

## Review Article

# Are Women Misled on Issues of Family Planning and Birth Control? An International Meta-Analytic Review

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## Abstract

On the background of a vast, ever-increasing literature on family planning, birth control, and contraception, the paper aims to provide accurate and reliable information on women's health issues and to rectify-by way of an international comparison-several U.S. research publications as well as public health media which disseminate inaccurate and error-prone information on contraceptive methods. The methodological concept of the paper consists in a meta-analysis of the most salient research publications as well as websites provided by public health agencies, which are compared to their European equivalents. The study concludes that present-day U.S. research contains incomplete, inaccurate and misleading information and does not enable women to exercise their rights as autonomous patients who are informed according to the bioethical principles of "Informed consent" and "Nil nocere." The implications of such deficits is an appeal to researchers and publishers to intensify efforts in their strife for accuracy and completeness so as to enable women to exert their autonomy as fully informed patients.

**Keywords:** Birth Control; Contraception; Family Planning

## Introduction

U.S. research generally provides accurate, complete, and conclusive information on a wide array of health topics and women's issues. As birth control and family planning are still of pivotal interest worldwide [1] U.S. researchers have taken a leading role with publications on a variety of themes such as family planning as a cost-saving service [2] long-acting contraception and teenage pregnancy [3] teen sexual health [4] and contraception as a primary care service [5,6].

The undisputed hegemony of U.S. research on women's health issues, however, seems challenged when the topic of "Efficacy of contraceptive methods" is at stake. An analysis of the most pertinent publications focusing on contraceptive methods viewed from an international perspective reveals that women in the U.S., compared to women in other countries, have access only to frag-

mented and misleading information.

## Discussion

### The Ethical Dilemma of Withholding Information on Contraceptive Options

In seeking information on contraceptive methods millions of women turn to the publications by one of the most influential agencies, the U.S. Food and Drug Administration (FDA). In fact, the FDA provides information on contraception by presenting a consumer-friendly survey of FDA-approved contraceptive methods, indicating the "Number of women out of 100 who will not get pregnant" [7] (Table 1: FDA 2013. Cf. Appendix). Yet, to the disappointment of many women seeking alternatives to drugs and devices, there is no mention of such methods as Symptothermal, Ovulation, TwoDay, and Standard Days, ie, methods that have been part and parcel of international research and research on contraceptive technology since 2011 [8].

Methods	*Number of women out of 100 who will not get pregnant: "Perfect use"	*With typical use, number of women out of 100 who will not get pregnant	How to Use It
Sterilization Surgery for Women	>99%	>99%	One-time procedure; nothing to do or remember.
Surgical Sterilization Implant for Women	>99%	>99%	One-time procedure; nothing to do or remember.
Sterilization Surgery for Men	>99%	>99%	One-time procedure; nothing to do or remember; condoms should be used for at least 3 months until stored sperm are cleared from the reproductive tract.
Implantable Rod**	>99%	>99%	Nothing to do or remember, lasts up to 3 years, inserted by clinician.
IUD**	>99%	>99%	Nothing to do or remember, lasts 3-10 years, inserted by clinician.
Shot/Injection	>99%	94%	Need a shot every 3 months, prescription needed.
Oral Contraceptives (Combined pill) "The Pill"	>99%	91%	Must swallow pill every day, prescription needed.
Oral Contraceptives (Progestin-only) "The Pill"	>99%	91%	Must swallow pill everyday. Must be taken at the same time each day. Prescription needed.
Oral Contraceptives Extended/Continuous Use: "The Pill"	>99%	91%	Must swallow pill everyday. Prescription needed.
Patch	>99%	91%	Put on a new patch each week for three weeks (21 total days). Don't put on patch during the fourth week. Prescription needed.
Vaginal Contraceptive Ring	>99%	91%	Put the ring into the vagina yourself. Keep the ring in vagina for three weeks and remove for one week. Prescription needed.
Male Condom	98%	82%	Must use every time you have sex; requires partner's cooperation. Except for abstinence, latex condoms are the best protection against HIV/ AIDS and other STIs.
Diaphragm with Spermicide	94%	88%	Must use every time you have sex.
Sponge with Spermicide	80-91%	76-88%	Must use every time you have sex.
Cervical Cap with Spermicide	74%	60%	Must use every time you have sex.
Female Condom	95%	79%	Must use every time you have sex. May give some protection against STIs.
Spermicide	82%	72%	Must use every time you have sex. Associated with risk of STI and HIV due to vaginal irritation with frequent use.
<b>Emergency Contraception – If your primary method of birth control fails</b>			

Emergency Contraceptives, "Plan B," "Plan B One Step," "Ella"	85%	7 out of 8 women would not get pregnant after using Emergency Contraceptives	Must use within 72-120 hours of unprotected sex. It is most effective taken as soon as possible after the unprotected act. It should not be used as a regular form of birth control.
*Effectiveness rates are listed for "Perfect use" and "Typical use."			
**Implantable rod and IUD considered Long-Acting Reversible Contraceptives (LARC) and are highly recommended for young women who do not wish to become pregnant, but may want to have children later. Source: Contraceptive Technology 20th, 2011			

**Table 1:** FDA (2013)Food and Drug Administration (FDA) Approved Methods of Birth Control.

Contraceptive technology research presents, besides other up-to-date information, a rating of methods in which there is a distinction between perfect use and typical use and a differentiation between "First year of use" and "continuing use at one year [8]. A summary of the methods including their estimates (percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception) is available in form of a "Contraceptive Failure Table [9]. (Table 2: CTFailure Table. pdf. Cf. Appendix).

Unintended Pregnancy within Continuing Use the First Year of Use at One Year3 Method (1)	Typical Use(2)	Perfect Use(3)	(4)
No method 4	No method 4	85	85
Spermicides 5	28	18	42
Fertility awareness-based methods	Fertility awareness-based methods	24	47
Standard Days method6	Standard Days method6	5	5
TwoDay method6	TwoDay method6	4	4
Ovulation method6	Ovulation method6	3	3
Syntothermal method6	Syntothermal method6	0.4	0.4
Withdrawal	22	4	46
Sponge	Sponge	36	36
Parous women	Parous women	24	20
Nulliparous women	Nulliparous women	12	9
Condom 7	Condom 7	Condom 7	Condom 7
Female (fc)	21	5	41
Male	18	2	43
Diaphragm8	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Evra patch	9	0.3	67
NuvaRing	9	0.3	67
Depo-Provera	6	0.2	56
Intrauterine contraceptives	Intrauterine contraceptives	Intrauterine contraceptives	Intrauterine contraceptives

ParaGard (copper T)	0.8	0.6	78
Mirena (LNg)	0.2	0.2	80
Implanon	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.1	100

**Table 2:** Contraceptive Technology.

Table 2,3 Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception, and the percentage continuing use at the end of the first year. United States. % of Women Experiencing an % of Women

