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Women's Rights Disregarded by the US Food and Drug Administration and Government-Funded Agencies

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Abstract

On the background of a vast, ever-increasing literature on women's issues, the paper aims to prove, by way of an international comparison that US research publications as well as public health media do not respect women's rights and provide unsatisfactory and at times error-prone information on contraceptive methods. The methodological concept of the paper consists in an analysis of the most salient publications as well as websites of public health agencies, which are compared to their European equivalents. The study concludes that present day US research prevents women from exercising their rights as autonomos patients who are informed according to the bioethical principles of informed consent and "nil nocere".

Keywords: Women's rights; Print media; Symptothermal method; Spermicide method; Fertility awareness; Cervical Mucus; Mastalgia; Peritoneal irritation

Introduction

Day after day millions of women worldwide choose for the first time or continue to use a method of contraception in order to engage in family planning and birth control. It has to be feared that many of them do not make the right choice and expose themselves unknowingly to adverse events, side effects, and risks. Why? Because they base their decisions on incomplete, inaccurate, or misleading information which they find in websites, print media, and research publications.

Discussion

In seeking information on contraceptive methods millions of women turn to the publications by one of the most influential agencies, the US Food and Drug Administration. In fact, the FDA provides information on contraception by presenting a consumer-friendly survey of FDA-approved contraceptive methods [1].

Yet, to the disappointment of many women seeking alternatives to pills and devices, there is no mention of such methods as Symptothermal, Ovulation, Two Day, and Standard Days, i.e., methods that have been included in international research and in research on contraceptive technology since 2011 (Table 3.2 from Trussell [2]).

According to this research, the perfect use failure rates of 0.4 (Symptothermal), 3 (Ovulation), 4 (Two Day), and 5 (Standard Days) respectively (Figure 3.1 from Trussel [2]) indicate that these methods are by no way inferior to some of the methods included in the FDA survey, e.g., diaphragm with spermicide, sponge with spermicide, and cervical cap with spermicide. Disregard for those methods on the part of an information-provider is not reconcilable with the bioethical principle of "informed consent" which requires complete and accurate information for the patient on all aspects of a medical issue, in this case availability of contraceptive methods. In addition, the principle of "nil nocere" must be taken into account because it draws attention to the issue of safety and stipulates priority for the least harmful methods. As the FDA makes no mention of any other method besides the 19 listed in the survey, several methods are concealed from the consumer although they are recognized by international experts in the field and have the advantage of being unblemished by any side effects and risks. It has to be feared, therefore, that US women inquiring about contraceptive options at the FDA website are left with the disappointing impression that there are no other contraceptive methods available than the 19 listed by the FDA. Such disappointment is particularly painful for women whose primary interest is safety; they remain ignorant of the safest of all presently available methods involving neither drugs nor devices but requiring merely diligent observation of cervical mucus and basal body temperature (BBT). More precisely, the Ovulation and Two Day method are based on evaluation of cervical mucus, i.e., women observe that during

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ovulation, under the influence of estrogen, mucus is thinner and more alkaline than under the influence of progesterone. It increases in elasticity ("spinnbarkeit") so that a drop can be stretched into a long, thin thread up to a length of 8 cm to 12 cm or more at the time of mid-cycle. The Standard Days method uses a calendar and avoids intercourse on cycle days 8-19. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of both cervical mucus and temperature to determine the last fertile day (Figure 3.1 from Trussel [2]). 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 the FDA passes them over in silence.

The lack of completeness conspicuous in the FDA survey is particularly striking from an international perspective. More specifically, European research has investigated the issue of contraception as a long-known phenomenon in the history of medicine and has endeavored as early as 2000 to establish for each single method its proper failure rate, including each one of the so-called natural family planning methods [3]. Instead of collectively attributing failure rates to a group of methods, European scholars over the years have made efforts to assess each method individually [4]. As a result of these efforts, the Symptothermal method with a Pearl Index of 0.8 has emerged as one of the reliable methods, surpassed only by tubal sterilization (Pearl Index 0.09-0.4), depot gestagens (Pearl Index 0.03-0.9), and oral contraceptives (Pearl Index 0.1-1.4) [3]. According to German research in 2000, the basal temperature method (Pearl Index 1-3), is superior to chemical spermicide (Pearl Index 12-20), while the cervical mucus (Pearl Index 15-32), and calendar after Knaus-Ogino (Pearl Index 15-40) are somewhat comparable to coitus interruptus (Pearl Index 8-38). The assessment of each single method with a Pearl Index and the inclusion in taxonomy customary in German research is rather an exception in US research publications as well as in public health media where methods are not distinguished from one another and inaccurate failure rates are attributed to methods that are frequently defined in an ambiguous fashion.

The US Department of Health and Human Services (Office on Women's Health) [5] 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 5 (Standard Days) [2]. Interestingly enough these methods are described only in a different website with focus on fertility awareness, provided by the Office of Population Affairs [6]. 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 "Symptothermal" is described as a combination of BBT and cervical mucus, but all four methods are grouped under one single failure rate, namely 25, although it seems conclusive 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") [7].

