

ПРАВОВАЯ ЖИЗНЬ: НАУЧНО-ПРАКТИЧЕСКИЕ ЗАКЛЮЧЕНИЯ, КОММЕНТАРИИ И ОБЗОРЫ

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Legal and ethical implications of voluntary non-therapeutic sterilization as a way of realization of human reproductive rights

*S. Del Sordo*¹, *E. A. Chesnokova*²,
*U. Genovese*¹, *I. M. Akulin*², *N. G. Stoyko*²

¹ State University of Milan

7, via Festa del Perdono, Milan, 20122, Italy

² Saint Petersburg State University,

7–9, Universitetskaya nab., St. Petersburg, 199034, Russian Federation

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This article deals with legal and ethical aspects of sterilization of capable women of reproductive age. The authors point to the ethical and legal contradiction of establishing a high age criterium. Also, the authors consider the most common reasons for litigation during voluntary sterilization.

Keywords: reproductive rights, medical sterilization, voluntary non-therapeutic sterilization, wrongful pregnancy, wrongful birth, informed consent to medical procedures, defects in medical care delivery, civil liability in obstetrics and gynecology.

1. Introduction

Reproductive rights are an integral part of human rights and citizens in modern society. They are enshrined in national constitutions, in international instruments, and in national laws. One of the most important components of reproductive rights is the right to free and conscious choice in the existence of posterity. This right can be exercised in the form of a right for contraception, including permanent sterilization. The principle of

private autonomy implies that every capable woman has the right to decide on her own what is best for her, for her body, for her way of life.

The irreversible non-therapeutic sterilization is a most complex problem in the ethical aspect. There is a high risk that a woman who has made such a decision at a young age may deeply regret it later. But does the state have the right to limit her in what it is desirable and necessary for this moment of life, based only on the fact that some years later she can change her mind? Moreover, it should be borne in mind that for medical science it is now possible to have genetically related children for those women who, as a result of surgical intervention, have lost their ability to conceive a child naturally.

On the other hand, the demographic and economic situation, as well as the peculiarities of gender behaviors in the country can to some extent justify the government's interference in such a sensitive sphere of regulation of private life.

For this issue, as also for a number of other issues, the emergence of which is due to the rapid development of medical technologies, it is necessary to find the right balance between private and public interests, adherence to the principle of private autonomy, the public foundations¹ (Stoyko 2006) and the needs of the state demographic policy.

2. Non-therapeutic permanent sterilization as a way of realization of human reproductive rights

Permanent sterilization is the permanent deprivation of the power of reproduction and giving birth.

It can be divided in therapeutic sterilization and non-therapeutic sterilization: in the first one, the aim is therapeutic, as in case of cancer or other organic pathologies of the reproductive organs, while in second one (non-therapeutic sterilization) the aim is contraceptive, although permanent sterilization reduces the risk of ovarian cancer but increases the risk of ectopic pregnancies (Varma, Gupta 2004).

In males, the most common type of permanent sterilization is vasectomy, in females surgical postpartum fallopian tube ligation, interval surgical tubal ligation, and hysteroscopic tubal occlusion (Patil, Jensen 2015).

Female sterilization, above all tubal ligation, is a widely used method of contraception in some world countries, especially in developing countries, although the total number is slightly declining through years.

However, this problem fully affects the economically developed countries, acquires its importance also in relation to women belonging to socially and financially prosperous layers of the society.

It should be noted that permanent sterilization is a highly effective method to prevent unintended pregnancy. In this connection, many women are considering sterilization as a way to realize their reproductive rights and, specifically, the right for conscious choice not to carry and not to give birth to children. Some modern women believe that limiting their right to permanent sterilization puts them in an unequal position in comparison

¹ More detailed in theoretical context look — The Idea of Law (London) by Dennis Lloyd (Lloyd 1974); *Obshchee uchenie o gosudarstve* (St. Petersburg) by d-r G. Ellinek (Ellinek 2004). More detailed in comparative law context look — *Ugolovnyj process zapadnyh gosudarstv i Rossii: sravnitel'noe teoretiko-pravovoe issledovanie anglo-amerikanskoj i romano-germanskoj pravovyh system* by Nikolay Stoyko (Stoyko 2006, 114, 115–116, 119–120).

