

# Safety of contraception challenged by recent adverse events and threats to women's health

Kurt Kraetschmer

Kraetschmer K. Safety of contraception challenged by recent adverse events and threats to women's health. *J Basic Clin Reprod Sci* April 2019;8(1):1-6.

**AIM:** On the background of media reports about serious harm to the health of thousands of women engaged in birth control and contraception, the paper aims at emphasizing the importance of the parameter safety in birth control and contraception.

**METHOD:** The method consists in an in-depth analysis of those sources of information that are most-widely used by women and their health care providers, i.e., packaging labels of manufacturers and statements by the FDA. In addition, the information presented by high-ranked scholarly journals, which are most commonly accessed by health care professionals is analysed.

**RESULTS:** Presently, women do not obtain information suitable for preventing harm and injury caused by contraceptive drugs and devices. Health care providers, frequently misled by journal articles, apparently fail to comply with the requirements of the principle of informed consent, despite urgings by manufacturers and the FDA.

**CONCLUSION:** At present it is difficult for women to access comprehensive, complete, and reliable information on the safety of methods of contraception. Counsel through health care providers is difficult to obtain, because doctors are frequently guided by economic principles and are also misled by editors who publish studies adulterated by conflicts of interest.

**Key Words:** Safety; Birth control; Contraception; Health care providers; Sterilization.

## INTRODUCTION

In reviewing articles on birth control, family planning, and contraception published in professional journals, it appears that there is general agreement on the safety of the methods most commonly used world-wide. In one of the more recent salient studies on Long-Acting Reversible Contraception (LARC) the authors claim repeatedly that all women can safely use these methods. Safety of IUDs and hormonal implants for almost all women is highlighted as one of the “clinical key points of the article: “IUDs and hormonal implants are safe for almost all women, including adolescents, as well as women in the postpartum or post abortion period [1]. In focusing on intrauterine devices, the authors affirm that they are safe for almost all women: “Almost all women can safely use IUDs. Exceptions include women who have hypersensitivity to copper [1], For implants it is reaffirmed: “Almost all women can safely use implants; exceptions are women who have hypersensitivity to barium or to the components of the implant [1], Concerning special populations, almost all women, including young and nulliparous, can safely use Long-Acting Reversible Contraception: “LARC methods are safe for use in almost all women, including young and nulliparous women [1]. The safety of LARC is affirmed also for postpartum and post abortion periods: “Both IUDs and implants are safe for use in the postpartum and post abortion periods, including immediately post-partum and post abortion [1]. Even for expulsion, which some authors consider as the most serious complication besides ascending infection [2], no special concerns are indicated in the study on LARC: “Although IUDs are generally safe for use in the postpartum period, the relative risk of expulsion of IUDs that are placed immediately post-partum is higher than the risk with IUDs placed at 6 weeks post-partum or later [1]. In their conclusion the authors reaffirm that safety for women of all ages is one of the noteworthy characteristics of LARC methods and stipulate world-wide dissemination of their insights: “All adolescents and adult women should be informed about the availability of LARC methods, given their extremely high effectiveness, safety, and high rate of continuation [1].

## LITERATURE REVIEW

This safe world of contraception and birth control depicted by numerous authors has been severely shaken in 2018, when a contraceptive device for sterilization became the focus of interest of news media. This interest was sparked by complaints lodged by thousands of women who had used the device and experienced severe adverse events. “But there have been reports women experienced changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergic reactions and immune-type reactions after being implanted with the device [2]. Other media highlighted additional adverse events: “Patients have reported cases of pain, bleeding, allergic reactions and cases where the implant punctured the uterus or shifted out of place [3]. Given such serious adverse events it is not surprising that legal reverberations followed suite. “It has been the subject of an estimated 16,000 lawsuits or claims filed by women who reported severe injuries, including perforation of the uterus and the fallopian tubes. Several deaths, including of a few infants, have also been attributed to the device or to complications from it [4]. One of the most crucial issues in the troubled history of the device is the role of the FDA which had approved the insert as safe and still insists on its safety 16 years later. This insistence on the safety of the device is surprising not only in light of complains by thousands of women but also in the face of the company's announcement that the device will be removed from the market. “Bayer announced that they will no longer sell or distribute Essure in the U.S. after December 31, 2018, for business reasons. This information does not change the FDA's understanding of the safety and effectiveness of the device; however, the FDA emphasizes that women with Essure should speak with their physician about any medical questions they may have [3]. The FDA's emphasis on intensified consultation by physicians brings to light the second crucial issue of the troubled history of the device, namely the role of the health care providers. In fact, the FDA implies that serious problems could have been avoided, if health care providers had paid heed to the company's appeal to inform women about risks and potential complications.

