The State of the Science of Natural Family Planning Fifty Years after *Humane Vitae*: A Report from NFP Scientists' Meeting Held at the US Conference of Catholic Bishops, April 4, 2018

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Abstract

A one-day meeting of physicians, professional nurses, and scientists actively involved in Natural Family Planning (NFP) research was held to review the state of the science of NFP and consider future priorities. The meeting had four objectives: (i) determine the gaps in research evidence for secure methods of NFP among women of all reproductive categories, (ii) determine the gaps in the research and development of new technology for providing NFP services, (iii) determine the gaps in the research that determine the benefits and challenges with use of NFP among married couples, and (iv) provide prioritized ideas for future research needs from the analysis of evidence gaps from objectives above. This article summarizes the discussion and conclusions drawn from topics reviewed. While much has been accomplished in the fifty years since *Humane vitae*, there are still many gaps to address. Five areas for future research in NFP were identified as high priority: (1) well-designed method effectiveness studies among various reproductive categories including important subpopulations (postpartum, perimenopause, posthormonal contraceptive), normally cycling women (especially US women), and comparative studies between NFP methods; (2) validation studies to establish the benefit of charting fertility signs (both currently known and potential new indicators) as a screening tool for women's health issues; (3) ongoing independent evaluation of fertility monitoring apps to provide users perspective on the relative merits of each and to identify those most worthy of further effectiveness testing; (4) studies evaluating the impact of new technologies on NFP adoption, use, and persistence; and (5) creation of a shared database across various NFP methods to collaborate on shared research interests, longitudinal studies, and so on.

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Summary: This summarizes a meeting to review the scientific and medical progress related to natural family planning made in the 50 years since *Humane Vitae* and to define priorities for future work. Areas reviewed included the evidence for avoiding pregnancy in normally cycling, postpartum, and perimenopausal women, the impact of new technology, including fertility charting apps, on NFP, and the impact on relationships and personal well-being from use of NFP. Five priority focus areas for future research were also identified.

Keywords

NFP, Fertility awareness, Fertility awareness information technology, Marriage and family, Reproductive technology, Sexuality and marriage, *Humane vitae*

Introduction

A symposium celebrating the fiftieth anniversary of the encyclical *Humane Vitae* at the Catholic University of America in April 2018 provided the opportunity to hold a one-day meeting of physicians, professional nurses, and scientists actively involved in Natural Family Planning (NFP) research to review the state of the science of NFP and consider future priorities. Supported by the NFP program of the US Conference of Catholic Bishops (USCCB), Marquette University College of Nursing Institute for NFP, the Couple to Couple League, and anonymous donors, the meeting was based on the call of Pope Paul VI (1968) in *Humanae vitae* for scientists to develop more secure methods of NFP and for delineating the best conditions for their use. The meeting had four objectives:

- Determine the gaps in research evidence for secure (i.e., evidence-based effective) methods of NFP among women of all reproductive categories.
- Determine the gaps in the research and development of new technology for providing NFP services.
- Determine the gaps in the research that determine the benefits and challenges with use of NFP among married couples.
- Provide prioritized ideas for future research needs from the analysis of evidence gaps from objectives above.

This meeting was also inspired by a similar gathering of NFP researchers and educators held in Canada in 2016 under the leadership of the International Institute for Restorative Reproductive Medicine. That event brought together experts with a diversity of perspectives and yielded valuable insights that underscored the benefits of collaboration in a field of research that is traditionally

underfunded and generally disregarded in family planning programs. This meeting built on the groundwork laid in Canada.

The following is a summary of the information and discussions from the April meeting along with the results of an exercise intended to focus attention on those areas in highest need of future work. Our hope is that by sharing this summary, more investigators will be motivated to continue to conduct and publish research on NFP and its impact on marriage and family life.

