

Review Article

Asian Pacific Journal of Reproduction

Journal homepage: <https://journals.lww.com/apjr/>

doi: 10.4103/apjr.apjr_185_24

Embryologists' perspective on medical, legal, and ethical frameworks in assisted reproductive technologies in India: A narrative review

Pavantej Macha¹, Rachana Reddy^{2✉}, Avanti Kalbande³, Vinod Kumar⁴¹Department of Clinical Embryology, Datta Meghe Medical College, Datta Meghe Institute of Higher Education and Research (DU), Wanadongri, Nagpur, Maharashtra, India²Department of FMT, Datta Meghe Medical College, Datta Meghe Institute of Higher Education and Research (DU), Wanadongri, Nagpur, Maharashtra, India³Department of IVF, Shalinitai Meghe Hospital and Research Center, Wanadongri, Nagpur, Maharashtra, India⁴Department of Law, Parul Institute of Law, Parul University, Limda, Whagodia, Vadodara, India

ABSTRACT

Reproductive medicine has been transformed by assisted reproductive technologies (ART), providing multiple options for infertile couples to conceive biological offspring. The medical and legal frameworks, governing the practice of embryologists in ART, focus on the ethical and safe handling of gametes and embryos. Embryologists play a crucial role in the success of ART procedures, requiring technical expertise and a thorough understanding of legal and ethical considerations. The importance of quality control, safety protocols, and sterility in ART laboratories is essential to ensure optimal embryo development and patient well-being. The legal responsibilities of an embryologist under the Assisted Reproductive Technology (Regulation) Act, 2021 in India are required. This review emphasizes the importance of record-keeping, patient confidentiality, informed consent, and adherence to legal and ethical standards to minimize the risk of malpractice claims. Overall, this narrative review provides a detailed overview of the medical, legal, and ethical frameworks governing embryologists' practice in ART, underscoring the significance of responsible and ethical conduct in this rapidly advancing field.

KEYWORDS: Bioethics; Legislation; Assisted reproductive technologies; Ethical dilemmas; Human rights and legal issues of health

children[2]. ART includes various treatment options designed to assist in achieving pregnancy when it is naturally challenging or unfeasible[3]. Advancements in medical diagnostics and therapeutic technologies in reproductive medicine led to the development and utilization of ART, which includes procedures such as IVF and embryo transfer[4]. Even today, a significant number of the estimated 27 million infertile couples in India, particularly those from low-income backgrounds, face limited access to ARTs[5]. ART involves a series of complex and often stressful procedures, such as daily self-administered injections, blood tests, ultrasounds, and laparoscopic surgeries[6,7]. Clinical embryology, an essential branch of ART, deals with the handling and examination of embryos for fertility treatments[8]. Clinical embryologists handle, assess, and care for human gametes and preimplantation embryos in an ART laboratory[9]. Embryologists are required not only to possess technical expertise but also to have a detailed understanding of the legal and ethical frameworks that govern their practice[10]. Advances in ART and clinical embryology raise ethical, legal, regulatory, and policy concerns that require frameworks and careful thought to ensure patient safety, ethical practices, and fair access[8]. When developing a framework to regulate ART practices in India, it is essential to consider various social, legal, ethical, and scientific factors[11]. Ethics and regulations in ART enable

✉To whom correspondence may be addressed. E-mail: rachanareddy739@gmail.com

This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

©2025 Asian Pacific Journal of Reproduction Produced by Wolters Kluwer- Medknow.

How to cite this article: Macha P, Reddy R, Kalbande A, Kumar V. Embryologists' perspective on medical, legal, and ethical frameworks in assisted reproductive technologies in India: A narrative review. *Asian Pac J Reprod* 2025; 14(2): 49-55.

Article history: Received: 24 October 2024; Revision: 29 December 2024; Accepted: 31 January 2025; Available online: 26 March 2025

1. Introduction

Assisted reproductive technology (ART) involves fertility treatments where gametes or embryos are managed outside the female body to enhance the chances of successful pregnancies and healthy offspring[1]. Since the birth of the world's first *in-vitro* fertilization (IVF) baby, Louise Brown, in 1978, the use of ART has grown, offering infertile couples hope for having their biological

