



THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021: BALANCING REPRODUCTIVE AUTONOMY AND STATE REGULATION

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ABSTRACT

With the rapid growth of science and technology, the field of assisted reproduction techniques has seen a quantum leap not only in the scientific aspect but also as a business model with rapidly mushrooming growth of ART clinics all over India and nearly complete regulatory vacuum. It thus created a situation where everyone was at risk of being exploited from the donor to the receiver and even the child born with the help of ART. This necessitated the creation of a law to regulate these ART clinics and safeguard the rights of all the parties involved. This situation led the parliament to pass the Assisted Reproductive Technology (Regulation) Act, 2021. The Act brings in the much-needed Standardisation, regularisation, and legal protection for the parties involved. But it also raises questions on the aspects on individual autonomy, privacy and the definition of family. The article discusses the provisions of the Act and the pertinent questions related to it.

I. Introduction

Background and Evolution of ART Services in India

The range of assisted reproduction techniques (ART) has grown with the establishment and growth of such techniques in the country. Initially occurring in a few urban settings, ART in India blossomed into a national ecosystem over the years, capable of providing IVF, ICSI, banking, and donation of gametes. These same dynamics prevailed then in the early Indian ART market as anywhere else in the world: rapid centralisation around a few commercial clinics-universally fast expanding number of ART cycles due to the domestic and international demand among part of the couple-marked the demonstration of a highly ambiguous form of market very little monitored. With time, ethical dilemmas on exploitation, medical risks involved, donor anonymity, and parentage began to be actively engaged widely, pushing policymakers to work on formulating guidelines to address the requirement for a strong regulated ART practice. This expansion, combined with significant socio-economic disparities

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in access to infertility services, forms the backdrop against which India began contemplating statutory regulation of ART.

Need for Statutory Regulation Leading to the ART Act, 2021

Since there were no clear-cut statutory regulations, inconsistent norms in medical practices evolved along with variable pricing and unmonitored donor practices-the safety of the patients and the welfare of the donors and the children born through ART¹. these voluntary guidelines deficient enough, especially since increasingly ART comes into contact with such sensitive topics as cross-border reproductive care, trafficking in gametes, and medical malpractices. India's rise to being a worldwide centre for fertility services, along with no regulation in place saw increasing opportunities for exposure to risks amongst vulnerable women who were repeatedly subjected to hormonal stimulation and invasive procedures. These developments led to comprehensive legislative framework to ensure transparency and ethical practice, as well as accountability among clinics and ART banks.

Research Problem: Tension Between Reproductive Autonomy and State Oversight

This significant advance in the protection of reproductive rights requires not just understanding the very essence of ART but also brings with it significant political and human constitutional claims. Made law in 2021, the ART (Regulation) Act seeks to "regulate the procedures and practices of ART for the prevention of misuse in the fields of pre- and postnatal sex determination in place of selected practices"². It is also argued that the Act has ample potential for inclusively protecting personal rights if the restrictions do not go on to foreclose pre-existing practice, if it is properly interpreted. The central research problem therefore arises from examining whether the Act genuinely protects women, donors, and children, or whether it reinforces state-driven moral and social norms that limit individual reproductive autonomy.

Objectives of the Study

The main aim of this article is to assess the applicability of the ART Act with respect to the reproductive technology regulation and the need for regulations for protecting women, children and donors from being exposed or hurt with improper medical practices³ And to

¹ Soumya Kashyap, "Assisted Reproductive Technology (Regulation) Act 2021: Critique and Contestations", 16(2), *Asian Bioethics Review*, 149-164. (2023)

² Assisted Reproductive Technology (Regulation) Act, 2021

³ Amanda Mackay, "Inequity of Access: Scoping the Barriers to Assisted Reproductive Technologies," 11, *Pharmacy MPDI*, 17, 2023.

determine whether the Act complies with the principles of equality and non-discrimination under Article 14 and the right to personal liberty held in Article 21, which upholds reproductive autonomy. Lastly, it will highlight the voids, ambiguity, and areas that need improvement at the present regulatory framework.

