

Scientific Journal of the Faculty of Medicine in Niš 2010;27(3):171-178

Professional article ■

Ethical Aspects in the Area of Assisted Reproduction

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SUMMARY

The authors analyze the modern approach in treating infertility by means of the assisted reproduction method, procedure, benefit, as well as many ethical questions, which arise from the very conception of the embryo: the controversial commencement of pregnancy, a new paradigm in the understanding of life, human rights, family and religious issues, the treatment of the “surplus” of embryo, the issue of surrogate parenting, donors, embryo experiments, commercialization of reproduction, providing adequate information and legal solutions for these complex problems. Progress in this area of medical science and technology requires casting more light into the much of the last ethical unknown and many dilemmas when it comes to the issue of assisted reproductive technology.

Key words: assisted reproduction, ethics, embryo, donors, and experiments

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INTRODUCTION

The term "Assisted Reproductive Technology" (ART) stands for a set of techniques that increase the possibility of making pregnancy possible with the married couples or individuals with the sterility problems.

In everyday practice the most commonly used methods are intrauterine inseminations and in vitro fertilizations, the most radical aspect of the same being ICSI-method. There is also a GIFT technique, even though it is not so often used today. Intrauterine insemination is the insertion of laboratorically prepared and purified sperm into the uterus, so as to shorten the path of a spermatozoon to the ovum. This technique requires the exact determination of the ovulation in a woman. IVF (In Vitro Fertilization) includes the ovary simulation, the ovum aspiration, theirs in vitro fertilization, embryo cultivation and embryo transfer into the female uterus. ICSI (Intracytoplasmatic Sperm Injection) is injecting a chosen spermatozoon into the ovum and it requires very expensive and complicated equipment, together with the specially trained staff.

BACKGROUND

The first serious consideration of the issue of sterility in people originate from the ancient Egypt. However, success in treating sterility needed a technically-technological development of medical science and profession. The first successful attempt of insemination in people (even though technically simple) was published in 1785 by John Hunter, a surgeon from Scotland. A Harvard explorer, John Rock, infertilated four human ova, which is considered to be the first in vitro insemination in history. In Australia in 1973 the first IVF pregnancy in the world took place, but it ended by a premature death of the fetus. Finally, in England in 1978 Louise Brown, the first "test tube baby" was born. (2) That was the 104th (and the first successful) attempt of dr. Patrick Steptoe and embryologist Robert Edwards, who in 2010 won the Nobel prize for his long-term successful work in the area of in vitro fertilization.

Success Rate

There is no general agreement concerning the success rate in ART. As the public, by terms of success rate, we usually consider the percent of the children born after the conducted ART techniques (in English „take baby home“). Even the first studies presented on this topic presented the public with contradictory results as a result of different approaches of many authors. There is a disagreement concerning the success rate in relation to the following:

- should it start with the number of aspirated ova after the proper stimulation of a woman,

- does the issue concern the number (percent) of fertilized ova,

- or is it about the number of the quality embryos,

- is it about the number of transferred embryos, implanted embryos, etc.

Data from the bibliography reveal that in European countries out of all pregnancies to ART come between 1.1% (Great Britain) and 3.8% (Slovenia); however, in the future a higher incidence of ART in the treatment of sterility and increase of human population is expected (3,4).

ETHICAL ISSUES (controversial areas)

Controversial Commencement of Pregnancy

Fertilization (Latin, ferstilisatio) includes the whole range of events related to the agglutination of a spermatozoon with an ovum, which leads to creating the first cell of the new organism - zygote. In the first 24 hours after the fertilization begins the process of zygote furrowing, and its slowly moving from the oviduct to the uterus. On the fifth day of fertilization the embryo has evolved into the stadium of blastocyst. The implantation presents the initial agglutination and plunging of the blastocyst into a decidually altered endometrium. This is followed by a post-implantational development period, which in our species eventually leads to childbirth (5).

