Original papers
UDC 618.177-089.888.11+364.013+614.2
https://doi.org/10.56871/MHCO.2026.36.13.005

Evaluation of the clinical effectiveness of IVF protocols within the framework of compulsory medical insurance programs

Olesya S. Vakhlova[1, 2], Natalya A. Roslaya[2]

[1] Family Medicine Center, 1/3 Nachdiv Vasilyev str., Ekaterinburg, 620043, Russian Federation
[2] Ural State Medical University, 3 Repina str., Ekaterinburg, 620014, Russian Federation

For citation: Vakhlova O.S., Roslaya N.A. Evaluation of the clinical effectiveness of IVF protocols within the framework of compulsory medical insurance programs. *Medicine and Health Care Organization*. 2025;10(4):61–73. https://doi.org/10.56871/MHCO.2026.36.13.005.

Received: 15.10.2025 ***Revised: 09.12.2025*** ***Accepted: 28.01.2026***

ABSTRACT. ***Introduction.*** Assisted reproductive technologies are considered to be the most prominent biomedical technologies worldwide, influencing demographic indicators. There is no unified approach to insurance strategy in the field of assisted reproductive technologies in world practice. In the Russian Federation, since 2016, compulsory medical insurance funds have been defined as a source of funding. Since 2019, the national project "Demography" provides for the possibility of carrying out the in vitro fertilization procedure at the expense of the basic compulsory medical insurance program. ***Aim*** — to assess the effectiveness of in vitro fertilization programs at the expense of compulsory medical insurance funds. ***Materials and methods.*** The study was based on statistical reports from the assisted reproductive technologies departments of JSC Family Medicine Center (Yekaterinburg) on in vitro fertilization programs at the expense of compulsory medical insurance in the period 2014–2023. Electronic clinical and statistical records of 10,243 patients were analyzed. The analysis criteria were the women's age, the number of in vitro fertilization attempts, the frequency of embryo transfers in in vitro fertilization cycles, and the frequency of clinical pregnancies. The statistical analysis was performed using the STATISTICA software package, version 10.0 (StatSoft Inc., Original Articles, USA). The description of the statistical analysis of the material was carried out in accordance with the requirements of the SAMPL guidelines. ***Results.*** Between 2014 and 2023, an increase in the number of women of older reproductive age (40 years and older) seeking pregnancy planning using in vitro fertilization has been noted. The effectiveness of *in vitro* fertilization programs in the older age group was significantly lower compared to women of the younger reproductive age group. The proportion of women with low ovarian reserve averaged 32%. The effectiveness of small-cell in vitro fertilization programs in the group of women under 35 was significantly higher than in women aged 40 and older. The probability of clinical pregnancy decreased by 2.6 times (OR=2.613 [2.194–3.112]), if the woman's age exceeded 40 years. The use of donor oocytes did not prove to increase the pregnancy rate. The effectiveness of in vitro fertilization cycles significantly decreased ($p < 0.001$) with an increase in the frequency of 4 or more programs. The tactics of transferring one embryo did not lead to a decrease in the clinical pregnancy rate ($p=0.321$). ***Conclusion.*** The criteria for the clinical effectiveness of the in vitro fertilization programs under compulsory medical insurance are proved to be presented by the woman's age under 40 years, high and normal ovarian reserve, the number of in vitro fertilization attempts of no more than 3; tactics aimed at transferring one embryo.

KEYWORDS: in vitro fertilization, IVF, compulsory health insurance, infertility, assisted reproductive technologies, ART

Funding. The authors declare that they have no external funding for the study.

✉ Olesya S. Vakhlova. E-mail: dr.vakhlova@mail.ru

Оригинальная статья

https://doi.org/10.56871/MHCO.2026.36.13.005

Оценка клинической эффективности протоколов ЭКО в рамках программ обязательного медицинского страхования

Олеся Сергеевна Вахлова[1, 2], Наталья Алексеевна Рослая[2]

[1] Центр семейной медицины, 620043, г. Екатеринбург, ул. Начдива Васильева, д. 1, корп. 3, Российская Федерация
[2] Уральский государственный медицинский университет, 620014, г. Екатеринбург, ул. Репина, д. 3, Российская Федерация

Для цитирования: Вахлова О.С., Рослая Н.А. Оценка клинической эффективности протоколов ЭКО в рамках программ обязательного медицинского страхования**.** *Медицина и организация здравоохранения.* 2025;10(4):61–73. https://doi.org/10.56871/MHCO.2026.36.13.005.

Поступила: 15.10.2025 ***Одобрена: 09.12.2025*** ***Принята к печати: 28.01.2026***

РЕЗЮМЕ. ***Введение.*** Вспомогательные репродуктивные технологии считаются важнейшими биомедицинскими технологиями во всем мире, оказывающими влияние на демографические показатели. Единый подход к страхованию в области вспомогательных репродуктивных технологий в мировой практике отсутствует. В Российской Федерации с 2016 г. в качестве источника финансирования определены средства обязательного медицинского страхования. С 2019 г. национальным проектом «Демография» предусмотрена возможность проведения процедуры экстракорпорального оплодотворения за счет базовой программы обязательного медицинского страхования. ***Цель исследования*** — оценить эффективность программ экстракорпорального оплодотворения за счет средств обязательного медицинского страхования. ***Материалы и методы.*** Материалами для исследования стали данные статистических отчетов отделений вспомогательных репродуктивных технологий АО «Центр семейной медицины» (г. Екатеринбург) по программам экстракорпорального оплодотворения за счет средств обязательного медицинского страхования в период 2014–2023 гг. Проанализированы электронные клинико-статистические карты 10 243 пациенток. Критериями анализа были возраст женщин, количество попыток экстракорпорального оплодотворения, частота переносов эмбрионов в циклах экстракорпорального оплодотворения, частота наступления клинической беременности. При статистическом анализе использовали пакет прикладных статистических программ STATISTICA, версия 10,0 (StatSoft Inc., Original Articles, США). Описание статистического анализа материала проводилось в соответствии с требованиями руководства САМПЛ. ***Результаты.*** В период 2014–2023 гг. отмечено увеличение обращаемости женщин старшего репродуктивного возраста (40 лет и более) для планирования беременности при помощи экстракорпорального оплодотворения. Эффективность программ экстракорпорального оплодотворения в старшей возрастной группе была значимо ниже в сравнении с женщинами молодого репродуктивного возраста. Доля женщин с низким овариальным резервом составляла в среднем 32%. Эффективность в малоклеточных программах экстракорпорального оплодотворения в группе женщин до 35 лет была значимо выше, чем у женщин 40 лет и старше. Вероятность наступления клинической беременности снижалась в 2,6 раза (ОШ=2,613 [2,194–3,112]), если возраст женщины превышал 40 лет. Использование ооцитов донора не увеличивало частоту наступления беременности. Результативность циклов экстракорпорального оплодотворения значимо снижалась ($p < 0,001$) при увеличении кратности проведения четырех программ и более. Тактика по переносу одного эмбриона не приводила к снижению частоты наступления беременности ($p=0,321$). ***Выводы.*** Критериями клинической эффективности программ экстракорпорального оплодотворения обязательного медицинского страхования являются возраст женщины менее 40 лет, высокий и нормальный овариальный резерв, количество попыток программ экстракорпорального оплодотворения не более трех, тактика, направленная на перенос одного эмбриона.