According to media reports, the FDA went so far as to restrict the use of the implant to those women who had signed a statement acknowledging familiarity with the risks and had received also their doctor's signature prior

Austrian American Medical Research Institute, Hermannng 4, A-2700 Wr. Neustadt, Austria

**Correspondence:** Kurt Kraetschmer, Austrian American Medical Research Institute, Hermannng 4, A-2700 Wr. Neustadt, Austria. Tel: +084413335, e-mail: kurt.kraetschmer@aon.at

**Received date:** February 02, 2019; **Accepted date:** February 22, 2019; **Published date:** March 15, 2019



This open-access article is distributed under the terms of the Creative Commons Attribution Non-Commercial License (CC BY-NC) (<http://creativecommons.org/licenses/by-nc/4.0/>), which permits reuse, distribution and reproduction of the article, provided that the original work is properly cited and the reuse is restricted to noncommercial purposes. For commercial reuse, contact [reprints@pulsus.com](mailto:reprints@pulsus.com)

to insertion. The Food and Drug Administration said only women who read and have the opportunity to sign a brochure about the risks of the device will be able to receive the implant made by Bayer. The checklist of risks must also be signed by the woman's doctor [3].

As can be seen, the lack of cooperation on the part of health care providers has been the target of critique by both, the FDA and the producing company. Apparently, women choosing the implant for permanent contraception were not adequately informed about adverse events, risks, and possible complications. "Despite previous efforts to alert women to the potential complications of Essure, we know that some patients still aren't receiving this important information," said FDA Commissioner Scott Gottlieb, in a statement. "That is simply unacceptable [3].

In describing the prevailing lack of information as "unacceptable" the FDA implicitly refers to the ethical obligation of health care providers to honor the principle of "informed consent." "This principle emphasizes the patient's right to obtain comprehensive and comprehensible information so that she is enabled "to make an intelligent choice [5]. Apparently, in the case of the sterilization insert, this principle was gravely neglected, and women could not make an intelligent choice but remained ignorant of highly important information that should have been conveyed to them.

The principle of informed consent brings a third issue to the forefront, i.e., the quality of information provided by manufacturers. In the case of the controversial tubal insert for permanent contraception, the manufacturer was criticized by a member of the consumer advocacy group that the information provided is "too lengthy, too technical and confusing."

"How many people do you know who would carefully read a 22-page document before signing it?" said Diana Zuckerman, president of the National Centre for Health Research, a consumer advocacy group. In addition to being much too long and technical, the information provided will be confusing to many consumers [3].

## DISCUSSION

Given that the manufacturer's information is judged inappropriate, given the FDA's role in approving products as safe, and given critical comments regarding the lack of cooperation on the part of physicians three crucial issues must be examined.

**First:** Is information provided by producing companies adequate for the consumer to recognize adverse events, risks, and complications?

**Second:** Can the judgments on safety made by the FDA be trusted?

**Third:** Are physicians willing or in a position to counsel their patients in conformity with the bioethical principle of informed consent?

