



## A CRITICAL ANALYSIS OF ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021

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### ABSTRACT

Infertility is a public health problem, and worldwide, millions of couples are affected. WHO defines Infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse." Infertility has always been considered a social stigma, and childless women are always subjected to discrimination and social stigmatization. Several reports indicate that at least 50 million couples worldwide experience infertility. Assisted reproductive technology (ART) can ease the burden of infertility on individuals and families. The birth of the World's first test tube baby, Louise Brown, in 1978 has given hope to millions of women across the globe who are suffering from infertility. Today, several infertile couples opt for ART. ART does not treat infertility but helps infertile couples have children through assisted techniques. India is preferred as a major centre of the global fertility industry. On the one hand, it has given hope to childless couples; on the other hand, ART poses new challenges, some of them ethical, legal, and social questions that society must address. Several countries have adopted mechanisms to regulate Assisted Reproductive Technology. Assisted Reproductive Technology (Regulation) Act, 2021, enacted by the government, intends to regulate ART clinics with the objective of providing "safe and ethical" reproductive procedures to infertile couples. This paper aims to critically analyse the Assisted Reproductive Technology (Regulation) Act of 2021.

**KEYWORDS :** Infertility, fertility, assisted reproduction, assisted reproductive technology.

### INTRODUCTION

Infertility is generally considered a social issue, and childless women are always subjected to discrimination and social stigmatization.

Assisted reproductive technology involves handling of egg and sperm cells outside the body so as to help infertile couples have children. According to the CDC (Centre for Disease Control), "ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman". An assisted reproductive technology includes a range of methods used to overcome human infertility. This includes embryo transfer (ET), frozen embryo transfer, gamete intra-fallopian transfer (GIFT), intracytoplasmic sperm injection (ICSI) and in-vitro fertilisation (IVF) and all manipulative procedures involving gametes and embryos. In addition to this, motherhood through surrogacy is also increasingly being considered as an option for those couples who have difficulty in not naturally conceiving. Medical complications like the inability to produce eggs or when one is not able to carry a child to full pregnancy term are some of the reasons that prevent natural conception. In vitro fertilisation (IVF) is a laboratory process in which eggs and sperm are fertilized outside of the body in a laboratory and the resulting embryo is transferred into the womb. IVF is the most effective and most commonly practised form of ART. ART process usually starts with ovarian stimulation followed by egg retrieval, fertilisation, in vitro embryo culture and ultimately embryo transfer (1). The first known case of IVF was reported as early as 1980 by Prof. Walter Heape of Cambridge University, who successfully transplanted embryos in rabbits (2).

### Assisted reproductive technology in India

Indian doctor Dr. Subhas Mukherjee announced the birth of Kanupriya alias Durga, the world's second and India's first test tube baby. Unfortunately, his work remained unpublished due to a lack of scientific evidence, and Kanupriya's birth remained scientifically undocumented (3). India officially entered the brave new world of assisted reproduction on 6 August 1986, with the birth of the first 'scientifically documented' test-tube baby, Harsha (4). Since then, Assisted

reproductive technology (ART) has grown to multifold. India has one of the highest growth rates in ART centres and the number of ART cycles performed every year (5). Assisted fertility clinics are available in almost all cities in India. Today, many young women are also opting for egg freezing. Increasing number of young women are opting for egg freezing.

### Current scenario:

Owing to the concentration of fertility clinics in all major cities and the lower price of treatment in comparison to other countries, India is also a preferred destination for foreign couples for ART procedures.

India has made several news headlines over issues related to assisted reproduction and IVF treatment. Some are welcome, and some are controversial. Mushrooming fertility clinics in our country are also a cause of concern. Some clinic offers the IVF facility to post-menopausal women. In 2016, Daljinder Kaur from Haryana made international news when she gave birth to a baby boy at the age of 72. Several such geriatric pregnancies above the age of 60 are being reported from India. In 2019, a 74-year-old woman gave birth to twin girls in the state of Andhra Pradesh. Soon after this, "a joint statement was released by Doctors from the Indian Society for Assisted Reproduction (ISAR), the Indian Fertility Society, and the Academy of Clinical Embryologists expressed that they are 'deeply appalled [by the] unprofessional conduct of some health providers in misusing current ART procedures'" (6).