Scope and Limitations

The focus of the investigation is with the Assisted Reproductive Technology (Regulation) Act, 2021, pinpointing sections within this particular law covering the issues characterizing the access, eligibility, safety standards, donor protocols, and parentage related safeguards (Kaur, 2022). It has some overlap with the Surrogacy (Regulation) Act, 2021, yet as such does not delve into the intricate details of surrogacy-specific laws. Material for this study includes statutory provisions, policy reports, judicial developments, and secondary literature, meaning that the status of empirical knowledge concerning clinic-based implementations could be affected. Because of state-level implementation variations and reduced access to reliable ART industries data, generalizing findings is limited.

Methodology

It involves primarily doctrinal legal research analyzing the statutory provisions. The parliamentary debates and judicial pronouncements that have interpreted reproductive rights and regulatory limits.

II. Overview of the ART Act, 2021

Legislative Intent and Policy Rationale

One of the most burning issues the ART (Regulation) Act, 2021 addresses is the governance vacuum in the fertility sector, which has grown rapidly in India. This legislation is intended to provide a standard for ethical and safe Assisted Reproductive Technologies (ART), avoiding malpractices such as "a risk of using unethical practices, misuse of gametic cells in ART practice and misuse of women, children, and/or communities through gamete trade into the gamete economy"⁴ This is evidenced by the existing vulnerability of the woman receptionists and donors because of the unregulated medical clinics, varying medical standards, and the commercialising of gamete exchange, whilst biomaterials, gametes, and reproductive

⁴ Roopa Surya Sri Gullepalli, "Emergence Of Surrogacy And Assisted Reproductive Technology (Art) Laws In India- Recent Changes And Way Forward", 2(6), *INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS*, 5-18, 2022.

tissues assume commercial value. Therefore, legislation against these activities has become necessary to bring uniformity, conformity, and transparency across all ART centres. It is the broader idea of public health and human rights principles that necessitate it.

Key Definitions: ART Clinics, Banks, Commissioning Couple, Donors

The law has established specific definitions in the Act to delineate the institutional roles for different stakeholders that are involved in the in vitro fertilization ecosystem. ART clinics are seen as authorized medical facilities, providing ART services such as IVF, ICSI, oocyte retrieval, embryo transfer, and associated services. It is comprised of ART banks, which deal with gamete collecting, processing, testing, freezing, and distribution and acts as a regulated bank for reproductional material.⁵ "Commissioning couple"⁶ refers to those who are married opposite-sex partnerships with a view toward seeking ART services, in which LGBTQ+ as well as single men do not have a place. Donor—an individual who, with regulated terms and conditions, is giving a donation of sperm or an oocyte, assures the former be properly screened, guarantees his anonymity, and states rules that are shaped based on health precautions and to prevent exploitation⁷

Institutional Mechanisms: National Board, State Boards, Registration Authorities

The law has had provided a 3 tier regulatory framework : the central National Assisted Reproductive Technology and Surrogacy Board, corresponding State Boards, and the designated Registration Authorities. The task of the National Board is to advise the central government and oversee policy formulation as well as monitor national compliance⁸. State Boards supervise guidelines for clinics of ART within their region, audit performance of clinics, and ascertain whether ART banks are operating properly within their area⁹. The Registration Authorities act as licensed regulators handling applications for licensing, periodically inspecting clinics, and maintaining digital registers of authorized ART units.

⁵ Sonu C Thomas, "Dispelling hope and leaving couples in a state of "in betweenness": Moral dilemmas in infertility research"⁶ *Indian Journal of Medical Ethics*, 229, 2021

⁶ Assisted Reproductive Technology (Regulation) Act, 2021. s 2 (e).

⁷ Assisted Reproductive Technology (Regulation) Act, 2021. S 2 (h).

⁸ Jaydeep Tank, "Voices From Healthcare Providers Assessing The Impact of The Indian Assisted Reproductive Technology (Regulation) Act 2021, On the Practice of IVF In India, 73 *The Journal Of Obstetrics And Gynaecology of India*, 301-308, (2023).

⁹ D. Roy, "Harmonising ART and Surrogacy Regulations in India: Legal and Policy Challenges", *Indian Journal of Law and Society*, 119-145. (2023)

Altogether, these three provide themselves a structured regulatory ecosystem that ideally ensures uniformity as well as accountability.