Current State and Gaps in the Evidence for NFP When Used to Postpone Pregnancy

Systematic reviews of the effectiveness of NFP when used to postpone pregnancy are rare. Grimes et al. (2005) examined only randomized controlled studies and found two, each with serious methodological flaws. He concluded that the comparative efficacy of these methods remains unknown but suggested that, based on these flawed studies, unintended pregnancy rates are high using NFP. Manhart et al. (2013) reviewed English-language studies published since 1980 and concluded that each of the major methods has at least one high-quality prospective cohort study based on the criteria developed and employed by the authors using Strength of Recommendation Taxonomy (SORT; Ebell et al. 2004). Those studies meeting the high-quality standard had typical unintended pregnancy rates ranging from less than five to twenty-two per 100 women over twelve months of use and perfect use rates of less than five per 100 women over twelve months of use.

A more recently completed comprehensive review was presented at the meeting (Urrutia et al. 2018). The protocol for the review is available through PROSPERO, the International Prospective Register of Systematic Reviews (CRD42015017760,

accessible at http://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=17760&VersionID=31281). The multidisciplinary team undertaking the review included a wide spectrum of attitudes, from NFP-only to pro-contraceptive scientists. The review included all studies published as of June 2017 in English, French, Spanish, or German that prospectively evaluated a specific method of NFP for at least one year when used to avoid pregnancy. A total of fifty-one unique papers were identified that met the screening criteria, reflecting the paucity of research on NFP in general. These studies were independently reviewed by two authors, and a consensus quality rating was obtained.

When evaluated by the quality metrics developed for this review, no high-quality studies were identified, twenty-one studies were of moderate quality, and thirty were judged low quality. Possible differences between the criteria used for a study to be considered high quality by Manhart et al. (2013) and Urrutia et al. (2018) were discussed. For the latter, a greater emphasis on articulation of the inclusion/exclusion criteria, lower levels of lost-to-follow-up, exclusion from analysis of any cycles where no sexual activity occurred, and inclusion of specific subpopulation analysis were required to be defined as high quality.

Whether or not studies used to support the approval and use of hormonal contraceptives, devices, or barriers would be scored as high quality by this scheme was acknowledged as an unknown at this time. Dumitru, Gilbride, and Duane (2016) compared the quality of studies of oral contraceptives published since 2000 to the quality of studies of fertility awareness-based methods (FABMs) using the SORT criteria and concluded that five of the forty-seven (11 percent) oral contraceptive studies met the high-quality standard, while ten of the thirty (30 percent) FABM studies published since 1980 met the high-quality standard. The Dumitru review underscores that Urrutia et al.'s (2018) finding that there are no high-quality NFP studies is not necessarily worse than the status among the contraceptive literature.

Among the various methods, the Sensiplan Sympto-Thermal Method (STM) and Marquette (urinary hormone only) Method had the lowest typical unintended pregnancy rates (both less than five per 100-women years), while the other methods had typical unintended pregnancy rates ranging from ten to thirty-three per 100-women years. Perfect use was similar with Sensiplan and Marquette, both less than one per 100-women years unintended pregnancy rates, and the other methods had rates generally less than five per 100-women years.

The discussion of the systematic reviews also focused on the heterogeneity of the concept of unintended pregnancy. Stanford et al. (2000) demonstrated that in the National Survey of Family Growth, unintended pregnancies cover an extremely wide range of actual circumstances when the respondents' own words are used—from hardly unexpected (“The pregnancy came a few months earlier than expected”) to clearly unexpected and unwanted (“I don’t want it and am getting rid of it”).

In the context of NFP, where couples are fully aware of when conception is a distinct probability and the methods are used to achieve as well as avoid pregnancy, unintended pregnancy is a far more complex concept than can be expressed as a single statistical number. Recognizing the complexity and multifaceted meaning of “unintended pregnancy,” the Urrutia et al. (2018) group plans future work focused on the evidence for impact of relationship factors, motivation, sexual behavior, demographics, breastfeeding, and other reproductive factors on unintended pregnancy rates.

The group concluded that more research is needed on all methods when used to postpone pregnancy. Future studies need to integrate the learning from the past decades to assure high-quality study results. The lack of information on use of most methods among US users is a notable outage. Finally, the inclusion of all pregnancies, both intended and unintended, will increase transparency of reporting and help others judge overall effectiveness.

