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Establishment of a Unified Register of Donor Sexual Gametes in the Republic of Kazakhstan

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Abstract

Objective. The purpose of this narrative review paper was to review the state and development of the field of donor gametes in Kazakhstan, compare its legislative and technical capabilities with other countries and identify key steps towards the establishment of a unified register of donor gametes in the Republic. **Materials and Methods.** The narrative review paper conducted an analysis of scientific publications and legal documents to examine the implementation of Assisted Reproductive Technologies (ART), focusing on Donor Sexual Gametes (DSG), globally. It utilized medical publications from 2019 to 2023, legal acts, and recommendations from global health organizations to analyze eligibility criteria, legal regulations, and the social aspects of ART across different regions. **Results.** In Kazakhstan, ART is regulated by legislation, with DSG procedures governed by age limits, medical screening, and restrictions on the number of children born from donated gametes. Worldwide, practices vary, but there is growing interest in establishing a unified register of reproductive donor material to enhance transparency and accountability. However, legal gaps and ethical considerations must be addressed. **Conclusion.** The study identifies gaps in Kazakhstan's legislation compared to Western countries, emphasizing the necessity for enhanced legal rights for donors and recipients, including options for anonymity. Ethical concerns highlight the importance of confidentiality and data security in accessing the donor registry. Overall, implementing such a register promises to enhance transparency, safety, and accountability in reproductive medicine.

Key Words: Assisted Reproductive Technologies ▪ In Vitro Fertilisation ▪ Reproductology ▪ Infertility ▪ Fertilisation.

Introduction

The most common causes of infertility in medical practice are tubal-peritoneal pathologies, endocrine disorders, organic lesions of the reproductive system, and male factor infertility (1). Regardless of the aetiology of infertility in each case, a country's healthcare system should establish the most effective legal and technical conditions for assisted and curative therapy for patients. One of the key areas of medical and public health development in the last decades in the world is reproductive medicine, namely the issue of the donation of sexual gametes (DSG) and the development of legislative and material basis for its implementation (2, 3). Reproductive medicine is intended to solve problems with conception and carrying a pregnancy in patients where in vitro fertilisation (IVF) methods are the only possible method for successful conception (4, 5). Donor-to-recipient DSG is one of these techniques.

The latest reproductive medicine technologies have already been incorporated into infertility treatment protocols, which underlines the significance of developing companion bases and registries for the successful use of DSG. In the Republic of Kazakhstan, the problems of preserving and supporting motherhood and childhood, and ensuring

the reproductive health of citizens, are always emphasised, both by presidential programmes and by the Ministry of Health (6). Despite the active introduction of new reproductive developments in the field of assisted reproductive technologies (ART), statistical indicators of infertility prevalence remain stable. Globally, more than 15% of couples of reproductive age experience infertility each year (7).

Due to the availability of genetic and molecular diagnostic methods, the number of diagnoses leading to infertility remains high (8, 9). With the development of reproductology in Kazakhstan, there is an increased need for the development of both treatment and counselling centres within the health care system (10) and modern registers of DSG for the legislative activity of such institutions (11).

The purpose of this narrative review paper was to analyse the scientific data on the experience of the legal regulation of ART, in particular donation of sexual cells (DSC) in the Republic of Kazakhstan and countries in Europe and the United States, to establish basic principles for the development of a unified register of donor cells in Kazakhstan, as part of the implementation of modern ART methods.

Materials and Methods

This section gives an analysis of the scientific data on assisted reproductive technology (ART), particularly gamete donation, in the Republic of Kazakhstan and other countries worldwide. A comprehensive search of scientific publications in obstetrics, gynaecology, reproductology, laboratory diagnostics, embryology, internal medicine, and social medicine was conducted using reputable databases, such as: Ebsco, Google Scholar, ResearchGate, PubMed, Medscape, and Clarivate. Only publications from 2019 to 2023 from high-impact factor journals and evidence-based global scientific publications were included.

