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Infertility and assisted reproductive technologies in Serbia

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Abstract

Infertility is a significant challenge, both on individual and macro levels. The overall aim of this paper is to contribute to better understanding infertility in Serbia by analysing relevant policies and programmes, data on the epidemiology of infertility, health services, and research findings. The investigation is grounded in the action research methodology, which is built on a shared process of reflection between researchers and participants on selected data and documents. The legal framework reflects modern approaches to a number of challenges in this area. Since the end of 2006, the Republic Health Insurance Fund (RHIF) has been financing the National Infertility Treatment Program with biomedically assisted reproduction (BMAR) procedures. The data on the epidemiology of infertility is not sufficiently addressed in health statistics and representative research. The quality of infertility treatment in Serbia is on par with developed countries, but it doesn't include the donation of reproductive cells and surrogacy. There is also a lack of research on various aspects of infertility in Serbia from the perspective of different scientific disciplines. It is also hard to understand why, despite considerable possibilities for individual solutions to the problem of infertility in Serbia, the share of children born from BMAR procedures is relatively low.

KEYWORDS

infertility, assisted reproductive technologies, action research methodology, epidemiology of infertility, Serbia

1 INTRODUCTION

Serbia first faced the issue of below-replacement fertility as early as the 1960s. In 2019, the total fertility rate was 1.52, or 28% below the replacement level (Statistical Office of the Republic of Serbia 2020) and also below the European average of 1.6 children per woman (Pison 2019). This sustained below-replacement fertility is the fundamental cause of the negative natural growth, population decline, and profound changes in the age structure of Serbia's population. It is difficult to explain the low fertility rate over the past two decades without an in-depth investigation of this phenomenon. Unlike a large number of European countries, Serbia has not conducted any significant demographic surveys during that time. Despite this lack of information that could help identify the reasons for low birth levels after the year 2000, the most logical seem to be those related to and/or resulting from the severe economic and social crisis that has been affecting Serbia for a prolonged period of time. In addition to these factors, the low birth levels can be explained by a deep transformation of society corresponding to changes that began earlier in developed European countries, which are causes of low fertility (Sobotka 2004). These include, on the one hand, the promotion of individualism, the desire for self-actualisation, a changed concept of family, different partner relationships, and insisting on the quality of one's own life and the life of children. On the other hand, there is also strong inclination towards consumption and leisure (Rašević 2017). Becoming a parent in Serbia is hampered not only by primary infertility, but also secondary infertility, which is a consequence of risky health behaviour, including factors that contribute to sexual and reproductive ill-health. An integral reason for below-replacement fertility in Serbia is the decrease in the number of women in reproductive age, which consequently becomes an important factor in the birth crisis. The continuous emigration of young people from Serbia also contributes to this problem.

Infertility is a crucial public health issue that calls for action from the healthcare system on several levels, from prevention and diagnosis to treatment. From the moment the first baby was born through assisted reproductive techniques (ART) more than 40 years ago, it has become very important from an individual psychological and social point of view to ensure that these methods are available to people suffering from infertility. At the same time, the right to ART has become an important right of every individual in the context of other human rights (the right to life, the right to privacy, the right to a family life, health rights, children's rights etc.), with which it is interconnected and interdependent (Živojinović 2012).

Biomedically assisted fertilisation (BAF) began to develop early in Serbia; the first baby from in vitro fertilisation (IVF) was born in 1987 (Bjelica 2017). Acknowledging the various benefits of treating infertility, the state has been financially supporting the implementation of BAF since 2006 (Bjelica 2017). With this, Serbia has contributed to achieving the UN's sustainable development goals (SDGs) (Government of the Republic of Serbia 2017). Namely, addressing infertility falls under the domain of several SDGs: SDG 3 - good health and well-being; SDG 4 - quality education; SDG 5 - gender equality; and SDG 10 - reduced inequalities (United Nations 2015).

The overall aim of this research is to contribute to better understanding infertility

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in Serbia in the contexts of demography, public health, and human rights.
The specific objectives were:

- Analysing policies and programmes on reproductive health and infertility;
- Collecting data on the epidemiology of infertility;
- Mapping health services in infertility treatment;
- Reviewing existing and relevant research.

2 METHODOLOGY

The investigation conducted for the this paper was part of the project "Infertility and Assisted Reproductive Technologies in Kazakhstan, Serbia and Ukraine" developed by UNFPA's Eastern Europe and Central Asia Regional Office (EECARO) and the World Health Organization (WHO) Europe in 2021. The project use the action research methodology, an approach built on a shared process of reflection between researchers and participants on relevant data and documents. The expected result is integration through data interpretation by critical thinking (Reason and Bradbury 2012).

In order to reveal relevant data and documents, the following databases were searched: 1) the Statistical Office of the Republic of Serbia; 2) the Institute of Public Health of the Republic of Serbia; 3) legal documents of the Republic of Serbia; 4) Medline, Popline, Web of Science, ScienceDirect, SCIndex, and Kobson. In this way, relevant demographic and health indicators, current laws, strategies and programs, and scientific and professional papers on infertility published in journals and conference proceedings were identified and taken into account. Google searches were used to obtain reports from non-governmental organisations (NGO).

