Hormonal Contraception and the Informed Consent*

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Abstract

Since the 1960s, hormonal contraceptives have become the most commonly used method of pregnancy prevention in the United States and the world. Oral contraceptives are used by a large percentage of women, including Christian women. There are known health risks to women demonstrated in research published since Pope Paul VI's prophetic encyclical *Humanae vitae* in 1968. These risks include venous thrombosis, cardiovascular risks, and an increased risk of cancer. These risks are medically recognized with continued scientific debate on the degree. The risks are significantly increased with preexisting conditions and in certain demographic groups. Discussing known and potential treatment risks is a standard that is both accepted by the medical community and is increasingly expected by patients. This discussion can be accomplished by the mechanism and principle of informed consent. Depending on the circumstances, abstinence or fertility awareness-based methods (FABMs) should be presented to patients. FABMs are licit, safe, and effective methods of pregnancy prevention. Informed consent is the most effective means of providing patients with pertinent information on the significant risks of contraception.

Summary: This article discusses the use of the informed consent to provide patients with information on the medical and ethical risks of oral contraceptives. FABMs and abstinence are presented as effective, safe, and licit preferences to oral contraceptives. Discussing known and potential treatment risks is accepted by the medical community and expected by patients (shared decision making). The authors discuss the historical context of Pope Paul VI's encyclical *Humanae vitae* in relationship to the development and rapid adoption of oral contraceptives.

Keywords

Breast cancer, Fertility awareness-based method, *Humanae vitae*, Informed consent, Natural family planning, Oral contraception, Shared decision making, Venous thrombosis

Overview and History of Oral Contraceptives and Catholic Moral Ethics

In 1968, Pope Paul VI published the landmark encyclical, *Humanae vitae* (*Of Human Life*). This encyclical restated the Church's tradition and teachings on the immorality of contraception and reaffirmed the essential link between the unitive and procreative dimensions of human sexuality. This document is based on natural law and states that the Church cannot "declare lawful what is in fact unlawful" (Paul

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VI 1968, no. 18). Pope Paul VI (1968) called the Church to act by “safeguarding the holiness of marriage, in order to guide married life to its full human and Christian perfection” (no. 30).

Pope Paul VI (1968) states, “It is anticipated that perhaps not everyone will easily accept this particular teaching” (no. 18). This statement was an accurate prediction. By proclaiming the truth, Pope Paul VI knew that this document would contradict the secular culture and also be challenging within the Church itself.

It is important to consider the scientific and cultural changes that were taking place at the same time that *Humanae vitae* was written, in order to understand the reaction that occurred. By the time this encyclical was written, Western culture had already adopted a contraceptive mentality.

Synthetic oral contraceptives were first manufactured in the 1950s. Enovid was approved by the Food and Drug Administration (FDA) in 1957 to treat menstrual disorders. Enovid was widely used by women for various “gynecological disorders” before it was approved for contraception by the FDA in 1960 (Junod and Marks 2002). It took another decade of research data to show convincing evidence of the increased risk of venous and arterial thromboembolic events from oral contraceptives. In this interval of time, the use of oral contraceptives had accelerated. By the early twenty-first century, oral contraceptives were being used by more than one hundred million women worldwide and by over eleven million women in the United States (Mosher et al. 2004). Despite Catholic teaching condemning the use of contraception, hormonal contraceptives are widely used by Catholics (Goldscheider and Mosher 1991).

Humanae vitae generated considerable theological challenges, debate, and dissension from the secular culture and within the Catholic Church (Shannon 1970). The Magisterium has steadfastly supported the truths that were stated in *Humanae vitae*. The teachings were confirmed and expanded by Pope St. John Paul II (2006) between 1979 and 1984 through 129 addresses relating the nature of marital love in the *Theology of the Body*. Catholic teachings regarding contraception are clearly stated and supported by the US Conference of Catholic Bishops (USCCB 2009) in the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs): “Catholic health institutions may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction both about the Church’s

teaching on responsible parenthood and in methods of natural family planning” (dir. 52).

