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Review Article

Medical negligence in assisted reproductive technology: a comparative legislative analysis of India and selected jurisdictions

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ABSTRACT

Assisted reproductive technology (ART) has rapidly advanced treatment of infertility and created new forms of medical malpractice that strain existing legal structures. This study investigates the treatment of medical malpractice with ART and analyzes the cases of India, Australia, Switzerland, Sweden, and New Zealand. This examination is both doctrinal and comparative. It studies primary legal documents, such as statutes, regulation, and case law, and focuses on recent publications. Common themes of negligence include failure to obtain informed consent, confused identity of embryos, false representation regarding success rates, violation of medical confidentiality, and insufficient regulatory oversight of fertility clinics. Based on comparisons, states with systems of independent accreditation and ethics - driven oversight have stronger protections. The ART Regulation Act, 2021 is a major improvement for India, but has significant shortcomings concerning negligence and compensation issues in ART. Clearer definitions and thresholds of negligence and stronger regulations and oversight of ART with mandatory periodic inspections and grievance redress mechanisms are needed to protect the rights of ART clients in India.

Keywords: Assisted reproductive technology, Legislative analysis, Medical negligence

INTRODUCTION

Assisted reproductive technology (ART) encompasses a variety of medical techniques designed to aid individuals and couples facing infertility. ART plays a crucial role to help families realize their dreams of parenthood when natural conception is not possible. ART is one of the latest and unique mechanism for a remarkable transformation in human reproduction as traditional methods do not work then the parents have to work in with reference to the ART where the technology has advanced using pharmaceutical and technological innovation is fundamentally changing the way parents have children. Rapid technological developments in ART have outpaced the evolution of regulatory frameworks, where the legislative or the regulatory authority is lagging behind with the laws from fertility drudge to inter uterine in semination to *in vitro* fertilization (IVF) and intracytoplasmic sperm injection (ICSI), modern medicine has paved the way for millions.¹

Infertility is a condition of your reproductive system that causes a male and female reproductive system by the failure to achieve pregnancy after 12 months or more of regular unprotected sexual intercourse, infertility may occur due to male, female or unexplained factors.

Some causes of infertility are preventable; treatment may require some forms of intervention through IVF or other types of ART.

Research gap

Existing scholarship predominantly focuses on the ethical and regulatory dimensions of ART. However, limited attention has been devoted to examining ART - specific medical negligence through a comparative legislative lens, particularly within the Indian context and to provide reproductive justice.²

Research questions

What forms of medical negligence arise within ART practice? How do selected jurisdictions regulate ART - related negligence? Does the Indian framework adequately address such negligence? and What reforms are necessary?

METHODS

The study adopts a doctrinal and comparative legal research methodology. Primary sources include the ART (Regulation) Act, 2021, foreign statutes, governmental reports, and judicial decisions. Secondary sources comprise peer - reviewed journal articles, policy documents, and scholarly commentaries. Australia, Switzerland, Sweden, and New Zealand were selected owing to their distinct regulatory approaches to ART and varying mechanisms of stakeholder protection. Comparative analysis was undertaken to identify best practices relevant to the Indian legal framework.

STAKEHOLDERS IN OF ASSISTED REPRODUCTIVE TECHNOLOGY

Medical professionals and clinics clinical teams perform procedures, maintain records, and carry duties of care and informed consent; regulatory frameworks focus on licensing, standards, and malpractice accountability. Intended parents and commissioning couples' prospective parents seek services, make treatment choices, and may bring negligence claims when outcomes or disclosure practices are problematic. Gamete and embryo donors supply genetic material and raise legal questions around anonymity, consent, and future parentage or access to information, which legislation treats variably across jurisdictions. Surrogates and gestational carriers' surrogates' legal status, remuneration rules, and criminalisation (in some states) affect the availability and legality of surrogacy arrangements and parenthood recognition. Children born from ART The child's legal status, rights to identity and welfare, and the implications of parental recognition are recurrent concerns in statutory and judicial analysis. Regulators, courts, and professional bodies government agencies, legislation, judicial decisions, and professional organizations shape standards, enforce compliance, and adjudicate disputes over parentage and malpractice.³

