

Should Women Opt for “Natural” or “Artificial” Family Planning and Birth Control

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Received: February 08, 2020; **Published:** June 26, 2020

Abstract

Background: For many years now, the importance of family planning has been elucidated from a medical as well as economic perspective. The latter highlights the advantages for the taxpayer, the former investigates whether the benefits of contraception outweigh in fact the risks of a pregnancy. Women who are persuaded by the arguments that unintended pregnancy and abortion should be averted have to make difficult decisions regarding suitable methods for family planning and birth control.

Aim: The aim of the present study is to assist women in their decision-making process regarding the personally most suitable method of family planning and birth control. In pursuing this aim it analyses the most important presently available methods by underscoring safety. To clarify the concept “safety” for family planning and birth control it draws attention to adverse events, risks, and potential complications. The emphasis on safety aims at enabling women to assess each possible method critically in accord with principles of personalized medicine.

Material and Method: The method consists in an analysis of the various contraceptive possibilities with respect to safety and efficacy. This analysis is guided by the principles of “nil nocere” (no harm) and “informed consent”. The former emphasizes safety, the second completeness of information for each woman. The material analysed comprises publications gathered from the most influential and authoritative sources, i.e. WHO, U.S. FDA, U.S. CDC, Planned Parenthood, the most renowned international research institutes and top-ranked scientific journals.

Results: Women who prioritize safety in their contraceptive pursuits are advised to engage in natural methods of family planning which have to be implemented with strict compliance in order to achieve perfect use estimates. Women who value efficacy more than safety are advised to carefully consider adverse events, risks and potential complications. In these considerations they should avail themselves of reliable sources of information and avoid unreliable sources, such as those proposed by the U.S. Food and Drug Administration (FDA), the U.S. CDC, Planned Parenthood, misleading social media, and publications by authors declaring conflicts of interest. In their search for trustworthy information, they should consult such sources as Contraceptive Technology, evidence-based publications by the World Health Organization (WHO), the “Safety-based Summary of Contraception/Synoptic Overview of Contraceptive Methods” of 2020 (contained in this article) and ongoing research in pharmacovigilance and pharmaceuticovigilance.

Keywords: *Family Planning; Birth Control; Decision-Making Process*

Introduction and Methodology

The importance of family planning and birth control can be appreciated owing to studies that focus not only on health-related problems but also on socio-cultural and economic aspects of birth control and contraception. Studies devoted to the economic benefits of family planning claim: “...every \$1 spent on public funding for family planning saves taxpayers \$3.74 in pregnancy-related costs” [1, p. 364].

In health-related publications emphasis is placed on the assumption that contraceptive methods are suitable means for preventing unintended pregnancy and for averting ensuing abortions. The need for contraceptive measures has been repeatedly emphasized, and in 2017 one of the leading medical journals drew attention to statistical findings indicating that the US had a higher percentage of unintended pregnancies than Western Europe: “However, the most recent U.S. data still indicate that 45% of all pregnancies in the United States are unintended, as compared with 34% in Western Europe [2, p. 461].

Despite numerous arguments advanced to underline the benefits of contraceptive measures, a considerable percentage of women abstain from implementing such measures. In 2012, a US health statistics report observed that 38% of women are not engaging in contraceptive pursuits [3].

The reasons for which women abstain from contraception and birth control have not yet been illuminated by reliable health statistics. Based on clinical experience, it can be hypothesized that these reasons involve health-related concerns, fear of harm, religious beliefs or doctrines, sociocultural traditions, and others. Most importantly, women planning to engage in contraceptive pursuits have to make difficult decisions, especially about the method which seems best suited for them personally given their age, marital status, career plans, sociocultural background and other factors.

In choosing an appropriate method the basic distinction between natural and artificial methods should be considered. The natural methods for women comprise essentially only the symptothermal, the cervical mucus, the temperature, the calendar (rhythm), and the lactational amenorrhea method. The artificial methods, on the other hand, encompass a wide array of options, and can be classified into barrier methods (spermicide, vaginal diaphragm or vaginal sponge, cervical cap, female condom, vaginal rinsing), hormonal methods, interceptive (morning-after pill), intrauterine devices, and definitive contraception (sterilization for women); besides these options for women there are possibilities for male contraception, namely GnRH (Gonadotropin Releasing Hormone) analogue, Gossypel, coitus interruptus, condom and definitive contraception (ductus deferens ligation and section) [4, p. 61-87].

