

Legal subtleties of the Indian Assisted Reproductive Technology Act of 2021

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ABSTRACT

Infertility is a widespread medical issue that profoundly affects couples, subjecting them to a roller coaster of emotions often marked by grief and loss. For many, the natural occurrence of conception holds a sense of miraculous success, often overshadowing the prospects of surrogacy or assisted reproductive technology (ART). Diverse factors contribute to infertility, including unidentified causes, age-related concerns, lifestyle choices and medical conditions. ART treatments are vital in aiding infertile couples facing these challenges. The Government of India introduced The ART (Regulation) Act, 2021, which brought much-anticipated regulation to reproductive practices. The Act's primary objectives are to oversee ART clinics and banks, ensuring the ethical and safe delivery of services while preventing potential abuse. However, it falls short in addressing critical issues related to the equal rights of LGBTQIA+ community, single fathers and unmarried couples residing together. These omissions are important. We discuss how the ART Act contradicts the principles of equal rights and the existing legal stance on the rights of same-sex couples. Although the Act brings regulation to the industry, it simultaneously gives rise to a range of legal issues, encompassing rights, scientific advancements, international surrogacy, obligations and moral dilemmas. The focus on equal rights for all, irrespective of sexual orientation or relationship status, remains a pivotal aspect that must be addressed in the context of reproductive regulations.

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INTRODUCTION

It is conservatively estimated that there are over 40 000 assisted reproductive technology (ART) clinics in India.¹ The birth of Kanupriya, also known as Durga, in Kolkata in 1978 as the country's first test-tube baby marked the initiation of a complex and enduring journey with ART.² Consequently, a thriving reproductive tourism industry began to flourish, even in the absence of a suitable regulatory or legal framework to govern it. The sector witnessed major expansion, prompting the need for standardized protocols to address the numerous legal, moral and societal challenges that emerged.³ The first-ever national guidelines made by the Indian Council of Medical Research (ICMR) in 2005 introduced the National Guidelines for Accreditation, Supervision, and Regulation of ART Clinics. These guidelines aimed to set standards for surrogacy and

address the legislative gap in the country. The Ministry of Home Affairs has periodically issued instructions for regulating surrogacy, complementing the dynamic landscape of ART regulation in India, while the Law Commission's 228th report in 2009 recommended enacting a law to promote the proper use of ART and legalize surrogacy.⁴

On 8 December 2021, the Parliament approved the ART (Regulation) Act, 2021, which was later signed into law by the President on 18 December 2021. The Act's primary objectives encompass the regulation and monitoring of ART clinics and banks, safeguarding against abuse, and ensuring the ethical and secure delivery of ART services and closely monitoring these to prevent any unethical practices. The Act was submitted to the Lok Sabha in September 2020, but it was deemed unsuitable for enforceable legislation during its first presentation to the legislature. In response, a parliamentary standing committee was established to address the concerns and bridge the gaps in the Bill before presenting it to the parliament. The committee effectively tackled several issues raised by the legislature and stakeholders concerning the Bill. However, despite their efforts, issues related to equal rights of Lesbian, Gay, Bisexual, Transgender, Queer, Intersex and Asexual (LGBTQIA+) people, single fathers, and unmarried couples living together remained unaddressed both by the committee and the legislature.⁵ The ART Act, as it stand, contradicts the principles of equality and the current legal stance on the rights of same-sex couples. Moreover, the Act, despite its eventual regulation of the industry, gives rise to a myriad of legal issues concerning rights, scientific advancements, international surrogacy, obligations and moral dilemmas.

KEY ASPECTS OF THE ACT

The Act mandates the enlistment of every ART clinic and bank in the National Registry of Banks and Clinics of India, which serves as a centralized database overseen by scientific and technical personnel, with state governments responsible for appointing individuals to facilitate the registration process. For conducting ART operations, it is imperative that a person, clinic or bank be registered with the National Registry of Banks and Clinics of India. Additionally, the Act requires the establishment of a National ART and Surrogacy Board. This Board is responsible for formulating a code of conduct for employees of ART clinics and banks, setting minimum requirements for their physical facilities, laboratory and diagnostic equipment, and ensuring adequate expert staffing levels. The Board also oversees the functioning of the National Registry of Banks and Clinics of India.⁵

Moreover, the Act outlines the responsibilities that ART banks and clinics must fulfil, which include verifying the eligibility of the couple seeking ART services, woman, and gamete donor to receive ART services. The Act mandates that clinics acquire gametes from banks, which must conduct disease examinations on donors. Furthermore, ART clinics must provide counselling to couples seeking ART services and women, explain the implications of ART procedures, and uphold the rights of the children involved.