REGULATIONS IN ASSISTED REPRODUCTIVE TECHNOLOGY

Australia

A comprehensive evaluation of assisted reproduction (AR) in Australia, balancing medical history with a critique of current social research. The legislative frameworks and funding structures, such as Medicare rebates, that govern how fertility services are delivered across different states. A significant portion of the text addresses the discrepancy between public perceptions of success and the actual, often

lower, clinical birth rates. Furthermore, the source examines the emotional and physical toll on women, highlighting how the process can reinforce gender inequalities and objectify the female body. Ultimately, it creates a shift toward holistic social research that prioritizes the lived experiences of patients over purely biomedical outcomes. This overview serves to inform ongoing debates regarding government expenditure and the need for more transparent communication in the fertility industry. Assisted reproduction in Australia, highlighting the tension between medical advancements and the lived experiences of patients.⁴ The author critiques the dominance of the biomedical model, arguing that the industry's focus on technical success often obscures the significant emotional, physical, and financial tolls placed on women and their partners. By contrasting inflated public expectations with actual clinical success rates, the text exposes a lack of transparent information regarding the risks and the likelihood of involuntary childlessness following treatment. A shift toward qualitative social research to better understand the gender inequities inherent in these technologies and to provide more holistic psychosocial support for those navigating the complexities of infertility.

A rapid review of Australia's ART sector was commissioned to evaluate whether the industry's historical model of self - regulation remains sufficient in a modern, high - demand market. That has identified a fragmented governance landscape involving six entities, which has led to inconsistent oversight, limited enforcement powers, and barriers to informed consumer choice.⁵ To address these weaknesses, this study proposes ten strategic reform opportunities, most notably the establishment of an independent accreditation entity and the creation of rigorous national quality standards. Ultimately, this review serves as a blueprint for national reform, aiming to transition the ART sector toward a more transparent, harmonized, and patient - centered regulatory framework by 2027. The Western Australian government has introduced the ART and Surrogacy Act 2025, a modernized legislative framework designed to replace outdated laws by mid - 2027.⁶ This new statute prioritizes the best interests of the child while significantly expanding access to fertility treatments and surrogacy for single individuals, same - sex couples, and gender - diverse individuals. By streamlining administrative processes and disbanding the reproductive technology council, the reform reduces the regulatory burdens on clinics and clarifies the legal pathways for parentage transfers in surrogacy arrangements. Furthermore, the Act enhances the protection of donor - conceived individuals by facilitating better access to identifying information and maintaining strict oversight of clinical safety standards. With a specific focus on the state of Victoria's pioneering role in establishing world - first, comprehensive legislation.⁷ Its regulatory frameworks were designed to provide a legal and ethical structure for IVF, evolving over decades to prioritize the welfare of donor - conceived children through mandatory counselling and transparent

information registers. Key ideas include the shift toward prohibiting anonymous donations, the strict regulation of altruistic surrogacy, and the implementation of national quality assurance standards to improve medical outcomes, such as reducing multiple births. Ultimately, it highlights the ongoing challenges posed by an increasingly corporate and globalized fertility industry, emphasizing the need for regulations to keep pace with cross - border care and shifting societal demographics. A comprehensive statistical report, produced by the national perinatal epidemiology and statistics unit at UNSW Sydney, details the state of assisted reproductive technology across Australia and New Zealand. Published on medical data from 2023 to provide a comprehensive overview of fertility treatments, including IVF procedures, donor cycles, and pregnancy outcomes. Serving as a formal accountability and accreditation tool, the report utilizes the ANZARD database to track clinical success rates, long - term treatment trends, and perinatal health statistics. By compiling these data, the report aims to offer transparent national information to assist healthcare providers and researchers in improving reproductive health services.⁸ Australia also has a statutory body for accreditation under the department of health, disability and ageing under which they have suggested that the Australian commission on safety and quality in health care should be developed an independent national accreditation system for ART's services across Australia which the project began in April 2026 which focuses on standards of the ART and to safe guards the consumers protection from Medical Negligence and as well as to maintain the standards.

Switzerland

A comprehensive evaluation of assisted reproductive technologies, balancing medical history with a critique of current social research. The legislative frameworks and funding structures, such as medicare rebates, that govern how fertility services are delivered across different states. The discrepancy between public perceptions of success and the actual, often lower, clinical birth rates. Furthermore, the emotional and physical toll on women, highlighting how the process can reinforce gender inequalities and objectify the female body. It calls for a shift toward holistic social research that prioritizes the lived experiences of patients over purely biomedical outcomes. This serves to inform ongoing debates regarding government expenditure and the need for more transparent communication in the fertility industry. ART, beginning with the biological reality that humans possess a relatively low natural fertility rate.⁹ Medical interventions into three levels of complexity, ranging from simple insemination to advanced IVF and surgical gamete retrieval. Beyond describing procedural mechanics like ICSI and genetic screening. Clinical success rates alongside potential public health risks, such as multiple births and ovarian hyperstimulation. The growing crisis of infertility in Switzerland, positioning it as a significant public health and demographic challenge. The structure first highlights the emotional and financial toll on