patients to better understand their fertility treatments while also safeguarding them against exploitation by unethical individuals[4]. An infertility diagnosis can have psychological, emotional, and social consequences for the woman and those around her[12]. In clinical embryology, ethical concerns include, the rights of donors and recipients, and the moral standing of embryos[13]. It is estimated that there are over 5000 large and small centres in India providing ART services and there are prominent organizations like the Indian Society for Assisted Reproduction, the Indian Fertility Society, and the Association of Clinical Embryologists[14]. To regulate the operations of ART clinics and ART banks in India, the Assisted Reproductive Technology (Regulation) Act, 2021, was enacted by the Parliament on December 20, 2021[15]. This legislation focuses on ensuring proper oversight, regulation, licensing, and adherence to ethical practices within the rapidly advancing field of assisted reproduction and also these laws promote ethical practices, safeguard the rights of patients and children born through ART and prevent the exploitation of donors. The ART Act regulates the functioning of ART clinics and banks, ensuring standardization and accountability. ART law enhances transparency, protects vulnerable individuals, and upholds ethical standards in reproductive healthcare[2].

This narrative review aims to explore and evaluate the medical, legal, and ethical frameworks that govern the practice of embryologists in the field of ART. The review focuses on understanding how these frameworks ensure ethical and safe practices in the handling of gametes, embryos, and the overall ART procedures. Additionally, the objective is to provide a detailed overview of the medical frameworks, legal responsibilities, ethical considerations, and regulatory standards that embryologists must adhere to, highlighting the impact of recent legislation, such as the Assisted Reproductive Technology (Regulation) Act, 2021, on the profession and its practices in India and globally.

2. Methodology

A thorough literature search was conducted using electronic databases including primarily PubMed and Google Scholar, along with additional relevant sources, including government documents and reputable reports. Search terms included "assisted reproductive technology", "embryology", "legal framework", "ethical considerations", and "ART regulations in India". The review focused on peer-reviewed articles, government documents, and reputable reports published in English within the last 10 years, with emphasis on the most recent publications. Articles were selected based on their relevance to medical and legal aspects of ART for embryologists. Data extraction involved full-text review of selected articles to identify key information on medical protocols, legal regulations, and ethical guidelines. The extracted data were synthesized to identify major themes and frameworks. Critical analysis evaluated the strengths and limitations of existing frameworks, compared

regulations across regions, and identified gaps in current guidelines. The findings were organized into coherent sections on medical frameworks, ethical considerations, and legal regulations, with a focus on implications for embryologists' practice and recent legislative changes in India.

3. Results

The Indian government has recognized that commercial IVF treatments could lead to potential issues in the country. To ensure proper oversight and safeguard individual rights, there is a need for regulation in this area. Legal and ethical frameworks are crucial for embryologists to conduct research responsibly and ethically, safeguarding the rights of patients and the public[16].

3.1. Medical frameworks and quality control in ART laboratories

IVF and andrology laboratories are the core of ARTs, where technicians and embryologists handle gametes and preimplantation-stage embryos intended to produce the optimal embryo for transfer[17]. The objective of an IVF cycle is to achieve the birth of a healthy baby[18]. The methods of ART were categorized into four approaches based on sperm quality parameters and genetic factors: conventional IVF, intracytoplasmic sperm injection (ICSI), percutaneous epididymal sperm aspiration (PESA) or testicular sperm aspiration (TESA), and preimplantation genetic testing (PGT)[19]. The clinical embryologist is a vital professional, playing a key role in the care of patients undergoing IVF[20]. In IVF treatment, embryos with the greatest implantation potential are selected for either embryo transfer or cryopreservation. Research indicates that the ideal number of oocytes to retrieve per cycle is 15[21]. The final clinical outcomes of infertility treatment are significantly influenced by maintaining standard laboratory conditions, along with the manual skills, precision, persistence, and expertise of clinical embryologists[22]. Clinical embryologists have responsibilities beyond their technical expertise, particularly in ethical decision-making. They play a crucial role in making ethical decisions regarding embryo selection, cryopreservation, and handling gametes from seropositive individuals. This requires balancing medical knowledge with ethical considerations, ensuring compliance with regulations, and safeguarding patient privacy. Their decisions impact patient outcomes, require clear communication, and uphold ethical standards, especially in sensitive areas like ART and gamete handling. The embryology laboratory should have sufficient space to support proper laboratory practices and be located as close as possible to the operating theatre where clinical procedures are conducted[23]. Operating incubators require substantial quantities of specialty gases, while the cryopreservation and storage of gametes, embryos, and reproductive tissues rely heavily on liquid nitrogen[24].