Mandatory Registration, Licensing, and Compliance Requirements

Before starting work, an Assisted Reproductive Technology (ART) clinic or ART bank must comply with the Act. For example, detailed guidelines on minimum infrastructure, technical and minimum personnel requirements should be complied with to guarantee patient safety and high procedural quality¹⁰ Records need to be kept in every procedure, and donations are limited, whether consents are well-informed or detailed, and tests for donor screening and recipient screening before receiving gametes. The Registration Authority conducts regular audits or looks into whether the requirements laid down in the law are indeed being met. Compliance mechanisms like these, therefore, can help ensure that the newly regulated market will be cleansed of unscrupulous and malpracticing activities or fraudulent practices prevalent in the earlier unregulated market.

Penalties and Offences

The Act has very stringent penal framework. As the legislature wanted to safeguard reproductive governance. Some of the offenses would be in situations where ART procedures are conducted but there is no filing, exploiting rather than aiding the donor or the woman involved in an ART procedure, trafficking of gametes or embryos, or sharing any such information sating high success rates in achieving pregnancy. There are fines go up to jail terms¹¹ a provision with higher punishment to the repeating offenders. Few misdeeds, for example, promotional deals concerning selling of sperm, ovum, and zygote, have been classified as offences. Such legal sanctions have been included to deter the practice of malpractice and further ingrain ethical grounds to the use of ART procedures in India.

III. Access to ART Services under the Act

Eligibility Criteria for Commissioning Parties

The ART Act, which specific criteria for those individuals who want to avail assisted reproductive procedures. The concentration is on the medical suitability, briefing the patient psychologically, and to implement the statutory conditions consisting of age limits, marital

¹⁰ P. Gupta, "Medicalisation of Infertility and ART Standards in India", *Journal of Medical Law & Ethics*, 39–58. (2022).

¹¹ Assisted Reproductive Technology (Regulation) Act, 2021. s. 33.

status, and documentation criteria respectively. That the goals for safe and responsible use of ART services are necessary, but these criteria like strict door-keeping rules are likely to stifle legitimate reproductive aspirations. In particular, mandatory cycles of medical certification of infertility raise concerns about the medicalization of reproductive choice and the possible exclusion of people who do not fit traditional definitions of infertility.

Age Conditions for Men and Women

The Act specifies the age within which children can normally be given birth: women from 21 to 50 and men from 21 to 55 age¹². They are deemed necessary in acknowledgment of the risks arising out of these advanced parental age situations and safety of interest to the unborn child. These age limits can be strictly maintained, but a female may fail to conceive until fifty, or a male up to completion of fifty-five years of age due to some economic or social issue¹³. The constraint may exclude older couples seeking ART services who are likely to be highly affected, strengthening age-based disparities in accessing reproductive aid.

Marital Status Requirements and Exclusion of LGBTQ+ Individuals and Single Men

Probably the most discussed part of the new Act is its eligibility requirement- people who want to be a commissioning parent should be married to the opposite sex. No sooner had the Act been signed than its clash with heterosexist norms suddenly attained lime light, particularly in India, where it prohibited LGBTQ+ couples, unmarried couples, and single men¹⁴ from accessing ART services. This has been perceived as reinforcing heteronormative assumptions about the structure of a family and failing to mirror contemporary constitutional principles, which enshrine an inalienable right to equality and personal liberty. There is an exception--single women are allowed access to ART if and only if. This differential treatment of genders throws up more discrimination concerns.

Financial Barriers Created by Compulsory Insurance and Medical Screening

The Act mandates couples to arrange for insurance coverage for oocyte donors and insists on complying with rigid medical screening tests¹⁵ which, thereby, enhance the cost of all forms of ART procedures. Though meant to protect donors from possible health risks, this

¹² Assisted Reproductive Technology (Regulation) Act, 2021. s. 21 (g)

¹³ P. Gupta, Medicalisation of Infertility and ART Standards in India, *Journal of Medical Law & Ethics*, 39–58. (2022)

¹⁴ Assisted Reproductive Technology (Regulation) Act, 2021

¹⁵ Assisted Reproductive Technology (Regulation) Act, 2021, S 23

rule can actually increase costs—pushing ART services further away from low- and middle-earning families. In addition, having obligatory insurance costs, mandatory diagnostic testing, multiple trips to the clinic, and mandatory compliance with procedural protocols are all factors that increase the financial burden. When implemented, these measures will further the cumulative effect of widening socio-economic gaps to access reproductive technology, leaving only well-endowed sections to use ART¹⁶

Impact on Equitable Access to ART in India

ART accessibility in India may decrease due to age restrictions, marital requirements and financial obstacles, and the total effect of the narrowness of other eligibility criteria. People who are more vulnerable by these regulations, namely, LGBTQ+ members, aged or single men, people from lower-income families, and people living farther away in remote rural populations where clinics should be located, all of which will reduce the quota. The supposed standardisation of ethical practice, as framed in the Assisted Reproductive Technology Act, ironically also creates structural barriers that hinder accessibility to care for those with infertility. Without reforms addressing inclusivity and affordability, the regulatory framework risks widening existing health inequities and undermining the broader reproductive justice agenda.