Safety-the most valued asset of natural methods

As can be seen from manufacturers’ product descriptions and publications by the FDA or other health agencies, efficacy and safety are the most salient parameters for the users of products for contraception and birth control. Ideally, women would prefer highest safety coupled with highest efficacy. Thus far, however, it has not been possible to endow the most effective methods with the highest degree of safety. What has been made possible, however, is a comprehensive overview of all available methods with emphasis on safety. This possibility exists now owing to the recently developed “Safety-based Summary of Contraception (SSC),” a synoptic overview of contraceptive methods (SOCM), which is shown in table 1.

Method	Safety (no harm in the sense of “nil nocere”)	Efficacy Perfect-Non-perfect use	Satisfaction [% of women continuing after one year] Convenience	Cost and Specifications
Symptothermal (measure body temperature and observe cervical mucus)	High	0.4 - 24	High	No cost. Cervix palpated has soft consistency and is open.
Ovulation (based on cervical mucus).	High	3 - 24	High	No cost. Observe cervical mucus (“spinnbarkeit” indicates fertile period).
Two Day (based on cervical mucus) Fertility not to be assumed after 2 consecutive “dry” days (or absence of secretion).	High	4 - 24	High	No cost. Fertile days to be assumed when cervical mucus is present (watch color and consistency).
Standard Days Method (SDM) – based on calendar (to track fertile period).	High	5 - 24	High	No cost. Fertile period usually days 8-19 of each 26-32 day cycle.

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Basal Body Temperature (BBT) Fertile period has passed when body temperature has risen (by 0.2-0.5°C) and remained such for 3 days.	High	1 - 25	High	No cost. Does not predict end of fertile period, but conception is unlikely from the 4th day following rise of temperature (until next period).
Calendar (rhythm) method Monitor menstrual cycle for at least 6 months by using calendar.	High	9 - 25	High	No cost. Check calendar to find shortest cycle and subtract 18: this is the estimated FIRST fertile day. Find longest cycle and subtract 11: this is the estimated last fertile day. Caution with drugs such as NSAID, antibiotics, anxiolytics, anti-depressants, and others (consult physician).
Withdrawal (coitus interruptus)	High	4 - 22	46% High	Semen must be discharged outside the vagina.
Lactational Amenorrhea (LAM) Requires breastfeeding day and night of infant less than 6 months old.	High			Effective in preventing ovulation as long as monthly bleeding has not yet resumed.
Male condoms Latex allergy possible.	Moderate	2 - 18/ 43%	43% High	Low cost. Protects against sexually transmitted diseases (STD) including HIV.
Implant (Small, flexible rod or capsule placed under the skin of the upper arm; contains progesterone hormone only).	Moderate Incorrect placement is possible, device can break or travel to pulmonary artery. Irregular vaginal bleedings common.	0.05 - 0.05	84% High	High cost. Has to be implanted by clinician.
Mirena (LNG) Intrauterine device (IUD) (T-shaped plastic device inserted into the uterus; releases continuously small amounts of levonorgestrel).	Moderate Pelvic inflammatory disease (PID) common, ascending infection and expulsion possible.	0.2 - 0.2	80% Moderate	High cost. Prevents contact between sperm and egg by thickening cervical mucus. Amenorrhea common.

ParaGard (copper IUD)	Moderate	0.6 - 0.8	78% Moderate	High cost. Copper component damages sperms.
Depo-Provera	Moderate	0.2 - 6	56% Moderate	High cost.
Combined oral contraceptives (COCs)= “the pill”	Moderate	0.3 - 9	67% Moderate	Moderate cost. Contains estrogen and progesterone.
Progestogen-only pill (POP) or “minipill”	Moderate	1 - 3 (10)	67% Moderate	Moderate cost. Thickens cervical mucus and prevents ovulation.