Embryos produced through ARTs are vulnerable to contamination by microorganisms at different stages of the process. Particular focus is placed on viral pathogens like human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), with ART protocols specifically designed to minimize the risk of transmitting these potentially life-threatening viruses[25,26]. It emphasizes the importance of using rigorous sterile methods at every stage of the procedure; recent guidelines on IVF lab conditions revealed the need to minimize the time of exposure of the gametes to uncontrolled external environments[27]. Furthermore, while current guidelines require all IVF clinics and laboratories to maintain records of all procedures, their annual reports infrequently provide data on the prevalence of microorganisms, making it challenging to accurately estimate the frequency of microbial contamination in ART laboratories[25]. In ART laboratories, strict protocols are implemented to minimize contamination risks and ensure the safety and quality of gametes and embryos. High-efficiency particulate air (HEPA) filters are used to maintain clean air by removing airborne particles, including dust, bacteria, and viruses, ensuring a sterile environment. Sterile workspaces, such as laminar flow hoods, are designed to provide contamination-free zones for handling sensitive biological materials. Regular sterilization of equipment, adherence to aseptic techniques, and controlled laboratory conditions further enhance safety and reduce the risk of contamination during procedures.

Quality control and safety protocols in ART and embryology laboratories are essential for successful fertility treatments, safeguarding patient well-being, and upholding ethical standards[28]. Recent studies have demonstrated that strict compliance with quality control measures, such as regulating laboratory temperature, humidity, and gas concentrations, can greatly enhance the developmental potential of embryos, resulting in higher implantation

and live birth rates[29]. A study conducted by Zander-Fox *et al* revealed that regular monitoring of environmental parameters leads to a reduction in embryo arrest and degeneration, ultimately resulting in improved clinical outcomes in ART cycles[30,31]. Ensuring sterility in ART laboratories is crucial to avoid contamination of gametes and embryos, as it can impact fertilization success and embryo growth.

3.2. Legal framework: Regulation of ART in India

After sixteen years of exploration, including eight drafts and three parliamentary committees, the Indian government concluded its legislative process with the passage of the ART (Regulation) Act, 2021 in December 2021[5]. Durga, the first IVF baby born in Kolkata in 1981 through Dr. Subhash Mukhopadhyay's efforts, was not officially recognized by the government for moral and ethical reasons, while in 1986, Dr. T. C. Anand Kumar and Dr. Indira Hinduja's claim of having created India's first IVF baby, Harsha, was accepted by the Indian Council of Medical Research (ICMR)[2]. The 2021 Act describes a couple as an "Indian man and woman" who are married, over the ages of 21 and 18, respectively, thereby excluding individuals in live-in relationships from accessing these services[32].

3.2.1. Key provisions of the Assisted Reproductive Technology Act

The Assisted Reproductive Technology Act defines ART as mentioned in Figure 1 and it is any method aimed at achieving pregnancy by handling sperm or oocytes outside the human body and transferring the gametes or embryos into a woman's reproductive system. This includes procedures such as gamete donation (sperm or egg), IVF. ART clinics will deliver related treatments and procedures,