with men. In this context, the position of supporters of the child free community deserves a special attention. But it should be noted that women who are not related to this citizen group and do not even know about its existence are often interested in this type of intervention. The reasons may be simply unwillingness to have children, consideration of children as a financial burden and the resulting reluctance to lower their financial status; unwillingness to change their lifestyle; the feeling that existence of a child can prohibit many life choices, including the opportunity to have fun and to travel; the unwillingness to be pregnant can have a special meaning for people in model business, for actresses, journalists, athletes and all those women for whom pregnancy can adversely affect their professional career. In addition, the intention to recourse to permanent sterilization can be caused by serious anxieties about the risk of medical complications during a pregnancy and childbirth. After all, modern reproductive technology allows a woman to have a genetically-related child, without to carry it or to give it birth, but using the services of a surrogate mother. In the case that woman after the tubal ligation still wants to become pregnant, she can resort to expensive services of in vitro fertilization.

The topic of non-therapeutic permanent sterilization arouses ethical and medico-legal matters, which rely also on different cultural and legislative basis. These differences affect both the frequency of women's requests for permanent sterilization, and the number of litigations and trends in law enforcement practices in this area.

In the United States, surgical sterilization is the second most common form of contraception (Patil, Jensen 2015; Borrero, Zite, Potter, Trussell 2014; Shreffler, McQuillan, Greil, Johnson 2015).

Conversely, in other countries, as Italy or Russia, surgical sterilization is an unusual procedure and women achieve their family planning goals opting for other methods.

3. Non-therapeutic permanent sterilization in the United States

In the United States, the use of tubal ligation as a contraceptive method increased during the 1970s because of the legalization of the procedure, the improvements of the surgical techniques and the creation of federal-funded family planning programs (Borrero, Zite, Potter, Trussell 2014). In those years, a contemporaneous negative eugenics movement was occurring, with reports on forced and nonconsensual sterilizations of minority, institutionalized, handicapped, and poor women (Block-Abraham, Arora, Tate, Gee 2015).

In USA, the health system is primarily based on private insurances. President Johnson introduced a social healthcare program for families and individual with limited economic resources called "Medicaid". In 1979, the U.S. Department of Health, Education and Welfare enacted regulations about public and federal funds to desired permanent sterilization procedures and introduced a specific consent form to permanent sterilization for Medicaid percipient called "Medicaid title XIX form" (Brown, Chor 2014). The form is composed by several parts and begins with a fundamental notice: it says that the decision at any time not to be sterilized will not result in withholding of any other benefits provided by programs receiving federal funds. The second part is dedicated to the patients, who state that they have asked for and received information about sterilization and that they have understood that sterilization is permanent and not reversible. The last part is dedicated to physician's statements: the doctor declares he had explained about risks, benefits and complications of the sterilization procedure.

The U.S. Government prohibits sterilization of Medicaid insured woman younger than 21 years old and initially required a 72-hour waiting period between consent and procedure. Afterwards, this waiting period was extended to 30 days and Government forbade physician to obtain consent from woman in labor (Borrero, Zite, Potter, Trussell 2014; Brown, Chor 2014).

Although these regulations were at first designed to protect vulnerable populations, these rules have instead become a barrier to many women willing permanent contraception.

First of all, even if the title 19th consent form contains information about the risks and the benefits of the sterilization procedure, assessments on the form's readability indicate that it's overly complicated and its literacy level is too high for the average American adult (Block-Abraham, Arora, Tate, Gee 2015; Zite, Philipson, Wallace 2007).

Moreover, the patient's reproductive autonomy is interfered with the timing imposition of the 30-day waiting interval. "Logistical" problems related to obtain a copy of the consent form signed by the woman months earlier can arise, so that a lot of women are unable to get the desired sterilization due to a lack of a valid signed Medicaid form.

