UNDERSTANDING KEY ISSUES AND CONSTRAINTS IN IMPLEMENTING THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 WITH SPECIAL REFERENCE TO STATE OF KERALA.

Dissertation submitted to the National University of Advanced Legal Studies, Kochi in partial fulfillment of the requirements for the award of LL.M. Degree in Public Health Law

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Submitted by:

ANUSREE M G

(Register Number: LM0323002)
Under the Guidance and Supervision of

Dr. ANIL R. NAIR ,
ASSOCIATE PROFESSOR
May 2025

CERTIFICATE

This is to certify that **ANUSREE M G** Register No**: LM0323002**, has submitted her Dissertation titled **"UNDERSTANDING KEY ISSUES AND CONSTRAINTS IN IMPLEMENTING THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 WITH SPECIAL REFERENCE TO STATE OF KERALA."** in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi, under my guidance and supervision. It is also affirmed that the dissertation submitted by him is original, bona fide and genuine.

Date: 27-05-2025

Place: Ernakulam

Dr. ANIL R. NAIR
Guide and Supervisor
NUALS, Kochi

DECLARATION

I declare that this Dissertation titled **"UNDERSTANDING KEY ISSUES AND CONSTRAINTS IN IMPLEMENTING THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 WITH SPECIAL REFERENCE TO STATE OF KERALA"** is researched and submitted by me to the National University of Advanced Legal Studies, Kochi, in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Dr. ANIL R. NAIR, Associate Professor, NUALS, and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

Date: 27-05-2025

Place: Ernakulam

ANUSREE M G
Register No: LM0323002
LL.M. (public health law)
NUALS, Kochi

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ANUSREE M G

(LM0323002)

TABLE OF ABBREVIATION

Abbreviation	Full Form
ART	Assisted Reproductive Technology
IVF	In Vitro Fertilization
ICMR	Indian Council of Medical Research
AIH	Artificial Insemination with Husband's Semen
AID	Artificial Insemination with Donor Semen
IUI-H	Intrauterine Insemination using Husband's Semen
IUI-D	Intrauterine Insemination using Donor Semen
ET	Embryo Transfer
GIFT	Gamete Intrafallopian Transfer
TET	Tubal Embryo Transfer
ICSI	Intracytoplasmic Sperm Injection
IMSI	Intracytoplasmic Morphologically Selected Sperm Injection
ROSNI	Round Spermatid Nucleus Injection
ELSI	Elongated Spermatid Injection
PESA	Percutaneous Epididymal Sperm Aspiration
MESA	Microsurgical Epididymal Sperm Aspiration
TESA	Testicular Sperm Aspiration
TESE	Testicular Sperm Extraction
PGD	Preimplantation Genetic Diagnosis
PGS	Preimplantation Genetic Screening
ERA	Endometrial Receptivity Array
WHO	World Health Organization
UN	United Nations
ICPD	International Conference on Population and Development

TABLE OF CASES

S. No.	Case Name
1	Rakhi Bose and Another v. Union of India, Represented by its Principal Secretary, Prime Minister's Office and Others;2022 SCC Online Ker 3250
2	Nandini K. v. Union of India; 2023 (1) KHC 149
3	Pushpa Babu and Another v. Union of India Represented by its Secretary and Others: 2023 SCC Online Ker 6608
4	xxxxx vs. State;2021 (4) KHC 641
5	xxxxxx v. Union of India; 2023 ICO 151

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CHAPTER 1

INTRODUCTION

The Assisted Reproductive Technology (Regulation) Act, 2021 (ART Act) is a significant legislative initiative aimed at regulating assisted reproductive technologies (ART) in India. It addresses the complexities of ART procedures like surrogacy and embryo manipulation amid evolving societal norms and technological advancements in reproductive medicine.[1] This dissertation explores the challenges and constraints in implementing the ART Act, focusing specifically on Kerala, a state in southern India. ART includes medical techniques that help couples conceive by manipulating reproductive materials.[2] These technologies offer hope to those facing infertility but also raise ethical, legal, and social questions. The ART Act was enacted to provide a regulatory framework ensuring the well-being of all involved—patients, healthcare providers, donors, and surrogate mothers—while upholding ethical standards.

This dissertation examines the ART Act's implementation by analyzing its regulatory framework, roles of National and State Boards, clinic registration requirements, and enforcement mechanisms in Kerala. It aims to assess how these legal provisions promote safe and ethical ART practices in the state. The dissertation also explores practical challenges faced by ART clinics and regulatory bodies in Kerala, such as infrastructure limitations, resource scarcity, and societal attitudes towards reproductive technologies. By identifying these barriers, it seeks to propose strategies for overcoming them and improving ART regulation. Ethical considerations are crucial. The dissertation examines issues like consent, autonomy, and the commercialization of reproductive materials within Kerala's socio-cultural context. It evaluates how well the ART Act addresses these ethical concerns and identifies areas needing legislative clarity.

Additionally, the dissertation investigates the impact of the ART Act on healthcare providers. By understanding their perspectives, it aims to reveal how the ART Act shapes reproductive practices and influences healthcare delivery in the state. The dissertation places its analysis within India's broader healthcare policy context, exploring how national laws interact with state-level implementation strategies and

1 R. Rao, Regulating Reproduction in India, Indian Journal of Medical Ethics, Vol. 3, 2022.

2 Indian Council of Medical Research (ICMR), National Guidelines for ART Clinics, 2005.

local healthcare practices. It aims to contribute insights into health policy, medical ethics, and the regulation of emerging medical technologies, offering guidance for policymakers and healthcare professionals.

Assisted Reproductive Technology (ART) is a medical approach to fertility treatment that assists individuals or couples in achieving pregnancy when they have difficulty conceiving naturally."ART involves various procedures and techniques to handle sperm, eggs, and embryos outside the body to facilitate conception. ART is often used when other fertility treatments have failed or when there are specific medical conditions that make natural conception difficult. It has helped many individuals and couples overcome infertility and achieve their goal of having a child"[3]. However, ART can be expensive and emotionally demanding, and success rates can vary depending on various factors, including the age and health of the individuals involved. In 1981, Dr. Subhash Mukhopadhyay successfully delivered the first baby through in vitro fertilization (IVF) in Kolkata, named Durga. However, the Indian government did not recognize this significant milestone due to moral and ethical reasons. Five years later, in 1986, Dr. T. C. Anand Kumar and Dr. Indira Hinduja claimed India's first IVF baby, named Harsha, and it was accepted by the Indian Council of Medical Research (ICMR). Since then, there has been a remarkable increase in the number of Assisted Reproductive Technology (ART) clinics and ART banks in the country, especially in recent decades. However, the public health sector fertility services are scarce and poorly equipped. Most ART clinics are in the private sector and are commercialized. Although ICMR guidelines exist, the sector is mostly unregulated as there is no mechanism in place to ensure compliance. Infertile couples seeking infertility treatment are at risk of unethical practices in this sector.

1.1 SCOPE OF THE STUDY

Access to healthcare is both a fundamental human right and a constitutional right for every citizen, encompassing not just the absence of illness but overall well-being. In India, ensuring a minimum standard of healthcare facilities across the country is crucial. Despite India's complex healthcare system, which spans the entire nation, there remains a pressing need for a unified regulatory framework to govern healthcare

[3] Meaghan Jain & Manvinder Singh, *Assisted Reproductive Technology (ART) Techniques*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (June 7, 2023), https://www.ncbi.nlm.nih.gov/books/NBK576409/.

providers effectively. The implementation of the Assisted Reproductive Technology (Regulation) Act, 2021 in Kerala serves as a critical case study in addressing these challenges. This study aims to explore the key issues and constraints hindering the effective implementation of this legislation, focusing on regulatory compliance, healthcare infrastructure, ethical considerations, and the impact on access to reproductive healthcare services. By examining these aspects, the study seeks to provide insights into enhancing the regulation of assisted reproductive technologies in Kerala and contributing to broader healthcare policy discussions in India

1.2. RESEARCH PROBLEM

The problem highlighted here is determining the efficiency of the Assisted Reproductive Technology (Regulation) Act, 2021 which regulates the registration of ART clinics and banks establish minimum standards for their operation. The researcher's objective is to provide an overview of the Act and to identify the challenges and shortcomings associated with its implementation.

1.3 RESEARCH OBJECTIVES

1. To identify and analyze the primary challenges and obstacles faced by healthcare providers in adhering to the legal and regulatory norms.

2. To evaluate the effectiveness of the regulatory framework in ensuring the compliance with the statutory and regulatory norms.

3. To examine the perspectives of healthcare institutions and healthcare professionals regarding the regulatory burden imposed by the Assisted Reproductive Technology (Regulation) Act, 2021.

1.4 RESEARCH QUESTION

1. What are the key objectives and provisions of the Assisted Reproductive Technology (Regulation) Act, 2021?

2. What is the current state of implementation of the Assisted Reproductive Technology Regulation Act in the State of Kerala?

3. What are the major challenges and obstacles faced by healthcare providers in adhering to the regulations outlined in the Act?

4. How do the regulatory institutions monitor and enforce compliance with the Assisted Reproductive Technology (Regulation) Act, 2021?

1.5 RESEARCH METHODOLOGY

This research is based on a purely doctrinal method, where I analyzed various primary and secondary legal sources such as statutes, case law, government orders, books, journals, and scholarly articles. The aim was to understand and evaluate the effectiveness of the Assisted Reproductive Technology (ART) Act. Through this analysis, several recurring themes emerged, including awareness of the regulations, how these regulations are implemented, challenges faced by patients, the cost and number of treatment attempts allowed, the use of donor sperm or eggs, and the side effects of fertility drugs. To complement the doctrinal study, I also conducted informal interviews with doctors who specialize in reproductive health. While these interviews don't serve as empirical data, they offered valuable insights and helped me understand the practical side of the issues being discussed..

1.6 LITERATURE REVIEW

This literature review critically examines the Assisted Reproductive Technology (ART) legal and ethical constraints with a particular focus on the Assisted Reproductive Technology (Regulation) Act, 2021. Framed around four doctrinal research questions, this review synthesizes jurisprudential insights, statutory interpretations, and ethical concerns to identify unresolved issues within the existing legal framework. This doctrinal approach relies on primary and secondary legal materials without empirical fieldwork.

The ART Act, 2021 marks a significant legislative effort to regulate the growing ART industry in India. Scholars such as Yadav and Jamwal have highlighted the Act's intent to institutionalize ethical standards and provide safeguards for donors and surrogates.[4] Gautam offers a comprehensive doctrinal critique of the Act, addressing socio-economic inequities and legislative gaps.[5] Ra's early work provides a foundational understanding of ethical and legal questions arising from modern

4 Arun Kumar Yadav & VishanDev Singh Jamwal, The Assisted Reproductive Technology (Regulation) Act, 2021: A Step in the Right Direction, 48(2) Indian J. Cmty. Med. 80 (2023).

5 Leena K. Gautam, A Critical Analysis of the Assisted Reproductive Technology (Regulation) Act, 2021, J. Soc. Sci. & Human., (2025).

reproductive technologies.[6] The role of state-mandated insurance coverage and its implications for marginalized groups like the unmarried and LGBTQ+ communities is addressed by Blake.[7] Alon et al. map the global discourse on the ethical, legal, and social implications of ART, contextualizing the Indian framework within international trends. Assisted Reproductive Technologies (ARTs) have played a crucial role in helping individuals and couples who experience infertility to form families. This often involves third parties such as gamete donors and surrogates. Even now, a large portion of the (estimated 27 million) infertile Indian couples, especially the poor, lack easy access to ARTs. The provision of ART in India occurs overwhelmingly via the private sector.[8] Together, these works illustrate the Act's scope but also reveal persistent issues around inclusivity, accessibility, and enforceability.

The interface between ART and Indian family law raises questions about parentage, legitimacy, and reproductive autonomy. Aremo and Eniola examine ART's interaction with African family law, offering useful comparative insights. ART significantly affects cultural practices and societal norms, advocating for culturally sensitive approaches and equitable policies to address these changes[9]. Majumdar delves into the age-related cultural norms surrounding ART in India, highlighting how doctrinal norms are shaped by social constructs and the rapid growth of ART in India and its impact on women. They highlight issues like the commercialization of reproduction, exploitation of vulnerable women, lack of regulatory oversight, and the social pressures faced by women to conceive. The article calls for stronger regulations and better support systems to protect women's health and rights in the context of ART[10]. Rao critiques regulation through high-profile legal cases, emphasizing the tensions between personal freedom and public morality. The study delves into the perspectives of both clients and service providers to understand the complex ethical landscape. The authors highlight key ethical concerns, such as the exploitation of vulnerable individuals, the commercialization of reproduction, and the lack of

6 R. Ra, Assisted Human Reproductive Techniques—Emerging Ethical and Legal Implications, 20 Med. & L. 295 (2001).

7 V.K. Blake, It's an Art Not a Science: State-Mandated Insurance Coverage of Assisted Reproductive Technologies and Legal Implications for Gay and Unmarried Persons, IRPN: Innovation & Health L. & Pol'y (Topic) (2011).

8 Ido Alon et al., Mapping International Research Output within Ethical, Legal, and Social Implications (ELSI) of Assisted Reproductive Technologies, 40 J. Assist. Reprod. & Genetics 2023 (2023).

9 J.I. Aremo & B.O. Eniola, Assisted Reproductive Technology (ART) Within the Family Law Dynamics: Imperatives for a Legal Framework, Int'l J. Innovative Res. & Dev. (2020).

10 Anindita Majumdar, Assisted Reproductive Technologies and the Conceptualization of Ageing in India, Anthropol. & Aging (2021).

regulatory frameworks. They discuss how these issues affect the decision-making process for clients and the operational practices of service providers. The study emphasizes the need for robust ethical guidelines and regulatory oversight to protect the rights and well-being of all parties involved in ART[11]. Blake also investigates the doctrinal challenges posed by ART when considered within non-traditional family contexts.[12] Muraoka et al. explore judicial interpretations of male consent in ART, further complicating legal understandings of reproductive rights[13]. These discussions underscore the inadequacy of existing law concerning family, individual, society etc. in fully incorporating ART realities.

While the ART Act provides a legal framework, doctrinal ambiguities remain regarding the liability and ethical responsibilities of ART providers. Brezina and Zhao document how technological advances often outpace legal standards, leading to interpretive challenges.[14] Inhorn and Birenbaum-Carmeli add a cross-cultural dimension, discussing how ART ethics are mediated by local customs and religious doctrines.[15] Nadimpally and Venkatachalam critique the commercialization of ART services, arguing that it creates doctrinal inconsistencies around consent and exploitation.[16]Similarly, the Sama Team analyzes how ART reinforces gendered vulnerabilities, particularly for economically weaker women.[17] Hiadzi et al. emphasize the lack of codified ethical guidelines in jurisdictions like Ghana, mirroring doctrinal gaps seen in Indian law.[18] These perspectives expose the legal profession's ongoing struggle to reconcile technological practices with statutory clarity.

Legal analysis has shown that enforcement mechanisms under the ART Act are often weakened by institutional fragmentation and commercial interests. Chakravarthi critiques India’s broader regulatory culture, arguing that commodification undermines

11 Radhika Rao, How (Not) to Regulate Assisted Reproductive Technology: Lessons from 'Octomom', 49(1) Fam. L.Q. 135 (2015).

12 V.K. Blake, It’s an Art Not a Science: State-Mandated Insurance Coverage of Assisted Reproductive Technologies and Legal Implications for Gay and Unmarried Persons, IRPN: Innovation & Health L. & Pol’y (Topic) (2011).

13 Yuko Muraoka, Minori Kokado & Kazuto Kato, The Role of Male Consent in Assisted Reproductive Technology Procedures: An Examination of Japanese Court Cases, Asian Bioethics Rev. (2024).

14 Paul R. Brezina & Yulian Zhao, The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies, 2012 Obstetrics & Gynecology Int’l 686253.

15 Marcia C. Inhorn & Daphna Birenbaum-Carmeli, Assisted Reproductive Technologies and Culture Change, 37 Ann. Rev. Anthropol. 177 (2008).

