Natural Family Planning as a Means of Preventing Pregnancy

Introduction

Natural Family Planning (NFP) relies on the ability to track ovulation in order to prevent pregnancy. These methods predict fertile and unfertile days to identify when to avoid unprotected sex and are only used by a small fraction of women. Some women may choose to use these methods because they have a religious objection to contraception that involves drugs, devices, or surgical procedures. Others may use them because they prefer to use a hormone-free method. However, these methods are less effective than other forms of contraception such as the oral contraceptive pill, IUD, implant, and condoms.

Natural family planning has recently gained attention following the Trump Administration's release of the 2018 Funding Opportunity Announcement (FOA) for the federal Title X family planning program. The updated FOA emphasizes abstinence and natural family planning methods, a major departure from prior administrations that have prioritized counseling women about the most effective methods. While NFP has always been included in the full range of contraceptive options offered to women seeking family planning care, some are concerned that the new emphasis on NFP in the Title X program will reduce already limited access to more effective and long-acting methods for low-income women who wish to use them. This fact sheet provides an overview of Fertility Awareness Methods and their efficacy, reviews some of the new apps and natural family planning models, and discusses limitations as well as associated costs and insurance coverage of these methods.

Calendar-Based and Fertility Awareness-Based Methods

The average woman is fertile for a 6-day period each month -- the 5 days before ovulation and the day of ovulation. Natural family planning methods use a combination of methods to help women identify these days. There are a range of tools including apps that have been developed to help women identify these fertile days (**Table 1**). Women practicing NFP who want to prevent pregnancy may choose to remain abstinent during these fertile days or if they are not opposed to using a non-hormonal barrier method, may choose to use a condom.

Calendar-based methods, such as the Rhythm Method, track the menstrual cycle in order to identify the days a woman is most likely to become pregnant and are the oldest form of natural family planning. Fertility Awareness-Based Methods (FABMs) generally track changes in one or more signs of fertility associated with ovulation: basal body temperature, cervical mucus, hormone production, and cervical position, though they may also include calendar tracking as well. The basal body temperature method (BBT) requires a woman to take her temperature every morning immediately when she wakes up, before she gets out of bed, while the cervical mucus monitoring method requires her to track changes in vaginal discharge daily. Sympto-thermal methods track multiple signs, most typically the BBT method and the cervical mucus monitoring method, and is considered to be more effective than using only one of these methods. Other methods may also track hormone levels in the urine and changes in the position of cervix.

Breastfeeding may also be used as a method of contraception for postpartum women. Lactation amenorrhea is a temporary period of infertility immediately following the birth of a baby during which the hormones that produce breast milk prevent ovulation. In order to rely effectively on this method of contraception, a woman must exclusively and frequently breastfeed her baby for up to 6 months or until her period returns. This method will not work for women using a breast pump or formula.

Headquarters / 185 Berry Street Suite 2000 San Francisco CA / 94107 / 650 854 9400 Washington Offices and Conference Center / 1330 G Street NW Washington DC 20005 / 202 347 5270





Table 1: Natural Family Planning and Fertility Awareness Methods				
Туре	Method	Protocol	Days to avoid unprotected sex	
Tracking Days of Menstrual Cycle	Calendar Rhythm Method Standard Days Method (SDM)	Track cycle lengths to calculate fertile window. Avoid unprotected sex on days 8-19 of cycle.	Avoid unprotected sex during the fertile window.	
Cervical Mucus Monitoring (CMM)	Billings Ovulation Method Creighton Model Fertilitycare System (CrMS)	Monitor characteristics of cervical mucus (vaginal discharge) daily Monitor cervical mucus daily; uses a more detailed classification system Check cervical mucus	Any day with menstruation or secretion; Alternate sexual intercourse during "infertile days"	
	Two Day Method (TDM)	secretions at least twice a day.	present "today" or "yesterday"	
Temperature	Basal Body Temperature Method (BBT)	Take and chart temperature every morning before getting out of bed to identify postovulatory increase in temperature.	Avoid sex from start of menstruation until three days after seeing temperature rise.	
Multiple Indicators	Sympto-thermal Method (STM) Sympto-hormonal Method (Marquette Model, Persona)	Combines BBT and CMM Combines the CMM with a fertility monitor that measures hormones present in the urine.	During fertile window identified by the various markers.	
Postpartum	Lactation Amenorrhea Method (LAM)	Exclusively breastfeed baby up to 6 months postpartum (or until period returns)	None until period returns.	

