



Should Women Consult Health Agencies in Matters of Birth Control and Contraception?

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Abstract

Background and Aim: On the background of recent developments revealing the harmful effects of contraceptive devices which are recommended by health agencies the paper aims at analyzing publications and other information material emanating from these agencies. This analysis – guided by the bioethical principle of informed consent -- focuses on flawed science, ambiguous language, and misleading data.

Method and Material: The method consists of collecting and analyzing information provided by health agencies for consumers inquiring about the safety and efficacy of contraceptive products. The material comprises documents, charts, leaflets and other publications emanating from the most authoritative and most frequently consulted health agencies, in particular those active in the US and European countries.

Results and Implications: As a result of the investigation women must be advised to consult only a selected number of health agencies, especially those which take into account findings of pharmacovigilance, pharmaceutical vigilance, and scholarly publications focusing on the safety of contraception. The implications from an economic perspective are the discontinuation of funding through taxpayer money for those health agencies which continue to disseminate flawed science and demonstrate incompetence in questions about the safety of contraception.

Keywords

Birth Control; Contraception; Food and Drug Administration; Centers for Disease Control and Prevention; Planned Parenthood; Pharmacovigilance

Introduction

Millions of women worldwide consult health agencies in matters of birth control and contraception, and the question arises whether such consultations can be recommended. Given past and recent developments concerning harm caused by contraceptive products, it must be examined as to whether or not the information provided by health

agencies is correct, accurate, complete comprehensible, and reliable.

FDA - Incompleteness and Misleading Data on Efficacy

Based on clinical experience it can be assumed that the US Food and Drug Administration (FDA) is the

most frequently consulted health agency. Millions of consumers take it for granted that the FDA as the highest authority in matters of food and drugs is reliable. Unfortunately, the FDA does not stand up to these expectations in the area of birth control and contraception because its most recent Chart of Birth Control Methods [1] is incomplete, mentions only a limited number of trivial adverse events, and presents data on efficacy which make it impossible to distinguish the most effective methods from those that are less effective.

Similar to an earlier published ranking -- the "FDA Approved Methods of Birth Control" of 2013 [2] -- the new chart of 2018 fails to address the parameter safety. Instead, it contains only a small rubric entitled "some risks or side effects." Unfortunately, this rubric is incomplete and provides only rudimentary information by using vague terminology. Thus, in the case of intrauterine devices the most feared complications, namely pelvic inflammatory disease (PID), perforation, and expulsion, are not mentioned at all. Instead of drawing attention to these well-known adverse events, only a few side effects are enumerated, namely "Irregular bleeding. No periods (amenorrhea). Abdominal/pelvic pain" [1].

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; rather, only trivial symptoms -- commonly attributed to oral hormonal contraceptives -- are mentioned, namely "Menstrual Changes, Mood swings or depressed mood, Weight gain, Headache, Acne" [1]. 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 [3].

Besides describing a device that is no longer available on the market due to the harm experienced by users, the FDA chart suffers from another fundamental flaw, namely a lack of precision regarding efficacy. The imprecise data on efficacy are 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 [4], the World Health Organization (WHO) [5], and the Synoptic Overview of Contraceptive Methods [6] 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 makes it impossible to recognize the undisputed superiority of implants. The FDA chart misleads the consumer into believing that there is no difference in efficacy between implants and intrauterine devices. As a consequence, women are at risk to choose inappropriate methods, and quite a number 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 looms large 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 [5], the Contraceptive Technology Failure table [4], and the Synoptic Overview of Contraceptive Methods [6].

The natural methods omitted in the FDA chart are internationally acknowledged and belong to the safest of all methods [7]. The importance of these natural methods particularly for women who do not tolerate hormones or devices has been highlighted infrequent publications, including the one by the American Congress of Obstetricians and Gynecologists (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" [8].

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” [9].

By omitting these methods also in its latest chart of 2018, the FDA violates again -- as in the 2013 published survey[2] -- the principle of informed consent and denies women the right of self-decision [10]. As is known, this principle requires completeness of information so that the patient is enabled to make “an intelligent choice” [11]. 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) [4]. In failing to provide complete information on safety and efficacy, the FDA not only ignores the fundamental bioethical principle of *nil nocere* (no harm) but also infringes on civil law through negligent misrepresentations.