КЛЮЧЕВЫЕ СЛОВА: экстракорпоральное оплодотворение, ЭКО, обязательное медицинское страхование, бесплодие, вспомогательные репродуктивные технологии, ВРТ

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

✉ Олеся Сергеевна Вахлова. E-mail: dr.vakhlova@mail.ru

INTRODUCTION

Infertility is a significant socio-demographic public health issue that requires intensive strategic solutions [1–3]. In 2009, the World Health Organization defined infertility as a "disease", seeking to refute the assumption that its treatment is optional [4]. Approximately 18 million people worldwide suffer from infertility [5]. The rising prevalence of infertility globally is associated with numerous factors: age, acute and chronic somatic diseases, infectious and inflammatory diseases of the reproductive tract, genetic factors, and previous surgical interventions [6–9].

Reproductive technologies (RT) are considered among the most important biomedical technologies worldwide, influencing demographic indicators; they are the most effective methods for overcoming infertility, while raising numerous social, ethical, and legal issues in the field of reproductive medicine [2, 3, 6, 10–13]. In vitro fertilization (IVF), as one of the main RT methods, is included in state-guaranteed programs in many countries around the world [12].

There is no uniform approach to RT insurance in global practice. Full or partial insurance coverage for RT costs exists in Russia, the United States, Europe, Japan, South Korea, and Australia. In the Middle East, China, and Greece, certain forms of medical insurance for RT exist, but they are subject to restrictions and strict government oversight [1]. In countries such as France, Germany, Sweden, Belgium, Australia, Serbia, and South Korea, there are schemes providing full insurance coverage for the costs of infertility diagnosis and treatment at public expense [1, 2, 5]. In a number of countries, the age of women participating in RT programs is regulated: in the U.S. — up to 37 years old, in Turkey — up to 39 years old, in Belgium and Iran — up to 42 years old, and in Serbia — up to 45 years old [1, 5, 14]. The United Kingdom provides all infertility testing and treatment services for women aged 18–39 and insurance coverage for three full IVF cycles; for women aged 40–42, coverage is provided for one cycle [2, 5]. In Israel, the costs of all necessary RT procedures are covered for couples wishing to have two children [1]. Limits on the number of IVF cycles covered by public health insurance exist in many countries: in the U.S. — up to 6 IVF attempts; in the Czech Republic — 1 attempt; in Slovenia — up to 4; in Belgium — up to 6 cycles; and in the Netherlands — up to 3 IVF cycles [1, 2, 4, 5, 15]. In many countries, there is no health insurance coverage for RT, but there is government support for specialized medical centers to increase public access to infertility treatment [1]. In Portugal, RT procedures performed in a public hospital are reimbursed at 100%, but medications are reimbursed at only 40% [2]. In Japan, couples can receive up to $2,700 for their first IVF attempt and up to $1,350 for the second and each subsequent attempt [1]. In Iran and Turkey, the government covers 20 to 80% of the costs for diagnosis and treatment; in Iran, the United Arab Emirates, Vietnam, and Malaysia, the government provides financial support for the development of fertility centers for low-income citizens [1, 5]. A system of subsidies for RT programs is in place in Turkey and Egypt [1, 5]. In Chile and Colombia, reimbursement for RT costs is regulated by government and nongovernmental organizations [1]. In India, the number of companies offering insurance for RT is growing [1]. As a result, in many middle- and low-income countries, government funding for infertility treatment is either limited, non-existent, or excluded from insurance coverage; consequently, patients bear the costs of treatment themselves, making these technologies expensive, inaccessible, and leading to inequities in treatment [5, 10].

Different approaches to covering the costs of infertility treatment influence the number of children born through RT [2]. When patients pay for RT services out of pocket, priority is given to transferring two embryos in order to maximize the chance of having twins in a single pregnancy. When RT programs are publicly funded, priority is given to transferring a single embryo, which reduces obstetric risks, increases the chances of a normal pregnancy, and leads to the birth of a full-term, healthy child [1, 4, 10, 16]. Single-embryo transfer is mandated in Sweden. In the United States and Russia, single-embryo transfer is a priority [10].

In the Russian Federation (RF), state-funded IVF programs have been in place since 2007;

since 2013, they have been included in the state-guaranteed program for the free provision of medical care to citizens; and since 2016, Mandatory Health Insurance (MHI) [3, 12, 13, 16]. Since 2018, a program for the transfer of cryopreserved embryos has been available under the MHI [12]. This approach has increased the accessibility of RT for the population [3, 13, 17]. The introduction of IVF programs into practical healthcare is enshrined in Article 55 of Federal Law No. 323-FZ of November 21, 2011, "On the Fundamentals of Health Protection of Citizens in the Russian Federation"[1]. The details are specified in sectoral documents of the Ministry of Health of the Russian Federation, which regulate the conditions for admitting patients to these programs [1, 12]. The regional compulsory medical insurance program includes the provision of a basic IVF program; however, the order does not provide for discrimination based on age or family composition, nor does it regulate restrictions on the number of IVF cycles performed at the expense of MHI funds [1–3]. In 2019, the national "Demography"[2], project was approved, which provides, among other things, for the possibility of undergoing IVF procedures at the expense of the basic compulsory medical insurance program [2, 3, 13].

Over the past decades, there has been a persistent trend toward intentionally delaying motherhood, which leads to physiological loss of fertility and an increase in the rate of infertility, ultimately contributing to the aging of the population. At the same time, cultural and social factors can serve as barriers to access to infertility treatment services [5, 14, 18] . Consequently, there is a growing influx of older patients seeking IVF treatment, for whom the likelihood of achieving pregnancy — even with IVF — is low [18]. An increase in the average maternal age may lead to a rise in the number of IVF cycles, but not to an increase in live birth rates [10]. According to data from the Russian Association of Human Reproduction (RAHR) registry for 2022, the average success rate of IVF cycles in women under 35 years of age was 24%, and in women over 40 years of age, 9.3%[3]. According to U.S. studies, the success rate of IVF programs reaches 55% for women under 35 and 4.3% for women over 42 [14].

