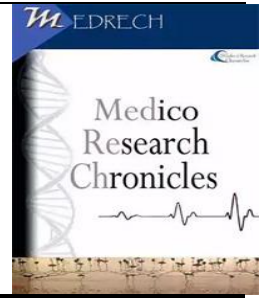




Medico Research Chronicles
ISSN NO. 2394-3971
DOI No. 10.26838/MEDRECH.2024.11.6.743

Contents available at www.medrech.com



The Frozen Frontier: Who Owns Your Embryos?

Dr. Anju Choudhary¹, Rupali Mehta²

1. Associate Professor, University Institute of Legal Studies, Panjab University, Chandigarh – 160014

2. Research Scholar, Department of Laws, Panjab University, Chandigarh – 160014

ARTICLE INFO

Article History

Received: October 2024

Accepted: December 2024

Key Words:

ART, Embryos, eggs, sperms, IVF, infertility.

Corresponding author

R. Mehta*

ABSTRACT

This research article examines the intricate legal, ethical, and fraudulent dimensions associated with eggs, sperm, and embryos within the framework of In Vitro Fertilization (IVF) facilities. This examination addresses the legal status of embryos, ethical issues surrounding reproductive materials, and the rising incidence of illicit activities such as embryo and egg theft, smuggling, and fraud in the global IVF sector, particularly in India. The report emphasizes the pressing necessity for regulatory reforms and stringent enforcement measures to address the obstacles associated with fertility clinics and reproductive technology, focusing on issues of ownership, consent, and the disposition of surplus embryos.

REVIEW ARTICLE

2024, www.medrech.com

INTRODUCTION:

Recent breakthroughs in Assisted Reproductive Technology (ART) have broadened conception possibilities while also introducing intricate legal and ethical dilemmas. Instances of sperm theft, embryo trafficking, and the illicit trading of ova have emerged in both domestic and international arenas, prompting significant apprehensions over the regulatory supervision of reproductive facilities. The Assisted Reproductive Technology (Regulation) Act, 2021, seeks to mitigate these issues; yet, existing loopholes and fraudulent activities persist, compromising ethical standards within the fertility sector.

The tremendous growth of Assisted Reproductive Technology (ART) has generated unparalleled prospects for individuals and couples desiring to conceive. Nonetheless, these breakthroughs also provide intricate legal, moral, and ethical challenges, especially with the disposition of surplus embryos. The discourse on the classification of embryos as persons, property, or just waste reproductive material has intensified with the increasing global accumulation of stored embryos. In numerous instances, these embryos remain unutilized, frequently preserved forever or disposed of, resulting in challenging inquiries regarding their ethical and legal status.

Recent incidents of embryo theft, smuggling, and the illicit sale of ova and sperm have exacerbated this discourse. These incidents reveal a concerning trend within the reproduction industry, where embryos, typically generated with the aspiration of life,

may be regarded as commodities for unlawful exchanges or as expendable leftovers of reproductive procedures. The moral position of embryos—whether they possess intrinsic rights or are owned by the commissioning parents—continues to be a contentious issue.



Legal Status of Eggs, Sperms, and Embryos:

The legislative framework governing ART in India has significantly developed, culminating in the Assisted Reproductive Technology (Regulation) Act, 2021. This legislation aims to govern IVF clinics, set standards for the utilization of gametes and embryos, and tackle ethical issues including consent, ownership, and the commercialization of reproductive materials. The Act stipulates that eggs and embryos may only be utilized with the full consent of the donors, and the transfer, sale, or commercialization of gametes is strictly forbidden without appropriate license.

Notwithstanding these stipulations, gaps persist. A case at the All-India Institute of Medical Sciences (AIIMS) exemplifies these deficiencies. A physician was charged with utilizing ova from a patient having IVF therapy without her consent to aid two other patients. Notwithstanding the infringement of Indian Council of Medical Research (ICMR) norms, the physician received merely a

warning from the National Medical Commission (NMC), highlighting the inadequate accountability for violations of medical ethics and consent in the fertility sector.

International Legal perspectives:

Worldwide, legal regulations pertaining to ART differ substantially. In the United States, although the Food and Drug Administration (FDA) governs therapies utilizing human cells and tissues, numerous fertility clinics function with less supervision. The absence of regulation has resulted in multiple instances of embryo mishandling and destruction, exemplified by the storage system failure at the Pacific Fertility Centre in San Francisco, which resulted in the loss of 4,000 eggs and embryos owing to cryopreservation failure. These occurrences highlight the vulnerability of legal mechanisms designed to safeguard patients' reproductive materials and the necessity for more robust and comprehensive regulatory frameworks.

