



Unveiling the Cracks in Assisted Reproduction: Legal Liabilities in Wrongful Life and Birth"

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ABSTRACT

Assisted Reproductive Technology (ART) has revolutionized fertility treatments, providing hope to several families experiencing infertility. This breakthrough raises substantial legal and ethical issues, particularly regarding wrongful life and wrongful birth instances. Such instances result from flaws in ART treatments, including inadequate management of genetic materials, resulting in genetic anomalies or inaccuracies in embryo implantation. This article examines the legislative framework governing ART in India, specifically the Assisted Reproductive Technology (Regulation) Act, 2021. We will examine the liabilities encountered by ART clinics and medical practitioners, comparing them with legal systems in India. This article also examines the legal and ethical issues related to wrongful life and wrongful birth cases in India, specifically concerning medical negligence in Assisted Reproductive Technologies (ART), especially In Vitro Fertilization (IVF) treatments.

Keywords: ART, genetic material, cryopreservation, IVF.

Introduction:

According to the American Centre for Disease Control (CDC), assisted reproductive technologies (ART) encompass all fertility therapies involving the manipulation of eggs or embryos. Procedures involving solely the manipulation of sperm, such as intrauterine inseminations, are excluded from this definition. Furthermore, operations involving ovarian stimulation conducted without a strategy for egg harvesting are also excluded from the criterion.

Since then, IVF technology has advanced and become more accessible globally. This study will examine contemporary methods in assisted reproductive technologies, along with their indications and related hazards. In vitro fertilization (IVF) is the predominant assisted reproductive technology (ART) process, which will be primarily examined alongside related methods such as cryopreservation and intracytoplasmic sperm injection (ICSI).

Over the last fifty years, advancements in reproductive and prenatal technologies have significantly increased in sophistication and availability to the general public. As potential parents gain a deeper understanding of the diverse reproductive choices at their disposal, a framework of legal principles has emerged that articulates and safeguards the inherent right of individuals to determine their own paths in conceiving and bearing children. This right is currently safeguarded by the constitutional framework of the right to privacy. If this right is breached due to the negligence of one or more health care providers, the parents who claim to be injured may pursue legal action for the wrongful birth of an unplanned or defective child.

The advancement and application of Assisted Reproductive Technologies (ART) have yielded substantial progress in reproductive medicine, providing hope to couples confronting infertility challenges. Nevertheless, the intricacies inherent in these treatments also present potential dangers of medical blunders. The Assisted Reproductive Technology (Regulation) Act, 2021 (ART Act) permits the cryopreservation of gametes, embryos, and other associated biological components. Notwithstanding the rigorous procedures implemented, mishaps such as gamete mixing or the implantation of an incorrect embryo have elicited apprehensions over culpability and accountability in instances of wrongful life, wrongful birth, or improper embryo implantation.

The utilization of various technologies for prenatal diagnosis is on the rise in artificial reproduction techniques and has established itself as a standard approach in obstetric care. The tests play a vital role in empowering mothers to make informed choices regarding the option of terminating a pregnancy. Numerous bioethical and legal controversies have emerged in the realm of 'wrongful life' claims, which involve actions initiated by or on behalf of a child against the mother or others, asserting that they are forced to endure a life deemed not worth living. Additionally, 'wrongful birth' claims arise when a mother or parents take legal action against a physician for the burden of raising an unwanted, often disabled child, a situation that could have been prevented.

The Parameters of Wrongful Life and Wrongful Birth Claims

Wrongful Life:

Wrongful life lawsuits are initiated by children born with impairments as a result of medical negligence. These arguments frequently depend on the assertion that, absent the carelessness of the healthcare practitioners, the kid would not have been brought into a life of pain. The ART Act of 2021 in India does not explicitly acknowledge wrongful life claims. Nevertheless, instances of genetic testing failures prior to embryo implantation may be addressed under expansive tort law frameworks, so facilitating compensation claims. Indian law, particularly the ART Act of 2021, has a specific provision allowing a child to seek compensation for wrongful life. The Act delineates responsibilities for ART clinics on the management of gametes and embryos, including the requirement for genetic testing (Pre-implantation Genetic Diagnosis) to identify hereditary disorders prior to implantation (ART ACT 2021). Neglecting to conduct such testing may constitute grounds for negligence claims, while compensation structures for minors are lacking. Negligence claims may be initiated under basic tort law or the Consumer Protection Act, 2019, which mandates service providers to be liable for inadequate services (ART ACT 2021).

