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EFFICACY OF NATURAL FAMILY PLANNING METHODS

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Our understanding of how to determine the efficacy and effectiveness of natural family planning (NFP) methods has developed over the last fifty to sixty years. Leo Latz was one of the first physicians to report on the efficacy of the rhythm method in a scientific medical journal.¹ His report was based on the number of women users (cases), the frequency of intercourse, and the number of pregnancies achieved. Modern studies of family planning methods may be controlled prospective (usually cohort) studies of a specific method, comparison studies of two or more methods of NFP, or retrospective surveys of pregnancy rates among a large population of users.²

There is a difference between effectiveness and efficacy studies involving family planning methods. Efficacy studies determine whether a method works as expected in specified research conditions; effectiveness studies measure how well a method works in real life. The efficacy of a family planning method is usually determined prospectively by studies conducted in a controlled environment. Effectiveness, on the other hand, is based on the unintended-pregnancy rate among a large population of users over time, usually determined retrospectively through chart reviews or surveys. Most studies of NFP are controlled studies—that is, they are efficacy rather than effectiveness studies.

Early studies of contraceptive and NFP methods used a simple formula, called the Pearl formula, to determine pregnancy rates. The Pearl rate for a family planning method is the number of unintended conceptions per hundred women per year of use. It is calculated as the number of unintended conceptions among study participants divided by the number of months or cycles of use, with the quotient multiplied by 1,200 if months are reported or 1,300 if cycles are reported. The pregnancy rate that the Pearl formula provides becomes deflated over time, however, as participants

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drop out of a study or become pregnant. Modern contraceptive efficacy studies use a statistical technique called survival analysis, which takes into account varying durations of use and controls for dropouts.

Correct-Use and Typical-Use Rates

Two numbers should be provided when the efficacy of a family planning method is reported—specifically, the correct-use (or perfect-use) pregnancy rate and the typical-use pregnancy rate. The correct-use rate tracks unintended pregnancies that occur only while a method is being used correctly and consistently by couples in the study—that is, during the months or cycles when the couples did not have intercourse during the fertile phase as determined by the method. The typical-use rate is a total pregnancy rate that includes unintended pregnancies that occur during both correct-use and imperfect-use cycles. Imperfect use means the couple either used the method inconsistently or did not follow the instructions for the method. The formula for determining typical use involves the total number of months or cycles of use.³ Only correct-use cycles or months are included in the analysis of correct-use pregnancy rates.

Perfect-use efficacy rates can be obtained only in prospective clinical studies. Retrospective survey studies of populations provide only typical-use pregnancy rates. Unintended-pregnancy rates are affected by the number and difficulty of the behaviors needed for the method to be used efficiently and effectively. Birth-control methods that require few if any behaviors during use, such as sterilization, the intrauterine device, or contraceptive implants, have very low unintended-pregnancy rates. Methods that require more complex behaviors, like using a condom appropriately with every sexual act, usually have higher unintended-pregnancy rates.

NFP methods require not only the daily observation and monitoring of one or more natural indicators of fertility but also the use of periodic abstinence. These behaviors are relatively complex and, at times, difficult to carry out. The unintended-pregnancy rates of NFP methods thus tend to be higher than those of nonbehavioral birth control methods. The correct-use rate of cervical-mucus-only methods is around one to three unintended pregnancies per one hundred women over twelve months of use, whereas the imperfect-use rate is around eighty-six unintended pregnancies per hundred users over twelve months of use. (Imperfect-use rates are not the same as total, or typical-use, rates.)⁴

NFP methods in general have the very low correct-use rates of one to three pregnancies per one hundred women

users over twelve months of use. One reason for this is that the natural indicators of fertility used with them tend to overestimate the actual physiological six-day fertile window. On average, NFP methods estimate the fertile window to be between ten and seventeen days, which is four to eleven days longer than necessary. The longer the estimated fertile window, the less likely are correct-use unintended pregnancies. For example, if only the first and last day of the menstrual cycle were considered infertile, the method would be 100 percent perfect. The imperfect-use rate would be much higher, of course, depending on whether couples were capable of near-total abstinence from intercourse.