According to this table, the "Long Acting Reversible Contraceptives," i.e, implants and intrauterine devices, appear as the most effective, especially the implant Implanon (precursor of Nexplanon) with a failure rate of 0.05 for both perfect and typical use. Among intrauterine contraceptives, Mirena (Levonorgestrel=LNg) with a perfect and typical use failure rate of 0.2 is superior to ParaGard (copper T) with a perfect use failure rate of 0.6 (typical use failure rate of 0.8). About equally effective are Depo-Provera with 0.2 perfect use (6 typical use), NuvaRing 0.3 perfect use (9 typical use), Evra patch 0.3 perfect use (9 typical use), as well as combined pill and progestin-only pill with 0.3 perfect use (9 typical use). Among the so-called "Fertility awareness-based" methods- whose typical use failure rate of 24 is based inappropriately on obsolete data from 1995 [9], (note 1)-the symptothermal method with a perfect use failure rate of 0.4 appears almost as effective as such methods as combined pill and progestin-only pill (0.3), Evra patch (0.3), and NuvaRing (0.3), but even more effective than ParaGard (copper T) with a perfect use failure rate of 0.6. The ovulation method with a perfect use failure rate of 3 is nearly as effective as male condom without spermicide (perfect use failure rate of 2) but superior to female condom without spermicide (perfect use failure rate of 5). The TwoDay method with a perfect use failure rate of 4

equals withdrawal (perfect use failure rate of 4), and the Standard Days method with a perfect use failure rate of 5 is still superior to diaphragm (with spermicidal cream or jelly) whose perfect use failure rate is 6.

The symptothermal method with a perfect use failure rate of 0.4, the most effective of the so-called “Fertility awareness-based methods,” is based on evaluation of cervical mucus to determine the first fertile day of the cycle and on evaluation of both cervical mucus and temperature to determine the last fertile day [9]. (note 6) The evaluation of cervical mucus is the basis for the Ovulation and TwoDay methods, with perfect use failure rates of 3 and 4 respectively. The Standard Days method with a perfect use failure rate of 5 avoids intercourse on cycle days 8 through 19. Among the definitive methods, male sterilization with a perfect use failure rate of 0.10 (typical use 0.15) is superior to female sterilization with 0.5 for both perfect and typical use.

Concerning “Emergency” contraception, ie, pills or insertion of a copper intrauterine contraceptive, subsequent to unprotected intercourse, contraceptive technology claims that they substantially reduce the risk of pregnancy. Products marketed for emergency contraception are Ella, Plan B One-Step, and Next Choice. Plan B One-Step, whose one dose is 1 white pill, suggests that the pill be taken within 72 hours of unprotected coitus; according to research it is effective when used within 120 hours. Similarly, Next Choice, whose one dose is 1 peach pill, suggests that one pill be taken within 72 hours subsequent to unprotected coitus and another one 12 hours later; according to research both pills can be taken at the same time and are effective when used within 120 hours subsequent to unprotected coitus. In addition, the U.S. Food and Drug administration has declared “19 brands of oral contraceptives to be safe and effective for emergency contraception” [9] (note 9): Ogestrel, Nordette, Crystelle, Levora, Low-Ogestrel, Lo/Ovral or Quasence, Jolessa, Portia, Seasonale or Trivora, Seasonique, Enpresse, Lessina, Aviane or LoSeasonique, Lutera or Sronyx, and Lybrel.

As a historical footnote to present-day notions of emergency contraception it should be noted that a physiology-based analysis from the last century explains the mechanism of action of the so-called morning-after-pill, ie, mifepristone (RU-486), by underscoring the abortifacient effect. Mifepristone, a synthetic steroid, binds to the progesterone receptor and—in contrast to progesterone—does not release the heat shock protein to which the receptor is bound, but merely blocks the binding of progesterone. “Since the maintenance of early pregnancy depends on the stimulatory effect of progesterone on endometrial growth and its inhibition of uterine contractility, mifepristone causes abortion. In some countries, mifepristone combined with a prostaglandin is used to produce elective abortion.” [10](p. 409)

While the mechanism of action of emergency contraception

is still open to discussion especially regarding abortogenic effects, other forms of contraceptive options, such as lactational amenorrhea are rather undisputed also from a physiological viewpoint. Contemporary contraceptive technology considers “Lactational Amenorrhea” Method (LAM) to be a remarkably effective though only temporary method of contraception, and recommends that another method of contraception be implemented for effective protection against pregnancy, as soon as one of the following conditions arises: “Menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.” [9] (note 10) From a physiological viewpoint it is important to keep in mind that nursing has long been known to be an important if only partly effective method of birth control and that “Almost 50% of the cycles in the first 6 months after resumption of menses are anovulatory.” [10](p. 416)

It is noteworthy that lactational amenorrhea similar to fertility awareness-based methods is not always included in contemporary surveys—in contrast to information provided by contraceptive technology and in contrast to data provided by research on contraceptive failure [11]. The perfect use failure rates of 0.4 (symptothermal), 3.2 (ovulation), 3.5 (TwoDay), and 4.8 (Standard Days) respectively indicate that these methods are not inferior to some of the methods included in the FDA survey, eg, diaphragm with spermicide, sponge with spermicide, and cervical cap with spermicide. Omission of such internationally recognized methods is not only indicative of flawed science but is also irreconcilable with the bioethical principle of “Informed consent” which requires accurate, complete, and comprehensible information for the patient on all aspects of a medical issue, in this case availability of contraceptive methods. In addition, bioethics requires that the principle of “nil nocere” be taken into account because it draws attention to the issue of safety and stipulates priority for the least harmful methods. As long as these two principles are not honored, the third fundamental principle, patient autonomy, cannot come into force. Since the FDA as information provider makes no mention of any other method besides the 18 listed in its survey, these principles are patently neglected, and several methods are doomed to fall into oblivion although they have been recognized by international scholarship for a considerable number of years [12,13]. It has to be feared, therefore, that U.S. women inquiring about contraceptive options are left with the disappointing impression that there are no other contraceptive methods available than the 18 listed by the FDA. Such a disappointment is particularly painful for women whose primary interest is safety, meaning absence of adverse events and risks. Quite a number of women trust in the completeness of the survey presented by the FDA and on its ethical commitment to mention also internationally recognized methods, even if they are not approved by the FDA. These women remain ignorant of the safest of all presently available methods requiring nothing more than diligent observation of cervical mucus and Basal Body

Temperature (BBT).