### Adverse events, risks, and complications of permanent contraception by means of sterilization

The mechanism of action of the above-mentioned controversial device for permanent contraception is remotely comparable to tubal sterilization. Routinely, tubal sterilization is performed as laparoscopic coagulation in the area of the tubal isthmus on both sides [6]. Press reports describe a somewhat similar procedure when they specify that the insert made of a nickel alloy and a polyester-like fibre causes scar tissue to form and this tissue inhibits contact between the sperm and the ovum.

"The Essure implant consists of two small coils made of a nickel alloy and a polyester-like /sic! fiber. It is placed through the vagina into the fallopian tubes and is designed to create an inflammatory response that causes scar tissue to form, blocking the tubes [4]. In contrast to laparoscopic sterilization, this device does not require general anaesthetic or surgery. "It does not require general anaesthetic or surgery, unlike laparoscopic sterilization [4].

Obviously, the underlying physiological reasoning is avoidance of fertilization, i.e., contact between sperms and ovum. Physiologically speaking, 50-100 sperms reach the ovum, and many of them contact the zona pellucida, a membranous structure that surrounds the ovum. During the so-called acrosomal reaction the acrosome, a lysosome like organelle on

the head of the sperm, breaks down and "various enzymes are released, including the trypsin-like protease acrosin [7].

As can be seen from the above-mentioned media reports, the aversion of this process through a scar tissue that prevents contact between the ovum and the sperm has given rise to severe adverse reactions. Concerning the physiological explanation for the mechanism of action the question arises as to whether the infliction of a wound is an ethically justifiable procedure. The manufacturer argues that the necessary information about adverse events had been provided and that health care providers had been urged to inform patients accordingly.

In fact, the FDA offers comprehensible information by identifying the population for which the device might be suited and by insisting on its efficacy and safety. The reader can be expected to understand that the device is a permanent form of birth control, which is not appropriate for all women of child-bearing age. The FDA also specifies for whom the device might be a suitable option, namely for those women who do not plan to have any more children, who desire not only a reversible but a permanent form of birth control, who prefer a sterilization procedure that does not require an incision or general anesthesia (some gynecologists may administer a local, i.e., numbing anesthetic to reduce potential discomfort during the implantation), and those who are interested in a permanent birth control which does not include hormones [8].

The FDA also warns that the inserted device is not immediately effective in preventing pregnancy. Thus, another form of birth control must be implemented to prevent pregnancy until a confirmation test has been performed. This confirmation test verifying that the inserts are positioned correctly is performed three months subsequent to Essure placement [8] of ectopic pregnancy, dislocation and migration to the abdominal or pelvic cavity. Neglect of these risks might be the reason that the FDA feels justified to insist - despite evidence-based threats to the health of thousands of women on the "safety" of the device. Additional shortcomings in information on contraception provided by the FDA have been analysed recently in a scholarly study on women's rights to obtain complete information regarding birth control and contraception [9].

The deficits of the FDA information become particularly conspicuous in light of the information provided by the manufacturer who addresses not only the confirmation test but also long-term risks. As one of the Essure Confirmation Tests (a modified HSG) necessitates an x-ray, the patient is informed that she will be exposed to very low levels of radiation. According to the manufacturer, some patients can experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare cases, it is specified, a patient will experience spotting and/or infection [10].

As to the long-term risks, the manufacturer explains that pain (acute or persistent) of varying intensity and duration can occur and persist subsequent to placement of the device. Women with a history of pain are more likely to experience such discomfort. The manufacturer also mentions reports according to which the insert had been located in the lower abdomen and pelvis. In such a case, the contraceptive efficacy of the device can no longer be guaranteed. Allergic reactions are also mentioned. "Patients with known hypersensitivity to any of the components of the Essure system may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement [10]. Symptoms in women using the device may be associated with an allergic reaction including hives, rash, swelling and itching. One of the most serious adverse events that might occur is ectopic pregnancy, and the manufacturer appropriately stresses the life-threatening character of such a condition: "This can be life-threatening. If insert removal is indicated, surgery will be necessary [10].