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As part of the Act's requirements, clinics and banks must establish a grievance redressal cell and ensure the confidentiality of information concerning commissioning couples and women. Additionally, the Act empowers the Central Government to formulate regulations for the effective implementation of its provisions whenever deemed necessary.

Moreover, the Act imposes stringent penalties for any violations of its provisions. For repeated offences, offenders may face imprisonment for a term of 8 to 12 years, along with a fine ranging from ₹10 to ₹12 lakhs (1–1.2 million). First-time offenders could be fined between ₹5 lakhs and ₹10 lakhs (0.5–1 million). Additionally, ART clinics or bank owners involved in providing or promoting sex-selective ART procedures may be liable for a prison term of 5 to 10 years, a fine ranging from ₹10 to ₹25 lakhs (1–2.5 million), or both.⁵

RESPONSIBILITIES OF THE ART CLINICS AND BANKS⁵

1. The clinics and banks need to ensure that the commissioning couple, woman, and gamete donors meet the required qualifications to undergo ART procedures, as per the relevant mandated criteria.
2. The banks will provide the clinics with donor gametes, and it is the responsibility of these banks to ensure that the donor has undergone all necessary medical screenings for any prescribed disorders.
3. The clinics are required to inform the commissioning woman or couple about the legal rights of a child born through ART.
4. Every hospital and bank must establish a grievance cell to address issues related to their respective institutions. The process for submitting a complaint to the grievance cell has to be specified.
5. The clinics must furnish the commissioning couple or woman with a discharge certificate detailing the specifics of the ART conducted on them.

OFFENCES AND PENALTIES UNDER THE ACT⁵

1. The clinic, bank, or any of their agents are prohibited from issuing, publishing, distributing or transmitting any advertisement for sex-selective ART facilities in any medium, including the Internet.
2. Violations of the law are subject to penalties, as described above.
3. Any medical geneticists, gynecologists, registered physicians, or any other person, shall not:
 - a) Abandon, disown, or exploit children born through ART, or cause harm to them in any manner.
 - b) Engage in a business involving the sale, purchase, or exchange of human embryos or gametes, or operate an organization that partakes in such activities.
 - c) Import human gametes or embryos, or assist in their importation in any way.
 - d) Exploit couples seeking ART services, women, or gamete donors in any manner.
 - e) Conduct embryo transfer into a male human or animal.
 - f) Engage in the sale of human embryos or gametes for scientific study.
 - g) Engage intermediaries to procure donors for gametes or buy donors for gametes.

Any violation of the provisions stated in clauses (a) to (g) is subject to penalties, with a fine ranging from ₹5 to ₹10 lakhs for the first violation and imprisonment for a term of 3–8 years

for subsequent violations, in addition to a fine ranging from ₹10 to ₹20 lakhs.

GAP IN THE ACT: ADDRESSING LACUNAE IN ART REGULATION

In clause 2(1)(e) of the ART (Regulation) Act, 2021, the term 'commissioning couple' means an infertile married couple who approach an ART clinic or ART bank for obtaining the services authorized of the said clinic or bank. Additionally, Section 2(1) of the Act employs the gender-specific term 'woman', as defined in Clause 2(1)(u).⁵

Upon conducting a comprehensive study and examination of the ART Act regulations, it becomes evident that it does not allow members of the LGBTQIA+ community, single fathers, and unmarried couples living together to access the services provided by the ART Act. This exclusion is unjust, as it infringes upon their constitutional rights and violates the principle of equality.

Moreover, limiting access to the aforementioned facilities may result in unintended consequences contrary to the Act's original intentions. This exclusion may drive individuals towards resorting to the black market and engaging in unprofessional practices that the Act aims to eradicate within ART clinics and banks.

CHALLENGES WITH THE ART ACT

The Act is undoubtedly an important step in addressing the risks posed by unlicensed and unlawful ART facilities and safeguarding the health of donors and women seeking ART, it falls short of fully addressing several pressing concerns.