Modern cultures and societies have undergone radical changes since *Humanae vitae* was written nearly fifty years ago. Pope Paul VI (1968) predicted the dangers of contraception including “marital infidelity and general lowering of moral standards,” loss of reverence and respect for women, and “the danger of this power passing into the hands of those public authorities who care little for the precepts of the moral law” (no. 17).

Since the writing of *Humanae vitae* and the original FDA approval of oral contraceptives over forty years ago, there has been accumulating evidence and scientific literature on the risks of hormonal contraception. Communicating medical risks and benefits is the duty of the patient’s physician and medical provider prescribing oral contraceptives. This can be accomplished by means of an informed consent.

Prescribing oral contraceptives for contraception is illicit for Catholic physicians, and their patients should be informed prior to establishing the physician/patient relationship. However, the risks of oral contraceptives can be described when counseling patients on the advantages of licit pregnancy prevention in a manner similar to informed consent. For the Catholic physician, the moral truths of pregnancy prevention do not contradict scientific truths.

The Principle of Informed Consent

Informed consent means that a provider has communicated the risks and benefits of a treatment plan and that the patient (or surrogate) understands and agrees. There are two types of informed consent. Simple or implied consent is satisfactory for many procedures such as an X-ray or lab work where there is minimal risk of complication from the procedure. Explicit or formal informed consent is required for procedures or treatments that are not simple or carry significant risk of complication or side effect. This type of informed consent should be documented in the medical record (Hall et al. 2012).

Informed consent consists of three basic moral and legal requirements. There are no major differences between Catholic and secular ethics regarding the structure for informed consent; however, there are some important differences in the details. As stated in the ERDs, “Free and informed consent requires that the person or the person’s surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side effects, consequences and cost; and any

reasonable and morally legitimate alternatives, including no treatment" (USCCB 2009, dir. 27).

The first requirement is that of providing the patient (or surrogate) with relevant information about the purpose (foreseen beneficial results), risks, alternatives, and uncertainties of the procedure or treatment. There is often debate over the amount of information that has to be given to the patient for informed consent. Insufficient information, particularly about serious risks, is unsatisfactory. However, too much information can also be problematic, since the patient may be overwhelmed with information which may cause indecision and unnecessary procedures (Coulter 1997).

There are two standards that can be used to help determine the appropriate amount of information for an informed consent. The *reasonable physician* standard is based on what a typical physician would disclose about the intervention or treatment. The *reasonable patient* standard is based on what an average patient would need to know in order to make an informed consent. Although the physician standard has been traditionally more commonly used, there is modern legal precedent supporting the reasonable patient standard (*Canterbury v. Spence* 1972).

The second requirement for informed consent is that the patient or surrogate understands the information. This requires the physician to explain the procedure in a manner that a layperson can understand and to answer all of the patient's questions. The patient also has a responsibility to ask pertinent questions in order to understand the procedure and potential consequences.

The ERDs address this second requirement, "Each person or the person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed healthcare decision of the person or the person's surrogate is to be followed so long as it does not contradict Catholic principles" (USCCB 2009, dir. 28). This requirement differs from secular ethics in that it involves conscience and Catholic principles.

The third requirement is that the patient be free to make an informed consent without coercion. The physician should be free to express his medical opinion, and the patient should be free to decline the procedure, or to obtain a second opinion. This decision-making process protects the dignity and conscience of both physician and patient, and neither should be coerced. This has been recently referred to as shared decision making. There is one major difference with this process in Catholic versus secular

ethics. Those operating under secular ethics increasingly pressure physicians to refer patients for procedures or treatments that the physician will not illicitly perform due to conscience.

In the discussion of informed consent for oral contraceptives, it is pertinent to discuss the issue of whether explicit informed consent is appropriate or even necessary for oral contraception. Informed consent involves an analysis of benefit versus risk. Risks can be broadly classified into severe risks, nominal risks, and risks with negligible probability.

Medical legal experts at the Mayo Clinic believe that informed consent is required for all severe risks such as death, paralysis, and loss of cognition, even if the probability is low. They also state that nominal risks with low probability need not be disclosed (Patrick et al. 2008). It is generally supported that severe risks should be disclosed by explicit informed consent, but there is a conundrum regarding when an infrequent risk is so uncommon that it becomes negligible. For example, the Iowa Supreme Court ruled that only "material risks" be disclosed and that a 1 per 100,000 incidence of death from contrast reaction did not meet that threshold (*Pauscher v. Iowa Methodist Medical Center et al.* 1987).