A "poor" ovarian response to stimulation, a decline in ovarian reserve, and a decrease in oocyte quality with age are the main factors that negatively impact the clinical efficacy of IVF [14, 18, 19]. According to the global literature, the proportion of patients with a "poor" response accounts for approximately 33% of all patients in RT programs, while the pregnancy rate in such cases reaches up to 20%, and up to 30% of programs may be terminated due to a lack of oocytes or arrested embryo division [18]. Factors contributing to reduced oocyte quality in women of advanced reproductive age include mitochondrial dysfunction, oxidative damage, and abnormal gene expression. Embryos derived from such oocytes are typically of low quality, exhibit reduced implantation potential, and carry a high risk of aneuploidy [14, 18]. According to Cimadomo's study, 45 years of age should be considered the maximum age threshold for IVF using autologous oocytes [14]. The probability of detecting a euploid blastocyst after age 45 is close to zero; therefore, any cycle using autologous oocytes after age 45 can be considered low-efficacy and should not be encouraged [14, 19]. Women over the age of 42 are at a higher risk of spontaneous abortion and obstetric complications compared to younger women [14].

AIM

The aim of the study is to evaluate the effectiveness of IVF programs covered by mandatory health insurance.

MATERIALS AND METHODS

A retrospective study was performed to evaluate the clinical effectiveness of IVF programs funded by the Mandatory Health Insurance (MHI) system during the period 2014–2023. Data were obtained from statistical reports of the RT departments at "Center for Family Medicine" (Ekaterinburg). Electronic clinical and

[1] Federal Law of November 21, 2011 No. 323-FZ (as amended on July 23, 2025) "On the Fundamentals of Health Protection of Citizens in the Russian Federation." Available at: https://www.consultant.ru/cons/cgi/online.cgi?req=doc&base=LAW&n=502639&dst=100001#QvJRMyUFQMSPUKeB (accessed: October 1, 2025).

[2] Demography: National Project. Available at: https://xn--80aapampemcchfmo7a3c9ehj.xn--p1ai/projects/demografiya/ (accessed: October 1, 2025).

[3] Russian Association of Human Reproduction. Available at: https://www.rahr.ru/index.php (accessed: October 1, 2025).

statistical records of 10,243 patients were analyzed. The analysis criteria included the following parameters: women's age, number of IVF attempts, frequency of embryo transfers in IVF cycles, and pregnancy rate (PR). Age groups up to 35 years, 36–39 years, and 40 years and older were analyzed. The number of IVF attempts was categorized into ranks: 1, 2, 3, 4, and more. A number of oocytes retrieved up to and including 5 was considered an indicator of a low-yield cycle.

For statistical analysis, the STATISTICA software package, version 10.0 (StatSoft Inc., Original Articles, USA), was used. To describe quantitative parametric variables, the mean and standard deviation (M(SD)) were calculated; for non-parametric variables, the median (M) was calculated along with the Q1–Q3 quartiles (25–75th percentiles). Qualitative indicators are presented as absolute (n) and relative (%) values (n/total (%)). For the comparative analysis of qualitative nominal variables, Pearson's χ^2 test was used; a p-value of <0.05 was considered statistically significant. To assess associations, the odds ratio was used with the calculation of confidence intervals (OR, 95% CI) [20]. The description of the statistical analysis of the biomedical research data was conducted in accordance with the requirements of the "Statistical Analysis and Methods in Published Literature (SAMPL)" guidelines [21].

RESULTS

The average age of female patients participating in the compulsory medical insurance IVF programs was 34.3±4.54 years, with a mean of 34.0 (31.0–38.0) years, a minimum of 21.0 years, and a maximum of 50.0 years; this value remained stable over the 2014–2023 period. However, from 2019 to 2023, there was a significant decrease in the number of women under 35 years of age seeking treatment: from 671/1062 (63.2%) to 380/698 (54.4%), p <0.001, accompanied by an increase in patients in the 36–39 age group: from 265/1062 (24.9%) to 216/698 (31%), p=0.006, and a trend toward an increase in the number of women aged 40 and older — from 126/1062 (11.9%) to 102/698 (14.6%), p=0.093 — in the compulsory medical insurance IVF programs (Fig. 1).

An analysis of the success rate in IVF programs under the compulsory medical insurance system among women by age, using only autologous oocytes, revealed that with increasing age, the proportion of programs using exclusively autologous oocytes decreased significantly and uniformly: 98.6; 95.5, and 85.5% for groups 1, 2, and 3 in Table 1, p <0.001 when comparing all age groups; the frequency of embryo transfer using the patient's own biological material decreased significantly in the older reproductive group (40 years and older) compared to the group

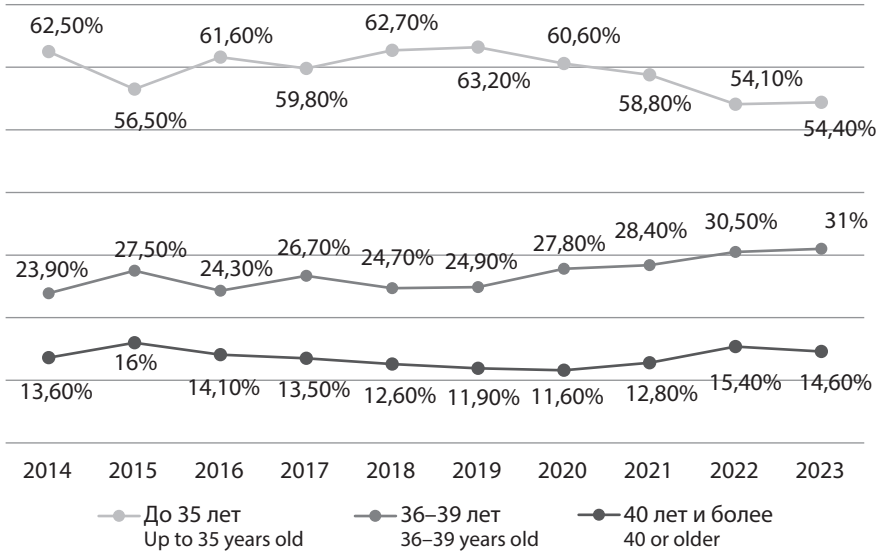

Fig. 1. Dynamics of changes in the age structure of women in in vitro fertilization programs in the period 2014–2023 (the figure is prepared by the authors based on data from their own research)

Рис. 1. Динамика изменения возрастной структуры женщин в программах экстракорпорального оплодотворения в период 2014–2023 гг. (рисунок подготовлен авторами по результатам собственного исследования)

under 35 years of age (p <0.04); implantation and the onset of clinical pregnancy were significantly lower in the older reproductive group (p <0.001) (Table 1). It was found that in IVF programs under the Mandatory Health Insurance system using only autologous oocytes, the probability of achieving a clinical pregnancy decreases by a factor of 2.6 if the woman is over 40 years of age (OR=2.613 [2.194–3.112]).