Evra patch	Moderate	0.3 - 9	67% Moderate	High cost.
NuvaRing	Moderate	0.3 - 9	67% High cost	
Combined contraceptive patch and combined contraceptive vaginal ring (CVR)	Moderate	1 - 8	Low	High cost. Continuously releases progestin and an estrogen directly through the skin (patch) or from the ring. Pharmacokinetic profile similar to COCs. (Research on efficacy limited).
Monthly injectables or combined injectable contraceptives (CIC)	Moderate Irregular vaginal bleeding	1 - 3	Low	High cost. Injected monthly into muscle.
Progestogen-only injectables	Moderate Irregular vaginal bleeding; delayed return to fertility after use.	1 - 3	Low	High cost. Injected into muscle or under skin every 2 to 3 months (depending on product)
Diaphragm Must be used for each coitus.	Moderate	6 - 12	57% Low	High cost.
Emergency Contraception (EC) Pills ulipristal acetate 30 mg or levonorgestrel 1.5 mg should be taken twice to prevent pregnancy up to 5 days subsequent to coitus.	Moderate - Low	1 - 15	High	Moderate cost. Instead of pill IUD (copper or levonorgestrel) can be inserted.

Male sterilization (vasectomy)	Moderate Adverse events and risks associated with surgery.	< 1 (after 3-months semen evaluation). 2 - 3 (without semen evaluation).	100% High	High cost. Permanent contraception due to cutting vas deferens tubes (which transport sperm from testicles).
Female sterilization (tubal ligation) Permanent contraception (due to blocking or cutting fallopian tubes).	Low Adverse events and risks associated with surgery.	0.5 - 0.5	100% High	High cost. Surgery required.
Sterilization through creation of scar tissue (ESSURE)	Very low		Low	Device has been withdrawn from the market in several countries, including the U.S.
Sponge	Moderate	20-24 (parous women) 9 - 12 (nulliparous women)	36% Moderate	Moderate cost. Must be used for each coitus.
Spermicides	Moderate	18-28	42% High	Moderate cost.

Table 1: Safety-based Summary of Contraception/Synoptic overview of contraceptive methods.

As can be seen, this overview ranks methods according to safety but provides also estimates for ranking methods according to efficacy. Owing to the emphasis on safety it will be of greater interest to many women than the other most frequently consulted surveys, overviews, charts, and tables, such as the Contraceptive Failure table (CF Table) propounded by Contraceptive Technology in 2011 [5], the WHO's overview of 2017 entitled “Effectiveness to prevent pregnancy” [6], the WHO's Family Planning Handbook [7], the FDA's Food and Drug Administration (FDA) Approved Methods of Birth Control of 2013, [8] the FDA's Birth Control Chart of 2018 [9], the CDC's Effectiveness of Family Planning Methods of 2016 [10] or the CDC's Medical Eligibility Criteria of 2018 [11].

Vital and reliable data contained in the above mentioned ratings and rankings are incorporated in the Safety-based Summary of Contraception (SSC)/Synoptic Overview of Contraceptive Methods (SOCM) so that its comprehensiveness is an additional aid for consumers who seek accurate, complete, and comprehensible information. Due to its synoptic character, it remedies shortcomings of the CT Failure Table [5] which does not rank methods, does not mention adverse events, and uses obsolete data for the typical use efficacy of Fertility Awareness-Based Methods. The SSC, on the other hand, ranks methods according to safety, highlights adverse events and includes descriptions of the salient features of each method. In comparison with the FDA chart, the SSC provides precise figures for the efficacy of each method, specifies in detail adverse events, and lists also the natural methods, which are ignored by the FDA.

The most distinctive feature of the of SSC - the priority of safety -- is the result of recent publications which draw attention to the commonly neglected parameter safety [12-16]. The wide-spread neglect of safety became a topical issue recently when women worldwide experienced harm due to the use of a contraceptive device declared as “safe” and approved by the FDA in 2002. The harmful effects of this “safe” device and the ensuing forensic reverberations have been cogently commented by the US press: “The implant has had a troubled history. It has been the subject of an estimated 16,000 lawsuits or claims filed by women who reported severe injuries, including perforation of the uterus and the fallopian tubes. Several deaths, including of a few infants, have also been attributed to the device or to complications from it [17]. Similar reports emanated from Australia: “The device, known as Essure, is a soft, flexible insert placed into each of the patient's fallopian tubes. But there have been reports women experienced changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergic reactions and immune-type reactions after being implanted with the device, which is manufactured by the pharmaceutical company Bayer [18].