individuals, then explores the medical and societal causes - such as delayed parenthood - and concludes by critiquing Switzerland's restrictive legislation and high costs compared to other European nations. By weaving personal narratives with expert commentary, the current Swiss policies create barriers to reproductive care, forcing many to seek treatment abroad or abandon their hopes of starting a family. The purpose is to advocate for a reassessment of family support systems and healthcare coverage to address falling birth rates and ensure more equitable access to assisted reproduction.¹⁰ ART to nations with limited resources, marking a transition from skepticism to constructive innovation. Historically, infertility in these regions was overlooked due to high costs and a focus on prevention; however, the profound social stigma of childlessness necessitates the development of low - cost IVF protocols. The international initiatives aimed at simplifying medical procedures and improving surveillance and reporting to ensure safety and quality.¹¹ ART may act as a critical factor in fetal programming, potentially influencing a person's health from birth into adulthood. While these technologies have successfully addressed global infertility, synthesize evidence suggesting that the in vitro environment and embryo manipulation may trigger epigenetic changes that increase the risk of certain complications. The heightened liability for preterm births, low birth weight, and specific congenital malformations affecting the cardiovascular and urogenital systems. Because the oldest individuals conceived via ART are only in their mid - forties, there is a need for long - term monitoring and transparent clinical counseling to prepare families for potential late - onset metabolic or neuropsychiatric conditions.¹¹ ART in Switzerland, highlighting a significant tension between medical progress and restrictive national legislation. While global advancements in embryo selection and freezing techniques have successfully lowered the risks of multiple pregnancies and neonatal complications, the Swiss legal constraints have prevented the adoption of safer, more effective protocols. Consequently, it increases health risks for mothers and infants due to the continued transfer of multiple embryos and the prohibition of cryopreservation.¹³

Sweden

The UppStART study is a comprehensive Swedish research project designed to investigate how ART and various lifestyle factors influence both the success of fertility treatments and the long - term health of resulting offspring. By tracking nearly a thousand participants through clinics in Stockholm and Uppsala, researchers collected extensive biological samples and survey data to explore potential epigenetic alterations in infants conceived via procedures like IVF. This prospective cohort study uniquely includes data from both women and men, linking their personal health and habit information to national quality registers for lifelong monitoring of medical and educational outcomes.¹⁴ The CoNARTaS project leverages the unique personal registration systems

of Nordic countries to build a massive, integrated database tracking the health of children conceived through assisted reproductive technology. By linking national health and socio - economic records, researchers can conduct long - term epidemiological studies on medical risks like cardiovascular disease and diabetes, as well as academic performance. This collaborative effort provides unparalleled data quality and scale, allowing scientists to compare tens of thousands of ART - conceived infants against a much larger control group of naturally conceived children.¹⁵ By analyzing over a million children, researchers concluded that those conceived through medical intervention do not face a significantly higher risk of mood or anxiety disorders compared to those conceived naturally. While a minor initial link was found between ARTs and obsessive - compulsive disorder, this connection largely vanished once the researchers accounted for parental characteristics and background factors.¹⁶

The Swedish national council on medical ethics concerning the legal and moral frameworks of fertility treatments in Sweden. Driven by advancements in medical science and shifting societal values, the text proposes expanding access to treatments while maintaining a focus on the best interests of the child and the principle of human dignity. Key themes include the endorsement of embryo donation, the debate over altruistic versus commercial surrogacy, and the right of children to eventually access information about their genetic origins.^{17,18} Influence of public acceptance of ART in Italy. Using a factorial survey experiment, they presented respondents with hypothetical scenarios to determine why attitudes toward fertility treatments are often highly polarized yet simultaneously context - dependent. The ideological and cultural orientations drive extreme opinions, support for medical intervention increases significantly when couples face advanced maternal age or long - term infertility. Conversely, factors such as high costs, the use of donor gametes, and already having children tend to reduce societal approval. Infertility should be viewed through a socio - demographic lens rather than a purely medical one, as the decision to seek help is deeply embedded in socially constructed values regarding family and biological relatedness.¹⁹

