Ethical legal aspects in assisted reproductive technologies

Etičko-pravni aspekti asistiranih reproduktivnih tehnikacija

Svetlana Dragojević*, Branka Nikolić*, Snežana Rakić*, Vladimir Pažin*, Srđan Dikić†, Barbara Damnjanović*

*Gynecology and Obstetrics Clinic “Narodni Front”, Belgrade; †University Clinical Center “Bežanijska kosa”, Belgrade

Key words: reproductive techniques, assisted; ethics; jurisprudence; infertility; spermatozoa; embryo; cryopreservation; cloning, organism.

Introduction

Infertility is a topical problem in gynecology, which requires delicate approach, analysis and treatment. Infertility reasons, being nowadays met in about 15–20% of couples, are numerous: tubal, ovarian, anatomical, immunological, endometriosis, cervical and male factors of infertility, psychological, idiopathic, whereat the infertility is most often of multifactorial nature. Development of reproductive biology enabled infertility treatment by use of assisted reproductive technologies (ART), and/or introduction of up-to-date methods with an aim of reproductive function restoration. The term “assisted reproduction” is brought into connection with appropriate treatments, which according to the public opinion give hope to many individuals – patients, clinical personnel, researchers, but also opens numerous ethical, legal, religious and social questions 1.

In vitro fertilization (IVF); donation of gametes, embryos and pre-embryos; cryopreservation of gametes, embryos, ovarian and testicular tissues; embryo transfer; genetic reproductive techniques; cloning and other sophisticated methods in resolving infertility, require cooperation of medical profession and ethical – legal vocation, with an aim of connecting the scientific – research work and individualized clinical approach. Ethical aspects of human reproduction, and the assisted fertilization are based on respecting life of an individual even before establishing a conception, from pre-embryo stage, via embryo stage, stage of fetus and a newborn infant. Such a position in further investigation and clinical projects understands legalizarion of any procedure within assisted reproductive techniques, properly being informed thereof and having the approval for their realization, by observing the basic ethical principles: autonomy, benefit, justice and common welfare.

In 1990 in the United Kingdom, the Parliament passed the Human Fertilization and Embryology (HUGE) Act, which provides legislation for the control of the procedures of assisted reproduction. In our country Ethical Committee of the Yugoslav Section for Fertility and Sterility made a draft of ethical codex on assisted reproduction, which was revised by in the meantime established Serbian Ethical Committee and which is finally going to be legislated in the near future being involved in the law on assisted reproduction 2–4. The HUFE Act requires experts engaged in assisted reproduction, to consider “the welfare of the child…..born as a result of the treatment (including the child's need for a father), and any other child that may be affected by the birth”. On the basis of the HUFE Act the use of embryos for research is permitted within five categories: 1) for promoting the treatment of infertility; 2) for increasing knowledge of the causes of congenital diseases; 3) for increasing knowledge of the causes of miscarriages; 4) for developing more effective techniques of contraception, and 5) for developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation. After almost 30 years from the birth of the first IVF child, the necessity for embryo research, and its implications for the status of the embryo as an entity, is less challenged than in the previous decades, in particular at a time when the therapeutic potentials of embryo stem cells provides convincing arguments regarding its necessity and further analysis 5.

Law and ethics are indeed in an inevitable interaction with each other as different systems of normative ordering, which sometimes overlap and sometimes conflict. On one hand, the law may seem a more powerful instrument than ethics, because its provisions are more authoritatively and comprehensively presented by political legislation and
courts, more systematic and more transparent, while its use is more practical, instrumentally versatile and institutionally challengeable.

On the other hand, the law is seen to lack an ethical dimension, to be cruelly pragmatic at best, impoverished in its capacity to educate and inspire those it governs to distinguish the right conduct from wrong. The law sets a framework for practical utilization of ethical choices, but the ethics sets limitations that are voluntarily obeyed, as expressed through respect for the law, which in its turn asserts the merits of society it governs.