In the same vein, quite a number of women might appreciate it to obtain not only information on drugs and devices but also to gain insights into physiological processes during their menstrual cycle. As mentioned above, the Ovulation and TwoDay method are based on evaluation of cervical mucus [9], whereby a woman observes that during ovulation, under the influence of estrogen, mucus is thinner and more alkaline than under the influence of progesterone. “The mucus is thinnest at the time of ovulation, and its elasticity, or spinnbarkeit, increases so that by mid-cycle, a drop can be stretched into a long, thin thread that may be 8-12 cm or more in length. In addition, it dries in an arborizing, fernlike pattern.”[10] (p.402-403) The Standard Days method is based on the calendar and avoids intercourse on cycle days 8-19. The symptothermal method has been defined as a “Double-check” method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day”[9]. (note 6) Given the simplicity of these methods-which nowadays can be used in conjunction with smart phone applications-and the absence of risks as well as adverse events, it remains unresolved why information on these methods is withheld from the consumer expecting to find complete and accurate data in publications by the FDA.

The lack of completeness conspicuous in the FDA survey is particularly striking from an international perspective. In fact, European scholars have illuminated the issue of contraception as a long-known phenomenon in the history of medicine and endeavored to establish for each single method its proper failure rate[12]. Instead of attributing collective failure rates to a group of methods, efforts have been made to assess each method individually[13].

As early as 2000, a chronological overview of the phenomenon of contraception in the history of medicine has been presented by German authors, and 15 different methods have been highlighted under the traditional terminology together with a ranking according to the Pearl-Index (number of unwanted pregnancies per 100 woman years or 1200 months of application) [12]. This ranking shows “Tubal sterilization” (Pearl index 0.09-0.4) together with “Depot-gestagens” (Pearl index 0.03-0.9), as the most efficacious, followed by “Monophasic combined pill” (0.1-1.0), “oral hormonal sequential contraceptives” (0.2-1.4), “Minipill” (1), “Intrauterine pessary” (0.14-2) and the symptothermal method (0.8) [12].(p.60) Concerning the other “Natural family planning” methods (“Natürliche Empfängnisverhütung”), “Basal temperature (Basaltemperatur)” (Pearl index of 1-3) appears comparable to “Diaphragm and spermicide” (Pearl index 2-4) or “Condom” (4-5), while “Cervical mucus” (15-32) and “Calendar” (15-40) roughly approximate the efficacy of “Chemical spermicides” (12-20) or “Coitus interruptus” (8-38).

Due to the Pearl index of 0.8, the symptothermal method

was recognized by German scholars already in 2000 as the most effective of the natural family planning methods and considered to be one of the “Safe contraceptive methods,” [12](p.64)-notwithstanding the problem of irregular menstrual cycles, which limits for some women the practicability of the method and necessitates the additional use of another method.

The rating of each single method according to a proper Pearl index and the systematic inclusion in a historically evolved taxonomy-customary in German scholarship-is rather an exception in U.S. research publications as well as in public health media where methods are not properly distinguished from one another so that inaccurate and inappropriate failure rates are disseminated. In addition, definitions of methods are frequently ambiguous and at times utterly incorrect.

### **Inaccurate and Misleading Information on Contraceptive Options Presented by U.S. Government Agencies and Organizations**

The U.S. Department of Health and Human Services (Office on Women’s Health) [14] adapted WHO data to provide information on family planning and assigned collectively 24% (“Number out of every 100 women who experienced an unintended pregnancy within the first year of typical use”) to the so-called “Fertility-awareness based methods.” These are considered as the least effective, just slightly superior to the “Spermicide method” (28%). Such an assessment, exclusively for typical use and not for perfect use, does not take into account that the nomenclature “fertility awareness” encompasses at least four different methods, each one with a failure rate of its own, ranging from 0.4 (symptothermal) to 4.8 (Standard Days) [11]. Interestingly enough these methods are described individually in a different website with focus on fertility awareness, provided by the Office of Population Affairs [15] Here again, a common failure rate of 25% is indicated for the four methods, as if all of them were equally effective-or rather ineffective. What is noteworthy in this website is a new classification of “Fertility Awareness,” namely “Basal Body Temperature” (BBT), “Cervical Mucus,” and “Computation of Standards Days.” The “sympto-thermal” is not included in this classification, but described correctly as a combination of BBT and cervical mucus. All four methods, however, are grouped under one single failure rate, namely 25, although it seems logical that a method combining two other ones should show increased efficacy. Moreover, the website fails to provide a description of all the salient characteristics of the symptothermal method, namely observation of “symptoms” such as low backache, mastalgia, peritoneal irritation, and fleeting lower abdominal pain (“Mittelschmerz”) [16].

Incompleteness is patent also in information presented by other U.S. government agencies, such as the “Womenshealth” publication by the Office on Women’s Health [17]. In this website, natural family planning is erroneously identified as the “Rhythm

method“ and attributed a failure rate of 24. This identification obscures the fact that “Natural family planning“ is not a method per se but just a taxonomic nomenclature, and the figure quoted might be correct for the calendar method but not for the ovulation method (perfect use failure rate of 3.2) or symptothermal method (perfect use failure rate of 0.4) [11] In a different version of the “Womenshealth“ website, some of the characteristics of the symptothermal method are correctly outlined but under the ambiguous heading of “Natural family planning/rhythm method“ and the failure rate of 25 is defined as the “Number of pregnancies expected per 100 women,“ ie, without any differentiation between typical and perfect use.

Surprisingly, the lack of accuracy in websites offered to the public by government agencies appears also in publications by specialists on gynecological issues such as the American Congress of Obstetricians and Gynecologists who stated as recently as 2015 that natural family planning “Is not as effective as other methods of birth control.“[18] From an international viewpoint it seems misleading to speak indiscriminately of natural family planning without distinguishing among the various methods, and it is obviously incorrect to state that they are not as effective as other methods because the symptothermal method with a Pearl index of 0.8 is superior to intrauterine devices (Pearl index of 0.14-2), and the temperature method (Pearl index of 1-3) is more effective than the condom (Pearl index of 4-5) or chemical spermicides (Pearl index of 12-20) [12]. Paradoxically, the ACOG contradicts its own statement in another website, devoted to frequently asked questions (FAQ) [19]. In this website, the fertility awareness-based methods are no longer discarded as ineffective but are praised for their advantages concerning cost and safety: “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.“

Interestingly enough, it is not this favorable comment contained in the FAQ website, but the misleading statement from 2015 that reappears in an assessment of fertility awareness-based methods by one of the most influential agencies, the Center for Disease Control (CDC), in 2017 [20]. This agency perseveres on using obsolete data even in a 2016 “U.S. Medical Eligibility Criteria for Contraceptive Use.“ In a ranking of methods according to effectiveness, the fertility awareness-based methods (24%) appear as the least effective together with spermicides (28%).

(Table 3: Center for Disease Control (CDC). Cf. Appendix).

