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Socio-economical, Legal and Ethical Issues raised by Infertility and Assisted Reproductive Techniques in Romania

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Abstract

Infertility is defined as the inability of a couple to conceive a child after 12 months of regular and unprotected sexual intercourse or after 6 months, in case of women who are over 35 years. Currently, assisted human reproductive techniques (ART) can help infertility couples worldwide and promise unquestionable benefits to humanity. The study proposes an assessment of problems that couples with fertility issues are facing in Romania using a special questionnaire composed of 8 segments and 65 items. The questionnaire was completed by 860 women who benefited from ART in different fertility clinics nationwide. By analyzing the results, we identified the socio-economical and legal concerns that occurred when

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couples approached these methods. They all represent direct challenges for society in order to review how these methods are applied. Moreover, the presented results may pursue decision makers to modify the existing laws in order to adapt them to the challenges that have arisen.

Keywords: infertility, assisted reproductive techniques (ART), ethical aspects

Introduction

As one of the CEE (Central and Eastern Europe) countries, Romania experienced its lowest low fertility rate of 1.27 in 2002 (World Bank 2017) and has maintained relatively low levels of period fertility ever since. The fertility levels are low yet this is despite the traditional context of family formation encouraging the reproductive behaviour. The total fertility rate in Romania has decreased constantly in the last 30 years, reaching its lowest value (1,46 versus 1,55 EU average) in 2013 (EUROSTAT, 2014), (United Nations, 2020).

The first successful in vitro fertilization procedure in Romania was performed in 1995 at Bega University Clinic of Obstetrics and Gynecology in Timișoara. Romania was the 18th country in the world to use this technique. Now, 35 years later, Romania is the only country in the EU that so far does not have specific legislation in this field. Moreover, only partial funding and only for some couples undergoing IVF (in-vitro fertilization) treatment is provided through the “Sub-Program for In Vitro Fertilization and Embryo Transfer”. This program does not cover screening procedures or medical support for fertilization during treatment (ESHRE, 2017). Without public funding and educational campaigns, the understanding of this topic is significantly lower at national level. The SOS Infertility Patients’ Association organizes annually the National Week for Increasing the Awareness of Infertility in Romania and the Romanian Society for Fertility and Assisted Reproduction has implemented various educational programs about infertility. Availability of treatment is a limiting factor, patients are required to fund most of their procedures. The eligibility criteria restrict access to the national reimbursement program, in order to maximize the results compared to the allocated budget (SOS Infertility Association, 2016; Onofriescu, 2014).

However, in January 2020, a joint meeting of the Romanian Society of Obstetrics and Gynecology and The Ministry of Health concluded that the IVF Sub-Program suffered from chronic sub-financing and promises for reorganization and increased funding were made (Costache, 2020). Initially presented as a treatment for „infertility”, artificial human reproduction is used today not only by naturally infertile couples, but also by single persons and couples made up of same-sex fertile individuals for whom human reproduction is not possible naturally. Even if in the academic environment interest are mainly focused on ethical and moral

issues, medically assisted human reproduction is a challenge for the Law, as is artificial intelligence (Brezina, 2012), (Hanevik, 2016).

Artificial human reproduction is possible only with the intervention of the technology by specialists (biologists and doctors) in the fertilization clinics, where human genetic material (female and male gametes) and human embryos are created and stored (Soini, 2006). In this article, we will focus on the access of infertile couples from Romania to assisted reproductive techniques, regarding the implication of the government in covering the costs for procedures, as well the level of information offered to infertile couples regarding their condition and their opportunities to obtain a pregnancy. Furthermore, we will deal with other issues, such as socio-economical, ethical and legal aspects that surround the domain of Assisted Reproductive Techniques.