Afterwards, 15 interviews were conducted with stakeholders between 12 May and 14 June 2021. All interviews were a mix of semi-structured and unstructured formats, in line with the aim and objectives of the paper. They were held live or via Zoom and lasted an average of about 60 minutes. At the end of the interview, consent was obtained for an additional interview in case needed.

The interview was conducted with prominent representatives of: 1) the Ministry of Health of the Republic of Serbia; 2) the Directorate for Biomedicine of the Ministry of Health of the Republic of Serbia; 3) the RHIF; 4) the Republic Expert Commission for Biomedically Assisted Fertilisation Procedures of the Ministry of Health of the Republic of Serbia; 5) the Ministry of Family Welfare and Demography of the Republic of Serbia; 6) the Statistical Office of the Republic of Serbia; 7) the Institute of Public Health of the Republic of Serbia; 8) professional teams dealing with the treatment of infertility in the centres for BAF, both privately and publically owned; 9) the academic community; 10) NGOs. During the interviews, stakeholders discussed their views on various relevant aspects of infertility; the most important reflections[1] from stakeholders form an integral part of this paper. Additional information on the principle of the snowball effect was obtained.

3 RESULTS

3.1 INTERPRETATION OF THE LEGAL AND STRATEGIC FRAMEWORK

The Law on Biomedically Assisted Reproduction regulates the framework and or

1 The findings obtained during the interviews were marked with the use of italic font.

ganisation of this process, as well as the types of procedures, the conditions under which the right is exercised, and the monitoring of its implementation (Zakon o biomedicinski potpomognutoj oplodnji 2017).

The BAF procedure includes testing, obtaining, processing, freezing, thawing, preserving, storing, and distributing reproductive cells, zygotes, and embryos, as well as importing or exporting reproductive cells.

BAF involves the following procedures:

1) Fertilisation in the body, which involves the introduction of sperm cells into a woman's genitals or the introduction of eggs together with sperm cells into a woman's genitals;
2) In vitro fertilisation, which involves the fusion of eggs and sperm cells outside a woman's body in order to create a zygote or embryo, which is then transferred to a woman's genitals.

Both private and public health institutions that have received a permit from the Directorate for Biomedicine of the Ministry of Health of the Republic of Serbia can perform BAF procedures.

The Director of the Directorate issues a licence for the Reproductive Cell Bank to only one state health institution that deals with BAF.Only a team of professionals with expertise in the field can conduct BAF procedures.

This law specifically regulates the donation of reproductive cells and embryos.

Most importantly, the reproductive cells of one donor – as well as the donated embryos of one pair of spouses or extramarital partners – can be used for a BAF procedure for one pair of spouses or extramarital partners. Offering reproductive cells or embryos in exchange for property or any other benefit is forbidden, as is advertising the offer or need for reproductive cells of women or men.

Donors of reproductive material must be of legal age, healthy, and capable of making business decisions. They must also sign documents providing informed consent for their donation. The promotion of voluntary donations of reproductive material is the responsibility of the Ministry of Health of the Republic of Serbia.

The law regulates that the Directorate for Biomedicine keeps a unique register of biomedically assisted reproduction (BMAR) procedures for the territory of Serbia. The data to be entered in the State Register is defined.

Data from the State Register may be used as aggregate statistical indicators, as well as in individual cases specified by this law. It is prescribed that the State Register contains data on: the BAF centre, i.e. the Bank; users of BAF procedures and the birth of children conceived using BAF procedures; donors and recipients of reproductive cells and embryos and donated reproductive cells, tissues, and embryos. The data in the State Register is kept permanently.

A child conceived by BAF using the reproductive cells of the donor has the right to request that the Directorate for Biomedicine provide data from the State Register for medical reasons. The child can request this data – which refers to the donor of the reproductive cells – when they turn 15 and are able to reason. The right refers to data of medical significance for the child, their future spouse, and their offspring. A healthcare worker treating a child conceived using BAF may request, for medical reasons, access to the State Register in order to best cater to the child's health needs.

In BAF procedures, genetic diagnosis before implantation is allowed only in cases where there's a danger of transmission of hereditary disease, a diagnosis of chromo-

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somal or genetic diseases, or if it's necessary due to repeated unsuccessful BAF procedures. Permission for this diagnostic procedure is given by the Biomedicine Directorate based on the opinion of the multidisciplinary council for diagnostic issues, established in accordance with the law governing the prevention and diagnosis of genetic diseases, genetically determined anomalies, and rare diseases.

The law also defines restrictions for BMAR. Two seem significant: 1) it is forbidden to perform BAF procedures with the simultaneous use of donated eggs and donated sperm; 2) it is forbidden to choose the sex of the child if there are no medical indications for that (e.g. haemophilia). The law also prohibits other unethical practices.

If reproductive cells cannot be provided in Serbia, they may be imported. The Director of the Directorate for Biomedicine issues a license for each individual case of import or export of cells to assess the justification for it.

Surrogacy is prohibited by the law.