IV. Protection of Women, Donors, and Children

Safeguards for Women Undergoing ART Procedures

Informed Consent and Counselling

The law considers informed consent among the fundamentals of protection, requiring that women be given a clear, comprehensive description of medical risks, procedural steps, the expected outcome of the procedure, and the potential complications involved in the procedure. Counseling that is both medical and psychological is required to comprehend the implications of ART, such as hormonal stimulation, oocyte retrieval, and the physical and emotional requirements that a treatment would require. On the one hand, the informed consent does safeguard personal autonomy and holds the measures against coercion or uninformed decision making.

Medical Risk Mitigation

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The Act also stipulates that specific risk-mitigation protocols need to be laid down to safeguard the health of women¹⁷, including from complications that arise in ART such as ovarian hyperstimulation syndrome (OHSS), infections, or injury. Standard clinical standards must be maintained in the ART clinics together with sufficiently practical medical personnel in ART clinics; every patient must be cared for by a specific specialist. Evidence-based protocols need to be followed in order to minimise harm. Every ART clinic should strive to provide at least minimum standards of care, and women's health is at the core of the procedure for reproduction.

Donor Protection

Prohibition on Sale of Gametes

Buying or selling human gametes has been forbidden everywhere by the act so as to discourage commercialisation. The purpose of this prohibiting regulation lies, in that context, in the protection of individuals of lower financial starta from exploitation in the assisted reproductive arena. A stringent curtailment of creating a transaction of a direct financial nature retains the actual essence of voluntary donation of human gametes, hence ensuring ethical thresholds are consolidated.

Anonymity, Screening, and Limits on Donations

The Act makes it obligatory medical examination of the donors who are providing sperm or oocytes as healthy and free from any transmissible disease. Donor anonymity is made compulsory by the legal enforcement, which prevents disclosure of identity, except under a few limited circumstances specified by law¹⁸. Moreover, the number of donations allowed per individual is restricted¹⁹ to ensure protection of donors from too many hormonal interventions- to which women submitting might be subjected- and also to guard against the risk of genetic clustering. These compliance provisions reflect an attempt to balance donor welfare, ethical considerations, and public health considerations.

Child Protection

Legal Parentage

¹⁷ Assisted Reproductive Technology (Regulation) Act, 2021.s 24.

¹⁸ Assisted Reproductive Technology (Regulation) Act, 2021.s 21(e)

¹⁹ Assisted Reproductive Technology (Regulation) Act, 2021.s 27

Children born of ART have a great degree of protection ie the protection of clear legal parentage²⁰. As per the Act, such commissioning parents can be declared to be the lawful parents from the time of birth. This measure has been designed to make certain that the child will not face any confusion about custody, guardianship, or inheritance issues after birth.

Prohibition of Child Trafficking or Commercial Misuse

To prevent exploitation, the Act explicitly prohibits any form of commercial trade, sale, or trafficking of embryos or children²¹. This prohibition addresses past concerns regarding unregulated fertility markets and ensures that ART procedures are not misused for illicit purposes . Strict monitoring and reporting obligations placed on clinics further reinforce safeguards against commercial malpractice involving children

Debate on Whether the Act Is Overly Paternalistic

Despite its protective intent, it can be argue that the ART Act's approach may be excessively paternalistic. One can say that the Act imposes state-driven moral and social norms under the guise of protection, particularly through restrictive eligibility rules, rigid screening requirements, and limitations on who may access ART services²² While the Act seeks to shield women, donors, and children from exploitation, its stringent provisions risk undermining individual reproductive autonomy by prioritising state oversight over personal choice. This ongoing debate highlights the tension between protection and autonomy within reproductive governance frameworks.