An argument can be made that explicit informed consent is appropriate for oral contraceptives. This argument is based on the reasonable patient standard and proven severe cardiovascular risks of pulmonary embolism and stroke. Also supporting this argument are the risk of sexually transmitted diseases (STDs; by biological and behavioral mechanisms) and increased risk of malignant neoplasms of the breast, cervix, and liver. There are numerous less severe risks that can be considered side effects.

The converse argument, that oral contraceptives are a treatment that can be implicitly or casually consented, lacks support based on the medical literature and patient standard. Yet these medical treatments are often consented to implicitly and casually. Oral contraceptives involve significant risks, and it is reasonable that these be presented to patients by means of informed consent.

Medical Risks of Hormonal Contraceptives

Proponents for the use of hormonal contraceptives argue that the risks associated with pregnancy are greater than the risk of these synthetic hormones. This argument is not reasonable for informed consent when there is an effective and licit alternative, such as fertility awareness-based methods (FABMs) which will be discussed below.

There are a number of minor risks or side effects of hormonal contraceptives that should be mentioned but would not require explicit informed consent. These include mood swings, depression, headaches, breast lumps, abnormal bleeding, and nausea, which can resolve after a few months. Another effect of these drugs upon discontinuation is amenorrhea resulting in temporary infertility, which usually also resolves. The major risks of oral contraceptives involve the cardiovascular system and the increased risk of certain cancers.

Cardiac and Neurological Events

The reasonable patient standard would suggest that a severe or life-threatening risk should be mentioned unless it is a negligible risk. The risk of venous thrombosis is relatively severe and is not a negligible risk. The risk of venous thrombosis with hormonal contraceptive users is between three and six times that of nonusers, and the risk depends on the type of contraceptive (Tanis and Rosendaal 2003; de Bastos et al. 2014). Deep venous thrombosis is a treatable condition but can have severe consequences. A certain percentage of deep venous thromboses dislodge and cause pulmonary emboli, and a certain percentage of pulmonary emboli result in death. By one estimate, the overall risk of death in hormonal contraceptive users is 10.5 per million women years or about 1 per 100,000 per year (Blanco-Molina and Monreal 2010). This would be considered a negligible risk according to the Iowa Supreme Court ruling several decades ago (*Pauscher v. Iowa Methodist Medical Center* et al. 1987).

The venous thrombosis that can place an individual at risk of a pulmonary embolus usually occurs in the lower extremities. However, venous thrombosis can occur in other locations including the brain. This is also a treatable condition but can have neurological consequences. The other type of thrombosis that can occur is an arterial thrombosis. When this occurs in the carotid arteries or brain, it can result in a stroke. And when this occurs in the heart, it can result in a myocardial infarction.

Individuals with an underlying risk of clotting (thrombophilia), who smoke or have hypertension, and other factors carry a significantly higher risk of these cardiovascular events including deep venous thromboses, pulmonary emboli, strokes, and cardiac events (Tanis and Rosendaal 2003). Individuals can be screened for many of these by history and physical prior to being placed on hormonal contraceptives.

Mutations of the prothrombin gene and Factor V Leiden gene place individuals at high risk of cerebral vein thrombosis, causing stroke type symptoms and effects (Martinelli et al. 1998). However, screening tests for clotting disorders are not usually performed prior to placing a young woman on these drugs.

The risk of thrombosis also varies depending on the type of hormonal contraceptive used. It was the goal and hope that newer generation hormonal contraceptives would have less risk. The cardiac (heart attack) risks may have been reduced with the newer generations of oral contraceptives. However, the risks of venous and arterial thrombosis remain elevated with third-generation hormonal contraceptives with variation in risk depending on the dosage, type, and combination of estrogen and progestogen (Tanis and Rosendaal 2003; de Bastos et al. 2014; Kemmeren et al. 2002).