Wrongful Birth:

Conversely, wrongful birth lawsuits are filed by parents contending that they were denied the chance to make informed reproductive decisions, such as terminating a pregnancy, as a result of medical negligence. According to Section 25 of the ART Act, ART facilities must deliver comprehensive genetic counselling to parents, ensuring they are thoroughly aware of the dangers linked to ART operations. The inability to execute due diligence may lead to negligence allegations. In India, pursuant to the ART Act of 2021, hospitals and ART clinics must apprise commissioning parents of all hazards, including genetic abnormalities, via expert counseling. When these responsibilities are violated, and a child is born with a genetic disease, parents may have the basis to pursue a negligence lawsuit under the Consumer Protection Act, 2019, and tort law, seeking compensation for emotional and financial hardships. This situation can arise if the clinic fails to conduct pre-implantation genetic testing as mandated under Section 25 of the ART Act (ART ACT 2021). Indian courts have not completely acknowledged wrongful birth claims; nonetheless, civil litigation for medical malpractice is permissible under tort law under the Consumer Protection Act.

Wrongful Fertilization:

Wrongful fertilization claims occur when erroneous gametes (eggs or sperm) are utilized in assisted reproductive technology (ART), resulting in a kid that is genetically unrelated to one or both parents. In *Priyanka Tandon vs. Bhatia Global Hospital* (2023), a hospital was penalized ₹1.5 crore for utilizing donor semen without the couple's consent, so disrupting the genetic connection between the father and the twin daughters. The National Consumer Disputes Redressal Commission (NCDRC) highlighted the necessity of obligatory DNA profiling to avert future errors, stressing the significance of rigorous protocols in ART facilities. For instance, if ova from one woman are fertilized with sperm from another man and subsequently implanted into an incorrect uterus, it prompts significant inquiries over parental rights and obligations. According to Indian law, Section 31 of the ART Act stipulates that a child conceived via ART is legally recognized as the biological offspring of the commissioning spouse (ART ACT 2021). Nonetheless, instances of erroneous fertilization may still result in legal action under tort law, pursuing damages for emotional anguish and violation of trust. An incident at an IVF clinic in India led to the birth of a kid with an unintended genetic profile, prompting significant ethical and legal concerns. The ART Act, 2021 delineates stringent sanctions for such violations, classifying them as negligence or even criminal offenses (ART ACT 2021). Furthermore, compensation claims may be sought under tort law and the Consumer Protection Act, 2019, for inadequate service provision.

Criminal and Civil Liability:

The ART Act of 2021 establishes civil and criminal obligations for ART clinics and medical practitioners engaged in ART procedures. Section 33 delineates consequences for negligence and infractions of the Act, encompassing fines between ₹5 lakh and ₹25 lakh, and imprisonment for a maximum of ten years for egregious breaches. Art Act 2021.

When medical negligence leads to the birth of a child with disabilities, parents may initiate a civil lawsuit for damages under the tort of medical negligence or the Consumer Protection Act. If it is demonstrated that the

clinic failed to adhere to established protocols, such as pre-implantation genetic testing, or erroneously combined the incorrect gametes, the clinic may be held accountable for damages.

Moreover, criminal culpability may be contemplated in exceptional instances where negligence or wrongdoing results in grave repercussions for the kid or the parents. The ART Act does not specify whether physicians or clinics may face criminal liability for wrongful life or wrongful birth allegations, allowing for legal ambiguity. The Assisted Reproductive Technology (Regulation) Act, 2021 imposes rigorous requirements on ART clinics to guarantee that procedures such as gamete collection, embryo transfer, and cryopreservation are executed with precision. Specific regulations encompass: • Guaranteeing appropriate gamete procurement and averting the amalgamation of genetic material (ART ACT 2021).

- Mandating the consent of all parties prior to any procedure, including comprehensive notification regarding the associated risks (ART ACT 2021).
- Requiring genetic testing to identify hereditary illnesses before implantation (ART ACT 2021) (Surrogacy Act).

Noncompliance with these stipulations may render clinics and physicians accountable for negligence pursuant to the ART Act. Criminal culpability may also occur if the infraction is willful or careless, with penalties encompassing fines and imprisonment (ART ACT 2021).

The Surrogacy (Regulation) Act, 2021 complements the ART Act by putting analogous responsibilities on surrogacy facilities, particularly in instances of erroneous embryo implantation. It also incorporates stipulations about the rights of children conceived via surrogacy, guaranteeing that they get all legal protections afforded to biological children (Surrogacy Act).