The application and development of ART techniques has imposed a question at the very start: when does pregnancy exactly begin? (6). All the serious research on this topic, especially from the area of embryology, shows that it begins by the moment of conception, and not by the act of implementation of blastocyst into the female uterus, endometrium. Fertilization, in natural conditions, is by rule taking place in the ampullar part of the oviduct. However, when performing a classical IVF, the fertilization happens in a special container with the fertilization medium which is located in an incubator, thus, outside the woman's body. A man and a woman, parents to be, therefore do not have any direct share in the conception, i.e. the beginning of pregnancy, but that role is passed onto technical means (7). German engineers have named, not without a reason, firstly built incubators "uteruses with an inside look." During fertilization in the classical IVF comes t the phase of capacitation which is characterized by changes in the spermatozoon glycol-calyx, which is what makes them quite mobile. That represents a certain kind of competition between spermatozoon, which regularly takes places in natural conditions as well (8, 9). However, with ICSI method, the situation is even more complicated, for there the pregnancy actually begins under the microscope

lens with extremely precise micromanipulators. If the incubator where the fertilization, i.e. pregnancy commencement takes place, is an uterus imitation, then in the case of ICSI method, during the fertilization there is no such and that kind of surrogate of such an organ (10).

What exactly is Embryo in ART?

Pre-embryo development period (early development) lasts from the moment of fertilization till the second week. The embryo in that period is called early embryo or pre-embryo. Pre-embryo period is divided into pre-implantational (from 1st to 6th day of development) and post-implantational (from 7th to 14th day of development). The embryo development period lasts from the beginning of the 3rd week until the end of the 8th week. The embryo in this period is called the embryo. The embryo period is characterized by a rapid growth and production of germ leaves of ectoderm, endoderm and mesoderm. These are official and accepted definitions. While performing ART techniques what is required is the permanent control, supervision and evaluation of fertilized ovum and embryo. While describing and registering data, terms as, e.g., “4th cell embryo, 8th cell embryo and similar” are used regularly. This stands in fierce opposition with the previous definition of the embryo.

The embryos that are composed of a few cells may be handled in different ways: they can be transferred and even the blastomeres can be taken out of them, whereas those few weeks old by the rule do not undergo any sort of manipulation. Both 8-week embryo and 3-day embryo, together with the 5-week embryo are a new human being; they are alive and their natural imperative is growth and development. People often ask a question: why can a blastomere be taken from an 8-cell embryo and why can experiments be performed with it? The official position of science is that the same does not cause any damage to the embryo. Without the answer, the question always remains what and how an organism whose one eighth of the whole mass is removed suffers. From a few-week-old embryos cells are not taken, because that could lead to their damage. Taking away a single cell from such, more developed embryo would be substantially smaller loss of total mass. Does that mean that the first embryo, 3 days old, is less valuable, that it deserves less attention, that it can be treated of one's own free will? Sometimes, very roughly, considering the proportions and sensitivity, it is evident that morphological differences between embryos on a different level of development dictate introducing completely new terminology, so as to determine an adequate approach towards them in an easier and better way.

From the fact that modern science after the decades of dealing with embryos still does not have a unique understanding of what embryo is or how it should be handled, various possibilities of the abuse of the

same arise. Drake (11) illustrates problems, related to the embryo status by quoting Thomas Aquinas as “a small mistake at the beginning may lead to big mistakes at the end.”

Many researchers hold an opinion in relation to the basic embryo status that it represents a “genetic human being” which is created at the moment of human fertilization and which throughout its development does not experience significant genetic changes. Opponents to this attitude point out the possibilities of the emergence of genetic mutations and phenotype as the result of not only the genotype influence, but also of the environment. Therefore, we can talk about “embryo potential” to develop into a human being, which implies only a physical possibility for creating a potential human being. According to Annas, “as human embryos are neither things nor persons, their status is defined through attitudes like those that a balance should be found between respect, inherited by any human being, and the freedom of scientific research” (12).

