

The Assisted Reproductive Technology Act 2021- Provisions and Implications

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ABSTRACT

The desire for parenthood among infertile individuals is often fulfilled by resorting to the ever-evolving Assisted Reproductive Techniques (ART). Since the birth of Durga, India's first baby born using ART in 1981, the lucrative fertility industry has grown exponentially in our country. The Government of India passed the Assisted Reproductive Technology (Regulatory) Act in 2021 to provide regulatory support to these services. The legislation offers clarity on various aspects of ART, including measures to safeguard children born through these procedures. The effective implementation of the ART Act is crucial to ensure that ART services become affordable, ethical, and socially acceptable in India. This article aims to discuss the controversies with ART services and issues that could compromise the wellbeing of children, while highlighting the provisions provided under the Act to address these.

Keywords: Embryo transfer, Infertility, Legal, *In vitro* fertilization, Surrogacy

INTRODUCTION

Subfertility is a prevalent global issue impacting approximately 10-15% of couples. According to the World Health Organization, the overall prevalence of primary infertility in India is around 3.9-16.8% [1]. The landscape of infertility treatment unfolded globally in 1978 with the birth of Louis Brown, the first baby conceived through Artificial Reproductive Technology (ART). India followed suit and witnessed a sharp surge in ART services within its already dense population, albeit without commensurate regulatory measures. This led to mushrooming of infertility clinics dominated by the highly commercialized private sector, and emergence of several legal, ethical, moral and health concerns regarding the ART services.

The United Kingdom (UK) pioneered the regulation of ART with the enactment of the Human Fertilization and Embryology Act in 1990 [2]. In India, the initial strides were taken by the Indian Council of Medical Research (ICMR) which issued the National Guidelines for Accreditation, Supervision, and Regulation of ART Clinics in India in 2005 [3]. However, a mechanism to ensure compliance was lacking, forcing the Indian Parliament to pass the Assisted Reproductive Technology (Regulation) Act and the Surrogacy (Regulation) Act in 2021 [4,5] (**Web Table 1**). This coordinated legislative intervention by the Indian government is perceived as a pivotal and much-needed step in the right direction [6,7].

Diverse medical techniques including *in vitro* fertilization (IVF), intracytoplasmic sperm injection (ICSI), gestational surrogacy, and adjuvant techniques like preimplantation genetic testing (PGT) constitute ART [8]. The ART Act clause 25.1 mandates PGT before all procedures to mitigate genetic diseases by screening human embryos for known or pre-existing heritable or genetic conditions. This makes it mandatory for clinics and IVF laboratories performing PGT and embryo biopsies to be registered as Genetic Clinic under the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act 1994.

General Issues and Controversies in ART and Surrogacy

Since 1978, over 9 million infants have been born worldwide following ART procedures, thus offering the joy of parenthood to those struggling with infertility. The reproductive market recorded a profit of \$12.5 billion in 2018 and is likely to keep growing. However, access to fertility treatments is not uniform with 48% of such births happening in Europe, while a mere 2% are from Africa [9]. In India, the majority of the infertile couples lack access to fertility procedures and faces emotional and financial constraints. Unethical practices, targeting vulnerable individuals or pressuring the family members into acting as donors or surrogates, can promote exploitation and trafficking [10]. An additional concern is the health of donors and surrogates who are subjected to stimulation cycles with its inherent risks and potential complications of pregnancy and childbirth. Regulatory acts aim to address these challenges by stipulating that donor/surrogacy services should be altruistic, commissioning parents must provide insurance coverage, and no one should be coerced into becoming donors or surrogates.

Ethical and Moral Issues

Designer babies and eugenics: Preimplantation diagnostics raise concerns about potential eugenic practices, and right to life since conception. It enables the selection of embryos free of genetic disorders but could potentially be misused to create 'designer babies' with desired traits [11]. The Act prohibits the use of PGT for such purposes by restricting its use to screen genetic diseases only.

Sex selection: Preimplantation diagnostics allow identification of sex of embryo justified for medical reasons such as X-linked disorders. Unfortunately, there is a risk for misuse for sex selection. The ART Act in India, linked with the PCPNDT Act 1994, prohibits ART clinics from providing couples with a child with pre-determined sex except for preventing or treating sex-linked disorders.