Criminal responsibility in instances of wrongful birth, wrongful life, or wrongful fertilization occurs when the negligence of medical experts or ART clinics transcends simple oversight and constitutes reckless or purposeful injury. The Assisted Reproductive Technology (Regulation) Act, 2021, stipulates that the misuse of reproductive technology, poor management of embryos, or lack of informed consent may incur civil and criminal consequences.

Criminal negligence in ART operations may be prosecuted under Section 106(1) of The Bharatiya Nyaya Sanhita, 2023, which pertains to causing death via negligence, or under Section 117 of The Bharatiya Nyaya Sanhita, 2023, which addresses causing grievous harm through actions that jeopardize life or personal safety. According to the ART Act, if a hospital or clinic is determined to have intentionally or carelessly implanted an incorrect embryo or confused gametes, the accountable individuals may incur criminal liability. This may include the annulment of the clinic's license and incarceration for individuals implicated in the infraction. Due to the delicate nature of ART treatments and their emotional and physical repercussions on families, the establishment of criminal culpability aids in enforcing care standards.

Failure of an ART facility or IVF laboratory to conduct essential genetic screenings or medical evaluations of embryos prior to implantation elevates the chance of delivering a child with genetic anomalies or physical defects. If a child is born with problems like Down syndrome and the parents were not apprised of the associated genetic risks, the hospital and physicians may be liable under negligence statutes.

The Consumer Protection Act, 2019, may be used for the inadequate provision of medical services. In such instances, compensation may be pursued for the financial and emotional burdens experienced by the parents, as well as the ongoing care necessitated for the kid. The responsibility of establishing negligence rests with the commissioning parents, who must show that the hospital or clinic did not apply the requisite due diligence in managing embryos.

Legal issues and Challenges of ART:

The legal issues concerning wrongful life and birth claims generally focus on demonstrating negligence and defining the duty of care. According to Indian law, the onus of proof rests with the complainants to establish that the medical practitioners strayed from recognized norms of care. Moreover, ethical issues are essential as courts contend with reconciling patient rights with the interests of medical practitioners and unborn children. Furthermore, the intricacy of ART techniques presents distinct obstacles, including concerns around informed consent, standards of care, and the emotional and psychological effects on impacted families. The concerns are exacerbated by the evolving nature of India's legal environment, including the ART Act, 2021, which lacks comprehensive provisions to address these issues.

1. Medical Negligence and Diagnostic Procedure Failures:

The present situation highlights the significance of meticulous and precise diagnostic protocols throughout ART cycles in the realm of wrongful birth claims. When a clinic or hospital neglects to identify a genetic anomaly that could have been discerned through appropriate testing, the impacted parents may assert a claim of medical negligence. The clinic or doctor's culpability would stem from their inability to uphold the required standard of care in such operations. The ART Act of 2021 mandates clinics to do genetic testing and notify

parents of possible hazards. Neglecting to perform such tests or misinterpreting the results may be considered negligent, rendering the medical institution accountable.

2. Informative Consent and Communications

In ART operations, obtaining informed consent is essential. Medical professionals, clinics, and IVF laboratories are legally required to furnish comprehensive information concerning all risks, success rates, and potential problems, including the probability of congenital defects. If a clinic neglects to warn the commissioning parents of potential dangers or fails to do essential tests for genetic abnormalities, it may be held accountable for medical negligence. This case underscores the necessity for transparency and comprehensive communication between the medical staff and the parents.

3. Responsibility According to the Consumer Protection Act and the ART Act

The accountability of IVF clinics, hospitals, and physicians may encompass not only negligence in the procedure's execution but also the quality of service rendered. The ART Act, 2021, in conjunction with consumer protection legislation, enables parents to hold medical practitioners liable for inadequate services, including diagnostic testing or genetic screenings. The hospital is responsible for maintaining procedural integrity, accurate diagnoses, and the proper management of gametes and embryos. In the event of any failure, they may be held accountable for paying parents for the increased financial and emotional strain associated with parenting a kid with disabilities.

4. Accountability for Physical Anomalies and Genetic Disorders:

Wrongful birth complaints, entail holding medical providers liable for not providing essential information that would have enabled parents to make informed choices, such as selecting an abortion or deciding against IVF treatment. Clinics, physicians, and IVF laboratories may be held liable if a child is born with a genetic or physical anomaly resulting from inadequate testing or mishandling of the ART procedure. This case demonstrates that hospitals and clinics must provide thorough prenatal care, including genetic testing, to mitigate liability for the birth of a child with unexpected medical issues.

