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## ETHICAL AND LEGAL DILEMMAS IN INFERTILITY TREATMENT

**ABSTRACT:** One of the main characteristics of the new millennium is the affirmation of human rights in all aspects of human existence, with the intention of turning declarative statements into reality. Development of up-to-date assisted reproductive technologies (ART) and their application in infertility treatment have raised numerous ethical, legal, religious, social and other questions. In vitro fertilization, 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 used in infertility treatment require cooperation between the medical and legal professions. 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 possible ethical dilemmas, protecting the rights of doctors and participant in relevant procedures alike and reasserting the crucial principle — respect of human dignity.

**KEY WORDS:** infertility, ethics, jurisprudence

### INTRODUCTION

Infertility is a topical problem in gynecology, which requires delicate approach, analysis and treatment. Causes of infertility, presently encountered in about 15—20% of couples, are numerous: tubal, ovarian, anatomical, immuno-

logical, endometriosis, cervical, psychological, idiopathic and male factors, whereat the infertility is most often multifactorial in nature. Developments in reproductive biology have enabled infertility treatment by means of assisted reproductive techniques (ART) and/or introduction of up-to-date methods for reproductive function restoration. The term „assisted reproduction” is associated with certain treatments which give hope to many — patients, clinical personnel, researchers — but which also open numerous ethical, legal, religious and social questions (P a p p, 2000).

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 used in infertility treatment require cooperation of medical, ethical and legal professions, with the aim of combing research work and individualized clinical approach. 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.

In 1990 in the U. K., the Parliament passed the Human Fertilization and Embryology Act (HUFÉ) 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 the ethical code on assisted reproduction, which is going to be legislated in the near future (1990, M i l a č i ć, 2000). The HUFÉ Act requires the 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 its birth”. The Human Fertilization Act permits the use of embryos for research in five categories: for promoting the treatment of infertility; for improving the knowledge of the causes of congenital diseases; for improving the knowledge of the causes of miscarriages; for developing more effective techniques of contraception, and for developing methods of detection of the presence of gene or chromosome abnormalities in embryos before implantation. After 23 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 challenging 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 (S t r o n g, 1998).

Law and ethics are indeed in an inevitable interaction with each other, as two systems of normative ordering, which sometimes overlap and are sometimes in 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 crudely pragmatic at best, and 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 the society it governs (Dickens, 1999).

Before undergoing the various procedures of the assisted reproductive techniques, 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 and legally foreseen cases, while other treatments (in vitro fertilization — IVF, intrauterine insemination of husband's spermatozoa — IUI, intracytoplasmic sperm injection — ICSI) can also be made secret at the explicit request of patients. The Yugoslav Ethical Committee is of the opinion that it is indispensable to establish a center for registration of all donation data (Milačić, 2000). Legally controlled secrecy and conscious consent of the patient are significant characteristics in the field of reproductive medicine, ensuing from the establishment of the constitutional right to privacy in reproductive treatment, and the reactions of political and moral opponents to the realization of such rights (Rockett et al., 2000).

## DONATION OF GENETIC MATERIAL

Genetic material donation has become an integral part of infertility treatment. Donations of spermatozoa, oocytes, embryos and pre-embryos (embryo not older than 14 days) are successful in the medical and technical sense and ethically approved. Medical problems and ethical dilemmas that require understanding and evaluation are: selection of donors, evaluation of recipients, quality control of genetic material, relationship between biological and social parents, and protection of the rights of offsprings through specially legislated 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 patients with inferior-quality oocytes and in patients 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 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 (Kahn et al., 1998, Baetens, 2002).

Indications for embryo donation are women without oocytes and men with azoospermia, in which cases only embryos obtained from spermatozoa and oocytes of mutually unknown donors can be donated. Embryo donation can be achieved in two ways: (I) using a combination of oocytes and sperm donation — such donors should already have been properly counseled; 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 Yugoslav Ethical Committee is that embryos have certain moral status, hence they cannot be preserved longer than 14 days (until „primitive streak” appearance), with permission to use the treatments that do not diminish the genetic status of the embryo (embryo defragmentation and ooplasm transfer, Milačić, 2000). Although in the U.S.A. donation of couples’ embryos has been permitted, very few couples decide to donate their embryos (a greater percentage preserves the embryos for possible future use), however, as proved in studies, which is interesting and important, transfer of „donated” couples’ embryos has resulted in a high percentage of successful pregnancies per treated cycle (50%, Van Voorhis et al., 1999). 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 interests of infertile couples, but also the interests of the embryo, i.e., of future descendants (Eisenberg, 1998).

## CRYOPRESERVATION OF GENETIC MATERIAL

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 Societies (IFFS).

Ovarian tissue cryopreservation is permitted, with significant prospects for clinical use in reproductive medicine and oncology. Ovarian cryopreservation, which lately has been in the focus of experimental research, opens 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 the criteria for future clinical use and benefits of such procedures (De Wert et al., 2000).