An analysis of the number of IVF attempts among women in the compulsory medical insurance programs between 2014 and 2023 showed that the proportion of women with one, two, and three IVF attempts remained unchanged over the 10-year period: 65.9% and 63.3% in 2014 and 2023, respectively, p=0.278; 20.5% and 21.4%, p=0.677; 8.9% and 8.1%, p=0.578. At the same time, the proportion of women with four IVF

Table 1

Pregnancy rate in *in vitro* fertilization programs under compulsory medical insurance using only autologous embryos depending on the woman's age

Таблица 1

Частота наступления беременности в программах экстракорпорального оплодотворения обязательного медицинского страхования с использованием только аутологичных эмбрионов в зависимости от возраста женщины

Показатель Indicator	**Возраст**			**p (χ^2)**
	≤35 лет ≤35 years old, n=6135	**36–39 лет 36–39 years old, n=2720**	**≥40 лет ≥40 years old, n=1388**	
	Количество/всего (%) No / total (%)			
	1	**2**	**3**	
Количество программ Number of programs	6051/6135 (98,6%)	2597/2720 (95,5%)	1243/1388 (89,5%)	1–2 <0,001, 1–3 <0,001 2–3 <0,001
Количество переносов эмбрионов Number of embryotransfers	4291/6051 (70,9%)	1821/2597 (70,1%)	845/1243 (68%)	1–2=0,457, 1–3 <0,04, 2–3=0,179
Частота наступления беременности Pregnancy rate	1823/4291 (42,5%)	635/1821 (34,9%)	173/845 (20,5%)	1–2 <0,001, 1–3 <0,001 2–3 <0,001

Таблица составлена по данным собственного исследования авторов / The table is based on data from the authors' own research

Table 2

Pregnancy rate depending on the number of *in vitro* fertilization attempts

Таблица 2

Частота наступления беременности в зависимости от количества попыток экстракорпорального оплодотворения

Количество попыток Number attempts	**Количество женщин Number of women**	**Перенос в целом (аутологичный + + донорскими ооцитами) Transfer in general (autologous and donor oocytes)**	**Частота наступления беременности в целом Pregnancy rate in general**	**Перенос аутологичных эмбрионов Autologous embryotransfer**	**Частота наступления беременности с аутологичными эмбрионами Pregnancy rate with autologous embryos**
1	5443	3812/5443 (70%)	1500/3812 (39,4%)	3749/5359 (70%)	1472/3749* (39,3%)
2	2606	1875/2606 (72%)	705/1875 (37,6%)	1818/2528 (71,9%)	685/1818* (37,7%)
3	1267	892/1267 (70,4%)	317/892 (35,5%)	841/1205 (69,8%)	300/841* (35,7%)
≥4	927	646/927 (69,7%)	207/646 (32%)	549/799 (68,7%)	174/549* (31,7%)
p (χ^2)		1:2=0,078 1:3=0,797 1:4=0,831 2:3=0,318 2:4=0,191 3:4=0,718	1:2=0,204 1:3=0,036 1:4=0,001 2:3=0,294 2:4=0,012 3:4=0,154	1:2=0,076 1:3=0,911 1:4=0,475 2:3=0,181 2:4=0,082 3:4=0,608	1:2=0,255 1:3=0,054 1:4=0,001 2:3=0,319 2:4=0,011 3:4=0,127

Таблица составлена по данным собственного исследования авторов / The table is based on data from the authors' own research

* p(χ^2) >0,05 for pregnancy rate in general and pregnancy rate with autologous embryos.* p(χ^2) >0,05 для частоты наступления беременности в целом и частоты наступления беременности с аутологичными эмбрионами.

attempts increased significantly — from 4.7% to 7.2%, p=0.030.

An analysis was conducted of pregnancy rates depending on the number of attempts in the compulsory medical insurance IVF programs. The frequency of embryo transfer in the IVF cycle as a whole (using both the patient's own gametes and donor oocytes) and in the cycle involving embryo transfer using only the patient's own gametes did not differ depending on the number of MHI-funded IVF cycles performed (Table 2). The highest rates of implantation and clinical pregnancy were observed in the first and second IVF attempts, which were significantly higher compared to the third and fourth attempts. Thus, the lowest clinical pregnancy rate was observed in the fourth attempt and beyond, both overall and when using exclusively autologous oocytes (Table 2).

No differences were found in the rate of clinical pregnancy among women using only their own oocytes versus those using donor oocytes in addition: the cumulative pregnancy rate over a 10-year period was 37.8% (2,631/6,957) when using only autologous biological material and 37.8% (2,729/7,225) when additionally using donor biological material. Furthermore, the pregnancy rate with both autologous and donor biomaterial did not differ depending on the number of IVF cycles performed (see Table 2). The rate of embryo transfer cancellations (Table 3) in programs with the additional use of donor oocytes and in programs using only autologous oocytes did not differ depending on the number of IVF attempts performed under the compulsory medical insurance program. The data obtained indicate that programs using donor oocytes do not contribute to the clinical efficacy of IVF-ICSI protocols.

The proportion of low-follicle punctures remained roughly the same over 10 years — ranging from 1/5 to 1/3 of all IVF cycles performed (Table 4, Fig. 2).

An assessment of outcomes in low-follicle (up to 5 follicles) IVF protocols revealed a correlation between pregnancy rates and women's

Table 3

Frequency of embryo transfer cancellations in *in vitro* fertilization programs depending on the use of donor oocytes

Таблица 3

Частота отмены переноса эмбриона в программах экстракорпорального оплодотворения в зависимости от использования ооцитов донора

Номер попытки **Number attempts**	**Отмена переноса** **Cancel transfer,** **Количество/всего (%) No / total (%)**		**p (χ^2)**
	в целом (собственные ооциты + + ооциты донора) **in general (own oocytes + donor oocytes)**	**с аутологичным биоматериалом** **with autologous biomaterial**	
1	1631 / 5443 (30%)	1610 / 5359 (30%)	0,930
2	731 / 2606 (28%)	710 / 2528 (28,1%)	0,978
3	375 / 1267 (29,6%)	364 / 1205 (30,2%)	0,741
4	281 / 927 (30,3%)	250 / 799 (31,3%)	0,662