Methodology

This study was descriptive cross-sectional research. The sample population included patients who attended specialized infertility treatment in Fertility Clinics from Romania. The study was conducted between 2017 and 2019 and data was gathered through an infertility questionnaire made by the researchers. The questionnaire was distributed in multiple gynaecology clinics and hospitals (both in Bucharest and Timișoara) and was also made available online for ease of use. Thus, one-third of the data was collected from the hospitals, and two-thirds was collected online, through a Google Forms questionnaire. A number of 829 women who struggled to obtain a pregnancy and resorted to ART completed the questionnaire. Participants were assured about the privacy of research and their right to remain anonymous.

This study was conducted after obtaining ethical approval from the Local Ethics Committee of Scientific Research and from „Pius Brînzeu” Emergency County Hospital Timisoara, Romania.

The study questionnaire is organized in 8 sections: the first section represents the patients' consent for completing the questionnaire; the second section deals with demographic characteristics. The next sections highlights the obstetrical and gynaecological status, possible medical and surgical conditions related to infertility. The last section is comprised of questions evaluating the socio-economic and psychological implications of the procedures followed (academic background, monthly income, financial investment, impact of infertility on the relationship and overall quality of life).

Statistical Analysis

The collected data was analysed by SPSS software for Windows, performing Chi2 Test, Kruskal-Wallis Test, Mann-Whitney U test, and Spearman correlation.

Results

Patients who were enrolled in this study had less than 35 years in 65.3% of cases, while 34.7% had more than 35 years (as seen in *Table 1*). Concerning their level of education, 78.3% graduated University or have a Master/PhD degree, 20.3% of them graduated High School and only a small percentage (1.4%) finalized just primary school studies. This huge discrepancy in the level of access to ART between women with different educational backgrounds is one of the major problems of the actual system. Unfortunately, only 16.4 % of all patients had the procedures and treatment covered partially by the Health Insurance Programme and just 0,6 % had total costs covered by Health Insurance Programme. The significant part, representing 82.9% of them, payed the total costs for treatment from their own resources.

As for pregnancy results, 29.6% of them obtained a pregnancy by either one of the procedures, IUI/IVF/ICSI (IUI-intrauterine insemination; ICSI-intracytoplasmic sperm injection), while 10.6% of patients obtained it spontaneously, 3.2 % after ovarian stimulation and 56.5% did not obtain any pregnancy. As for which method was involved in obtaining a pregnancy, results showed that by IVF in most cases (56.1%), by ICSI in a significant number of cases 40.7%, by IUI in 22% cases and by GIFT in obly 3.3%.

When asked about quitting, 62.9% responded they took this option into consideration. Out of these 55,8 % said it was because of financial reasons, for 66,8 % the psychological aspect was the most incriminated, for 18,6% of patients was a professional aspect and for 6,3 % was a family aspect involved.

Regarding embryo reduction, 44.6% responded that they would not accept this, while 39.2% did not know already, and only 16.2 % would agree to this technique. When asked if adoption was considered as an alternative, the results showed that for 54.7% of the participants it was a viable option. Only 19.1 % did not take this possibility into consideration, while 26.3% have not decided yet regarding this matter. Couples were also asked if they consider that in other country their chances to obtain a pregnancy would be bigger, 50.6% considered that their chances would be bigger abroad, while 36.9% did not know the answer and the others (12.9%) responded yes. As well, regarding legal aspects, 58.8% of them responded that the law on assisted human reproduction methods is not fully regulated in Romania, while 38% did not know how to answer to this question and only 3.2% considered that the law is fully regulated.