The search strategy employed advanced and evidence-based data, reflecting results from long-term studies and observations in practical medicine. Comparative legal analysis was conducted by examining legal acts, including constitutions, codes, ministry of health orders, United Nations conventions, and protocols from organizations such as the American Society for Reproductive Medicine. The inclusion criteria for research data were strict, focusing on medical publications from relevant and reputable sources. The analysis also incorporated the latest recommendations from the World Health Organization and international associations related to ART regulation. Additionally, social aspects of gamete donation were explored using data from large-scale social surveys of donors and recipients.

The review compared legal regulations of ART across different countries, examining factors such as: eligibility requirements, donor and recipient rights, age criteria, compensation options, and anonymity policies. Both the legal and social dimensions of gamete donation were scrutinized to provide a comprehensive understanding of its practice and implementation globally.

Moreover, the review assessed the integration of international recommendations into the practice of reproductive and epidemiological institutions in Kazakhstan, encompassing both state-run and private facilities. By synthesizing data from various sources, this review aims to contribute to the current understanding of ART regulation and practice, with implications for policy development and clinical management in Kazakhstan and beyond.

Results

Legislative Framework and Terminology of ART in the Republic of Kazakhstan

The Constitution of the Republic of Kazakhstan presents one of the basic rights of citizens in Article 27: the right to establish a family and continuation of birth: “marriage and family, maternity, paternity, and childhood are under the protection of the state.” The right to receive reproductive medical services is inherent and a constitutive right of citizens of the Republic governed by international regulations, specifically the United Nations

Convention on "the elimination of all forms of discrimination against women" (18.12.1979), to which the Republic of Kazakhstan is a party. In Kazakhstan, reproductive medicine programmes, in particular ART, are implemented with the active participation of legislation (11). It ensures that medical workers in the field of reproductive medicine and obstetrics follow clear rules when working with the subjects of ART, and excludes unfair conduct of ART programmes or using gametes, organs, and tissues beyond their intended use.

ART is a set of medical interventions aimed at treating infertility, in which the fusion of male and female gametes and the subsequent stages of embryonic development occur outside the female body (12). The first laboratory facility for IVF in the Republic of Kazakhstan was established in 1995; in 1996, the first child was born using ART (10). In 2020, the Code on Public Health and the Health Care System was updated in the Republic of Kazakhstan, which defines the basic principles for conducting ART programmes in the population. The principles regarding the organisation of ART are outlined in Article 148 of the Code, separate from other types of ART. In addition to the Code, the Republic of Kazakhstan has Orders No. KR DSM 236/2020 ("On Approval of the Rules and Conditions for the Conduct of DSC, and Tissues of Reproductive Organs") and 272/2020 ("On Approval of the Rules and Conditions for the Conduct of ART"), which outline the rules and legitimacy of DSC in the country. The current Code of the Republic of Kazakhstan defines other options for ART, including artificial insemination and IVF. The DSC procedure is defined at the legislative level of the Republic (6, 10) as a method of overcoming diagnosed infertility when used in the scope of treatment. In vitro fertilisation is included in several guaranteed-free services in the health care system within the framework of state programmes for a cohort of patients with direct medical indications for its performance as part of infertility treatment.

The subjects who can legitimately use ART methods in the Republic of Kazakhstan, especially DSG, include married couples (a man or a woman with a diagnosis of infertility) or single people who are not married but have indications for a reproductive procedure. For the subjects of ART who are not officially married, it is necessary to provide written consent for the medical manipulation. The general regulation of legislative relations during the implementation of ART is delegated to the Ministry of Health of the Republic of Kazakhstan (10). In addition to written consent and the requirements listed in the Code, there is also an Order of the Minister of Health of Kazakhstan No. KR DSM 272/2020 that lists extra requirements for ART. These include medical indications that have been diagnosed (as listed above), being of reproductive age, and not having any immediate reasons why the manipulation should not be done.

DSG is considered within the legal framework as one of the ART options used to treat infertility but is frequently interpreted as a technique outside the list of ARTs. According to the Code, DSG can be applied to subjects in the age range of 18–35 years who have proof of full somatic and psychological health and have undergone genetic screening. The limit of 35 years of age for DSG appears in other Ministry Orders, meaning that it always remains lower than for participants in ART. In addition, such subjects must sign consent to implement the rules outlined in the protocol of the DSC. The quantitative range for the possible continuation of participation in the DSC for donors is prescribed: the birth of ten children from one donor during the DSG is a criterion for the exclusion of the subject from the ART programmes and using the gametes of this respondent for recipients. In addition, the donor does not receive information about the use and trajectory of sexual gametes as part of the commitment to implement the ART procedure.