The FDA’s failure to comply with the principle of informed consent appears particularly problematic from the perspective of consumers’ rights because as early as 2013 similarly negligent information had been proposed by the FDA. The 2013 version was entitled FDA “Food and Drug Administration (FDA) Approved Methods of Birth Control” [2]. In this ranking, percentages are indicated for the “number of women out of 100 who will not get pregnant”, and the usual distinction is made between “perfect” and “typical” use. According to this FDA survey, several methods achieve more than 99 percent for both perfect and typical use, namely Sterilization Surgery for Women, Surgical Sterilization Implant for Women, Sterilization Surgery for Men, Implantable Rod, and IUD. These percentages are indicated in the FDA survey as follows:

Sterilization Surgery for Women	>99%
Surgical Sterilization Implant for Women	>99%
Sterilization Surgery for Men	>99%
Implantable Rod	>99%
IUD	>99%

As can be seen, all the above-listed methods are rated as equally effective in both perfect and typical use and are ranked higher than those whose typical use estimates are inferior to their perfect use estimates, namely:

- Shot/Injection >99% perfect use (91% typical use)
- Oral Contraceptives (Combined pill: “The Pill“) >99% perfect use (91% typical use)
- Oral Contraceptives (Progestin-only: “The Pill“) >99% perfect use (91% typical use)
- Oral Contraceptives (Extended/Continuous use: “The Pill“) >99% perfect use (91% typical use)
- Patch >99 perfect use (91% typical use)
- Vaginal Contraceptive Ring >99 perfect use (91% typical use)

Among the less effective methods are Male Condom (98% perfect use - 82% typical use); Diaphragm with Spermicide (94% perfect use - 88% typical use); Sponge with Spermicide (80-91% perfect use - 76-88% typical use); Cervical Cap with Spermicide (74% perfect use - 60% typical use); Female Condom (95% perfect use - 79% typical use); Spermicide (82% perfect use - 72% typical use).

Besides indicating misleading estimates for efficacy the FDA survey presents controversial information on Emergency Contraception (EC). As EC pills are administered a posteriori, the relevant estimates are purely hypothetical because they are based on prospective assumptions. Besides indicating the controversial estimate of 85% for EC, the FDA erroneously recommends that EC should not be used as a regular form of birth control and should be implemented within 70 to 120 hours of unprotected coitus. Contrary to this recommendation by the FDA new research has shown that EC can be used as a regular form of birth control, especially by women whose sexual activity is reduced to no more than one incidence per month [12,13].

In a comparison of this FDA survey with the table proposed by Contraceptive Technology [4], it becomes obvious that the FDA survey lacks the precision inherent in reliable tables and charts. While the latter

show unambiguously that the implant Implanon (precursor of Nexplanon) with a 0.05 failure rate for both perfect and typical use is by far more effective than all the other methods, the FDA survey does not reflect this superiority. Consequently, the woman who opts for the ParaGard (copper T) intrauterine device (<99% for both typical and perfect use according to FDA) does so in neglect of all those methods whose perfect use failure rates are superior to ParaGard's perfect use failure rate of 0.6, namely implants (0.05), Mirena (LNg) (0.2), Depo-Provera (0.2), NuvaRing (0.3), Evra patch (0.3), or combined pill and progestin-only pill (0.3) [4].

As can be seen, the FDA perpetuates the errors which had been disseminated already in the 2013 FDA Approved Methods of Birth Control. Both these charts present misleading information, and quite a several women who follow FDA guidelines might choose an inappropriate method and incur substantial financial damage. In the same vein, 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 material comes to the forefront also in other rankings such as the one proposed by the Center for Disease Control (CDC) in 2015 [14] or by Planned Parenthood [15].

CDC and Planned Parenthood – Neologistic Redundancy and Neglect of Adverse Events

In its ranking of 2016, entitled “Effectiveness of Family Planning Methods” the CDC fails to make the essential distinction between typical and perfect use, a distinction that is crucial to recognize the most effective of the natural methods. Instead of furnishing precise data, the CDC comments on the fertility awareness-based methods by recommending abstinence and condom and by drawing attention to the efficacy of “newest methods”: “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” [14].

As can be seen, the CDC fails to mention the symptothermal method as the most effective of these methods with a perfect-use estimate of 0.4 (according to Contraceptive Technology [4]) and a Pearl Index of 0.8 (according to German research [7]). Besides omitting the most effective of the fertility awareness-based methods, the CDC fails to adhere to the standard terminology and introduces the unscientific designation “newest methods”. A similar terminological idiosyncrasy appears in the latest “US Medical Eligibility Criteria (US-MEC) for Contraceptive Use” (last reviewed February 1, 2017) [16].