Despite the emphasis on safety in recent publications and in the SSC, consumers will encounter numerous sources of information which fail to acknowledge the importance of this vital parameter for birth control and family planning. Regrettably among the institutions and agencies which provide only vague and unreliable information on the safety of contraceptive products are some of the most influential and authoritative. The fundamental problem is the absence of an evidence-based definition of safety in most publications and documents. Consequently, claims about safety are unverifiable and the dissemination of flawed arguments concerning safety is meanwhile beyond control. Why some of the most influential and authoritative institutions must be disqualified as reliable sources of information can be seen from the following analysis.

The dilemma of elusive promises in favor of artificial methods and the disregard for natural methods

Among the institutions and agencies which fail to define safety in an unambiguous fashion the FDA must be mentioned in first place because millions of consumers take it for granted that the FDA as highest authority in matters of food and drugs is reliable. Unfortunately, the FDA does not stand up to these expectations because its most recent Chart of Birth Control Methods [9] is incomplete, mentions only few and trivial adverse events, and presents data on efficacy which make it impossible to distinguish the most effective methods from those that are less effective [9]. Like its predecessor - the “FDA Approved Methods of Birth Control” of 2013 [8]- the new chart of 2018 fails to address the parameter safety. Instead, it contains only a superficially and simplistically formulated rubric entitled “some risks or side effects.” Unfortunately, this rubric is incomplete and imprecise. Thus, for intrauterine devices, the most feared complications -- namely pelvic inflammatory disease (PID), perforation, and expulsion - are not mentioned.

Rather, the consumer is informed solely about: “Irregular bleeding. No periods (amenorrhea). Abdominal/pelvic pain” [9]. For implants, there is no indication of the risk of dislocation and migration to the pulmonary artery or of breakage of the device already during insertion; instead only trivial symptoms, commonly attributed to oral hormonal contraceptives are mentioned “Menstrual Changes. Mood swings or depressed mood. Weight gain. Headache. Acne” [9]. The device ranked in second place and described as sterilization is no longer available because it has been withdrawn from the market in 2018 by the manufacturer due to thousands of lawsuits and complaints by women worldwide who had experienced severe harm caused by the device [17].

Besides describing a device that is no longer available on the market due to severe harm experienced by thousands of users, the FDA chart suffers from another fundamental flaw, namely lack of precision regarding efficacy. The imprecise data on efficacy are extremely misleading because the terminology used “less than one” makes it impossible for the consumer to perceive that implants are far more effective than other methods. While the estimates presented by Contraceptive Technology [5] and the WHO [6] clearly indicate the superiority of implants (owing to an estimate of 0.05) and the inferiority of intrauterine devices (due to an estimate of 0.89) the FDA chart does not allow to recognize the absolute superiority of implants. Obviously, the FDA chart misleads the consumer into believing that there is no difference in efficacy between implants and intrauterine devices. Therefore, women are at risk to choose inappropriate methods, and quite several of them might incur harm because they could not identify the most effective among all the methods due to the unscientific designation “less than one” chosen by the FDA.

The risk of choosing an inappropriate method is prevalent also due to another flaw in the FDA chart, namely the omission of natural methods which are commonly included in surveys, as can be seen from the WHO survey [6] and the Contraceptive Technology table [5]. The natural methods omitted are internationally acknowledged and belong to the safest of all methods [4]. The importance of these natural methods particularly for women who do not tolerate hormones or devices has been highlighted in frequent publications, including the one by the American Congress of Obstetricians and Gynaecologists (ACOG). In these publications the ACOG rectifies previous comments and emphasizes the advantages of the Fertility Awareness-Based Methods, namely low cost and the absence of adverse events caused by medications: “They cost very little... Many women like the fact that fertility awareness is a form of birth control that does not involve the use of medications or devices” [19]. Another area where these methods are appreciated is research on HIV. In an investigation on serodiscordant couples, the Fertility Awareness Methods (FAM) appeared as particularly suitable, and the authors concluded: “FAMs provide effective, economical, and accessible options for HIV serodiscordant couples to conceive while minimizing unnecessary viral exposure” [20].