Nevertheless, providers should not shy away from recommending effective NFP methods due to gaps in the current knowledge. Similar gaps have not prevented manufacturers and medical organizations from promoting widespread use of contraceptives. In addition, it is well-documented that women who use hormonal contraception, particularly oral contraceptives, often stop using it due to side effects and then as a result get pregnant; yet this pregnancy is not counted as a failure of the contraceptive. In addition, research shows that women prefer methods that are safe (i.e., no side effects), and NFP has a clear advantage over the alternatives here (He et al. 2017; Jackson et al. 2016).

Evidence for Effectiveness of NFP When Used in Special Circumstances

NFP effectiveness when used in postpartum breastfeeding transition

The postpartum transition, defined as the time between the birth of the baby and the return of

regular menstruation, is a time when many users of NFP are particularly concerned about an unexpected pregnancy. The length of this transition is variable and is highly influenced by feeding patterns of the child (exclusive and continued nursing can significantly delay the return of ovulation) and the mother's own physiology.

Unfortunately, there is a paucity of high-quality data regarding NFP effectiveness in this period. Only ten studies were identified for this review; nine were a prospective cohort design, and one was a retrospective cohort trial. Nine of the trials used six or twelve months as a time-based end point, and only one used return of the menstrual cycle as the end point. Calculations using months of use instead of cycles can overestimate effectiveness rates since postpartum amenorrhea is a single cycle with highly variable lengths. Further complicating comparison, cervical mucus is often subjectively defined and thus not comparable across studies.

Several challenges with using NFP methods when postpartum were discussed. First, cervical mucus is sometimes a poor indicator of fertility in this transition. Some users experience intermittent patches of peak type mucus due to high estrogen from an active follicle that is not progressing toward ovulation, adding uncertainty and extended periods of abstinence; postpartum breastfeeding women often have continuous mucus patterns that make it difficult to define a basic infertile pattern; finally, arousal fluid can also look like peak type mucus, confusing some users. Second, basal body temperature when used alone in the transition is inconvenient for mothers with nursing babies and not specific in identifying the infertile time prior to the initial postpartum ovulation. Recognizing these difficulties, most NFP methods have postpartum algorithms that are complex and require long periods of abstinence, which in many cases are likely longer than necessary. The lactational amenorrhea method (LAM) is a short-term method of NFP that applies to exclusively breastfeeding women and is reported to be highly effective in the first six months postpartum. It, too, has limitations, most notably the definition of "exclusive" breastfeeding which was found to vary across studies and the low percentage of women that meet the criteria through the first six months postpartum.

Reported typical unintended pregnancy rates of mucus-only NFP methods used postpartum are nineteen to twenty-four per 100 women over twelve months of use. The STM, used postpartum, has been characterized as highly sensitive but not specific; it detects 77–94 percent of potentially fertile days (high sensitivity) but calls for abstinence on about

half the days when women were not fertile based on direct hormonal measurements (low specificity; Kennedy et al. 1995). More recently, Bouchard, Fehring, and Schneider (2013) reported that urinary hormone monitoring using the Marquette Model postpartum protocol yielded eight unintended pregnancies per 100-women years with typical use and two per 100-women years with correct use.

The advent of at-home urinary hormone detection (including estrogen, luteinizing hormone [LH], and progesterone [PdG] metabolites) provides an opportunity to significantly improve our understanding on how to help women manage this transition as these tests may provide a less subjective approach to determining daily fertility status and potentially reduce unnecessary abstinence. For example, a woman using LAM who experiences an interim bleed might determine with hormone detection that it reflects estrogenic breakthrough bleeding activity that is not rapidly progressing toward an ovulatory event and therefore would not be excluded from continuing LAM.