Table 1. Studied parameters in women with infertility from Romania

Variables	Values	N (%)
Age	< 35 years	496 (65.3%)
	≥ 35 years	264 (34.7%)
Level of education	Primary	12 (1.4%)
	High School	168 (20.3%)
	Bachelor/Master/PhD	649 (78.3%)
Procedures covered by the government	None	705 (82.9%)
	Partially	139 (16.4%)
	Totally	6 (0.7%)
How much time you tried to conceive?	<5 years	227 (31.1%)
	5-10 years	296 (40.5%)
	>10 years	207 (28.3%)
Pregnancy results	Spontaneously	88 (10.6%)
	After ovarian stimulation	27 (3.2%)
	After IUI/FIV/GIFT	246 (29.6%)
	No pregnancy	468 (56.5%)
Pregnancy obtained by ART	IUI	54 (22%)
	FIV	138 (56.1%)
	ICSI	100 (40.7%)
	GIFT	8 (3.3%)
Did you consider quitting at some point?	Yes	541 (62.8%)
	No	320 (37.2%)
If Yes, which were the reasons?	Financial aspects	326 (56.9%)
	Familial aspects	37 (6.5%)
	Psychological aspects	381 (66.5%)
	Professional aspects	107 (18.7%)
	Other reasons	55 (9.6%)
Do you think that in other country your chances to obtain a pregnancy would be bigger?	Yes	434 (50.6%)
	I don't know	317 (36.9%)
	No	107 (12.5%)

Would you agree with embryo reduction, if your doctor suggests you?	No	382 (44.6%)
	I don't know	336 (39.2%)
	Yes	139 (16.2%)
Would you consider adoption a possibility?	Yes	470 (54.7%)
	I don't know	226 (26.3%)
	No	164 (19.1%)
Do you think that the law on assisted human reproduction methods is fully regulated in Romania?	No	500 (58.8%)
	I don't know	323 (38 %)
	Yes	27 (3.2%)

Discussion

Fertility rate of Romania decreased gradually from 2.82 children per woman in 1970 to 1.63 children per woman in 2019, with its lowest value at 1.46 in 2013 (EUROSTAT 2014). We can clearly see an increase in the last years, with a value of 1,76 in 2018 according to Eurostat, but other reports such as UN World Population Prospects show a different value of 1,63 (United Nations, 2020).

The decline in fertility in Romania after 1990 is due to women's biggest interest in tertiary education, professional activity or simply as a consequence of the use of modern techniques of birth control (Ciritel, 2019). The postponement of first births has implications on the ability of women to conceive and is visible in both couples who are married, but as well in cohabitation, even though non-marital births are not as frequent in Romania as in other Western countries. Massive postponement is the consequence of the unbalance between the optimal biological period for women to have children and the possibility to continue further studies and focus on the career (Mills, 2011).

In our study infertile patients who adressed specialized treatment had less than 35 years in 65,3% of cases, while 34.7% had more than 35 years (as seen in Table 1). More specifically, the mean age of women resorting to Assisted Reproductive Techniques in Romania was 33 years. The average age of women receiving infertility specialized treatment in the United Kingdom was 35 years, compared with 36 years in the United States (Nicole, 2018).

Regarding the educational level, almost 80% of the women included in the study have graduated university. This clearly shows that the level of education is very important and may have some impact in the way women face infertility problems. Higher education level was associated with an increase in female fertility impairment, independently of other demographic and behavioural characteristics. The strong correlation between female education and age at conceiving is well-

documented in a lot of studies. There is a strong inverse relationship between education and fertility, with a lot of arguments that highlight that continued education might lead to childbearing delay (Kim, 2010).

Regarding the involvement of the Government in covering costs for infertility treatment, our results showed that only 16,4 % of all patients had the procedures and treatment covered partially by the IVF Sub-Programme and just 0,6 % had total costs covered. There are big differences regarding reimbursement for infertility issues among countries in the European Union, as political priorities and public attitudes determine the scope and availability of publically funded treatments. Criterias for inclusion such as: age, marital status or sexual orientation also vary significantly among EU countries. In Czech Republic, there is a 100% coverage by mandatory health insurance for up to four cycles IVF and six IUI, for women having between 22 and 39 years of age (Czech Republic Ministry of Health, 1997). In France, the situation is also propitious, up to six IUIs and four IVFs are fully reimbursed for women under 43 years of age (French Government, 2016). In Italy, IVF is generally covered at 65%, depending on a woman's age and the number of previous attempts. In contrast, Poland offers no reimbursement or state funding for medically assisted reproductive treatments (ESHRE, 2017). In Spain, infertility treatment is free for Spanish residents, with approximately 25% reimbursement for medications depending on the region (ESHRE, 2015). Sweden offers almost complete coverage within public healthcare system.