Use and Efficacy

Utilization of natural family planning methods in the United States is low. It is estimated that roughly 2% of sexually active women ages 15-44 used a natural family planning method in 2014.² Women may chose these methods because they are hormone-free, low cost, or for religious or personal reasons. The typical use effectiveness of NFP methods in preventing pregnancy depends on the accuracy of the method chosen, the ability of the woman to correctly interpret their biological signs of fertility, and the couple's ability to avoid unprotected sex during the fertile window (**Table 2**). With perfect use, clinical trials suggest NFP methods have very low failure rates. However, perfect use is hard to achieve. There is significant room for human error, and even just one miscalculation can lead to unintended pregnancy. In addition, many of the clinical trials measuring the efficacy of these methods have been criticized for their findings of low failure rates due to selection bias and non-representative samples.³ One recent systematic review found that there are few studies evaluating the effectiveness of fertility awareness—based methods, and the existing studies are of moderate to low quality. As a group, NFP methods have a failure rate up to 25 pregnancies for every 100 women per year.⁴ Lactation amenorrhea, however, is highly effective for roughly the 6-month period following childbirth, only if a women exclusively breastfeeds her infant and

only for 6 months. In comparison, for every 100 women, less than one woman using an IUD or implant for a year, and roughly 5 to 9 women using oral contraceptive pills for a year, may become pregnant.⁵

(pregnancies per 100 women in first year)			
Method	Perfect Use	Typical Use	
Standard Days Method	5	8-25	
Billings Ovulation Method	3	3-22	
Two Day Method	4	14	
Sympto-thermal method	0.4	2-33	
Sympto-hormonal method (Marquette Model)	1-2	11-14	
Lactation Amenorrhea	0-8	*	

Limitations

Natural family planning methods can work to prevent pregnancy for some women. However, there are many limitations to these methods, making them less effective than most other hormonal and non-hormonal contraceptive options. NFP methods are time-intensive and require significant commitment from both the woman and her partner. Women are advised to track their cycles for at least 6 cycles to learn about their cycle length and signs of fertility before relying on this method to prevent pregnancy, leaving them vulnerable to unintended pregnancy if no other contraceptive method is used during this initial period. Women must also pay attention to signs of fertility such as vaginal discharge and temperature daily or multiple times a day, and correctly interpret their observations. Finally, the woman must be able to remain abstinent during the fertile window, which can last up to 12 days a month depending on the method, or use a barrier method.

Many women may not be good candidates for the use of NFP including women with multiple sexual partners and women with irregular cycles (**Text Box 1**). Some methods, such as the calendar-based methods will not work for women with cycles shorter than 26 days or longer than 32 days. In addition, cycles and signs of fertility may vary for each woman, and even from month to month, due to a wide range of reasons including stress, sickness, sleep deprivation, use of certain medications and alcohol, making these methods less reliable. Finally, these methods do not protect again sexually transmitted infections.

Text Box 1: Many Women May Not Be Good Candidates for NFP

- Women with irregular cycles, which could include those who:
 - o just began menstruation
 - o just discontinued use of a hormonal contraceptive method
 - o just gave birth
 - o are approaching menopause
 - o have Polycystic Ovary Syndrome
- Women with multiple sexual partners
- Women and their partners who do not want to avoid sex on fertile days
- Women who cannot track their fertility daily and keep careful records
- Women with STIs or abnormal discharge

SOURCES: Office of Population Affairs, US Department of Health and Human Services. <u>Natural Family</u> Planning and Fertility Awareness factsheet. Planned Parenthood. Fertility Awareness Methods factsheet.

Tools, Providers, and Instruction

Natural family planning methods require varying levels of training and technology to use correctly. For calendar-based methods, women may use a physical calendar or CycleBeads to track the days of their menstrual cycle. However, most methods now have mobile apps, including iCycleBeads. Some apps simply make it easier for women to log their biological fertility markers online. For example, Kindara, a fertility awareness app, even syncs with its own Bluetooth-enabled BBT thermometer, called the Wink, to track a woman's temperature throughout her cycle. Other apps actually interpret these data to predict a women's daily risk of pregnancy. Cycle Technologies, in partnership with the Institute for Reproductive Health at Georgetown University, is a prominent developer of natural family planning methods and mobile apps, including CycleBeads, the 2Day Method, and Dynamic Optimal Timing (DOT). DOT is currently undergoing an extensive efficacy study with funding from US Agency for International Development (USAID), with results expected in fall 2018.

Mobile health apps that are not considered medical devices do not require FDA approval for promotion and use in the United States.⁶ Certain medical devices such as the Kindara Wink are classified as exempt from FDA review but must comply with general controls including registering with the FDA. One app, Natural Cycles, was certified in the EU as a contraceptive device in 2017, the first app to gain government approval. It operates by tracking a woman's temperature and identifying the days on which women should use protection or abstain from sex. Recently, Natural Cycles has come under scrutiny. Less than a year after its certification by the EU health agency, a Swedish hospital reported that 37 out of 668 women seeking abortions there between September and December 2017 had used Natural Cycles as their primary contraceptive method.⁷ Nonetheless, in August 2018, this app was approved as a medical device by the FDA for use in the United States among women 18 years and older.