New Zealand

New Zealand has integrated ethical review into the governance of assisted human reproduction, moving from early secrecy to a structured national framework. It highlights a shift toward bi - culturalism, where policy is increasingly shaped by the Treaty of Waitangi to ensure that both European and indigenous Maori values - particularly regarding tribal identity and genetic heritage - are respected. Because the government initially lacked a centralized regulatory body, ethics committees effectively became the primary policy makers, establishing standards for clinical accountability and patient rights. Ultimately, how New Zealand has pioneered a uniquely open system

of information sharing that prioritizes the rights of the child and cultural sensitivity over traditional medical paternalism.²⁰ Ethical and legal contradictions in New Zealand's medical landscape, where advanced fertility treatments like IVF and genetic screening are widely accessible while human embryo research remains strictly prohibited. The "restrictive by default" status is inconsistent because the safety and progression of IVF inherently rely on the very research that the country currently forbids. By exploring various regulatory models, how New Zealand depends on scientific data from overseas while thousands of local surplus embryos are eventually destroyed rather than used to advance medical knowledge.²¹ Aotearoa - New Zealand established a ten - year limit on frozen embryo storage, arguing that the policy was driven by a Pākehā cultural desire for "tidy housekeeping" rather than universal bioethical principles. Through a critical discourse analysis of parliamentary debates, they reveal how officials prioritized conflict avoidance and the prevention of embryo accumulation while systematically marginalizing indigenous Māori perspectives regarding spiritual kinship and genealogical sovereignty. A significant disconnect between rigid bureaucratic regulations and the social suffering experienced by families and clinic staff forced to navigate the emotional burden of mandated embryo destruction.²² Bill Atkin interpreted the human ART Act 2004, a legislative framework that replaced New Zealand's former unregulated approach with a flexible "middle way" model. Where he begins by comparing this system to those in Canada and Australia, highlighting how New Zealand balances pluralist social values and ethical concerns through seven core statutory principles. At its heart, a tripartite regulatory structure consisting of clear prohibitions on controversial acts like cloning, an advisory committee for evolving policy, and an ethics committee to review specific medical applications.²²

The report, produced by the University of New South Wales and the advisory committee on ART, provides a comprehensive statistical analysis of fertility treatments in New Zealand for the year 2021. This is structured into nine chapters that detail various procedures, ranging from IVF to embryo donation and surrogacy, while specifically monitoring the success rates and demographic trends of patients. The data is the continued increase in the use of these technologies, noting that a significant majority of patients utilize their own genetic material in autologous cycles. The report serves a statutory role in monitoring clinical outcomes and providing essential data to healthcare providers, researchers, and consumers to ensure the transparency and advancement of reproductive health services.²⁴

India

ART offer a vital solution for infertility, they simultaneously introduce a complex web of ethical, social, and legal challenges within the Indian context. The text explores the evolution of these technologies - from the

historic birth of the first IVF baby to modern procedures like surrogacy - while highlighting the absence of a comprehensive national regulatory framework to govern clinics and protect stakeholders.²⁵ Legal complications, such as tortious liability for medical negligence and disputes over parental rights in commercial surrogacy cases, underscore the urgent need for formal legislation like the surrogacy (regulation) bill.²⁶ Beyond the law, the source addresses deep - seated social stigmas and economic barriers, noting that high costs and unequal access often limit these life - changing procedures to the wealthy.²⁷ India's evolving legislative framework for ART and surrogacy. The progression of national guidelines from their inception in 2002 to the 2014 ART Bill and 2016 surrogacy bill, highlighting a shift toward stricter regulations and the prohibition of commercial surrogacy. By identifying various "grey zones," such as the lack of provisions for HIV - discordant couples and overly restrictive donor age limits, the text argues that current proposals need further refinement to balance patient rights with the protection of medical practitioners. The standardized national registry and updated legal standards that can keep pace with rapid advancements in reproductive science.²⁸ ART (regulation) bill, 2020, arguing that the proposed legislation is exclusionary and structurally flawed. They highlight how the bill reinforces heteronormative marriage by denying access to single men, cohabiting couples, and the LGBTQ+ community, which likely violates constitutional guarantees of equality and privacy. It critiques the shift toward an altruistic model that prohibits compensating women for their reproductive labor, suggesting this lack of remuneration qualifies as forced labour under Article 23 of the Indian constitution. The significant lack of complementarity between this bill and the surrogacy (regulation) bill, noting that their contradictory definitions and mismatched penalties will likely result in ineffective regulation and legal challenges.²⁹ Indian legal framework governing ART, highlighting the persistent tension between a rapidly expanding fertility industry and inadequate regulatory oversight. To explore critical medical malpractices, such as the operation of unregistered clinics, the dissemination of deceptive advertisements regarding success rates, and the failure to obtain genuine informed consent from patients and surrogates. While the 2021 ART and surrogacy acts established new standards, the text argues that significant legislative gaps remain, often leaving victims to seek financial redress through the consumer protection act instead and the advocates for stringent enforcement mechanisms, including mandatory audits and fast - track courts, to protect vulnerable stakeholders from exploitation and substandard care.³⁰ The medical, legal, and ethical frameworks that direct the work of embryologists within India's expanding ART sector. How the ART (regulation) act, 2021 serves as a vital foundation for standardizing laboratory practices, ensuring informed consent, and maintaining strict patient confidentiality to prevent exploitation.³¹ Beyond legal compliance, it emphasizes the technical necessity of quality control and