More than 50% of women spent minimum 5 years to benefit from specialized infertility treatment, while 25% of them spent more than 10 years in order to obtain a pregnancy. This delay in the diagnosis of infertility negatively impacts the future chances of obtaining a pregnancy, as a significant percentage of women may have underlying causes of infertility which should be treated before attempting specific infertility treatments.

Despite the delay in conceiving, the results regarding assisted reproductive techniques in Romania are encouraging, as a significant percentage of 29,6% obtained a pregnancy after IUI/FIV/GIFT (Gamete intrafallopian transfer). Concerning which type of technique lead to these results, the most efficient was IVF (56,1% obtained a pregnancy), followed by ICSI (40,7% obtained a pregnancy). These results are superior to results obtained worldwide, but this paradox is generated by a clear selection bias of the cases in the private clinics and the limiting criterias of the National Sub-Programme. The latest annual data collected by ESHRE from European national registries (for 2016) show another rise in the cumulative use of IVF in the treatment of infertility, while success rates were calculated at 27.1% after IVF and 24.3% after ICSI (ESHRE, 2019).

Regarding the adoption phenomena in Romania, national adoptions have remained relatively stable, with about 1,000 children adopted each year since the moratorium on international adoption in Romania relased in 2004. On the other hand, international adoptions have been rare in the latest years (Popescu, 2019). In

our study, when couples were asked if adoption was considered as an alternative, 54,7% of them considered that this was an option to take into consideration.

Concerning the possibility to access specialized treatment abroad and possibly obtain better results, 50.6% of patients responded that they would rather choose a clinic from abroad. A lot of Romanian couples who can afford this kind of expenses travel to other countries to access specialized infertility treatment, more often in: Hungary, The Czech Republic, Spain, Greece and Cyprus. Still, there are no official reports regarding the numbers of couples who resort to this solution.

Access to specialised treatment

In Romania, access to specialized infertility treatment is restricted. A small number of couples get support from the government, others decide to pay for the treatment in Romania and a big number of couples decide to go abroad in order to receive treatment. As we found out in our study, only 16.4% of couples had the costs for specialized treatment partially covered by the Government, and less than 1 % (more exactly 0.6%) of them were completely covered.

Equitable access to IVF remains a fundamental issue in Romania where only a very small fraction of the population have their treatments reimbursed by the government. The “National Program for Organ, Tissue and Cell Transplantation” includes a “Sub-Program for In Vitro Fertilization and Embryo Transfer” which provides partial funding for IVF treatments. As a matter of fact, ART is mainly private sector driven, in contrast to most European countries where costs for assisted reproductive techniques are covered by the state. Most advances in the field were due to patient associations and the support of health professionals (Puppinck, 2012).

In Romania, in order to be included in the National Sub-Program and get reimbursed through the National Insurance House for IVF treatments, couples must meet multiple eligibility criteria. Some clear limitations are: the age of the woman between 24-40 years, the woman’s body mass index between 20-25, a normal ovarian reserve AMH > 1.1ng/ml (with the necessary documentation, screening results and legal documents as proofs). Moreover, the program is limited to autologous couples (excluding donation of oocytes, semen or surrogacy). The program does not cover prior or medical examinations or the related medication necessary for the treatment. An accepted couple can receive funding for procedures such as: oocyte extraction, sperm processing, oocyte insemination, embryo transfer and monitoring up to a maximum cost of 1375 euro (Bors, 2015).