16 Sarojini Nadimpally & Deepa Venkatachalam, Marketing Reproduction: Assisted Reproductive Technologies and Commercial Surrogacy in India, 23(2) Indian J. Gender Stud. 237 (2016).

17 Sama Team, Assisted Reproductive Technologies in India: Implications for Women, 42(23) Econ. & Pol. Wkly. 2184 (2007).

18 Indira Chakravarthi, Regulation of Assisted Reproductive Technologies: Gains and Losses, Indian J. Gender Stud. (2016).

the law's ethical core.[19] Soini et al. discuss the regulatory interface between ART and genetics, suggesting a need for integrative policies.[20] Gullo et al. explore the implications of embryo transfer techniques and their under-regulation, pointing to the doctrinal need for more specific medical jurisprudence.[21] Kosiva and Bakaraki evaluate the legality of postmenopausal IVF, revealing gaps in statutory interpretation related to maternal age[22].Mohanty and Sahoo's sociological work touches on the unregulated growth of fertility clinics in India, calling for a more robust regulatory doctrine[23].Together, these legal assessments indicate the necessity of clearer enforcement structures and judicial oversight.

Identified Research Gap

Despite a wide range of doctrinal literature, most discussions remain abstract and focused on broad legal interpretations. There is a clear gap in jurisprudential analysis of how the ART Act aligns with constitutional rights, personal autonomy, and international human rights frameworks. Moreover, legal scholarship often lacks a focused doctrinal assessment of regional variations in implementation and interpretation, particularly in legally advanced states like Kerala. This dissertation seeks to bridge these doctrinal gaps by analyzing statutory language, judicial commentary, and secondary literature within a cohesive theoretical framework.

1.7 CHAPTERISATION

Chapter 1- Introduction

This chapter provides an overview of the research project by outlining the purpose of the study and the topic's relevance. It contains the research questions and the research hypothesis. Additionally, the chapter discusses the research method and provides a brief overview of the literature reviewed.

Chapter 2- Assisted Reproductive Technologies

19 Indira Chakravarthi, Regulation of Assisted Reproductive Technologies: Gains and Losses, Indian J. Gender Stud. (2016).

20 S. Soini et al., The Interface Between Assisted Reproductive Technologies and Genetics, 14 Eur. J. Hum. Genetics 588 (2006).

21 G. Gullo et al., Fresh vs. Frozen Embryo Transfer in Assisted Reproductive Techniques: A Single Center Retrospective Cohort Study and Ethical-Legal Implications, 27 Eur. Rev. Med. & Pharmacol. Sci. 6809 (2023).

22 A. Kosiva & M.P. Bakaraki, IVF Pregnancy in Post-Menopausal Women: Ethical Considerations, Int'l J. Sci. & Healthcare Rsch. (2025).

23 Mohanty, S. & Sahoo, S., The ART of Manufacturing: Ethical Considerations in Quest of a Child, 65(3) Sociol. Bull. 380 (2016).

Assisted Reproductive Technologies; This chapter discusses the various forms of assisted reproductive technologies and growth of the assisted reproductive technologies in India and its history. This chapter also discussed the ethical and legal concerns regarding assisted reproductive technologies, the analysis of women health and ART and cultural change and ART.

Chapter 3- Regulatory Landscape of ART Before Commencing Assisted Reproductive Technology (Regulation) Act, 2021 In India/ Kerala

This chapter deals with Regulatory landscape of ART before commencing Assisted Reproductive Technology (Regulation) Act, 2021. It discussed United Kingdom ART regulations and India ICMR Guidelines.

Chapter 4 - Analysis and Critics of Art Act 2021

This chapter deals with the Overview of Assisted Reproductive Technology (Regulation) Act, 2021. This Chapter discusses the objective of Assisted Reproductive Technology (Regulation) Act, 2021 and also deals with the provisions concerning the registration and regulation of ART clinics and banks in India.

Chapter 5- Ethical And Legal Implications Of The ART Act ,2021

This chapter deals with the ethical and legal implications of the ART Act. This chapter discusses the changes or consequences that have occurred in India since the Act's inception. That is, it discusses the problems that exist in the healthcare system and how they can be resolved, as well as the solutions to the problems. This chapter provides a detailed analysis of the changes and benefits that the act has brought about, as well as a clear indication of whether the act is a boon or a bane.

Chapter 6- Suggestions and Conclusion

This chapter concludes the analysis of the act's establishment, the changes it has brought in the field of healthcare, and the act's necessity, advantages, and disadvantages. Additionally, it makes suggestions for expanding the act's applicability and for properly regulating it to ensure that the public receives high-quality care.

CHAPTER-2
ASSISTED REPRODUCTIVE TECHNOLOGIES

2.1.INTRODUCTION

Assisted Reproductive Technologies (ART) have truly changed the lives of countless individuals and couples struggling with infertility. This chapter is a journey into the world of ART, where hope, innovation, and ethical dilemmas intersect to shape the field of reproductive medicine in profound ways.

Imagine a world where the dream of parenthood becomes a reality through the pioneering work of individuals like Dr. Subhas Mukherjee and his team in Kolkata. Just 67 days after the birth of Louise Brown, the first IVF baby in the world, Dr. Mukherjee successfully delivered India's first IVF baby, Kanupriya. His innovative techniques, from ovarian stimulation to embryo freezing, showcased the power of determination and creativity in overcoming infertility challenges.

The ripple effect of Dr. Mukherjee's success resonated across borders, leading to the birth of Harsha, India's first scientifically documented IVF baby in 1986. This milestone was not just a scientific achievement but a testament to the dedication and expertise of researchers and clinicians striving to make a difference in the lives of those longing for a child.

The impact of these breakthroughs extended beyond medical advancements, sparking conversations about the ethical considerations surrounding ART. The right to health, information, and freedom from discrimination became central themes in the evolving landscape of reproductive medicine.

In a world where every individual deserves access to quality healthcare, including reproductive care, the principles of human rights underscore the importance of dignity, well-being, and equitable access to treatments like ART. These rights remind us of the fundamental values that guide our journey in the realm of assisted reproduction.

As we navigate the complexities of ART, from in vitro fertilization to embryo freezing, we are reminded of the human stories behind each procedure. The joy of a couple holding their long-awaited baby, the resilience of individuals facing infertility

challenges, and the dedication of healthcare professionals striving to make a difference – these are the threads that weave the tapestry of ART.

This chapter invites you to explore the world of assisted reproductive technologies through a human lens, where science and compassion intersect to create new possibilities for families around the globe. Join us on this journey as we delve into the heart warming stories, ethical dilemmas, and transformative impact of ART on individuals, families, and societies worldwide.

2.2. ASSISTED REPRODUCTIVE TECHNOLOGY (ART)

Any treatment that deals with "means of conception other than vaginal intercourse" is termed as ART[24]. Assisted Reproductive Technology (ART) is a medical approach to fertility treatment that assists individuals or couples in achieving pregnancy when they have difficulty conceiving naturally. ART involves various procedures and techniques to handle sperm, eggs, and embryos outside the body to facilitate conception. ART is often used when other fertility treatments have failed or when there are specific medical conditions that make natural conception difficult. It has helped many individuals and couples overcome infertility and achieve their goal of having a child. However, ART can be expensive and emotionally demanding, and success rates can vary depending on various factors, including the age and health of the individuals involved. In 1981, Dr. Subhash Mukhopadhyay successfully delivered the first baby through in vitro fertilization (IVF) in Kolkata, named Durga. However, the Indian government did not recognize this significant milestone due to moral and ethical reasons. Five years later, in 1986, Dr. T. C. Anand Kumar and Dr. Indira Hinduja claimed India's first IVF baby, named Harsha, and it was accepted by the Indian Council of Medical Research (ICMR). Since then, there has been a remarkable increase in the number of Assisted Reproductive Technology (ART) clinics and ART banks in the country, especially in recent decades. However, the public health sector fertility services are scarce and poorly equipped. Most ART clinics are in the private sector and are commercialized. Infertile couples seeking infertility treatment are at risk of unethical practices in this sector.

[24] NICE guideline 2013

2.3. HISTORY OF ART

In vitro fertilization (IVF) has revolutionized reproductive medicine, offering hope to countless couples facing infertility. The journey of IVF began with the birth of Louise Brown, the world's first IVF baby, on July 25, 1978, in the United Kingdom. This monumental event was made possible through the groundbreaking efforts of Dr. Robert G. Edwards and Dr. Patrick Steptoe. Their pioneering work demonstrated that it was possible to conceive a child outside the human body, a concept that was previously unimaginable. Louise Brown's birth was not just a medical marvel but also a significant cultural and social milestone. It opened new possibilities for individuals and couples struggling with infertility, providing them with a new avenue to achieve their dreams of parenthood. The process involved stimulating a woman's ovaries to produce multiple eggs, retrieving those eggs, fertilizing them with sperm in a laboratory, and then transferring the resulting embryo back into the woman's uterus. This complex procedure required precision, innovation, and a deep understanding of human reproductive biology.

The success of Edwards and Steptoe's work did not go unnoticed. It spurred a wave of interest and research in the field of assisted reproductive technologies (ART). However, the journey was far from over, and many researchers around the world were eager to build on this foundation. One of the most notable contributions to the field came just 67 days after Louise Brown's birth, from a team of Indian researchers led by Dr. Subhas Mukherjee in Kolkata.

On October 3, 1978, Kanupriya, also known as Durga, was born, becoming the world's second and India's first IVF baby. Dr. Mukherjee and his colleagues achieved this remarkable feat under challenging conditions, with limited resources and technology compared to their Western counterparts. Despite these obstacles, they developed innovative techniques that set their work apart. Dr. Mukherjee was the first to use gonadotropins for ovarian stimulation prior to ovum pick-up in an IVF treatment cycle, the transvaginal route by colpotomy for harvesting oocytes, and freezing and thawing of human embryos before transferring them into the uterus. These techniques were significant advancements in the field of IVF.

Dr. Mukherjee’s contributions were documented in a short note published in the Indian Journal of Cryogenics (Vol. 3, page 80, 1978). This publication highlighted the distinct methods employed by Mukherjee and his team, which differed markedly from those used by Edwards and Steptoe. The use of gonadotropins for ovarian stimulation was a particularly notable innovation. Gonadotropins are hormones that stimulate the ovaries to produce multiple eggs, which can then be harvested for fertilization. This method increases the chances of successful fertilization and implantation, a critical factor in the success of IVF treatments.

The transvaginal route by colpotomy for oocyte retrieval was another significant advancement. Colpotomy involves making a small incision in the vaginal wall to access the ovaries and retrieve eggs. This technique was less invasive and more precise compared to the abdominal approach used by Edwards and Steptoe. Additionally, Mukherjee's use of embryo freezing and thawing was groundbreaking. This method allowed embryos to be preserved for future use, giving patients multiple opportunities to achieve pregnancy from a single cycle of ovarian stimulation.

Despite these significant contributions, Dr. Mukherjee's work did not receive the immediate recognition it deserved. Due to bureaucratic hurdles and lack of support from the Indian medical establishment, Mukherjee faced considerable challenges in gaining acceptance for his work. It was only years later that his pioneering contributions were acknowledged, and he was posthumously honored for his role in advancing IVF technology in India.

The success of Mukherjee and his colleagues paved the way for further advancements in IVF in India. On August 6, 1986, India celebrated another milestone with the birth of its first scientifically documented IVF baby, Harsha, in Mumbai. This achievement was the result of a collaborative effort between the Indian Council of Medical Research's (ICMR) Institute for Research in Reproduction and the King Edward’s Memorial (KEM) Hospital. The project was meticulously planned and executed, receiving approval from the Scientific Advisory Committee of the ICMR’s Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of KEM Hospital.

The birth of Harsha was a significant scientific achievement, as it was documented in detail and subjected to rigorous peer review[25]. These publications provided comprehensive accounts of the methodologies used, the ethical considerations involved, and the scientific implications of the research.

Harsha's birth marked a new era for IVF in India. It demonstrated that the country had the expertise and infrastructure to conduct advanced reproductive research and offer cutting-edge treatments. Following Harsha's birth, two other clinics in India reported successful IVF births within the same year, indicating a rapid expansion and adoption of IVF technology across the country.

The impact of these early successes in IVF was profound. They led to the establishment of numerous IVF clinics across India, catering to the growing demand for assisted reproductive services. “Today, it is estimated that there are over 2500 IVF clinics in India, providing a wide range of fertility treatments to patients from all walks of life. These clinics offer state-of-the-art facilities and employ highly skilled medical professionals, ensuring that patients receive the best possible care.”[26]The proliferation of IVF clinics in India has been accompanied by significant advancements in reproductive medicine. Researchers and clinicians have continued to refine and improve IVF techniques, leading to higher success rates and better outcomes for patients. Innovations such as preimplantation genetic testing (PGT), intracytoplasmic sperm injection (ICSI), and the development of improved culture media have all contributed to the success of IVF treatments.

Preimplantation genetic testing (PGT) allows for the screening of embryos for genetic abnormalities before they are transferred to the uterus. This technique has significantly improved the success rates of IVF by ensuring that only healthy embryos are selected for transfer. PGT has also helped reduce the incidence of genetic disorders, providing peace of mind to prospective parents.

[25] Full details of this work were published in the ICMR Bulletin (1986, No. 16) and in esteemed peer-reviewed national and international journals, including the National Medical Journal of India (Natl. Med. J. India 1:10, 1988) and the Journal of In Vitro Fertilization and Embryo Transfer (J. In Vitro Fertilization & ET 5:376, 1988).
[26] World IVF Day 2023: Unveiling India's Best IVF Clinics, TIMES OF INDIA (July 26, 2023), https://timesofindia.indiatimes.com/life-style/parenting/getting-pregnant/world-ivf-day-2023-unveiling-indias-best-ivf-clinics/articleshow/102111631.cms.

Intracytoplasmic sperm injection (ICSI) is another significant advancement in IVF technology. This technique involves the direct injection of a single sperm into an egg, bypassing potential fertilization issues that can arise in cases of male infertility. ICSI has opened up new possibilities for couples where the male partner has low sperm count or poor sperm motility, significantly increasing their chances of achieving pregnancy.

Improved culture media have also played a crucial role in enhancing IVF success rates. The development of specialized media that closely mimic the conditions of the human reproductive tract has improved the survival and development of embryos in the laboratory. This has led to higher quality embryos and increased the likelihood of successful implantation and pregnancy.

The growth of IVF in India has not been without its challenges. Ethical considerations, regulatory frameworks, and access to treatment remain important issues. Ensuring that IVF services are accessible to all segments of the population, including those in rural and underserved areas, is a critical goal. Additionally, the regulation of IVF clinics and the establishment of standardized protocols are essential to maintain the quality and safety of treatments.

The Indian government and various medical organizations have taken steps to address these challenges. Regulatory bodies such as the Indian Council of Medical Research (ICMR) have developed guidelines and standards for IVF practices, ensuring that clinics adhere to ethical and medical protocols. These regulations help protect patients and ensure that they receive safe and effective treatments.

Furthermore, initiatives to raise awareness about infertility and the availability of IVF treatments have been implemented. Public awareness campaigns, educational programs, and support groups for individuals and couples undergoing fertility treatments have all contributed to destigmatizing infertility and promoting the benefits of assisted reproductive technologies.

The journey of IVF in India, from the pioneering work of Dr. Subhas Mukherjee to the birth of Harsha and beyond, reflects the remarkable progress made in the field of reproductive medicine. The dedication and innovation of researchers and clinicians

have transformed the landscape of infertility treatment, providing hope and solutions to countless individuals and couples.

As we look to the future, the continued advancement of IVF technology holds promise for even greater success rates and new possibilities. Research into areas such as stem cell therapy, gene editing, and personalized medicine may further revolutionize the field, offering new hope to those facing infertility.

In conclusion, the development and growth of IVF in India have been marked by significant achievements and advancements. From the early days of Dr. Mukherjee's pioneering work to the widespread availability of cutting-edge treatments today, India has made remarkable strides in reproductive medicine. The contributions of dedicated researchers, clinicians, and medical institutions have paved the way for countless individuals and couples to realize their dreams of parenthood. The legacy of these efforts continues to inspire and drive innovation in the field of assisted reproductive technologies, ensuring that the promise of IVF remains a beacon of hope for future generations.