The group concluded that more studies of NFP in the postpartum transition period are needed. In addition, NFP protocols that are less complex and less subject to user misinterpretation would be important improvements. With increasing accessibility to in-home hormonal monitoring and ability of mobile devices to bring complex computing power directly to users, the technology for improved protocols appears to be in place. What is needed are high-quality effectiveness studies with unintended pregnancy as an outcome employing these latest advances, ideally in comparison to traditional NFP postpartum protocols.

NFP effectiveness in older women

The Staging of Reproductive Aging Workshop Model (STRAW) proposes an objective measure for the beginning of perimenopause—a persistent difference of seven days or more in the length of consecutive cycles, with persistence defined as recurrence of this difference within ten cycles of the initial event (Harlow et al. 2012). Secondary indicators include low levels of Anti-Müllerian hormone and inhibin B and variable to elevated levels of follicle-stimulating hormone (FSH) when measured on cycle days two to five. Vasomotor symptoms often appear at the later stages of perimenopause.

Changes in reproductive capacity occur prior to perimenopause: ovarian egg supply is diminished significantly at around age thirty-five and after forty-two may be down to less than fifty. Further, the

remaining eggs, and sperm of men over thirty-five, have a higher proportion of frayed chromosomal ends. This chromosome damage may result in conceptions that lead to early pregnancy loss, most likely completely undetected. In addition, NFP users and those who track their cycles may notice subtle changes in both menstrual and cycle patterns as they move into their midthirties.

For many (but not all) couples, pregnancy in their early forties can bring serious concerns including possible health problems that can occur with pregnancy at older age, the challenges of raising their current children, and the deep-seated belief that their family is “complete.”

An important factor in this transition is the likelihood of pregnancy in the absolute. Previous studies in Israel indicate a pregnancy rate of only 0.2 percent among women over forty-five, and population-based studies where contraception was never used indicate live births cease by age forty-two to forty-three. In contrast, other studies show a reasonable proportion of women are still ovulating in their forties. A World Health Organization (1994) study of menopause indicated that at age forty-five, fertility is about 10 percent of maximal and by age fifty is reduced to 1 percent of maximal. However, the study also indicated that use of NFP during perimenopause would be difficult because of the variability of the menstrual cycle. Thus, while the probability of pregnancy is low for women in their forties, it is not zero.

Regarding the evidence for NFP use in this transition period, there are fewer studies of NFP in this cohort than found in postpartum women. Fehring and Mu (2014) examined 160 women aged forty to fifty-five who were using online or in-person NFP instruction. An additional cohort has supplemented this to yield a total cohort of 206 perimenopausal women. No pregnancies were observed among women older than forty-three. Among women aged forty to forty-three, unintended pregnancy rate is about four per 100-women years with typical use. There are studies of other methods of NFP on small subsets of older women using NFP that show promising results, but they lack statistical power to draw firm conclusions regarding effectiveness.

The group concluded that more studies among perimenopause women using NFP are needed to understand better the perimenopause transition with the parameters of the menstrual cycle. There is a particular need to develop algorithms that can help women and health-care providers predict infertility and menopause. For example, a study by Taffe and Dennerstein (2002) indicates that when the differences of the length of the menstrual cycle goes

beyond forty days, menopause will occur within eighteen months and women with this cycle length difference are infertile.

Technology and NFP

Apps for charting fertility cycles

Menstrual cycle tracking apps are extremely popular; they are the fourth most common health app among adults and the second most popular among adolescent females (Moglia et al. 2016). Today, these apps are used for help in avoiding pregnancy, achieving pregnancy, and simply tracking cycles. While popular, there is little objective evidence supporting the claims of most; most reviews and ratings refer to user characteristics rather than the underlying science supporting the predictions made by the app. The explosion in apps has significantly expanded the awareness of natural methods, but whether this translates into increased use of NFP broadly remains an open question today.

Duane et al. (2016) conducted a systematic review of ninety-five charting apps focused on the evidence-based method employed and accuracy in predicting the fertile window. Fifty-six (59 percent) of the identified apps had either no evidence-based support or were not designed to help avoid pregnancy. Ten apps did not interpret cycles, they only allow users to input data and make their own interpretation.

