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NATIONAL PROGRAM FOR IN VITRO FERTILIZATION AND EMBRYO TRANSFER IN ROMANIA: ETHICAL, LEGAL, AND SOCIAL CHALLENGES

Review
Article

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Abstract

This review summarizes aspects regarding the national program for in vitro fertilization and embryo transfer in Romania, emphasizing on the ethical, legal and social challenges associated with assisted reproduction technologies. Romania is one of the few countries from the European Union that does not have a specific law for human assisted reproduction, but infertile couples in Romania may benefit from the national program for in vitro fertilization and embryo transfer although, unfortunately, the allocated public funds are not in line with the demand. There are a series of inclusion criteria when applying for the program and unlike other countries, only one in vitro fertilization (IVF) procedure may be publicly funded. Despite the legal, ethical and social challenges, this program, however, represents an extremely important step in aligning our country with the standards of other developed countries.

INTRODUCTION

Assisted reproductive techniques (ART) is a general term referring to medical procedures in which the female and male gametes as well as the oocytes are in vitro handled with the purpose of achieving a pregnancy. In vitro fertilization (IVF) is one of the most important techniques of human assisted reproduction and IVF is one of the most important human assisted reproductive techniques and implies collecting oocytes from the female partner, fertilizing them in vitro with spermatozoa, subsequently the embryos are cultured up to day 3 or 5 and then transferred.

In Romania, the bases of assisted human reproduction began with the first IVF procedure, which was performed in 1996, in Timisoara, thereby making Romania the 18th country in the world to have a successful pregnancy using this reproductive technique.

In 2011, the Romanian Ministry of Health launched, for the first time, the national In vitro fertilization (IVF) and embryo transfer (E.T) program. The program had a budget of 4 million Ron in 2011, a total number of 296 IVF procedures being completed in the clinics included in the program. Under the program launched in 2011, the Ministry of Health financially supported a single IVF procedure per couple, in two stages: 4,920 Ron after the fertilization procedure (collection of oocytes through follicular puncture, sperm collection and processing, oocyte fertilization and embryo transfer) and 1,230 Ron after the confirmation of that the IVF/ET procedures were completed and followed by a pregnancy. Unfortunately, the in vitro fertilization program was discontinued in 2013, but resumed later in 2015.

LEGAL ASPECTS

From the twenty-eight European Union member states, eight states, including Romania, do not have a specific legislation regulating human assisted reproduction. The legal norms applicable in Romania are the national (Law 71/2011, Order no. 860 from 12 July 2013) and the European ones Directive 23/2004 / EC of the European Parliament and of the Council of 31 March 2004, Commission Directive 17/2006 / EC from 8 February 2006, Commission Directive 2006/86 / EC of 24 October 2006) related to donation and transplantation of organs, tissues and cells of human origin.

The national program for in vitro fertilization and embryo transfer is addressed to infertile couples, defined as couples who were unable to conceive naturally after at least one year of unprotected sexual activity. Additionally, these couples have to be diagnosed properly by obstetrics-gynecology

specialists, with competence in human assisted reproduction.

Overall, there is a list of inclusion criteria stated by the Order of the Minister of Health no. 386/2015, the eligibility of a couple for applying to the program being largely determined by a series of mandatory analyzes the partners have to perform. There are 6 major inclusion criteria, which are briefly listed as follows: the couple should have an indication from a specialist in human assisted reproduction techniques, both partners should possess health insurance, the age of the female patient should be between 24 and 40 years, the body mass index should range between 20 and 25 and the ovarian reserve, as measured by the AMH should be minimum 1.1 ng/ml.

ETHICAL CONCERNS

From the first IVF performed in 1978 in UK, assisted human reproduction is one of the branches of medicine that has developed steadily so that nowadays more and more infertile couples may benefit from these assisted reproductive techniques to fulfill their desire to have a baby. According to a study conducted by Ferrarreti et al, 2012, the number of IVF cycles performed in Europe back in 2008 was significantly higher as compared to USA. However, precisely the apparition of new opportunities for infertile couples determined the emergence of ethical considerations regarding the applicability of these techniques.

These technologies should be applied taking into account the legislation, the selection criteria as recommended by the good clinical practice guide (2015) elaborated by ESHRE (<https://www.eshre.eu>) and last but not least the best interest of the patient.

One of the key points of the debate has been and continues to be the right to assisted human reproduction, since these procedures have high costs in both high developed and developing European countries (Chambers et al., 2009) and in some, including Romania, availability of public funding for IVF treatment is limited (Culley et al., 2011).

In 2016, The Ministry of Health has allocated around 2,000,000 lei for this program, which could cover about 330 fertilization procedures (www.ms.ro), while the estimated number of IVF procedures performed annually in Romania is around 2000. It is worth mentioning that the data is reported by the IVF clinics in Romania voluntary to an international organism such as ESHRE (Eshre Final Report, 2010), there is not a national authority or organism that centralizes clinical data and conducts careful statistics and monitoring of the quality of IVF practice (Nahman, 2016). Nevertheless, the participation of IVF clinic in the

national program of ivf is conditioned by a performance criteria of minimum 30% successful outcome.

Moreover, this public financial support does not cover the costs of hormonal treatment necessary for ovarian hyperstimulation, nor other other medical investigations needed to diagnose infertility or procedures designed to improve their chances of achieving pregnancy, such as ICSI or assisted hatching. Although controversial in some countries, the genetic screening of the embryos is legal to perform in Romania (Anton et al, 2009), but it is not financially supported by National Program for in vitro fertilization and embryo transfer, therefore, couples with an history of genetic disorders or recurrent failed implantation, have to bear the costs of such investigation.

Through the National Program of in vitro fertilization and embryo transfer, only one IVF procedure is financed, meanwhile in other countries such Belgium, France or Germany up to 6 procedures are publicly funded to citizens which are medically ensured (Brigham et al., 2013). This issue may rise another ethical concern, since couple who have a failed IVF and cannot afford to carry out other procedure may feel that their fundamental right to procreation is prohibited.

SOCIAL ISSUES

In well developed and developing countries across Europe there is currently an upward trend in postponing procreation (Mills et al, 2011) in spite of the alarm signals drawn by doctors specialized in assisted reproduction according to which fertility decreases vertiginously with age. Unfortunately, many women become more and more aware that later is not necessarily better, at least not when it comes to reproduction. Because the ovarian reserve, which may be established by determining the anti-mullerian hormone (AMH) decreases very much with age, the chances of conceiving naturally are also vertiginously diminishing (Doroftei et al, 2015).

The social component has wider implications due to religious considerations, given that 85% of the population is Christian-Orthodox, and the Orthodox Church has been reluctant to accept these assisted reproductive procedures, currently considering the use of oocytes or sperm from donors as adultery and embryo reduction a form of abortion.

CONCLUSIONS

Infertile couples in Romania may benefit from the national program for in vitro fertilization and embryo transfer although, unfortunately, the allocated public funds are not in line with the

demand. Also, the additional costs that are not covered by this program for medical investigation prior the IVF procedure itself as well as any other procedures meant to increase the chances of obtaining a pregnancy are a limitation for many couples who can not afford these costs.

Despite legal, ethical and social challenges, this program, however, represents an extremely important step in aligning our country with the standards of other developed countries.

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