2.4. FORM OF ASISSTED REPRODUCTIVE TECHNOLOGY

The Ministry of Health & Family Welfare and Indian Council of Medical Research (ICMR) are setting up a National Registry of Assisted Reproductive Technology (ART) Clinics and Banks in India with a view to providing appropriate help and assistance to all those who are engaged in taking care of infertility problems in the country through practice of anyone or more for the following techniques.[27]

Detailed Description of Assisted Reproductive Technologies and Related Procedures

2.4.1. Artificial Insemination with Husband's Semen (AIH)

Artificial Insemination with Husband's Semen (AIH) involves the collection and processing of the husband's semen, which is then artificially introduced into the wife's reproductive tract. This procedure is primarily used to address infertility issues such as low sperm count, low sperm motility, or unexplained infertility.

[27] Announcement_National Registry of ART Clinics and Banks in India_17.05.2018

2.4.2. Artificial Insemination with Donor Semen (AID)

Artificial Insemination with Donor Semen (AID) uses semen from a donor instead of the husband. This method is employed when the husband has no viable sperm, carries genetic disorders, or in cases involving single women or same-sex couples.

2.4.3. Intra-uterine Insemination using Husband Semen (IUI-H)

Intra-uterine Insemination using Husband Semen (IUI-H) is a type of artificial insemination where the husband's sperm is placed directly into the uterus. This procedure aims to increase the number of sperm that reach the fallopian tubes, thereby improving the chances of fertilization.

2.4.4. Intra-uterine Insemination using Donor Semen (IUI-D)

Intra-uterine Insemination using Donor Semen (IUI-D) involves placing donor sperm directly into the uterus. This technique is used when the male partner is infertile, has genetic issues, or in the cases of single women and same-sex couples.

2.4.5. In vitro Fertilization-Embryo Transfer (IVF-ET)

In vitro Fertilization-Embryo Transfer (IVF-ET) involves fertilizing eggs by sperm outside the body and then transferring the resulting embryos to the uterus. This method is used for various infertility issues, including blocked fallopian tubes, male infertility, and unexplained infertility.

2.4.6. Commercial Surrogacy

Commercial Surrogacy is an arrangement where a surrogate mother is compensated for carrying and delivering a baby for another couple or individual. This option is often pursued by those who cannot carry a pregnancy to term due to medical reasons, but it raises concerns about exploitation, legal parentage, and the rights of the surrogate and intended parents.

2.4.7. Altruistic Surrogacy

Altruistic Surrogacy involves a surrogate mother who receives no financial compensation beyond medical and pregnancy-related expenses. Typically involving

close relatives or friends, this arrangement is considered more ethical than commercial surrogacy but still involves complex emotional and legal issues.

2.4.8. Gamete Intrafallopian Tube Transfer (GIFT)

Gamete Intrafallopian Tube Transfer (GIFT) is a procedure where eggs are mixed with sperm and immediately placed into the fallopian tubes. This method, which requires laparoscopy, mimics natural conception more closely than traditional IVF.

2.4.9. Tubal Embryo Transfer (TET)

Tubal Embryo Transfer (TET) is a variation of GIFT where embryos are placed in the fallopian tubes after fertilization has occurred in vitro. This approach aims to replicate natural conception more closely than transferring embryos directly to the uterus.

2.4.10. Intra-cytoplasmic Sperm Injection (ICSI)

Intra-cytoplasmic Sperm Injection (ICSI) is a specialized form of IVF where a single sperm is injected directly into an egg. This technique is used for severe male infertility issues, such as low sperm count or poor motility.

2.4.11. Intra-cytoplasmic Morphologically Selected Sperm Injection (IMSI)

Intra-cytoplasmic Morphologically Selected Sperm Injection (IMSI) is an advanced ICSI technique that selects sperm based on detailed morphological criteria. High-magnification microscopy is used to select the healthiest sperm for injection, thereby improving success rates.

2.4.12. Round Spermatid Nucleus Injection (ROSNI)

Round Spermatid Nucleus Injection (ROSNI) involves injecting a spermatid nucleus (an immature sperm cell) into an egg. This technique provides an option for males with no mature sperm, allowing them to use their genetic material.

2.4.13. Elongated Spermatid Injection (ELSI)

Elongated Spermatid Injection (ELSI) is similar to ROSNI but uses elongated spermatids, a later stage of sperm development. This method is used when mature sperm are absent but elongated spermatids are available.

2.4.14. Percutaneous Epididymal Sperm Aspiration (PESA)

Percutaneous Epididymal Sperm Aspiration (PESA) is a technique to retrieve sperm directly from the epididymis using a fine needle. This procedure is useful for men with blockages or absence of the vas deferens.

2.4.15. Microsurgical Epididymal Sperm Aspiration (MESA)

Microsurgical Epididymal Sperm Aspiration (MESA) is a surgical procedure to extract sperm from the epididymis. This technique is used for men with obstructive azoospermia and involves an open surgical approach under a microscope.

2.4.16. Testicular Sperm Aspiration (TESA)

Testicular Sperm Aspiration (TESA) is a procedure to extract sperm directly from the testicles using a needle. This method is applied in cases of non-obstructive azoospermia.

2.4.17. Testicular Sperm Extraction (TESE)

Testicular Sperm Extraction (TESE) is a surgical procedure to extract sperm from testicular tissue. It is used when no sperm are found in the ejaculate, involving the removal of testicular tissue and extraction of sperm from it.

2.4.18. Pre-implantation Genetic Diagnosis (PGD)

Pre-implantation Genetic Diagnosis involves genetic testing of embryos before implantation to detect genetic disorders or chromosomal abnormalities. A few cells are biopsied from the embryo and tested for genetic conditions.

2.4.19. Pre-implantation Genetic Screening (PGS)

Pre-implantation Genetic Screening (PGS) is the screening of embryos for aneuploidy before implantation. This procedure ensures that embryos have the correct number of chromosomes, involving the analysis of biopsied cells from the embryo.

2.4.20. Blastocyst Separation Technique

The Blastocyst Separation Technique involves separating and analyzing cells from the blastocyst stage of embryo development. This method is used for advanced genetic testing and improving implantation rates.

2.4.21. Endometrial Receptivity Array

The Endometrial Receptivity Array is a test to determine the optimal time for embryo transfer based on endometrial receptivity. A biopsy of the endometrium is analyzed to determine the window of receptivity, enhancing the chances of successful implantation.

2.4.22. Time-Lapse Imaging

Time-Lapse Imaging is a technique that continuously monitors embryo development, allowing for the selection of the best embryos for transfer. Embryos are observed in real-time under a microscope equipped with a time-lapse camera.

2.4.23. Processing or Storage of Gametes and/or Embryos

Processing or Storage of Gametes and/or Embryos involves the handling, freezing, and storage of sperm, eggs, and embryos. This procedure preserves reproductive material for future use, employing cryopreservation techniques like vitrification and storage in specialized facilities.

2.5. ETHICAL CONCERNS REGARDING ART

Embryo Disposition: Deciding what to do with surplus embryos raises ethical questions, as it involves choices such as donation, disposal, or indefinite storage.

Selective Reduction: The practice of selectively reducing multiple pregnancies to improve the chances of a healthy outcome raises ethical dilemmas regarding the value of each embryo's life.

Designer Babies: The ability to select certain genetic traits in embryos through technologies like pre-implantation genetic diagnosis (PGD) raises concerns about eugenics and the ethics of altering human traits.

Exploitation of Donors: Concerns arise regarding the potential exploitation of egg and sperm donors, especially regarding informed consent, compensation, and the potential long-term health risks associated with donation.[28]

Commercialization: The commercialization of ART services raises ethical concerns about access to fertility treatments, equity in healthcare, and the commodification of human reproduction.

Surrogacy: Ethical concerns surround the practice of surrogacy, including issues related to the autonomy of surrogate mothers, the rights of the child, and the potential for exploitation or coercion.

Informed Consent: Ensuring that all parties involved in ART treatments fully understand the procedures, risks, and implications is essential for ethical practice, but achieving truly informed consent can be challenging.

Social Implications: ART raises questions about the changing dynamics of family structures, parenthood, and societal norms, which may have ethical implications for how we define and perceive families.[29]

Access and Equity: Concerns arise regarding equitable access to ART treatments, as cost, geography, and other factors can create disparities in who can afford or access these services.

Unintended Consequences: Ethical concerns include the potential unforeseen consequences of widespread ART use, such as the long-term effects on children conceived through these technologies and the broader societal impact on concepts of family and reproduction.

[28] *Assisted Reproductive Technologies in India: Implications for Women*, 42 Econ. & Pol. Wkly. 2190 (June 9, 2007)

29 Vol 10. No 3. 2005 310-319 Reproductive BioMedicine Online; www.rbmonline.com/Article/1539 on web 13 January 2005

2.6. LEGAL CONCERNS REGARDING ART[30]

Parental Rights: Legal questions arise regarding the parental rights of individuals who use ART, particularly in cases of sperm or egg donation, surrogacy, or disputes over custody of embryos.

Regulation: The regulation of ART varies widely between jurisdictions, leading to inconsistencies in standards of care, legal rights, and protections for individuals involved in ART treatments.

Reproductive Rights: Legal debates center on reproductive rights, including the rights of individuals to access ART treatments, make decisions about their reproductive health, and use ART to pursue parenthood.

Surrogacy Laws: Surrogacy laws vary greatly between countries and states, leading to legal complexities regarding the legality of surrogacy agreements, the rights of surrogate mothers, and the recognition of intended parents.

Gamete Donation: Legal concerns surround gamete donation, including issues related to anonymity, consent, ownership of genetic material, and the rights and responsibilities of donors and recipients.

Embryo Disputes: Legal disputes can arise over the ownership, custody, and disposition of embryos, particularly in cases of divorce, separation, or disagreement between individuals who contributed genetic material.

Genetic Testing and Privacy: Legal questions arise regarding the use of genetic testing in ART, including concerns about privacy, consent, and the potential for discrimination based on genetic information.

Medical Malpractice: Legal issues may arise in cases of medical malpractice or negligence related to ART treatments, including failure to properly screen donors, provide adequate informed consent, or perform procedures with reasonable care.

30 Assisted Reproductive Technology and the Developing World Source: Reproductive Health Matters , Nov., 2005, Vol. 13, No. 26, The Abortion Pill (Nov., 2005), p. 183 Published by: Taylor & Francis, Ltd.

International Surrogacy: Legal complexities arise in cases of international surrogacy, including issues related to citizenship, immigration, parentage, and the enforcement of surrogacy agreements across borders.

Regulatory Gaps: Concerns exist about regulatory gaps in ART oversight, including the lack of standardized protocols, monitoring, and enforcement mechanisms to ensure the safety, efficacy, and ethical practice of ART treatments.

2.7. RIGHT TO REPRODUCTIVE HEALTH AND WOMEN

Human rights offer a practical legal framework and a moral compass for public health initiatives, reinforcing governmental accountability. Aligned in their aim to safeguard the welfare of all, human rights and public health share a common goal. Upholding human rights is essential for tackling the root causes of health disparities, empowering individuals and communities to address health issues, and ensuring fair and efficient delivery of healthcare services.[31]

Over time, the concept of human rights has evolved to encompass newer dimensions. These include rights such as the right to a pollution-free environment, the right to information, the right to development, the right to leisure, the right to be free from discrimination and torture, and the right to health, among others. These rights complement foundational rights like equality, religious and cultural freedoms, and education. Of particular significance is the right to life, which has been consistently underscored. Numerous international declarations, treaties, conventions, and protocols have repeatedly reaffirmed this right.

Article 25 of the Universal Declaration of Human Rights, 1948, states, "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family…." Similarly, the Preamble to the World Health Organisation's (WHO) Constitution also declares that it is one of the fundamental rights of every human being to enjoy "the highest attainable standard of health". This right also includes the right to the underlying conditions of health as well as medical care.[32]

31 Women's Health And Human Rights: Monitoring the Implementation of Cedaw (WHO publication, 2007) .

32] Franklin D. Roosevelt also advocated for a right to medical care in 1944. See, Franklin D. Roosevelt, "The Economic Bill of Rights" — Excerpt from 11-1-1944 message to Congress on the State of the Union.

Article 12(1) of the Protocol on Economic, Social and Cultural Rights States parties have agreed to "… recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." [33]

Article 12(2) provides that the steps to achieve the full realisation of this right shall include those necessary for:

12.(2)(a) The provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child;

(d) The creation of conditions which would assure all medical services and medical attention in the event of sickness.

This article is reinforced by Article 24(2)(f) of the Convention on the Rights of the Child, which requires States parties to "develop preventive health care, guidance for parents and family planning education and services". This right to health carries more importance with reference to women keeping in view their biological structure and child-bearing capacity and necessity.

Article 17 of the Beijing Conference of 1995 also declared, "The explicit recognition and reaffirmation of the right of all women to control all aspects of their health, particularly their own fertility, is basic to their empowerment". The Declaration further states that the states must "ensure the full enjoyment by women and the girl child of all human rights and fundamental freedoms and take effective action against violations of these rights and freedoms". It also provides that international law, including humanitarian law, must be respected in order to protect women and girls in particular and promote and protect all human rights of women and girls. A significant declaration was also made where it was said that 'Women's rights are human rights'. Thus, the right to health, particularly regarding women's reproductive health, was ascertained and recognised.[34]

The Convention on the Rights of Persons with Disabilities of 2006 has recognised that persons with disabilities have the right to enjoyment of the highest attainable standard

33 Lancet, T. (2015). Remembering the right to health. The Lancet. https://doi.org/10.1016/s0140-6736(15)01230-1

34 Article 14 of the Beijing Declaration of 1995.

of health without discrimination based on disability, and the right encompasses the right to reproductive health as States have been directed to "provide persons with disabilities with the same range, quality and standard of accessible or affordable health care including in the area of sexuality and reproductive health.

Thus, the right to health and women's right to reproductive health have been saddled on firm footing by the international declarations mentioned above. It has also been proved beyond doubt that the right to health, including women's right to reproductive health, has also been recognized as a part of human rights. Through ratification, all States have directly and indirectly become parties to these declarations and are now bound to abide by them. As a sequel to it, most of the world's States have passed various laws relating to health and women's right to reproductive health.

2.8. ASSISTED REPRODUCTIVE TECHNOLOGIES AND CULTURE CHANGE[35]

"Assisted reproductive technologies (ARTs) shake up long-held cultural beliefs and practices surrounding fertility and reproduction in profound ways"[36]. These technologies, often more invasive for women, can mistakenly reinforce the idea that women bear the burden of reproductive issues, challenging the traditional notion that fertility is solely a woman's concern.[37] Moreover, the emphasis on women's bodies in ART procedures can sideline men in discussions and practices, despite male infertility being a significant factor in many cases. "This shift challenges traditional gender roles and perceptions of fertility, highlighting the need for a more inclusive approach to reproductive health."[38] Additionally, the use of third parties like gestational surrogates and gamete donors in ARTs introduces new forms of kinship that may diverge from conventional family structures, sparking conversations about the evolving nature of parenthood and lineage[39]. Furthermore, ARTs enable individuals to become parents at older ages, challenging societal norms around age-related fertility and parenthood,

35 Assisted Reproductive Technologies and Culture Change Author(s): Marcia C. Inhorn and Daphna Birenbaum-Carmeli Source: Annual Review of Anthropology, 2008, Vol. 37 (2008), pp. 177-196 Published by: Annual Reviews

36 Marcia C. Inhorn & Daphna Birenbaum-Carmeli, Assisted Reproductive Technologies and Culture Change, *Ann. Rev. Anthropol.* 37, 177 (2008)

37 Sarah Franklin, Embodied Progress: A Cultural Account of Assisted Conception 102 (1997); also see Inhorn (2008) above

38 Heather Paxson, Reproducing Subjects: Pregnancy, Childbirth, and Parenting in the Age of the ARTs, in *Reproducing Reproduction* 115 (Sarah Franklin & Helena Ragoné eds., 1998).