Saviour siblings: PGT can be used to select Human Leucocyte Antigen (HLA) compatible embryos for transplant purposes, particularly in diseases like β -thalassemia. Saviour siblings are children who are deliberately born to play the role of compatible donors to their former affected siblings. While offering a cure, this raises concerns about the psychological impact on these children, potentially leading to feelings of being born solely for rescue purposes [12].

Discrimination towards disabled: Preimplantation diagnostics can screen and eliminate embryos with disabilities that may inadvertently foster societal prejudice against individuals with disabilities. The choice of having a child with disability is largely dependent on the perceived availability of support to care for such children. Comprehensive counselling before PGT is crucial to avoid bias and ensure informed choice [12].

Uncertainty of tests: Preimplantation diagnostics raise ethical concerns of child's future autonomy regarding testing, uncertainties around mosaicism and late-onset disorders and potential stigmatization of carrier status.

Research: The ART Act clause 22.3, 24.g, and 30.1 outlines strict research guidelines, prohibiting the use of embryos for other purposes or using ovum derived from a fetus in any process of IVF and absolutely prohibits the transfer of gametes/embryos outside India for research or as source of stem cells. In specific situations when an embryo is affected by a pre-existing/heritable/life-threatening/genetic disease, precluding its use for ART, the Act clause 25.2 allows embryo donation for research, subject to written consent from the commissioning party.

Clinical Issues

The majority of children born out of ART are healthy, but may have a few concerns regarding the health, cognitive, and psychological development. The potential risks associated with ART, are generally considered low. However, these risks can vary depending on individual circumstances such as the specific ART procedure used and the underlying cause of infertility.

Short-term health concerns: A higher likelihood of preterm births, lower birth weight, and high perinatal mortality may be seen in ART-conceived children. These adverse outcomes can be attributed to multiple gestation but are also seen in singleton ART conceptions. Compared to natural conception, ART singletons have a doubled risk of very preterm births (around 2%). Both fresh and frozen embryo transfers increase the risk of babies being small for gestational age, while frozen embryo transfers raise the risk of large for gestational age babies [13-15]. Additionally, multiple embryo transfers in ART increase the risk of cerebral palsy. For every 1000 live births, risk is 2 in natural conception, 5 in ART singletons, 4 in natural twins vs 9 in ART twins [16]. Health care professionals can ensure advocacy of a single embryo implantation wherever feasible.

Non-chromosomal birth defects: The incidence of birth defects for specific ART procedures such as fresh ICSI are double the population rates. Imprinting errors like Beckwith–Wiedemann and Silver–Russell Syndrome are also more prevalent in ART children, especially in males and twins [17]. It remains unclear whether these effects stem directly from ART or are influenced by factors such as infertility, maternal age, quality of gametes or other perinatal considerations [18,19].

Growth: Even though ART children are more likely to be born underweight, they typically catch up in growth during their first year of life and show no significant difference compared to naturally conceived children on long term follow up [18,19].

Attention deficit hyperactivity disorder (ADHD) and autism spectrum disorder (ASD): A large study from Canada including 925,488 children showed higher adjusted hazard ratio for ADHD as 1.19 (95% CI 1.16, 1.22) among the infertile without fertility treatment group, 1.09 (95% CI 1.01, 1.17) in the ovulation induction/ IUI group, and 1.12 (95% CI 1.04, 1.20) in the IVF/ICSI group compared to spontaneous conception group [20]. A moderately increased risk of ADHD in ART children is likely due to parental factors and multiple births, rather than the ART procedures themselves. The severity of ADHD has not been associated with use of ART [20-22].

Respiratory disorders: The Swedish registry study [23] and UK prospective study [24] suggest a possible link between ART and asthma but the findings are inconclusive and require further investigation. Subfertility may be a contributing factor, rather than ART itself [25].

Cancer risk: Large-scale studies from multiple countries including UK, Nordic countries, the United States and the Netherlands do not show a significant increase in overall cancer risk in ART children. While studies suggest a slight increase in specific cancers like leukemia, retinoblastoma, hepatic or embryonic tumours, the findings are inconclusive [26-29].