By omitting these methods also in its latest chart of 2018, the FDA violates again - as in the 2013 published survey [8] - the principle of informed consent and denies women the right to self-decision [21]. As is known, this principle requires completeness of information so that the patient is enabled to make “an intelligent choice” [22]. It is obvious that the FDA chart does not enable women to make an intelligent choice because they are lacking vital information about several methods which are not only the safest but range in perfect use efficacy higher than some hormonal methods, namely from 0.8 (symptothermal) to 4 (Standard Days Method). In failing to provide complete information on safety and on efficacy, the FDA not only ignores the fundamental bioethical principle of *nil nocere* (no harm) but also infringes on civil law.

From an economic viewpoint the question arises what kind of costs for the taxpayer result from medical treatments due to harm caused by an inappropriate method. A similar question concerns the economic damage resulting from the distribution of thousands of error-prone free publications for consumers as well as the payroll costs for incompetent federal employees who disseminate flawed science. The burden for the taxpayer resulting from the distribution of misleading information comes to the forefront also in other surveys and rankings, such as the one presented by the Centers for Disease Control (CDC) [10] and Planned Parenthood [23]. The CDC fails to make the distinction between typical and perfect use, a distinction that is crucial to recognize the most effective of the natural methods. Because of this failure, women are unable to identify the symptothermal method as the most effective among the Fertility Awareness-

Based Methods (FAM). Unfortunately, this method is omitted not only in the CDC’s ranking entitled “Effectiveness of Family Planning Methods” of 2016 [10] but also in its latest “MEDICAL Eligibility Criteria (US-MEC)” of 2017 [11]. In its ranking entitled “Effectiveness of Family Planning Methods” [10] the CDC comments on the fertility awareness-based methods: “Fertility awareness-based methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and Two-day Method) may be the easiest to use and consequently more effective” [10]. Instead of drawing attention to the symptothermal method as the most effective of these methods with a perfect-use estimate of 0.4 (according to Contraceptive Technology [5]) and a Pearl Index of 0.8 (according to German research [4]) the confusing terminology “newest methods” is introduced. The same terminological idiosyncrasy appears also in the latest US Medical Eligibility Criteria (US-MEC) for Contraceptive Use (last reviewed February 1, 2017) [11]. In this document the CDC employs again a confusing and idiosyncratic terminology by introducing the neologisms “Symptoms-based” and “Calendar-based” methods: “Methods: Fertility awareness-based methods, including symptoms-based and calendar-based methods”.

Clarifications/evidence/comments [11]

As the CDC fails to identify the methods belonging to these two categories, it is unresolved which methods are at stake. The consumer might be even more perplexed by the confusing nomenclature, if she/he is familiar with the standard classifications in international scholarship which do not classify methods as “calendar-based” or “symptoms-based” but distinguish clearly between each one of them and their proper efficacy, namely the symptothermal, the temperature, the cervical mucus, and the calendar method -- which are known also as Periodic Abstinence Methods [4,23].

The terminological redundancy inherent in the CDC’s MEC classification becomes particularly patent if one considers that the symptothermal method owes its high perfect use efficacy to the use of a calendar. According to the CDC this method would be both a symptoms-based and a calendar-based. The confusing nomenclature used in the CDC classification makes the primary target of taxonomies even more difficult, namely the characterization of each individual method including the proper estimates for typical and perfect use.

The improper classification of natural methods and the emphasis on artificial methods in the latest CDC’s Medical Eligibility Criteria [11] might be due to the influence of economic interests. As can be seen from a section entitled “Conflicts of Interest for Invited Meeting Participants, August 26 - 28, Atlanta, Georgia” the declaration of competing interests abound. In this section an astonishing number of participants must declare competing interests as recipients of grants, stipends and various other financial incentives. Given the bias generated by financial gains it is obvious for the consumer that participants will place emphasis on pharmaceutical products and not on natural methods which do not involve chemical substances.