39 Charis Thompson, *Making Parents: The Ontological Choreography of Reproductive Technologies* 120 (2005)

prompting discussions on the ethics and implications of later-life parenting[40]. "The ethical dilemmas raised by the use of ARTs in religious communities also challenge traditional beliefs about conception and parenthood, sparking reflections on the intersection of technology, culture, and faith."[41] In some societies, the use of ARTs for sex selection challenges traditional gender preferences and societal norms, opening up dialogues about cultural values and preferences in reproduction.[42] Overall, ARTs disrupt traditional cultural beliefs by introducing new possibilities for conception, redefining gender roles in fertility, and prompting discussions on ethics, kinship, and parenthood in diverse cultural contexts[43].

The utilization of assisted reproductive technologies (ARTs) carries significant cultural implications across diverse societies worldwide. These technologies challenge traditional cultural beliefs and practices surrounding fertility and reproduction, leading to a reevaluation of societal norms and values. In many cultures, the introduction of ARTs prompts discussions on gender roles and responsibilities in reproduction, as well as reshaping perceptions of parenthood and family structures. The use of third-party reproduction methods like surrogacy and gamete donation raises questions about kinship, inheritance, and the definition of family ties in various cultural contexts. Additionally, the ability of ARTs to enable postmenopausal pregnancies and older individuals to become parents challenges age-related norms of fertility and parenthood, sparking debates on ethics and societal views on family planning. Moreover, the ethical considerations surrounding ARTs, such as sex selection and genetic screening, intersect with cultural beliefs and values, influencing decisions about family building and reproductive choices. The global spread of ARTs also highlights disparities in access to these technologies, reflecting broader inequalities in healthcare and social systems. Overall, the cultural implications of utilizing ARTs in different societies underscore the complex interplay between technology, tradition, ethics, and societal norms, shaping the landscape of reproductive practices and family dynamics around the world.

[40] Susan Golombok, *Modern Families: Parents and Children in New Family Forms* 44–47 (2015).
[41] ohn D. Loike & Alan Jotkowitz, Ethical Challenges in Reproductive Technologies: Perspectives from Judaism, 9 *Rambam Maimonides Med. J.* (2018
[42] Sunita Reddy, *Sex Selection and the ART Market in India*, 42 *Econ. & Pol. Wkly*. 30 (2007
[43] Marcia C. Inhorn & Frank van Balen, *Infertility Around the Globe: New Thinking on Childlessness, Gender, and Reproductive Technologies* 3 (2002)

Understanding the cultural dimensions of assisted reproductive technologies (ARTs) is essential for making these methods more accessible and accepted in diverse communities. By respecting and acknowledging cultural beliefs surrounding fertility and reproduction, healthcare providers can build trust and open communication channels with patients from different backgrounds. Tailoring ART services to align with cultural norms and values not only increases acceptance but also ensures that individuals feel respected and understood in their healthcare journey. Engaging with community leaders and organizations helps dispel misconceptions and stigma around ART, fostering a supportive environment for those seeking fertility treatments. Educating healthcare professionals on cultural competence enhances their ability to provide personalized care and informative support to patients. Developing healthcare policies that consider cultural factors ensures that ART services are inclusive and accessible to all, promoting equity in reproductive healthcare. Addressing ethical considerations within diverse cultural contexts promotes ethical decision-making and demonstrates a commitment to respecting the diversity of beliefs and values within communities.

2.9. CONCLUSION

The world of Assisted Reproductive Technologies (ART) is a testament to the power of innovation, compassion, and ethical considerations in the realm of reproductive medicine. From the pioneering work of individuals like Dr. Subhas Mukherjee to the birth of India's first IVF babies, each milestone represents a triumph of hope and perseverance in the face of infertility challenges.

As we reflect on the evolution of ART, it becomes clear that the field has not only transformed the lives of individuals and couples longing for a child but has also sparked important conversations about ethics, human rights, and the intersection of science and compassion. The journey of ART is a reminder of the profound impact that advancements in reproductive medicine can have on society as a whole.

Looking ahead, the continued advancement of ART holds promise for even greater success rates and new possibilities in the field of assisted reproduction. Research into areas such as stem cell therapy, gene editing, and personalized medicine opens doors

to innovative approaches that may further revolutionize infertility treatments and offer hope to those facing reproductive challenges.

The legacy of dedicated researchers, clinicians, and medical institutions in the field of ART serves as a beacon of hope for future generations, inspiring ongoing innovation and progress in the realm of assisted reproductive technologies. As we celebrate the achievements and advancements in ART, we are reminded of the profound impact that compassionate care, ethical practice, and scientific excellence can have on the lives of individuals and families worldwide.

In closing, the chapter on Assisted Reproductive Technologies invites us to embrace the human stories, ethical considerations, and transformative potential of ART, reminding us that at the heart of every procedure and technique lies the shared desire to create new beginnings and fulfill the dreams of parenthood.

CHAPTER 3
REGULATORY LANDSCAPE OF ART BEFORE COMMENCING ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 IN INDIA/ KERALA

3.0. INTRODUCTION

Assisted Reproductive Technology (ART) represents a significant leap in medical science, providing new avenues for individuals and couples facing infertility to achieve their dreams of parenthood. Techniques such as in vitro fertilization (IVF), gamete donation, and surrogacy have revolutionized reproductive medicine. However, alongside these advancements come complex ethical, medical, and legal challenges that necessitate robust regulatory frameworks. This chapter delves into the varied regulatory landscapes governing ART across different countries, highlighting how the United Kingdom, the United States, and India have addressed these challenges through their unique legal, cultural, and ethical contexts.

"In the United Kingdom, the Human Fertilisation and Embryology Acts of 1990 and 2008 set the groundwork for a comprehensive regulatory regime. The establishment of the Human Fertilisation and Embryology Authority (HFEA) marked a pioneering step in global ART regulation, ensuring that procedures involving human embryos and gametes are conducted ethically and safely."[44] Key provisions of these Acts include stringent guidelines for the creation, use, and storage of embryos, a ban on non-medical sex selection, and mandates to consider the welfare of the child in all ART treatments.

The regulatory approach in the United States involves a blend of state and federal oversight. States regulate medical practice through licensing boards and specific reproductive medicine regulations, while federal agencies like the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS) ensure safety, efficacy, and quality standards in ART procedures. This dual regulatory system aims to maintain high standards in ART while addressing the ethical and safety concerns associated with these technologies.

[44] Human Fertilisation and Embryology Act 1990, c. 37 (UK); Human Fertilisation and Embryology Act 2008, c. 22 (UK).]

India's journey towards comprehensive ART regulation culminated in the Assisted Reproductive Technology (ART) Act of 2021. Before this Act, the lack of national legislation led to inconsistencies and ethical dilemmas within the rapidly growing ART industry. The Indian Council of Medical Research (ICMR) provided guidelines in 2005, but these were advisory and not legally binding. The ART Act of 2021 emerged from increasing public awareness, advocacy, and judicial intervention, aiming to standardize ART practices and protect the rights and welfare of all stakeholders involved.[45]

This chapter examines how these regulatory frameworks in the UK, the US, and India have evolved to address the multifaceted challenges of ART. By comparing these approaches, it provides a comprehensive understanding of the global efforts to balance scientific innovation with ethical responsibility, ensuring safe and effective reproductive technologies for all.

3.1. INTRODUCTION TO GLOBAL REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY (ART)

Assisted Reproductive Technology (ART) has brought profound changes to reproductive medicine, offering new possibilities for individuals and couples struggling with infertility. These technologies have not only transformed the prospects of parenthood but have also highlighted the need for stringent regulatory frameworks to ensure that their application is ethical and safe. The regulation of ART is multifaceted, encompassing medical, ethical, legal, and social dimensions. This introduction explores the regulatory landscapes of three countries with significant ART practices: the United Kingdom, the United States, and India, examining their approaches and the challenges they face in managing this complex field.

3.1.1. UNITED KINGDOM: HUMAN FERTILISATION AND EMBRYOLOGY ACTS OF 1990 AND 2008

The United Kingdom has been a global leader in the regulation of ART and human embryo research, primarily through the Human Fertilisation and Embryology Acts of 1990 and 2008. These Acts established a comprehensive legal framework and created

[45] Assisted Reproductive Technology (Regulation) Act, 2021, No. 42, Acts of Parliament, 2021 (India)

the Human Fertilisation and Embryology Authority (HFEA), the world's first statutory body dedicated to overseeing in vitro fertilization (IVF) and embryo research. The HFEA began its operations on August 1, 1991, and has since been instrumental in ensuring that ART practices are conducted ethically and safely.[46]

Key Provisions of the 1990 Act

The 1990 Act introduced several stringent regulations governing ART:

Creation of Human Embryos: The Act strictly regulates the creation of human embryos outside the human body, ensuring rigorous ethical oversight in both treatment and research contexts.

Use of Donated Gametes and Embryos: It establishes protocols for the ethical handling and proper consent for the use of donated sperm, eggs, and embryos.

Storage of Gametes and Embryos: The Act provides guidelines for the storage of gametes and embryos, ensuring their viability and integrity are maintained.

In 2001, the Act was extended to allow for broader research purposes, enhancing scientific understanding of embryonic development. A significant amendment in 2004, the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations, enabled children conceived through donor gametes to access information about their donors upon reaching adulthood, recognizing their right to know their genetic origins.

Human Fertilisation and Embryology Act 2008

The 2008 Act further refined and modernized the regulatory framework with several key elements:

Comprehensive Regulation of Human Embryos: This Act extended regulation to all embryos created outside the body, including those produced through cloning.

[46] Human Fertilisation and Embryology Act 1990, c. 37 (UK); Human Fertilisation and Embryology Act 2008, c. 22 (UK).].

Ban on Sex Selection: The Act prohibited sex selection for non-medical reasons, aiming to prevent gender imbalances and ethical dilemmas associated with choosing a child's sex based on parental preference.

Welfare of the Child: Clinics are mandated to consider the welfare of the child in all fertility treatments, emphasizing the future well-being of ART-conceived children.

The HFEA continues to play a crucial role in ensuring ethical and safe ART practices, balancing scientific innovation with societal and individual needs.

3.1.2. UNITED STATES: STATE AND FEDERAL REGULATION

In the United States, ART regulation is a collaborative effort between state and federal authorities, ensuring comprehensive oversight of medical practices and the safety of reproductive technologies.

State Regulation

Each state regulates the medical profession through medical licensing boards that enforce standards via medical practice acts. These acts define the scope of practice, require ongoing education, and authorize disciplinary actions for misconduct. Specialization in reproductive medicine is further regulated through board certification. Some states have specific regulations for reproductive medicine, ensuring the ethical handling of reproductive tissues.

Federal Regulation

At the federal level, multiple agencies oversee various aspects of ART:

Centers for Disease Control and Prevention (CDC): Under the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992, the CDC monitors ART data and publishes success rates, helping prospective parents make informed choices. The CDC also sets quality standards for embryology labs.

Food and Drug Administration (FDA): The FDA ensures the safety and efficacy of drugs and medical devices used in reproductive medicine, regulating the screening and testing of reproductive tissues to ensure donors are free from infectious diseases.

Centers for Medicare and Medicaid Services (CMS): Through the Clinical Laboratory Improvement Act (CLIA), CMS oversees the quality of diagnostic testing in reproductive medicine, ensuring accuracy and reliability.

These state and federal regulations collectively maintain high standards in ART, ensuring safety, quality, and ethical practices.

3.1.3. HARNESSING WHO INSIGHTS TO REVOLUTIONIZE ASSISTED REPRODUCTIVE HEALTH POLICIES**[1]**

To advocate for better assisted reproduction policies using insights from the WHO report on sexual, reproductive, maternal, newborn, child, and adolescent health, consider these approaches:

Highlighting Importance: Show how assisted reproduction helps people overcome infertility and build families. Push for including these services in national health policies.

Identifying Policy Gaps: Use the report to find where current assisted reproduction policies fall short. Advocate for new policies that improve access, affordability, quality, and ethical standards.

Comparing Policies: Compare how well assisted reproduction services are covered compared to other health services. Use this to argue for fairer treatment and more resources.

Advocating for Inclusivity: Push for policies that make assisted reproduction accessible to everyone, no matter their income, gender, or sexual orientation. Use the report to show why inclusive policies are crucial.

Engaging Everyone: Get policymakers, doctors, community groups, and the public involved. Use the report's data to explain why better policies and more investment in assisted reproduction are needed.

Supporting Innovation: Advocate for policies that encourage new technologies and research in assisted reproduction. Use the report to highlight the benefits of staying at the forefront of reproductive health.

Monitoring Progress: Push for systems that track how well assisted reproduction services are working. Use the report's findings to stress the importance of monitoring outcomes and safety to ensure high-quality care for those who need it.

. Here are some common gaps that may exist in assisted reproduction policies found by WHO summary report[47]:

Access and Affordability: One significant gap in assisted reproduction policies is limited access to services due to high costs. Many individuals and couples may not be able to afford assisted reproduction treatments, leading to disparities in access based on socioeconomic status. Advocates can push for policies that address affordability issues and ensure that assisted reproduction services are accessible to all who need them.

Regulation and Oversight: In some regions, there may be gaps in regulations and oversight of assisted reproduction services. This can lead to concerns regarding the quality, safety, and ethical standards of procedures. Advocates can advocate for robust regulatory frameworks that govern assisted reproduction practices to protect the well-being of individuals seeking these services.

Inclusivity and Diversity: Assisted reproduction policies may not always be inclusive of diverse populations, including LGBTQ+ individuals, single parents, and individuals with disabilities. Gaps in policies may exclude certain groups from accessing assisted reproduction services or may not adequately address their specific needs. Advocates can work towards policies that promote inclusivity and diversity in assisted reproduction services.

Ethical Considerations: Ethical considerations in assisted reproduction, such as the use of donor gametes, surrogacy arrangements, and genetic testing, may not be adequately addressed in existing policies. Advocates can advocate for policies that uphold ethical standards, protect the rights of individuals involved in assisted reproduction, and ensure informed consent and counseling services are provided.

[47] World Health Organization. Sexual, reproductive, maternal, newborn, child and adolescent health policy survey, 2018-2019: summary report. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO

Education and Awareness: Gaps in assisted reproduction policies may also include a lack of emphasis on education and awareness programs for the public. Individuals may not be fully informed about their reproductive options, the risks and benefits of assisted reproduction, and the legal implications of different procedures. Advocates can push for policies that prioritize education and awareness campaigns to empower individuals to make informed decisions about their reproductive health.

By identifying and addressing these gaps in assisted reproduction policies, advocates can work towards improving the quality, accessibility, and inclusivity of assisted reproduction services, ultimately ensuring that individuals and couples have access to safe and effective reproductive options.

3.1.4. INTERNATIONAL CONFERENCE ON POPULATION AND DEVELOPMENT (1994)

The International Conference on Population and Development (ICPD), held in 1994 in Cairo, Egypt, marked a significant milestone in global discussions on reproductive and sexual health. At this historic conference, representatives from 179 countries, along with numerous non-governmental organizations (NGOs) and international agencies, gathered to address critical issues related to population growth, reproductive health, and sustainable development.[48]

Central to the outcomes of the ICPD were two fundamental guiding principles that continue to shape international discourse and policy in reproductive and sexual health:

Empowerment of Women: One of the primary principles articulated at the ICPD was the recognition that empowering women and improving their social, economic, and political status are not only essential goals in themselves but also indispensable for achieving sustainable development globally. The conference underscored the critical role of women in decision-making processes related to their own reproductive health and well-being. By empowering women with access to education, healthcare, economic opportunities, and reproductive rights, the ICPD highlighted how women's empowerment is intricately linked to broader societal advancement and sustainable development goals.

[48] International Conference on Population and Development, Programme of Action (Cairo, 1994

Reproductive Rights as Human Rights: Another pivotal principle that emerged from the ICPD was the affirmation that reproductive rights are fundamental human rights. This perspective reframed the discussion on reproductive health from merely a demographic or family planning issue to one centered on human rights. The recognition that individuals have the right to make informed decisions about their own reproductive lives, free from coercion, discrimination, and violence, marked a significant shift in global policy frameworks. By placing reproductive rights within the broader context of human rights, the ICPD emphasized the importance of ensuring access to comprehensive reproductive health services, including family planning, maternal health care, and prevention and treatment of sexually transmitted infections.