The risks of stroke and pulmonary emboli may still be considered infrequent in healthy individuals. The question to be asked is whether they are so infrequent that they would be considered negligible and therefore might not require explicit informed consent. An argument could be made that the combined risks of vascular thrombosis, pulmonary emboli, and stroke are not negligible. Individuals with underlying risk factors including smoking, hypertension, diabetes, and clotting disorders are at even more risk (Tanis and Rosendaal 2003), reinforcing the argument for explicit informed consent.

Cancers

The next category of risk that is pertinent to informed consent is the risk of cancer. These risks are difficult to quantify exactly and are slower in onset. These risks also depend on the type of hormonal contraceptive and the duration of use. Hormonal contraceptives are known to increase the risk of breast, cervix, and liver cancer (Cogliano et al. 2005). These risks depend on the type of hormones, age of the patient, and other risk factors. From an epidemiologic perspective, breast cancer is by far the most common of these cancers and therefore is the largest risk to the population and to certain individuals with other risk factors. Lung cancer is the second most common cancer in women (a distant second), and colon cancer is third. There is also evidence that hormonal contraceptives decrease the risk of ovarian and colon cancer. When the risk and benefits are discussed in the medical literature, the carcinogenic risks are often presented together as if they balance and offset each other, as some risks are

increased and others decreased. However, these “offsetting risks” calls for a closer analysis.

Historically, the risks of hormonal therapy became most apparent after the Women’s Health Initiative study. This multimillion dollar study was funded by the National Institutes of Health and was a fifteen-year project involving over 160,000 women aged fifty to seventy-nine starting in the 1990s. The purpose of this study was to determine the health effects of hormone replacement therapy, dietary modifications, and supplementation (calcium and vitamin D).

There were two primary arms of the study: a group with an intact uterus that received conjugated equine estrogen and medroxyprogesterone acetate and a second posthysterectomy group that received conjugated equine estrogen only. The first arm of the study (conjugated equine estrogen/medroxyprogesterone acetate) was stopped prematurely in 2002 because of an increase in cardiovascular disease including stroke, heart attacks, and pulmonary emboli. There was also a significant increase in invasive breast cancer in this period of time (Rossouw et al, 2002). This study of postmenopausal women offers some important insights into *how powerful hormones are and the diversity of effects*. But these results also offer insight into the effects of hormonal contraceptives in younger women.

It is commonly known that full-term pregnancies offer some degree of protection or decreased risk from breast cancer. Normal pregnancy protects against breast cancer because it causes a proliferation of breast tissue that culminates in normal breast development for lactation. Natural progesterone is partly responsible for this normal proliferation. Artificial progestins have been implicated as the potential cause of proliferation that results in increased risk of breast cancer from combined oral contraceptives (Grosse et al. 2009).

There is also evidence of some relative increase of advanced-stage breast cancer in younger women (Johnson, Chien, and Bleyer 2013). The reason for this increase is not clearly known. However, there are some relevant studies and data available on breast cancer and oral contraceptive use in younger women of reproductive age.

A recent large study in Denmark followed 1.8 million women of reproductive age for 10.9 years and 11,517 cases of breast cancer. This study showed a 20 percent increased risk of breast cancer with current and recent users of oral contraceptives. The risk was small with less than one year of use and increased to 38 percent with more than ten years of use (Mørch et al. 2017). The study also showed that

the increased risk persisted longer with greater durations of contraceptive use. Various combinations of oral contraceptives were included in this large study (Mørch et al. 2017). This study and others show the risk of oral contraceptives to be highest with recent use (Mørch et al. 2017; Beaber et al. 2014).

The commonly quoted risk of breast cancer from oral contraceptives is from a meta-analysis in *Lancet* in 1996. This article is one of the most frequently cited and also describes the average risk to be around 20 percent (Collaborative Group on Hormonal Factors in Breast Cancer 1996), similar to the overall reported risk in the Denmark study. The weakness of a meta-analysis is that this type of study is affected by the “stack effect.” This means that statistics reflect high risk and lower risk situations. An analysis from the Mayo Clinic looked more closely at the data published in *Lancet* in 1996. This analysis demonstrated an over 50 percent increase in risk among women who used oral contraceptives four or more years before their first full-term pregnancy (Kahlenborn et al. 2006).

