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Review Article

Ethical Reflections on IVF- Ownership Issues of Gametes and Embryos, an Indian Perspective

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Abstract

Background- The initial attempts at achieving pregnancy through IVF procedures began more than half century ago and were limited to animals and the first successful IVF in mammals occurred in 1959. The world's first baby, Louse Brown, conceived by IVF was born in UK in the year 1978. Subsequently, these pioneering efforts of the scientists were successfully taken forward in India and the first IVF baby was born in 1986 giving hope to infertile couples, not being able to conceive naturally. With increased awareness, acceptance & accessibility, IVF became popular in spite of its restricted affordability in the society. As a result, number of social, ethical issues and dilemmas started surfacing in absence of specific regulatory framework in India. **Objectives:** The ICMR guidelines on Assisted Reproductive Technology, 2005 tried to address certain concerns. However, major milestone was reached when 'The Assisted Reproductive Technology (regulation) Act, 2021' came into existence, which addressed many delicate ethical concerns. The present work intends to identify such concerns and the extent to which they are addressed and tries to provide rationale explanations for those which are partly addressed or which still lack clarity in absence of specific guidelines. **Discussion:** Assisted Reproduction involves myriads of social, moral and ethical issues and challenges but the present discussion is restricted to ownership issues with respect to gametes and embryos in the light of ART (regulations) Act, 2021. The Act, vide section 28(2) addresses this issue and provides guidelines in this regard.

1. Introduction

Sexual Infertility has been defined as inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception. About one in six couples of reproductive age group encounter this type of problems with fertility. According to WHO estimate, overall prevalence of primary infertility in India is between 3.9 to 16.8%.[1]

Infertility has immense demographic, social, psychological, emotional and cultural implications. In addition, inability to procreate is considered as a personal tragedy, at times stigma and has a wrecking impact on life of the person for not fulfilling the biological role of parenthood.[2]

Accordingly, even in India, with increased awareness more and more infertile couples are

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seeking remedies and approaching the fertility clinics. The Center for disease Control and Prevention (CDC) defines ART to include "all fertility treatments in which both eggs and sperms are handled to help achieve a pregnancy". In general ART procedures are all about surgical removal of eggs from woman's ovaries and then combining them with sperms in laboratory and implanting them or storing for subsequent use.

2. Historical & legal background

Assisted reproductive technology (ART) came to limelight when the first report of successful use of AI in human beings was published in 1943, [2] which subsequently revolutionized IVF. With increased knowledge and understanding of reproductive physiology and advent of technology the major historical milestone of successful IVF in human was reached leading to birth of Louise Joy Brown, the first test tube baby on July 25, 1978.[2] This was immediately followed by the announcement of Dr Subhas mukherjee from Kolkata of birth of World's second and India's first test tube baby Kanupriya alias Durga in October 1978, the work which remained unpublished in absence of authentic scientific evidence.[2] Since then, couples deprived of progeny increasingly started to approach IVF centers and ART could fulfill reproductive aspirations of infertile couples across the globe. With the birth of first scientifically authenticated and well documented test tube baby, Harsha, in 1986 in India, IVF clinics 'mushroomed' across the country without any accreditating, supervisory and regulatory framework and/or control of the government.[3]

Indian Council of Medical Research (ICMR) took the initiative and developed draft 'National Guidelines for ART clinics in India' in the year 2002, the document was then subjected to extensive public debate in the country and suggestions from the stakeholders including National Commission for Women and National Human Rights Commission were also sought.[4] Incorporating the comments and suggestions received, the draft guidelines were submitted to Government of India. The Ministry of Health and Family Welfare, Government of India published them as 'National Guidelines for Accreditation, Supervision and Regulation of ART clinics in India' in 2000 [2,5] which was, subsequently, translated into 'Assisted Reproductive Technology (Regulation) Bill, 2017'. [6]

The Assisted reproductive Technology (Regulation) Act 2021 which is presently in vogue provides legal framework for regulation, supervision and accreditation of ART practices and clinics and addresses other related issues including ethical practice of assisted reproductive technology services in India.[7] The Act provides for establishment of National board, state Boards and National Registry and for accreditation and supervision of ART clinics and banks so as to ensure that the medical and socio-legal rights of the stakeholders are protected and the services provided are within the laid down ethical framework.[3]