The question of trustworthiness arises also in conjunction with information provided by Planned Parenthood. In its original chart [24] the FAMs are omitted without any further explanation. In its new chart entitled “Comparing Typical Effectiveness of Contraceptive Methods” however, Planned Parenthood discusses the natural methods in a section entitled “Fertility Awareness-Based Methods” [25]. Although Planned Parenthood explains accurately some salient features of the FAMs it discredits them altogether by claiming that they “don’t work as well” as other methods “because they can be difficult to use” [25]. And in promising more effective methods, Planned Parenthood draws attention to IUDs and implants: “Fertility awareness methods don’t work as well as other types of birth control because they can be difficult to use. Want a more effective way to prevent pregnancy? Check out IUDs and implants [25].

While it is true that fertility awareness require a considerable amount of discipline it is an unverifiable claim that these methods “don’t work as well as other types of birth control.” Some of these methods have a higher perfect use efficacy than commonly used artificial methods. Concerning difficulty in using these methods it should be noted that modern technologies, i.e. cycle-computer and measuring-sensor, greatly facilitate their use.

With respect to the Planned Parenthood’s recommendation to use intrauterine devices and implants one must bear in mind that both intrauterine devices and implants are causally related to severe adverse events and that their placement - which entails additional risks -- requires the intervention by a specialist.

Given its disregard not only for adverse events, but also for complications and potential risks, the Planned Parenthood chart is an eloquent example of how women are misled into believing that efficacy is the sole parameter in choosing a suitable method of birth control. Similarly, misleading are many of the hundreds of charts available which perpetuate flaw and error, as can be seen from the summary provided by the WHO [26]. Unfortunately, experience has shown that the neglect of adverse events, complications and potential risks can have lethal consequences; and pharmaceutical companies have good reason to alert the users accordingly in their Instruction for Use or Consumer Leaflets.

To exacerbate the dilemma for women, misleading information is disseminated not only by health agencies and institutions, but also by scholarly publications. The most noteworthy attempt to mislead women into neglecting adverse events is a publication in one of the world’s leading medical journals. In a widely disseminated article on Long-Acting Reversible Contraception (LARC) published in 2017, the authors hail implants and intrauterine devices due to their efficacy and safety: “All adolescents and adult women should be informed about the availability of LARC methods, given their extremely high effectiveness, safety, and high rate of continuation [2, p. 467].

What the authors do not mention, however, is a publication that had appeared four years previously and demonstrated the inadequacies of the very devices they recommend for “all women” in 2017. In fact, in 2013 Belgian authors drew attention to the shortcomings of the conventional intrauterine devices, namely “increased expulsion rates, complaints of pain and erratic or increased menstrual bleeding, and subsequent high rates of discontinuation [27, p. 215].

To remedy the inadequacies of conventional devices, a new device was developed by a Belgian manufacturer who emphasizes some of the improvements: “GyneFix differs from conventional IUDs by its very small size and because it has no frame which makes it completely flexible [28, p. 2]. It must be noted that it is evidence-based research on measurements of the uterine cavity that led European authors to the conclusion that the devices hailed by the US authors can cause serious harm to their users.

As can be seen from these controversial assessments of intrauterine devices, consumers have good reason to distrust also information contained in scientific publications. Increasingly, such publications are adulterated by conflicts of interest, and authors must admit that they were recipients of financial incentives from pharmaceutical companies whose products they discuss in their publications. Given the serious lack of reliability of an increasing number of scientific publications, the consumers are advised to turn to research that is still trustworthy, namely pharmacovigilance and pharmceuticovigilance.

Can pharmacovigilance and pharmaceuticovigilance

Raise awareness for risks inherent in artificial methods of contraception?

Over the years, pharmacovigilance has brought to light adverse events, risks, and potential complications not mentioned by pharmaceutical companies in their “Instructions for Use,” “Consumer Leaflets,” or “Packaging Labels”. In 2018, the problem of leukemia in children of mothers taking hormonal contraceptives has been described as a “...biological plausibility, on the basis of evidence that hormonal exposure in utero causes cancer in children” [29].

In the same year, the risk of depression and suicidal action owing to hormonal contraception has been emphasized by the European Medicines Agency (EMA): “Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behavior and suicide” [30].