The Status of Remaining Embryos: Person, Property, or Waste?

A crucial concern regarding the legal status of embryos is to their disposition after they are no longer required by the commissioning couple. Should these embryos be regarded as persons with intrinsic rights, property under the dominion of their creators, or as superfluous reproductive material to be disposed of? The ART Act of 2021 in India offers minimal direction on this matter, mostly delegating the decision-making to the commissioning parents.

Nonetheless, in the absence of rigorous regulatory supervision, the ethical and legal consequences of these judgments remain ambiguous.

Ethical and Moral Considerations:

Notwithstanding the comprehensive framework introduced by the Assisted Reproductive Technology (Regulation) Act, 2021, some ethical quandaries remain prevalent in the fertility sector. The principal ethical issues are consent, ownership of embryos, and the rights of children conceived via assisted reproductive technology (ART).

Consent and Ownership:

Consent and Ownership are fundamental to the ethical issues related to reproductive materials. The unauthorized utilization of eggs or embryos, exemplified by the AIIMS case, underscores substantial ethical breaches, especially when patients are oblivious to the application of their reproductive materials. In some nations, conflicts about embryo ownership emerge during divorce processes or upon the death of one partner. Judicial decisions have varied between cases, illustrating the absence of a cohesive moral or legal perspective on the classification of embryos as either potential life or personal property.

The Ethical Status of Embryos: Personhood vs Property Rights:

The ethical discourse around embryos centres on their classification as either

individuals or property. Some contend that embryos, as potential life entities, merit moral respect and legal safeguarding. Some argue that embryos are a byproduct of human reproduction and may be regarded as property, governed by the will of the commissioning parents. This perspective becomes complex when embryos are cryopreserved or allocated for research, prompting issues concerning their moral standing. The absence of standardized protocols regarding the disposition of these embryos intensifies these ethical quandaries.

Storage and Disposal of Reproductive Materials:

The ethical issues around the storage and disposal of eggs, sperm, and embryos generally centre on the obligations of reproductive clinics to guarantee the appropriate management and preservation of these specimens. The errors in cryo-storage, exemplified by the destruction of 4,000 eggs at the Pacific Fertility Centre, not only hurt prospective parents but also elicit profound ethical questions over the mismanagement of reproductive materials.

If embryos are regarded as potential human lives, their elimination without consent or appropriate control constitutes a substantial ethical transgression.

Deceptive Practices in IVF Clinics:

1. Egg and Embryo Theft:

The lack of regulation in the fertility industry has resulted in multiple instances of egg and embryo theft. In India, occurrences such as the illicit usage of eggs at AIIMS have underscored the ease with which unethical individuals in the fertility sector can exploit patients. These instances illustrate the necessity for more stringent legal frameworks and enforcement procedures to safeguard vulnerable individuals from exploitation.

2. Embryo Smuggling and Illicit Trafficking

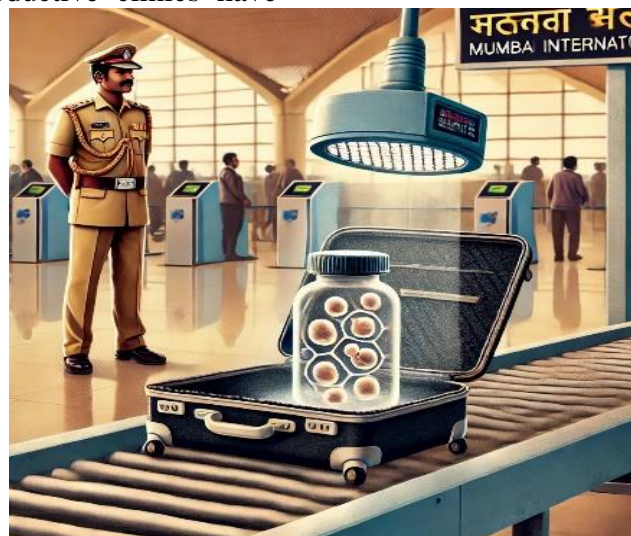
The smuggling of embryos and the illicit trafficking of reproductive materials have emerged as a significant global concern.

In 2019, a Malaysian citizen was apprehended for trafficking a human embryo into India for a reproductive clinic in Mumbai, revealing a broader embryo smuggling network between Malaysia and India. Such cases illustrate the nefarious aspects of the global fertility market, wherein embryos are commodified to satisfy the substantial demand for particular genetic characteristics or alien embryos.