Over the years, studies of the efficacy of NFP methods have become increasingly sophisticated and follow established standards. Note 5 shows the general perfect- and typical-use unintended-pregnancy rates for selected contraceptive and NFP methods. These efficacy rates are adapted from an article by James Trussell of the Population Institute at Princeton University.⁵ He is considered one of the top experts (if not the top) in providing accurate unintended-pregnancy rates for methods of family planning. His published pregnancy rates are cited in journal articles and in medical and nursing textbooks and are believed to be authoritative and accurate. NFP methods are considered third-level methods (in regard to efficacy and effectiveness) and are rated about the same as the male condom in efficacy. They are considered to have better pregnancy rates than spermicides and withdrawal.

Over the past ten years a number of good cohort efficacy studies of NFP methods have been conducted and published. These studies, for the most part, reflect the current state of the art in determining NFP efficacy. Note 6 shows data from studies that were published in peer-reviewed journals between 1999 and 2013 and from the classic five-country study of the ovulation method conducted by WHO.⁶ As it shows, the unintended-pregnancy rates of NFP methods vary considerably. It is hard to compare reported rates (for both correct use and typical use) because of methodological variations in studies, including how researchers define unintended pregnancy, whether a researcher calculates pregnancy rates by months or cycles of use, and whether researchers include only perfect-use cycles in the correct-use rates. Added to this difficulty is the problem that studies conducted by developers or promoters of NFP methods have built-in bias and tend to underreport unintended pregnancies or to redefine them. Finally, the menstrual cycles reported in these studies tend to be of regular lengths, that is, between twenty-six and thirty-five days.

Despite these caveats, some very good efficacy studies of NFP methods have been done. A large five-country study of the ovulation method by WHO analyzed the efficacy of the cervical-mucus-only ovulation method.⁷ A study by Margaret Howard and Joseph Stanford evaluates a standardized cervical-mucus-only method called the Creighton Model System.⁸ A 2002 study by Marcos Arévalo and colleagues evaluates the efficacy of the Standard Days Method,⁹ and a 2004 study by Arévalo and colleagues determines the efficacy of the TwoDay Method.¹⁰ A study by Petra

Frank-Herrmann and colleagues analyzes the efficacy of a European symptothermal method that uses temperature and cervical mucus observations plus a calendar formula—what they call the double-check method.¹¹ A 2007 study by Richard Fehring and colleagues determines the efficacy of a method combining cervical mucus observation with use of an electronic hormonal fertility monitor as an aid or as a second estimate of the fertile window.¹² And a 2008 paper by Fehring and colleagues is a retrospective efficacy study of a method that combines use of an electronic hormonal fertility monitor with observations of cervical mucus and basal body temperature.¹³

Most of these studies (except the one by Howard and Stanford) included only women with regular menstrual-cycle lengths.¹⁴ Of the unintended-pregnancy rates reported, the highest was the total rate of 22 percent reported in the WHO study of the ovulation method. The lowest was the total rate of 7.47 unintended pregnancies over thirteen cycles of use reported in the study of the European double-check method by Frank-Herrmann and colleagues among participants who used periodic abstinence to avoid pregnancy during the estimated fertile window.

Attempts to Simplify Methods

One of the reasons for difficulty in obtaining low unintended-pregnancy rates with NFP methods is the complexity of the methods, which involve not only observing and interpreting natural biological signs of fertility but also following detailed instructions. To address this problem, researchers have developed simplified methods of NFP, such as the Standard Days Method and the TwoDay Method, developed by researchers at the Georgetown University Institute for Reproductive Health (IRH). As mentioned above, the Standard Days Method is a simple fixed-day calendar-based method for women who generally have menstrual cycles between twenty-six and thirty-two days in length, in which days 8 to 19 are always considered fertile. The TwoDay Method is based on two simple questions: whether the woman has observed mucus secretions that day and the day before. If she answers no to both questions, she can consider herself infertile on that day.¹⁵ Both methods have respectable correct-use and imperfect-use unintended-pregnancy rates among a variety of people in various developing countries (many of whom are poor and less educated than subjects in the United States).

In 2019 researchers at the IRH published the efficacy of a simple modern calendar-based system of family planning for avoiding pregnancy that is built into a smartphone app called Dot (which refers to dynamic optimal timing, or DOT).¹⁶ All the user of the Dot fertility app has to do is enter the first day of her menses. The app then learns her cycle lengths and calculates the probability of pregnancy on a day-to-day basis. Researchers and clinicians at the IRH have a mission to develop and integrate simple but effective NFP methods into the family planning programs of developing countries.