These regulations appear to be defective because of arising different approaches to publicly insured women from privately insured ones: low-income women may not be able to exercise the same reproductive autonomy of richer ones (Block-Abraham, Arora, Tate, Gee 2015; Brown, Chor 2014).

Preventing women from obtaining a desired sterilization procedure affects the individual free to choose and puts women, especially low-income ones and women from racial minorities, at risk of unintended pregnancy, which is associated with social consequences for them and their families and with social costs (Borrero, Zite, Potter, Trussell 2014). Of course, other factors, such as socio-economic ones, sometimes prevent women to afford as many children as they would like to have and so do lifestyle behaviors (Shreffler, McQuillan, Greil, Johnson 2015).

4. Legal and ethical matters of non-therapeutic permanent sterilization

As we said before, in Italy and in Russia, unlike in the USA, voluntary permanent sterilization of healthy women of fertile age is an infrequent method of choice when selecting a method of contraception.

Another barrier to permanent sterilization is "conscientious objection": if a physician has moral or ethical opposition to perform a requested sterilization procedure, the physician can refuse his work, but he should direct the patient to another health-care provider (Stulberg, Hoffman, Dahlquist, Freedman 2014). Conscientious objection is a frequent choice of physician in Italy and other Catholic countries and it can explain the low percentage of permanent sterilization procedures in these areas.

In Italy, in 1998 The National Committee of Bioethics (Comitato Nazionale di Bioetica) said its opinion on the topic of voluntary and not voluntary sterilization, driven by international press reporting of cases of compulsory sterilization on mentally disabled persons or in ritual cases, like in USA before 1976. The National Committee of Bioethics stated that the matter of non-therapeutic sterilization is quite controversial. Italian physicians are allowed to withdraw their performance in case of non-therapeutic sterilization if they are conscientious objector. On the other hand, forced sterilization without consent is always illicit (Comitato Nazionale di Bioetica, 1998).

Beyond individual choices related to conscientious objection, in Italy there is no reference legislation on non-therapeutic permanent sterilization. In 1978 a law was promulgated (referred to as law 194/1978) about abortion and social protection of motherhood and established that Italian State ensures right to responsible procreation but protects human life.

On the other side, article 5 of Italian Civil Code forbids free disposal of one's own body if it causes a permanent diminution of physical integrity or it is otherwise contrary to the law. Article 583 of Italian Penal Code states that if someone makes someone else lose the ability to procreate (like in sterilization), he can be convicted to jail.

In the Russian Federation, statutory instruments provide for the right to sterilization. According to Part 1 of Article 57 of the Federal Law dated November 21, 2011 No. 323-ФЗ "On Fundamental Healthcare Principles in the Russian Federation", medical sterilization as a special intervention with the aim of depriving a person of the ability to reproduce posterity, or as a method of contraception, may only be carried out upon the written application of an individual of over 35 years of age or of one who has at least two children, but with a medical basis and the individual's consent, medical sterilization may be carried out irrespective of the patient's age or the presence of children (Federal Law dated November 21, 2011 No. 323-ФЗ "On Fundamental Healthcare Principles in the Russian Federation". Here and below all references to Russian legal acts are given by "ConsultantPlus". Accessed September 27, 2018. <http://www.consultant.ru>).

Thus, the Russian laws permit permanent medical sterilization as a method of contraception even without medical basis, but it provides for certain conditions: declaration of intention of a capable person made in writing, as well as reaching the age of 35 or having two children.

If there are medical grounds, no additional conditions are established by the statutory instruments.