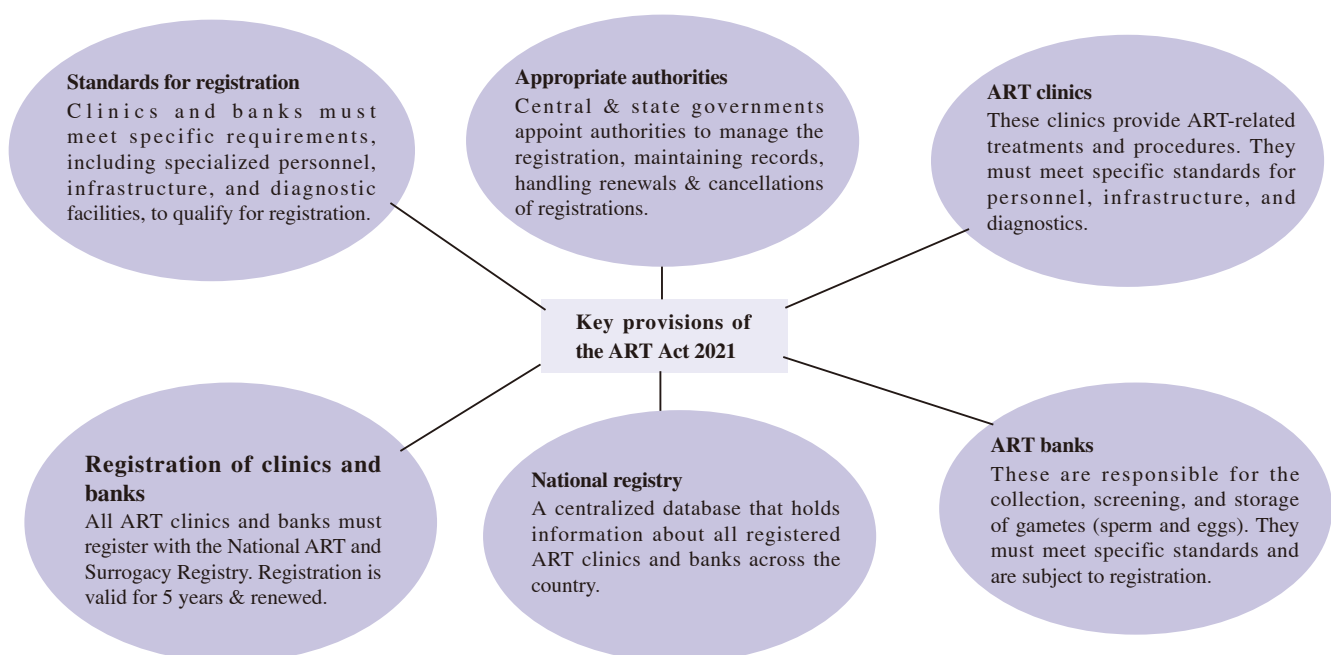


Figure 1. The key provisions of the Assisted Reproductive Technology Act, 2021 related to assisted reproductive technologies (ART).

and ART banks, are responsible for the collection, screening, and storage of gametes[33].

3.2.2. Legal responsibilities of embryologists

Embryologists must follow the responsibilities, rights, duties, and principles outlined in the Assisted Reproductive Technology (Regulation) Act of 2021[2]. They are responsible for ensuring that all actions taken, or any omissions, do not harm the well-being, safety, or interests of the patients, gametes, and embryos entrusted to them[34]. To fulfill the legal responsibilities of the embryologist, one should be aware of the Surrogacy (Regulation) Act, 2021, and the Assisted Reproductive Technology (Regulation) Act, 2021.

Embryologists must maintain detailed records of all procedures, including the retrieval, fertilization, storage, and usage of gametes and embryos. These records must be preserved for a minimum period, typically 10 years as mandated by law, and can only be accessed by authorized personnel under legally defined circumstances[35]. Failure to maintain proper records under the ART Act, 2021, can lead to penalties, suspension, or revocation of registration. If improper record-keeping causes fraud, privacy violations, or harm, criminal charges may apply. Accurate documentation is essential for accountability and legal compliance. Embryologists are responsible for safeguarding the privacy of patients and donors by ensuring the confidentiality of sensitive information, including donor identities, medical histories, and genetic data. Any unauthorized disclosure of this information would violate the ART Act and could lead to legal consequences[14].

Embryologists must obtain written informed consent from patients or donors before any procedures involving gametes or embryos, clearly explaining the risks, benefits, and alternatives. They must also ensure accurate documentation of consent forms in the patient's medical records, and obtain new consent for any procedural changes. The ART Act mandates that consent forms must be in the formats outlined in Forms 15 and 16 of the Assisted Reproductive Technology (Regulation) Rules, 2022. These standardized forms ensure consistency and clarity in obtaining consent from all parties involved.

Embryologists in India are legally liable under the Indian Penal Code and medical regulations. Negligence in handling gametes or embryos, such as damage, improper storage, or protocol breaches, can result in fines, penalties, or license suspension. Adhering to ethical practices and ART guidelines helps prevent malpractice claims, which may lead to civil or criminal charges[36]. Embryologists face challenges in maintaining legal and ethical standards, including record-keeping for up to 10 years, balancing patient privacy with legal requirements, and ensuring proper consent, which demands significant time and resources.

3.2.3. Sperm and oocyte donors

According to section 2(1)(h) taken from ART Act, a gamete donor is an individual who donates sperm or eggs to help an infertile couple or woman conceive a child[37].

3.2.3.1. Requirements for the sperm donor

The donor must be between 21 and 55 years of age and free from infections such as HIV, hepatitis B, and C, as well as conditions like hypertension, diabetes, sexually transmitted diseases, and genetic disorders like thalassemia. Additionally, the individual's semen must undergo analysis preferably using a semen analyzer, and meet the normal parameters outlined in the recent WHO manual for semen analysis if the sample is intended for use in ART. Relevant donor information, including height, weight, age, educational background, profession, skin and eye color, a history of major illnesses (including psychiatric conditions), and family medical history (particularly any hereditary disorders), should be documented in a suitable proforma.