FABMs that track multiple signs of fertility sometimes require training with a licensed provider. There are organizations, many of them religiously-affiliated, dedicated to teaching and promoting these methods of natural family planning, such as the Couple to Couple League. Some of these groups have also developed their own model of natural family planning, such as the Creighton Model Fertilitycare System (CrMS), Sensiplan, and the Marquette Model, although these brands still rely on some variation or combination of temperature, cervical mucus, hormone, and cervical position tracking.

Insurance coverage and cost

FABMs are generally inexpensive to use. Basal body thermometers generally cost between \$10 and \$15, and most fertility awareness apps in the US are free. However, there are exceptions. The Kindara Wink thermometer costs \$129, and the Natural Cycles app costs \$80 a year. Some methods, such as the Creighton Model Fertilitycare System, require training from licensed providers and follow up visits that can cost anywhere from \$100-\$600 in total.

These instructional classes are not often covered by private insurance plans or Medicaid. A few state Medicaid programs will cover the cost of basal body thermometers,⁸ and Washington will cover natural family planning education and supplies, including CycleBeads® and BBTs, for both women and men in their full scope Medicaid program as well as their family planning only program.⁹ Iowa's family planning expansion program also covers BBTs,¹⁰ and Arizona, California, and Minnesota identify natural family planning services and education as a component of their programs. However, it is unclear whether plans would cover branded classes such as the Creighton Model Fertilitycare System. Some states, such as Illinois¹¹ and Minnesota,¹² require state-regulated private plans to cover natural family planning services without cost sharing.

Conclusion

Natural family planning has always been an element of programs and providers that offer comprehensive family planning services. Federal guidelines such as the CDC's and the Office of Population Affairs' Providing Quality Family Planning Services (QFP) and HRSA's recommendations for preventive services for women clearly state that offering women the full range of FDA-approved contraceptive methods is a critical element of quality family planning care. In 2015, 82% of all clinics and 92% of Planned Parenthood clinics offered natural family planning instruction or supplies.¹³ While new NFP models and apps have been developed to assist women to record and track signs of fertility in recent years, they require a commitment to daily and consistent use and dedication from both the woman and her partner(s). While natural family planning is an approach that some women may seek, many women are precluded from using these methods, and the vast majority of women in the US prefer to rely on more effective methods of contraception to avoid pregnancy.¹⁴ For women who are precluded from using natural family planning methods or prefer to rely on other more effective contraceptive methods, easy access to the full range of FDA approved contraceptive methods is the most effective way for women to avoid unintended pregnancy.

Endnotes

Kaiser Family Foundation. (2013). Medicaid Coverage of Family Planning Services, results of a national survey report.

¹ Power to Decide. <u>Power To Decide Raises Concerns About Title X Funding</u>. February 2018.

² Kavanaugh ML, Jerman J. (2017). <u>Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014. *Contraception Journal.*</u>

³ Trussell J, Grummer-Strawn L. (1990). <u>Contraceptive failure of the ovulation method of periodic abstinence</u>. *Family Planning Perspective*; 22(2):65-75.

⁴ Office of Population Affairs. Department of Health and Human Services. <u>Natural Family Planning and Fertility</u> Awareness Factsheet.

⁵ Office of Population Affairs. Department of Health and Human Services. <u>Birth Control Methods</u>.

⁶ Food and Drug Administration. <u>Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications</u>. February 2015.

⁷ Ong, T. January 16, 2018. <u>Contraceptive app hit with complaints after being blamed for 37 unwanted pregnancies</u>. The Verge.

⁸ Kentucky, New York, Pennsylvania, Texas, Vermont, and Wisconsin.

⁹ Washington Apply Health (Medicaid). (2018). Family Planning Billing Guide.

¹⁰ Iowa Department of Human Services. <u>Family Planning Program.</u>

¹¹ Illinois 215 ILCS 5/356z.4

¹² 2017 Minnesota Statutes 62Q.14 Restrictions on Enrollee Services

¹³ Zolna MR, Frost JJ. (2015). <u>Publicly funded family planning clinics in 2015: Patterns and trends in service delivery practices and protocols</u>. Guttmacher Institute.

¹⁴ Lessard LN, Karasek D, et al. <u>Contraceptive features preferred by women at high risk of unintended pregnancy.</u> Perspectives in Sexual Reproductive Health. 2012 Sep;44(3):194-200