The remaining twenty-nine predicted the fertile window automatically using an algorithm. To test the accuracy of the algorithm to predict the fertile window, the beginning and end of the fertile window defined by the app was compared to the evidence-based fertile window in each of seven test cycles. Just six apps scored high on both authority (well-documented FABMs with evidence) and accuracy (complete agreement with the fertile window).

The Natural Cycles app, which employs basal body temperatures and a proprietary algorithm to define the fertile window, has recently obtained certification in the European Union as a medical device for contraception. While the certification is based primarily on meeting manufacturing quality standards, the developers have published an analysis of its initial users to define effectiveness when used to postpone pregnancy. Although the developers of this app system are to be applauded for conducting an effectiveness study, the study design includes several flaws including selection bias, lack of accurate pregnancy detection, and inappropriate analysis of perfect-use pregnancy rates (Frank-Herrmann, Stanford, and Freundl 2017).

Recently Freis et al. (2018) proposed a scoring scheme to evaluate apps that claim to help users achieve pregnancy by predicting clinical ovulation. The scoring scheme seeks to identify those apps worthy of field-testing to validate their benefit in helping couples become pregnant. They also conducted a pilot test using twelve apps available in German and English that could be used without the need for additional devices (e.g., a urinary hormone test strip) using a set of completed cycles with known days of high fertility. Six of the apps were calendar-based and of little value to accurately predict the best days of fertility. The two apps employing temperature-only calculations did only marginally better at predicting clinical ovulation, while the remaining four apps which included a marker of estrogenic activity all scored well.

New Technologies for monitoring the fertile signs

Beyond apps, other technologies to define the daily fertility status are emerging. Several of these claimed “new technologies” are based on old ideas with little support. For example, new products based on saliva ferning patterns are available. Ferning has been shown to be an inaccurate surrogate for estimating the fertile phase of the menstrual cycle and to be highly sensitive to operator error. Further, saliva of men and menopausal women have been shown to have so-called fertile saliva, raising questions about its linkage to reproductive hormones.

Several devices marketed as an aide to conception (but not contraception) employ temperature-based algorithms to predict ovulation. Studies (Ecochard et al. 2015) show that this approach is less precise than alternative at-home hormone tests or simply observing peak type cervical mucus. Similarly, electrical resistance measures, taken orally or vaginally, are inaccurate with many indeterminate results.

Electronic activity tracking bracelets and rings are widely available and popular. These wearable devices can passively monitor temperature, heart rate, skin conductivity, and other physiologic indicators. Whether or not these devices and the monitored physiologic parameters can make tracking fertility easier or more accurate is untested today. Continuous basal body temperatures (BBT) captured overnight while sleeping may be an alternative for waking BBT oral temperatures, but they need to be shown to be usable as an evidence-based

NFP method or when integrated as a part of another NFP method.

Of the newer technologies, urinary hormone monitoring is emerging as a proven approach with several options available today or in development. Daily, at-home monitoring of urinary metabolites of estrogen, LH, and PdG is available today. Integration of urinary hormone detection with smartphones may provide for more consistent reading, and easier, more user-friendly interfaces are in development. A prototype mobile phone-based app that integrates measurement of FSH, LH, and PdG in an algorithm to define the fertile window was shown at the meeting. For infertile couples, daily, in-home, quantitative monitoring of five reproductive hormones via blood microsampling (as used in monitoring for diabetes) is under development and may be a reality in the future.

Based on the information presented and subsequent discussion, the group highlighted several key points regarding technology and NFP:

- Apps are unlikely to disappear and may well become the common method of daily charting.
- App popularity is raising awareness of NFP among the public, but with so many unconnected to an evidence-based method, there is a risk the public will be more misled than better informed regarding their fertility status.
- It would be useful to have some sort of objective evaluation of apps that potential users could turn to for a measure of the quality of the various apps.
- Effectiveness studies employing apps are needed for nearly all methods. Few if any well-designed prospective studies employing app-based charting are available today.
- New technologies, once they are established to be at least as accurate in predicting the fertile window as currently available observations, may improve and/or simplify the daily observation of fertility signs, expanding the appeal of NFP to a wider audience. However, studies on the impact of these new technologies on NFP are needed: do they improve persistence of use, or improve outcomes in special populations (e.g., postpartum women), or increase adoption and use of NFP?
- Integration of these technologies with mobile devices holds promise to reduce user uncertainty in interpretation and may lead to simpler, more user-friendly algorithms that allow persistent use of NFP.