In other words, the Russian lawmaker admits the possibility of sterilization "at option" of a childless woman, but at the same time it establishes a fairly high age qualification. It is notable that the statutory age qualification of 35 years coincides with the age from which, according to medical science, the risk of having children with genetic or chromosomal abnormalities is significantly increased. However the authors interpret the decision of the lawmaker to establish an age qualification of 35 years as not a correlation with the criterion of the "older parturient", but rather a presumption of inconsiderateness and immaturity of the decision to be sterilized at a young age and, therefore, a high probability of its revision in the future (Salagai 2009). In particular, we cannot disagree with the fact that there is a certain contradiction in the regulation of this issue. As a general rule, in accordance with Art. 21 of the Civil Code of the Russian Federation, active capacity of an individual shall arise in full upon reaching the age of 18 years, and the right to voluntary informed consent to any medical intervention, in accordance with Part 2 of Art. 20 and Part 2 of Art. 54 of the Federal Law No. 323-ФЗ, occurs upon reaching the age of 15 years. Given that medical sterilization is a medical intervention, the establishment of a special legal regime for it seems rather controversial (Salagai 2009).

In addition, there is doubt as to how justified from the perspective of modern ethics and in the light of the principle of private autonomy is the limitation of the right of a capable healthy person to self-determination in the matter of condition of their body. We

should note the position of many authors who, when analyzing particular cases of young childless women, have come to conclusion that sterilization of young, childless adults for non-medical reasons is ethical if they are properly informed of all the risks including regret (Benn, Lupton 2005).

Undoubtedly, the decision to be sterilized at the beginning of the reproductive age carries a high probability of subsequent regret about the decision taken. Understanding this may cause a mandatory waiting period to be established by statutory instruments of a number of states. As pointed out above, in the United States the waiting period of 30 days between consent and procedure is required. Likewise, Article L 2123-1 of the French Code of Public Health provides for an interval of not less than 4 months between the signing of informed consent and the operation itself. As previously stated, the establishment of a waiting period also interferes with the patient's reproductive autonomy. However, it should be assumed that establishment of a waiting period for childless women under the age of 35, and possibly also the introduction of compulsory preliminary counseling could be a compromise decision that allowed for greater respect for the rights of this category of persons.

In this aspect, the key is the possibility of a free and informed choice on the basis of complete, reliable and understandable information about the upcoming intervention. A guarantee of respect for the patient's right to receive full information about the upcoming medical intervention should be the duty of the physician to obtain consent from the patient, which is given precisely on the basis of information provided in an accessible form (the voluntary informed consent).

In Italy, as well as in other countries, valid informed consent to medical procedures is an essential element that allows physicians to perform medical or surgical interventions, according to article 50 of Italian Penal Code ("anyone who harms or endangers someone's right with his/her valid consent is not punishable"). Case laws established that treating a patient without valid consent may constitute civil or criminal offence so that patient can claim for negligence and ask physicians for monetary compensation of damages (Bharathan, Rawesh, Ahmed 2009). It is well known that medical and ethical issues are often addressed in courtrooms and the judges' decisions influence the conduct of healthcare professionals (Genovese, Del Sordo 2015).

Recently, a law was promulgated in Italy (referred to as law 219/2017) which states that informed consent should be always written documented and included in medical records.

Also, in the Russian Federation in accordance with Art. 20 of the Federal Law No. 323-ФЗ, the necessary prerequisite for medical intervention is the provision of a voluntary informed consent of the citizen or their legal representative to medical intervention on the basis of the full information provided by the medical worker in an accessible form on the purposes, methods of rendering medical assistance, the associated risk, possible variants of medical intervention, its consequences, as well as the expected results of medical care. In accordance with Part 7 of the Article cited, the voluntary informed consent to medical intervention or refusal of medical intervention shall be formalized in the form of a written document and contained in the patient's medical records.

It is well known that there is relevant difference between information process and simple signature of consent form. A written consent form may be used in courts as an evidence of discussion between patient and physician, information and consent obtain-

ing, but in itself it is no proof of validity in obtaining that consent (Bharathan, Rawesh, Ahmed 2009).

Back to permanent sterilization, obviously is important that all women undergoing tubal ligation are counseled about the permanence of the procedure, the risks and the benefits of the surgical operation.

It is well known that information contents can affect patients' choices: clinicians who do not discuss sterilization with all patients for whom it might have been appropriate encourage them to use other reversible methods and thus missed opportunities to discuss sterilization as part of the full range of appropriate method (Kimport, Dehlendorf, Borrero 2017).

