



INDIAN FERTILITY SOCIETY

SIG Newsletter

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Laws and ART



Dr Prof (Col) Pankaj Talwar,
VSM, MD, PhD.
President, IFS



Dr (Prof) Shweta Mittal Gupta,
MD, DNB, FNB, MNAMS
Secretary General, IFS



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Dr R S Sharma
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Dr Suneeta Chandra
Co Convenor - SIG



Dr Madhab Chandra Das
Co Convenor - SIG

Latest Guidelines and gaps in the Laws & ART

Dr. Sunita Chandra, MD, FICOG

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
- 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.

It is conservatively estimated that there are over 40,000 assisted reproductive technology (ART) clinics in India. The sector witnessed major expansion, prompting the need for standardized protocols to address the numerous legal, moral and societal challenges that emerged. 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.

Legislative & Regulatory Framework

- The ART (Regulation) Act, 2021, enacted in December 2021, came into effect in January 2022 and establishes a legal structure for ART clinics and banks in India. It is enforced through accompanying rules effective June 2022.¹
- It operates alongside the Surrogacy (Regulation) Act, 2021, overseen by a common national and state level ART & Surrogacy Boards, as well as a National ART & Surrogacy Registry.

Definitions and Scope

- ART is broadly defined to include IVF, ICSI, IUI, gamete donation, and gestational surrogacy.²
- ART clinics and banks must be registered under the National Registry, with validity for five years. Entry is contingent on meeting staffing, infrastructure, and diagnostic capabilities

Commissioning & Donor Eligibility

Commissioning Parties:

- Married infertile couples: woman aged 21–50, man 21–55. Infertility defined as failure to conceive after one year.
- Exclusion: Single men, LGBTQ+ couples (married or cohabiting), live-in couples, and single unmarried women remain outside the Act's scope.³

Donor Criteria:

- Sperm donors: aged 21–55.
- Oocyte donors: aged 23–35, must be married with at least one child (≥ 3 years old), donate only once, with a maximum of seven eggs retrieved
- Any donor's gametes may be used for only one commissioning party.

Informed Consent, Screening, and Insurance

- Written informed consent is mandatory for commissioning couples and donors. Insurance must be provided for egg donors against loss, damage, or death.
- Genetic disease screening is required prior to embryo transfer.

Gamete Regulation & Insurance

- The 2023 Regulations introduced lifetime donation limits and reinforce single user per donor restrictions to prevent exploitation or commodification.
- Requirement for insurance coverage of egg donors and continued prohibition of pre-determined sex selection and sex-selective ART.

Offences & Penalties

- Offences include gamete/embryo sale or trade, sexual selection, exploitation of donors or couples, and improper use.
- Penalties range from ₹5–10 lakh (first offense), with repeat offenders facing 3–8 years imprisonment + ₹10–20 lakh fines.
- Sex-selective ART offenders face 5–10 years imprisonment and ₹10–25 lakh fines.

Implementation & Practical Concerns

- Increased costs due to mandatory insurance, genetic testing, formality, and compliance.
- Donor shortages and reduced availability due to stringent donor limits, illustrated by industry concerns.
- Regulatory burden: registration coverage is low (~5% of estimated 40,000 clinics/banks are registered), and enforcement is inconsistent.
- Service exclusions (single men, LGBTQ+, live-in couples) raise serious constitutional and ethical issues.

Ethical and Autonomy Considerations

- The donor restrictions and insurance requirements aim to prevent exploitation and ensure safety, but may undermine reproductive autonomy and push marginalized individuals towards unregulated, underground services.³
- There's a tension between fostering transparency/ethical practice and the unintended consequences of reduced access and increased medical tourism of ART services.

Recommendations for Policy and Practice

1. **Broaden Inclusion Criteria:** Amend eligibility to include LGBTQ+ individuals, single men, and live-in couples.
2. **Amend age/donor limits:** Consider permitting more flexible donor usage or revisiting the single-lifetime donation rule.
3. **Streamline Registration & Oversight:** Increase enrollment and empower boards to enforce compliance and data quality.
4. **Subsidize & Raise Awareness:** Alleviate cost pressures through subsidies, encourage donor participation, and disseminate information.
5. **Standardize Procedures:** Codify minimum professional qualifications, adopt standardized protocols across clinics, and balance ethics with practicality.

In a recent survey, it was found that 71.4% of the respondents had a high level of pre-implementation awareness about the key provisions of the Act. However, the understanding of these provisions was found to be variable among 96% of the respondents. While 78% of the participants received training, 72% of them felt the need for further clarity on certain aspects, especially regarding professional qualifications and third-party reproduction.