The ICPD in 1994 represented a paradigm shift in global understanding and action on reproductive and sexual health. By promoting the empowerment of women and recognizing reproductive rights as human rights, the conference set a transformative agenda for advancing individual well-being, gender equality, and sustainable development worldwide. Its principles continue to guide international efforts to this day, shaping policies and programs aimed at improving the lives of women, families, and communities around the world.

3.2. INDIA: REGULATORY LANDSCAPE BEFORE THE ART ACT OF 2021.

Before the enactment of the Assisted Reproductive Technology (ART) Act, 2021 in India, the regulatory landscape for ART in the country was marked by a lack of comprehensive legal and regulatory frameworks. This lack of regulation created a scenario where the ART industry grew rapidly but without consistent standards, leading to various ethical, medical, and legal challenges. Here's an in-depth look at the regulatory landscape before the ART Act, with a particular focus on India and Kerala:

3.2.1.EARLY DEVELOPMENT AND INITIAL CHALLENGES

Lack of National Legislation:

Prior to the ART Act, there was no national legislation specifically governing ART in India. The absence of a legal framework meant that practices varied widely among clinics, leading to inconsistencies in the quality and safety of treatments.

Ethical and Legal Concerns:

Ethical issues such as the commercialization of surrogacy, exploitation of surrogate mothers, and the sale of gametes and embryos were prevalent. Legal questions about parentage, especially in cases involving surrogacy and donor gametes, often led to complex court cases.

Self-Regulation by Clinics:

Many ART clinics operated independently, relying on their own standards and protocols. This self-regulation often resulted in a lack of transparency and accountability. Some reputable clinics adhered to international guidelines, but many others did not, leading to a significant variation in the quality of care.

3.2.2.ROLE OF THE INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)

In 2005, the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS) released the National Guidelines for Accreditation, Supervision, and Regulation of ART Clinics in India. These guidelines aimed to standardize practices across the country. The ICMR guidelines covered various aspects of ART, including the establishment and functioning of ART clinics, ethical considerations, patient rights, and the qualifications of ART practitioners.[49]

The key guidelines by the Indian Council of Medical Research (ICMR) regarding Assisted Reproductive Technologies (ART) include:

Preventing Misuse: The guidelines address the potential misuse of ART, such as the sale of embryos and stem cells, emphasizing the prohibition of sale or transfer of human embryos or gametes outside the country.

Research Approval: All research involving embryos created in vitro must be approved by the accreditation authority within the framework of public interest.

Informed Consent: While the guidelines mention the importance of informing patients about treatments and alternatives, they do not make informed consent mandatory, highlighting the need for comprehensive information provision.

[49] Indian Council of Medical Research & National Academy of Medical Sciences, National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India (2005).]

National Database: Proposing the establishment of a National Database for Human Infertility to track trends in transmitting abnormal genes through ART.

Redefining Legitimacy: Recommending changes in laws to consider children born through artificial insemination as legitimate, irrespective of existing legal presumptions.

Access to ART: Advocating for ART availability to consenting adults regardless of marital status or sexual orientation, emphasizing the need to update language to be inclusive.

Screening of Patients for ART: It outlines criteria for selecting patients undergoing ART and discusses potential complications.

Code of Practice, Ethical Considerations, and Legal Issues: This section addresses ethical and legal aspects related to ART clinics.

Sample Consent Forms: The guidelines include sample consent forms for patients undergoing ART procedures.

Training: Details about training requirements for ART clinic staff are covered.

Future Research Prospects: The guidelines explore potential areas for future research in ART.

Providing ART Services to Economically Weaker Sections: Strategies for ensuring ART services are accessible to economically disadvantaged populations are discussed.

Establishing a National Database for Human Infertility: This chapter focuses on creating a comprehensive database related to infertility.

Composition of the National Accreditation Committee: Information about the committee responsible for accrediting ART clinics is provided.

These guidelines aim to regulate and ensure ethical practices in the field of ART in India, emphasizing the protection of individuals' rights and the prevention of potential misuse of reproductive technologies.

Limitations of the Guidelines:

Despite their comprehensive nature, the ICMR guidelines were advisory and not legally binding. Compliance was voluntary, and enforcement was weak, leading to continued irregularities in the sector.

3.2.3. REGULATORY ENVIRONMENT IN KERALA

Adoption of ICMR Guidelines:

In Kerala, like in other states, many ART clinics followed the ICMR guidelines to some extent. Kerala, known for its relatively advanced healthcare infrastructure, had several reputed ART clinics that adhered to higher standards. However, without a mandatory regulatory framework, there was still a lack of uniformity in practices across the state.[50]

State-Level Initiatives:

Some states, including Kerala, began to recognize the need for more stringent regulation of ART services. There were discussions and proposals at the state level to implement stricter oversight and to establish regulatory bodies, but these efforts were limited in scope and impact.

3.2.4. KEY ISSUES FACED IN THE PRE-ART ACT ERA

Quality and Safety Concerns

The Assisted Reproductive Technology (ART) sector, despite its potential to bring hope to many, has faced significant challenges in maintaining consistent quality and safety standards across clinics. This variability in standards has raised several critical issues:

Medical Malpractice:

The absence of a stringent regulatory framework in the past led to instances of medical malpractice. These included improper administration of ART procedures, which sometimes resulted in adverse health outcomes for patients. The lack of standardized protocols meant that some clinics operated without the necessary

[50] Indian Council of Medical Research & National Academy of Medical Sciences, National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India (2005

expertise or equipment, increasing the risk of complications during and after procedures.

Inadequate Patient Counseling:

Proper counseling is crucial in ART services to ensure that patients are fully aware of the potential risks, benefits, and outcomes associated with the procedures. However, many clinics in Kerala were found lacking in this aspect. Inadequate counseling led to unrealistic expectations, emotional distress, and sometimes even psychological trauma for patients and their families. It also meant that patients were not always informed about alternative treatment options or the ethical implications of their choices.

Insufficient Follow-up Care:

ART procedures require comprehensive follow-up care to monitor the health of both the patient and the resulting pregnancy. Unfortunately, many clinics did not provide adequate follow-up services, leading to neglect of post-procedure complications. This lack of follow-up care also meant that any long-term side effects of ART procedures went unaddressed, potentially endangering the health of patients.

Ethical Dilemmas

The rapid advancement and increased accessibility of ART have brought to the fore several ethical dilemmas, particularly in the context of surrogacy, egg donation, and the handling of excess embryos:

Surrogacy:

Surrogacy, especially commercial surrogacy, has been a contentious issue due to ethical concerns about the exploitation of surrogate mothers. In many instances, vulnerable women were coerced into becoming surrogates for financial reasons, often without a full understanding of the medical risks and emotional toll involved. The lack of regulation meant that surrogate mothers did not always receive adequate healthcare, compensation, or support, leading to cases of exploitation and abuse.

Egg Donation:

Similar ethical concerns surrounded egg donation, where young women, often from economically disadvantaged backgrounds, were incentivized to donate their eggs. The process of egg retrieval carries significant medical risks, and donors were sometimes subjected to repeated procedures without proper medical oversight. Additionally, the lack of informed consent and adequate compensation further exacerbated the exploitation of these women.

Handling of Excess Embryos:

The creation and handling of excess embryos during ART procedures posed serious ethical questions. Decisions regarding the fate of unused embryos—whether to freeze, donate for research, or discard—were often made without clear guidelines or the consent of all parties involved. This lack of regulation led to dilemmas about the moral and ethical status of embryos, raising concerns about their potential misuse or destruction.

Legal Uncertainties

The legal framework surrounding ART has struggled to keep pace with the rapid technological advancements, leading to several uncertainties:

Status of Children Born Through ART:

The legal status of children born through ART, particularly those involving donor gametes or surrogacy, was often ambiguous. This ambiguity created complications in areas such as inheritance rights, parental responsibilities, and citizenship. For instance, in cases where the biological and legal parentage did not align, determining custody and parental rights became a complex legal issue.

Inheritance and Parental Rights:

ART procedures often resulted in disputes over inheritance and parental rights. For example, in cases of anonymous sperm or egg donation, establishing the legal parentage of a child could be challenging. This uncertainty affected the child's rights

to inheritance and support, leading to potential legal battles and emotional distress for all parties involved.

Citizenship:

In cross-border surrogacy arrangements, determining the citizenship of children born through ART was particularly problematic. Different countries have varying laws regarding surrogacy and ART, leading to situations where children were left stateless or faced significant legal hurdles in acquiring citizenship. These legal uncertainties not only affected the children but also posed challenges for intended parents in securing their parental rights and responsibilities.

3.2.5. STEPS LEADING TO THE ART ACT

Growing Awareness and Advocacy:

The increasing number of ART clinics and the rising demand for infertility treatments brought greater public and governmental attention to the need for regulation. Advocacy by medical professionals, ethical bodies, and patient groups played a crucial role in pushing for legal reforms.

Draft ART Bills:

Over the years, several draft ART bills were proposed, reflecting the growing consensus on the need for comprehensive legislation. These drafts addressed key issues such as the accreditation of ART clinics, the rights of patients, and the ethical dimensions of ART practices.

Involvement of Judiciary:

The judiciary also played a role in shaping the regulatory landscape through landmark rulings on issues related to surrogacy, parentage, and the rights of ART children. These rulings highlighted the gaps in the existing framework and underscored the need for robust legislation.

3.3 CONCLUSION

The regulatory landscape of Assisted Reproductive Technology in India, and specifically in Kerala, before the enactment of the ART Act was characterized by significant gaps and inconsistencies. The reliance on voluntary guidelines, the absence of legally binding regulations, and the varied adherence to ethical standards posed numerous challenges. However, the efforts of organizations like the ICMR, the advocacy of various stakeholders, and the growing recognition of the need for regulation eventually paved the way for the ART Act, which aimed to bring much-needed uniformity, safety, and ethical oversight to the practice of Assisted Reproductive Technology in India.

CHAPTER 4
ANALYSIS AND CRITICS OF ART ACT 2021

4.1. INTRODUCTION

In the world of assisted reproductive technologies, the Assisted Reproductive Technologies Act, 2021 acts as a trusted companion, is guiding us through the intricate realm of fertility treatments and research. This chapter invites to explore the essence of the Act, sharing its aspirations, definitions, and vital provisions that aim to ensure a nurturing and ethical environment for Assisted Reproductive Technology services and advancements.

As we embark on this journey through the chapter, we are greeted with a warm embrace of the Act's objectives. These objectives resonate with the desire to oversee and support Assisted Reproductive Technology clinics and banks, fostering a culture of care, safety, and inclusivity. The Act stands as a beacon of hope for individuals seeking to start a family or preserve their reproductive options, offering a reassuring hand along their path.

This chapter introduces to a colorful palette of definitions that paint a vivid picture of the Assisted Reproductive Technology landscape. From unraveling the mysteries of Assisted Reproductive Technology (ART) and clinics to illuminating concepts like embryos, gametes, and the National Registry, these definitions serve as friendly signposts, guiding us through the language of the Act with clarity and understanding.

As we meander through the provisions outlined in this chapter, we encounter a tapestry of regulations and guidelines designed to nurture a culture of professionalism and compassion in Assisted Reproductive Technology services. Whether it's the formation of national and state boards or the requirements for clinics and banks to register, each provision is crafted with a caring touch, ensuring that individuals embarking on their fertility journey are met with respect, dignity, and support.

This chapter stands as a comforting presence in the ever-evolving landscape of fertility treatments and research. It embodies the spirit of empathy, companionship, and empowerment, shaping a future where assisted reproductive technologies in India flourish in a garden of ethical considerations and human connection.

4.2. OBJECTIVE AND KEY PROVISIONS UNDER THE ACT

The Object of the Act for the regulation and supervision of the Assisted Reproductive Technology clinics and the Assisted Reproductive Technology banks, prevention of misuse, safe and ethical practice of Assisted Reproductive Technology services for addressing the issues of reproductive health where Assisted Reproductive Technology

is required for becoming a parent or for freezing gametes, embryos, embryonic tissues for further use due to infertility, disease or social or medical concerns and for regulation and supervision of research and development and for matters connected therewith or incidental thereto. This Act contain 6 chapters 46 sections.

THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 PROVIDES DEFINITIONS FOR KEY TERMS USED IN THE LEGISLATION. HERE ARE SOME OF THE IMPORTANT DEFINITIONS OUTLINED IN THE ACT:

"Assisted Reproductive Technology (ART)[51]: Refers to the techniques used to achieve pregnancy by artificial or partially artificial means."[52]

Clinic[53]: Any institution, establishment, or facility that provides services related to Assisted Reproductive Technology.

Embryo[54]: A fertilized egg up to the eighth week of development.

Gamete[55]: A male or female reproductive cell (sperm or egg) that can unite with another cell to form a new organism.

National Registry[56]: A database maintained by the National Assisted Reproductive Technology and Surrogacy Board containing information about clinics and banks providing ART services.

Oocyte: A female egg cell.

Sperm[57]: Male reproductive cells.

Surrogacy[58]: An arrangement where a woman agrees to carry a pregnancy for another person or couple.

Eligibility Criteria for Donors:

A sperm bank may collect semen from men aged 21-55 and eggs from women aged 23-35. The woman may donate eggs only once in her life and not more than seven

[51] Section 2 (a)) of ART ACT, 2O21

[52] Section 2 (a) of ART ACT, 2O21

[53] Section 2(c)) of ART ACT, 2O21

[54] Section 2 (f)) of ART ACT, 2O21

[55] Section 2(h)) of ART ACT, 2O21

[56] Section 2 (I)) of ART ACT, 2O21

[57] Section 2 (r)) of ART ACT, 2O21

[58] Section 2 (t)) of ART ACT, 2O21

eggs may be retrieved from her. A bank must not supply gamete of a single donor to more than one commissioning party (i.e., couples or single women seeking services).

Conditions for Offering Services:

Commissioning parties and donors must give written consent for ART procedures. The commissioning party will be required to provide insurance coverage in favour of the egg donor (for any loss, damage, or death).

Rights of a child born through ART:

A child conceived with the help of Assisted Reproductive Technology (ART). Will be considered the biological child of the commissioning couple and will have the same rights and privileges as a naturally born child of the commissioning couple. The donor involved in the ART process will not have any parental rights over the child.

These definitions are crucial for understanding the scope and application of the Act in regulating Assisted Reproductive Technology practices in India.

4.3.AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY

4.3.1. THE NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARD

Composition of National Assisted Reproductive Technology[59]

[59] **Section 17 in The Surrogacy (Regulation) Act, 2021**

17. Constitution of National Assisted Reproductive Technology and Surrogacy Board.— (1) The Central Government shall, by notification, constitute a Board to be known as the National Assisted Reproductive Technology and Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act. (2) The Board shall consist of— (a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, ex officio; (b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, ex officio; (c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, ex officio; (d) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, ex officio; (e) the Director General of Health Services of the Central

The Central Government shall constitute a Board, called the National Assisted Reproductive Technology and Surrogacy Board, through a notification to exercise the powers and perform the functions under this Act.

The Board shall consist of:

(a) The Minister of Health and Family Welfare as Chairperson, ex officio;

(b) The Secretary of the Department dealing with surrogacy as Vice-Chairperson, ex officio;

(c) Three women Members of Parliament (two from the House of the People and one from the Council of States), ex officio;

(d) Three Members from the Ministries of Women and Child Development, Law and Justice (Legislative Department), and Home Affairs, not below the rank of Joint Secretary, ex officio;

(e) The Director General of Health Services, ex officio;

(f) Ten expert Members appointed by the Central Government, including:

(i) Two medical geneticists or embryologists;

(ii) Two gynaecologists and obstetricians;

(iii) Two social scientists;

(iv) Two representatives of women welfare organisations;

Government, Member, ex officio; (f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst— (i) eminent medical geneticists or embryologists; (ii) eminent gynaecologists and obstetricians; (iii) eminent social scientists; 10 (iv) representatives of women welfare organisations; and (v) representatives from civil society working on women's health and child issues, possessing such qualifications and experience as may be prescribed; (g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, ex officio; and (h) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member Secretary, ex officio.