Choosing Life or the Reduction of Life

While aspirating the follicle, depending on the woman's medical condition, her age and ovaries response to the stimulation, a larger number of ova can be produced, even over 20. By all means, not all the ova are of the equal quality, nor they can all be fertilized while performing IVF/ICSI method. In any case, almost regularly more embryos are produced, which also do not share equal potential for development. However, all those embryos represent a new human being which has only stated developing; therefore, they require close attention and care. After a while, embryos of greater quality (or blastocysts) are sent back to the woman's body by means of embryo-transfer (13).

The choice of embryos depends on their noticeable characteristics. But, as there are no two exactly the same persons, the embryos also do not have the same potential for development. Embryos that are exactly the same may progress at a completely different pace, including the arrest as well. If an embryo is a new homo sapiens, with what right is one of them being denied the right to life and to the other is given the same? Not so rarely does it happen that the embryo of a poorer quality produces a healthy child, whereas the embryo of a much higher quality falls behind in progress or stops with its development. What is more, it often happens that apparently weak embryo suddenly starts developing progressively, at embryologist's surprise. Therefore, the question may be posed: are the criteria for assessing the quality and development potential of an embryo valid or not? If we are witnesses of understanding human rights, do those rights apply to an embryo as well (14)?

After the already made selection of embryos and rejecting the “candidates” for embryo-transfer which

end their existence, now we have a legal interruption of life in mother's womb. Those kinds of mothers often have health problems after the fetal reduction: hypertension, pre - eclampsia or psychological disorders. In addition, the embryo that remains may have serious health problems, such as: respiration problems, brain damage, development problems, cerebral paralysis, etc., even a still-born child. In the European Union, a decision has been made (and it is already put into action in Slovenia) that, therefore, the embryo-transfer of only one embryo may be performed, whereas others are frozen by plunging into liquid nitrogen.

Apart from that in western countries, it is almost the usual practice to, at their own request, a child's gender may be chosen by means of examining the DNA of a blastomere taken out of the embryo, which may have both negative and positive connotations: preventing some inherited diseases (e.g. hemophilia, dystrophy, etc.) but also demographic and social consequences (16, 17).

Getting a male gender is a usual aspiration, except in Japan where even two thirds of female population voluntarily decides for female children, which is explained by a traditional relationship of female children towards the parents and avoiding some diseases such as dystrophy and hemophilia (18).

Pregnancy after Menopause

Most of the women that undergo ART are in the group older than 35. On the world level, over 10% of them are more than 40 years old. The specific nature of female reproductive system and its functioning is closely linked to the age of a woman, first of all, which means that the age-limit of women adequate for ART needs to be defined by means of bringing mandatory solutions on an international plane (the age-limit of 36 years is being speculated), all the sooner because the application of in vitro fertilization in older women may lead to unwanted effects for the very woman, family or society.

Homosexual Relationships, Single People, Extramarital Couples

According to the attitudes of many authors who deal with reproductive medicine, in future, this practice will advance not only with the married couples, but also with the people who live alone, with the couples that live in extramarital communities, as well as those who live in homosexual unions. The attitudes of scientists, medical experts, psychology experts and theologians are not in accordance, and very often they are in a serious collision: according to some of them, human right of every one of them is to have posterity no matter what their marital status is, whereas for some societies growing up

and child-rearing is unacceptable in the conditions where one of the biological parents is absent.

Religious Issues

If there is something common for all the mankind, then it is religion. As there are hundreds of religious communities (and new ones emerge every year), they are followed by various ways of approach to ART on part of certain religious categories.

Orthodox Christianity supports the view which may be described as conditionally positive: ART is positively evaluated with sterile married couples. The condition of all the conditions is that the formed embryos do not get destroyed and that they are not used for experimental purposes (19).

Catholicism is of the opinion that "the gift of life should be accomplished in marriage and it is specific and exclusive through the act performed by a husband and wife." The act of a donor is taken as morally ill, together with embryo use in commercial and experimental purposes, their freezing and insemination. Single unmarried women are not allowed to undergo ART application, nor the surrogate motherhood (20).