sterility in the laboratory to improve clinical outcomes and safeguard the health of both patients and embryos.³³

MEDICAL NEGLIGENCE IN ART PRACTICE CASE ANALYSIS

In the case of Samira Kohli versus Dr. Prabha Manchanda and Anr, the supreme court ruled in favor of Samira Kohli, holding Dr. Manchanda liable for performing a surgery without the requisite informed consent.³⁴ The court awarded Kohli compensation for the violation of her rights, marking a significant precedent in patient rights and informed consent in India. It shows a key aspect that the clinics or hospitals have to undergo the principle of disclosure and consent related to the failure of informed consent which can lead to medical negligence. M/s. Spring Meadows Hospital Ano Anr versus Harjol Ahulwalia through K.S. Ahulwalia and Anr the supreme court of India's judgment in M/s. Spring Meadows Hospital and Anr V. Harjol Ahluwalia is a case in Indian consumer law, profoundly impacting the scope of medical negligence compensation and clarifying the broad ambit of the consumer protection act, 1986.³⁵ This pivotal ruling, which is authoritatively documented on CaseOn, establishes that in cases of medical negligence, not only the patient but also their parents can be considered 'consumers' and are entitled to separate compensation for the mental agony they endure. The child was admitted to Spring Meadows Hospital for the treatment of typhoid fever. A hospital nurse, later found to be unqualified, administered an intravenous injection of Lariago without conducting a preliminary sensitivity test. Immediately after the injection, the child suffered a cardiac arrest and collapsed. The resulting delay in proper medical intervention caused irreparable brain damage, leaving the child in a permanent vegetative state. The child's parents filed a complaint before the national consumer disputes redressal commission (NCDRC), alleging gross negligence and deficiency in service. The NCDRC ruled in their favor, awarding compensation because of the medical negligence that the hospital ignore the principle of the duty of care which led to the medical negligence and the victim who fell into persistent vegetative state. In the case of Sushil Kumar versus Javitri Hospital and Test Tube Baby Center judgement decided by state consumer disputes redressal commission, U. P. Lucknow an infertile couple underwent IVF treatment and successfully conceived.³⁶ During pregnancy, the hospital conducted several prenatal tests and scans, all of which reportedly indicated normal fetal development. However, the child was born prematurely with severe congenital abnormalities, including VACTERL association and anal atresia. The parents alleged medical negligence, claiming that the hospital failed to detect these anomalies despite repeated examinations. The commission examined the standard of care required in prenatal diagnosis and ART services, emphasizing that fertility clinics may be held liable for deficiencies in diagnosis, monitoring, and patient care.

Table 1: Comparative table.

Country	Licensing	Negligence	Compensation	Oversight
Australia	Strong regulations	Developed	Available	Independent body
Switzerland	Strict compliances	Moderate description	Limited to certain issues	Federal body
Sweden	Child - centric provisions	Moderate description	Under administrative authority	National body
New Zealand	Ethics - based system	Moderate description	Regulatory provisions	Advisory committee on art
India	Developing system	Unclear provisions	As per consumer law	Ministry of family welfare

In the case of Johathan Yearworth and others Versus North Bristol NHS Trust (2009) is a landmark decision concerning the legal status of stored human sperm and liability for its negligent destruction in England and Wales Court of Appeal.³⁷ Six men undergoing cancer treatment deposited sperm samples with the NHS Trust for storage before chemotherapy, which could render them infertile. Due to the Trust's failure to maintain liquid nitrogen levels in storage tanks, the sperm samples were irretrievably destroyed. The claimants sought damages for negligence and the emotional distress caused by the loss of their opportunity to father children.