Effectiveness of Family Planning Methods	
Most Effective	Less than 1 pregnancy per 100 women in a year
Reversible Implant	0.05 %*
Intrauterine Device (IUD)	LNG - 0.2 % Copper T - 0.8 %

Permanent Male Sterilization (Vasectomy)	0.15 %
Female Sterilization (Abdominal, Laparoscopic, Hysteroscopic)	0.5 %
How to make your method most effective	After procedure, little or nothing to do or remember
Vasectomy and hysteroscopic sterilization: Use another method for first 3 months.	6-12 pregnancies per 100 women in a year
Injectable	6 %
Pill SUN MON TUES WED THUR FRI SAT 1234	9 %
Patch	9 %
Ring	9 %
Diaphragm	12 %
Injectable:	Get repeat injections on time.
Pills:	Take a pill each day.
Patch, Ring:	Keep in place, change on time.
Diaphragm:	Use correctly every time you have sex. 18 or more pregnancies per 100 women in a year
Male Condom	18 %
Female Condom	21 %
Withdrawal	22 %
Sponge	24 % parous women 12 % nulliparous women
Fertility-Awareness Based Methods 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 1 2 3 4 JANUARY	24 %
Spermicide Spermicide	28 %
Least Effective	* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.
Condoms, sponge, withdrawal, spermicides: Use correctly every time you have sex. Fertility awareness-based methods:	Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be the easiest to use and consequently more effective.

Condoms Should Always Be Used To Reduce The Risk Of Sexually Transmitted Infections.	Other Methods of Contraception
Lactational Amenorrhea Method:	LAM is a highly effective, temporary method of contraception.
Emergency Contraception:	Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy. Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive CS 242797

**Table 3:** Center for Disease Control (CDC).

For connoisseurs in the history of medicine it does not come as a surprise that this unfavorable assessment can be traced back to the last century, where it emerges in a publication by one of the most prominent international opinion leaders, the Harvard School of Medicine. In a “Family Handbook” of 1995-as well as in a second edition of 2005-a disapproving judgement is pronounced on the basis of an assumed effectiveness rate of 19%: “Natural birth control methods are the least reliable of the contraceptive methods [21].”

This kind of unscientific rating of an entire group of methods not only puts into question the credibility of presumably competent authorities, but it also raises scepticism in the face of comments made by highly respected agencies, as for example the U.S. Center for Disease Control (CDC). In a website accessible as recently as 2017, the CDC comments ingenuously on some of the fertility awareness-based methods: “Newest methods (Standard Days Method and TwoDay Method) may be the easiest to use and consequently more effective [20]. “ As it might be true that these two fertility awareness methods are among the easiest to use, it is definitely not true that they are the newest methods. The Standard Days Method is nothing more than a new formulation of the calendar method described by Knaus and Ogino as early as 1932-1933, and the TwoDay method is based on the cervical mucus structure method delineated by Billings in 1964 [12].(p. 63) Given such ig-

norance in matters of historical facticity, typical for quite a number of U.S. publications, it does not come as a surprise that even academic institutions do not stand up to the expectations of international scholarship regarding accuracy and precision.

### **U.S. Academic Institutions: Error-Prone Nomenclature and Taxonomies**

In the face of unscientific and unverified comments on certain contraceptive methods made by numerous government agencies and organizations, it is astonishing that several U.S. academic institutions depict a far more serene scenario of the fertility awareness-based methods, although some overt blemishes cannot be overlooked. The most frequently encountered error-prone statements are caused by flawed nomenclature and distorted taxonomies.

Under the heading “Temporary contraception options“ by “UWHealth [22],“ Only the ovulation, the symptothermal, and the rhythm method are mentioned. In a description of their characteristics, the symptothermal method is apparently confounded with the Basal Body Temperature method and assigned an effectiveness rate (“90-95 percent effectiveness rate“) somewhat similar to the Standard Days method; in addition, it is discredited as involving “a lot of details.“ The truth, however, is that the symptothermal method involves nowadays only few details, especially in conjunction with easily available smartphone applications. In the originally designed calendar-based “Cycle sheet,“ body temperature and changes in cervical mucus had to be recorded, including position, opening and consistency of the portio vaginalis cervicis[12]. (p. 64) Regarding the symptoms to be observed, such as mastalgia, it should not be overlooked that for some women attention to regularly occurring physiologic processes is a welcome opportunity to get better acquainted with their own body and a conditio sine qua non for the efficacy of infertility treatments.

Although some publications furnished by academic institutions follow the traditional classification of fertility awareness-based methods and contain veridical descriptions of the symptothermal method they fall short of indicating distinctive features or appropriate failure rates [23]. Other publications add unverified comments linking fertility awareness-based methods to religious convictions by stating that these methods are recommended only for those “Whose strong religious beliefs prohibit standard contraceptive methods [24].“ While it is true that for some women a specific cultural background or a religious conviction might encourage use of one of the natural methods, in many instances the primary motif is intolerance to hormones, aversion to drugs and devices, or a fear of complications. Other websites avoid prejudice and strive for objectivity, as for example that of the Mayo Clinic [25]. This website is one of the few where the calendar method is correctly identified as the rhythm method and not as a conglomerate of several unidentified methods. Also, the symptothermal

method is defined correctly as a combination of the cervical mucus method and body temperature. Besides the Mayo Clinic, it is difficult to find other top-ranked U.S. academic institutions which seem dedicated to providing up-to-date reliable information or to foster the advancement of knowledge about natural family planning methods. As an exception, the Stanford University appears committed to propagating knowledge about the Billings ovulation method and describes also the Creighton Model (CrM) or NaPro Technology, a method in which the characterizations of cervical mucus are standardized [26].

Besides leading U.S. medical schools and Ivy League universities there are of course other academic institutions which offer websites devoted to birth control and family planning. One of the most controversial is Georgetown University's website which uses as its source Planned Parenthood for a ranking of methods. Given the image of Georgetown University as one of the leading Catholic institutions, it comes as a surprise that it provides information in imitation of an organisation that promotes-in contradistinction to Vatican teaching-abortion and excludes precisely those methods that are commonly sanctioned by the Catholic church. In short, the distinctive feature of Planned Parenthood's ranking of contraceptive methods is the neglect of all the fertility awareness-based methods [27], dilettantishly formulated comments, and idiosyncratic failure rates, eg, 91%-99% for the Pill-which contradicts the international estimate of 0.1-1.4 [12]. (p.60) What is particularly important in this context, Planned Parenthood's chart entitled "Contraceptive methods" points to a most perilous fallacy inherent in the use of internet, namely availability of outdated information that is not recognizable as such. Although the office of Planned Parenthood presently considers this chart as "Out-of-date" and does not endorse it, millions of users still access it and regard it as a reliable source of information.