Islam supports ART, but only within the marriage union. The exception is made for the donation of ovum or spermatozoon, surrogate motherhood and experiments performed on human embryos (21) .

Judaism does not strictly prohibit ART, but it considers the same from two aspects: life as a priceless value and the obligation to treat human beings with respect, as in life, so as in death, too.

Buddhism as a religiously/philosophical system opposes surrogate motherhood due to the following consequences: a child is separated from its biological mother, the separation of child is harmful for physical and mental health of the mother who would get attached to the child, and problems arise in family and social relations (22).

In Hinduism, the sexual act is not the way to make pregnancy happen, but it is rather the act dedicated to the divinities which onto children bestow gifts at their own will, to some married couple once, to another more than once and to the other never. Therefore, in this religion the official attitudes of ART cannot be determined.

Human Rights (of fetus, mother, father donor)

The question of human rights requires first of all adopting the attitudes about the moment when life is created. Embryo rights are created as a side product of ART techniques where their potential to become human beings is based on the procedure which does not exist in nature. Considering human rights in ART concern not only the embryo, but also the donor, parents and profe-

ssionals. Apart from the fact that the fewest dilemmas, prejudices and technical problems arise when we talk about providing sperm for ART, ethical dilemmas related to the donor status represent the basis for plenty of research related to knowing the identity of a donor, his possible relations with the posterity, as well as the permission to keep his frozen sperm in case of possible illnesses that would make the fertilization impossible (23).

The next issue is the origin and identity of a sperm donor. Usually a donor remains anonymous for parents. Nevertheless, in Sweden and New Zealand children can trace their biological fathers. This moment is pointed out regarding debates that stress children rights to know their biological parents opposed to the proclaimed protected donor privacy. In case of known donors in Belgium sperm saved from a husband can be used posthumously, whereas such an act is not allowed in Great Britain. Apart from the fact that in many countries donors are anonymous, the interested potential mothers may find numerous ads on the Internet in the countries such as Germany or Japan. In order to prevent the problems that may arise in case of kinship crossing, some countries like Greece advise and recommend to mothers who have the posterity from the same donor to be introduced to one another. To a great surprise of gynecologists and psychologists, a large portion of women from those groups have refused to make any kind of contact with the women who became mothers in the same way. That kind of attitude may lead their posterity into a potential danger, as far as their reproduction in the future is concerned.

Giving away ova voluntarily on women's part is a bit more complex, considering the particularity of female reproductive organs and constant dying of follicles. In Great Britain, women are encouraged to give away their ova to the in vitro fertilization clinics, and in return they may receive money, lower prices for medical treatments or in vitro fertilization benefits.

In our country, as in the most of others, the legislation does not follow up the progress of medical technology, so as the advice of Ethical Committee is respected. The advice is based on Helsinki Declaration (do not harm, bring benefit, respect the anonymity of a patient). For women without a partner, sperm from European centralized bank is taken from donors, while the genetic material may be used only after a year from frosting and check-up. However, according to the opinions of some experts with the longest tradition in ART, in our country, every woman who undergoes this procedure has to receive complete information.

Surrogate Parents

Out of all ethical dilemmas and disputes, the issue of surrogate parents is the most sensitive and draws most attention, considering the inclusion of diffe-

rent biological actors in human reproduction. In relation to these problems there are unique negative attitudes of all confessional communities. According to Leon Kass, an American doctor, philosopher and scientific opponent to certain bioethical issues, the procedure of certain surrogate-parenting is assessed as a depersonalized, inhuman, which he literally calls "baby-making." This kind of reproductive technology is by certain authors estimated as "opening Pandora's box of bioethical areas."

Experiments in ART

Bearing in mind the definition of Helsinki declaration, experiments on embryos can be marked as non-therapeutic undertakings for a concrete embryo, which means that the use of this kind of embryo might be marked as unethical, and especially if the situation is about the abuse for the purpose of eugenics or the "improvement of race."