Long term cognitive effects: Though a possible mild increase in intellectual disability has been suggested [30], a recent meta-analysis reported no significant difference in cognitive development, school performance, and social skills among children born using ART [31-33].

Long-term cardiovascular and metabolic diseases: Beyond short-term effects, there is conflicting evidence suggesting potential long-term cardiovascular and metabolic issues [34, 35]. A large, multi-cohort analysis reported no significant differences in blood pressure, heart rate or blood glucose related markers between naturally conceived children and those delivered using ART.

Fertility issues: Additional concern is about the transmission of infertility to male offspring when sperm retrieval techniques are employed in azoospermic fathers with SRY deletions or Klinefelter syndrome.

Legal Issues

Right to parenthood: The commonly used personal laws to assigning parenthood are parentage by marriage or by giving birth or by contributing gametes or by contract [36]. There can be more than two parents to children born by ART or surrogacy if these laws are applied which may lead to legal, emotional and social issues. The ART and Surrogacy Act of 2021 clause 31.1 and 31.2 address these complexities and declares ART-born children as the commissioning couple's biological child. The donor and surrogate mother must relinquish the parental rights, and the baby to the commissioning mother, who is considered the legal mother. Conceptions arising from cryopreservation and posthumous gamete collection need written consent from all involved parties. A child born through artificial insemination with a deceased husband's sperm is considered the legitimate child of the couple (ART Act clause 22.2 and 24.f).

Coparcenary issues: Coparcenary property termed as any property inherited for the past four generations without division was traditionally limited to natural-born males, later extended to include females and adopted children. Under the new ART Act clause 31.1, children born through ART have been granted the coparcenary status equating them with naturally born or biological children and thus granting them legitimacy. Similarly, the Surrogacy Act declares a child born out of surrogacy to be a biological child of the intending couple or woman and thus entitled to all the rights of a natural child [Point 8, Surrogacy Act]. However, there is a lack of clarity on retrospective application to children born before the Act's existence which could lead to legal friction compromising the safeguarding of these children [37].

False allegations leading to legal issues: The Surrogacy Act strives for ethical practices but leaves room for potential misuse. For example, a surrogate mother could exploit a presumption of coercion to make false claims against the commissioning couple leading to legal battles and jeopardizing the child's well-being.

Cross-country transfers: Reproductive tourism, where individuals seek ART and surrogacy services abroad, presents intricate global challenges. People from resource-limited countries may be exploited, and conflicting laws can leave children stateless. Prior to 2015, when foreign nationals were not restricted, almost 50% of the 25,000 surrogate children born in India were for couples from the western world [10]. The amended act now restricts foreign access and outbound fertility journeys.

Social Issues

Child trafficking: Globally, there is a risk of producing babies through unscrupulous ART practices for human trafficking, sex trade, and illegal activities. Unborn children lack legal recognition making them vulnerable to

objectification for contracts, transfers, and trade. Surrogacy Act explicitly prohibits surrogacy for sale, prostitution, or exploitation [38].

Right to know self origin: While ART procedures are done by the adults who have prioritized their own interests, the child so born might want to know about their biological parents or surrogate mother when attain adulthood. The child's right to know their origin varies across different countries as challenges may arise when they seek property rights. Germany protects the right to know origin by maintaining donor databases until the child's approval or for 110 years [39]. In the new ART Act, children retain the right to request information excluding personal identification of the donor or surrogate. The donors or surrogates cannot be legal parents (ART Act clause 31.2).

Risk of abandonment: The Surrogacy Act prohibits abandonment of children born through surrogacy by the intending parents, regardless of reasons (Point 7, Surrogacy Act). Indian Penal Code section 317, which prescribes imprisonment for a term that can extend to 7 years or fine or both for abandoning a child less than twelve years can be imposed on such parents after due enquiry [40].

Upbringing challenges: The concerns of parents' ability to care for the children born by ART or surrogacy has led to adoption of conducting prior background check on their social, economic and legal standing. However, ART children are usually born to socioeconomically advantaged parents capable of affording the treatment and investing in the child's education and overall development [41]. The stress experienced by parents during conception is unlikely to negatively impact the parent-child relationship, fostering a positive connection instead [42].