Unexpectedly, lack of accuracy 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" [8]. From an international perspective it seems misleading to speak collectively 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 IUDs (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).4 Paradoxically, the ACOG contradicts its own statement in another website, devoted to frequently asked questions [9]. In this website, the fertility awareness methods are no longer discarded as ineffective but are praised for their advantages: "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 on fertility awareness-based method, but the misleading statement from 2015 which is reiterated in a website of 2017 by one of the most influential government agencies, namely the Center for Disease Control [10]. This agency perseveres on obsolete data even in a 2016 "US 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%).

For specialists 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 appears in a publication by one of the most prominent US opinion leaders, the Harvard School of Medicine. In a Family Handbook of 1995 as well as in a second edition in 2005 - an annihilating judgment is pronounced due to an effectiveness rate of 19%: "Natural birth-control methods are the least reliable of the contraceptive methods" [11].

Besides unscientific statements contradicting modern contraceptive technology research, it is inaccurate assessments of an entire group of methods that deprive institutions and agencies of credibility, as for example the misleading comment made by the US Center for Disease Control (CDC) in 2017: "Newest methods (Standard Days Method and Two Day Method) may be the easiest to use and consequently more effective" [10]. As it might be true that fertility awareness methods are among the easiest to use, it is not true that they are the newest methods. The Standard Days Method is nothing more than a new version of the calendar method described by Knaus-Ogino as early as 1932-1933, and the Two Day method is based on the Ovulation method formulated by Billings in 1964 [3].

What is particularly notable from a sociopolitical aspect is the publication on contraceptive methods by Planned Parenthood, an organization which continues to use considerable amounts of tax-payer money, but does not provide reliable, accurate, and complete information on the full range of contraceptive options for all women [12]. The distinctive feature in the Planned Parenthood's overview of contraceptive methods is the dichotomy between hormonal and non-hormonal methods. What strikes the reader familiar with international data is unusual failure rates, e.g., 91% to 99% for the

Pill as well as a complete absence of natural family planning methods. Interestingly, it is one of the most renowned US private universities [12] which use the survey of Planned Parenthood for its own website instead of a scientifically sound summary such as the one provided by contraceptive technology research [2].

Conclusion

The socio-economic importance of access to contraception for all women has been sufficiently proven and underscored by the stipulation of saving taxpayer money through family planning [13]. What remains to be accomplished is dissemination of information in compliance with women's political rights and bioethical principles, i.e., accurate and complete descriptions of all available methods of contraception, including those that are most suitable for women who prioritize safety and seek to avoid risks as well as side effects [14].

As in other societies [15], a considerable segment of the US population professes a preference for a "natural" lifestyle. This segment might be particularly inclined to embrace contraceptive methods that are non-hormonal and most fittingly labeled "natural" so that the percentage of US (38%) and European (8% to 34%) women who are presently not using contraception could be reduced further [16]. From a bioethical viewpoint it seems mandatory that information on all available methods including side effects be provided in accordance with the principles of informed consent and nil nocere. Such measures will assure that each woman is enabled to exercise her autonomy and make a well-reflected choice according to her political rights, her personal needs, and her convictions, as has been claimed as early as 2003 [17].

References

1. http://www.fad.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm.
2. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, editors. Contraceptive Technology. 20th ed. New York: Ardent Media, USA; 2011.
3. Gröger S, Grüne B. Contraception. In: Diedrich K, editor. Gynecology and obstetrics. Berlin: Springer; 2000. p.60-87.
4. Frank-Herrmann P, Heil J, Gnoth C, Toledo E, Baur S, Pyper C, et al. The effectiveness of a fertility awareness-based method to avoid pregnancy in relation to a couple's sexual behaviour during the fertile time: a prospective longitudinal study. Human Reprod. 2007;22(5):1310-9.
5. https://www.womenshealth.gov/a-z-topics/birth-control-methods.
6. http://www.hhs.gov/opa/pregnancy-prevention/non-hormonal-methods/natural-family-planning/index.
7. http://www.familydoctor.org/familydoctor/en/prevention-wellness/sex-birth-control/natural-family-planning.
8. Birth Control (Contraception): Resource Overview. Washington DC: American Congress of Obstetricians and Gynecologists (ACOG), USA; 2016.
9. Fertility Awareness-Based Methods of Family Planning. Washington DC: American Congress of Obstetricians and Gynecologists (ACOG), USA; 2017.
10. Center for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR Morb Mortal Wkly Rep. 2016;65(3).
11. Komaroff AL. The Harvard Medical School Family Health Guide. New York: Simon & Schuster; 2005.
12. http://www.thehoya.com/contraception-restricted.
13. Cleland K, Peipert J, Westhoff C, Spear S, Trussell J. Family planning as a cost-saving preventive health service. N Engl J Med. 2011;364(18):e37.
14. Pill choice affects clot risk. UK: NHS Choices; 2009.
15. Blankoff R. The sympto-thermal method of birth control. J Nat Glob Health. 2009.
16. Ulrich RE. Most European Women Use Contraceptives. Population Reference Bureau. 2016.
17. Birth Control: A woman's choice. Washington, DC: American College of Obstetricians and Gynecologists; 2003.