The fact is, however, that human progress is based on scientific enterprises, into which the pre-implantational genetic diagnostics is also included (PGD), the intervention by means of which the existence of genetic births with embryos in vitro is determined for the purpose of avoiding the entity transfer with the presence of genetic anomalies.

The so-called embryo surplus made during in vitro fertilization can be frozen in liquid nitrogen at the demand of married couples, and it may also be applied onto spermatozoon and ovum. At the beginning of the era of new reproductive technologies, authors of texts from the area of medical ethics have presented arguments against the experiments performed on frozen embryos along with drawing a conclusion that this issue should be regulated by passing legal acts (24).

On international plane there is no *consensus omnium* between ethical committees and governmental agencies, concerning the further actions with frozen embryos, which makes these problems even more complex. American and Australian fertility association as well as the American ethical committee agreed that the research may be performed until the 14th day of the embryo's lifetime, human embryo. In Australia, preservation of a frozen embryo is limited to 5 years during which a permit for their disposition may be granted.

Apart from primarily negative attitudes about experiments on preserved frozen embryos, they were continued with the results that tell us about the construction of genetic maps with the identification of genes located on certain chromosomes and sequences with specific DNA nucleotides. It remains unknown whether the biological parents of those embryos agree with those experiments. At our disposal today, there is a display of genes responsible for certain illnesses marked from 1 to 22 as well as X-chromosome and Y-chromosome.

From a scientific and ethical standpoint, a certain kind of experiments with embryos in vitro cannot be approved, even though such enterprises might have a

certain scientific value (cloning, hybrid-production, interventions into non-pathological genetic heritage, etc).

Commercialization of Reproduction

According to the new evaluations, today ART represents, apart from modern medical technology, the sum of procedures that makes a very big profit. It is estimated that for this purpose around \$ 12. 400 per cycle is appropriated in the USA. In European countries, the means that are appropriated for the same purpose are much more modest. Into the price of services very often the value of compensation to donors is included, wherever the law allows the same. Experience of the ex-YU countries shows that in their living area, the price of one attempt for in vitro fertilization on average is 3.000 Euros. Under the conditions of very often parallel existence of state and private sector, there are fair possibilities for many financial manipulations. Into the same not only the patients and medical workers do find themselves involved, but primarily firms and companies which produce technical and technological means and mediums for in vitro fertilization. There we should also add the following: the imposed transport expanses and preservation of the already mentioned means that are often extremely fragile, together with the marketing support (25).

Family and Social Relations

The development of reproductive technology has conditioned moral dilemmas, among other things, regarding family relations as well, for ART does not represent only a medical issue, but it also has the influence on the natural development of childhood and forming a balanced personality as a family member. From a psychological point of view, it is an especially sensitive question regarding the development of a children psychosexual identity in homosexual relations, even though the research has not confirmed specificities in differences in relation to the development of children from common heterosexual families.

According to the research of bioethical questions for workers in clinics who deal with the ART technologies, the following is pointed out: whereas in the parenting role we find a father and mother, in techniques of ART those roles may be distributed to five persons. Those are: genetic mother and father (or a sperm donor), gestation mother and social parents. Each of them has their own interest and a certain level of vulnerability. Other family variations give more new possibilities.

Providing the Information for Patients

The wish to secure the posterity is related to the questions of the obligation of medical professionals to

give to future parents detailed information about all the stages (phases), duration, efficiency and possible risks. For performing the procedure, the consent must be signed by a patient. That will allow the patients to become active participants into reproduction, and not only addicts to technological solutions and medical interventions. In many countries there are "guides" (information-providers) for women that are in the programme of in vitro fertilization.

Legal Solutions

Taking into the consideration the need to regulate the problems of ART from a medical and social aspect in all the countries proper laws have been passed starting with Hungary in 1981, leading to later legal solutions in other countries. In USA, there is no federal law that regulates the issues of assisted conception, apart from the regulations on the obligatory reporting on in vitro insemination (26).

