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Safety of Birth Control and Contraception Challenged by Recent Reports about Harm to Women's Health

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Abstract

***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 clarifying the importance of the parameter safety in birth control and contraception.*

***Material and 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 healthcare professionals, is analysed.*

***Findings:** Presently, women are not in a position to find reliable information suitable for preventing harm and injury caused by contraceptive drugs and devices. Heath care providers do not always comply with the requirements of the principle of informed consent, despite urgings by manufacturers and the FDA.*

***Conclusion:** In view of presently available information 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 the economic principle of cost effectiveness.*

Keywords: *contraception; sterilization; healthcare provider; pharmaceutical company; bioethics; FDA.*

Discussion

For many years, women had been assured that the use of pills and devices for contraception is safe, that is to say causing no serious harm or even death. This notion of safe contraception and birth control for all women has been shaken severely in 2018, when a U.S. Food and Drug Administration (FDA)-approved contraceptive device for permanent contraception was withdrawn from the U.S. market by the manufacturer with the argument that business was no longer sustainable in the face of declining sales.

"Bayer to voluntarily discontinue U.S. sales of Essure at end of 2018 for business reasons."[1]

Despite the decision to withdraw the product also from the U.S. market, the manufacturer insisted on its safety and efficacy. In the same vein, the U.S. FDA continued to defend the safety of the product despite claims made by thousands of women world-wide who had used the device and experienced severe adverse events.

In Australia media reported about adverse events ranging from menstrual bleeding to immune-type reactions. "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 press reports 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 the severity of injuries experienced by users of the product, legal repercussions were a logical

consequence. "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." [3]

In light of such reports about harm caused by a device that had been declared as safe by the U.S.FDA as early as 2002, the question arises as to why the FDA could approve a device that appears utterly unsafe in the eyes of the consumer.

Actually, it is not only the FDA that apparently uses an idiosyncratic definition of safety; a vast body of literature has accumulated over the years which hails pills and devices as safe, although there is evidence to the contrary.

Safety of Contraceptive Devices According to Professional Publications

In 2017 one of the leading medical journals published an article on Long-Acting Reversible Contraception (LARC), ie, implants and intrauterine devices (IUD), which are considered as the most effective methods of contraception with estimates ranging from 0.05 (implants) to 0.2 (levonorgestrel-containing IUD) and 0.8 (typical use for copper-containing intrauterine device).[4] The authors of this journal feature claim repeatedly that all women can safely use these products. Safety of IUDs and hormonal implants for almost all women is actually 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 postabortion period."[5,p.461]

In focusing on intrauterine devices, the authors affirm that they are safe for almost all women.[5,p.462] For implants it is reaffirmed that they can be used safely by almost all women except by those "who have hypersensitivity to barium or to the components of the implant."[5, p.463] Concerning special populations, almost all women, including young and nulliparous, can safely use Long-Acting Reversible Contraception. [5, p.465]

The safety of LARC is affirmed also for postpartum and postabortion periods.[5,p. 465] As regards expulsion, which some authors consider as the most serious complication besides ascending infection,[6,p.84] no special concerns are indicated in the study on LARC. Mentioned is only the relative risk of expulsion that is higher if the IUD is inserted immediately post partum and lower if it is inserted 6 weeks post partum or even later. [5,p.466]

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."[5,p.467]

The insistence on the safety of LARC in this article of 2017 is difficult to understand in light of research published four years earlier, but not mentioned in the 2017 publication. The study of 2013 had drawn attention to serious shortcomings of the devices recommended for their safety in the publication of 2017. In their article of 2013, the authors argue that there is sufficient evidence for "increased expulsion rates, complaints of pain and erratic or increased menstrual bleeding, and subsequent high rates of discontinuation"[7] in association with the devices hailed for their safety in the article of 2017.

The authors of the 2013 study argue on the grounds of clinical evidence proving that the mean transverse diameter of the uterus in parous and nulliparous women is significantly shorter than the length of the transverse arm of the two intrauterine devices approved for the U.S. market, namely ParaGard (copper T) and Mirena (levonrogestrel- containing). [7]

Not only research, but also clinical experiece demonstrates the inadequacies of the U.S.FDA-app roved products, namely a geometric incompatibility of the uterine cavity on the one hand and the rigid or semi-rigid copper- or levonorgestrel-containing device on the other. Such an incompatibility, the authors argue, "can lead to partial or total expulsion, embedment and perforation of the uterine wall, pain, unintended pregnancy, and abnormal or heavy uterine bleeding, resulting in removal of the device."[7]

Given the inappropriate proportions of the two U.S.-approved devices, the authors feel justified in recommending a different product, namely the European-made (Contrel Europe, Belgium) GyneFix, a copper-releasing intrauterine device.[8]