V. Reproductive Autonomy vs. State Regulation

Concept of Reproductive Autonomy in Indian Jurisprudence

Reproductive autonomy has gained judicial recognition in India as an integral component of personal liberty and bodily integrity. The Supreme Court has consistently affirmed that decisions relating to reproduction, fertility choices, and family formation fall within the protected domain of individual autonomy under Article 21²³ One can interpret reproductive autonomy as encompassing the freedom to decide whether and how to have

²⁰ Assisted Reproductive Technology (Regulation) Act, 2021.s 2

²¹ Constitution of India, Article 21.

²² Assisted Reproductive Technology (Regulation) Act, 2021

²³ A. Chandrachud, The Right to Privacy and Personal Autonomy in India,9 *Indian Journal of Constitutional Law*, 23–56. (2018)

children, free from coercion or unreasonable state interference²⁴ Within this jurisprudential framework, reproductive autonomy is understood not merely as a negative right—freedom from state intrusion—but also as a positive right requiring the state to facilitate access to safe and equitable reproductive healthcare.

Concerns Regarding Excessive State Control

Although the ART Act aims to promote safety and ethical practice, several of its provisions raise concerns about disproportionate state intervention in personal reproductive decisions.

Restrictions on Eligibility and Mandatory Medical Conditions

The state has established restrictive provisions which allow married heterosexual couples to access ART services as well as some single women...some categories of individuals affected include LGBTQ+ individuals and single men who are not eligible.

The requirement for medical certification of infertility imposes an additional barrier, as it forces individuals to conform to medicalised definitions of reproductive need.

Information Disclosure Requirements

The Act also require compliance with the documentation and disclosure provisions relating to personal information up to the regulator for scrutiny and oversight. This certainly goes to some extent in ensuring oversight; it raises the concern about privacy and information. Autonomy more so in the tabloid culture of our age. Constitutional protection is for decisional privacy. A chilling effect may be by the obligation to disclose something to a certain third party, especially those who are seeking ART services.

Whether the Act Aligns with Global ART Rights Frameworks

With respect to global frameworks, Indian ART legislation, indeed, reveals some strong and weak aspects. The reinforcement of ART access within a set of norms that emphasize inclusivity, non-discrimination, and autonomy²⁵ The use of cloud storage, facilitation of donor data exchange, utilization of tele-services, and provisions that promote direct contact between

²⁴ Cynthia Soohoo, “Reproductive Justice and Transformative Constitutionalism”42 (3) *Cardozo Law Review*,(2021).

²⁵ Aniruddh Saraswat and Oindrila Mondal, The Assisted Reproductive Technology (Regulation) Act, 2021: A Step Forward, Two Steps Back?, *The Contemporary Law Forum*, Available at : <https://tclf.in/2022/04/21/the-assisted-reproductive-technology-regulation-act-2021-a-step-forward-two-steps-back-2/> (Visited on 20 May 2022.)

donors and intending parents in global best practice for ART all find a near equivalent in the provisions of the Indian ART Act.

Comparative Perspective: ART Regulation in the UK, Australia, and the US

*United Kingdom*²⁶

The UK's Human Fertilisation and Embryology Authority (HFEA) framework promotes a rights-based approach by allowing access to ART for married couples, unmarried partners, single women, and LGBTQ+ individuals. The regulatory focus is on procedural safety rather than moralistic restrictions, making the UK model comparatively more inclusive.

Australia

Australia²⁷ has adopted a different approach where ART is subject to the state's control but with significant emphasis on individual rights. Under state regulations, access to ART must be granted, while the legality of one's marital status or sexual orientation should not have any bearing. Ethical guidelines also prioritise counseling and informed consent, as well as child welfare, without relying on black-and-white rules of access. The autonomy standards adopted by Australia under this broader conceptualisation are closer to what continues to evolve in terms of autonomy worldwide.

United States

The US operates predominantly on a market-driven model, with minimal interference from the federal government and high levels of autonomy for both individuals and clinics. Whereas in the United States the principal factor governing access is affordability rather than legality, high costs of treatment and cost of insurance seem less stringent from an eligibility or reproductive decision-making perspective.

On the other hand, regulations of these jurisdictions tend towards respect for autonomy, inclusiveness, and antidiscrimination.