In 2008, Polish government prepared a new bioethical programme for the European Council about ART, so as for there to be less controversy about the used methods and available rights of the interested parties. In a working group that made this document, the following people took part: medical doctors, lawyers, biologists, philosophers, psychologists and people of religion, who prepared the content of this paper for the ratification by the European Council.

In our legislative system these issues had not been regulated by means of law for years, but they had been the result of regulations that regulate the therapy given in treating sterility, which was directly mentioned in the Law about Medical Protection. Finally, in Serbia in 2009 a suggestion for a Law on Sterility Treatment and steps of biomedically supported fertilization was composed (27), which will probably be edited during 2010 (for this year regulation of creating reproduction cells bank was planned). The current proposition of law in Serbia regulates in detail the norms of actions of bio-medically assisted fertilization.

The motto for making the future regulative in the domain of biomedically supported fertilization could be found in what was said by Dawson: *"Interest in the welfare of human being should be the priority in relation to the interest of the society and science"*(28).

CONCLUSION

Bearing in mind many of the analyzed ethical questions related to the ART technology, we should remember the words of Dr. Patrick Steptoe who brought the first "test-tube baby" into the world. *"We have now touched the sky with our finger, but we have also shrugged our shoulders under the burden of critique."* Making future solutions in many areas which regulate health, legal, ethical and social issues related to ART may considerably prevent and decrease the mentioned pro-

blems, but it is certain that in the future all the active participants included into ART will meet new challenges.

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ETIČKI ASPEKTI U OBLASTI ASISTIRANE REPRODUKCIJE

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Sažetak

Autori analiziraju savremeni pristup u tretmanu infertiliteta putem metoda asistirane reprodukcije, procedure, koristi, kao i brojna etička pitanja, koja se javljaju od samog začeća ploda: kontroverzni početak trudnoće, novu paradigmu u poimanju života, ljudska prava, porodična i verska pitanja, tretman „viška” embriona, pitanja surogat-roditeljstva, donora, eksperimenti na embrionima, komercijalizacija reprodukcije, obezbeđenje adekvatnih informacija i zakonska rešenja u ovoj kompleksnoj problematici. Napredak u ovoj oblasti medicinske nauke i tehnologije zahteva unošenje više svetla u dosadašnje brojne etičke nepoznanice i dileme kada je u pitanju asistirana reproduktivna tehnologija.

***Ključne reči:* asistirana reprodukcija, etika, embrion, donori, eksperimenti**

The Committee was established on 19th Feb 1985 and has continuously addressed ethical concerns in the research and practice of women's health. It has also propagated public awareness, as well as awareness amongst practitioners and policy makers on these issues. There are more than 79 existing FIGO Ethics and Professionalism Guidelines in a volume which is constantly updated every few years by the committee. The committee also has a bioethical curriculum which is most suited for practicing gynecologists as well students and teachers of the faculty and it is freely available on FIGO website. Thi Assisted reproduction ethical aspects Summary of a report The Swedish National Council on Medical Ethics Summary of the original report Assisterad befruktning etiska aspekter 2013:1 published in Feb 2013. Since the conference, the Council has discussed the issues with a number of experts on various topics in the field, and current research and debate have been surveyed. The Council has also consulted young people to obtain their views on several key issues. The aim of the report is to highlight and analyse the ethical aspects associated with new and more established methods of assisted reproduction. Ethical aspects of human reproduction and assisted fertilization are based on full respect of the life of an individual even before conception, from pre-embryo stage, via embryo stage and fetus stage to a newborn infant. Regarding investigative and clinical projects, this standpoint implies the legalization of all ART procedures, unencumbered exchange of information and consensus about their application, and adherence to the basic ethical principles of autonomy benefit, justice and common welfare. Ethical postulates provide unequivocal directions in the creation of new life and resolve all pos