## POSTHUMOUS REPRODUCTION

Recent events posing ethical dilemmas relate to posthumous reproduction, pre-implantation genetic diagnosis (PGD) and cloning. They illustrate the difficulties for closed, legally controlled systems to forecast all the possibilities of scientific progress and ethical dilemmas arising from it. The advent of successful techniques of spermatozoon and embryo cryopreservation makes the birth of a child whose genetic father is dead technically possible, following the usual period deemed legally necessary to recognize the paternity of the posthumous child. Most of the centers for infertility treatment in the U. K. support the idea of posthumous reproduction, hence the posthumous treatment is permitted provided and explicit prior written consent has been given after the ga-

mete(s) provider(s) had received counsel. General attitude is that each case should be individually analyzed and approved by a multidisciplinary committee consisting of a gynecologist, a psychiatrist, a sociologist, a clergyman and other appropriate specialists (B e n s h u s h a n et al., 1998).

## PREIMPLANTATION GENETIC DIAGNOSIS

Preimplantation genetic diagnosis (PGD) is a result of development and convergence of assisted reproduction techniques and genetic methods, allowing the couples at risk an early diagnosis of hereditary diseases, even before the conception. PGD, however, triggers the fear of potential genetic manipulation and of getting closer to criminal eugenics, and therefore the standpoint of the Yugoslav Ethical Committee is that PGD is justified only in medically indicated cases. Within the framework of infertility treatment, pre-implantation genetic diagnosis is part of a range of potential diagnosis options, which help our patients when making an important decision about screening their future child from serious diseases (P a p p, 2000; M i l a č i ć, 2000).

## CLONING

Human reproductive cloning is unjustified and unnatural for it offends 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 the ethical aspects in the context of genetic reproductive techniques are to be evaluated separately. Many countries and institutions have analyzed possibilities of therapeutic cloning when other alternatives are exhausted, as well as the cloning within the framework of genetic engineering with the aim of producing appropriate human proteins.

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 damaged by poisoning. Stem cells may be derived from the embryo (more precisely, from blastocysts), the fetus or the adult. There are several types of embryonic stem (ES) cells: those issued from blastocysts either as supernumerary or created *de novo* and those created by nuclear transfer from somatic cells (SCNT). The latter method is usually referred to as cloning (S h e n f i e l d, 2002).

The final report of the European Group on Ethics (EGE), made public in November 2000, forbids reproductive cloning. It deems ethically unacceptable to create embryos from donated gametes, because supernumerary embryos are an alternative available source. In the case of embryos obtained by SCNT, extreme concern is voiced, despite the awareness that the creation of such embryos may be the most effective way for obtaining pluripotent stem cells genetically identical to the patient's and thus obtaining perfectly compatible tissues with the aim of avoiding rejection after transplantation (2000). Nevertheless, the concerned scientists 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.

Cloning is due to receive extensive legislation, 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 the entire mankind (De Wert, 2000, Lupton, 1999).

## CONCLUSION

Sex selection, multiple pregnancies and embryocide, surrogate parentage and treatment of older women open numerous ethical and legal dilemmas and call for multidisciplinary and expert approach to analyzing each individual case, as well as to defining clear ethical and legal regulations, open to correction in respect to further investigative work. Ethical postulates provide unequivocal directions in the creation of new life and resolve all possible ethical dilemmas, protecting the rights of doctors and participant in relevant procedures alike and reasserting the crucial principle — respect of human dignity. Defined legal principles are to be reconciled with the „natural laws” for the sake of protection of the freedom of thought and the right of individual choice and for the realization of the goal aimed at the preservation of life and justification of the purpose of existence.

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## ЕТИЧКО ПРАВНЕ ДИЛЕМЕ У ТРЕТМАНУ ИНФЕРТИЛИТЕТА

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### Резиме

Једно од основних обележја новог миленијума је афирмација људских права у свим областима људског битисања са тежњом оживотворења декларативних у реалистичко постулиране односе. Развој савремених асистираних репродуктивних техника (АРТ) у третману инфертилитета отворио је многобројна етичка, правна, религиозна и социјална питања: *in vitro* фертилизација; донација гамета, ембриона и преембриона; криопрезервација гамета, ембриона, оваријалног и тестикуларног ткива; ембрио трансфер, генетске репродуктивне технике; клонирање и друге софистициране методе у решавању важног и деликатног животног и медицинског питања — инфертилитета, захтевају кооперацију медицинске професије и етичко-правне струке, у циљу повезивања научно-истраживачког рада и одговарајућег, мудрог и индивидуализованог клиничког приступа. Етички аспекти хумане репродукције, као и асистираних фертилизације, заснивају се на поштовању живота јединке и пре успостављања концепције, од преембрионалног стадијума, преко ембрионалног стадијума, стадијума фетуса и новорођеног детета. Овакав став у даљим истраживачким и клиничким подухватима подразумева легализацију свих процедура у оквиру асистираних репродуктивних техника, информисаност и сагласност о њиховом спровођењу, уз поштовање основних етичких принципа: аутономије, користи, правде и опште добробити. Етички постулати у поступцима креирања новог живота помажу својим јасним упутствима у решавању могућих етичких дилема, штитећи права лекара и свих учесника у одговарајућим процедурама, уз уважавање круцијалног принципа — поштовања људског достојанства.