The Act restricts access to ART services for unmarried men, single fathers, widower men, heterosexual cohabiting couples, transgender individuals, and homosexual couples (regardless of marital status).

Furthermore, the Act solely applies to couples seeking ART services who have faced one year of unsuccessful attempts at conceiving through unprotected coitus. Consequently, its scope is limited, leaving disqualified individuals with fewer alternatives for achieving pregnancy. Additionally, the Act lacks regulation on the costs of services, which can be addressed with a few straightforward guidelines.

ACT'S CONSTITUTIONALITY DISCORDANT WITH EXISTING LAWS

Every person has the right to be accepted and respected, allowing them to live a life of dignity within society. These principles should extend to all aspects of an individual's life, including the freedom to build a family and access reproductive health services, regardless of their sexual preference, matrimonial status or gender. These rights are fundamental and protected by the Indian Constitution for all Indian citizens.

Article 14 of the Indian Constitution ensures equal rights before the law and forbids the enactment of arbitrary legislation that lacks just, fair or reasonable grounds for treating individuals unequally. Thus, the government cannot unjustly deny a specific group of individuals the opportunity to avail themselves of ART services. However, the ART Act violates this principle by not treating all groups of people equally and arbitrarily denying some of them access to the Act's benefits.

In addition to contradicting the letter of the Constitution, the Act also violates several earlier Acts. For instance, Indian law permits single fathers and unmarried individuals to adopt. The

Hindu Adoptions and Maintenance Act of 1956 (Sec 7 & 8) and the Juvenile Justice (Care and Protection of Children) Act of 2015 (Sec 57) permit single fathers and unmarried individuals to adopt children, highlighting the progressive and inclusive nature of Indian adoption laws. The justification for the aforementioned rules provides a compelling argument for giving single and divorced people, regardless of their gender, the opportunity to utilize ART services.^{6,7}

The ART Act also runs counter to several important judgments of the Supreme Court. In the landmark case of Navtej Singh Johar & Ors v. Union of India, the Supreme Court declared Sec 377 of the Indian Penal Code, 1860, as unconstitutional, leading to the legal recognition of homosexuality in India.⁸ Couples who live together for a 'significant period' are presumed to be married, as per the Supreme Court's ruling in the case of Tulsa & Ors v. Durghatiya & Ors.⁹ Furthermore, the Supreme Court, in the case of S.P.S. Balasubramanyam v. Suruttayan established that children born from unmarried couples who live together are to be regarded as equal to the biological children of a married couple.¹⁰

Based on the aforementioned legal principles, it can be contended that excluding members of the LGBTQIA+ community, unmarried couples living together, and single fathers from the benefits offered by the ART Act based on their sexual orientation, gender, or marital status is unconstitutional, arbitrary, discriminatory, and goes against the intent of previous legislation. The Act not only stands as unlawful and non-constitutional, but the legislature has also failed to provide a valid justification for enacting an evidently prejudiced statute. Every time the matter was raised in the legislature, the sole defense offered was that it contradicts our ethos for live-in couples, LGBTQIA+ individuals, and single fathers to have children through ART.

As per the Standing Committee's evaluation, accepting a child whose parents are cohabiting but not in a legal marriage might be challenging due to India's traditional family structure and prevailing mindset. The Committee raised concerns about the well-being of children born through ART and potential parentage issues in case of separation, resulting in their decision to bar unmarried couples living together and same-sex couples from accessing the ART Act's facilities. However, this justification contradicts widely accepted norms regarding a child's well-being. The Committee imposes its own views, which do not align with the contemporary needs and the law's reform-oriented objective. The concept of 'child welfare' has been subject to contentious debates, but the Supreme Court, in the case of Mausami Moitra Ganguli v. Jayanti Ganguli, defined it as a comprehensive notion encompassing stability, security, affection, and a conducive environment for a child's development.¹¹ The ART notification 2023 stipulates that an oocyte donor must be a woman who has been married at least once in her life, has at least one living child of her own (who is a minimum of 3 years old). She is permitted to donate oocytes only once in her lifetime, with a maximum of 7 oocytes retrievable. Additionally, an ART bank is prohibited from supplying the reproductive cells of a single donor to more than one commissioning couple. Moreover, those seeking ART services must provide insurance coverage in favour of the oocyte donor, covering any loss, damage or potential harm to the donor. It is also prohibited for a clinic to offer the option of selecting the sex

of the child. Furthermore, screening for genetic diseases prior to embryo implantation is mandatory. As is apparent with the current amendment, the number of donors will be restricted and the overall cost of the procedure will increase. However, even with notification, the spectrum of the recipient party remains restricted and unexplored.¹²

There is no evidence that same-sex couples are less capable of providing nurturing upbringing than heterosexual couples. A child's well-being depends on the overall environment and parental qualities, not gender or sexual orientation. Barriers to accessing ART services based on sexual orientation, gender or marital status are unjustified and irrelevant to a child's welfare.