Complex family structures: The traditional concept of family has changed in recent times into more diverse family arrangements, encompassing complex relations [9]. Some countries allow ART and surrogacy services for same-sex parents, unmarried couples, or single individuals. In India, according to the ART Act, commissioning parents can only be married infertile couples or single women. Surrogacy is limited to legally married couples or ever-married single women, thus precluding single men, unmarried women, and live-in couples from availing the services. It may be argued that these restrictions infringe upon reproductive rights. However, the Act has been devised keeping in mind the best interests of the child, aligning with prevailing family norms in India.

Disadvantages of the Act

Single father, same sex couples, and unmarried couples are unable to utilize the ART procedures and feel left out and disadvantaged by the restrictions posed on their access to fertility treatment and their desire for parenthood. The Act do not specify the retrospective implementation of the Act for children born before the Act was commissioned concerning status as legal heir. By making it a strictly altruistic volunteering, it has become extremely difficult to find willing donors or surrogates.

Role of the Pediatrician

It is imperative for the pediatrician to be cognizant of ethical, clinical, legal, and social complexities associated with ART and advocate for the rights of children born through ART.

Proactive role in preconceptional counselling: The pediatrician can utilize opportunities to guide the prospective parents opting for ART during prenatal consultations. They can discuss the short-term and long-

term health implications of ART for children, including both genetic and epigenetic risks, and advocate for non-maleficence while enabling informed decision making. They can be involved in providing a comprehensive evaluation of desirous parents for various factors like age, socioeconomic status, mental health, and parenting history to ensure a stable and nurturing environment for the future child.

Collaborative approach: Expecting parents are not routinely referred to pediatricians for prenatal counselling. However, a collaborative approach involving the pediatrician, genetic counsellor, and treating obstetrician can be highly beneficial for ART. The team can equip prospective parents with the knowledge needed to make informed choices, considering their desires and the best interests of the future child. The inclusion of specialists in reproductive medicine, and genetics will help address specific concerns related to the child's conception during prenatal period.

Complementing legal framework: While the legal framework is robust to uphold the interests of the future child, the successful implementation and strengthening of legal safeguards lies on responsible health care practices.

General healthcare: Once a child is born of ART, the routine health check-ups, vaccinations, health concerns and follow-up of the child is similar to any child. The pediatrician should be aware of the potential health issues as described above and monitor for specific conditions depending on the specific ART procedure.

Addressing psychosocial needs: The pediatrician can play a supportive role in addressing any emotional or psychological concerns that may arise for children born through ART, such as questions about their identity or origin story.

CONCLUSION

The ART and Surrogacy Acts of 2021 aim to regulate the burgeoning ART services in India. The success of these acts depends on the collaborative efforts of the service providers, service seekers, regulators, and all the stakeholders. Like the PCPNDT Act of 1994, strict implementation is crucial to safeguard the interests of infertile patients, donors, surrogates, and, most importantly, the vulnerable children born through these procedures.

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Table I Terminologies Used in ART