Oral hormonal contraceptives have been identified also as causally related to increased intraocular pressure and the associated risk of blindness: “The association between female sex hormones and intraocular pressure (IOP) changes has long been known. However, reports on the increased risk of open angle glaucoma in females taking oral contraceptive pills for three years or more is a recent finding, which requires further studies to probe the causal association between estrogen, progesterone, and rise in IOP” [31, p. 51].

Studies devoted to hormonal contraceptives have illuminated also their impact on the quality of life [32] and the increased risk of breast cancer has been highlighted by press reports [33].

Artificial methods are at the core of research also in pharmaceuticovigilance, a discipline which aims at rectifying error, inaccuracy, and ambiguity in documents generated by pharmaceutical companies destined to inform the consumer about their products. The most recent findings in pharmaceuticovigilance pertain to a device -- named Essure -- for permanent contraception through sterilization, approved by the FDA in 2002 and withdrawn from the US market in 2018 after previous removal from the Australian market in 2017.

The manufacturer of Essure provides information in two documents, namely in a 51-page “Instructions for Use,” copyrighted in 2002, and in a “News Release” of 2018 announcing the withdrawal from the US market “for business reasons” [34,35]. Although the manufacturer endeavours to provide comprehensive information on the device and mentions also the life-threatening risks of an anaphylactic reaction and of an ectopic pregnancy, explanations concerning the mechanism of action are inadequate. The manufacturer uses a terminology that is confusing not only for consumers but also for specialists because the process of “eliciting” a benign tissue “ingrowth” lacks a scientific basis: “Subsequently, the insert elicits a benign tissue in-growth that permanently occludes the lumen of the fallopian tube, resulting in permanent contraception” [35, p. 1]. In a different context PET fibers, i.e. “polyethylene terephthalate (PET) fibers”, are described as instrumental for tubal occlusion and tissue in-growth [34, p.4]. According to the manufacturer, these fibers cause tissue ingrowth which facilitates not only retention of the device but also tubal occlusion. “Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention, resulting in tubal occlusion and contraception” [34, p. 4].

As it is unclear from a physiological and biochemical viewpoint how the device can “elicit” a “benign” tissue ingrowth, different processes have been proposed, such as an inflammation and ensuing fibrotic growth. “The small, flexible inserts are made from polyester fibers, nickel-titanium, stainless steel and solder. The insert contains inner polyethylene terephthalate fibers to induce inflammation, causing a benign fibrotic ingrowth” [36]. Press reports too circumvented the ambiguous terminus “in-growth” and mentioned “scar” tissue, i.e. tissue which results from a wound inflicted to healthy tissue. “Essure consists of two nickel-titanium coils inserted into the fallopian tubes, where they spur the growth of scar tissue that blocks sperm from fertilizing a woman’s eggs” [17].

Besides improper information provided by the manufacturer of Essure, pharmaceuticovigilance has revealed also inadequacies in publications on two other artificial methods, namely Emergency Contraception (EC) and Female Condom (FC). In various publications, these two methods have been highlighted due to several advantages. EC has been described as the most convenient method of birth control because it does not require the burden of daily administration of oral pills [37]. In fact, women with restricted sexual activity who engage in sexual intercourse no more than once a month will be able to use EC as a standard method of contraception. However, as ulipristal acetate is a progestin receptor modulator which has an impact on the process of nidation, the question of abortogenicity for ulipristal acetate has not yet been resolved [38].

Besides the possibility of oral EC pills, the insertion an intrauterine device has been recommended to prevent pregnancy a-posteriori. However, the adverse events associated with intrauterine devices and above all the lethal consequences in case of an ectopic pregnancy are routinely discussed by manufacturers [39]. Thus, for the levonorgestrel containing IUD common side effects include discomfort, expulsion, missed menstrual period, changes in bleeding, and cysts on the ovary. Concerning Pelvic Inflammatory Disease (PID), life-

threatening complications are admitted: “PID is usually treated with antibiotics. More serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death” [39, p. 32]. Regarding perforation, the loss of efficacy and the serious consequences of dislocation are specified: “If your uterus is perforated, Mirena may no longer prevent pregnancy. It may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Mirena removed” [39, p. 32].