### **Inconclusive Data on Failure Rates and Unorthodox Classifications in Scholarly Research**

In view of information that is neither dramatically unsound nor blatantly untrustworthy in websites of U.S. academic institutions, one notes with bewilderment that numerous scholarly publications are still plagued by serious shortcomings, especially regarding data on the efficacy of contraceptive methods and taxonomic nomenclature. In research articles the issue of efficacy has been a focal point of discussion at least since the 1982 publication of a ranking described as the "Relative effectiveness of frequently used contraceptive methods [28]."

The appearance of this ranking in one of the world's leading medical journals has obviously contributed to the continued unchecked dissemination of error originating from this publication, ie, the identification of "rhythm" with all natural family planning methods. Not only did the authors choose the equivocal terminus "Rhythm" without any further specification, but they also ranked

the rhythm method-instead of each one of the four individual methods-as the least effective, due to 15.5 "Failures per 100 Woman-Years." With this failure rate the rhythm method ranked last, not only far behind the most effective, ie, vasectomy (0.02) and tubal ligation (0.13), but also behind oral contraceptives (0.32-1.2), IUD Copper 7 (1.5), IUD Loop D (1.3), diaphragm (1.9), condom (3.6), withdrawal (6.7), and spermicide (11.9).

Contemporary rankings differ fundamentally from this 1982 archetype, but nomenclature and taxonomy remain crucial problems. Thus, the widely-known National Health Statistics Report [29] speaks in an unspecific manner of "Fertility awareness" and indicates the probability of pregnancy as 25.3 ("Probability of a contraceptive failure within the first 12 months of typical use of a contraceptive method"). As there is no definition of the methods belonging to fertility awareness and no reference to perfect use, this figure leads to the assumption that all the methods that usually are considered as fertility awareness have the same probability of a contraceptive failure, regardless of typical or perfect use. In addition, this statement contradicts the findings of international research where the pregnancy rates of Fertility Awareness-Based (FAB) methods with perfect use "have ranged between 0.3 and 5.0 per 100 users per year [30]."

Inconclusive failure rates appear also in one of the leading medical reference books, the MSD Manual [31], which uses the nomenclature "Periodic abstinence" to discuss the natural family planning methods. Although this scholarly remarkable work with a long history stated correctly as early as 1999 that the symptothermal method is the most precise in determining the days where abstinence is mandatory, it attributed to this periodic abstinence method a failure rate of 10%, which does not agree with the failure rate established by an evidence-based longitudinal study [13].

What is particularly perplexing to the reader of contemporary publications is the fact that specialists in reproductive health still assign failure rates to an entire group of methods without consideration for the specificity of each individual method. In a study emanating from an established research institute, fertility awareness-based methods are not distinguished from one other but indiscretely assigned a failure rate of 0.4 -5 for perfect use and 24 for typical use [32]. In addition, a new taxonomy is introduced listing three groups of methods as belonging to the fertility awareness-based methods, ie, "Cervical mucus methods," /sic!/ "body temperature methods," /sic/ and "periodic abstinence." Besides the problem of an unorthodox taxonomy this study raises the question as to how a method with a remarkable perfect use failure rate of 0.4 (symptothermal) or 3.2 (ovulation) can deteriorate to a disappointing failure rate of 24 in case of typical use.

A possible answer to this question is provided by a most recent study (2016) on failure rates in case of typical use, based on demographic as well as health survey data from 43 countries out-

side the U.S [33]. In a comparison of data the authors explain that their estimates regarding periodic abstinence were surprisingly lower for the developing world (ie, 13.9) than for the U.S. (ie, 24). A feasible explanation for such an unexpected disparity might be that the figure for the U.S. (24) is an outdated estimate, not based on recent investigations but taken “ . . . From 1995 and 2002 National Surveys of Family Growth . . . ” [34] (p. 35) This assertion parallels the statement made by contraceptive technology research affirming the use of outdated figures: “Estimates of the probability of pregnancy during the first year of typical use . . . Are taken from the 1995 National Survey of Family Growth [9]” (Note 1)

It is not only such references to obsolete data but also a new idiosyncratic taxonomy that contributes to a confusing picture of contraceptive methods in contemporary research [34]. By introducing a dichotomy between “modern” and “Traditional” methods authors explain that they defined the following to be modern methods: male and female sterilization; implants; IUDs; injectables; oral contraceptive pills; male and female condoms; diaphragms; foam, jelly, and spermicides; Standard Days Method; emergency contraception; fertility wheel calculator; and the Mucus/Billings/Basal body/ Symptothermal method /sic!. As “traditional” methods they define the following: periodic abstinence (calendar rhythm); withdrawal; Lactational Amenorrhea Method (LAM); “and other traditional lokal or folk methods[34].“ As can be seen, not only the arbitrary dichotomy between “Modern” and “traditional” methods appears disconcerting but above all the designation “Mucus/Billings/Basal body/Symptothermal method”, ie, the semantic amalgamation of four different methods into one. Although these four methods have emerged in the history as separate entities with distinctive characteristics, they are now described as being one single method.

In addition to the unresolved problem of taxonomies there is still lack of unanimity regarding the distinction between “perfect” and “Typical” use. For some authors the former still has the flair of fictitious or imaginary because the “Real-world failure rates” are those calculated on the basis of “Typical use [35].“ (p.149) The truth however is not unattainability of perfect use, but the necessity of in-depth instruction for the potential users of a specific method. While it is immaterial as to whether the woman who receives an implant is knowledgeable about the effects of estrogen, just the opposite is true for the symptothermal, ovulation, and TwoDay methods. The woman who envisages use of one of these methods must be well-informed and experienced in measuring basal body temperature (namely in the morning before getting up), evaluating cervical mucus (namely recognition of “Spinnbarkeit”) around the ovulation phase, and observing symptoms such as mastalgia. It must be feared that in the past it was lack of communication between user and care provider that led to poor failure rates of some natural methods and not so much shortcomings inherent in the method per se. Especially the results of studies on contracep-

tive use in developing countries might have been plagued by deficits in communication processes so that, among others, the figures for maternal mortality ratio [36], ie, the risk of maternal death per 100.000 live births, were derived inappropriately, and failure rates were flawed for those methods requesting in-depth instruction a priori for the women embarking on their use.

In the face of deficient communication processes, inconclusive taxonomies, obsolete figures in scholarly publications, and inaccurate data in media disseminated by government agencies, it is not surprising that research authors frequently refrain from even mentioning such methods as Symptothermal, Ovulation, TwoDay, and Standard Days and shift their focus on those contraceptive methods that do not necessitate time-consuming counselling but allow simple one-time procedures—even if they involve avoidable costs for the consumer and ensuing financial gains for pharmaceutical companies, as is the case for drugs and devices.