During the interviews, representatives of the profession and relevant NGOs agreed that the main shortcoming of this law is that it does not regulate the issue of surrogacy, i.e. that there is a complete ban on this procedure. Namely, most of the interviewees believe that surrogacy should be allowed only for heterosexual women who have a medical indication (e.g. uterine deficiency). At the same time, they emphasise that so far, the law has only been partially implemented. In that sense, the Directorate for Biomedicine's work in this area remains extremely limited: there are only two employees in this field, the State Register of BAF procedures has not been formed, it's not known whether inspections prescribed by the law are conducted, there are no defined criteria on which the Director issues a permit for each individual case of import/export of reproductive cells, and the Bank – which was only established in mid-2019 – has so far only deposited the minimum number of reproductive cells and embryos. The opinion of the Republic Expert Commission for Biomedically Assisted Fertilisation Procedures of the Ministry of Health of the Republic of Serbia is that every public or private centre that performs BAF should be able to establish its own bank of reproductive cells.

Since the end of 2006, the RHIF has been financing the National Infertility Treatment Program with BMAR procedures. According to the existing instruction (Republički fond za zdravstveno osiguranje 2021), people who meet the following cumulative criteria can qualify for financed BMAR procedures:

- spouses or common-law partners for whom other treatment options for infertility have been exhausted;
- women diagnosed with infertility despite appropriate treatment;
- women up to the age of 43 at the time of obtaining a certificate of eligibility for a BMAR procedure;
- women whose ovarian function is preserved;
- women with a normal body mass index (BMI below 30 kg/m2);
- men who have live or morphologically correct sperm in their ejaculate.

Namely, the RHIF pays the costs of infertility treatment only if there is preserved ovarian function and if there are live and morphologically correct sperm in the ejaculate. A woman must not be older than 43 years and must not be obese (BMI > 30 kg/m^2).

The right to infertility treatment with BMAR procedures for insured people includes:

1. The right to an unlimited number of stimulated BMAR procedures and three

cryoembryo transfers for a woman[1] up to 43 years of age at the time of obtaining a certificate of fulfilment of conditions for a BMAR procedure who has no children in her existing marital or extramarital union;

2. The right to two stimulated BMAR procedures and one cryoembryo transfer – for a woman up to 43 years of age at the time of obtaining a certificate of fulfilment of conditions for a BMAR procedure who has one child obtained via a BMAR procedure in her existing marital or extramarital union.

As part of the procedure, the insured woman may also freeze up to six embryos with a shelf life of up to five years.

Couples who underwent a BMAR procedure at the expense of the RHIF in 2021[2] could opt for one of 17 health institutions, of which six are state-owned and 11 are privately owned.

The process of approving BAF at the state's expense begins with the chosen doctor - a gynaecologist for women and a chosen general practitioner for men, each of whom work in primary healthcare institutions in the couple's area of residence. The first step is for both women and men to undergo a series of analyses defined by the instruction to assess their health condition and fertility, or reproductive capacity. Then, the chosen gynaecologist sends those couples who meet the conditions to the first-instance commission in the RHIF. Once their documentation is complete and has been checked, the couple – with a notary's confirmation that they are in a marital or extramarital union – is referred to a second-instance commission in one of the six state-owned BMAR centres, usually the one closest to where they live. This commission assesses the justification for implementing BAF. If the couple meets the required conditions, they go again to the RHIF, where they apply for BAF at the IFV centre of their choice. At this stage, if a couple submits an application for a second child, they must also enclose a document proving that the first child was born from a BMAR procedure. In the case of a cryoembryo transfer, a similar procedure must be repeated.

Representatives of professional teams, the academic community, and NGOs criticise the state-funded BMAR procedure for only being available to heterosexual couples who provide proof that they live in a marital or extramarital union. Thus, on top of same-sex unions not being recognised in Serbia, heterosexual women in Serbia who do not have a partner also have a problem exercising one of the most basic human rights: the right to parenthood. Opinions are divided on the upper age limit for the inclusion of women in the National Programme, ranging from advocating for a reduction to 41 years because the success of the BMAR procedure is significantly lower when women are older, to the removal of the upper age limit, because experts should assess each woman's reproductive capacity on an individual basis. In addition, several experts argued that setting the age limit for state-funded BMAR treatments to 43 years for women contributes to people's decision to postpone childbearing. In the interviews conducted with professionals for the purposes of this paper, the question was asked whether the right to an unlimited number of stimulated BMAR procedures at the state's expense for couples who meet the statutory requirements is medically justified. This is because couples who require more

1 The coverage of the population with compulsory health insurance amounted to 97.2% in 2016 (Government of the Republic of Serbia 2018).

2 Each calendar year, the RHIF signs contracts with all certificated health institutions that carry out BMAR procedures. Couples who undergo BMAR procedures at the expense of the RHIF opt for one of these health institutions.

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than six attempts rarely get pregnant but often suffer great psychological distress. In addition, the interviewees believe in simplifying the procedure so that once it has been obtained, consent for BMAR procedures does not need to be re-evaluated every year. It was also emphasised that the cost of BAF medication – 430 euros – which is reimbursed by the RHIF, is not sufficient, especially for older women who usually need more medication to stimulate ovulation. Because of this, IVF centres use less expensive drugs that are less effective at stimulating ovulation.