Before undergoing the various procedures of ART, patients should be fully acquainted with the following: how the treatment will be carried out, how long it will take, how effective it will be and what possible complications are, whereat they have to sign their consent for the performance of the treatment. Gamete and embryo donation procedures are absolutely secret, except in rare legally foreseen cases, and other treatments can also be made secret at the explicit request of patients (IVF, intrauterine insemination of husband’s spermatozoon, intracytoplasmic sperm injection). The Yugoslav Ethical Committee was of the opinion that it was indispensable to establish a center for registration of all donation data. Legally controlled secrecy and informed consent of the patient are significant characteristics in the field of reproductive medicine, occurred as a result of established constitutional right to privacy in reproductive treatments, and the reactions of political and moral opponents in realization of such rights.

**Genetic material donation**

Genetic material donation has become an integral part in infertility treatment. Donation of spermatozoon, oocyte and embryo (embryo not older than 14 days, or pre-embryo) is successful in medical and technical sense of meaning and ethically approved. Medical problems and ethical dilemmas that require understanding and evaluation are: selection of donors, evaluation of the recipients, quality control of the genetic material, relationship between biological and social parents, and protection of the rights of the off-springs through specially legalized decisions. Sperm donation has to be anonymous, and the donors cannot be known donors, friends or relatives.

Oocyte donation is also ethically permissible in specific cases: in patients with premature ovarian failure and regular menopause, in women with inferior quality oocytes and after several unsuccessful IVF treatments. In order to avoid a long waiting period, different procedures to recruit oocyte donors are proposed, such as oocyte-sharing (donors share their oocytes with an anonymous recipient and in return, recipients share the costs of the treatment of the donor) and the recruitment of a donor by the patients themselves. Attention should be paid to possible psychological consequences of this decision.

Indications for embryo donation are women without oocytes and men with azoospermia, in which case only donation of embryos obtained from spermatozoon and oocyte of mutually unknown donors can be performed. Embryo donation can be achieved in two ways: (I) using a combination of oocyte and sperm donation – such donors should already have been properly counselled, and (II) using spare cryopreserved embryos from patients who have already been successful and have consented to the donation of their remaining embryos. The Standpoint of the Serbian Ethical Committee is that embryos have certain moral status, hence they cannot be preserved more than 14 days (until “primitive streak” appearance), with permission of use of those treatments that do not diminish genetic status of embryo (defragmentation of embryo and transfer of ooplasm). Although in the United States of America donation of couples’ embryos has been permitted, a few couples decide to donate their embryos (greater percentage preserve the embryos for possible future use), however, as proved in studies, which is interesting and important, transfer of “donated” couples’ embryos has resulted in high percent of developed successful pregnancies per treated cycle (50%) 10. Pre-embryo banks are to be specifically legalized and issued appropriate individual permits; the concerned professional medical and social institutions would have to take into consideration the interest of infertile couples, but also the interest of the embryo, i.e. of future descendants.

**Genetic material cryopreservation**

Sperm and embryo cryopreservation is permitted and they can be preserved up to 10 years. Sperm cryopreservation has long been routine and helpful in preserving the fertility potential of many young men treated for iatrogenic sterility or threatened by cancer. Oocyte cryopreservation, however, is not permitted in any of the countries belonging to the International Federation of Fertility Society.

Ovarian tissue cryopreservation is permitted, with possibility of significant clinical use in reproductive medicine and oncology. Ovarian cryopreservation, which has been lately in focus of experimental researches, opens a new moral and ethical dilemma, requiring critical consideration for tissue preservation (“bank”), and also require working out specific instructions by medical, ethical and legal experts on criteria for future clinical use and benefit of such procedures.

**Posthumous reproduction**

Recent events posing also ethical dilemma relate to posthumous reproduction, pre-implantation genetic diagnosis (PGD) and cloning. They illustrate the difficulties for closed legally controlled systems in forecasting all the possibilities of progress in science and the ethical dilemma arising from the new technology. The advent of successful cryopreservation of spermatozoon and embryos, now makes the birth of a child whose genetic father is dead, technically possible following the usual period deemed legally necessary for the recognized paternity of the posthumous child. In the United Kingdom most of the centers for infertility treatment support the idea of posthumous reproduction, hence the posthumous treatment is permitted provided explicit prior written consent has been given, and, after the opportunity of counseling has been given to the gamete(s) pro-

vider(s). General attitude is that each case should be individually analyzed and approved by multidisciplinary committee consisting of gynecologist, psychiatrist, sociologist, clergy and other appropriate parties 13.

