <http://fphandbook.org/sites/default/files/global-handbook-2018-full-web.pdf>
- Free webinars from the National Clinical Training Center for Family Planning, supported by the US Office of Population Affairs Title X Family Planning Program
 - Understanding and counselling potential users on fertility awareness based methods for pregnancy prevention: <https://vimeo.com/264114233>
 - Effectiveness of fertility awareness based methods for pregnancy prevention. <https://vimeo.com/284453322>
 - Fertility apps: a new approach for fertility awareness based methods. <https://vimeo.com/277724852>

Fertility awareness based methods may be chosen for religious reasons (box 3). Be aware that some patients hold religious beliefs that forbid use of other methods of pregnancy prevention, or which advise that the act of intercourse must allow for the possibility of pregnancy.^{17 18} Fertility awareness based methods may be the only acceptable option for such individuals. Some religious groups prohibit any genital contact unless it is for the purposes of procreation. For such patients, using a fertility awareness based method that is in accordance with their beliefs may require abstinence from all sexual activity (not only from penile-vaginal intercourse), during the “fertile window.”

Box 3: Fertility awareness based methods or natural family planning?

The terms “fertility awareness based methods” and “natural family planning” have come to have distinct definitions. Fertility awareness based methods is an umbrella term for all methods based on tracking indicators of fecundability. Natural family planning indicates use of a fertility awareness based method in conjunction specifically with abstinence during the “fertile window,” often arising in a religious context¹⁶ where alternative methods (eg, barrier methods) or sexual practices are contrary to those specific religious teachings.⁴

How should clinicians include fertility awareness based approaches in contraceptive options counselling?

Fertility awareness based methods should be included as an option in patient centred counselling. Clinicians need to be able to communicate the general advantages and disadvantages of such methods as well as the known effectiveness data and the limitations of those data. Note that some companies that manufacture fertility related technologies, as well as some proponents of fertility awareness based methods, have made misleading claims about effectiveness in marketing directly to consumers.⁹ For example, some have promoted improperly calculated effectiveness rates or inappropriately applied effectiveness rates from other fertility based methods to the method they are advertising. In one case, a misleading publication on effectiveness of a fertility awareness based device called Daysy was contested and eventually retracted from the scientific literature.^{9 19}

Clinicians who wish to develop their skills in counselling on the use of fertility awareness based methods can undertake training in person and online (box 2).

Education into practice

Do you present fertility awareness based methods as an option during contraceptive counselling? If so, for which types of patient?

How might you change your counselling about fertility awareness based methods in the future?

What local resources exist in your community or can be accessed by your patients for fertility awareness based method instruction and education?

Sources and selection criteria

The authors of this manuscript, in conjunction with a larger group of experts, conducted a systematic review of studies which prospectively identified pregnancies and prospectively tracked pregnancy intentions, and which evaluated fertility awareness based methods' effectiveness for pregnancy prevention in PubMed, CINAHL, Embase, and Web of Science until 6 June 2017.⁸ In this article we included information from studies identified in the process of that review, in addition to information gleaned from a standing ongoing PubMed search, and articles already known to us from our research and clinical work on fertility based and contraceptive provision and counselling.

How patients were involved in the creation of this article

Individuals using fertility awareness based methods of pregnancy prevention were invited to read a draft of the article and offer feedback. Their comments were used to modify the wording and content of the final article by including clearer language and including patient centred information about use of these methods

Harmonisation with international guidelines

Guidance on fertility awareness based methods issued by the Faculty of Sexual and Reproductive Healthcare in 2015 recommends that "women wishing to use fertility indicators for contraceptive purposes should [...] be informed that combining indicators is considered more effective than using single fertility indicators alone."²⁰ This guidance was based on expert opinion as a result of limited evidence being available. In our 2018 systematic review, effectiveness estimates for multiple marker methods and for single indicator methods varied widely.⁵ Of the evidence identified in that systematic review, moderate quality studies suggested that two multiple marker methods (Sensiplan and Marquette) may have the lowest unintended pregnancy rates among fertility awareness based methods with comparable evidence. However, other multiple marker methods had much higher pregnancy rates.

Neither the Centers for Disease Control and Prevention (United States) nor the World Health Organization have similar recommendations but simply list the methods with available effectiveness data.²¹⁻²³

The American College of Obstetricians and Gynecologists has no formal guidance on the use of fertility awareness based methods for avoiding pregnancy.