It has been described as "a flexible, frameless, intrauterine contraceptive implant that is anchored to the fundal myometrium by a polypropylene knot."[9]

In recommending the Belgium-made GyneFix, which had been used in the United Kingdom (U.K.) since 1997, the authors refer to studies examining differences in uterine volume and size of uterine cavity, with consideration of age and parity. In the opinion of the authors, these studies demonstrate for GyneFix a "high acceptability and low rate of discontinuation of use."[7] And in the face of the deficits of standard-size conventional IUDs the authors argue that

"Small, frameless, flexible, and unidimensional copper IUDs appear to be well tolerated, with less impact on menstrual bleeding, resulting in low discontinuation rates."[7]

Unfortunately the authors underscoring the super iority of GyneFix to the copper- or levonorgestrel-containing products, available on the U.S. market, fail to mention severe adverse events caused by the device, especially perforation. This failure is the more surprising as the topic of perforation with GyneFix had been extensively studied as early as 2003.[9] In fact, by 2003 six case reports of perforation with the device had been published. In reviewing the previous five case reports, the authors of the sixth case report explain that in five instances the device had been removed laparoscopically of by laparotomy. The one remaining device was thought to have exited out of the abdomen via the intestines. As GyneFix contains copper, the authors draw attention to the crucial problem with copper-containing intrauterine devices, namely adhesions, and state: "Copper IUDs such as the GyneFix are thought to predispose the patient to adhesions once inside the peritoneal cavity."[9,p.155] This risk of adhesion combined with a woman's concern about the presence of a foreign object free in her abdomen was sufficient indication for the authors to retrieve the device laparoscopically.[9,p.155]

Despite the severity of perforation and despite serious side effects caused by the GyneFix intrauterine device, some authors recommend the product, but withhold vital information from the reader. Their claims about failure rates lack evidence-based research, and it seems particularly inappropriate to state that an "atraumatic" design minimizes adverse events and discomfort. "GyneFix has the lowest failure rate of all copper IUDs currently available. Its performance is further optimised by the atraumatic frameless design which minimises the side effects and discomfort experienced with conventional IUDs."[10]

This claim made by an international study group on Intrauterine Drug Delivery appears almost paradoxical in light of the extensive literature on contra-indications and adverse events, such as pelvic inflammatory disease and perforation, associated with intrauterine devices.[6,p.84]

The emphasis on the advantages of GyneFix in research publications mirrors the manufacturer's information on the product, which fails to mention any risks of complications. This information on GyneFix is available in a leaflet entitled "information for the user" provided by the Belgium manufacturer.[8] In contrast to the extensive information for users provided by other manufacturers, the information for GyneFix users comprises no more than 3 pages. No mention is made of the most common complications associated with IUDs, namely pelvic inflammatory disease (PID), and of the most feared risk, namely perforation.

The safety of contraceptive devices is underscored not only in publications on implants and IUDs discussed above but also in publications on oral contraceptive pills, the most widely used form of birth control and contraception during the past decades.

Safety of Contraception Highlighted in Publications on Oral Hormonal Contraceptives

In a study reviewing extended and continuous oral contraceptives, the authors affirm the safety of these products, although they cannot avoid to mention a considerable number of side effects and complications, such as breakthrough vaginal bleeding as the most common side effect, headaches, genital irritation, tiredness, bloating, vaginal spotting, and menstrual pain.[11] As rare adverse events the authors list cholecystitis, thrombotic event, ectopic pregnancy, and enlarged uterine fibroids; as metabolic effects they mention production of clotting factors resulting in increased risk of venous thromboembolism, increased gallstone formation, and risk of liver adenomas. Despite these adverse events, the authors conclude that continuous oral contraceptive pills are not only safe but also reliable in attaining the ultimate goal, ie, amenorrhea.

"Continuous OCPs are a safe and reliable form of birth control. . . . The most commonly reported side effect of continuous OCP dosing is irregular vaginal bleeding, but the incidence of this decreases over time and most patients will obtain amenorrhea after 1 year of treatment."[11] As an additional advantage of OCP,

the existence of excellent safety data for endometrial histology is underscored. "Additionally, there is no temporal limitation to the use of continuous OCPs as excellent safety data exist for endometrial histology."[11] Especially women desiring limitation of cyclic bleeding are encouraged to use continuous oral contraceptive pills: "Women who wish to limit cyclic bleeding, for personal or medical reasons, are excellent candidates for continuous OCPs."[11]

In a study on the use of combined oral hormonal contraceptives by obese women, the authors conclude that progestin-only methods are safe and that LARC combine optimally safety, efficacy, and convenience.