<p>ART includes all techniques which attempt to obtain a pregnancy by handling the sperm or oocyte outside the human body and transferring the gamete or the embryo into the reproductive system of a woman.</p>
<p>In Vitro Fertilisation (IVF) refers to a procedure designed to overcome infertility and produce a pregnancy as a direct result of the intervention, which generally involves stimulation of ovary by a combination of fertility medications, oocyte retrieval and fertilization <i>in vitro</i> with sperms (partner or donor), after which, one or more embryo(s) are transferred into the uterine cavity.</p>
<p>Intra-Cytoplasmic Sperm Injection (ICSI) differs from conventional IVF in that the embryologist selects a single sperm to be injected directly into an egg.</p>
<p>Gestational Surrogacy is a practice whereby one woman bears and gives birth to a child to be handed over after birth to another intending couple.</p>
<p>Preimplantation Genetic Testing (PGT)</p> <p><i>Preimplantation Genetic Diagnosis</i> is defined under the ART Act as “the genetic diagnosis when one or both genetic parents have a known genetic abnormality and testing is performed on an embryo to determine if it also carries a genetic abnormality” AND</p> <p><i>Preimplantation Genetic Testing</i> is defined as a technique used to identify genetic defects in embryos created through IVF before pregnancy. There are 3 types of PGTs currently used in ART,</p> <ul style="list-style-type: none"> PGT-A to check for aneuploidies, PGT-M for monogenic/multigene defects PGT-SR for chromosomal structural rearrangements <p>Sample for testing can be obtained from polar bodies, blastomere or blastocyst (currently preferred).</p> <p>Indian Society of Assisted Reproduction Consensus on Preimplantation Genetic Testing [6]</p> <p>PGT-A is recommended for advanced maternal age (36–40 years), repeated pregnancy loss for known etiologies and may help in a small subset of repeated implantation failure (RIF) where recurrent aneuploidy may be the cause.</p> <p>PGT-M is indicated for couples with previous child with known genetic defect, carrier state of couples found for monogenic or multigenic disorders of reproductive significance and as an alternative to prenatal genetic diagnosis for couples with a significant risk for transmitting the defect such as with family history of any X-linked, autosomal dominant, and recessive conditions. PGT-M tests have technical limitations hence their results should be confirmed by Prenatal Diagnostic testing to avoid false-negative reports.</p> <p>PGT-SR is usually done when one or both parents have a balanced translocation, most common rearrangements involve Robertsonian translocation with Hot spots at 11q23, 17q11, and 22q11.</p>

Web Table 1: Summary of ART (Regulation) and Surrogacy (Regulation) Acts of 2021 [2,3]

Assisted Reproductive technology Act, 2021	Surrogacy Act 2021
<p>Chapter I: PRELIMINARY</p> <ul style="list-style-type: none"> • “Assisted reproductive technology”: All techniques which attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive system of a woman. • “ART bank”: Organisation responsible for collection, storage and supply of gametes, and embryos to the ART clinics or their patients. • “ART clinic”: Any premise equipped with necessary facilities and medical practitioners registered with the National Medical Commission for carrying out the procedures related to ART. • “Commissioning couple”: Infertile married couple who obtain the services authorised of the said clinic or bank. • “Gamete donor” is a person who provides sperm or oocyte with the objective of enabling the infertile to have a child. <p>Chapter II: AUTHORITIES TO REGULATE ART</p> <p>This chapter deals with the powers and functions of the National and State Board, and lays down rules for establishing the National Registry, Banks and Authorities at the State and National level.</p> <p>Chapter III: PROCEDURES FOR REGISTRATION</p> <p>Deals with the procedures for registration of the ART clinics or banks, for displaying a valid certificate of registration, to be renewed every 5 years, rules for suspension or cancellation of the registration.</p> <p>Chapter IV: DUTIES OF ART CLINIC AND ART BANK</p> <p>1. To assess the eligibility of the commissioning couple, gamete donors and ensure that they have</p>	<p>Chapter I: PRELIMINARY</p> <ul style="list-style-type: none"> • Intending couple: Eligible couple who intend to become parents through surrogacy. • Intending woman: Indian woman who is a widow or divorcee between the age of 35 to 45 years intending to avail surrogacy. • Surrogate mother: Woman who agrees to bear a child (genetically related to intending couple/woman) through surrogacy from the implantation of embryo in her womb. • Altruistic surrogacy: No charges/ expenses/ fees/ remuneration/ monetary incentive except medical expenses & insurance are given to surrogate mother. • Commercial surrogacy: Commercialized in the form of selling/ buying/ trading of embryo/ gametes/ surrogate motherhood by paying the surrogate mother. <p>Chapter II: REGULATION OF SURROGACY CLINICS</p> <p>Registered clinics will not involve in commercial surrogacy of any form, employ qualified personnel, not conduct abortion during period of surrogacy, not store embryo or gamete for the purpose of surrogacy and not conduct sex selection.</p> <p>Chapter III: REGULATION OF SURROGACY & PROCEDURES</p> <ul style="list-style-type: none"> • No surrogacy to be conducted other than for a medical indication for the intending couple of Indian origin certified by the Board to avail surrogacy. • Will do only altruistic surrogacy after obtaining certification of eligibility for the commissioning parents and surrogate mother.