Some municipalities in Serbia further financially subsidise BAF services for their residents.

A special example of good practice is the municipality of Kikinda (a city located in the north of Serbia), which finances the costs of drugs, supplements, and analysis for couples who have been approved for state-funded BMAR procedures. Also, Petrovac na Mlavi (a municipality in the east of Serbia) pays BMAR costs in any BAF centre in the country and abroad for couples who do not meet the conditions for financing from the state budget. There are also municipalities that finance BMAR procedures for couples where the woman is older than 43 (Arandjelovac in Central Serbia and Lajkovac in Western Serbia). Representatives of the Ministry of Family Welfare and Demography provided this data.

The National Programme for Preservation and Improvement of Sexual and Reproductive Health of the Citizens of the Republic of Serbia (Nacionalni program očuvanja i unapređenja seksualnog i reproduktivnog zdravlja građana Republike Srbije2017) does not directly address infertility. However, the programme defines measures and activities that indirectly affect the prevalence of infertility. The programme aims to prevent induced abortions and sexually transmitted infections, to develop healthy forms of sexual and reproductive behaviour in adolescents and young people, to promote regular systematic gynaecological examinations in accordance with current national recommendations, and to remove barriers to sexual and reproductive rights, particularly in vulnerable groups such as Roma people, those living in or at risk of poverty, people from rural areas, women with disabilities, and people living with human immunodeficiency virus (HIV).

Officially, there are no reports on the implementation of the programme. However, research by the Autonomous Women's Centre shows that the measures and activities from the programme have not been not operationalised or supported by appropriate funds and human resources, as the action plan for the implementation of the programme has not been adopted yet. The planned mechanism of data collection according to defined indicators – as well as their periodic submission, processing, and reporting – has not been established. Educational activities (for both health professionals and the general population, especially young people) need improvement. There is no data on counselling activities, issues of free and informed decision-making, and free women's choice (Ignjatović and Mališić 2021).

Addressing infertility is defined as one of the eight goals of the Birth Promotion Strategy (Strategija podsticanja rađanja 2018). The document underlines that achieving this goal requires informing public opinion about the causes and possibilities of infertility treatment, adjusting the health system for a modern and rational approach to the diagnosis and treatment of infertility, financial support for those interested, and an appropriate database of BMAR procedures. It is expected that the long-term implementation of these measures, together with those listed in other

objectives of the strategy, would contribute to a larger number of individuals achieving their desired number of children, which in Serbia is usually higher than the number they actually have.

Thus, in 2019, the total registered fertility rate was 1.52. In the same year, in Multiple Indicator Cluster Survey 6, it was determined that the average desired number of children of women of reproductive age was 2.46 (Statistical Office of the Republic of Serbia and UNICEF 2020). The evaluation of the implementation of the Birth Promotion Strategy two years after adoption showed that within the goal we're investigating, a measure defined as "increasing the number of attempts at biomedically assisted fertilisation in accordance with the content and scope of compulsory health insurance rights" is being implemented (Rašević 2020).

3.2 THE EPIDEMIOLOGY OF INFERTILITY

Infertility is estimated to affect 9% of reproductive-aged couples worldwide (Inhorn and Patrizio 2015). Applied to Serbia, this estimate would mean that the number of infertile couples in which a woman is of reproductive age is 84,031. Since Serbia does not have a population register, the census (which was last conducted in 2011) is the source of the total number of couples of reproductive age (Statistical Office of the Republic of Serbia 2013).

Only in one representative survey at the national level was the question of attitudes towards future childbirth posed to women of reproductive age who are married or cohabiting. Among them, 2.6% answered that they cannot plan to have children in the future because they are infertile (Statistical Office of the Republic of Serbia and UNICEF 2020). This study included women; as yet, no similar study has been conducted with men.

Although there is an obligation for it to exist under the Law on Biomedically Assisted Reproduction from 2017, there is still no state register of BMAR activities in Serbia. The National Infertility Treatment Program still doesn't record causes of infertility with BMAR procedures, nor is this data collected by the Institute of Public Health of the Republic of Serbia, whose scope of work includes health statistics.

What's more, there are no representative studies – either small-scale clinical studies or in-depth qualitative surveys with infertility experts – on this issue.

Therefore, the interviews with infertility experts from professional teams covered this issue as well. Their undivided opinion is that the proportions of female and male infertility are equal and that the cause is unknown in 15-20% of couples.

Among the causes of female infertility in Serbia, reduced ovarian reserve dominates. This is primarily related to the postponement of childbearing until advanced age. Another reason is the obstruction of the fallopian tubes, which is most often caused by endometriosis or genital chlamydial infection.

Induced abortion is no longer considered an important factor in infertility in Serbia. No infertility expert from professional teams mentioned infectious diseases, including tuberculosis, as an etiological factor in infertility.