VI. Constitutional Dimensions: Articles 14 and 21

Article 14 – Equality and Reasonable Classification

²⁶ Human Fertilisation and Embryology Authority (HFEA)

²⁷ ASSISTED REPRODUCTIVE TECHNOLOGY BILL 2023, Available at : <https://classic.austlii.edu.au/au/legis/act/bill/artb2023377/> (last visited on 20 February 2023)

Exclusion of Unmarried Men, LGBTQ+ Persons – Discriminatory Classification?

Article 14 of the Constitution is to ensure that any law made in the country has a sufficiently clear and rational basis to classify the persons or actions the legislation regulates (intelligible differentia). The ART Act reserves the right to access technologies to husbands and wives by virtue of their marriage and some categories of single females which implies that it leaves out single males, persons who are any how connected to LGBTQ persons and other members of non-conventional families. Critically speaking these exclusions are too uncalled for and should not be treated as simply that but being part of the unconstitutional acts of discrimination. Classification of this kind, as a result, can be termed as discriminatory for no medical or scientific grounds can be cited as necessitating such obligations, instead they are shaped by the moral compass of the state.

Moralistic vs. Rational Basis Classification Debate

The constitutional debate surrounding Article 14 hinges on whether the Act's classifications are rationally connected to legitimate state objectives such as child welfare and safety or whether they are merely moralistic exclusions lacking empirical justification. The restrictions based on marital status or sexual orientation do not advance the stated aim of regulating ART practices; rather, they reinforce a narrow conception of the family. As a result, the Act's classification scheme arguably fails the test of reasonable classification and could be viewed as constitutionally suspect.

Article 21 – Personal Liberty and Reproductive Choice*Privacy and Autonomy After Puttaswamy case²⁸*

The Indian Supreme Court's decision on the Puttaswamy case challenged the current concept of privacy by including reproductive autonomy in decisional privacy, which is protected under Article 21. Such a wider understanding of privacy concentrates more on individual's right to take personal decisions, which involve inter alia, reproductive rights, without excessive state intervention. The ART Act, with its strict requirements in terms of

²⁸ Justice K.S. Puttaswamy (Retd.) & Anr. v. Union of India & Ors. AIR 2017 SC 4161

eligibility criteria and elaborate paper work, comes under scrutiny whether it aims to serve such reformed notion of privacy.

Right to Create A Family as A Part of Dignity

Dignity includes the right to create a family too. Indian constitutional law has expanded lately, allowing the right to marriage, comprising the concept of dignity. This view of the right to family emphasizes the right of such couples to use ART to become parents, as this offers an avenue to exercise substantive freedom for the individual. Exclusionary eligibility rules may therefore infringe upon constitutionally protected dignity interests by denying individuals the freedom to form families based on their own life choices.

Compulsory Medical Restrictions and Autonomy Concerns

Restriction of medical reproductive rights and privacy, contributes to the infringement of rights and of ability to justice concerns. Imposing constraints as mandatory medical check-ups, restrictive screening and age requirements can be considered overly controlling, when it comes to reproductive rights. Though justified as protection, these limits threaten personal liberty. This type of restrictions would undermine rights of body integrity and autonomy to make choices as allowed in the constitution.

Proportionality Analysis of ART Restrictions

A proportionality assessment tests whether the limitations imposed by the statute are in line with the objectives pursued in the public interest. Among the public's legitimate concerns are the safety of the beneficiaries and intervention of humanitarian organizations. Unfortunately, simply isolating this standard from single and LGBTQ+ people, in such circumstances, may be considered as unfair.

Compatibility with Expanding Constitutional Morality Doctrine

Constitutional morality is the principle that maintains that laws must uphold the equality, dignity, and non-discrimination elements of society and its people and not the standards and values of the day. For this reason the approach towards family under the ART Act might fail to hold ground.

VII. Ethical Dimensions

Bodily Integrity and Autonomy in Reproductive Technologies

The ethical debate surrounding ART underscores the importance of bodily autonomy and freedom in the context of health matters. Women receiving ART treatment are present in a clear and immediate physical operational field, suffer due to over medicalization and technology every day, as new technologies change everyday medical practices, and it needs to be ensured that their decision making process is informed, free and is respected. Ethics demands that people be able to decide what to do with their bodies, so that they are not forced, unduly encouraged or otherwise jeopardized. A dilemma and a controversial subject that has continued to surface in ART practices is the conflict between medical care and personal freedom especially concerning reproductive services.