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.” 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 taxonomies 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 symptothermal, temperature, cervical mucus, and the calendar method -- which are known also as Periodic Abstinence Methods [17].

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 symptoms-based and calendar-based. Unfortunately, the confusing nomenclature used in the CDC classification makes the primary target of taxonomies even more difficult, especially 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 [16] might be due to the prevalence 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 abounds. In this section, an astonishing number of participants have to 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 emphasized pharmaceutical products at the expense of 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 [15], the FAMs are omitted without any further explanation. In its new chart entitled "Comparing Typical Effectiveness of Contraceptive Methods", [18] however, Planned Parenthood discusses the natural methods in a section entitled "Fertility Awareness-based Methods" [18].

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" [18]. 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..." [18].

While it is true that fertility awareness methods 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, ie, cycle-computer, and measuring-sensor, greatly facilitate their use.

With respect to 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 the hundreds of charts presently available that perpetuate flaw and error, as can be seen from the summary provided by the WHO [19]. It is unresolved why the WHO invests financial resources into disseminating misleading information. Data in most of these charts are copied from error-prone sources; and the dissemination of error due to an astonishing number of multipliers - including numerous health agencies -- is meanwhile beyond control.

In light of flawed science perpetuated also by health agencies, women and their doctors are faced with the dilemma of how to circumvent unreliability and untrustworthiness. The best way to cope with this dilemma is to avoid publications adulterated by conflicts of interest and to consult such sources as pharmacovigilance, pharmaceutical vigilance, and surveys acknowledging the priority of safety.

Trustworthy Sources of Information: Pharmacovigilance, Pharmaceuticovigilance, and Surveys Prioritizing Safety

Pharmacovigilance over the last decades has brought to light adverse events, risks, and potential complications not mentioned by pharmaceutical companies in their "Instructions for use" of "Packaging Label". Among the most important findings is suicide causally related to hormonal contraception [20,21], and leukemia in children borne by mothers using hormonal contraceptives [22]. As an adjunct discipline, pharmaceutical vigilance has identified and rectified inaccuracies, ambiguities, and misrepresentations in publications by manufacturers

destined to inform the consumer about their products. Thus, regarding the device for permanent contraception that had to be removed from the market at the end of 2018 pharmaceutical vigilance drew attention to the misleading description of the mechanism of action [23]. For the Belgian intrauterine device Gynefix, pharmaceutical vigilance called attention to the harm caused by perforations and proved that claims about efficacy had been made

without providing evidence [24]. For the Emergency Contraception pill ulipristal acetate, pharmaceutical vigilance has brought to light the open question of abortogenicity [13].

Besides paying heed to findings in pharmacovigilance and pharmaceutical vigilance women and their doctors can be encouraged to consult surveys of contraceptive methods that

Table-1: Safety-centered overview of contraceptive methods

Method	Safety (no harm in the sense of “nil nocere“)	Efficacy Perfect- Non-perfect use	Satisfaction [% of women continuing after one year] Convenience	Cost & Specifications
Symptothermal (measure body temperature and observe cervical mucus)	High	0.4-24	?	No cost. Cervix palpated has soft consistency and is open.
			High	
Ovulation (based on cervical mucus).	High	Mar-24	?	No cost. Observe cervical mucus (“spinnbarkeit” indicates fertile period).
			High	
TwoDay (based on cervical mucus) Fertility not to be assumed after 2 consecutive “dry” days (or absence of secretion).	High	Apr-24	?	No cost. Fertile days to be assumed when cervical mucus is present (watch color and consistency).
			High	
Standard Days Method (SDM) – based on calendar (to track fertile period)	High	May-24	?	No cost. Fertile period usually days 8-19 of each 26-32 day cycle.
			High	
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	Jan-25	?	No cost. Does not predict end of fertile period, but conception is unlikely from the 4th day following rise of temperature (until next period).
			High	
Calendar (rhythm) method Monitor menstrual cycle for at least 6 months by using calendar.	High	Sep-25	?	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 last fertile day. Caution with drugs such as NSAID, antibiotics, anxiolytics, anti-depressants, and others (consult physician).
			High	