(v) Two representatives from civil society on women's health and child issues; (g) Four Chairpersons of State Boards nominated by the Central Government on a rotational basis, ex officio;

(h) An officer, not below the rank of Joint Secretary in the Ministry of Health and Family Welfare's Surrogacy Division, as Member Secretary, ex officio.

Powers and Functions of the National Board

Policy Advisor: Advises the Central Government on Assisted Reproductive Technology (ART) policies.

Oversight: Reviews and monitors the implementation of the ART Act and suggests changes to the Central Government.

Standards and Conduct: Sets codes of conduct, minimum standards for infrastructure, lab equipment, and staffing for clinics and banks.

Performance Monitoring: Oversees the performance of bodies established under the Act and ensures they function effectively.

Registry Supervision: Supervises the National Registry and coordinates with State Boards.

Regulatory Orders: Issues orders as per the provisions of the Act.

Additional Functions: Carries out other prescribed powers and functions.

4.3.2. Composition of State Assisted Reproductive Technology

Constitution of State Assisted Reproductive Technology and Surrogacy Board[60]

Each State and Union Territory with its own Legislature will set up a board called the State Assisted Reproductive Technology and Surrogacy Board, or the Union Territory Assisted Reproductive Technology and Surrogacy Board, as appropriate. These boards have several important functions:

1. Reviewing Activities: They will review the activities of relevant authorities within the State or Union Territory and recommend any necessary actions against them.

2. Monitoring Implementation: The boards will monitor the implementation of the provisions of the Act, including the rules and regulations, and make suitable recommendations to the Board.

[60] section 26 of the Surrogacy (regulation) act, 2021

3. Reporting: They are responsible for sending consolidated reports on various activities undertaken in the State under the Act to both the Board and the Central Government.

4. Additional Functions: The boards may also perform other functions as prescribed.

These measures ensure that Assisted Reproductive Technology and surrogacy practices are properly regulated and that the laws are effectively implemented across the country

Composition of the State Assisted Reproductive Technology and Surrogacy Board[61]

The State Assisted Reproductive Technology and Surrogacy Board will be made up of the following members:

1. Chairperson: The Minister in charge of Health and Family Welfare in the State will serve as the Chairperson, ex officio.

2. Vice-Chairperson: The Secretary in charge of the Department of Health and Family Welfare will serve as the Vice-Chairperson, ex officio.

3. Members from Various Departments: Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice, and Home Affairs, or their nominees, will be members, ex officio.

4. Health Department Representative: The Director-General of Health and Family Welfare of the State Government will also be a member, ex officio.

5. Legislative Representatives: Three women members from the State Legislative Assembly or Union Territory Legislative Council will be members, ex officio.

6. Expert Members: Ten expert members will be appointed by the State Government, including:

- Two eminent medical geneticists or embryologists.

- Two eminent gynecologists and obstetricians.

- Two eminent social scientists.

- Two representatives of women welfare organizations.

- Two representatives from civil society working on women's health and child issues.

[61] section 27 of the Surrogacy (regulation) act, 2021

7. Member-Secretary: An officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare will serve as the Member-Secretary, ex officio.

This diverse composition ensures that the board is well-equipped with expertise and representation from various sectors crucial to overseeing Assisted Reproductive Technology and surrogacy practices effectively.

Powers and Functions of the State Board

Policy Implementation: Responsible for following the policies and plans set by the National Board for ART clinics and banks in the state.

Enforcement Coordination: Ensures the enforcement and implementation of the National Board's policies and guidelines for assisted reproduction.

Additional Duties: Carries out other prescribed functions and powers as needed.

Compliance: Issues directions or orders as instructed by the National Board

4.3.3. National Registry and Authority

Establishment and Composition:

According Section 9 of ART Act, The National Assisted Reproductive Technology and Surrogacy Registry (National Registry) will be established by the Central Government within 90 days of the Act's commencement. This registry will serve as a central database for all fertility clinics and banks across the country. It will be staffed with scientific, technical, administrative, and support personnel as needed.

Functions of the National Registry:

Central Database: The National Registry will maintain comprehensive records of all clinics and banks, including the services they offer and their outcomes.

Support to the National Board: It will provide crucial data to the National Board, aiding in policy-making and guideline formulation.

Research Facilitation: The data collected will help identify new research areas and support studies related to assisted reproduction.

Additional Functions: Other responsibilities as prescribed by the governing authorities.

Appropriate Authorities:

The Central Government will also appoint one or more appropriate authorities for each Union territory within 90 days. Similarly, State Governments will appoint appropriate authorities for their regions within the same timeframe.

Composition of Appropriate Authorities:

For a whole State or Union territory, the appropriate authority will include:

Chairperson: An officer of the Health and Family Welfare Department of or above the rank of Joint Secretary.

Vice-Chairperson: An officer of the Health and Family Welfare Department of or above the rank of Joint Director.

Women's Representative: An eminent woman from a women's organization.

Legal Officer: An officer from the Law Department of or above the rank of Deputy Secretary.

Medical Practitioner: An eminent registered medical practitioner.

For specific parts of a State or Union territory, the composition may vary based on the government's discretion. Non-ex officio members will be reimbursed for travel expenses for attending meetings.

Functions of Appropriate Authorities:

Registration Management: Grant, suspend, or cancel the registration of clinics or banks.

Standards Enforcement: Ensure clinics and banks meet the required standards.

Complaint Investigation: Investigate breaches of the Act and take necessary legal action.

Technology Misuse Prevention: Initiate independent investigations against misuse and take legal actions.

Supervision: Oversee the implementation of the Act and its regulations.

Advisory Role: Recommend necessary changes to rules and regulations to the National and State Boards.

Complaint Response: Act on complaints against ART clinics or banks.

Additional Duties: Perform other prescribed functions.

Powers of Appropriate Authorities:

Information Gathering: Summon inividuals possessing information on violations of the Act.

Document and Material Production: Request documents or materials related to potential violations.

Search Operations: Conduct searches in places suspected of violating the Act.

Additional Powers: Exercise other powers as prescribed.

4.4. REGISTRATION OF ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS AND BANKS[62]

Mandatory Registration: No clinic or bank can provide Assisted Reproductive Technology (ART) services without proper registration under this Act.

Application Process: Clinics or banks must apply for registration through the National Registry via the appropriate ART and surrogacy authority, following the prescribed format and fee.

Deadline for Existing Clinics/Banks: Clinics or banks already offering ART services must apply for registration within 60 days of the National Registry's establishment. They must cease operations if not registered within six months from the Act's commencement or until their application is processed.

Compliance Requirements: Registration will only be granted if the appropriate authority is satisfied that the clinic or bank meets all prescribed standards, including specialized staff, infrastructure, and diagnostic facilities.

When an application for registration is submitted, the appropriate authority has 30 days to either grant registration and provide a registration number or reject the application with written reasons. No application can be rejected without first giving the applicant an opportunity to be heard. If the authority fails to make a decision within this period, they must explain the delay within seven days.[63]

Once registered, the clinic or bank must be inspected by the State Board, and this registration is valid for five years. The registration certificate must be prominently displayed and include the validity period. For renewal, applications must be made before the five-year period ends, and no renewal application can be rejected without a hearing.[64]

[62] Section 15 of ART Act

[63] Section 16 of ART Act

[64] Section 17 of ART Act

If there are complaints, the authority can issue a notice to the clinic or bank to explain why their registration should not be suspended or canceled. After a hearing, if a breach is confirmed, the registration can be suspended or canceled, and the State Board will be notified.[65]

Appeals against decisions to reject, suspend, or cancel registration can be made within 30 days to the State Government or Central Government, depending on the jurisdiction.[66]

The National Board, National Registry, and State Board have the authority to inspect premises and request documents related to Assisted Reproductive Technology to ensure compliance with the Act.[67]

4.5. GENERAL DUTIES OF ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS AND BANKS(SEC.21)[68]

Eligibility Criteria: Clinics and banks must ensure that commissioning couples, women, and gamete donors meet prescribed eligibility criteria to avail Assisted Reproductive Technology procedures.

Medical Testing: Clinics should obtain donor gametes from banks that have ensured the donor's medical testing for prescribed diseases.

Professional Counseling: Clinics must provide professional counseling to commissioning couples and women about the implications, success rates, advantages, disadvantages, costs, medical side effects, risks (including multiple pregnancy risk), and help them make informed decisions.

Child's Rights Awareness: Clinics should make commissioning couples or women aware of the rights of a child born through Assisted Reproductive Technology.

Confidentiality: Clinics and banks must maintain confidentiality of information about commissioning couples, women, and donors, disclosing information only to the National Registry database, in medical emergencies at the request of the relevant commissioning couple, or by court order.

Grievance Cell: Every clinic and bank must maintain a grievance cell to address complaints related to their services.

Age Restrictions: Clinics can apply Assisted Reproductive Technology services to women aged 21 to 50 years and men aged 21 to 55 years.

[65] Section 18 of ART Act

[66] Section 19 0f ART Act

[67] Section 20 ART Act

[68] Assisted Reproductive Technology Act, 2021

Discharge Certificate: Clinics should issue a discharge certificate to the commissioning couple or woman, detailing the Assisted Reproductive Technology procedure performed.

Cooperation with Authorities: All clinics and banks must cooperate and make their premises available for physical inspection by the National Board, National Registry, and State Boards.

Information Sharing: Clinics and banks are required to provide information related to the enrollment of commissioning couples, women, and gamete donors, the procedures being undertaken, and outcomes periodically to the National Registry in a prescribed manner.

4.6. DUTIES OF ASSISTED REPRODUCTIVE TECHNOLOGY (ART) CLINICS USING HUMAN GAMETES AND EMBRYOS

Clinics must retrieve oocytes according to specified regulations.

During a treatment cycle, no more than three oocytes or embryos may be placed in a woman's uterus, as per regulations.

A woman cannot be treated with gametes or embryos derived from more than one man or woman during a single treatment cycle.

Clinics must never mix semen from two individuals for ART procedures.

Embryos cannot be split or manipulated for twinning purposes to increase the number of available embryos.

Collection of gametes posthumously is allowed only if prior consent of the commissioning couple is available as prescribed.

Clinics are prohibited from using ovum derived from a fetus in any in-vitro fertilization process.

: Clinics must fulfill any other duties prescribed by regulations.

4.7. PROHIBITION AND RESTRICTION UNDER ART ACT

Sex selection in Assisted Reproductive Technology (ART)- Section 26[69]

Prohibition of Sex Selection: ART clinics are prohibited from offering to provide a couple or woman with a child of a predetermined sex, in accordance with the Pre-

[69] Assisted Reproductive Technology Act, 2021

conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994).

Prohibition of Sex Determination: It is prohibited for anyone, at any stage of the ART process, to determine the sex of the child to be born or to separate or yield fractions enriched in sperm of X or Y variations.

Limitations on Sex-Related Procedures: Individuals are not allowed to knowingly provide, prescribe, or administer anything to ensure or increase the probability of an embryo being of a particular sex, except for diagnosing, preventing, or treating sex-linked disorders or diseases.

Sex selective ART—Punishment-imprisonment for a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both.(Section 32)

Restriction on sale, etc., of human gametes, zygotes and embryos- Section 29[70]

The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within or outside India shall be prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board

Research on human gametes and embryos- Section 30

(1) The use of any human gametes and embryos or their transfer to any country outside India for research shall be absolutely prohibited.

(2) The research on human gamete or embryo within India shall be performed in such manner as may be prescribed.

4.8. OFFENCES AND PENALTIES

Section 33 of ART Act deals with offences and penalties.

1. Prohibited Actions:

Medical geneticists, gynecologists, registered medical practitioners, or any person are prohibited from:

a. Abandoning, disowning, exploiting, or causing the abandonment, disownment, or exploitation of children born through ART.

b. Selling human embryos or gametes, running agencies, rackets, or organizations for the sale, purchase, or trade of human embryos or gametes.

[70] Assisted Reproductive Technology Act, 2021

c. Importing or assisting in the importation of human embryos or gametes.

d. Exploiting commissioning couples, women, or gamete donors in any form.

e. Transferring human embryos into male persons or animals.

f. Selling any human embryo or gamete for research purposes.

g. Using intermediates to obtain or purchase gamete donors.

2. Penalties for Contravention: Violators of these provisions face strict penalties:

- For the first contravention, a fine of not less than five lakh rupees but may extend to ten lakh rupees.

- For subsequent contraventions, imprisonment for a term of not less than three years but may extend to eight years, along with a fine of not less than ten lakh rupees but may extend to twenty lakh rupees.

Section 34 ensures that violations of the Act or rules made under it, which are not explicitly addressed with specific penalties, are still subject to punishment as prescribed under subsection (2) of section 33 of the Act.

4.9. POWERS OF CENTRAL GOVERNMENT AND STATE GOVERNMENT

Central Government Directives

The Central Government has the power to direct the National Board, National Registry, and other relevant authorities to act in the interests of India's sovereignty, security, foreign relations, public order, decency, or morality. This means that the central government can intervene and issue guidelines to ensure that ART practices align with national priorities and ethical standards.

These bodies must comply with government policy directions, ensuring that their actions and decisions align with broader national policies. Before any directive is issued, the National Board can express its views, ensuring that expert opinions are considered. This promotes a balance between government oversight and professional autonomy.

If there is any disagreement between the National Board and the Central Government about whether an issue is a matter of policy, the Central Government's decision is final. This clause ensures that there is a clear and authoritative resolution mechanism for any policy disputes.[71]

State Government Directives

[71] Section 38 (3) of ART Act

State governments have similar powers within their jurisdiction to direct the State Board and appropriate authorities. This ensures that state-level ART practices are also in line with national interests like sovereignty, security, and public morality.

The State Board and appropriate authorities must follow state government policies and can provide their input before directives are issued. This provision ensures that state-specific concerns and professional insights are taken into account.

Any disputes about whether an issue is a matter of policy between the State Board and the state government are resolved by the State Government, ensuring clarity and consistency in policy implementation at the state level.

Inspection and Seizure

The National and State Boards, or authorized officers, can inspect any ART facility if they suspect a violation of the Act. They can enter the premises, examine records, and seize documents or materials that may serve as evidence of an offence. This ensures compliance with legal and ethical standards and helps in maintaining the integrity of ART practices.

Legal Protections

Good Faith Actions: Officials acting in good faith under the provisions of this Act are protected from lawsuits, prosecutions, or other legal proceedings. This clause provides legal immunity to those enforcing the Act, encouraging diligent and unbiased enforcement.[72]

Rule-making Powers

1. *Central Rules:* The Central Government is empowered to create detailed rules to implement the Act effectively. These rules cover all necessary aspects to ensure that ART practices are conducted safely and ethically.

2. *Specific Areas:* The rules can include specifics on the powers and functions of the National and State Boards, conditions for licensing, registration processes, donor criteria, and reporting procedures. This comprehensive rule-making authority ensures that all operational aspects of ART are regulated.

Regulation Powers

National Board Regulations: The National Board, with the approval of the Central Government, can create regulations consistent with the Act. These regulations ensure that the ART practices adhere to the standards and procedures established by the Act, covering areas like oocyte retrieval, embryo placement, and other technical processes.

[72] Section 41 of ART Act

Parliamentary Oversight

Review Process: All rules and regulations must be presented to Parliament for review. This process ensures that the legislative branch oversees the regulatory framework, providing an additional layer of scrutiny and accountability.

Complementary Laws

Additional Legislation: The provisions of this Act complement other laws such as the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act and the Clinical Establishment (Registration and Regulation) Act. This integration ensures a cohesive regulatory environment for reproductive and clinical practices.

Addressing Difficulties

Resolution of Issues: If any issues arise in implementing the Act, the Central Government can make necessary provisions to address them, provided these adjustments are made within three years of the Act's commencement. This allows for flexibility in the initial phase of implementation, ensuring that unforeseen challenges can be effectively managed.