Another investigator found that there was a significantly increased incidence of triple negative breast cancers in women under the age of forty-five using oral contraceptives at age twenty-two or later, and higher if usage started before age eighteen (Dolle et al. 2009). Triple negative breast cancers have a worse prognosis and are more difficult to treat.

These data suggest that oral contraceptives are associated with a significant risk of breast cancer in certain groups and circumstances. These include early age, before a first full-term pregnancy, and risk increases with duration of use (Dolle et al. 2009; Kahlenborn et al. 2006; Mørch et al. 2017). Breast cancer is a serious disease, especially if diagnosed at an early age and at an advanced stage.

There is also evidence that oral contraceptives increase the incidence of liver tumors and cancers (Giannitrapani et al. 2006). And oral contraceptives have been shown to increase the risk of benign hepatic adenomas. These benign tumors can hemorrhage in women with prolonged contraceptive use. Although uncommon, this complication of liver hemorrhage can be a serious event.

STDs and Other Risks

There is literature to support a relationship between oral contraceptive use and increased risk of STDs. Recent oral contraceptive use increases the risk of cervical cancer (International Collaboration of Epidemiological Studies of Cervical Cancer. 2007). The

human papilloma virus is a known cause of cervical cancer, and oral contraceptives increase the risk of cervical cancer in individuals with the HPV virus (Moreno 2002). There is also an increased risk of HIV among at-risk individuals who are taking oral contraceptives (Baeten et al. 2007). Because of the risks of STDs, at-risk individuals taking oral contraceptives are urged to also use protective measures to prevent STDs. The most commonly used method of protection (the condom) is an imperfect method and has a known failure rate with use by individuals at risk (Weller and Davis 2002).

There are other potential risks associated with oral contraceptives including risk of autoimmune disease, depression, and decreased absorption of certain vitamins and micronutrients. These may not meet the criteria for explicit informed consent but could also be mentioned as nominal risks.

There is sufficient evidence from the medical literature that the combined cardiovascular risks, cancer risks, and alterations in immunity constitute substantial risks that justify an informed consent, and possibly in the explicit form. There are a number of coexisting risk factors that can place an individual at high risk. Some of these are able to be discovered from a medical history, and others (congenital risk of thrombosis) require laboratory testing.

Patient Autonomy and Shared Decision Making

Modern culture has seen an increasing trend in patient autonomy. In terms of informed consent, this means increased patient involvement in medical decision making. This is a relatively new development in the history of medicine. For over 2,000 years of medical history, the beneficence model was predominant (Will 2011). This traditional model is based on the physician taking primary responsibility for treatment decisions.

The beneficence model has changed to a model in which there is greater patient autonomy and shared decision making. A primary criticism of shared decision making is that it may lead to increased tests and cost (Coulter 1997). On the other hand, providing more information can increase respect for the dignity of patients. When used appropriately, informed consent allows for the patient to exercise free will with full disclosure of benefits, risks, and alternatives.

Patient autonomy is balanced by the physician's ability to explain what is appropriate for the patient and depends on the personal nature of the physician/patient relationship (Entwistle et al. 2010).

There are potential problems when external influences, such as governmental, political, or institutional, dictate this relationship. The patient's dignity is respected by his or her ability to decide with informed consent and without coercion. The physician should also be able to exercise his or her free will and protect his or her conscience, in recommending or advising what is best for the patient. A violation of the physician's conscience from doing what is best for the patient, occurring from an outside influence, disrupts and harms the patient/physician relationship.

Autonomy also depends on the individual's ability to make prudent choices. Adolescence is a time when a more paternalistic role by the physician may be beneficial. Adolescents are susceptible to social pressures and misinformation. Adolescents are more vulnerable because they consider themselves to be invulnerable. This is a time when the informed consent may be an important tool to educate about the medical risks of oral contraceptives and can lead to a discussion of the ethical risks. In the case of contraceptives being used for menstrual disorders in the adolescent period, alternatives should be considered that involve less risk.