In the elaboration of the stated causes, according to the Population Census of 2011, childless women accounted for 82.1% of the 20–24 age cohort, 55.3% of the 25–29 age cohort, and 31.6% of the 30–34 age cohort (Rašević 2015). This particular period of life was taken into consideration because, from the medical perspective, the incidence of complications during pregnancy and childbirth increases as wom-

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en get older, especially after 35 years of age. The average childless respondent in the 30–34 age group declared that they live in a city (77.8%), are single (73.0%), employed (63.9%), and with a higher level of education (48.2%). The reasons behind the postponement of childbearing in Serbia identified by qualitative research were: livelihood problems, dissatisfaction with the political context and uncertain future, difficulties in achieving a stable relationship, women bearing the burden of heavy family duties, as well as a mentality of individualism, hedonism, and consumerism (Rašević and Sedlecki 2016). Data on the number of women diagnosed with endometriosis is not available, while the annual number of reported cases of genital chlamydial infection is extremely small and cannot be considered realistic (Institut za javno zdravlje Srbije ,,Dr Milan Jovanović Batut" 2021).

Infertility experts from professional teams believe that the reasons for the increase in the frequency of male infertility in Serbia relate to lifestyle (obesity, insufficient physical activity, unhealthy food, and consumption of alcohol and tobacco), stress, and a polluted environment.

Obesity is a growing problem in Serbia. According to the results of a representative health survey conducted in 2019 (Statistical Office of the Republic of Serbia 2021a), more than half (57.1%) of the population of Serbia aged 15 or over was overweight (36.3%) or obese (20.8%). Among males, 43.4% were overweight and 21.7% were obese.

Insufficient physical activity also has an adverse effect on health and fertility in Serbia. A 2019 study found that 22.1% of men aged 18-64 lead an excessively sedentary lifestyle (sitting ≥ 420 min per day).

Smoking is widespread among the population of Serbia. In 2019, more than a third of men (38.8%) in the same age group (18-64) consumed tobacco products daily or occasionally.

Excessive alcohol consumption is also common in Serbia. According to the results of the aforementioned research, 13.2% of men aged 15 or over were addicted to alcohol.

In addition to an unhealthy lifestyle, many exogenous factors contribute to the increase in the incidence of male infertility. Not taking into account the unfavourable consequences of climate change that emerge in the near future, many environmental problems are already present in Serbia. The accumulation of solid municipal (about 2.5 kg per capita per day) and industrial (about 11.6 million tons per year) waste is one of the biggest environmental challenges. Air pollution is extremely high in some areas during certain periods of the year, and this topic has become especially relevant over the past few years, since Belgrade is increasingly at the top of the list of the most polluted cities in the world. The problem also includes the large proportion of wastewater that goes untreated (about 90%), as well as the deteriorating quality of drinking water. Soil analyses in urban areas indicate high levels of heavy metal pollution (Veljković et al. 2019).

Data from the European Quality of Life Survey conducted by Eurofound in 2016 indirectly refers to the potential for exposure to stress in Serbia (Eurofound 2016). The findings indicated that 69% of Serbian citizens could barely get by on the income they had at their disposal. Also, 66% of respondents said it was difficult to fulfil their family obligations due to the time they spent at work. The level of optimism regarding one's own future was lower in Serbia compared to other countries in the region and the average in the European Union, and a decline was registered compared to the same survey conducted in

2012 (Government of the Republic of Serbia 2018).

Infertility experts from professional teams also think that the causes of infertility in Serbia don't differ by territory. However, they note that couples living in Southern Serbia, which is the poorest area in the country, typically wait a long time before deciding to seek professional help and enter the infertility treatment process.

3.3 MAPPING HEALTH SERVICES IN INFERTILITY TREATMENT

Sexual and reproductive healthcare in Serbia starts in primary institutions (health centres), where specialists in gynaecology and obstetrics provide preventive systematic examinations, counselling on contraception, pregnancy care, and treatment of reproductive health disorders for women, while general practitioners care for the sexual and reproductive health of men. When necessary, primary healthcare doctors refer patients for further examination and treatment in secondary and tertiary healthcare institutions (Zakon o zdravstvenoj zaštiti 2019).

The treatment of infertility also begins in primary healthcare, where it is possible to conduct a clinical examination, microbiological investigation, basic laboratory diagnostics (blood count, blood biochemistry), and ultrasonography. When more complex diagnostic procedures are needed, the woman or couple is referred to a secondary or tertiary healthcare institution for semen analysis, hysterosalpingography, hormone analysis, laparoscopy, surgical treatment if indicated, and intrauterine insemination with sperm from the husband or partner. BAF procedures are performed in clinics that specialise in BMAR (Republički fond za zdravstveno osiguranje 2021).

The RHIF does not reimburse the costs of examinations and treatment in privately owned healthcare institutions, except in the case of infertility treatment. All institutions that are qualified to deal with BAF have a one-year contract with the RHIF for a certain number of these procedures. Currently, RHIF-funded BAF procedures are available at six state-owned healthcare institutions (two university clinics of gynaecology and obstetrics in Belgrade and one each in Novi Sad, Kragujevac, and Niš, as well as the Clinical Hospital Centre in Valjevo) and 11 private clinics that specialise in infertility treatment (five in Belgrade, four in Novi Sad, and one each in Kragujevac and Leskovac). All of these BMAR centres also have accompanying laboratories that provide IVF and cryopreservation of reproductive cells.