Besides Emergency Contraception, the Female Condom has been recommended owing to several advantages. In fact, this device does not involve hormones and is composed of a material without risk for allergies. One of the most authoritative institutions, the May Clinic, underscores the benefits by specifying: “Is immediately effective. Offers protection from sexually transmitted infections. Is available without a prescription or special fitting. Can be inserted up to eight hours before sex. Rarely causes allergic reactions and has minimal risk of side effects. Doesn’t require a partner’s cooperation or an erect penis as the male condom does” [40]. In the same vein, the manufacturer of FC2 underlines among other advantages the material used: “FC2 contains a silicon-based lubricant does not contain spermicidal additives, preservatives, paraben and is gluten free” [41].

In contrast to this emphasis on benefits of the FC2, the FDA has published “Safety and Effectiveness Results” where adverse events were collected from “the coital logs and exit interviews”. The “adverse effects reported in the RHRU Study” included discomfort during insertion, discomfort after insertion before sexual intercourse, pain after insertion previously to sexual intercourse, pressure/urge to urinate, discomfort during sexual intercourse, uncomfortable to use, burning/ itching and bleeding [42].

Earlier, at the time of the approval in 1993, the FDA’s statement draws attention to a relatively high pregnancy rate among users, uncertainties about efficacy and protection against HIV - which should be exercised more propitiously with the help of latex condoms for men: “The Food and Drug Administration approved the first so-called female condom on May 7. Despite limited data on the effectiveness of the Reality Vaginal Pouch in sexually transmitted diseases (STDs) and a relatively high pregnancy rate among users, the device was approved because it is the first barrier contraceptive for women that provides some protection against STDs. The label will be required to emphasize that for “highly effective protection” against STDs, including AIDS, latex condoms for men are the best choice” [43].

As can be seen in this statement issued by the FDA, despite the frequent use of the terminus safety, there is no clearly defined concept of this parameter. One of the futile attempts to define safety can be found in a publication devoted to EC. In this publication of 2016, the authors proposed a definition of safety whose benchmark were death or a serious complication [38]. In contrast to this restrictive definition the present author defines safety in an extensive fashion with quality of life as a germane benchmark: “A product can be considered safe only as long as it does not cause more than a minor (moderate) but not major impact on the user’s quality of life”.

Regarding the problem of safety it should be noted that the importance of this parameter has become the object of numerous publications also in the popularizing literature [44]. In these publications women give testimony of their own sufferings resulting from hormonal contraception; and many of them recommend the switch to natural methods. Interestingly enough they report extremely satisfying efficacy with natural methods - a fact that contradicts the publications of several US health agencies where the efficacy of natural methods is commonly described as one of the most unsatisfactory [10,25].

Results and Implications

The foregoing discussion shows that the decision to engage in contraceptive pursuits is complicated by a considerable number of factors that have to be taken into account to ascertain safe use of the method chosen. While all natural methods of birth control offer the undeniable advantage of absolute safety, artificial methods are plagued with sometimes dangerous adverse events, risks, and potential complications.

From an economic perspective, the natural methods save taxpayer money also with respect to the absence of therapeutic interventions due to adverse events or complications. As has been demonstrated by pharmaceuticovigilance, the possibilities of life-threatening complications -- as for example ectopic pregnancy or perforation -- are admitted by most manufacturers of contraceptive products, and the costs for hospitalization including surgery exceed by far the cost for pregnancy-related symptoms and delivery.

On the basis of data from medical and economic research it can be stipulated that efforts be intensified to inform women not only about all known risks of artificial methods but draw their attention also to alternatives in the form of natural methods. Especially for women who are capable of exercising disciplined use of natural methods the chances of achieving perfect use estimates are good.

Conclusion

The foregoing discussion shows that the decision to engage in contraceptive pursuits is complicated by a considerable number of factors that have to be taken into account to ascertain safe use of the method chosen. While all natural methods of birth control offer the undeniable advantage of absolute safety, artificial methods are plagued with sometimes dangerous adverse events, risks, and potential complications.

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Volume 9 Issue 7 July 2020

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