Таблица составлена по данным собственного исследования авторов / The table is based on data from the authors' own research

Table 4

Small-cell punctures in compulsory medical insurance programs

Таблица 4

Малоклеточные пункции в программах обязательного медицинского страхования

Год **Year**	**Количество/всего (%)** **No / total (%)**	**Год** **Year**	**Количество/всего (%)** **No / total (%)**
2014	320 / 985 (32,5%)	2019	353 / 1062 (33,2%)
2015	219 / 1086 (20,2%)	2020	301 / 1005 (29,9%)
2016	375 / 1286 (29,2%)	2021	224 / 725 (30,9%)
2017	418 / 1424 (29,3%)	2022	191 / 695 (27,5%)
2018	278 / 1277 (21,8%)	2023	225 / 698 (32,2%)
Итого / Total: 2904 / 10243 (28,4%)			

Таблица составлена по данным собственного исследования авторов / The table is based on data from the authors' own research

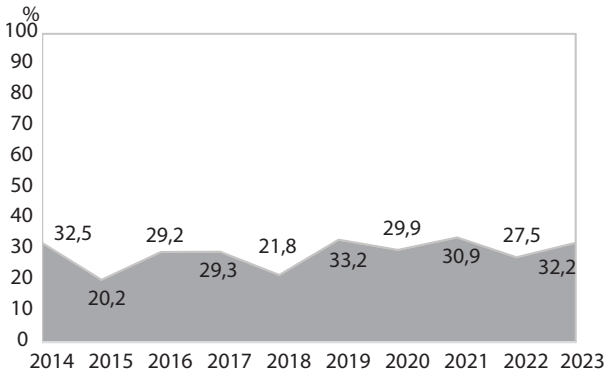

Fig. 2. The share of small cell punctures in the structure of all conducted in vitro fertilization programs under the compulsory medical insurance in the period from 2014 to 2023 (the figure is prepared by the authors)

Рис. 2. Доля малоклеточных пункций в структуре всех проведенных программ экстракорпорального оплодотворения обязательного медицинского страхования в период с 2014 по 2023 гг. (рисунок подготовлен авторами)

age: pregnancy rates in low-follicle protocols were significantly higher among women under 40 years of age (Table 5). It was found that the probability of achieving a clinical pregnancy in low-follicle IVF protocols was 2.6 times lower if the woman's age exceeded 40 years — 95% CI=2.636 [1.96–3.54].

Analysis of the pregnancy rate in low-dose protocols depending on the number of IVF attempts under the Mandatory Medical Insurance program showed no differences and stood at 28.9% (253/874) for a single attempt, 32.8% (141/430) for two attempts, 30.2% (68/225) for three attempts, and 27.6% (45/163) for four attempts. This generally indicates the low effectiveness of low-dose protocols.

An analysis of the compulsory medical insurance IVF programs during 2014–2023 revealed a clear decrease in the proportion of two-

Table 5

Pregnancy rates in small-cell protocols with transfer of only autologous embryos depending on age

Таблица 5

Частота наступления беременности в малоклеточных протоколах с переносом только аутологичных эмбрионов в зависимости от возраста

Возраст, лет Age, years		**Количество переносов эмбрионов Number of embryo transfers**	**Частота наступления беременности Pregnancy rates**
		Количество/всего (%) No / total (%)	
≤35	1	734 / 1047 (70,1%)	253 / 734 (34,5%)
36–39	2	583/877 (66,5%)	193/583 (33,1%)
≥40	3	375/578 (64,8%)	61/375 (16,3%)
p (χ^2)		1:2=0,089; 1:3=0,031; 2:3=0,530	1:2=0,604; 1:3=0,001; 2:3=0,001

Таблица составлена по данным собственного исследования авторов / The table is based on data from the authors' own research

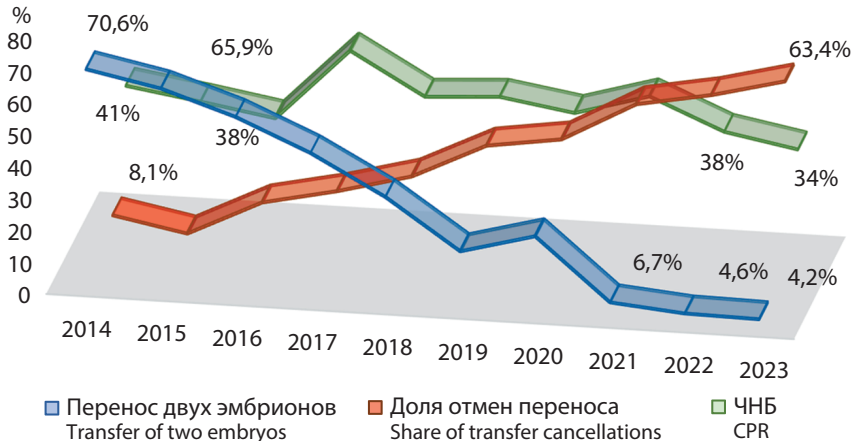

Fig. 3. Dynamics of changes in clinical approaches in in vitro fertilization programs for the period 2014–2023. CPR — clinical pregnancy rate (the figure is prepared by the authors based on data from their own research)

Рис. 3. Динамика изменения клинических подходов в программах экстракорпорального оплодотворения за период 2014–2023 гг. ЧНБ — частота наступления беременности (рисунок подготовлен авторами по результатам собственного исследования)

embryo transfers (from 630/892 (70.6%) to 28/670 (4.2%), p=0.001) with a simultaneous increase in the frequency of transfer cancellations in the IVF cycle (from 72/892 (8.1%) to 425/670 (63.4%), p=0.001). However, the pregnancy rate using only autologous biomaterial did not change significantly: in 2014 — 337/820 (41.1%), in 2023 — 92/245 (37.5%), p=0.321 (Fig. 3).