In addition to emphasizing compliance with FDA requirements, the manufacturer also issued special safety information. In a warning, attention is drawn to some severe adverse events, including perforation of the uterus and/or fallopian tubes, localization of the device in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. "If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with

patients considering sterilization with the Assure System of Permanent Birth Control during discussion of the benefits and risks of the device<sup>[11]</sup>.

As can be seen, the manufacturer endeavors not only to explain possible adverse events but also requests that there be intensified communication between patient and health care provider to discuss all pertinent issues. Concerning adverse events, the manufacturer appropriately mentions the serious condition of an ectopic pregnancy.

Despite extensive information provided by the manufacturer, there remains the question of comprehensibility. Women have different levels of educational backgrounds and some of them might not be able to make an intelligent choice, especially if there is no additional counseling by their physician. It is precisely this lack of counseling that has become the target of critique. If the blame put on the health care providers is in fact justified the forensic proceedings will have to address this issue. Judging from the clinical practice this blame seems to be justifiable so that health care providers will have to be prepared to explain their lack of compliance with legal and ethical requirements. This justification might include time urgency, cost-effectiveness, and other economic principles as embraced also by their counterparts in the European Union (EU) [12-15].

### CONCLUSION

The foregoing discussion, based on the troubled history of the device which had been approved by the FDA in 2002 and was withdrawn by the manufacturer by the end of 2018, has drawn attention to the parameter safety of contraception. On the basis of the foregoing analysis it can be concluded that women are not adequately informed about possible risks and complications. This inadequacy will be the main issue in upcoming litigations and the forensic proceedings will clarify as to whether or not is the FDA should use more stringent criteria for declaring a device as "safe." An additional issue of controversy will be the manufacturers' inability to put sufficient emphasis on the most serious complications possible in their information for the patient and for physicians. Finally, health care providers will have to prove whether they honour the principle of informed consent by counselling and encouraging women to read attentively the appropriate packaging labels before making a decision.

### CONFLICT OF INTEREST

The authors declare that they have no competing interests.

### REFERENCES

1. Curtis KM, Peipert JF. Long-acting reversible contraception. *N Engl J Med* 2017;376:461-8.
2. The Guardian. Mon 13 Aug 2018 01.40 BST Last modified on Mon 13 Aug 2018 02.55 BST.
3. Washington Post, April 11, 2018. [https://www.washingtonpost.com/politics/polling/washington-postabc-news-poll-april-8-11-2018/04/20/6bd4d6b6-3f09-11e8-955b-7d2e19b79966\\_page.html](https://www.washingtonpost.com/politics/polling/washington-postabc-news-poll-april-8-11-2018/04/20/6bd4d6b6-3f09-11e8-955b-7d2e19b79966_page.html)
4. New York Times, July 20, 2018. <https://www.nytimes.com/issue/todayspaper/2018/07/20/todays-new-york-times>
5. Code of Medical Ethics. Current Opinions. American Medical Association. Chicago, Illinois, USA. 1992.
6. Gröger S, Grüne B. Kontrazeption. In: Diedrich K, ed. *Gynäkologie und Geburtshilfe*. Berlin: Springer; 2000:60-87.
7. Ganong WF. *Review of Medical Physiology* (17th edn). East Norwalk, Connecticut: Prentice-Hall International Inc., 1995
8. U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD.
9. Essure Permanent Birth Control: Information for Patients Essure Permanent Birth Control.
10. Essure Benefits and Risks Essure Permanent Birth Control: Information for Patients.
11. Essure Permanent Birth Control: Information for Health Care Providers FDA Activities: Essure.
12. Essure Permanent Birth Control: Reporting problems to the FDA.
13. Regulatory Board. History Essure Labeling Information for Patients and Health Care Providers.
14. Kraetschmer, K. Are women denied the right of self-decision in matters of birth control and contraception. Saarbrücken: Scholars' Press. 2017.
15. Kraetschmer K. Is the "lege artis" principle obsolete? *J Forensic Res.* 2013;4:3.