Preimplantation genetic diagnosis

Preimplantation genetic diagnosis is a result of development and convergence of assisted reproduction techniques and genetic methods, allowing the couples at risk of transferring hereditary diseases to their offspring to diagnose such abnormalities as early as immediately before or after conception. Preimplantation genetic diagnosis, however, triggers the fear of potential genetic manipulation and of getting closer to criminal eugenics, and therefore the standpoint of the Serbian Ethical Committee is that PGD is only justified in medically indicated cases. Preimplantation genetic diagnosis within the infertility treatment is part of the range of potential diagnosis options, which enhance our patients when making an important decision about screening their future child from serious diseases 1,4. Our opinion is that ethical principles allow us to protect the vulnerable infertile couple, to allow them the optimal chances of becoming parents and protect the future child of the couple, while showing respect to all preimplantation stages of the embryo.

Cloning

There are two kinds of cloning: therapeutic, which may allow the generation of stem cells in vitro, with their potential ability to repair damaged tissues. Many countries and institutions have been analyzing the possibilities of therapeutic cloning if other alternatives are lacking, as well as cloning within genetic engineering with the aim of producing appropriate human proteins. Because of the potential in curing serious disease we consider this technique acceptable.

The second is reproductive cloning, which can be achieved by embryo splitting or by somatic cells nuclear transfer.

Human reproductive cloning is unjustified and unnatural for it affects human dignity and violates the individual rights to genetic uniqueness. One can consider reproductive cloning of embryos by means of nucleus transplantation or embryo splitting, and ethical aspects in a context of genetic reproductive techniques are to be evaluated separately 14. The European Society of Human Reproduction and Embriology (ESHRE) statement issue in February 1997 declared a 5-year voluntary moratorium on cloning human beings but indicated that research using human cells would be a necessary step following animal research, including mammals, on cell differentiation and nuclear cytoplasmic interactions 15.

Therapeutic cloning technology serves to culture stem cells that are genetically identical to those of the patient, with an aim of replacing diseased cells, for example in nerves damaged by neurodegenerative disorders, in the heart muscle affected by infarction, in diabetes or in liver after poisoning. Stem cells may be derived from embryo (precisely from blastocysts), from the fetus or the adult. There are several types of embryonic stem cells: those issued from blastocysts either supernumerary or created de novo and those created by nuclear transfer from somatic cells (SCNT). The latter method is usually referred to as cloning 16.

In the final report of the European Group on Ethics, made public in November 2000, reproductive cloning is forbidden. It deems ethically unacceptable the creation of embryos from donated gametes, because supernumerary embryos are an alternative available source. In the case of embryos obtained by SCNT, it voices its extreme concern, while aware that the creation of such embryos may be the most effective way of obtaining pluripotent stem cells genetically identical to the patients and thus obtaining perfectly compatible tissues with the aim of avoiding rejection after transplantation 17. Nevertheless scientists in the field agree that research should continue with all sources of stem cells, as we cannot yet know which source – if any – is going to fulfill the therapeutic expectations.

Embryo stem cells can be used for their potential ability to repair damaged tissues. They may come from aborted fetuses or research embryos. In the case of aborted fetuses the separation principle (i.e. separate consent for a termination of pregnancy and for the use of any tissue) should apply. The comments on research pre-implantation embryos and cloning apply to the second source. Because of the huge potential in curing devastating diseases the method is considered ethically acceptable 15. In our opinion research should continue with all sources of stem cells, as we can not yet know which source, if any, is going to fulfill the therapeutic promise.

Cloning is due to receive extensive legalisation, but it has to be carefully and selectively performed in order to make room for further improvements in this field of research for the benefit of entire mankind 16,19.

Conclusion

Sex selection, multiple pregnancies and embryocide, surrogate parentage, treatment of older infertile women, also open numerous ethical legal dilemma in ART treatment and request multidisciplinary expert approach in analyzing any individual case, as well as defining of clear ethical-legal regulations, with a possibility of correction towards further investigations. Ethical postulates provide unequivocal directions in the creations of new life and resolve all possible ethical dilemmas, protecting doctors’ rights and the rights of any participant in relevant procedures, by taking into consideration the crucial principle – respect of human dignity. Defined legal principles are to be reconciled with the natural “laws” for the sake of protection of freedom of thought and the right of individual choice and for the realization of the goal aimed at preservation of life and justification of the purpose of existence.

REFERENCES


The paper received on September 7, 2007.