A current example of the value that our culture places on providing individuals with information is the "breast density legislation" that is sweeping the country. Currently, this legislation has been passed in over thirty states. This legislation requires that patients be informed if their mammograms show that they have increased breast density. Increased breast density is a moderate risk factor for breast cancer (McCormack and dos Santos Siva 2006). This demonstrates the trend in our culture to disclose not only severe risks and risk factors but also moderate risk factors. Hormonal contraceptive use may also be in (at least) a moderate risk category, taking into consideration all of the possible risks.

Moral and Ethical Risks of Contraceptive Use

The primary mechanism of oral contraception is to inhibit ovulation. Breakthrough ovulation may occur and there is potential for unintended pregnancies depending on the type and use of oral contraceptives (Baerwald and Pierson 2004). The secondary effects of oral contraceptives include alterations of the endometrium that may result in failure of the embryo to implant into the lining of the uterus or failure to maintain the early pregnancy (Larimore and Stanford 2000).

These secondary or postfertilization effects are potential abortifacient mechanisms of oral contraceptives and are a significant concern to people of faith and those who value human life including at its earliest stages. Ethical and moral risks do have significant relevance to these individuals, and this information may be an important part of the informed consent (Larimore and Stanford 2000).

Respect of patient autonomy includes respect for the personal preferences of patients according to their personal identity and values (Entwistle et al. 2010). The emphasis on autonomy and personal values suggests that providers should have at least some knowledge of the religious beliefs of their patients and consider the relevance of these beliefs in a conversation of medical treatments. Autonomy would, therefore, suggest that moral risks that contradict an individual's faith be discussed by and with the physician or provider.

When a Catholic is prescribed an oral contraceptive by their pediatrician, dermatologist, or gynecologist, it may be an opportunity for them to share with that provider their beliefs and the reasons for refusing contraceptives. An increasing number of young Catholics are informed and can express the principles of Theology of the Body. The principles of autonomy would suggest that providers should be open to this conversation and work with patients in the context of their faith.

Catholic physicians and institutions have a higher duty to educate Catholic patients and their fellow physicians regarding the moral and medical risks of hormonal contraceptives. The position of the Church is clearly stated in the *ERDs of the Catholic Church* (USCCB 2009, dir. 52). Statistics show that many Catholics take hormonal contraceptives. Education for Catholic patients can start with a conversation on the medical risks of contraceptives. Modern culture values science highly, and informed consent can be an opportunity to discuss the lower risks and advantages of FABM (also known as natural family planning). Data show that only 1–2 percent of US women use natural family planning, but a significant percentage may be interested if presented the alternative (Stanford, Lemaire, and Thurman 1998). If time were taken to give informed consent, the use of FABMs might be significantly higher.

Irrespective of belief systems, the informed consent is an accepted method to explain the risks of oral contraceptives and the alternatives of ethical fertility care. Besides having low medical risk, FABMs offer additional benefits over contraception.

Applying the Principle of Informed Consent and Ethical Fertility Care

The purpose of informed consent is to give the patient information on the proposed treatment and alternatives. FABMs are the licit alternatives to hormonal contraception and other method of contraception, such as barriers or intrauterine devices. FABM is the only licit method of family planning. Ethical fertility care is completely open to life, as evidenced by the fact that it is also an effective method for achieving pregnancy. Pope St. John Paul II (1981) clearly stated the differences between contraception and ethical methods as “two irreconcilable concepts of the human person and of human sexuality” (no. 32).

The most significant medical advantage of FABM over hormonal contraceptives is that ethical fertility care has no medical risks or side effects. In regard to a legal informed consent, the only other valid discussions are regarding the effectiveness of FABM versus oral contraceptives. Another significant advantage is the cost, with minimal cost for FABMs.

Studies of contraceptives' effectiveness attempt to determine the unintended pregnancy rates according to correct (perfect) use and typical use. Oral contraceptives have a very low failure rate with perfect use (0.3 percent) and up to a 9 percent failure rate with typical use (Trussell 2011).