Conclusions

The Act is undoubtedly an important step, given that India is one of the major centres for these issues. For the Act to become more inclusive, amendments should be made to allow single fathers, unmarried individuals, and members of the LGBTQIA+ community to have and raise children. However, continuous monitoring and dynamic oversight are essential to ensure that the law remains relevant to evolving cultural changes, moral expectations and rapidly advancing technology. This legislation will undoubtedly require careful scrutiny over time to assess its impact, benefits and drawbacks. It undeniably represents a historic milestone that will shape future developments and the trajectory of this field.

Conflict of interest. None declared

REFERENCES

- Gopal KM, Gopal KU. The ART (Regulation) Act of 2021 is a game-changer and a paradigm shift for India's fertility industry and couples. Available at <https://osf.io/preprints/osf/qrxnc> (accessed on 22 Jul 2023).
- Bharadwaj A. The Indian IVF saga: A contested history. *Reprod Biomed Soc Online* 2016;2:54–61.
- Murthy L, Subramanian V. ICMR guidelines on Assisted Reproductive Technology: Lacking in vision, wrapped in red tape. *Indian J Med Ethics* 2007;4:123–4.
- Indian Council of Medical Research (ICMR) [Internet]. 2005. Available at https://main.icmr.nic.in/sites/default/files/art/ART_Pdf.pdf (accessed on 22 Jul 2023).
- The Assisted Reproductive Technology (Regulation) Act, 2021; Ministry of Law and Justice (Legislative Department) [Internet], 2021. Available at https://main.icmr.nic.in/sites/default/files/upload_documents/4_The_Assisted_Reproductive_Technology_Regulation_Act_2021.pdf (accessed on 22 Jul 2023).
- The Hindu Adoptions and Maintenance Act, 1956; Ministry of Law and Justice (Legislative Department), 1956 Available at <https://ddashboard.legislative.gov.in/sites/default/files/1956-78.pdf> (accessed on 28 Jul 2023).
- Juvenile Justice (Care and Protection of Children) Act of 2015; Ministry of Law and Justice (Legislative Department) [Internet], 2016. Available at <https://cara.nic.in/PDF/JJ%20act%202015.pdf> (accessed on 28 Jul 2023).
- Navtej Singh Johar vs Union of India Ministry of Law; The Supreme Court of India Criminal Original Jurisdiction Writ Petition (Criminal) No. 76 of 2016 [Internet], 2018. Available at <https://indiankanoon.org/doc/168671544/> (accessed on 28 Jul 2023).
- Tulsa & Ors vs Durghatiya & Ors; The Supreme Court of India Case no.: Appeal (civil) 648 of 2002 [Internet], 2008. Available at <https://indiankanoon.org/doc/988131/> (accessed on 28 Jul 2023).
- S.P.S. Balasubramanyam vs. Suruttayan alias Andali Padayachi & Ors. Madras High Court in S.A.No.2113 of 1977. [Internet], 1993. Available at <http://court.verdict.com/supreme-court-of-india/s-p-s-balasubramanyam-vs-suruttayan-alias-andali-padayachi-ors> (accessed on 28 Jul 2023).
- Mausami Moitra Ganguli vs Jayanti Ganguli; The Supreme Court of India; Civil Appeal No. 3500 Of 2008 [Internet], 2008. Available at https://ijtr.nic.in/Mausami_Moitra_Ganguli_vs_Jayanti_Ganguli_on_12_May,_2008.PDF (accessed on 28 Jul 2023).
- National assisted reproductive technology and surrogacy board (Department of Health Research). Ministry of Health and Family Welfare [Internet], 2023. Available at <file:///C:/Users/HP/Downloads/1680759159Ministry-of-Health-and-Family-Welfare.pdf> (accessed on 28 Jul 2023).