3.2.3.2. Requirements for the oocyte donor

The donor must be not less than 23 and not more than 35 years of age and free from infections such as HIV, hepatitis B, and C, as well as conditions like hypertension, diabetes, sexually transmitted diseases, and genetic disorders like thalassemia. Relevant information about the donor, including height, weight, age, educational background, profession, skin and eye color, as well as family history regarding any genetic or familial disorders, should be documented using a standardized proforma.

The guidelines for the security, recording, and identification of gametes and human embryos during storage and handling, as outlined in subsection (1) of Section 28 taken from ART Act. A bank must gather all required information regarding a sperm or oocyte donor, including the donor's name, Aadhaar number (as defined in clause (a) of section 2 of the Aadhaar [Targeted Delivery of Financial and other Subsidies, Benefits, and Services] Act, 2016 [18 of 2016]), address, and any other prescribed details. The law requires that the identities of sperm and egg donors remain confidential and not be disclosed to the child, the intended parents, or any other party. This ensures donor anonymity, safeguarding the confidentiality of the process and preventing potential legal or social complications that could arise from revealing the donor's identity in the future and the bank must also obtain a written agreement from the donor to ensure this information's confidentiality as mentioned in Table 1[37,38]. The donor must be covered by insurance, and children conceived through ART should have rights equivalent to those of biological children, as stated by the government[39].

3.3. Ethical considerations in ART

Ethics in medicine contains a framework of principles that professionals can utilize when facing challenging decisions and

Table 1. The regulatory framework designed to balance the rights of donors with their responsibilities, ensuring ethical practices in gamete donation in India.

Aspects	Rights of gamete donors	Responsibilities of gamete donors
Anonymity	Gamete donors have the right to remain anonymous.	Must not attempt to reveal identity to the recipient or offspring.
Consent	Donors must provide informed consent before donation.	Must be fully aware of the process and provide explicit written consent.
Compensation	Donors are entitled to compensation for expenses.	Cannot demand or receive additional payments beyond permissible limits.
Medical testing	Donors have the right to receive detailed medical evaluations.	Must undergo medical and genetic screening as per legal requirements.
Legal parenthood	Donors have no parental rights or responsibilities.	Must waive any future claims to parental rights over the offspring.
Withdrawal of consent	Donors have the right to withdraw consent before the use of gametes.	Must communicate any withdrawal of consent before the gametes are used.
Health and safety	Donors have the right to safe medical practices during the donation process.	Must follow medical guidelines and attend required medical appointments.
Confidentiality	Personal information of donors is kept confidential.	The confidentiality of the process and participants must be respected.
Usage of gametes	Donors have the right to be informed about the purpose of the donation (<i>e.g.</i> , research, fertility treatment).	Must agree to the intended use of the gametes and cannot dictate their usage after donation.

the principles include respect for autonomy, non-maleficence, beneficence, and justice[40]. The field of clinical embryology presents crucial ethical dilemmas regarding the moral status of embryos, as well as the rights and responsibilities of both donors and recipients. Additionally, it raises concerns about the well-being of children conceived through ART. Navigating these ethical considerations requires careful attention to maintaining a balance between the progression of reproductive technologies and the protection of human dignity and rights. For example, decisions regarding the fate of embryos, the application of genetic screening, and the potential for selecting specific traits create significant moral challenges that must be thoughtfully addressed[8].

Preimplantation genetic diagnosis (PGD) improves the chances of selecting and transferring embryos that do not have genetic mutations or chromosomal abnormalities. Research indicates that it can boost implantation and lower the risk of miscarriages, particularly when paired with 24-chromosome aneuploidy screening[41]. PGD enables the identification of an embryo's sex for medical purposes, such as detecting X-linked disorders. However, this technology also poses the risk of misuse for non-medical sex selection. PGD requires embryo biopsy, which can affect implantation rate. Risks associated with PGD include lower pregnancy success rates compared to traditional IVF cycles and the technical complexity of the procedure, which demands specialized expertise. Non-invasive preimplantation genetic testing (niPGT) is a rapidly advancing area of reproductive medicine, designed to detect genetic abnormalities in embryos without requiring invasive procedures such as trophoctoderm biopsy. Recent studies have concentrated on examining cell-free DNA (cfDNA) present in spent culture medium (SCM) and blastocoel fluid to identify aneuploidies and monogenic disorders[42]. The use of non-invasive genetic testing poses ethical concerns related to embryo selection. Embryonic mosaicism, where cells within the same embryo have differing genetic compositions, can complicate

the interpretation of niPGT results. The presence of mosaicism may result in inaccurate assessments of embryo quality and viability[43]. Setting clear guidelines and regulations is crucial to address these issues effectively. In India, the ART Act, in conjunction with the Pre-conception and Pre-natal Diagnostic Techniques (PCPNDT) Act of 1994, strictly prohibits ART clinics from assisting couples in selecting a child's sex, except in cases where it is necessary to prevent or treat sex-linked genetic conditions[44]. Although cases involving PGD remain legally and ethically debated, many patients view it as their preferred or, the only viable option for achieving a pregnancy with a healthy child. Children born through ART procedures will have the same rights as natural heirs or biological children of the couple. They will be recognized as the biological offspring of the couple and will be entitled to all the rights and privileges afforded to a natural child of the commissioning couple. Donors will have no rights concerning the child[39].