The Trust argued that sperm could not constitute property and therefore could not support a claim for property damage. The court of appeal rejected this argument and held that the men possessed proprietary rights over their stored sperm because they had generated it, retained control over its use, and could direct its destruction. The court further recognized a cause of action in both negligence and bailment, establishing that stored reproductive material can attract property rights and legal protection.

In the case of Perry - Rogers V. Fasano arose from an IVF clinic's error in which embryos created from the genetic material of Deborah Perry - Rogers and Robert Rogers were mistakenly implanted into Donna Fasano.³⁸ Although the mistake was discovered during pregnancy, the Fasanos retained custody of the child after birth until DNA testing confirmed that the infant, Akeil Rogers, was genetically related to the Rogerses.

The Fasanos subsequently relinquished custody but sought visitation rights based on their status as the child's gestational family and the emotional bond formed with the child. The New York appellate division held that the Rogerses, as the genetic and intended parents, were the child's legal parents and entitled to exclusive custody.

The court denied visitation rights to the Fasanos, reasoning that gestational motherhood alone did not confer parental status in these circumstances. The decision emphasized the primacy of genetic and intended parenthood in resolving disputes arising from accidental embryo implantation and reproductive technology errors.

MIS - INFORMATION RELATED TO ASSISTED REPRODUCTIVE TECHNOLOGY

Misinformation about reproductive health threatens to harm health outcomes, compromise medical trust, and enable misinformed policy restrictions.³⁹ In recent years, reproductive health misinformation has proliferated online due to ideological campaigns and limited content moderation for reproductive health topics.⁴⁰ Developing evidence - based practices to counter reproductive health misinformation requires an understanding of the content that women are exposed to online, which is currently lacking.

CONCLUSION

This study demonstrates that although the ART (regulation) Act, 2021 has strengthened regulatory oversight of fertility clinics in India, it does not adequately address ART - specific medical negligence and patient compensation. Then continue with: comparative analysis of Australia, Switzerland, Sweden, and New Zealand reveals that effective governance requires not only licensing and regulation but also independent accountability mechanisms, clear standards of care, and accessible remedies for patients affected by negligence. A comparison suggests that effective ART governance involves not only licensing and supervision, but also standard of care, independence of oversight, and the right to demand compensation. In India (as in some other countries) ART practitioners are covered by the general professional negligence framework. Therefore, victims are forced to seek fragmented remedies in consumer courts. India's reproductive healthcare would benefit from adopting the Australia and New Zealand model. The focus of reforms in these countries is on caring, safe reproduction service, and technological advancement in reproduction accompanied by legal responsibility.

Recommendations

The increasing complexity of ART procedures and the growing number of negligence claims necessitate comprehensive regulatory reforms to enhance patient safety and accountability. One significant reform would be the establishment of a specialized ART Negligence Tribunal to adjudicate disputes involving fertility

treatments. Such a tribunal, staffed by legal and medical experts, would ensure faster, technically informed, and cost-effective resolution of claims compared to conventional courts and to provide adequate financial protection to patients affected by medical errors, mandatory professional malpractice insurance should be required for all ART clinics and practitioners. This would ensure timely compensation for victims while promoting greater professional responsibility within the fertility sector. A National ART Incident Reporting System should also be developed to document cases involving embryo mix-ups, equipment failures, laboratory errors, informed consent violations, and other adverse events. Such a database would facilitate transparency, enable evidence-based policymaking, and help identify systemic risks within ART services. And uniform informed consent protocol should be introduced at the national level to ensure that patients receive complete, comprehensible, and standardized information regarding treatment procedures, risks, success rates, alternatives, costs, and potential complications. Regular annual audits of fertility clinics should be made mandatory to assess compliance with legal, ethical, and clinical standards. These audits should evaluate laboratory practices, record-keeping systems, quality assurance measures, and adherence to patient safety protocols. An independent accreditation authority should be established to oversee the licensing, monitoring, and quality certification of ART clinics like in Australia. Such an authority would ensure uniform standards across the country and conduct periodic evaluations to maintain clinical excellence. The creation of an ART Ombudsman would provide patients with an accessible and independent mechanism for grievance redressal. The Ombudsman could investigate complaints, facilitate mediation, recommend corrective measures, and address systemic concerns, thereby enhancing public confidence in the ART regulatory framework. Together, these reforms would strengthen accountability, improve patient protection, and foster ethical and transparent practices in the rapidly evolving field of assisted reproduction.

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