DISCUSSION

In vitro fertilization, as one of the primary RT technologies, is included in state-guaranteed programs in many countries around the world [12]. In the Russian Federation, since 2016, the Mandatory Health Insurance fund has been designated as the source of state funding for IVF programs [3, 12, 13, 16]. In 2019, the Russian government approved the national "Demography" project, which includes an initiative to fund IVF programs through the Mandatory Health Insurance system, with the ultimate goal of increasing the birth rate [2, 3, 13]. Increased state funding for IVF programs, higher utilization rates among women of relatively young reproductive age (up to 34 or 40 years old), and a reduction in religious restrictions will help maximize the demographic impact of RT [10]. At the same time, state support for RT technologies necessitates thorough preparation for planning RT programs, including differentiated approaches to patient selection for enrollment in mandatory health insurance IVF programs to ensure their successful implementation. From 2002 to 2022, according to data from the RAHR registry, the number of IVF cycles performed increased from 10,994 to 172,602, indicating high demand for these programs. Since 2020, Order No. 803n of the Russian Ministry of Health dated July 31, 2020, "On the Procedure for the Use of Assisted Reproductive Technologies, Contraindications, and Restrictions on Their Application" has been in effect, which regulates ovarian reserve parameters for inclusion in the compulsory medical insurance IVF programs (anti-Müllerian hormone 1.2 ng/mL or higher and 5 or more antral follicles); this document does not impose any age restrictionsz[1]. However, a woman's age is of key importance for predicting the effectiveness of an IVF program, as it is associated with the morphogenetic quality of oocytes, a physiological decline in ovarian reserve, and a higher prevalence of somatic pathology. According to several studies, oocyte quality declines rapidly from the age of 35, which is a risk factor for the development of fetal genetic abnormalities [14, 18, 19].

In many countries worldwide, IVF programs covered by public health insurance have age restrictions up to 37–45 years, which is due to the low success rates of IVF cycles in this age group, increased obstetric and perinatal risks, and the resulting higher economic costs [14, 19]. The results obtained in our study indicate that during the period 2014–2023, there was a trend toward an increase in the number of women of advanced reproductive age seeking to plan a pregnancy using IVF. This is generally associated with the global trend of consciously postponing motherhood to a later period, as well as the popularization and development of RT programs. It was shown that the success rate of IVF programs in the older age group was 20.5% and was significantly lower compared to women of young reproductive age. The proportion of women with low ovarian reserve remained stable during the analyzed period and averaged 32%. At the same time, the success rate in low-cycle IVF programs among women under 35 was significantly higher compared to that among women in the older age group (40 years and older). Thus, the probability of achieving a clinical pregnancy decreased by a factor of 2.6 (OR=2.613 [2.194–3.112]) if the woman's age exceeded 40 years, both in the group with normal ovarian reserve and in low-follicle IVF programs (OR=2.636 [1.96–3.54]).

The additional use of vitrified donor oocytes in IVF programs covered by compulsory medical insurance did not increase the pregnancy rate. On the one hand, this can be explained by the use of a small number of oocytes (up to 6) due to the high cost of donor material; on the other hand, by the association with patients' complicated obstetric-gynecological and somatic status. At the same time, this once again underscores the priority of selecting women for public health insurance IVF programs with normal and high ovarian reserve in order to achieve pregnancy with autologous embryos.

An unsuccessful IVF program necessitates repeating the procedure. Based on the experience of several countries, limits have been set on

[1] Order of the Ministry of Health of the Russian Federation dated July 31, 2020 No. 803n "On the Procedure for the Use of Assisted Reproductive Technologies, Contraindications and Limitations to Their Use" (registered on October 19, 2020 No. 60457). Available at: http://publication.pravo.gov.ru/Document/View/0001202010190041 (accessed: October 1, 2025)

the number of IVF cycles covered by the state budget — ranging from one to six cycles [1, 2, 4, 5, 15]. In the Russian Federation, Federal Law No. 323 does not regulate the number of attempts at state-funded IVF, which provides women with unlimited opportunities to achieve motherhood through RT programs. However, our data indicate that there is no increase in the success rate of IVF cycles with an increase in the number of attempts (more than four cycles). It follows that when planning public health insurance IVF programs, the number of attempts should be limited to no more than three, especially for women in the older age group, particularly since an increase in the number of attempts entails higher economic costs for implementing public health insurance IVF programs.

With the development of RT, approaches to conducting IVF programs have evolved, making them safer. According to data from the corporation "CSM" (Ekaterinburg), since 2014 there has been a decrease in the proportion of two-embryo transfers and an increase in the number of cycles with canceled transfers. These measures were aimed at reducing the risk of complications in IVF programs and ensuring a more physiological course of pregnancy. We have shown that when implementing such measures, the pregnancy rate with single-embryo transfer did not change significantly ($p=0.321$), even with an increase in the proportion of women in the older age group. This finding underscores the priority of single-embryo transfer as a criterion for the clinical effectiveness of public health insurance-funded IVF programs.

RT holds significant potential for increasing the contribution to fertility rates [10, 11]. Ensuring universal access to infertility treatment technologies and implementing state programs funded by the compulsory medical insurance system is important for the healthcare system [5]. A strategy aimed at the prevention and timely treatment of infertility is an investment in creating a productive and economically active generation for the country [5, 11].

CONCLUSION

An analysis of the effectiveness of IVF programs funded by the Mandatory Health Insurance system for the period 2014–2023 revealed the following:

- an inverse relationship was identified between the effectiveness of MHI-funded IVF programs and women's age;
- an age criterion of under 40 years may serve as one of the selection factors when referring patients to MHI-funded IVF programs; the additional use of vitrified donor oocytes in MHI-funded IVF programs does not increase the pregnancy rate, which determines the priority of including women with high and normal ovarian reserve in the planning and implementation of MHI-funded IVF programs;
- repeating baseline attempts (4 or more) in MHI-funded IVF programs does not lead to an increase in the clinical pregnancy rate; when planning MHI-funded IVF programs, the number of attempts should be limited to no more than three, especially for women in the older age group;
- a strategy aimed at transferring a single embryo should be prioritized in IVF programs, as it does not reduce the pregnancy rate, prevents the development of obstetric complications, and ensures a more physiological course of pregnancy.

ADDITIONAL INFORMATION

Authors' contribution. The authors jointly developed the concept and purpose of the study. Vakhlova O.S. analyzed the primary medical documentation using descriptive and analytical statistics and formulated the conclusions. All authors read and approved the final version before publication.

Competing interests. The authors declare that they have no conflicts of interest related to the publication of this article.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад авторов. Авторами совместно проведена разработка концепции и цели исследования. Вахловой О.С. осуществлен анализ первичной медицинской документации с применением методов описательной и аналитической статистики, сформулированы выводы. Все авторы прочли и одобрили финальную версию перед публикацией.

Конфликт интересов. Авторы заявляют об отсутствии конфликтов интересов, связанных с публикацией настоящей статьи.