As we said, a gynecologist has a duty to inform women about the surgical risks of sterilization procedures, the risks of failure, and to carry out the surgery in accordance with good medical practice and to avoid foreseeable complication.

An important root cause of many clinical adverse events that lead to medico-legal litigation is poor communication between the patient and the doctor. In Italy, the failure in consent obligation can lead to malpractice litigation and patients can get money claiming injury to their right of "self-determination".

Besides failure in communication, other circumstances eliciting malpractice litigation in sterilization procedures are the following (Varma, Gupta 2004).

Failed sterilization is defined as conception occurring after sterilization and can occur many years after the procedure. In case of wrongful conception, the psychological and physical consequences following failed sterilization often leads to malpractice litigation. If the negligent act deprived the mother of the possibility to have a lawful abortion or to prevent the birth of a disabled child, she can claim damage related to "wrongful birth".

Moreover, a breach of duty can arise when a procedure is not carried out in accordance with good practice or guidelines in case of surgical related-events, that are events due to laparoscopic surgical techniques (e.g. vascular or bowel injuries, pelvic pain, mesosalpingeal tears, tubal transection, tubal torsion, abscesses and so on).

5. Conclusion

Voluntary sterilization of capable women of reproductive age implies a number of very complex ethical problems. However, it is indisputable that in a modern state of law in the light of the principle of private autonomy and observance of the reproductive rights of a person and a citizen, sterilization as a method of contraception is one of the ways to realize these rights. The right to voluntary sterilization as a method of contraception is provided for by the laws of most modern economically developed countries. And, if poorer segments of the population and residents of developing countries used to resort to sterilization earlier, now the growth of economic well-being, the development of reproductive technologies, the changes in gender behaviors, the increase in social and professional activities of women may lead to an increase in the number of people willing to choose this method of contraception.

The establishment of a high age qualification for childless women is controversial, both ethically and legally. More justified would be the introduction of compulsory counseling for women under 35 years of age, as well as a mandatory waiting period of at least 30 days.

One of the most common causes for legal action is the disruption of communication between the doctor and the patient at the sterilization decision-making stage. A woman may not fully understand the irreversible nature of the intervention, may not understand what complications and adverse consequences may occur after the operation. And most importantly, a woman may underestimate alternative methods of reversible contraception. A few months later, the postdecision regret can morph into dissatisfaction with the doctors and the clinic, in the belief that if the woman had been properly informed at the right time, she would choose a different way of birth control. In this connection, it seems expedient to develop a special detailed form of informed consent to voluntary non-therapeutic sterilization. In this form, emphasis should be placed on the practically irreversible nature of this type of contraception. The low efficiency of surgical intervention to restore tubal patency after ligation should be particularly emphasized. The informed consent should also include sufficient information on the possibilities of in vitro fertilization after sterilization. Also, all available alternative methods of contraception, their efficacy parameters, indications for use, complications and side effects should be described in sufficient detail in the informed consent. Also in the consent, the possibility of developing of such a life-threatening and health-related condition as extrauterine pregnancy after the operation should be mentioned.

Other reasons for judicial recourse may be pregnancy after sterilization, as well as bodily injury to the woman because of improper surgical intervention.

Obviously, the medical organization or the physician will eventually be requested to compensate the eventual damage for pain and suffering and loss of money if an avoidable error, that should to be avoided but it was not avoided, is detected in diagnostic-therapeutic behavior.

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Author’s information:

Sara Del Sordo — MD, Specialist in Legal Medicine; sara.delsordo@gmail.com

Ekaterina A. Chesnokova — PhD, associate professor; e.chesnokova@spbu.ru

Umberto R. Genovese — MD, associate professor; umberto.genovese@unimi.it

Igor M. Akulin — Dr. Sci., professor; akulinim@yandex.ru

Nikolay G. Stoyko — Dr. Sci., professor; n.stoiko@spbu.ru