<p>been tested for prescribed diseases</p> <ol style="list-style-type: none"> 2. Provide pre-conception information and counseling regarding the implications, chances of success, pros and cons of ART procedure, including medication side effects and risks of multiple pregnancy. 3. Educate the commissioning couple about the rights of the child borne through the procedure. 4. Maintain confidentiality and maintain a grievance cell. 5. Obtain a written informed consent from all parties involved in ART and allows the commissioning couple to withdraw consent at any time before the gametes are transferred to the concerned woman's uterus. 6. Provide insurance coverage of prescribed amount in favour of gamete donor by the commissioning couple. 7. Will not cryopreserve human embryo/gamete or use reproductive material without specific consent of concerned persons. 8. Shall retrieve oocytes in prescribed manner, not >3 oocytes or embryos may be placed in the uterus, and embryos shall not be split for twinning. 9. PGT shall be used to screen the human embryo for known, pre-existing, heritable, or genetic diseases only. 10. Will conform to the provisions of the PCPNDT Act, 1994, and not offer to provide a child of a pre-determined sex. <ul style="list-style-type: none"> • Also deals with standards of screening/sampling/storage/ handling of human embryos/gametes/zygotes & rules for performing research. • Clarifies the rights of the child born through ART, who shall be deemed as the biological child of commissioning parents, entitled to all privileges as a natural child, with the donor relinquishing all parental rights. 	<ul style="list-style-type: none"> • Not to be done for producing children for sale, prostitution or any other form of exploitation. • An order of parentage and custody of the child has been passed by a Magistrate court which will be the birth affidavit of the child. • Insurance coverage to surrogate mother for a period of 36 months covering postpartum delivery complications must be provided. • Only an ever-married woman of 25-35 years with and a child of her own can be a surrogate mother and not more than once in her lifetime. • Surrogate mother will have an option to withdraw consent before the implantation of the embryo in her womb. • Intending couple should be married (age of female:23-50 years, of male :26-55 years), have not had any surviving child (biological or adopted or earlier surrogacy) or have a child who is mentally or physically challenged or suffers from life threatening or fatal disorder with no permanent cure. • A child born out of surrogacy whether within India or outside shall not be abandoned by the intending parent/s for any reason whatsoever (such as genetic defect, birth defect defects developing subsequently, medical condition, sex of the child or conception of more than one baby and the like). • A child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple/woman and thus entitled to all the rights and privileges available to a natural child under any law for time being in force. <p>Chapter IV: REGISTRATION OF SURROGACY CLINICS</p> <p>Valid certification to be obtained by appropriate authority which must be renewed every 3 years and displayed at the clinic.</p>
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<p>Chapter V: OFFENCES AND PENALTIES</p> <p>Specifies the offences & penalties for those who contravene, including commercialization of human gametes/embryos, providing sex selective ART.</p> <p>Chapter VI: MISCELLANEOUS</p> <p>Deals with administration & regulation of the ART, including the power of government to issue directions to registries, protection of actions taken in good faith, power to search & seize records, and power to make rules and regulations.</p>	<p>Chapter V& VI: NATIONAL/ STATE ART & SURROGACY BOARDS & APPROPRIATE AUTHORITY</p> <p>Chapter VII: OFFENCES AND PENALTIES</p> <ul style="list-style-type: none"> ● Violation of the rules are punishable with imprisonment for a term of up to 10 years and fine up to 10 lakh rupees. Involving in commercial surrogacy/racket, encouraging abandonment of child, exploitation of surrogate mother or child, importing or trading of gametes or embryos, conducting sex selection are all considered as punishable offense. ● For other contraventions, punishment can be 5 years imprisonment or 10 lac fine with continuation of offense leading to suspension of registration for 5 years. <p>Chapter VIII: MISCELLANEOUS</p> <p>All records, forms, reports, consents, agreements shall be preserved for 25 years and in case of criminal proceedings until the disposal of the case.</p>
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