DSG has some limitations in its application to date. On the one hand, it is associated with possible risks of accidental biological relatedness between offspring due to using material from the same donor for several recipients (8). It provides a space for the establishment of both a unified registry of reproductive material on a national scale and possibly a unified registry of donors (eggs and sperm),

which could operate on the scale of countries with a legally regulated process for the implementation of ART and DSC (13). In addition, medical tourism, where the export of reproductive material is realised in other countries, is a necessity.

Worldwide Practices in the Implementation of DSG

The legal position and accessibility of ART in Kazakhstan have some unresolved and unspecified issues in the sphere of medical provision of reproductive services and the sphere of the reproductive rights of donors and recipients during the implementation of DSG. The idea of establishing a unified register of ARTs today faces many enormous problems (14): from the collection of factual information on the institutions, health workers, and actors involved in the implementation of ARTs in the country, to the development of a legal framework for the establishment of an official state register to regular monitoring of donor material and the results of its (successful or unsuccessful) use. For example, embryo donation is prohibited in multiple countries, including Austria and Iceland (Table 1).

Examining the global landscape of ART implementation highlights diverse approaches across countries. While some nations, like Kazakhstan and the United States, offer both paid and free options for donation, others, like France and Spain, provide donation services free of charge. Variations also exist in quantitative restrictions for donors, with limits on the number of children born from donated gametes ranging from 3 to 10 across different countries. Mandatory medical screening before donation procedures ensures the safety and health of both donors and recipients, with age restrictions typically falling within the range of 18 to 35 years.

Despite all challenges, the idea of establishing a unified register of reproductive donor material

Table 1. Features of Implementation of the Donation of Sexual Gametes (oocytes and Sperms) in Different Countries of the World

Country	Donation of sexual gametes			
	Options for conducting	Quantitative restrictions for donors	Medical screening before donation procedure	Donor age range (Years)
Republic of Kazakhstan	Paid and free	Up to 10 children born	Obligatory	18-35*
United States of America	Paid and free	Up to 6 children born	Obligatory	18-35†. 18-43‡
France	Free	Up to 6 children born	Obligatory	18-35*
Spain	Paid and free§	Up to 6 children born	Obligatory	18-35*
Norway	Paid and free	Up to 6 children born	Obligatory	18-35*
Switzerland	Paid	Up to 8 children born	Obligatory	18-35*
United Kingdom	Paid and free	Up to 10 children born	Obligatory	18-35*
Denmark	Paid and free	Up to 6 children born	Obligatory	18-45*
Canada	Paid and free	Up to 8 children born	Obligatory	18-35*
Australia	Paid and free	Up to 5 children born	Obligatory	18-35*
Japan	Free	Up to 6 children born	Obligatory	18-49*
China	Free	Up to 3 children born	Obligatory	20-45†, 20-40‡
New Zealand	Paid and free	Up to 10 children born	Obligatory	18-45*
Brazil	Free	Up to 6 children born	Obligatory	18-35*
Argentina	Free	Up to 6 children born	Obligatory	18-35*

Source: Compiled by the authors; *Years for donors and recipients; †For donors; ‡For recipients; §Donor compensation is possible.

is gaining traction, especially in light of rapid advancements in reproductive technologies and the increasing prevalence of medical tourism in pursuit of ART services. However, it is essential to address legal gaps and ethical concerns to ensure the responsible and ethical implementation of such a register globally.

In conclusion, while the implementation of ART varies significantly across countries, the concept of a unified register holds promise for enhancing transparency, safety, and accountability in the field of reproductive medicine. Efforts to address legal and ethical challenges are crucial in realizing the potential benefits of such a registry and ensuring equitable access to ART services worldwide. Considering the rapid progress in the development of reproductive technologies and medical tourism to receive ART, which frequently outpaces changes in legislation and the ethical dogmas of countries (15), the idea of establishing a unified register of reproductive donor material becomes more realistic and feasible (16, 17).