3. Ethical Perspectives

Assisted Reproduction involves myriads of social, moral and ethical issues and challenges including broader concerns like access to ART clinics due to their inequitable geographical distribution and preferential availability to privileged couples based on their financial soundness and spending capacity.[8] The present discussion is restricted to ownership issues with respect to gametes and embryos in the light of ART (regulations) Act, 2021.

a. One of the common issues encountered in typical IVF procedure is the creation of supernumerary embryos which are in excess of those replaced in the first cycle and are frozen to be used later, either if the first trial is not successful or when the couple wants to have another child .[9] Lately, efforts are being made to reduce the number of embryos transferred so as to reduce the inherent risk of multiple pregnancies. Such restrictive policies in embryo transfer along with improved cryopreservation techniques has resulted in increasing the number of cryopreserved embryos [10] and gametes. Once the couple completes the family or discontinue the treatment, the fate of unused embryos becomes uncertain. They create ethical dilemmas about their fate as to what is to be done with them and how long they should be preserved.
b. The issue of ownership of gametes also arises when the gametes are preserved before vasectomy or cancer treatment where the fertility is threatened by chemotherapy or radiotherapy and the person dies. Should such gametes be used for IVF especially when the remaining partner is a woman? In other words, does the person who stores gametes/embryos can use them for procreation after death?[9]
c. The next important issue is what is the precise role & extent to which informed consent can address to some of the above issues and whether clear

prior directives (advanced directives) can be incorporated in the consent to deal with the issues likely to arise subsequently. Clarity on the validity of advanced directives also needs to be established. Such issues could include duration of cryopreservation & its discontinuation in appropriate situations, scope for possible future use and permission to use/donating the genetic material to laboratories for continued research. Validity of such directives in cases of death or incapacity of either party. Peculiar situation may arise in case of stored embryos when there is divorce or separation of spouses as the decision taken by two persons in wedlock as a 'single unit' no longer holds true.

d. The question of legitimacy of a child born through ART along with its rights and privileges needs attention. Whether such child can be considered as biological child and shall have the same rights and privileges similar to naturally born child needs to be established.
e. Privacy and confidentiality issue may arise when registration of birth under the Act is required to be done and the name of the father might be required.[11]

4. International scenario

Internationally, the guidelines address such issues but they are either insufficient to address vital issues or lack clarity and uniformity to be made applicable in Indian situation. In some countries the couple do have ownership rights over the gametes and embryos only up to the maximum age limit specified for IVF. In Canada, Spain and United States maximum period of cryopreservation has not been prescribed, where as Australia and UK have laid down relevant guidelines. [12] The Laws of France, Germany, Sweden and other countries prohibits use of gametes from deceased individuals even when there is written consent is available, whereas, in UK sperms from the deceased person can be used for IVF if informed consent is available. Human Fertilization & Embryology Authority (HFEA) is UK's independent regulatory authority for fertility treatment and research using human embryos. Article 5.9 of Human Fertilization and Embryology authority (HFEA) code of practice lays down that anyone who consents to storage must state what is to be done with the gametes or embryos in the event of his or her death or incapacity to give or revoke consent.[9]

The European Society of Human Reproduction and Embryology acknowledge that the donors relinquish all rights of ownership from the moment embryos are created, whereas American Society for Reproductive Medicine advocate dual consent and requires that donors should also have a role in decision making about use of the embryo created using their gametes.[12]

5. The Indian Act, strengths and gap.

Role of consent: The ART Act, 2021 mandates that no treatment should be offered without written informed consent from the couple.[13] Any couple or any partner in the couple has right to withdraw the consent at any time before the gametes or embryo is transferred to the uterus. The ART clinics/banks are obliged to maintain/ preserve the consent form and other related documents for the period of ten years from the date of completion of ART procedure. The various forms of consent signed by couple / woman to be used in appropriate situations have been prescribed (Form number 12 to 18 and 21). However, legal battles are on for the rights of the wife even without consent of the husband. A groundbreaking judgment of Delhi High Court has come in 2018 in favor of woman who sought IVF using donor's sperm without consent of the husband on the ground that requirement of husband's consent was 'discriminatory and violated the woman's fundamental right to reproductive autonomy'. In a parallel case Bombay High Court also delivered similar verdict in 2022 but currently the issue is sub judice and similar case is being considered by Supreme Court of India.