Impact of NFP on Marital Dynamics

For this meeting, sixteen studies published between 1970 and 2017 that focused on the marital dynamics of NFP use were identified and reviewed. Although all had one or more limitations—including small sizes, low response rates, use of convenience samples, and frequent use of unique unvalidated measurement devices—several consistent themes emerged that support beneficial effects of NFP on marital dynamics.

Across all studies, users consistently perceive that using NFP has provided a better understanding of their fertility, increased intimacy, improved self-control/self-mastery, improved communication, and improved spiritual well-being. Importantly, users commonly acknowledge that the practice of NFP is difficult at times, but the struggle is seen by most as beneficial overall.

The claim that using NFP results in lower divorce has long been made by advocates of NFP, but those claims relied on anecdotal or methodologically questionable studies. Recent studies (Fehring 2013, 2015) using population-based samples indicate those who use NFP divorce at significantly lower rates compared to those who never used NFP. These more recent population-based studies support that lower divorce rates are associated with NFP use but also suggest that regular church attendance and importance of religion are at least as strongly associated with decreased divorce. Use of contraceptives, sterilization, and abortion are all associated with an increased risk of divorce; an observation worthy of further study to understand the societal cost of widespread use of contraceptives.

Several gaps in the evidence for the impact of NFP on marital relationships were identified, including the need for larger cohort studies sampled with less biases in both selection and response, more consistent use of validated survey instruments, and studies that include comparisons to other family planning methods. Long-term longitudinal studies are also needed as it is entirely possible that the perceived benefits and challenges of NFP shift over time.

Priorities for Future Work

At the meeting's conclusion, the group generated a long list of potential research ideas and had a discussion to clarify each idea more fully. Afterward, the list was distributed to all who were invited to attend but could not. Each scientist was asked to prioritize the ideas and the results were collated. Five areas for future research in NFP were identified as high priority:

- (1) Well-designed method-effectiveness studies that incorporate learnings from the last decades of outcome-based studies among various reproductive categories including:
 - (a) important subpopulations (postpartum, perimenopause, posthormonal contraceptive);
 - (b) normally cycling women (especially US women); and
 - (c) comparative studies between NFP methods.
- (2) Validation studies to establish the benefit of charting fertility signs (both currently known and potential new indicators) as a screening tool for women's health issues (i.e., polycystic ovary syndrome, endometriosis, luteal phase insufficiencies, etc.).
- (3) Ongoing independent evaluation of fertility monitoring apps to provide users with perspective on the relative merits of each and to identify those most worthy of further effectiveness testing.
- (4) Studies evaluating the impact of new technologies on NFP adoption, use, and persistence. For example, smartphone reading of hormone test strips (i.e., FSH, LH, E3G, and PdG) to minimize interpretation confusion: do they impact persistence of use or improve outcomes in special populations (e.g., postpartum)?
- (5) Creation of a shared database across various NFP methods to collaborate on shared research interests, longitudinal studies, and so on.

In addition, it was unanimously agreed that a future meeting in two to three years would be extremely valuable. Both established and younger researchers should attend to encourage and mentor those who will continue the work in the next generation. Such a meeting would be consistent with blessed Pope Paul VI's (1968) directive to scientists in *Humanae vitae* (no. 24), who "can 'considerably advance the welfare of marriage and the family, along with peace of conscience, if by pooling their efforts they labor to explain more thoroughly the various conditions favoring a proper regulation of births.'"

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Invited Scientists Attending

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Invited Scientists Unable to Attend But Voting on Priorities

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