### **The Truth About Long Acting Reversible Contraception (LARC) and The Issue Of Fertility**

For many years now research projects have focused on the so-called Long-acting Reversible Contraception (LARC) methods, and it has been claimed: “Long-acting reversible contraception, or LARC, methods provide reliable, long-term, highly effective prevention of pregnancy after one-time placement of a device [37]. “ (p. 461)

LARC methods include Intrauterine Devices (hormonal IUDs and non-hormonal copper-containing IUDs) and subdermal hormonal implants. Since these methods do not require any compliance with a prescription, they can be designated as “Forgettable.” Although a high efficacy of LARC methods has been claimed by some publications, for many women it is not efficacy but safety that has highest priority. Regrettably, the issue of safety has not yet been addressed satisfactorily because it includes not only the well-known problems of adverse events, ie, any undesirable experience associated with the use of a medical product in a patient, but also the question of limited eligibility, contraindications, and presently unknown long-term consequences. It must be stressed that safety in this context refers primarily to adverse events, side effects, risks, and complications because the semantics of safety with respect to Sexually Transmitted Infections (STIs) must be kept in mind too. Regarding this latter connotation, latex condoms appear as the best protection, besides abstinence, as has been pointed out by the FDA [7].

As early as 1986 not only specialized investigations but also medical reference books have warned that estrogens favor the occurrence of thromboembolic events, such as cerebrovascular accidents and heart infarcts [38]. (p. 895) At that time, long use of estrogen- and gestagen-containing medication was known to cause hypertension, weight gain and edema. In 2000, researchers have

drawn attention to serious complications with IUDs, such as spontaneous expulsion, perforation, and ascending infections with the potential of causing infertility [12]. (p. 84)

Despite the contemporary claim made by advocates of LARCs to the effect that “Almost all women can safely use IUDs[37],” (p. 462) attention must be drawn to the numerous conditions where this claim cannot be considered valid. As proponents of LARCs admit, women should not undergo the insertion of an IUD in cases such as hypersensitivity to copper (use of the copper-containing IUD is precluded) or hypersensitivity to other components of either type of IUD; current pelvic infection or a Sexually Transmitted Disease (STD); gynecologic cancers; current purulent cervicitis or known chlamydial or gonococcal infection; and certain other serious medical conditions.

Regarding unpropitious medical conditions, they are numerous and have been summarized in the “Medical Eligibility Criteria for the Initiation of LARC methods [37],” (p. 464) namely: Distorted uterine cavity (which is incompatible with IUD placement); an anatomical abnormality that distorts the uterine cavity (might preclude proper IUD placement); current pelvic inflammatory disease; gonococcal or chlamydial infection, or purulent cervicitis; postpartum or postabortion sepsis; persistent intrauterine gestational trophoblastic disease (Risk of perforation, infection, and hemorrhage); cervical cancer (increased risk of infection and bleeding at insertion-the IUD probably must be removed at the time of cancer treatment); endometrial cancer (increased risk of infection, perforation, and bleeding at insertion; need for removal at the time of cancer treatment); unexplained vaginal bleeding (suspicion of serious condition); suspicion of pregnancy or an underlying pathologic condition (eg, pelvic cancer); irregular bleeding patterns (if associated with the method used, it might mask symptoms of underlying pathologic conditions); current breast cancer (hormonal stimulation may worsen the condition); history of breast cancer with no evidence of disease for 5 years; complicated solid-organ transplantation (data on risks and benefits are limited in this population); systemic lupus erythematosus (with severe thrombocytopenia raises concern about an increased risk of bleeding); systemic lupus erythematosus (with positive or unknown antiphospholipid antibodies raises concern about an increased risk of both arterial and venous thrombosis); severe, decompensated cirrhosis (hormonal exposure may worsen the condition); hepatocellular adenoma or hepatic malignancy (hormonal exposure may worsen the condition).

In addition to these 15 conditions which exclude from medical eligibility for LARCs there are, as for almost all medications, numerous adverse event, side effects, and risks. Concerning side effects, champions of LARCs concede: “A common side effect of using a copper-containing IUD is increased menstrual bleeding [37].”(p. 463) regarding one of the most perilous complications,

namely perforation, it has been admitted that “uterine perforation, although rare, may be more prevalent among women who are breastfeeding [37].”(p. 465) Perforation, occurring frequently straightway post partum, should be viewed as one of the most feared complications and has been discussed for quite a number of years. As early as 2000 it was recommended to perform an ultrasound immediately following insertion [12]. (p.83) Despite assertions belittling the risk of perforation, this complication must be heeded at all times, particularly in view of recently reported adverse events where perforation was described as penetration of the uterine wall and dislodgement of the device in the abdominal cavity.

Concerning thromboembolism associated with LARC use, proponents hold that conclusive studies are still missing, but regarding expulsion some data are available. According to these data, the relative risk of expulsion of IUDs that are placed immediately post partum is higher than the risk with IUDs inserted at 6 weeks post partum or later. “Expulsion rates vary widely by study population but are generally lower when the IUD is inserted immediately after delivery of the placenta (3 to 27%) than when it is inserted 10 minutes to 48 hours after delivery of the placenta (11 to 27%); both rates are higher than those with standard insertion at 4 to 8 weeks post partum (0 to 6%) [37].”(p. 466)

Regarding adverse events associated specifically with implants, studies have brought to light a number of conditions, besides bleeding as the primary complication [39]. “The most common adverse events besides unscheduled bleeding that were deemed possibly, probably, or definitely related to the etonogestrel implant included headache (16%), weight gain (12%), acne (12%), breast tenderness (10%), emotional lability (6%) and abdominal pain (5%).” In the case of Depot Medroxyprogesterone Acetate (DMPA), another progestin-only contraceptive that reduces estrogen levels, decrease of bone mineral density has been confirmed.

Regarding the complex issue of interactions, as for example the decreased effect of hormones in conjunction with the use of antibiotics, additional data should be provided as they are of interest also to the readers of print media [40]. The same is true for questions regarding systemic effects of oral contraceptives, such as lipid metabolism (eg, decreased High Density Lipoprotein =HDL/Low Density Lipoprotein=LDL quotient under the influence of gestagens), blood pressure (eg, hypertension as contraindication for hormonal contraception), carbohydrate metabolism (eg, latent diabetes considered as unfavorable for the use of oral contraceptives and patent diabetes as relative contraindication), liver function (eg, danger of cholelithiasis due to reduced formation of cholic acid), and clotting system (eg, positive correlation between dosis of ethynodiol and occurrence of thrombosis and embolism) [12]. (p. 73) Still unresolved, though implicitly deemed probable for a long time [38], (p. 895) is a causal relationship between hormonal con-

traception and psychiatric disorders, such as depression [41]. In the face of unresolved questions and still incomplete descriptions of side effects found in research publications, it is understandable that women seek alternatives in the area of non-hormonal natural contraception. These methods are not only considered to be free of adverse events and risks, but they also have the potential of being instrumental in infertility treatments.