In 2018, the first reported case of posthumous reproduction was reported from Pune. In this case, a 27-year-old man died of a brain tumour in Germany. Before his chemotherapy, he stored his semen in a cryobank in Germany. His parents used their unmarried son's cryo-preserved semen, and using a surrogate and egg donor, two children were born (7). This was the first reported case of posthumous assisted reproduction in India. This case raises serious ethical and legal dilemmas and questions about the appropriate use of assisted reproductive techniques.

### Need for Regulating Assisted Reproductive Technology:

The ART procedure starts with tracing the history of the

patients, followed by a physical examination and investigation of both partners. It involves a very detailed procedure. It requires retrieval, manipulation, storage and application of gametes, embryos, and gonadal tissues. The procedure is very sensitive and the nature of treatments being offered in the ART clinics, the legal consequences and the hardships that can be faced by the infertile couple requires a legislation to deal with the socio-economic and psychological issues related with ART. Although there are ICMR guidelines also but due to lack of mechanism to ensure the compliances there is always the scope of unethical and illegal practices being followed by the fertility clinics.

#### **Assisted Reproductive Technology (Regulation) Act, 2021:**

The government passed the Assisted Reproductive Technology (Regulation) Act 2021 on 20<sup>th</sup> December 2021 (8). The object of the Act is to regulate the functioning of assisted reproductive technology (ART) clinics and ART banks in the country. The women undergoing fertility treatment at the ART clinics needs to be protected. There is also an urgent need to monitor the functioning of the clinics. The Act has ensured that there is effective supervision, monitoring, regulation and licensing of ART banks and clinics. The Act also protects the rights of the surrogate mothers. It deals with the legal and ethical issues of ART.

The Act proposes to provide financial security to the oocyte donor by providing insurance coverage for a period of twelve months. Since the practice of surrogacy is banned in several European countries, several couples from these countries come to India for surrogacy. The Act has provided sufficient protection for surrogate mothers.

#### **Critical evaluation of the Act:**

The Act is a milestone in the area of Assisted Reproductive Technology. The interpretation clause of the Act defines the concepts very precisely; the complex terms are explained very precisely. The Act regulate the functions of ART clinics and ART banks. The significant aspect of research in assisted reproduction is covered in the Act. It provides the guidelines for using human gametes, embryos and gonadal tissues for research. The establishment of National and State ART Board and surrogacy boards will help in the implementation of the Act at the grassroots level.

The big data can be prepared with the help of National Registry. The Act ensures the good reproductive health of citizens. The transparency and accountability has been ensured with the provisions in the Act to obtain the necessary information including the Aadhar number of gamete donors and surrogate mothers for opening the bank account. The direct delivery of subsidies and benefits will be ensured by this important provision in the Act. The Act also protects the rights of the child born through assisted reproduction.

#### **Challenges in the Implementation of the Act:**

The Act has failed to clearly lay down the technical qualification and experience of the gynecologist, embryologist, counselor and other staff. Since they are mainly involved in the procedure, the lack of clarity on this aspect would make it difficult to regulate the assisted reproductive technology. The dispute regarding surrogacy contracts are not sufficiently been covered under the Act. In the current scenario many childless couples travel to India for seeking the surrogacy services, but in case if the child is born with some disability or with some genetic disorder, they leave the child, hence, there is a breach of surrogacy contract. In such adverse situations, surrogacy needs to be regulated.

The Act also is also not made more inclusive. The Act fails to include the LGBTQIA+ community, live-in couples, and single male parents from availing the facilities provided by the ART

Clinics and ART banks. On one hand, we have the constitutional protections available to all, equality of law and equal protection of law available to all, on the other hand this Act is not able to provide that equal treatment to all as per the Constitutional mandate. The apex court in *Navtej Singh Johar & others v. Union of India* held Section 377 of the Indian Penal Code to be unconstitutional and created the path for legal recognition of homosexuality in India (9). With reference to this judgment of the apex court non-inclusion of LGBTQIA+ community from availing the benefits of ART Act are deemed to be unconstitutional.

#### **Conclusion and Suggestions:**

There is a need of immediate setup of national registry so that record keeping may take place. In absence of record there are chances unethical practices by the ART clinics. For identity proof having the Aadhar only as a proof may create problems therefore other alternatives should also be made available. The privacy issues should also be considered. The Assisted Reproductive Technology is such a technology which has opened new frontiers. It has brought a new hope to the infertile couples. To avoid any unethical practice there must be more supervision and monitoring of the clinics, it should not become a practice for earning money and playing with the emotions of the people. Effective implementation of the Act will help society on a large scale, and society will accept new technology.

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