4.10. CRITICISM OF THE ACT

Exclusion of Unmarried and Heterosexual Couples: The Act prohibits unmarried men, divorced men, widowed men, unmarried heterosexual couples living together, trans persons, and both married and unmarried homosexual couples from accessing ART services. This exclusion is significant because the Surrogacy Act also prohibits these individuals from using surrogacy as a means of reproduction.

Reduces the Reproductive Choices: The Act only applies to infertile couples who have been trying to conceive for a year without success. It excludes those who are fertile and limits their reproductive options. This significantly reduces the choices available to them.

Unregulated Prices: The prices of services related to Assisted Reproductive Technology (ART) are not regulated, but this can be remedied with simple directives. While section 5 subsection (c) of chapter II briefly mentions the requisite infrastructure, equipment, and manpower required for ART clinics and banks, it would be helpful to elaborate on the minimum technical qualifications and experience required for gynecologists, embryologists, counselors, and other staff involved in ART. These details might be included in the rules and regulations under the Act.

Adoption is an important aspect of failed fertility treatment that many couples resort to after repeated failures with ART. However, adoption is also unregulated in our country. Therefore, regulation of adoption should have been included along with ART

and surrogacy. While the inclusion of surrogacy is a welcome step, it would have been helpful to elaborate on the provisions for disputes arising from surrogacy contracts. This is particularly important as many international couples from developed countries seek surrogacy services in developing countries like India.

Age restriction of commission couple[73] is violative of fundamental right.

4.11. THE CASE LAWS IN KERALA THAT GIVE EFFECTIVE IMPLICATION OF ART ACT

Rakhi Bose and Another V. Union of India, Represented by its Principal Secretary, Prime Minister's Office and Others [74]

Fact of the case: The couple got married in 2007 but couldn't have children even after 15 years. They tried infertility treatment at a hospital. The wife underwent a procedure to collect eggs, and some embryos were made from those eggs. They stored these embryos at the hospital. Later, they tried treatment at another hospital in Dubai but had to stop because of a medical issue. Then, they saw the wife's sister, who had similar problems, give birth to twins after treatment. So, they wanted to continue their treatment at another hospital and asked to transfer the embryos there. But, a new law came into effect in 2022, making it difficult to transfer the embryos under section 29. So, they filed a writ petition.

Court Finding: Section 29 of the law doesn't apply to the transfer mentioned here. This law aims to prevent the sale of human reproductive materials like eggs and embryos. But in this case, the embryos belong to the couple seeking treatment, not to any donors. The law doesn't address this situation of transferring embryos between the couple's own treatments. It's important to consider the rights of the embryos, which have been frozen for 8 years, to potentially develop into babies. The main goal of the law is to regulate and oversee fertility clinics and banks to ensure safe and ethical practices, not to create obstacles for people seeking fertility treatments.

Nandini K. v. Union of India [75]

Facts: The writ petitions are filed by couples undergoing or intending to undergo assisted reproductive services, driven by the desire to have children. The petitioners challenge the upper age limit of 50 years for women and 55 years for men prescribed under the Assisted Reproductive Technology (Regulation) Act, 2021 ('the ART Act'

[73] Section 2 (e) "commissioning couple" means an infertile married couple who approach an Assisted Reproductive Technology clinic or Assisted Reproductive Technology bank for obtaining the services authorised of the said clinic or bank;

[74] 2022 SCC OnLine Ker 3250

[75] 2023 (1) KHC 149

for short), which prohibits the application of ART services to persons above the prescribed age limit. According to the petitioners, prescription of the upper age limit under Section 21 (g) of the ART Act is irrational, arbitrary, unreasonable and violative of their right to reproduction, acknowledged as a fundamental right under Article 21, personal liberty.

Court Findings: prohibition under Sec. 21(g) if understood to be preventing even continuance of ART services already commenced would definitely amount to unreasonable and unjustified restriction on the reproductive choice of the commissioning couple and would militate against the liberty guaranteed under Article 21 of the Constitution of India. National board shall alert central government to relook into this provision under section 5 of ART Act.

Pushpa Babu and Another V. Union of India Represented by its Secretary and Others [76]

The writ petition requests permission to continue Assisted Reproductive Technology (ART) services without being bound by the age limit set in Section 21(g) of the Assisted Reproductive Technology (Regulation) Act, 2021. This is based on a previous court ruling (above mentioned) that such restrictions would infringe upon the constitutional right to reproductive choice. The petitioners seek to benefit from this ruling as they were undergoing treatment at that time. The court grants their request, allowing them to continue their ART services without age constraints. Any further issues can be brought to the court's attention later.

4.12. CONCLUSION

This chapter provides a comprehensive overview of the regulatory framework governing assisted reproductive services in India. Through clear objectives, precise definitions, and detailed provisions, the Act aims to ensure the safe, ethical, and effective practice of assisted reproductive technologies.

By establishing national and state boards, outlining registration requirements for clinics and banks, and emphasizing the importance of professionalism and compassion in fertility treatments, the Act sets a solid foundation for the regulation of assisted reproductive services. It strives to protect the well-being of individuals seeking fertility treatments while promoting integrity and ethical standards in the field.

Overall, the chapter underscores the significance of creating a supportive and regulated environment for individuals navigating the complexities of assisted reproduction. The Assisted Reproductive Technologies Act, 2021 emerges as a guiding force in shaping a future where fertility treatments are conducted with care,

[76] 2023 SCC OnLine Ker 6608

respect, and adherence to ethical principles, ensuring the dignity and rights of all individuals involved in the process.

CHAPTER -5

ETHICAL AND LEGAL IMPLICATIONS OF THE ART ACT ,2021

5.1 INTRODUCTION

This research explores the real-world hurdles and limits in putting the Assisted Reproductive Technology (Regulation) Act 2021 into action in Kerala. It zeroes in on how the Act's legal, administrative, ethical, and infrastructural rules mesh with what's happening on the ground. , it looks at how well healthcare providers can stick to the new rules how capable state bodies are to enforce the law, and what social and ethical roadblocks pop up during rollout. By taking a close look at Kerala, this study aims to gauge how well the ART Act hits its targets and where it runs into snags within the healthcare scene. The research sticks to a descriptive approach throughout.

This chapter looks at the real-world problems in putting the Assisted Reproductive Technology (Regulation) Act 2021 into action in Kerala. The law takes an important step to bring consistency ethical oversight, and responsibility to ART practices across India. However, making it work in Kerala has run into many roadblocks. We break down these barriers into four main areas: rules, ethics, management, and operations. Each area shows a different side of how the law works (or doesn't work) in real life. On the rules side many parts of the Act though meant to help cause big problems for those involved. Tight age limits strict rules for who can be parents leaving out some groups (like single men and LGBTQ+ people), and unclear laws about keeping donors secret and parental rights have worried legal experts, doctors, and community groups. These rules often don't fit with Kerala's open-minded public health approach where people are more accepting of different family types. The ethical issues are just as big.

The ART ecosystem in Kerala like elsewhere in India is shaped by sensitive issues such as the potential exploitation of economically vulnerable egg donors and surrogate mothers, inadequate informed consent mechanisms, and the commoditization of reproduction. Additionally, the Act’s insistence on altruistic surrogacy, while morally appealing, creates practical difficulties when set against the backdrop of a privatized fertility industry. Administrative challenges further complicate the picture. Delays in establishing the State Appropriate Authority, lack of procedural clarity during clinic registration, insufficient training of government officials, and weak coordination between state and central authorities have all slowed down or hindered effective implementation. The absence of a robust monitoring system leaves many clinics in a state of uncertainty, often dependent on ad-hoc interpretations of the law. And operational challenges faced by fertility clinics and healthcare providers on a day-to-day basis cannot be ignored. Many smaller or rural clinics struggle with the cost of compliance, infrastructure upgrades, and documentation requirements. Practitioners also report confusion due to shifting guidelines and fear punitive action in the absence of adequate legal literacy.

By analyzing these four dimensions, regulatory, ethical, administrative, and operational, this chapter seeks to offer a holistic understanding of the constraints in implementing the ART Act in Kerala, thereby contributing meaningful insights toward more effective and inclusive reproductive law and policy.

5.2 Administrative and Structural Challenges

The efficient execution of any law is bound by the law's own quality and the strength of the administrative system enforcing it. In the case of the Assisted Reproductive Technology (Regulation) Act, 2021, there are some serious problems of an administrative and organizational nature in the implementation phase in Kerala. These issues have inhibited the expected smooth facilitation of fertility services and, at times, resulted in confusion and lack of clarity around the services offered by care providers as well as the expectations of patients.

The most notable administrative stumbling block in Kerala was the delay in setting up the State Appropriate Authority (SAA) and the State Assisted Reproductive Technology and Surrogacy Board. These bodies are pivotal to the functioning of the Act. They are responsible for the registration, monitoring, compliance, grievance redressal of ethical practices, and supervision of ART and surrogacy clinics. The delay in their constitution meant that however compliant clinics and practitioners were, they remained from a legal standpoint in quasi-oblivion. During the law's grace period that precedes its enforcement period; several facilities did not know whether their operational procedures were lawful or reputable. This ungoverned area of regulation defeated the primary intervening path which guarantees an equal set of conditions.

Even after these bodies were formed, state health department staff and district-level officers were often tasked with responsibilities such as inspecting ART clinics, verifying consent procedures, or approving applications without receiving comprehensive orientation on the technical and legal complexities of ART. As a result, officials struggled to interpret the nuances of the law, leading to either overcautious approaches that delayed approvals or under enforced compliance in some regions. This gap between legal expectation and administrative capacity has become a recurring bottleneck in Kerala's execution of the ART Act.

Another key challenge relates to the registration of clinics and ART banks via the National ART and Surrogacy Registry (NARTSR) portal. Though the central online platform was introduced to streamline registration, many Kerala-based clinics have found the process cumbersome and unclear. The portal requires multiple levels of documentation, including proof of infrastructure, staffing qualifications, patient consent formats, and various affidavits all of which must be uploaded and verified within tight timelines. Smaller clinics, especially those in rural districts, reported

difficulties navigating the system due to limited digital infrastructure, lack of in-house legal counsel, or poor internet connectivity. Furthermore, some clinics complained that there was no clear helpline or point of contact to resolve issues, which left them in procedural limbo. These technical challenges have created backlogs in registration and delays in the issuance of approval certificates, directly affecting patients waiting for ART services.

In addition to procedural delays, there has also been a significant lack of public-facing documentation and transparency from the health authorities in Kerala. While the Directorate of Health Services (DHS) does maintain a portal with downloadable forms and FAQs, there has been limited outreach to ensure that clinics and patients are aware of their rights, obligations, and the steps required to comply with the law. In many cases, clinics were unsure whether certain procedures such as cryopreservation transfers or donor sourcing were still permissible under the new guidelines. The absence of frequent updates, circulars, or district-level workshops further widened the information gap. This lack of transparency particularly affected smaller clinics that do not have dedicated legal departments and rely heavily on government instructions to ensure compliance.

Moreover, the coordination between state-level administrative bodies and central regulatory agencies has not always been smooth. Kerala's health policy environment has traditionally emphasized inclusivity and decentralization, but aligning this with the more rigid and centralized structure of the ART Act has proven difficult. For instance, decisions regarding clinic eligibility or donor registration are often dictated by central guidelines that may not reflect Kerala's unique demographic and healthcare landscape. This misalignment has led to frustration among stakeholders who feel that the state's autonomy in health matters is being compromised, or that the ART Act fails to consider Kerala-specific needs such as rural healthcare delivery, gender-sensitive reproductive counseling, or linguistic accessibility of patient materials.

The administrative and structural challenges in implementing the ART Act in Kerala are multi-layered. The initial delay in forming statutory bodies created a foundational gap that took time to rectify. Once established, these bodies struggled with undertrained staff and lacked the operational readiness to roll out a highly technical and sensitive regulatory framework. Clinics faced procedural confusion, registration backlogs, and a lack of support when navigating the NARTSR portal. Most critically, there was a noticeable absence of transparent communication and public guidance from the state authorities. Collectively, these challenges underscore that legal enactment alone is not sufficient; successful implementation requires strong administrative capacity, digital literacy support, inter-agency coordination, and continuous engagement with the medical community. Unless these structural weaknesses are addressed, the goals of the ART Act to ensure ethical, accessible, and safe reproductive care will remain only partially fulfilled in the Kerala context.

5.3 Regulatory Burden on Healthcare Providers

The implementation of the Assisted Reproductive Technology (Regulation) Act, 2021, while essential in principle, has introduced considerable regulatory pressure on fertility clinics and healthcare providers, particularly in a diverse and healthcare-driven state like Kerala. Although the Act's primary aim is to establish a standardized and ethical framework for ART services, its on-ground applicability presents multiple challenges to the very institutions it seeks to regulate. The burdens imposed by the law span from infrastructural upgrades to legal compliance, making it difficult for clinics especially small or independent centers to adapt without significant strain.

One of the most pronounced burdens stems from the extensive infrastructural and documentation requirements imposed by the Act. Clinics are mandated to meet strict criteria related to laboratory infrastructure, staffing qualifications, equipment maintenance, and data storage protocols. For instance, ART clinics are now legally obligated to maintain patient records for up to ten years and to document every stage of the treatment process in prescribed formats. While these steps are aimed at transparency and patient safety, they have the unintended consequence of imposing a heavy administrative load on clinics that may not have the resources to manage large volumes of paperwork, digital compliance tools, or dedicated legal staff. The statutory emphasis on documentation especially consent forms, essentiality certificates, and donor information requires ongoing vigilance and precision, which is often difficult for smaller setups with limited human resources.

Moreover, the Act has introduced significant complexity in clinic registration and legal compliance, especially through the centralized online platform known as the National ART and Surrogacy Registry (NARTSR). While this portal was envisioned as a digital solution to streamline the regulatory process, it has posed practical difficulties for many providers. The portal demands accurate and comprehensive uploads of clinic credentials, facilities, technical staff lists, and treatment protocols. Many smaller clinics, particularly in semi-urban and rural areas, struggle with the digital infrastructure and procedural know-how required to complete these tasks accurately. Any delay or omission can result in registration rejections or procedural delays, effectively freezing the clinic's operations until compliance is achieved. For new clinics or those transitioning into ART services, the initial hurdle of registration alone becomes a barrier to entry.

The lack of accessible, practical guidance on legal obligations under the Act has further compounded the burden. While the legislation lays down a wide array of duties for ART clinics ranging from procedural ethics to the handling of cry preserved gametes it often lacks operational clarity. For instance, the law prescribes that clinics must obtain "essentiality certificates" before initiating ART procedures, but does not provide detailed, universally applicable criteria for how these should be evaluated or issued by the appropriate authorities. This lack of clarity causes confusion among clinics and results in inconsistent interpretations across different administrative

jurisdictions in Kerala. As a result, clinics that are otherwise willing to comply may inadvertently fall short due to the vagueness in the regulatory process.

Small and medium-sized clinics, particularly those that operate independently or serve patients in rural areas, have found the cost and effort of compliance particularly burdensome. Unlike corporate-affiliated fertility chains or large metropolitan hospitals, these clinics do not have dedicated compliance teams or legal consultants. For them, the pressure to meet infrastructure requirements such as maintaining advanced laboratory standards, hiring specialized embryologists, and setting up detailed electronic medical record systems can threaten their financial viability. This introduces a worrisome dynamic wherein regulation, rather than supporting ethical practice, risks driving smaller, community-based providers out of the sector, thereby reducing access to ART for lower-income or geographically distant populations.

Another layer of burden arises from the legal risks and penalties for non-compliance embedded within the Act. The legislation provides for severe consequences, including imprisonment and fines up to ten lakh rupees for certain violations. These include failures in record maintenance, unauthorized procedures, or insufficient documentation of consent. For providers who are attempting in good faith to adapt to the new law, the harshness of the penal provisions can create a climate of fear and hesitation. Rather than promoting confident and transparent engagement with regulation, it can lead to defensiveness, or worse, non-disclosure of grey areas in practice.