Information on legal rights for infertility treatment and the procedure for its realisation are available on the RHIF website (Republički fond za zdravstveno osiguranje 2021) and the website of the NGO "Chance for Parenthood" (Šansa za roditeljstvo 2021a). The NGO's site additionally provides couples facing the problem of infertility new research data in this area, offers the possibility of both exchanging experiences with other couples and online counselling, as well as many other contents.

Providing BAF procedures, depending on the type of procedure, includes:

1) examinations and preparation of patients for BMAR procedures;
2) ovulation stimulation;
3) cycle monitoring (ultrasound examinations and determination of hormone levels);
4) follicle aspiration;
5) all embryology laboratory services, including freezing and thawing embryos;
6) embryo transfer.

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The following BMAR procedures are performed in Serbia: intrauterine insemination with the sperm of a husband or partner, in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), and frozen embryo transfer (FET). Although they are fully legal, intrauterine insemination with donor sperm, egg donation, and frozen oocyte replacement are not yet available, while in vitro oocyte maturation is performed sporadically (Government of the Republic of Serbia 2017; Wyns et al. 2020). There are also attempts at biological cell and gene therapy to improve ovarian function (Tinjić et al. 2021). Patients or couples pay for the preimplantation genetic diagnosis and testicular sperm extraction themselves.

The number of BAF procedures performed in recent years is unknown, both in individual IVF centres and at the state level as a whole.

The latest available data from the RHIF refers to 2013, when three quarters (77%) of IVF procedures were performed in state institutions (Republički fond za zdravstveno osiguranje 2014).

Infertility experts and other representatives from professional teams, as well as NGO representatives, believe that today the share of BAF procedures performed in private infertility centres is higher than in state-owned institutions.

Scientific papers on BAF performance in Serbia are based on incomplete data. In the latest report published by the European Consortium for IVF organised by the European Society of Human Reproduction and Embryology (ESHRE) relating to 2016, the results from three IVF centres and 373 BAF cycles were presented, although 12 centres were operating in Serbia at that time. There were 263 classic IVF procedures, with a pregnancy rate of 26% and a delivery rate of 22%. The use of IVF ICSI in 87 patients resulted in 41% of cases leading to pregnancy and 38% leading to delivery. Frozen embryo transfer was performed in 23 patients with a pregnancy rate of 39% and the same delivery rate (Wyns et al. 2020).

That article on IVF monitoring pointed out that Serbia is one of the few countries with transfers of three embryos in more than 50% of cases. The undesirable result of this was a high proportion of triple births (4.4%).

Although there aren't that many BAF procedures performed in Serbia, the data – which is from 2016 – show that the success rate of these procedures was consistent with the European average (Wyns et al. 2020).

Infertility experts from professional teams said that infertility treatment in Serbia today is as effective as it is in the most successful countries in Europe.

As we've already pointed out, the State Register of BMAR procedures has not yet been established. The RHIF, which finances a certain number of BMAR procedures from the budget of the Republic of Serbia, does not inform the public about this data. For the needs of this investigation, the RHIF provided information that in 2019, 4,206 couples were approved as eligible for financing. However, the RHIF could not provide other data requested for the purpose of this research, including summaries or individual reports from BAF centres on: 1) the number of couples who applied for BMAR procedures; 2) the number of couples who achieved BAF up to the embryo transfer phase; 3) the number of cryoembryo transfers; 4) the number of assisted hatches; 5) the number of realised biochemical pregnancies; 6) the number of realised clinical pregnancies; 7) the number of pregnancies without childbirth; 8) the number of pregnancies that ended in

childbirth with a live-born child; 9) the number of pregnancies that ended in childbirth with a stillborn child; 10) the number of twins and multiple pregnancies of a higher order.

Interviewed experts from professional teams agree that the RHIF finances about 4,000 BAF procedures per year and believe that roughly an additional 2,000 self-financed BAF procedures are performed in Serbia and 2,000 in foreign centres. According to research by the European Society of Human Reproduction and Embriology, it's estimated that 1,500 ART cycles per million inhabitants need to be performed annually (ESHRE Capri Workshop Group 2001). Bearing in mind the estimated total population in Serbia (Statistical Office of the Republic of Serbia 2021b), the annual need for ART cycles in Serbia would be around 10,000.

The share of children conceived in Serbia using BAF procedures was studied in 2019 (Jovanović and Rakonjac 2020). In that year, 62,316 children were born alive from natural conception and 2,401 from BMAR procedures. Thus, the share of live births from BMAR procedures in the total number of live births in 2019 was 3.7% in Serbia.