*Guttmacher Institute affiliation included for informational purposes only; this work was not conducted under the auspices of the Guttmacher Institute. The views expressed herein are those of the authors and do not necessarily reflect the views of the Guttmacher Institute or Reply OB/Gyn & Fertility

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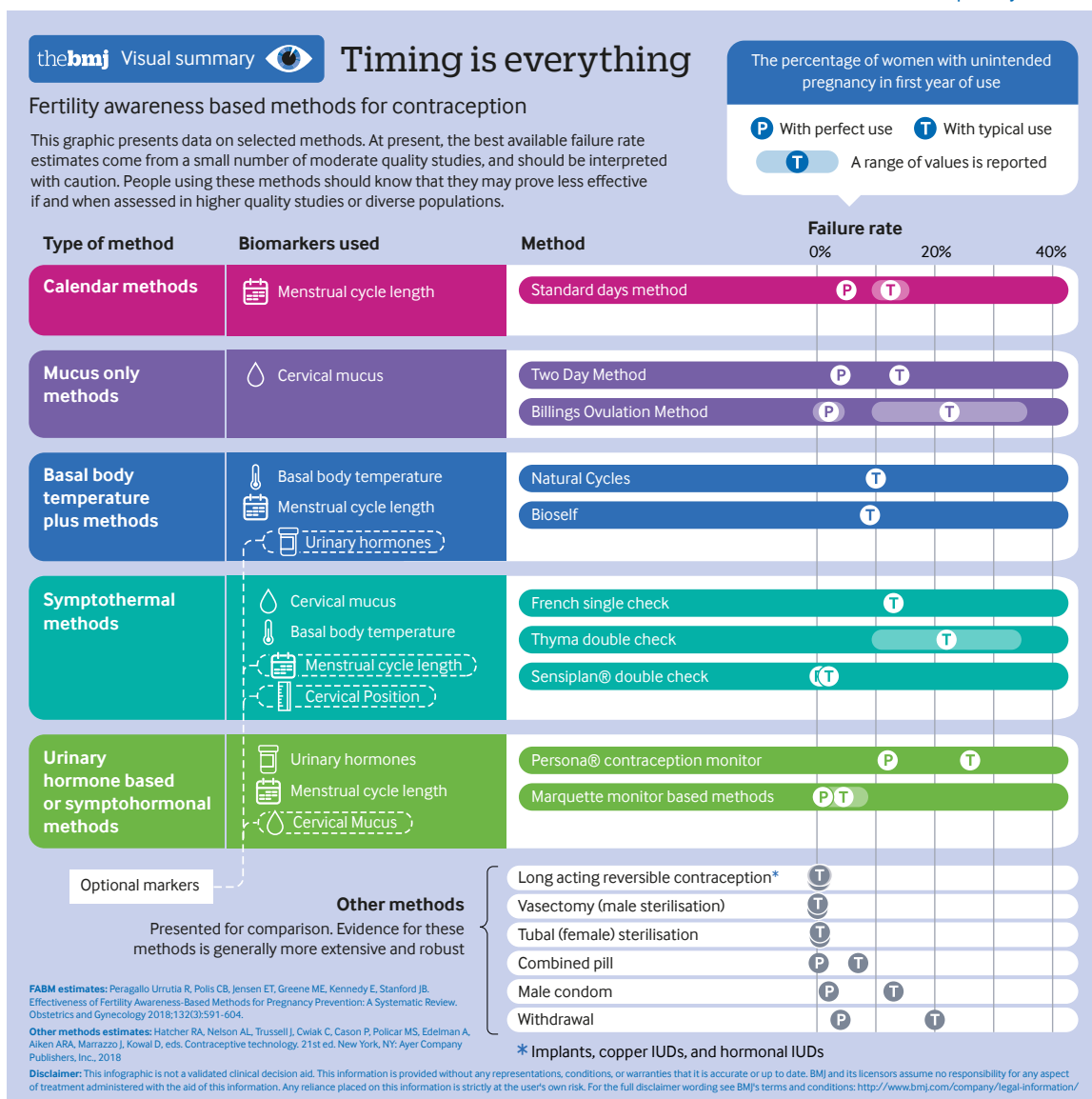
Table

Table 1 | Advantages and disadvantages of fertility awareness based methods of pregnancy prevention

Advantages
<ul style="list-style-type: none"> • No side effects • Appeal to people who prefer not to use hormones or devices • Help users acquire a deeper understanding and appreciation of the functioning of their own body • Adaptability of the method to trying to conceive or tracking health if pregnancy intentions change • Compatibility with the teachings of some major world religions
Disadvantages
<ul style="list-style-type: none"> • A requirement for either abstinence or use of a second contraceptive method during the “fertile window” • Lower inherent effectiveness than some other contraceptive options (infographic) • A strong dependence on the user maintaining correct use • No protection against HIV and other sexually transmitted infections • A lack of high quality effectiveness studies
Other considerations
<p>Fertility awareness based methods require partner communication and cooperation, daily tracking of biomarkers, determinations about daily fecundability, and appropriate behaviour modifications in response to that information (ie, abstaining or using another method on that day). Some methods may require working with an experienced instructor. We are not aware of any formal cost effectiveness studies available for fertility awareness based methods</p>

Infographic

See interactive version for features of individual methods: <http://bit.ly/BMJfabm>



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