Despite reporting a high adherence rate of 82%, 50% of the respondents felt the need for more comprehensive compliance support, citing challenges like ambiguous requirements, resource constraints, and gaps in staff training. Feedback regarding the Act's impact was mixed, with 62% perceiving an increase in administrative burden, while 40% acknowledged streamlined processes and enhanced safety measures. Opinions on the Act's future were diverse, with 79% of the participants desiring amendments for improved clarity and 78% foreseeing a positive or neutral influence on India's fertility medicine landscape. A small minority (4%) expressed concerns about potential government overreach and increased patient costs.⁶

Regulatory Structure & Oversight

- **India**

Governed by the ART (Regulation) Act 2021 and Amendment Rules 2023, India operates under a centralized system with mandatory registration of clinics/banks with the National ART & Surrogacy Registry. The Ministry-appointed National and State Boards oversee policy, ethics, and compliance

- **United Kingdom**

The Human Fertilisation and Embryology Authority (HFEA), founded under the HFE Acts (1990, 2008), regulates clinics, licenses embryo research, and manages gamete/embryo storage. It maintains an extensive national database of all procedures

- **United States**

No federal law governs ART; regulation exists at the state level. Clinics follow non-binding guidelines from ASRM on gamete donation, embryo handling, consent, etc., with considerable state-to-state variability

Donor & Commissioning-Party Rules

- **India**

Commissioning couples validly married: women aged 21–50, men 21–55. LGBTQ+, single/unmarried individuals are excluded .

Donor rules: sperm 21–55; egg 23–35, married with a ≥ 3 -year-old child; donation limited to one cycle and ≤ 7 oocytes; gametes shared with only one commissioning party

- **UK**

Egg/sperm donors can donate multiple times, provided clinics follow donor anonymity transparency rules. Same-sex couples and singles are eligible; gamete sharing is managed via a regulated registry .

- **U.S.**

Donor rules are set by clinics/ASRM: donors can donate multiple times, with recommendations for limits to reduce consanguinity risk. Eligibility is broader, and same-sex/single parties are accepted.

Recommendations

1. Extend donor usage & inclusivity—open access to singles, LGBTQ+, unmarried partners.
2. Adopt long-term storage consent and ensure registry privacy akin to UK practice.
3. Publish clinic performance metrics to improve accountability and patient trust.
4. Enhance proportional enforcement—like UK’s tiered licensing instead of only severe penalties.
5. Leverage registry data to inform policy and research while upholding confidentiality safeguards.

By learning from established global models—especially the UK’s balanced regulation and the adaptive innovation seen in the U.S.—India can evolve a regulatory framework that is ethical, inclusive, transparent, and responsive to modern reproductive needs.

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.

Conclusion

The ART (Regulation) Act, 2021 and its evolving regulation (2022 & 2023) mark a watershed in bringing clarity, ethics, and oversight to ART in India. While achieving critical goals—such as regulating clinics, protecting donors, and prohibiting abuses—the law also imposes challenges: operational compliance gaps, access limitations, and social exclusivity. Overcoming these requires a multi-pronged policy effort: liberalizing access, reinforcing professional standards, safeguarding privacy, and ensuring affordability.

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Dr. Prof (Col) Pankaj Talwar, VSM
President, IFS



Dr. (Prof) Shweta Mittal Gupta
Secretary General, IFS



For any Information, Contact

☎ +91 9899308083

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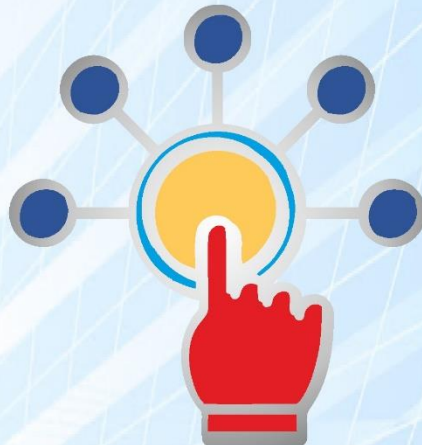
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President, IFS



Dr. (Prof) Shweta Mittal Gupta
Secretary General, IFS



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IFS SECRETARIAT

Flat No. 302, 3rd Floor, Kailash Building
26, Kasturba Gandhi Marg, C.P. New Delhi - 110001
☎ +91 9899308083 (Ms Farha Khan)
☎ +91 11 40018184

@ www.indianfertilitysociety.org

✉ indianfertilitysocietydelhi@gmail.com

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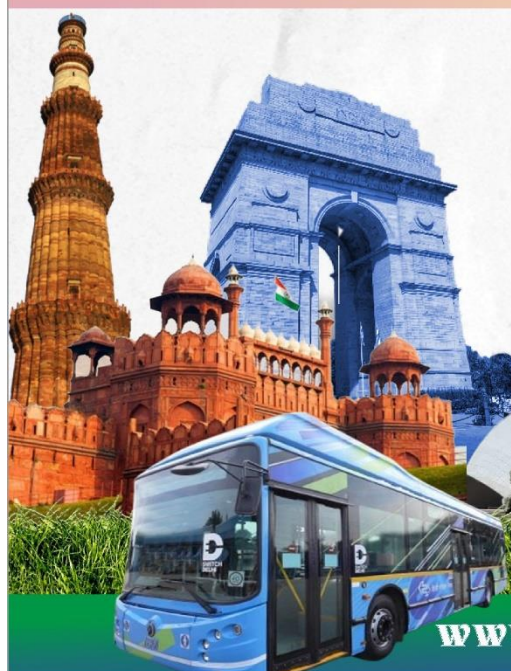
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