Ethical Concerns Regarding Gamete Commodification

The sale of sperm or ovarian tissues cannot be practiced since it devalues human dignity to a huge degree. The practice of treating gametes as commodities becomes worse in societies that are characterised by unequal classes, where individuals who need money can sell eggs or sperm to earn their living. Despite the clear line drawn by the ART Act on the prohibition of practice of selling gametes, the presence of a web of businesses which focus on ART encourages the purchase and sale of gametes among main players in the ART field, hence the distinction between donation and exploitation can easily blur.

Women's Labour and Exploitation Risks

ART treatments usually require hard physical and emotional work from women including, but not limited to, oocyte aspiration, multiple courses of hormonal treatment, and exposure to certain health risks that may even be classified as serious.

Interests of the Future Child—Welfare Principle

A key ethical consideration in ART is the welfare of the child who will be born as a result of reproductive technologies. The welfare principle emphasises that decisions about ART must prioritise the child's best interests, including stable parentage, physical safety, and psychosocial well-being. Ethical frameworks argue that safeguarding the child's welfare requires careful screening of commissioning parents, clear legal recognition of parentage, and prevention of commercial or exploitative practices. While the ART Act incorporates some of these protections, concerns remain regarding whether restrictive eligibility norms genuinely reflect child-welfare considerations or whether they serve broader moralistic objectives.

Ethics of Donor Anonymity and Informational Rights of the Child

Concerns about the ethics of donor anonymity revolve around protecting the privacy of the donor and in the same sense, the right of the donor conceived children.

Though the law provides for donor anonymity to ensure privacy and promote volunteering, there may exist needs for children in accessing genetic and medical information regarding their biological parent.²⁹ Research in other countries has shown that the prevailing opinion is in favour of donor identity disclosure when the child in question comes of age, as it is considered a component of individual's personal image and identity. The challenge lies in balancing in these two interests.

VIII. Critical Analysis

Strengths of the Act

Standardisation, Safety, and Accountability

A lot of the ART Act's success is derived from its steps towards standardizing the fertility sector in India which had previously been known for its fairly uncontrolled and loosely monitored practice of in vitro fertilization (IVF). The ACT also ensures the safety by taking such measures as making ART clinics and banks are registered, licensed, and audits are conducted, which enhances facilities in the clinics and therefore the services. These steps help keep the procedures in line especially in cases of emergencies and also help maintain the correct professional conduct in using ART procedures.

Protection Against Exploitation

The Act takes into account long-standing concerns that involve the abuse of donors and women who undergo ART procedures. By prohibiting the sale of gametes and making informed consent mandatory, medical screening, and insurance for donors, the law seeks to mitigate coercive practices and protect vulnerable people. These shielding provisions are an attempt to place ethical boundaries around commercial reproductive services

Weaknesses of the Act

Restrictive Eligibility and Lack of Recognition of Diverse Families

One major limitation is the strict boundaries of the eligibility criteria that restrict ART access mainly to married, heterosexual couples and few select categories of single women.

²⁹ Geeta Narayan, "Safeguards for the Protection of the Rights of Children Born from Surrogacy Arrangements", *22 Journal of NHRC*, 65-82.(2023)

The Act's precise description of a family does not provide any scope for inclusion of certain individuals, unwedded spouses or any other form of family types. The period of time attached to this aspect is limited and cannot coexist with the present social status and the essence of inherent freedom with absolute fairness to society at large and also with the constitution. In simpler words, the absence of inclusivity in family recognition shows that there is a sort of disconnect between the legal regime and the surrounding societal character.

Heavy Regulatory Burdens on Clinics

Even though some would argue that regulations are necessary, getting in as many checks and balances in the clinic's health care provisions, it may not be possible for small clinics to implement. To deal with this problem a lesser burden may be imposed on smaller clinics that are located in the more rural parts of India with basic safeguards in place.

Furthermore, because of the fear of disadvantages associated with the heavy ART regulation, some clinics with license to operate ART, may opt not to go forward.

Whether the Act Strikes a Constitutionally Permissible Balance

The main constitutional issue requires one to see whether the Act achieves a proper equilibrium between state interests in controlling ART and individual rights to reproductive freedom. The Act achieves legitimate purposes through its donor protection measures and its prohibition of illegal activities, but its eligibility criteria and required medical conditions and extensive procedural rules create constitutional boundaries that go may beyond acceptable limits. The proportionality analysis shows that protective objectives can be achieved through less restrictive methods which include increased counselling and risk-based screening and non-discriminatory eligibility criteria.