The National Sub-Program was initially implemented between 2011-2012 and 900 couples qualified to enrol in the program. 1.6 million euros were allocated for the procedures (in vitro fertilization and embryo transfer) and 11 clinics involved (out of a total of 24 /country): 4 in Bucharest, 2 in Timișoara and one in Cluj, Brașov, Iași, Sibiu and Craiova. Subsequently, between 2013-2014, the program

was suspended for political reasons and restarted in 2015 by the Ministry of Health (SOS Infertility Presentation - ESHRE Congress, 2016)

The National Sub-Program covered over 761 IVF procedures between 2015-2016, with total expenses covered by the state of approximately 6188 RON/couple (approximately 1375 EUR). The number of clinics included in the 2015-2016 subprogram also increased to 13 adding cities of Târgu Mureș and Târgoviște to the list (Parlamentul Romaniei, 2015; Ministerul Sanatatii, 2016).

For 2017-2018 the Sub-program also received funding. During the first 9 months of 2017, a little over 200 in vitro fertilization and embryo transfer procedures were performed, but well below the annual average of the first two subprograms. For 2019 the National Sub-Program aimed to increase the number of IVF cycles from 835 to 1000, the amount settled still remained of 6,188 RON/procedure and only one procedure/couple that meets the eligibility criteria (Agentia Nationala de Transplant, 2019).

According to the rules announced for 2020, the number of procedures to be settled in this program is 1,000, and the amount settled is 10,000 lei for procedure, only one being approved for a couple that meets the eligibility criteria. A similar project, but with more flexible criteria, was initiated in 2018 by the Bucharest City Hall (PMB). Through the project „A chance for infertile couples IVF 1”, carried out by the PMB through the Administration of Hospitals and Medical Services Bucharest (ASSMB), 1,000 couples from the Capital received substantial amounts (13,800 lei / couple) to become parents. In June 2019, the second round of the project (IVF 2) was started and will provides aprox. 3,000 euros for 2,000 couples who have an indication for IVF in the next 2 years (FIV 2, 2019).

Access to fertilization treatments is still low due to the lack of accurate information from the generalist, but also the gynecologist. The number of couples who are referred to an infertility specialist is still low. However, the National Health Strategy 2014-2020 mentions the need for at least one generalist doctor to specialize in infertility in a certain territorial unit. It could thus provide advice on reproductive health and guidance in family planning (Guvernul Romaniei, 2015), (Ministerul Sanatatii, 2015).

Legal issues

In Romania, patients do not trust the actual law regarding the regulation of Assisted Reproductive Techniques. A very small percentage responded positive about this regulation, which definitely shows there is a big problem surrounding this matter. It is either because patients are not well informed, or simply because there is lack of regulation.

The truth is there is no sole legislative regulation regarding the treatment of infertility, despite numerous attempts at national level. In 2009, a written request to the European Commission raised the question of the need for a national legislative framework. A legislative project on infertility is still under debate (ESHRE, 2015).

Even if Art. 447 of the Civil Code stipulates that the regime of human reproduction assisted medically with a third donor will be the subject of a special law, until now it has not been adopted. However, the embryo industry is constantly developing, as can easily be seen by accessing the Internet (Tec, 2018).

In Section 14, some activities in the area of MAR are banned, such as: “abusive production of embryos; genetic manipulation on embryos; post-mortem insemination; illegal donation of embryos; gametes trafficking; collection of gametes without consent; mixing gametes; selective abortion of embryos of a certain sex”. As well, human cloning is prohibited in the actual Romanian law and importing or exporting reproductive cells require special authorizations from authorities that are in charge of this regulations (Busardo, 2014).