REFERENCES

1. Symaniuk E.E., Bashmakova N.V., Polyakova I.G., Itskovich MM. Features of health insurance for reproductive health: recent trends in world and national practice. *Russian Journal of Human Reproduction.* 2021;27(2):33-40. (In Russian). https://doi.org/10.17116/repro20212702133.
2. Krylov V.A. Overview of global IVF reimbursement practices. *Pharmacoeconomics: Theory and Practice*. 2021;9(4):12–16. (In Russian). https://doi.org/10.30809/phe.4.2021.2.
3. Zheleznyakova I.A., Volkova O.A., Fedyaev D.V., Plakhotnik O.S., Mazurov A.M., Lazareva M.L., Kotsenbina E.V. Improving the model of payment for medical care for infertility using assisted reproductive technologies in the program of state guarantees of free medical care to citizens for 2023 and 2024–2025. *Medical Technologies. Assessment and Choice.* 2023;45(2):23–31. (In Russian). https://doi.org/10.17116/medtech20234502123.
4. Kawwass J.F., Penzias A.S., Adashi E.Y. Fertility — a human right worthy of mandated insurance coverage: the evolution, limitations, and future of access to care. *Fertil Steril*. 2021;115(1):29–42. https://doi.org/10.1016/j.fertnstert.2020.09.155.
5. Morshed-Behbahani B., Lamyian M., Joulaei H., Rashidi B.H., Montazeri A. Infertility policy analysis: a comparative study of selected lower middle- middle- and high-income countries. *Global Health*. 2020;16(1):104. https://doi.org/10.1186/s12992-020-00617-9.
6. Njagi P., Groot W., Arsenijevic J., Dyer S., Mburu G., Kiarie J. Financial costs of assisted reproductive technology for patients in low- and middle-income countries: a systematic review. *Hum Reprod Open*. 2023;2023(2):hoad007. https://doi.org/10.1093/hropen/hoad007.
7. Carini F., Margherita Mazzola, Gagliardo C., Scaglione M., Giammanco M., Tomasello G. Inflammatory bowel disease and infertility: analysis of literature and future perspectives. *Acta Biomed.* 2021;92(5):e2021264. https://doi.org/10.23750/abm.v92i5.11100.
8. Szubert M., Koziróg E., Olszak O., Krygier-Kurz K., Kazmierczak J., Wilczynski J. Adenomyosis and infertility — review of medical and surgical approaches. *Int J Environ Res Public Health*. 2021;18(3):1235. https://doi.org/10.3390/ijerph18031235.
9. Munro M.G. Uterine polyps, adenomyosis, leiomyomas, and endometrial receptivity. *Fertil Steril*. 2019;111(4):629–640. https://doi.org/10.1016/j.fertnstert.2019.02.008.
10. Isupova O.G. Assisted reproductive technologies: new opportunities. *Demograficheskoe obozrenie*. 2017;4(1):35–64. (In Russian). EDN: ZGFNJL.
11. Yagudina R.I., Kulikov A.Y., Tishchenko D.G. Pharmacoeconomic analysis of long-term effects of more widespread use of in vitro fertilization in infertility treatment at the regional and federal level from the standpoint of society at large in the Russian Federation. Pharmacoeconomics: Theory and Practice. 2017;5(1):41–46. (In Russian). https://doi.org/10.30809/phe.1.2017.29.
12. Krivolesova TA. Analysis of the provision of assisted reproductive technologies in the implementation of the program of state guarantees of free medical care. *Saratov Journal of Medical Scientific Research*. 2022;18(2):250–255. (In Russian). EDN: SEUNSU.
13. Songolova E.N. Control of IVF accounting according to compulsory medical insurance. In: Health Statistics of Modern times: Proceedings of the Second Congress of Medical Statisticians of Moscow. Moscow; 2020: 84–86. (In Russian). EDN: SJSQHH.
14. Havrljenko J., Kopitovic V., Pjevic A.T., Milatovic S., Pavlica T., Andric N., Pogrmic-Majkic K. The prediction of IVF outcomes with autologous oocytes and the optimal MII Oocyte/embryo number for live birth at advanced maternal age. *Medicina (Kaunas)*. 2023;59(10):1799. https://doi.org/10.3390/medicina59101799.
15. Boulet S.L., Kawwass J., Session D., Jamieson D.J., Kissin D.M., Grosse S.D. US State-level infertility insurance mandates and health plan expenditures on infertility treatments. *Matern Child Health J*. 2019;23(5):623–632. https://doi.org/10.1007/s10995-018-2675-y.
16. Dankova I.V., Yakornova G.V., Malgina G.B., Mazurov D.O., Chermyaninova O.V., Bychkova S.V., Fassahova A.F., Smirnova E.E. ART monitoring program under the Compulsory Health Insurance (CHI): first results. *Russian Journal of Human Reproduction*. 2017;23(4):65–70. (In Russian). https://doi.org/10.17116/repro201723465-70.
17. Malyshkina A.I., Pesikin O.N., Kuligina M.V. The evaluation of efficiency of application of axillary reproductive technologies on the territorial level. *Probl Sotsialnoi Gig Zdravookhranenniiai Istor Med*. 2019;27(4):394–398. (In Russian). https://doi.org/10.32687/0869-866X-2019-27-4-394-398.
18. Rudakova E.B., Fedorova E.A., Sergeeva I.V. Is it possible to help patients of older reproductive age implement their reproductive function within the framework of IVF and PE programs backed by state support? *Medical Council*. 2018;(7):116–124. (In Russian). https://doi.org/10.21518/2079-701X-2018-7-116-124.
19. Cakmak H. When is the right time to stop autologous in vitro fertilization treatment in poor responders? *Fertil Steril*. 2022;117(4):682–687. https://doi.org/10.1016/j.fertnstert.2022.02.027.

20. Kelmanson I.A. Principles of evidence-based pediatrics. Saint Petersburg: Foliant; 2004. (In Russian).
21. Lang T., Altman D. Basic statistical reporting for articles published in clinical medical journals: the sampl guidelines. *Medical Technologies. Assessment and Choice*. 2014;(1):10–15. (In Russian). EDN: TIXQTT.