3. Fraud and Storage Failures in Fertility Clinics:

Instances of fraud, negligence, and storage failures in reproductive clinics have

caused considerable emotional and financial harm to patients. The situation involving Kindbody, a large reproductive chain, disclosed that embryos were subjected to hazardous settings, resulting in recurrent mishandling and storage problems. The storage failures and subsequent litigation reveal the extent to which fertility clinics may compromise standards, endangering the prospects of potential parents and prompting significant ethical and legal inquiries over accountability and regulation.



Regulation and Supervision:

1. Necessity for Global Regulatory Frameworks

The advancement of reproductive technology necessitates a unified international regulatory framework to tackle the ethical, legal, and operational concerns in the fertility sector. Existing national legislation, exemplified by India's ART Act of 2021, offer limited direction; nonetheless, in the absence of international collaboration and supervision, problems like as smuggling, trafficking, and improper management of reproductive resources will persist.

2. Enhancing National Governance:

Countries such as India, which have experienced a swift proliferation of IVF clinics, must prioritize enhancing regulatory monitoring to avert unlawful and unethical

activities. A centralized register for reproductive materials, obligatory licensing protocols, and enhanced sanctions for infractions could mitigate these issues. Furthermore, the responsibilities of institutions such as the FDA in the United States ought to be augmented to encompass more stringent inspection and certification mandates for fertility clinics to avert future instances of fraud and mismanagement.

3. Ban on commercialization of sale of eggs and embryos:

IVF is an emerging trend for the society and is blooming at a faster pace than expected. Embryo freezing and donation present moral and ethical challenges, alongside legal disputes concerning the status of embryos, cryopreservation, stem cell research, and compensation for donation.

Legislation and policies should be established to address these concerns. The commercial utilization of embryos should be restricted via appropriate regulation. The sale and purchase of embryos should be rendered illegal by statute.

CONCLUSION:

The fertility industry, although providing hope to several individuals, is fraught with legal, moral, and ethical dilemmas. The improper management of reproductive materials, deceptive activities, and insufficient regulatory control indicate an urgent necessity for improvements in the ART sector. Regardless of whether embryos are seen as humans, property, or discarded reproductive material, it is imperative that governments, regulatory agencies, and medical practitioners collaborate to maintain ethical and legal standards, safeguarding both patients and the prospective lives they aim to generate. Ethical and transparent operation of the fertility sector necessitates significant reforms and international collaboration. The guidelines issued by the ICMR are non-binding and lack a monitoring authority. Legislation and policy should be developed in conjunction with many stakeholders.

The following are few recommendations to consider when formulating the policy:

1. Medical practitioners involved in ART are only regulated by ethical standards and non-mandatory directives. The liabilities and obligations of medical and technical professionals are significant matters that should be addressed by specific legal norms and principles.
2. India lacks standardized treatment guidelines for ART, including embryo preservation and donation. Authentic societal issues that extend beyond the sole proficiency of medical professionals and scientists, or patient market choices, must be integrated inside the regulatory framework.
3. Special provisions are necessary to safeguard the welfare of children conceived via embryo donation.
4. The social, ethical, and religious values must not be disregarded during the process of undergoing the process of embryo cryopreservation and donation.
5. There must be appropriate regulation of embryo cryopreservation and donation within the framework of stem cell research. The utilization of embryos for stem cell research ought to be unequivocally disallowed.

REFERENCES:

1. American Society for Reproductive Medicine (ASRM) - Ethics Committee Report, 2018.
2. British Fertility Society Guidelines on Embryo Freezing, 2016. Centers for Disease Control and Prevention (CDC) ART Success Rates Report, 2020.
3. International Federation of Fertility Societies (IFFS) Surveillance Report, 2019.
4. World Health Organization (WHO) - Infertility Guidelines, 2010.
5. European Society of Human Reproduction and Embryology (ESHRE) Guidelines, 2017.
6. International Guidelines for Cryopreservation of Embryos (International IVF Initiative, 2020).
7. Jha, T., & Deept, M. "Ethical and legal perspective of surrogacy in India", *International Journal of Community Medicine and Public Health*, 9(8), 3340–3345. <https://doi.org/10.18203/2394-6040.ijcmph2022202>.
8. [Juan Pablo Beca](#), [Alberto Lecaros](#), [Patricio González](#), "Medical, ethical and legal issues in cryopreservation of human embryos" doi: 10.4067/S0034-98872014000700011.

9. Sangeetha K., "Egg Donation in India: Legal Concerns and Ethical Dilemmas" – Indian Journal of Public Health, 2020. doi: 10.36348/sijlhcj.2020.v03i04.009.
 10. Surrogacy and IVF Laws Under Scrutiny: Supreme Court of India Intervention" – Times of India, 2022.
-