IX. Recommendations

Amend Eligibility Criteria to Ensure Gender-Neutral and Orientation-Neutral Access

Amending eligibility conditions is important to ensure that ART services comply with constitutional guarantees of equality and non-discrimination. Gender-neutral and orientation-neutral access that includes, single men, LGBTQ+ and diverse family structures should be allowed access under the ART Act. Present restrictions lack medical justification and reinforce old social norms. Changing the eligibility criteria would align the Act with evolving jurisprudence on personal liberty and dignity.

Adopt Rights-Based Safeguards Over Paternalistic Restrictions

It is increasingly difficult to ensure true autonomy and reproductive rights without switching from Paternalistic to rights-based controls. In May (2008) the Ministry of Health for the first time released Guidelines with treatment standards and requirements for infertility treatment that all favorable, infertile women and couples could identify their family. Reproductive decision-making ought to be based on the concept of informed consent or counselling or practice standards rather than strict limitations imposed by the state. Frameworks based on rights assume that individuals are capable of making free choices and exercise safeguards even as they protect them from harm and exploitation³⁰.

Introduce Clear Guidelines on Pricing, Insurance, and Counselling

It is difficult to access the compulsory insurance, medical examination, and ART procedures because of their high cost. This is because people who are less privileged financially, are hardly able to afford these services. There is a need to enhance the guidelines related to the setting of quotas rather than limit them to pricing structures only. There should be clear stipulations on the costs of infertility investigation and treatment thus minimizing the exploitative nature of these services. Moreover, its provisions should encourage the provision of standardized ART services to all and in so doing address the problem of disparities among service providers.

Align India's ART Laws with International Human Rights Norms

Aligning the ART Act with international human rights instruments is essential in order to make sure that India's reproductive governance is consistent with the global standards and has values worth upholding. ART rules that are inclusive and autonomy-based such as those found in the United Kingdom or Australia fosters more rights and benefits to the public. These approaches to regulation are finally the building blocks that supplement national laws concerning reproductive rights and the ideals to which a state like India, which is known to uphold human rights in principle should aspire to.

Strengthen Data Protection and Privacy Mechanisms for ART Clinics

In the context of treatment involving artificial reproductive technologies, it is widely agreed that the information gathered about patients and disorders in genes should be kept

³⁰ Andrew Heard, "HUMAN RIGHTS: CHIMERAS IN SHEEP'S CLOTHING?", available at : <https://www.sfu.ca/~aheard/intro.html> (Last visited on 23 April 2023)

confidential. Protections should include express informed consent, determination of safekeeping mechanisms as well as enabling suppression of data in certain circumstances to prevent abuse and respect individuals' informational self-determination.

X. Conclusion

The Assisted Reproductive Technology (Regulation) Act of India 2021 is in place to check the unbridled expansion of fertility clinics in the country without any regulations. It cannot be denied that there exists a need for ART clinics due to various reasons. The Act enforces higher clinical standards, it emphasises on responsible behaviour, it protects third-party donors and patients, and it creates an appropriate government structure. On the other hand, the main concern that the people who meet the eligibility conditions are able to take advantage of the ART technology, restrictive eligibility criteria, costs and said procedures impede their access to services. The Act attempts to address exploitation and unethical practices, yet in doing so, it creates structural and constitutional tensions relating to equality, autonomy, and reproductive justice.

The Act aims to curb abuses that may interfere with individual reproductive rights, while also recognising the societal need to protect potential children. The checks and balances that the Act introduced in what was hitherto unchecked brought much-needed supervision. However, there are some excessive paternalism characteristics one can point at in some of the sections of the Act. The limitations which are due the marital status based, sexual orientation based, age-based discrepancies etc. The rationality that is based on traditional family understanding and does not take into consideration the changing social structure and constitutionalism.

Though the Act is a welcome change and attempts to protect the interests of the parties, in order to maintain compliance with overall constitutional standards developing in India, there is a need to look at the ART Act in a new light. Rules under the Act governing Reproductive technologies and that ART should bring all under its umbrella, irrespective of gender, marital, or sexual orientation. Incorporating such egalitarian values would not only authenticate its constitutionality but would also lay the foundation for a reproductive governance regime in the emerging India that is rights-based and morally just as well as sensitive to the interests of society.