The ART Act enforces strict regulations under clauses 22.3, 24.g, and 30.1 taken from ART Act, which prohibit the use of embryos for purposes other than ART, forbid the use of ova derived from a fetus in IVF procedures, and strictly ban the export of gametes or embryos from India for research or stem cell purposes. However, in certain circumstances where an embryo is impacted by a pre-existing, hereditary, life-threatening, or genetic condition, making it unsuitable for ART, clause 25.2 of the Act allows for the donation of the embryo for research, provided that written consent is obtained from the commissioning couple[2,39,44].

4. Conclusions

The Assisted Reproductive Technology (Regulation) Act, 2021, provides a much-needed regulatory framework for the rapidly growing ART sector in India. Embryologists, as key players in

ART, must navigate both the technical demands and the legal responsibilities set forth by the ART Act to ensure patient safety, ethical integrity, and adherence to regulations. Continuous updates to the legal frameworks are much needed to address these issues and adapt to evolving societal, ethical, and medical contexts. Ultimately, a balanced approach that prioritizes patient safety, ethical practices, and scientific innovation will be essential to ensure that ART services in India are accessible and aligned with the principles of patient autonomy and welfare, providing the way for responsible advancements in reproductive technology in India.

Conflict of interest statement

The authors declare no competing interests.

Funding

The study receives no extramural funding.

Authors' contributions

Pavantej Macha contributed to the conception and design of the study, as well as the drafting and revision of the manuscript for important intellectual content. Rachana Reddy provided expertise in bioethics, contributing to the legal and ethical analysis and interpretation of data, as well as reviewing the manuscript for accuracy. Avanti Kalbande contributed to the clinical aspects of assisted reproductive technologies, providing insights into the practical implications of medical and ethical guidelines, and reviewing the manuscript for clinical relevance. Vinod Kumar provided expertise in legal frameworks, contributed to the analysis of regulatory policies governing assisted reproductive technologies in India, and ensured the legal accuracy of the manuscript.

Publisher's Note

The Publisher of the *Journal* remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