Features of Creating a Unified Register of DSGs in the Republic of Kazakhstan

When establishing a unified register of donor gametes, it is essential to consider the fact that the current legal documents of Kazakhstan do not include the recipient's right to possess information on the results of the donor's medical examination (general clinical, psychiatric, and genetic), nationality, or race. In addition, cyto- and molecular-genetic diagnostic methods are not included in the list of compulsory tests before participation in ART. Research conducted in private and public reproductive centres (8) on more than 1500 patients demonstrates that the risks of diagnosing chromosomal variability in couples with infertility and aggravated obstetric histories are significantly higher than in patients with normal reproductive functions. There is a need for legislative approval of compulsory cytogenetic and molecular genetic tests for patients with reproductive disorders before using DSG.

The establishment of a unified register of sexual gametes provides for clear control over the use of and implementation of sexual gametes in reproductive institutions. It establishes the foundation for obtaining objective information in court proceedings. The donor does not have the right to appeal against revelation of their biological parenthood in cases of genetic confirmation of paternity (18). An equally significant issue is the religious bias of the ethnic group (19) where DSG is performed. Whereas in some countries donors and recipients have more liberal opinions on the possibility of germ cell donation (single patients, patients with non-traditional orientation) (20), in others such possibilities will only be implemented for married couples. This is an essential aspect that should be considered both in the selection of participants in the DSG and for the designation of donation material in the registry.

Discussion

Kazakhstan has an emerging legislative framework to regulate assisted reproductive technologies such as gamete donation programmes, but there are still gaps compared to more established systems in European countries and the United States. Our results highlight the lack of mandatory genetic testing for donors and recipients, limited rights for recipients to access medical information on donors, the narrow age range for access compared to some countries, and no centralised registry to track the use and outcomes of donated materials.

The analysis highlighted the need to expand legal rights for both donors and recipients during the donation process. Similar to evolving standards in Western countries (21), participants should have clear options in relation to maintaining anonymity and access to medical records. Religious and ethnic considerations must also be carefully weighed (19). Ultimately, the legal framework in Kazakhstan must strive for an appropriate balance between safety, transparency, accessibility, and confidentiality—one that accounts for unique social norms while upholding international standards.

The ethical issue of access to the register of donors and recipients of sexual gametes (DSG) raises important considerations regarding privacy, confidentiality, and accountability (22). While recipients may have a vested interest in accessing the register for various reasons, including concerns about genetic health and familial history, granting direct access to individuals may compromise the confidentiality and anonymity of donors (23, 24). Social research on egg donors in Kazakhstan has highlighted the importance of maintaining donor confidentiality, with a significant percentage expressing a desire for complete anonymity. In the opinion of the authors of the current research, access to the register should be limited to authorized healthcare professionals and the national authorities responsible for oversight and regulation. Allowing recipients or donors direct access to the register could potentially breach confidentiality and compromise the anonymity of donors, which may deter individuals from participating in donation programs. Moreover, the establishment of a unified register should prioritize the protection of donor privacy and confidentiality, while still providing recipients with essential information about the use of reproductive material (25).

To address concerns about confidentiality and data security, it is crucial to implement robust safeguards and protocols to protect the integrity of the register. Informative meetings should be conducted regarding the safety of electronic technologies and the legal rights of donors to retain personal data, to ensure transparency and informed decision-making. Additionally, donor information agreements should explicitly address potential risks, such as technical vulnerabilities and data loss, and outline measures to mitigate these risks (26). Thus, while access to the register of donors and recipients of sexual gametes can provide valuable information for recipients and healthcare professionals, it is essential to prioritize the confidentiality and privacy of donors. Limiting access to authorized personnel and implementing stringent security measures can help maintain the integrity of the register while protecting the rights and anonymity of donors (27, 28).

These findings align with other recent research indicating that the rights of ART participants in Kazakhstan are not as robust as in many Western countries. A 2022 study found that only 43% of egg donors in Kazakhstan were satisfied with the information they received on the accounting and outcomes of their donations (16). This is far lower than rates of upwards of 80% seen in the United Kingdom and Spain (29-31). Our analysis also supports calls for expanded genetic testing, given research showing high risks of chromosomal variations in Kazakh couples struggling with infertility (8).