Another recent attempt to simplify NFP methods is the European double-check method, developed for women who

need to be very sure about their family planning method to avoid pregnancy. This method involves observing changes in cervical mucus and basal body temperature and applying a simple algorithm. The method provides a double check for both the beginning and the end of the fertile window. The study of this method by Frank-Herrmann and colleagues obtained efficacy rates that rival those reported for the birth control pill (see notes 5 and 6).¹⁷

Researchers at Marquette University have also been dedicated to developing both secure and simplified methods of NFP. Their efforts include integrating new technology—such as home-based hormone monitoring, the Internet, and fertility apps—into NFP practice, education, and support. They developed a method of NFP that, like the European double-check method, provides separate checks for the beginning and end of the estimated fertile phase by combining use of the electronic monitor with cervical mucus observation.

Researchers conducted a retrospective cohort comparison study (the NFP service programs and NFP charting systems have prospective data) and an Internet-based study to determine the efficacy of this method. The comparison study showed that significantly fewer unintended pregnancies occurred with the method combining cervical mucus observations with use of a fertility monitor as a double check than occurred with a standardized mucus-only method.¹⁸ These results are similar to findings of an earlier randomized study showing that the addition of basal body temperature to mucus observations enhanced efficacy.¹⁹ A study of an Internet-based NFP education, electronic charting, and user support system also showed high levels of efficacy with women in a variety of different reproductive categories, including postpartum breast-feeding.²⁰ A recent randomized comparison study that made use of this online system and an updated version of the Marquette method compared (1) a method combining use of the hormonal fertility monitor with a simple fertility algorithm and (2) a method combining use of cervical mucus monitoring with a simple fertility algorithm; it showed significantly fewer unintended pregnancies in the group that used the hormonal fertility monitor, specifically, seven unintended pregnancies per one hundred women over twelve months compared with nineteen in the mucus-monitoring group.²¹

In interpreting the efficacy of NFP methods, it is important to know that unintended-pregnancy rates increase considerably when studies include women of different reproductive statuses (for example, women who have recently stopped using contraceptive pills, women who have recently given birth, and perimenopausal women) and women who have menstrual cycles of irregular lengths. It is noticeable that few NFP studies include women from all reproductive categories and women with varying menstrual-cycle lengths. To illustrate the increase in rates, Howard and Stanford found that the total unintended-pregnancy rate for a cervical-mucus-only method jumped from 14 percent for women with uncomplicated regular cycles to 17 percent for women in all reproductive categories and 24 percent for women who

were breast-feeding postpartum.²² Another data set from the same study showed a total rate of approximately 22 percent for the cervical-mucus-only method, which is similar to the WHO study rate.

In summary, NFP methods are very effective when couples follow the instructions correctly and consistently and when women have menstrual cycles of regular length. Efficacy seems to be enhanced for methods that have simplified instructions, those that use simple means to estimate the fertile phase, those that use more than two indicators to estimate the fertile window, and those that use a more accurate and objective measure such as electronic hormonal monitoring. It is promising that the use of the Internet to teach and support NFP has been very effective and efficient.

When a couple wishes to avoid a pregnancy but have intercourse during the fertile window, they will most likely achieve a pregnancy. The five-country WHO efficacy study of the ovulation method showed an unintended imperfect-use pregnancy rate of about twenty-five per one hundred women over twelve months of use and an 85 percent rate when only cycles with incorrect use were included in the equation.²³ Most of the unintended pregnancies occurred with couples who had intercourse even though they knew they were in the fertile window of the cycle.

While the ovulation method can be very effective when used correctly, couples who have intercourse in the estimated fertile window usually become pregnant.²⁴ For this reason, researchers describe the ovulation method as “unforgiving of imperfect use.” In contrast, the birth control pill can be missed on occasion without affecting the unintended pregnancy rate too much. A recent systematic review of NFP and fertility awareness-based methods effectiveness studies found a wide range of both perfect- and typical-use pregnancy rates among women with regular-length menstrual cycles.²⁵

Notes

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