According to the latest available data from 2016 (Wyns et al. 2020), the highest share of live births by BMAR procedures in Europe was recorded in Spain (7.7%), Austria (6.2%), the Czech Republic (5.6%), Slovenia (5.5%), and Denmark (5.1%)

3.4 INFERTILITY FROM THE PERSPECTIVE OF USERS AND POTENTIAL USERS OF BIOMEDICAL ASSISTED FERTILISATION

Almost all of the research on infertility relevant to this paper was conducted by the Serbian non-governmental organisation called The Chance for Parenthood from 2017 until today (Šansa za roditeljstvo 2021b). Professional and scientific papers on this topic have deal with various diagnostic and therapeutic procedures relating to the work of one of the BAF centres, so they are not specific to Serbia.

We will present the most important findings of that research, which predominantly focused on the population and couples from Serbia with current or potential infertility problems.

The survey, which included 3,150 respondents from Serbia, showed that almost half of the respondents (44.9%) believe that information on infertility is not available (Šansa za roditeljstvo 2018). In addition, almost two-fifths (38.4%) of respondents do not know that the donation of reproductive cells and embryos is allowed in Serbia.

A study of 1,630 patients with infertility problems showed that 75% of respondents did not receive basic information about treatment from a gynaecologist at their primary health centre, where according to the law their infertility treatment should begin (Šansa za roditeljstvo 2019a). Furthermore, after their first visit to an infertility subspecialist, only 10% felt sufficiently informed about their problem, while 90% tried to get additional information from the internet.

A survey conducted on 497 respondents who are undergoing the BMAR process showed that three-fifths of couples (60%) perform the procedure at the expense of the RHIF (Šansa za roditeljstvo 2020). However, they also emphasised that there are additional costs (medications, laboratory tests, and other diagnostic tests) that couples pay themselves or with the financial support of the municipality in which they live. A large number (85%) of respondents

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opted for BAF in a private clinic, expecting to achieve a better relationship with doctors.

A study that included 656 people who filled out an online questionnaire showed that the need for egg donation is most often (61.3%) found in couples where women are aged between 36 and 45 years (Šansa za roditeljstvo 2019b). More than half of the respondents (51.8%) are ready to perform procedures with donated material, regardless of whether such a procedure is recommended or not. If it were possible, 65.1% of them would opt for the treatment process with donated reproductive cells in Serbia. The need for embryo donation is the lowest in relation to the need for egg and sperm donation. Respondents also expressed their opinion on how donation procedures should be regulated, and their suggestions are in line with modern practices in countries that have been conducting donations for a long time.

One of the studies also includes couples who go to BAF clinics abroad to make use of donated reproductive cells (Šansa za roditeljstvo 2021c). Most of them are either women of advanced years (35%) or those who have had more than three BAF procedures already performed in Serbia (25%). Respondents most often went to the Czech Republic (40%), then to Greece (21%) or North Macedonia (7.6%).

The following investigations were conducted by representatives from the Serbian scientific community.

In a study conducted at the University Clinic for Gynaecology and Obstetrics in Novi Sad, researchers investigated motives for motherhood in two groups: 50 women undergoing IVF and 50 pregnant women. Three categories of motives for parenthood were identified: 1) family continuity; 2) the nurturing and maternal care of the child; 3) social pressure. The strongest motives were for nurturing and caring for the child, and these motives were slightly stronger among women undergoing IVF. There was no difference in the intensity of the other two categories of motives (Kričković Pele and Zotović 2016).

In a qualitative in-depth study from Belgrade that included nine women who are undergoing IVF, it became apparent that there is a crisis of altruism. When it comes to reproduction, women are ready to receive reproductive cells, but not to donate them (Mitrović 2014).

4 DISCUSSION

The Law on Biomedically Assisted Reproduction can be assessed as good, because it defines the most important issues in the field of infertility, including the framework and organisation of this process, types of procedures, the conditions under which the right is exercised, and the monitoring of implementation. Although this law was put into effect four years ago, arguably the most important step – the establishment of the State Register of biomedically assisted reproduction procedures for the territory of Serbia – has not yet happened, while the Reproductive Cell Bank is only partially operational. The State Register is important because it will provide all the necessary data on infertility in Serbia. It is also essential that the Reproductive Cell Bank functions at full capacity, as this will enable couples who need reproductive cells to procure them in Serbia. Indeed, in line with the reproductive rights concept, surrogacy should be legal at least for women or couples with a medical indication, such as uterine deficiency. However, the Directorate for Biomedicine – which is essential for the implementation of the relevant law – has no capacity to fulfil this task. Additionally, the realisation of both

the National Program for Preservation and Improvement of Sexual and Reproductive Health of the Citizens of the Republic of Serbia and the Birth Promotion Strategy are compromised by a lack of respective action plans and financial resources defined by the state budget.

The data on the epidemiology of infertility in Serbia is not sufficiently addressed within the National Infertility Treatment Program, nor are some health statistics. Furthermore, issues focusing on the problem of infertility have not been an integral part of representative research in the field of sexual and reproductive health in Serbia.

The unanimous opinion of experts is that reduced ovarian reserve dominates among the causes of female infertility, and this is primarily related to the postponement of childbearing until advanced age. In addition to the factors that affect the prevalence of this phenomenon in more developed countries, socio-economic factors are also important in Serbia. Likewise, there are well-known reasons for the increase in the frequency of male infertility in Serbia, including lifestyle (obesity, insufficient physical activity, unhealthy food, consumption of alcohol and tobacco), stress, and a polluted environment. This shows that a more efficient and comprehensive implementation of the relevant strategies is needed.