The Spanish Fertility Association published data according to which almost four out of every ten children in Spain were born through ART in 2020 and were dependent on the DSG procedure. In the Republic of Kazakhstan, as indicated above, these figures are lower. A healthcare provider in Spain has the option of choosing the recipient's reproductive material while taking the donor's phenotypic traits into account (32). Our results provide a strong rationale for establishing a unified gamete registry in Kazakhstan, modelled after registries in the United States, Spain, and regional programmes in Europe (14). Centralised tracking of donor materials is the norm globally, and provides critical oversight while protecting confidentiality through encryption and access controls. As Kazakhstan continues to advance ART services, implementing such a registry will ensure best practices.

In some countries, the anonymous donation of germ cells is mandatory, in order to control the confidentiality of participants in ART (e.g., Spain). However, in other countries around the world, non-anonymous donation of gametes with open information about the recipient and the donor is the only option for participation in ART (Sweden, Norway). In a third option, as in several other countries, the status of the openness of personal data rests on the decisions of the donor or recipient themselves when registering for the procedure (e.g., USA and Iceland). Access to ART is only available to heterosexual married couples in countries such as Lithuania, Albania, the Czech Republic, Italy, Poland, Slovakia, and Switzerland, although in

most countries ART is available to single people or homosexual couples (e.g. in France) (33).

Cryopreservation of germ cells for diseases affecting fertility is permitted in most countries with ART, frequently despite restrictions in specific legislation (12). In addition to the preservation of gametes, the preservation of sex glands and embryos for medical reasons is practiced in European countries (33). During the legal regulation of ART, most countries offer financial assistance to families suffering from infertility and to donors of sexual gametes (34). State legislation should consider the main financial cost drivers of ART: drug prices, labour costs for health workers, and laboratory services. In Europe, public funding programmes for ART may cover donors and recipients for all three components of the procedure or for one of the components (medicines, health care providers in private or public reproductive centres, or laboratory screening). However, in Albania, Georgia, and Switzerland, there is no state financial coverage for ART.

Regulation of access to the register of donors and recipients, the balance between the legal protection of donors' personal information and the maximum medical awareness of reproductive material for the recipient, and the technical reliability of information digital data storage and processing—these and many additional issues are to be regulated during the development of a unified database of donor sexual gametes in the Republic of Kazakhstan.

Conclusion

The legislative framework in Kazakhstan, while comprehensive, exhibits gaps compared to more established systems in Europe and the United States. Key findings include the lack of mandatory genetic testing for donors and recipients, limited rights for recipients to access medical information on donors, and the absence of a centralized registry to track usage and outcomes of donated materials.

There is a need for expanded legal rights for both donors and recipients, clear options regarding maintaining anonymity, and careful consideration of religious and ethnic norms. Ethical concerns regarding access to the register of donors and recipients emphasize the importance of confidentiality, accountability, and data security. While recipients may have legitimate reasons for accessing the register, limiting access to authorized healthcare professionals and national authorities is essential to protect donor anonymity and confidentiality.

The study underscores the urgent need to address legal gaps and ethical concerns to ensure the responsible and ethical implementation of a unified register of reproductive donor material. Efforts to enhance transparency, safety and accountability in the field of reproductive medicine are crucial, considering the rapid advancements in reproductive technologies and the increasing prevalence of medical tourism. Overall, the establishment of a unified register holds promise for improving ART practices, but careful attention to legal, ethical, and technical considerations is paramount to its success.

What Is Already Known on This Topic:
In Kazakhstan, egg and sperm donation is regulated by the Code and several regulations, which outline the age range of participants, the list of tests for donor screening, and indications for the procedures. There is a need to establish a unified register of gamete donors to regulate using the material, control the number of children born from donors, and maintain the confidentiality of participants.

What This Study Adds:
This study provides a comparative analysis of the legal regulation of gamete donation in different countries, offering a theoretical basis for the development of a strategy for establishing a unified register of donors in Kazakhstan. It shows how important it is for lawmakers to agree that people with reproductive disorders who want to use sexual gamete donations must first go through cytogenetic and molecular genetic tests.

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