In conclusion, while the ART Act provides a necessary legal framework to regulate reproductive technologies, it has imposed a considerable regulatory burden on healthcare providers, particularly those operating outside large urban centres. The emphasis on infrastructure, paperwork, and legal risk though well-intentioned requires a more balanced approach that differentiates between levels of clinic capacity and supports incremental compliance. In the absence of operational clarity, digital support, and phased implementation, there is a real risk that the law could become a barrier to access rather than a vehicle for ethical reform. As this chapter highlights, addressing the regulatory burden on providers is essential not only for improving implementation but also for ensuring that reproductive healthcare remains inclusive and equitable across the state of Kerala.

5.4 Ethical and Social Dilemmas in Kerala

The implementation of the Assisted Reproductive Technology (Regulation) Act, 2021 in Kerala has raised numerous ethical and social dilemmas that go beyond the text of the law. While the Act aims to create a framework for responsible and regulated reproductive practices, the socio-cultural context of Kerala, along with certain embedded ethical tensions, complicates the law’s acceptance and real-world

application. These dilemmas reflect the intersection of reproductive rights, social norms, medical ethics, and inclusivity, all of which significantly influence the state's ART landscape.

One of the most persistent social dilemmas concerns the stigma surrounding infertility particularly in rural and semi-urban areas of Kerala. Despite high literacy rates and progressive health indicators, infertility continues to be associated with shame and social exclusion in many parts of the state. For women in particular, the inability to conceive is often viewed as a personal failing, impacting their social status, marital stability, and psychological well-being. While ART offers a medical solution, the secrecy with which many couples approach fertility clinics suggests that the social environment remains deeply judgmental. This stigma discourages open conversations, delays help-seeking behaviour, and reinforces the perception of ART as a "last resort" to be kept hidden. Thus, even with legal regulation in place, the cultural context continues to restrict equitable access to reproductive care.

Another pressing ethical concern arises from the potential exploitation of egg donors and surrogate mothers. The ART Act and the Surrogacy (Regulation) Act attempt to address this by banning commercial surrogacy and mandating altruistic arrangements. However, in practice, this has led to a grey zone where ethical intentions may not match actual outcomes. In Kerala, where economic disparities still exist despite overall development, there is a real risk that economically vulnerable women may be subtly coerced into donating eggs or becoming surrogates under the guise of altruism. The concept of "altruistic surrogacy," while noble in theory, presumes voluntary, informed, and emotionally motivated participation conditions that may not be realistically present in all cases. Without a clear enforcement mechanism and regular monitoring, there is a risk that the legal prohibition of payment may push such arrangements underground, making them harder to regulate and potentially more exploitative.

The exclusion of LGBTQ+ individuals and single men from ART access presents yet another ethical and legal dilemma. The current structure of the ART Act only permits legally married heterosexual couples and certain categories of single women to avail ART services. While this may have been intended to preserve a particular definition of the "family unit," it inherently discriminates against individuals on the basis of sexual orientation, gender identity, and marital status. In a state like Kerala, which has taken progressive steps toward recognizing transgender rights and LGBTQ+ inclusion through various state-level policies and welfare boards, this exclusion appears particularly regressive. By failing to accommodate the reproductive aspirations of LGBTQ+ individuals, single men, and same-sex couples, the law enforces a heteronormative framework that is increasingly at odds with Kerala's evolving social and legal ethos. The denial of ART access to these groups not only raises questions of equality and non-discrimination under Article 14 of the Constitution but also

undermines the reproductive autonomy of individuals seeking to form families outside traditional structures.

A related ethical dilemma stems from the tension between the law's preference for altruistic surrogacy and the commercial realities of the fertility industry. While altruistic surrogacy is promoted as a morally superior model one rooted in compassion, familial bonds, and voluntary service it overlooks the economic structure that has historically driven the fertility sector in India, including in Kerala. Many fertility clinics operated within a commercial framework prior to the legislation, and the sudden shift to altruism has created operational and legal confusion. In practical terms, finding a surrogate purely for altruistic reasons is a challenge, especially for couples who do not have close female relatives willing to undertake such a physically and emotionally demanding process. This disjuncture has led to criticism that the law is idealistic and detached from social realities, particularly when it presumes that altruism can function effectively in a domain previously governed by market principles.

Moreover, the lack of public awareness and open discourse around ART and surrogacy further intensifies these ethical and social dilemmas. Even though the law has been passed, its principles and objectives remain poorly understood among the general population. Without targeted awareness campaigns and inclusive dialogue, the law's intent to protect rights and ensure fairness may be lost in translation, leading to fear, misinformation, or non-compliance.

In conclusion, the implementation of the ART Act in Kerala brings to the surface multiple ethical and social dilemmas that are deeply rooted in the state's cultural, economic, and legal fabric. The stigma around infertility, risks of exploitation, exclusion of non-traditional family structures, and unrealistic expectations around altruism all point to the need for a more context-sensitive and inclusive approach. While the Act seeks to standardize and safeguard reproductive technologies, its success will ultimately depend on whether it can evolve to reflect the diverse realities and ethical complexities of contemporary Indian society particularly in a socially aware but culturally sensitive state like Kerala.

5.5 Legal Ambiguities and Case Law in Kerala

The Assisted Reproductive Technology (Regulation) Act, 2021 has undoubtedly brought a long-needed legal framework to a rapidly growing and ethically complex field. However, as its implementation unfolds, particularly in a legally active and socially progressive state like Kerala, several legal ambiguities have surfaced some of which have prompted judicial intervention. These ambiguities not only affect the clarity of the law for healthcare providers and intended parents but also highlight potential tensions between central legislation and Kerala's state-level health and social inclusion policies.

One of the most prominent areas of contention has been the age restrictions imposed by the ART Act. The law mandates that a woman undergoing ART must be between 21 and 50 years of age, and a man between 21 and 55 years. Although this provision was likely introduced to ensure the physical well-being of both parents and the future child, it has been subject to criticism for being overly rigid and lacking in exceptions for genuine cases. The Kerala High Court has played a significant role in interrogating the reasonableness of these limitations.

In a notable case from 2023, a 46-year-old married woman approached the High Court seeking permission to undergo in vitro fertilisation (IVF) using donor sperm, as her husband was over the age of 55 and therefore technically ineligible under the Act. The woman argued that denying her treatment based solely on her husband's age violated her reproductive autonomy. The Court, in its ruling, allowed the procedure and held that the Act does not explicitly prohibit the use of donor gametes in such circumstances, especially when the woman herself is within the permissible age bracket. The judgment also highlighted the absence of transitional provisions in the law, which could unfairly disadvantage couples already in the process of seeking ART when the Act came into force. The ruling is significant not only for its practical implications but also for how it underscored the lack of interpretive clarity within the legislation.

Another major legal grey area lies in the Act’s silence regarding transgender individuals and their eligibility to access ART services. While the law refers to "intending couples" and, in some provisions, to single women, it does not provide any explicit recognition of transgender persons, non-binary individuals, or same-sex couples. This omission becomes particularly problematic in Kerala, a state that has been at the forefront of inclusive health and gender policies. The state has instituted several progressive measures, such as a transgender welfare board, government-sponsored gender affirmation surgeries, and LGBTQ+ health initiatives. In light of these advancements, the exclusionary language of the central ART Act seems incongruous.

In early 2025, a transgender man in Kerala filed a petition before the High Court challenging the Act's failure to accommodate individuals like him who wished to preserve fertility before undergoing gender transition. The petitioner argued that this denial violated his fundamental rights to privacy, reproductive autonomy, and non-discrimination. While the final verdict in this case is pending, the matter brings to light the constitutional tensions arising from the restrictive interpretation of who qualifies as an "intending parent" under the Act. It also raises broader questions about whether national legislation can justifiably ignore gender diversity when states like Kerala have legally and socially embraced a more inclusive definition of personhood.

These legal developments point to a deeper structural contradiction between Kerala’s public health ethos and the central framework of the ART Act. Kerala’s healthcare system has long been recognised for its rights-based approach, decentralized planning,

and emphasis on universal access. In contrast, the ART Act appears to adopt a more traditional and conservative approach to family formation, privileging heterosexual, married couples and excluding a wide range of alternative family structures. This contradiction creates confusion not just for the courts, but also for clinics attempting to operate ethically while serving diverse patient populations.

The judiciary in Kerala has so far acted as an important check on overreach, by interpreting the Act in a manner that is sensitive to individual rights and practical realities. However, these piecemeal rulings cannot substitute for the need to amend or clarify the statute itself. Without legislative refinement or formal guidelines, inconsistencies will persist in the law's interpretation and application across districts and clinics.

In conclusion, while the ART Act has introduced vital legal oversight into a previously under regulated field, its implementation in Kerala has revealed critical legal ambiguities. High Court interventions on age limits and donor use, the ongoing lack of legal recognition for transgender and LGBTQ+ persons, and the conflict between Kerala's inclusive policy environment and the Act's rigid norms all suggest a need for more responsive, context-aware legislation. The law must evolve to meet the diversity of reproductive intentions and family forms in modern India particularly in progressive states like Kerala, where the judiciary and civil society have shown readiness to push for a more equitable interpretation of reproductive rights.

CHAPTER 6

FINDINGS AND SUGGESTIONS

6.1 Introduction

This chapter presents the key findings and doctrinally grounded suggestions derived from the legal analysis of the Assisted Reproductive Technology (Regulation) Act, 2021, with specific reference to its implementation in Kerala. The research has been conducted using a doctrinal methodology based on statutory interpretation, judicial decisions, constitutional principles, and academic commentary. The suggestions offered are normative in nature, informed by legal reasoning and the interpretive guidance of the Kerala High Court and other statutory frameworks.

6.2 Key Findings

1. Ambiguities and Rigidities in the ART Act

The age restrictions imposed under Section 21(g) are overly rigid and have been the subject of judicial challenge in Kerala. The absence of transitional provisions and case-specific flexibility undermines the Act's accessibility. Additionally, there is a lack of clarity on the legal use of donor gametes, particularly in marital scenarios involving older partners.

2. Exclusionary Framework

The Act's restrictive definition of 'intending couple' excludes LGBTQ+ persons, transgender individuals, and single men. This exclusion contradicts the constitutional guarantees of equality under Article 14 and Kerala's own progressive policies on gender and reproductive rights.

3. Implementation Barriers in Kerala

The delay in establishing the State Appropriate Authority and related bodies in Kerala hindered the timely rollout of the Act. Clinics face barriers in registration, often due to insufficient support and technological issues associated with the NARTSR portal. Smaller clinics, especially in rural regions, encounter particular difficulty in adapting to compliance procedures.

4. Ethical Tensions

The emphasis on altruistic surrogacy, while ethically commendable, fails to reflect the practical dynamics of fertility services in India. There are also concerns about the risk of exploitation of vulnerable women as egg donors or surrogates in the absence of enforceable protections.

5. Judicial Interventions

The Kerala High Court has played a constructive role in interpreting the ART Act, especially in challenging age-related provisions and addressing gaps in regulatory logic. However, in the absence of uniform guidelines or statutory amendments, courts alone cannot resolve systemic ambiguities.

6.3 Suggestions

1. Statutory Amendments

Introduce case-specific exceptions to age restrictions under Section 21(g), allowing discretionary approval in medically justified cases. Clarify the use of donor gametes and eligibility procedures in diverse family structures. Amend the Act to explicitly include transgender persons and single men as eligible individuals.

2. Harmonization with State Policies

Utilize the provisions under Section 54 to permit Kerala to issue localized implementation guidelines that align with its inclusive public health framework and gender policies. This harmonization can help balance national uniformity with state-level responsiveness.

3. Legal Literacy and Outreach

Provide translated templates, simplified regulatory guides, and model documentation to clinics across Kerala. Partner with legal aid authorities to offer training and workshops, especially in underserved regions. Clear communication will reduce inadvertent non-compliance and improve legal adherence.

4. Strengthening Ethical Oversight

Establish district-level ART Ethics Committees under state authority to monitor and review surrogacy and gamete donation cases. These committees can ensure that the altruism requirement does not mask coercion or informal commercial transactions.

5. Judicial Continuity and Standardization

Encourage the development of consistent judicial interpretations of ART-related provisions across High Court benches. A standard legal reference guide or benchbook could support judges and lawyers handling these cases with more uniformity.

6.4 Conclusion

The Assisted Reproductive Technology (Regulation) Act, 2021 represents a foundational attempt to regulate reproductive health services in India. However, its doctrinal analysis reveals critical gaps in inclusivity, clarity, and practicality. Kerala's experience marked by progressive public health commitments and active judicial oversight offers valuable insight into how ART regulation must evolve. Legal reform,

context-sensitive implementation, and sustained constitutional alignment are essential if the Act is to achieve its intended objectives without marginalizing vulnerable populations or burdening genuine providers.

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APPENDIX

APPENDIX

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Kalamassery, Kochi – 683 503, Kerala, India

CERTIFICATE ON PLAGIARISM CHECK

1.	Name of the Candidate	Ms. Anusree M.G.
2.	Title of Dissertation	Understanding Key Issues and Constraints in Implementing the Assisted Reproductive Technology (Regulation) Act, 2021 with Special Reference to State of Kerala
3.	Name of the supervisor	Dr. Anil R. Nair
4.	Similar content (%) identified	9%
5.	Acceptable maximum limit (%)	10%
6.	Software used	Turnitin
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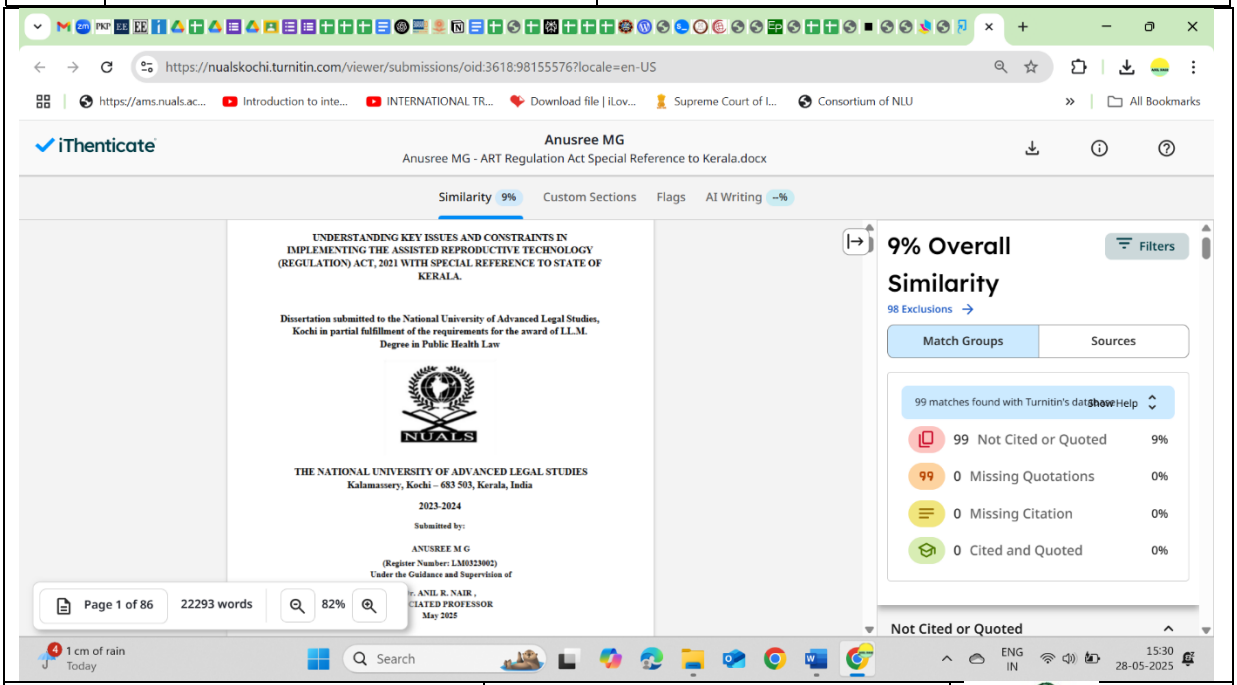

Checked By (with name, designation & signature)	Dr. Anil R. Nair, Associate Professor	
Name and Signature of the Candidate	Ms. Anusree M.G.	
Name & Signature of the Supervisor	Dr. Anil R. Nair, Associate Professor	