5. Ethical and Moral Considerations: Remuneration for Unjust Birth

The matter of compensation for wrongful birth is essential in situations concerning ART malpractice. Should clinics and physicians be held financially accountable for the expenses related to parenting a child born with a handicap or genetic issue that may have been identified during the assisted reproductive technology process? The Sushil Kumar case illustrates how courts might grant compensation for both current and prospective expenses, particularly in instances of evident negligence in medical treatment. Such verdicts underscore the necessity for explicit legislative guidelines regarding the extent of compensation in wrongful birth cases, especially in instances of medical errors or deficiencies in the ART procedure.

Some Famous cases of Wrongful birth and life:

1. Saha Family Case (2019):

The Supreme Court granted ₹11 crores to the Saha family following an erroneous IVF process that resulted in the delivery of a kid with profound impairments. The parents claimed that negligence in the management of their embryos resulted in the implantation of a foreign embryo. The court underscored the emotional and financial hardships imposed on families impacted by such wrongdoing, establishing a precedent for compensation in wrongful life cases.

2. Bhatia Global hospital case:

Recently. In a significant verdict, the National Consumer Disputes Redressal Commission (NCDRC) sanctioned Bhatia Global Hospital for malpractice during an IVF operation. The case concerned a couple who pursued IVF treatment, only to find that one of their twins was not genetically linked to the husband, as a paternity test indicated inconsistencies in blood types. The NCDRC mandated the hospital to compensate ₹1.5 crores for emotional pain and unethical activities, underscoring the grave consequences of sperm or egg contamination during IVF treatments.

3. Sushil Kumar vs Javitri Hospital & Test Tube Baby Centre:

In the Sushil Kumar case, the complainants asserted that the hospital failed to identify congenital defects (VACTERL association) in the fetus, despite the completion of several prenatal tests (NT Scan, TIFA Scan). This failure immediately resulted in the birth of a kid with significant congenital abnormalities, leading to a wrongful birth lawsuit. The court's ruling centered on whether the hospital, clinic, and physician shown due diligence in doing the requisite tests to detect possible complications in the pregnancy.

4. West Delhi IVF based hospital case:

Particularly in light of the liability of doctors, hospitals, clinics, and laboratories engaged in Assisted Reproductive Technology (ART) operations, the West Delhi-based Hospital IVF Case decided upon by the National Consumer Disputes Redressal Commission (NCDRC) has great relevance for your research on

wrongful life and wrongful birth claims. The case draws attention to certain ethical and legal questions that directly relate to particularly in how carelessness and unethical behavior could cause major emotional and genetic effects on parents and children. The NCDRC determined that the hospital's mix-up of semen during an Intra-Cytoplasmic Sperm Injection (ICSI) operation amounted to negligence. Direct breakdown of the genetic link between the father and the children resulted from the hospital using donor semen without the couple's knowledge or permission. This kind of carelessness closely relates to improper fertilization, in which case unwanted genetic paternity results from the incorrect sperm or egg utilized during the ART process.

The Need for Reform

The unregulated proliferation of ART clinics has resulted in widespread unethical practices, such as utilizing donor gametes without patient consent and neglecting to do obligatory genetic testing. To resolve these concerns, more stringent restrictions should be enforced on ART clinics, encompassing:

- **Mandatory DNA Profiling:** The NCDRC recommends that all ART facilities be obligated to do DNA profiling of infants delivered via ART procedures to guarantee genetic accuracy.
- **Accreditation of ART Clinics:** A definitive timeframe for the accreditation of ART clinics must be instituted to avert the operation of clinics by unqualified individuals lacking enough knowledge of reproductive gynecology.
- **Criminal culpability for Negligence:** In instances of egregious negligence, such as the utilization of erroneous genetic material or the omission of critical genetic tests, criminal culpability, including incarceration, should be enforced for the medical personnel implicated.

Conclusion:

The legal framework around medical negligence in India is progressing, marked by heightened awareness and available remedies for victims. Nonetheless, reconciling patient rights with equitable treatment for healthcare practitioners continues to be a significant concern. With the expansion of IVF and surrogacy operations, it is crucial to ensure compliance with legal norms to mitigate dangers linked to irresponsible activities in these delicate domains. Wrongful life and birth claims in India represent a burgeoning legal issue, especially with medical negligence in assisted reproductive technology operations. Recent verdicts have underscored the necessity for enhanced compliance with ethical norms and legal processes in ART clinics. As the legal landscape evolves, healthcare practitioners must maintain transparency and responsibility in their procedures to avert additional emotional and financial distress for families seeking reproductive assistance. Reconciling patient rights with the intricacies of ART treatments is a significant difficulty for the Indian legal system.

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