References

- [1] Graham ME, Jelin A, Hoon AH, Wilms Floet AM, Levey E, Graham EM. Assisted reproductive technology: Short- and long-term outcomes. *Dev Med Child Neurol* 2023; **65**(1): 38–49.
- [2] Jamwal VDS, Yadav AK. The Assisted Reproductive Technology (Regulation) Act, 2021: A step in the right direction. *Indian J Community Med* 2023; **48**(1): 4–6. doi: 10.4103/ijcm.ijcm_169_22.
- [3] Mapari SA, Shrivastava D, Bedi GN, Pradeep U, Gupta A, Kasat PR, et al. Revolutionizing reproduction: The impact of robotics and artificial intelligence (AI) in assisted reproductive technology: A comprehensive review. *Cureus* 2024; **16**(6): e63072. doi: 10.7759/cureus.63072.
- [4] Barnes T, Abakah-Nkrumah G, Oboshie Anim-Boamah O, Sefogah PE. Legal and ethical challenges in assisted reproductive technology practice in Ghana. *GMJ* 2024; **58**(1): 78–85.
- [5] Tank J, Kotiswaran P, Tank P, Tank D, Tank J. Voices from health care providers: Assessing the impact of the Indian Assisted Reproductive Technology (Regulation) Act, 2021 on the practice of IVF in India. *J Obstet Gynecol India* 2023; **73**(4): 301–308.
- [6] Di Trani M, Spoletini R, Renzi A, Greco F, Scaravelli G. Psychologists' representations about their professional functions within assisted reproductive multidisciplinary teams. *Prof Psychol Res Pract* 2021; **52**(3): 299–307.
- [7] Holter H, Gejervall A, Borg K, Sandin-Bojö A, Wikland M, Wilde-Larsson B, et al. *In vitro* fertilization healthcare professionals generally underestimate patients' satisfaction with quality of care. *Acta Obstet Gynecol Scand* 2017; **96**(3): 302–312.
- [8] Ilitis AS, Koster G, Reeves E, Matthews KRW. Ethical, legal, regulatory, and policy issues concerning embryoids: A systematic review of the literature. *Stem Cell Res Ther* 2023; **14**(1): 209. doi: 10.1186/s13287-023-03448-8.
- [9] Shapiro H, Brown TJ, Chronis-Brown P, Hamilton GS, Bentley DC, Kandel R, et al. Education of the clinical embryology laboratory professional: Development of a novel program delivered in a laboratory medicine department. *F S Rep* 2023; **4**(3): 262–269.
- [10] Sciorio R, Aiello R, Janssens R. Considerations on staffing levels for a modern assisted reproductive laboratory. *JBRA Assist Reprod* 2023; **27**(1): 120–130. doi: 10.5935/1518-0557.20220048
- [11] Indian Kanoon. *Discussion on the motion for consideration of the Assisted Reproductive Technology (Regulation) Bill, 2020 (Discussion Concluded and Bill Passed)*. [Online] Available from: <https://indiankanoon.org/doc/197742569/> [Accessed 16 October 2024].
- [12] Malina A, Pooley J. Psychological consequences of IVF fertilization—Review of research. *Ann Agric Environ Med* 2017; **24**(4): 554–558.
- [13] Taebi M, Bahrami R, Bagheri-Lankarani N, Shahriari M. Ethical challenges of embryo donation in embryo donors and recipients. *Iran J Nurs Midwifery Res* 2018; **23**(1): 36.
- [14] Malhotra J, Malhotra K, Talwar P, Kannan P, Singh P, Kumar Y, et al. ISAR consensus guidelines on safety and ethical practices in *in vitro* fertilization clinics. *J Hum Reprod Sci* 2021; **14**(5): 48.
- [15] Mishra R, Thakral S. Legal subtleties of the Indian Assisted Reproductive Technology Act of 2021. *Natl Med J India* 2024; **37**: 272–274. doi: 10.25259/NMJI_785_2023.
- [16] Rivron NC, Martinez Arias A, Pera MF, Moris N, M'hamedi HI. An ethical framework for human embryology with embryo models. *Cell* 2023; **186**(17): 3548–3557.
- [17] Simon C, Campbell A, Gardner DK, Meseguer M, Miller KA, Montag M, et al. *In vitro* fertilization and andrology laboratories in 2030. *Fertil Steril* 2021; **116**(1): 2–3.