"Current evidence supports the safe use of combined hormonal contraceptives by obese women . . . Progestin-only methods are generally safe, and long-acting reversible contraceptives hold the best combination of efficacy, safety and convenience for this group, although individualization is advisable."[12]

Safe use is ascertained also for ulipristal acetate, a substance used predominantly for emergency contraception (EC). As ulipristal acetate, a progesteron receptor modulator, is used primarily for EC, it is not surprising that EC in general is hailed as safe. "Safety. No deaths or serious complications have been causally linked to emergency contraception. According to the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC), there are no situations in which the risks of using combined, progestin-only or ulipristal acetate ECPs outweigh the benefits."[13]

As can be seen from this claim, no scientific definition of safety is provided, but only subjective notions such as "risk" and "benefit" are introduced. In view of a lack of scientific nomenclature for the parameter "safety" it is not surprising that some authors do not even mention well-known adverse events but hail only the alleged benefits of contraception: "Contraception has direct health benefits, such as prevention of unintended pregnancy and, subsequently, decreased maternal mortality and morbidity."[14]

The above analysis of research articles and scholarly publications shows that authors frequently emphasize the safety of contraceptive products discussed by them. This emphasis, however, is not understandable to the reader in light of numerous adverse events and risks of complications associated with the products declared as "safe." In fact, an analysis of information provided by manufacturers reveals that adverse events can be so serious that the terminus "safe" appears inappropriate, misleading, and even deceptive.

Safety of Contraceptive Pills and Devices According to Manufacturer's Information

In one of the recent discussions on a manufacturer's information for the user, criticism has been voiced regarding the content and nature of this information. In fact, in the context of complaints about injuries due to the use of the Essure implant, discussed above, the manufacturer's information has been criticized as being 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 Center 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]

In light of this critical comment on the information provided by the manufacturer of Essure, the question arises as to whether inadequate information is disseminated also by other manufacturers of contraceptive pills and devices. In a recent study on this topic it has been found that there are in fact serious deficits in packaging labels, highlights of prescribing information, and consumer leaflets destined to inform the consumer about adverse events, risks, and possible complications.[15]

One of the most obvious deficits is the information provided by the manufacturer of the controversial nickel-titanium coil for permanent contraception.[16] The packaging label fails to explicate the mechanism of action of the device in an unambiguous fashion when it describes a three-step process: tubal occlusion owing to the space-filling design; a benign occlusive response of tissue; and tissue in-growth owing to PET fibers. "Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention, resulting in tubal occlusion and contraception."[16,p.4]

How this tissue in-growth should take place due to PET, ie, polyethylene terephthalate fibers,[16,p.3] is inexplicable from a physiological viewpoint. It is not surprising, therefore, that some commentators avoid the imprecise terminus in-growth and speak of a scar tissue, ie, a tissue that is the result of a wound. "The Essure implant consists of two small coils made of a nickel alloy and a polytester-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."[17]

Given the unresolved issues of mechanism of action, the question arises as to whether or not the manufacturer chose to use a vague and misleading terminology instead of stating unambiguously that the device is an "implant" and not just an "insert," that it causes an inflammation, and that the "in-growth" is in fact a scar tissue.

A similar vagueness of nomenclature in describing the mechanism of action can be found in the "information for the user" provided by the Belgium manufacturer of the Gynefix intrauterine device.[8] According to the product description the device is an insert, fixated to the uterine fundus to avoid expulsion: "fixation to the uterine fundus, makes expulsion very rare."[8,p.2] If the device is in fact fixated to the uterine fundus it seems more precise from a physiological viewpoint to speak of an implant. Unfortunately the manufacturer fails to provide scientific information and speaks of a "tiny" knot without indicating its size in international units and without explaining its function in physiological terms: "A tiny knot at the upper end of the thread keeps the IUD in place."[8,p.2]

In addition to a lack of scientific terminology regarding the nature of the device, there is incomplete information on adverse events. Only a small number of side effects are mentioned, and no warning is issued concerning possible complications during insertion of the device, as for example GAS, ie, group A streptococcal infection, a complication extensively described by the manufacturer of the levonorgestrel-containing intrauterine device Mirena.[18]

Regarding adverse events it is obvious that the manufacturer's claims cannot be substantiated because there is no research proving that the bleeding during insertion and increased bleeding afterwards or spotting will gradually disappear as the woman's body "accustoms itself" to the device, and bleeding pattern "will steadily return to normal."[8,p.3] Also, the claim is made that discontinuation of use is warranted as Gynefix "is the first copper intrauterine device (IUD) which does not increase menstrual blood loss."[8,p.3] Such an increase, the manufacturer agues without citing evidence-based data, "is the most common reason to stop using a copper IUD." [8,p.3]

Possibly, the lack of scientific terminology and of evidence-based data is one of the reasons why the device had not been approved by the U.S.FDA and had not been included in its survey of contraceptive methods of 2013[19] or in the WHO table of 2016. [20] In light of the inadequacies contained in the manufacturer's "information for the user" it seems highly probable that a considerable number of consumers might feel misled into believing the device will cause only negligible adverse events. In comparison with other manufacturers, it is patent that the product description of GyneFix is one of the most unreliable, lacking the two most fundamental characteristics expected by the consumer, ie, precision and completeness.