Withdrawal (coitus INTERRUPTUS)	High High	4-22 ?	46%	Semen must be discharged outside the vagina.
			High	
Lactational Amenorrhea (LAM) Requires breastfeeding day and night of infant less than 6 months old.				Effective in preventing ovulation as long as monthly bleeding has not yet resumed.
Male condoms Latex allergy possible.	Moderate	2-18/ 43%	43%	Low cost. Protects against sexually transmitted diseases (STD) including HIV.
			High	
Implant (Small, flexible rod or capsule placed under the skin of the upper arm; contains progestogen 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 cost. Has to be implanted by clinician.
			High	
Mirena (LNG) Intrauterine device (IUD) (T-shaped plastic device inserted into the	Moderate Pelvic inflammatory disease (PID)	0.2-0.2	80%	High cost. Prevents contact between sperm and egg by
uterus; releases continuously small amounts of levonorgestrel).	common, ascending infection and expulsion possible.		Moderate	thickening cervical mucus. Amenorrhea common.
ParaGard (copper IUD)	Moderate	0.6-0.8	78%	High cost. Copper component damages sperms.
			Moderate	
Depo-Provera	Moderate	0.2-6	56%	High cost.
			Moderate	
Combined oral contraceptives (COCs)= "the pill"	Moderate	0.3-9	67%	Moderate cost. Contains estrogen and progestogen.
			Moderate	
Progestogen-only pill (POP) or "minipill"	Moderate	1-3(10)	67%	Moderate cost. Thickens cervical mucus and prevents ovulation.
			Moderate	
Evra patch	Moderate	0.3-9	67%	High cost.
			Moderate	
NuvaRing	Moderate	0.3-9 67%		High cost
Combined contraceptive patch and combined contraceptive vaginal ring (CVR)	Moderate	1-8(?)	?	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).

			Low	
Monthly injectables or combined injectable contraceptives (CIC)	Moderate Irregular vaginal bleeding	01-Mar	?	High cost. Injected monthly into muscle.
			Low	
Progestogen-only injectables	Moderate Irregular vaginal bleeding; delayed return to fertility after use.	01-Mar	?	High cost. Injected into muscle or under skin every 2 to 3 months (depending on product)
			Low	
Diaphragm Must be used for each coitus.	Moderate	06-Dec	57%	High cost.
			Low	
Emergency Contraception (EC) Pills ulipristal acetate 30 mg or levonorgestrel 1.5 mg should be taken twice to prevent pregnancy up to	Moderate - Low	Jan-15	?	Moderate cost. Instead of pill IUD (copper or levonorgestrel) can be inserted.
			High	
5 days subsequent to coitus				
Male sterilization (vasectomy)	Moderate Adverse events and risks associated with surgery.	<1 (after 3-months semen evaluation). 2-3 (without semen evaluation).	100%	High cost. Permanent contraception due to cutting vas deferens tubes (which transport sperm from testicles).
			High	
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 cost. Surgery required.
			High	
Sterilization through creation of scar tissue (ESSURE)	Very low	?	?	Device has been withdrawn from the market in several countries, including the U.S.
			Low	
Sponge	Moderate	20-24 (parous women) 9-12 (nulliparous women)	36%	Moderate cost. Must be used for each coitus.
			Moderate	
Spermicides	Moderate	18-28	42%	Moderate cost.
			High	

prioritize safety. The most comprehensive of these surveys which includes all the salient data contained in the most authoritative ratings and tables are shown in **Table-1**.

As can be seen, the Safety-Centered Overview of Contraceptive Methods is an innovative approach to provide trustworthy, comprehensive, and comprehensible information not only on the well-

known parameter efficacy but especially on safety, ie, adverse events, risks, and potential complications. This approach honors more than others the principle of informed consent as it enables the reader to make an “intelligent choice”. Thus, it should be of particular interest to the millions of women who have been the victims of hormonal contraception and have chosen to embark on viable alternatives such as natural methods [25].

Conclusion and Implications

The foregoing discussion shows that some of the most renowned and authoritative health agencies provide information that is inaccurate, misleading, and incomplete. Women are encouraged therefore to consult reliable sources of information, namely publications in pharmacovigilance, pharmaceutical vigilance and surveys emphasizing safety.

From an economic perspective, it must be borne in mind that health agencies in the US and many other countries are receiving substantial amounts of taxpayer money due to the fact that they are considered as reliable sources of trustworthy information. An intensified control of conflicts of interests should be implemented to bring to light the incidences of flawed science as a result of financial incentives. Efforts to eradicate financial interests from scholarly publications should be intensified not only to save taxpayer money but above all to protect women's safety.

Conflict of Interest

The author declares that there is no conflict of interest.

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