The classification of human embryos in one category or another is a matter disputed by doctors, biologists, theologians, philosophers, anthropologists and lawyers alike. The European Court of Human Rights has acknowledged that there is no consensus among the member states of the Council of Europe on the qualification of the human embryo. Thus, the human embryo in vitro remains a legal category not identified by law and courts (Tec, 2018). If the human embryo were to be considered a real human being, which should be protected regardless of its existence, uterine or in vitro, a series of legal paradoxes would arise. In this case, abortion should be a crime, the preservation of embryos would undermine human dignity, and the dispute between former spouses or partners regarding embryos should be resolved in accordance with the rules under which the dispute is resolved, child custody or parental authority, the best interest of the child prevailing. However, the best interests of the child are completely ignored in such cases, because the in vitro embryos belonging to the category of goods or persons is not decisive for resolving the dispute over in vitro embryos (George, 2019).

The legal context in Romania makes no difference concerning marital status or sexual orientation when it comes to accessibility to treatments. This could be due to the absence of legislation in this regard (Puppinck, 2012).

Ethical issues

In Romania, there are no statistics on the number of embryos conceived with third-party donors, carrying mothers, the number of cryopreserved embryos, the number of donors, the number of „consumers”. Or, if there is such a statistic, then there is no transparency. In our study, patients were asked if they would agree with embryoreduction if there was a clear indication for that and the results showed that 44.6% of them responded negatively and only 16.2 % responded positively.

A major ethical issue is that of the fate of excess embryos resulting from the application of assisted human reproduction techniques. In order to improve the results obtained from assisted reproductive techniques, a large number of embryos are usually produced, between 10 and 12, of which only 1 or 2 are transferred and the rest frozen (Aznar, 2020). The conflict between the right to procreate and

the right to life of these embryos is very acute, generating radically antagonistic ethical positions, especially from the Church. Indeed, none of the proposed variants are bioethically satisfactory: freezing of embryos, keeping them in embryo banks, with possible donation to another sterile couple, donation for medical research purposes, destruction (equivalent to an abortion), even utilities for commercial purposes (Mihai, 2019).

Another area of big interest regarding assisted reproduction techniques and genetics is the possibility to perform selection of gamete donors. In the actual context of early identification of diseases with strong genetic component, there is a big issue regarding the correct genetic screening of the donor, if there are clear guidelines regarding this matter (Ethics Committee of American Society for Reproductive Medicine, 2013).

From the point of view of the use of medically assisted human reproduction techniques, sampling and cryopreservation of gametes is a safe and preferable solution for cryopreservation of embryos, in case of divorce or death because, in accordance with the principle of the person's autonomy, the parent can use them in the future for fertilization in vitro, without the consent of the former spouse or partner, in case of divorce or death, being his own genetic material (Konc, 2014)

Conclusion

In the last years, there clearly has been an improvement in Romania in the area of assisted human reproduction field. However, the lack of regulation regarding assisted reproductive techniques led to multiple actions from Associations such as SOS Infertilitatea, which continue to put a lot of pressure on the government in order to modify the actual laws in favour of the patients. Despite all these efforts from Societies such as Romanian Society for Reproductive Medicine or Romanian Embryologists Association or from patient's associations, the progress is still slow and the majority of couples who struggle with infertility have to cover all costs for infertility treatment. Regarding the quality of MAR, the results in Romania are good, comparable to results in other European Countries, which positively impacts the development of these technologies and encourages patients to trust Fertility Clinics from Romania.

However, access is limited to a minority of infertile couples, and there is only general legislation covering ART procedures and no specific regulation. Despite the cooperation of European countries in order to balance the political, ethical and legal differences, there are still important issues in the legislation concerning the practice of ART. It is mandatory for our country to make all needed efforts in order to establish a clear legal framework surrounding MAR, provide medical and financial support to all couples who struggle with infertility and increase awareness regarding infertility and acces to assisted reproductive techniques.

Recommendations

During the last years, an improvement to what regards ART national programme was observed but future ethical, legal, and medical improvements are need it. The database derived from this paper is valuable for investigating the objective described in the text as well as additional hypotheses that will evolve. The critique, recommendations, and suggestions offered aboved are intended to describe the lacks in the IVF couple management but also to improve the therapeutic direction for these patients.

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