Supernumerary embryos: It is an established fact that with increase in success of in vitro fertilization outcomes, the issue of unused or supernumerary embryos has been increasingly surfaced. Notably in Europe, approximately one third of couples did not use their surplus embryos posing challenge for patients and clinics.[14] Section 22(2) of ART (regulation) Act, 2021 mandates that cryopreservation should be done only with specific instructions and consent as to what is to be done in case of death or incapacity of either party. Advanced directives are also mandatory for duration of cryopreservation. As per the Act, gametes from the donors or embryos should be preserved for ten years and afterwards may be allowed to perish or may be donated to research organizations for purposes of research, with the consent of commissioning couple or individual (The Assisted Reproductive Technology regulation Act, 2021). The ethical decision on the issue of use of human gamete and embryo for

research purposes depends upon conscientious application of principles of informed consent.[15-17] This endorses the fact that the right to decide the fate of genetic material by the gamete providers or commissioning couple is considered a 'fundamental right' and therefore the use of genetic material, especially for procreation, without valid informed consent is considered to be a serious violation of that person's autonomy.[9, 15] Patient has liberty to change his earlier decision or directives. He is at liberty to revoke earlier directives and re-decide the issue on the basis of new situation or new value structure. The Act provides for donation of embryo for research purposes to an approved laboratory with the consent of commissioning couple, in cases where embryo is found suffering from pre-existing, heritable, genetic or life threatening diseases. It further provides that the unused oocytes can be given for research to registered research organization only after seeking written informed consent from the commissioning couple (s. 27(5) of ART Act 2021).[18] In India, as per section 24(f) of the Act, collection of gametes posthumously shall be done only with prior consent of the commissioning couple.

With advanced directives, there is always a possibility that a person may not be able to make a correct decision about the event where there is a considerable temporal distance, highlighting the possibility to change his earlier decision at a later date. There are two possible solutions to the issue. Firstly, the consent taken earlier should include the couple's decision as to what should be done in case of divorce or separation. Secondly, advance directive can be given by the couple when they are together.[9]

Anonymity and confidentiality: There is an issue of anonymity in relation to gametes and embryo donation which needs to be addressed. The section 21, clause (e) of the ART Act specifies that the anonymity about the donor or the commissioning couple should be maintained. This anonymity protects the privacy of the donor and also prevents any possible future claims of parentage. Section 21(e) of the Act mandates that, 'clinics and the banks shall ensure confidentiality of the couple, woman and donor shall be disclosed only for the database maintained by National Registry or in a medical emergency, that too at the request of commissioning couple or by Court order.

Legitimacy: The question of legitimacy of a child needs attention. The ART Act, 2021 s 31(1) deals with the rights of the child born through ART.[20] The child born through ART shall be biological child of the 'commissioning couple' and such child shall have all the rights and privileges available to natural child from commissioning couple. Sub-section 2 clarifies that the donor shall relinquish all the rights over the child born from his gametes.

6. Summary & Conclusion

Rapid revolution in the treatment of infertility in form of ART is considered as one of the extraordinary accomplishments of medical science. It was rightly considered as a boon to the infertile couple as it could fulfill their innate desire of parenthood. However several moral, ethical and legal issues in relation to ART procedure and clinics required to be addressed as there was no regulatory legal framework in India before 'The Assisted Reproductive Technology (Regulation) Act, 2021' came into existence. Issues pertaining to informed consent, need and relevance of advanced directives use of gametes and embryos for research, issues of autonomy and anonymity, fate of embryo in the event of death, separation or divorce etc. have been addressed in the Act and certain other ethical issues still needs clarity and authentic elaboration. Efforts have been made to provide rational and ethical solutions to the issues partly addressed by the ART (Regulation) Act, 2021.

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