The published effectiveness of FABM is somewhat variable and depends on the method used. However, the effectiveness has improved significantly in recent decades. The Creighton Model and the Billings Ovulation Method depend mostly on cervical mucus evaluation. A meta-analysis of the Creighton Model showed an effectiveness of over 99 percent for correct use and over 96 percent for typical use (Hilgers and Stanford 1998).

Other studies have shown a similar high effectiveness of the sympto-thermal method of FABM. This method uses assessment of cervical secretions, basal body temperature, and historical cycle information. The sympto-thermal methods have been shown to be effective in different cultures and socioeconomic groups, with perfect use, unexpected pregnancy rates at 1–3 percent (Pallone and Bergus 2009). One study of over 19,000 women in India showed an unexpected pregnancy rate under 1 percent (Ryder 1993).

Methods developed since 2000 include the two Georgetown programs, the Standard Days Method

and the TwoDay Mucus Method, which are 95 percent and 96.5 percent effective (Arevalo, Jennings, and Sinai 2002; Arevalo et al. 2004). The Marquette Method of FABM teaches couples mucus observations, basal body temperature, and estrone/luteinizing hormone testing and has 98 percent perfect use effectiveness (Fehring, Raviele, and Schneider 2004).

These studies demonstrate that the effectiveness of modern natural family planning techniques is comparable to oral contraceptives. These methods are a safer alternative and should be included in an informed consent.

FABM has additional benefits to families and society. These methods foster communication and cooperation between spouses and, therefore, support both the unitive and procreative goodness of marriage. Natural family planning has been shown to strengthen marriages, and there is strong evidence for this. Couples who practiced natural family planning in the 1990s had a fraction of the divorce rate in the United States during that same time interval (Mercedes 2002).

A relatively small percentage of U.S. women use FABM despite the benefits, effectiveness, and low risks of these methods. There are several reasons for this. There is inadequate information and often misinformation regarding the effectiveness of FABM. Most patients are not made aware of this alternative. In a mailing to female patients, one study found that 43 percent of patients were interested in learning more and over 20 percent were likely to use natural family planning (Stanford, Lemaire, and Fox 1994).

The informed consent is also an important tool to explain the risks of oral contraceptives to the unmarried, including young adults and adolescents. In this case, the only licit alternative is abstinence. Our modern culture promotes "safe sex" including contraceptives for adolescents. Many adolescents and young women are not aware of the risks of hormonal contraception. They also are not aware of the pregnancy rate and rate of transmission of STDs using barrier methods. Therefore, the promotion of "safe sex" is misleading. The informed consent may allow an opportunity for educating the unmarried, perhaps especially adolescents and young adults, regarding these risks and may be an opportunity for further dialogue.

Informed consent is a formal tool, but also a principle with increasing patient interest and supported by trends in modern medicine. Even without a formal document, informed consent is implicitly utilized in the physician/patient relationship. Because of the significant risks versus benefits comparing

oral contraception and FABM, an explicit informed consent that discusses the medical risks along with the personal values of Catholic and Christian patients should be supported by the medical community.

Conclusion

Fifty years ago, Pope Paul VI (1968) correctly predicted the dangers of contraception including "marital infidelity and general lowering of moral standards," loss of respect for women, and the dangers of placing the power of contraception in the hands of "public authorities who care little for the precepts of the moral law" (no. 17). *Humanae vitae* was written at the time of the "sexual revolution," and development of contraception was considered by many to be an emancipating event.

Since the time that *Humanae vitae* was written, much has been discovered regarding both the cultural and personal risks of hormonal contraception. It was not until after oral contraception was widely utilized that many of the medical risks were published. Information regarding risks continues to be discovered and is available in the medical literature, but is not widely publicized.

The data in the medical literature can support an informed consent on the basis of the scientific evidence. This consent can be either a verbal (implicit) consent or a more formal explicit consent when there are significant high risk factors. The use of the informed consent is an effective means of providing patients with pertinent information on the risks of contraception; along with the benefits of the only licit alternatives, which are FABM for married couples and abstinence for individuals who are unmarried. Society values scientific evidence and autonomy. Both of these cultural trends support providing patients with this information. In addition to hormonal contraceptive risks, informed consent is a tool that could be used to educate patients on important bioethical issues and ethical risks.

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