ЛИТЕРАТУРА

1. Сыманюк Э.Э., Башмакова Н.В., Полякова И.Г., Ицкович М.М. Особенности медицинского страхования репродуктивного здоровья: современные тенденции в мировой практике. *Проблемы репродукции*. 2021;27(2):33–40. https://doi.org/10.17116/repro20212702133.
2. Крылов В.А. Обзор мировых практик возмещения технологии экстракорпорального оплодотворения. *Фармакоэкономика: теория и практика*. 2021;9(4):12–16. https://doi.org/10.30809/phe.4.2021.2.
3. Железнякова И.А., Волкова О.А., Федяев Д.В., Плахотник О.С., Мазуров А.М., Лазарева М.Л., Коценбина Е.В. Методика совершенствования модели оплаты медицинской помощи при бесплодии с использованием вспомогательных репродуктивных технологий в рамках реализации Программы государственных гарантий бесплатного оказания гражданам медицинской помощи на 2023 год и на плановый период 2024–2025 годов. *Медицинские технологии. Оценка и выбор*. 2023;45(2):23–31. https://doi.org/10.17116/medtech20234502123.
4. Kawwass J.F., Penzias A.S., Adashi E.Y. Fertility — a human right worthy of mandated insurance coverage: the evolution, limitations, and future of access to care. *Fertil Steril*. 2021;115(1):29–42. https://doi.org/10.1016/j.fertnstert.2020.09.155.
5. Morshed-Behbahani B., Lamyian M., Joulaei H., Rashidi B.H., Montazeri A. Infertility policy analysis: a comparative study of selected lower middle- middle- and high-income countries. *Global Health*. 2020;16(1):104. https://doi.org/10.1186/s12992-020-00617-9.
6. Njagi P., Groot W., Arsenijevic J., Dyer S., Mburu G., Kiarie J. Financial costs of assisted reproductive technology for patients in low- and middle-income countries: a systematic review. *Hum Reprod Open*. 2023;2023(2):hoad007. https://doi.org/10.1093/hropen/hoad007.
7. Carini F., Margherita Mazzola, Gagliardo C., Scaglione M., Giammanco M., Tomasello G. Inflammatory bowel disease and infertility: analysis of literature and future perspectives. *Acta Biomed*. 2021;92(5):e2021264. https://doi.org/10.23750/abm.v92i5.11100.
8. Szubert M., Koziróg E., Olszak O., Krygier-Kurz K., Kazmierczak J., Wilczynski J. Adenomyosis and infertility — review of medical and surgical approaches. *Int J Environ Res Public Health*. 2021;18(3):1235. https://doi.org/10.3390/ijerph18031235.
9. Munro M.G. Uterine polyps, adenomyosis, leiomyomas, and endometrial receptivity. *Fertil Steril*. 2019;111(4):629–640. https://doi.org/10.1016/j.fertnstert.2019.02.008.
10. Исупова О.Г. Вспомогательные репродуктивные технологии: новые возможности. *Демографическое обозрение*. 2017;4(1):35–64. EDN: ZGFNJL.
11. Ягудина Р.И., Куликов А.Ю., Тищенко Д.Г. Фармакоэкономический анализ отдаленных последствий более широкого использования экстракорпорального оплодотворения в лечении бесплодия на региональном и федеральном уровнях с позиции общества в целом в Российской Федерации. *Фармакоэкономика: теория и практика*. 2017;5(1):41–46 https://doi.org/10.30809/phe.1.2017.29.
12. Криволесова Т.А. Анализ предоставления вспомогательных репродуктивных технологий при реализации программы государственных гарантий бесплатного оказания медицинской помощи. *Саратовский научно-медицинский журнал*. 2022;18(2):250–255. EDN: SEUNSU.
13. Сонголова Е.Н. Контроль учета ЭКО по ОМС. В кн.: Статистика здравоохранения нового времени: Материалы Второго съезда медицинских статистиков Москвы. Москва; 2020. С. 84–86. EDN: SJSQHH.
14. Havrljenko J., Kopitovic V., Pjevic A.T., Milatovic S., Pavlica T., Andric N., Pogrmic-Majkic K. The prediction of IVF outcomes with autologous oocytes and the optimal MII Oocyte/embryo number for live birth at advanced maternal age. *Medicina (Kaunas)*. 2023;59(10):1799. https://doi.org/10.3390/medicina59101799.
15. Boulet S.L., Kawwass J., Session D., Jamieson D.J., Kissin D.M., Grosse S.D. US State-level infertility insurance mandates and health plan expenditures on infertility treatments. *Matern Child Health J*. 2019;23(5):623–632. https://doi.org/10.1007/s10995-018-2675-y.
16. Данькова И.В., Якорнова Г.В., Мальгина Г.Б., Мазуров Д.О., Чермянинова О.В., Бычкова С.В., Фассахова А.Ф., Смирнова Е.Е. Программа мониторинга вспомогательных репродуктивных технологий в рамках обязательного медицинского страхования: первые итоги. *Проблемы репродукции*. 2017;23(4):65–70. https://doi.org/10.17116/repro201723465-70.
17. Малышкина А.И., Песикин О.Н., Кулигина М.В. Оценка эффективности применения вспомогательных репродуктивных технологий на территориальном уровне. *Проблемы социальной гигиены, здравоохранения и истории медицины*. 2019;27(4):394–398. https://doi.org/10.32687/0869-866X-2019-27-4-394-398.
18. Рудакова Е.Б., Федорова Е.А., Сергеева И.В. Можно ли помочь пациенткам старшей возрастной группы

с реализацией репродуктивной функции в программах ЭКО и ПЭ в рамках государственной поддержки? *Медицинский совет*. 2018;(7):116–124. https://doi.org/10.21518/2079-701X-2018-7-116-124.

19. Cakmak H. When is the right time to stop autologous in vitro fertilization treatment in poor responders? *Fertil Steril*. 2022;117(4):682–687. https://doi.org/10.1016/j.fertnstert.2022.02.027.
20. Кельмансон И.А. Принципы доказательной педиатрии. Санкт-Петербург: Фолиант; 2004.
21. Ланг Т., Альтман Д. Основы описания статистического анализа в статьях, публикуемых в биомедицинских журналах. Руководство «статистический анализ и методы в публикуемой литературе (САМПЛ)». *Медицинские технологии. Оценка и выбор*. 2014;(1):10–15. EDN: TIXQTT.

AUTHORS' INFO

✉ **Olesya S. Vakhlova** — Cand. Sci. (Med.), Head of the Department of Assisted Reproductive Technologies JSC "Family Medicine Center"; Assistant Professor of Obstetrics and Gynecology with a course in Medical Genetics.
E-mail: dr.vakhlova@mail.ru;
https://orcid.org/0000-0001-5069-8177; SPIN: 9785-7530

Natalya A. Roslaya — Dr. Sci. (Med.), Professor. E-mail: naroslaya@gmail.com;
https://orcid.org/0000-0001-9076-9742; SPIN: 8327-2997.

ОБ АВТОРАХ

✉ **Олеся Сергеевна Вахлова** — к.м.н., заведующий отделением вспомогательных репродуктивных технологий АО «Центр семейной медицины»; ассистент кафедры акушерства и гинекологии с курсом медицинской генетики Уральского государственного медицинского университета.
E-mail: dr.vakhlova@mail.ru;
https://orcid.org/0000-0001-5069-8177; SPIN: 9785-7530
Наталья Алексеевна Рослая — д,м.н., профессор.
E-mail: naroslaya@gmail.com;
https://orcid.org/0000-0001-9076-9742; SPIN: 8327-2997