Regarding the topic of fertility, attention must be drawn to pharmacogenetic studies on Tamoxifen, a drug that originated in research on fertility in the 1960s [42]. This antiestrogenic drug is now widely used in the treatment of estrogen receptor-alpha-positive breast cancer. Tamoxifen is bioactivated by cytochrome P450 (CYP) enzymes such as CYP2B6 and CYP3A475, leading to the formation of metabolites with higher activity, including 4-hydroxytamoxifen and endoxifen [43]. Apparently, polymorphisms in the genes encoding these enzymes influence not only tamoxifen but also active tamoxifen metabolites in the serum and consequently affect patient response rates. Due to a high interindividual variability in response, a personalized approach to treatment has been envisaged. As to the question of tailoring tamoxifen treatment, multiple studies have been undertaken to clarify the influence of polymorphisms on the pharmacokinetics and pharmacodynamics of Tamoxifen. However, "Personalized treatment of tamoxifen based on genotyping has not yet met consensus [43]."

Besides studies on tamoxifen in the framework of fertility research, there are other studies focusing on the question of fertility for special populations. One of the most recent studies emphasizes the importance of the fertility awareness-based methods for a special group of patients, ie, HIV serodiscordant couples [44]. This study convincingly assumes that heterosexual HIV serodiscordant couples constitute a special group for whom the balance between desired pregnancy and the risk of viral transmission should be carefully considered and optimized. Concerning cost-effectiveness, the calendar, basal body temperature and cervicovaginal mucus secretions are considered as the most accessible and sensitive fertility awareness-based methods. In conclusion the study declares that these methods "Provide effective, economical and accessible options for HIV serodiscordant couples to conceive while minimizing unnecessary viral exposure [44]."

The question of special populations is crucial no only for fertility treatments but also for patients envisaging contraception while suffering from malignant diseases or in the aftermath of cancer treatment. Another open question is the causal relationship between ovulation inhibitors and neoplasias. Controversial results on these topics have been reported over the years, but at least the increased risk of cervical intraepithelial neoplasia for women taking the pill has been known for several decades [12].(p. 77)

## Can Drugs and Devices be Used Safely ?

In view of a great number of unresolved questions, contraindications, adverse events, and risks associated with hormonal contraception, women are well advised to exert caution vis-à-vis the frequently encountered claim that these and other contraceptive methods "Can be used safely." At times it might be advisable to disregard assertions of safety if they are uttered by authors who have to declare conflicts of interests such as fees for serving on advisory boards, grant supports from pharmaceutical companies, and similar incentives to favor a certain product. Above all, women must be aware of the ambiguities inherent in the notion of safety. Thus, in one of the most recent studies on emergency contraception [45], (p. 8) drugs are considered safe as long as they do not cause death or a serious complication: "No deaths or serious complications have been causally linked to emergency contraception." What remains to be clarified, of course, is the notion of a "Serious complication," because each woman might want to exercise her own judgement as to what a serious complication could mean for her personally, taking into account her age, professional pursuits, family status, etc.

What must be reiterated in this context is the lack of protection regarding Sexually Transmitted Infections (STI). As is true for most other hormonal methods and devices, except abstinence, LARCs cannot be considered "Safe, with regard to contagious diseases." Sexually active women are exposed to the risk of pregnancy as well as to the risk of Sexually Transmitted Infections (STIs), such as HIV, hepatitis B, human papillomavirus, Chlamydia trachomatis, syphilis, and gonorrhea the sequelae of which may be life-threatening. Implantable contraceptives neither increase the risk of nor offer protection against STIs [39]."

From an international standpoint it is noteworthy that for a considerable amount of time the topic of safety and adverse events has been a focus of interest not only for gynecologists as experts in the field but also for general practitioners. German general practitioners proposed as early as 1998 a scheme in which oral contraceptives are causally related to the incidence of certain conditions [46]. (p. 845) According to this scheme, the incidence is increased for hypertension, coronary angiopathies, rosacea, ulcus ventriculi, cystitis, Budd-Chiari syndrome (occlusion of vena hepatica due to idiopathic thrombosis, tumor, or other causes resulting in hepatosplenomegaly, jaundice, ascites, and portal hypertension), thromboembolism, adenomas of the liver, vitiligo, colitis ulcerosa, cervicitis, epileptic seizures, apoplexy, chloasma (patchy hyperpigmentation), gingivitis, cholelithiasis, porphyria (disturbance of porphyrin metabolism), and otosclerosis. The incidence seems to be unaffected for mammary carcinoma and cervical carcinoma. The incidence seems to be reduced for ovarian carcinoma, endo-

metrial carcinoma, adnexitis (salpingo-oophoritis), endometriosis, benign ovarian tumors, anemia, ulcer duodeni, myasthenia gravis, diseases of the thyroid gland, rheumatoid arthritis, scleroderma (increment in collagenous connective tissue in the skin), hypermenorrhea, dysmenorrhea, premenstrual syndrome, hirsutism (growth of hair in unusual places), acne (inflammatory condition of the sebaceous glands), and benign diseases of the breast.

Although this scheme enumerates an astonishing number of conditions it is far from being complete. With the advancement of research new insights are gained, as for example on the hereditary angioedema [47, 48] whose manifestations as larynx or glottis edema can lead to life-threatening conditions [49, 50]. Estrogen-containing medications, besides Angiotensin Converting Enzyme (ACE)-Inhibitors and acetic acid, have been found to be causally related to the hereditary angioedema, whose type III occurs-for reasons unknown-predominantly in women [51].

Given the possibility of complications that might be uncovered only by future research, statements regarding safety of drugs and devices must be examined with utmost care. Besides scientifically documented threats to safety, one must pay heed also to each woman's subjective intolerance to hormones or aversion to drugs and devices. Such subjective predispositions might be the primary motif for women to search for solutions in the area of definitely "Safe" contraception. As to the number of women who would be willing to engage in safe non-hormonal contraception national health statistics are called upon, but have so far apparently not addressed this issue.

## **Contraception and Pregnancy as A Focal Point of Health Statistics**

Although contraception per se is a predominantly gynecological issue, the intricate interlacing with other disciplines, especially with population studies, makes it understandable that researchers from numerous other areas feel qualified to elucidate various aspects of family planning and birth control. As regards statistical data which provide insight into such questions as frequency of contraceptive use, intended or unintended pregnancies, and abortion, caution must be exercised in the face of methodologies used, assumptions made, and estimates propounded. As can be seen from a 2012 study on intended and unintended pregnancies worldwide [52], serious problems arise in attempts to gather data from merely a limited number of regions and to use these data in propounding estimates for a large number of other regions, which are quite different from a cultural as well as socio-economic viewpoint.