- [18]Dimitriadis I, Zaninovic N, Badiola AC, Bormann CL. Artificial intelligence in the embryology laboratory: A review. *Reprod Biomed Online* 2022; **44**(3): 435-448.
- [19]Liu KE, Hartman M, Hartman A, Luo ZC, Mahutte N. The impact of a thin endometrial lining on fresh and frozen-thaw IVF outcomes: An analysis of over 40 000 embryo transfers. *Hum Reprod* 2018; **33**(10): 1883-1888.
- [20]Racowsky C. Training and recognition of clinical embryologists as professionals—now, but what does the future hold? *F S Rep* 2023; **4**(3): 254-255.
- [21]Simopoulou M, Sfakianoudis K, Giannelou P, Rapani A, Maziotis E, Tsioulou P, et al. Discarding IVF embryos: Reporting on global practices. *J Assist Reprod Genet* 2019; **36**(12): 2447-2457.
- [22]Maggiulli R, Cimadomo D, Fabozzi G, Papini L, Dovere L, Ubaldi FM, et al. The effect of ICSI-related procedural timings and operators on the outcome. *Hum Reprod* 2020; **35**(1): 32-43.
- [23]Magli MC, Van Den Abbeel E, Lundin K, Royere D, Van Der Elst J, Gianaroli L, et al. Revised guidelines for good practice in IVF laboratories. *Hum Reprod* 2008; **23**(6): 1253-1262.
- [24]Farlie F, Palmer GA, Cohen J, Calcagni C, Gorbunova A, Lawford Davies J, et al. Sustainability in the IVF laboratory: Recommendations of an expert panel. *Reprod Biomed Online* 2024; **48**(1): 103600.
- [25]Borges ED, Berteli TS, Reis TF, Silva AS, Vireque AA. Microbial contamination in assisted reproductive technology: Source, prevalence, and cost. *J Assist Reprod Genet* 2020; **37**(1): 53-61.
- [26]Jindal SK, Rawlins RG, Muller CH, Drobnis EZ. Guidelines for risk reduction when handling gametes from infectious patients seeking assisted reproductive technologies. *Reprod Biomed Online* 2016; **33**(2): 121-130.
- [27]Mortimer D, Cohen J, Mortimer ST, Fawzy M, McCulloh DH, Morbeck DE, et al. Cairo consensus on the IVF laboratory environment and air quality: Report of an expert meeting. *Reprod Biomed Online* 2018; **36**(6): 658-674.
- [28]Malhotra J, Malhotra K, Talwar P, Kannan P, Singh P, Kumar Y, et al. ISAR consensus guidelines on safety and ethical practices in *in vitro* fertilization clinics. *J Hum Reprod Sci* 2021; **14**(Suppl 1): S48-S68.
- [29]Considerations regarding embryo culture conditions: From media to epigenetics. *In Vivo* 2018; **32**(3): 451-460. doi: 10.21873/invivo.11261.
- [30]Zander-Fox D, Lam K, Pacella-Ince L, Tully C, Hamilton H, Hiraoka K, et al. PIEZO-ICSI increases fertilization rates compared with standard ICSI: A prospective cohort study. *Reprod Biomed Online* 2021; **43**(3): 404-412.
- [31]Sfakianoudis K, Maziotis E, Karantzali E, Kokkini G, Grigoriadis S, Pantou A, et al. Molecular drivers of developmental arrest in the human preimplantation embryo: A systematic review and critical analysis leading to mapping future research. *IJMS* 2021; **22**(15): 8353.
- [32]Kashyap S, Tripathi P. The Surrogacy (Regulation) Act, 2021: A critique. *Asian Bioeth Rev* 2022; **15**(1): 5-18. doi: 10.1007/s41649-022-00222-5.
- [33]Government of India. *Assisted Reproductive Technology (Regulation) Act, 2021. India Code*. [Online] Available from: <https://www.indiacode.nic.in/handle/123456789/17031> [Accessed 16 October 2024].
- [34]Wolff P, Rocha CC, Alvarenga RDLLS, Zuculo JVB, Guimarães FM, Pinheiro Neto JE, et al. Code of ethics and conduct of the Brazilian association of embryologists-PRONÚCLEO. *JBRA Assist Reprod* 2019; **23**(1): 58-61. doi: 10.5935/1518-0557.20180067.
- [35]Walker JV, Premannandan H, Barrie A, Kirkman-Brown JC, Newby H. Association of reproductive and clinical scientists. Good practice in clinical embryology laboratories: Association of reproductive and clinical scientists guidelines 2024. *Reprod Biomed Online* 2024; **49**(6): 104102.
- [36]Agrawal A. Medical negligence: Indian legal perspective. *Ann Indian Acad Neurol* 2016; **19**(5): 9.
- [37]Indian Kanon. *Sri. Lakshmi Janardhan K S vs State of Karnataka on 29 November, 2023*. [Online] <https://indiankanon.org/doc/198502482/> [Accessed 17 October 2024].
- [38]Ezeome IV. Gamete donation-A review of ethical and legal issues. *Afr J Reprod Health* 2022; **26**(3): 124-135.
- [39]Lal DR. The legal and ethical implications of assisted reproductive technology regulations on fertility clinics and the right of the children born out of ART. *Acta Sci* 2024; **7**(1): 124-138. doi: 10.17648/acta.scientiae.6838.
- [40]Von Schondorf-Gleicher A, Mochizuki L, Orvieto R, Patrizio P, Caplan AS, Gleicher N. Revisiting selected ethical aspects of current clinical *in vitro* fertilization (IVF) practice. *J Assist Reprod Genet* 2022; **39**(3): 591-604.
- [41]Goldman KN, Nazem T, Berkeley A, Palter S, Grifo JA. Preimplantation genetic diagnosis (PGD) for monogenic disorders: The value of concurrent aneuploidy screening. *J Genet Couns* 2016; **25**(6): 1327-1337.
- [42]Navarro-Sánchez L, García-Pascual C, Rubio C, Simón C. Non-invasive preimplantation genetic testing for aneuploidies: An update. *Reprod Biomed Online* 2022; **44**(5): 817-828.
- [43]Yang S, Xu B, Zhuang Y, Zhang Q, Li J, Fu X. Current research status and clinical applications of noninvasive preimplantation genetic testing: A review. *Medicine* 2024; **103**(40): e39964.
- [44]Gowda M, Deepthi B, Nichanahalli KS. The Assisted Reproductive Technology Act 2021-Provisions and implications. *Indian Pediatr* 2024; **61**(7): 675-681.