In addition to information being "confusing," as criticized in conjunction with the Essure implant,[17] there are indeed also instances where information is "too technical." Thus, the manufacturer of a levonorgestrel-containing intrauterine device (IUD) mentions capacitation of sperm as a mechanism of action and expects, rather unrealistically, the reader to recognize that this nomenclature refers to the process where sperms acquire additional capacity for fertilization within the female reproductive tract owing to alterations of the surface of spermatozoa by means of redistribution of glycoproteins and glycolipids.[6,p.130]

In the face of deficient information provided by manufacturers, it must be underscored that there is no justification for a global blame. On the contrary, some manufacturers make genuine efforts to highlight not only the benefits of their products but explicate also risks of complications as well as adverse events. Thus in the case of LARC methods, discussed above, the manufacturer of the implant Nexplanon explicitly warns about breakage, perforation, dislocation and migration of the etonogestrel-containing implant to the pelvic cavity or to the lungs via the pulmonary artery. Above all, the life-threatening sequelae of an ectopic pregnancy are appropriately underscored. [21]

An explicit warning to this effect has been issued also by the manufacturer of the nickel-titanium coil. "Ectopic pregnancies . . . may occur with Essure. This can be life-threatening."[1,p.4]

Along the same line the manufacturer of the levonorgestrel-containing intrauterine device

Mirena warns about the life- threatening character of a GAS (group A streptococcal) sepsis and insists on aseptic technique during the insertion of Mirena. "Aseptic technique during insertion of Mirena is essential."[18,p.6].

Concerning oral hormonal contraceptives, it is well-known that manufacturers consistently warn about lethal consequences of thromboembolic events and liver adenomas. Thus, the manufacturer of Orthonovum combined oral contraceptive pill draws attention to hepatic adenomas. "Rupture of benign, hepatic adenomas may cause death through intra-abdominal hemorrhage."[22] In the same vein, the manufacturer of the minipill mentions that in rare instances "combined oral contraceptives can cause benign liver tumours. These benign liver tumours can rupture and cause fatal internal bleeding."[23]

As can be seen from the analysis of information provided by manufacturers for the consumer of their products, communication is frequently hampered by a technical terminology, by misleading explanations of mechanism of action, and by downplaying risks and complications. It seems justified therefore to criticize manufacturers not only for too lengthy, too technical, and confusing information but also for failing to honor the principle of informed consent. As is known, this well-established bioethical principle underscores the patient's right to obtain sufficient information to "enable an intelligent choice."[24,p.38]

As the foregoing analysis shows, information for the user provided by manufacturers cannot always stand up to the expectations of the consumer and comply with the bioethical principle of informed consent. What exacerbates the dilemma for the consumer is the failure of health care professionals to provide appropriate counselling. This failure has been implicitly criticized by the FDA in conjunction with the Essure implant discussed above. "'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].

Clearly, health care providers are blamed for not conveying vital information to their patients, but this blame will be refuted by doctors with the argument that the principle of cost effectiveness deserves highest priority. As has been discussed as early as 2013, the priority of economic principles in health care is no longer a matter of dispute in countries of the European Union.[25]

Despite blames put on manufacturers for not communicating adequately with the consumers and on healthcare providers for neglecting their ethical responsibilities, additional challenges loom large, ie, hitherto unknown and unexplored consequences for the next generation. One of the most recent studies in this area addresses the question of leukemia in children of mothers taking birth control pills. In defining the scope of their research, the authors speak of the " . . biological plausibility, on the basis of evidence that hormonal exposure in utero causes cancer in children."[26]

Conclusion

Authors of research articles do not present an impartial and balanced account on the safety of the products they describe. In some instances their lack of impartiality can be explained by competing interests. Manufacturers do not always furnish information in accord with the principle of informed consent but make misleading statements about the mechanism of action and safety of their products. Consumers can therefore not rely on this sources of information. They must be advised to seek unadulterated information on the safety of contraceptive pills and devices in other sources, ideally in communication with their healthcare provider or, less ideally, in social media.

Implications

Editors of professional journals should exercise caution in assessing articles written by authors who have to declare competing interests. Manufacturers should provide complete and comprehensive information on their products without misleading or deceptive nomenclature. Health care providers should sense an ethical responsibility to counsel their patients according to the ethical principle of informed consent and "enable an intelligent choice."

Conflict of Interest

The author declares that there is no conflict of interest.

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