Thus, in targeting the entire European continent regarding data on unplanned birth, so-called "nationally representative" surveys-whose quality is rarely comparable to the surveys of the U.S. National Center for Health Statistics-were conducted in only

seven countries. For data from some specific areas three countries were chosen without a rationale for the choice of precisely these countries exhibiting considerable socio-economic inequalities: "For Europe, estimates of unplanned births in 2012 . . . are based on nationally representative surveys conducted between 2008 and 2012 in seven countries representing 55percent of births in Europe, and surveys conducted in 2004 to 2007 in three countries (Moldova, Romania, and Ukraine) representing 9 percent of births in the region [52]." (p. 304)

As the authors admit, some European subregions are under-represented by these studies so that subregional averages are not computed. In light of the assertion that "A weighted average of the survey-based estimates is applied to all of Europe [52]," (p. 304) the question arises as to how reliable such weighted averages are. This question is particularly prominent if one considers the historically deeply rooted socio-cultural differences between East and West Europe, the less pronounced but clearly evinced differences between North and South Europe, and the special status of Middle Europe.

The most crucial problem is of course terminology clarifying the primary aim of the study, ie, "intended and unintended" pregnancies. In formulating definitions, the authors propose that unintended pregnancies "Consist of unplanned births, induced abortions, and miscarriages resulting from unintended pregnancies." As "unplanned births" they define those "Occurring two or more years sooner than desired ("mistimed") and those that were not wanted at all by the mother ("Unwanted") [52]." (p.303) In the face of such definitions one senses scepticism about the assumption that women are capable of indicating with some degree of certainty at which point in time they planned to achieve pregnancy and at which point in time they did not desire to get pregnant. Along the same line, there is the problem of the retrospective character of questions asked and the change in women's perception of pregnancy over time. "For the most part, our estimates of the incidence of unplanned births rely on women's retrospective reports up to three years after the birth occurred [52]." (p. 311) such reports, it must be feared, are influenced by changes in women's attitudes toward their births over time. As has been shown by studies and is easily credible, women who affirm they do not desire to become pregnant but later do become pregnant and have a child, will report at the time of the survey that the pregnancy was intended.

Concerning the heterogeneous character of definitions used, the authors can only conjecture that biases created by non-uniform definitions can be outweighed by improved estimates: "We deem that the improvement in the subregional and regional estimates gained by using these data outweighs the relatively small biases introduced by the different definitions [52]." (p. 303)

Besides uniform definitions, a fundamental problem in statistical studies is the use of data sources. Not only are there data

sources that are utterly incomparable, but there are also data sources that differ with regard to time periods. It is such unreliable data sources that might have led to results showing an increase in the unintended pregnancy rate for Europe. “The observed increase in the unintended pregnancy rate in Europe could result in part from the use of noncomparable data sources and of data sources from different countries for the two time periods, and possibly from high unintended pregnancy rates in the growing population of immigrants [52].” (p. 312)

Although the concept of “Unintended pregnancy” is pivotal in some statistical studies, there is no unequivocal definition as to what constitutes an “unintended pregnancy.” This crux is considered to be a “Critical methodological challenge” and linked to several factors, namely changes in fertility intentions over time, a woman’s attitude towards a specific pregnancy, and the definition of “mistimed” pregnancy: “Moreover, defining unintended pregnancies presents a critical methodological challenge because (a) the intensity of fertility intentions can vary between /sic!/ women and over time in a woman’s life, (b) a woman’s feelings about a specific pregnancy can change with the passage of time, and (c) the degree of mistiming used to define mistimed pregnancies varies across studies and affects resulting estimates.” [52] (p. 312) Another methodological concern is the capacity of capturing more nuanced elements of fertility intentions, and not all studies succeed in capturing such elements: “The dichotomous measure employed here does not capture more nuanced elements of fertility intentions addressed in other research [52].” (p. 312)

Taking into account such methodological problems, one might or might not be convinced by the claim that 222 million women in the developing world “Had unmet need for a modern contraceptive method as of 2012 [52].” (p. 312) Hypothesizing on the possibility of meeting these needs, it is estimated that “54 million unintended pregnancies, including 21 million unplanned births and 26 million abortions, would be averted annually [52].” (p. 312)

Regardless of the preciseness of data propounded, the possibility of abortion as a solution to unintended pregnancy must be taken seriously, especially in view of its worldwide dimensions: “Eighty-five million pregnancies, representing 40 percent of all pregnancies, were unintended in 2012. Of these, 50 percent ended in abortion, 13 percent ended in miscarriage, and 38 percent resulted in an unplanned birth [52].” (p. 301) In view of such figures proponents of family planning are entitled, of course, to draw attention to the problem of abortion [53] and to express hope that the incidence of unwanted and mistimed pregnancies should decline in the coming years, as is the aim of the 2012 London Summit on Family Planning.

## Conclusion

In view of statistical studies plagued by methodological challenges, incomplete surveys of contraceptive methods presented by U.S. agencies, outdated figures in research publications, error prone websites, and unreliable data encountered in various media, it is doubtful that information presently accessible for U.S. women is sufficient to enable them to make decisions as fully informed autonomous patients. Patient autonomy, however, is one of the fundamental ethical principles and an epochal achievement of the American Hospital Association whose “Bill of Rights” for hospital patients came into existence as early as 1973 [54]. In addition to the neglect of the bioethical principle of informed consent-requesting completeness of information-there is presently also disregard for the principle of *nil nocere*-stipulating priority for the least harmful method. Indifference towards these principles is tantamount to denial of patient autonomy. The inadequacies found in scholarly publications and websites underline the need for revisions of data and heightened sensitivity to bioethics. Researchers and publishers are well advised, therefore, to reflect on their ethical responsibility to foster autonomous decision-making processes for each woman, regardless of her socio-cultural background or religious belief.

## Implications

The socio-political importance of access to contraception for all women has been sufficiently proven and underscored by the stipulation of saving taxpayer money through family planning [2]. What remains to be accomplished is dissemination of information in compliance with bioethical principles, ie, accurate and complete descriptions of all available methods of contraception, including those that are most suitable for women who seek to avoid drugs, devices, risks and side effects [55]. Heightened sensitivity for the needs of these women in the future seems the more mandatory as evidence-based research yields data proving that hormonal contraceptives impact negatively on women’s general well-being and on their quality of life [56].

Moreover, as in other societies [57], a considerable segment of the U.S. population professes a preference for a “natural” lifestyle. This segment might be particularly inclined to embrace contraceptive methods that are most fittingly labelled “Natural” so that the percentage of U.S. women who are presently not using contraception (38%) [29] could be reduced further. From a socio-political perspective, which upholds equal rights, and from a bioethical viewpoint, which emphasizes autonomy, it seems imperative that unadulterated information on all available methods be provided in accord with the principles of informed consent and *nil nocere*. The common goal of efforts in health care and health politics must be the legally anchored right of each woman to exert

her autonomy and make a well-reflected choice with regard to contraceptive options according to her own needs and convictions, as has been claimed as early as 2003 [58].

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