The quality of infertility treatment in Serbia, both in terms of the type of BMAR procedures and the results achieved, is at the level of more developed countries. Since 2006, state financing has also provided an incentive for professional engagement in this area. The current National Infertility Treatment Programme provides great opportunities for women and couples. However, from the perspective of reproductive medicine, it would be better to take a woman's ovarian reserve as the most important criterion rather than her age. It would also be better to pay for up to six IVF procedures per woman instead of an unlimited number.

Research data shows that most patients with an infertility problem do not receive relevant basic information from a gynaecologist at their primary health centre, where infertility treatment should begin according to the law. Further, nine out in 10 patients feel insufficiently informed by the infertility subspecialist after their first consultation. These findings highlight the insufficient education of health workers in the field of sexual and reproductive health counselling.

There is also a lack of representative and qualitative research on various aspects of infertility in Serbia and from the perspective of various scientific disciplines. It is also difficult to understand why, despite considerable possibilities for individual solutions to the problem of infertility in Serbia, the share of children born from BMAR procedures is relatively low. The action research methodology, applied in this research, has shown that it is a good instrument for an insufficiently studied issue.

5 CONCLUSION

Support for couples with an infertility problem is valuable for at least three reasons: the successful realisation of the human rights concept, the alleviation of the birth crisis, and better public health policy. This has been recognised in Serbia and important steps have been taken in this direction. Most crucial are the adoption of relevant laws, strategic frameworks, and programmes, as well as state funding for infertility treatment. However, the results of this study show that there is plenty of room for further steps in this area.

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Thus, current legal and strategic solutions regarding infertility treatment should be implemented more quickly and in their entirety. The law should allow surrogacy in certain situations. When the RHIF annually issues its instructions for the implementation of the National Infertility Treatment Program with BMAR procedures, i.e. state funding of infertility treatment, it should take into account the health statistics and representative research data on infertility, the opinion of infertility experts, and representatives of relevant non-governmental organisations. It is important to promote a healthy lifestyle throughout the life cycle. It's also necessary to reduce socio-economic barriers to the birth of the first child and spread understanding of the health risks of postponing childbearing.

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Infertilitet i asistirane reproduktivne tehnologije u Srbiji

Prošireni sažetak

Neplodnost predstavlja jedan od ključnih izazova, kako na individualnom, tako i na makro-nivou. Pored demografskog aspekta, podrška ostvarivanju roditeljstva jeste i pitanje javnog zdravlja i poštovanja ljudskih prava. Cilj rada je da doprinese boljem razumevanju infertiliteta u Srbiji putem analize relevantnih politika i programa, epidemiologije ovog fenomena, odgovarajućeg modela zdravstvene zaštite i nalaza istraživanja. Primenjena je metodologija akcionog istraživanja, koja se zasniva na razmeni mišljenja između istraživača i učesnika o odabranim dokumentima, podacima i iskustvima iz prakse. U istraživanju su učestvovali autori ovog rada i petnaest poznavalaca ove oblasti iz redova donosilaca odluka, eksperata i predstavnika nevladinog sektora. Legalni okvir osmišljen je s namerom da odgovori na većinu modernih izazova u ovoj sferi. Osnovni problemi u njegovoj realizaciji jesu to što nije uspostavljen Državni registar neplodnosti i što ne funkcioniše proces donacije reproduktivnih ćelija. Takođe, treba razmotriti davanje saglasnosti za surogat materinstvo onda kada za to postoje medicinske indikacije. Od kraja 2006. godine Republički fond zdravstvenog osiguranja finansira Nacionalni program o lečenju neplodnosti postupcima biomedicinski potpomognute oplodnje. Poslednjih godina država pruža parovima ozbiljnu, ali nekritičku pomoć za lečenje neplodnosti, jer ne uzima u obzir ekspertsko mišljenje da ne treba dozvoliti neograničen broj pokušaja, posebno ne ženama u odmaklom životnom dobu. Podaci o učestalosti, vrsti i uzrocima neplodnosti nisu sastavni deo zdravstvene statistike i reprezentativnih istraživanja. Na osnovu nepotpunih podataka i mišljenja eksperata, kvalitet lečenja neplodnosti je na nivou razvijenih zemalja. Iz tih procena su izuzete trudnoće ostvarene donacijom reproduktivnih ćelija i surogat materinstvo, koji se realizuju van Srbije. Takođe, nedostaju istraživanja o različitim aspektima infertiliteta iz perspektive više naučnih disciplina. Nije jasno ni zašto je, uprkos značajnim mogućnostima za individualno rešavanje problema neplodnosti, relativno nizak udeo dece rođene zahvaljujući postupcima biomedicinski potpomognute oplodnje.

Ključne reči:

infertilitet, asistirane reproduktivne tehnologije, metodologija akcionog istraživanja, epidemiologija infertiliteta, Srbija

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