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IN VITRO FERTILIZATION: PAST AND CURRENT DEVELOPMENT

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ABSTRACT

On December 20, 2021, an act of Parliament enacted the Assisted Reproductive Technology (Regulation) Act, 2021, which established regulations for the operation of ART clinics and ART banks across the country. Since the advent of in vitro fertilisation (IVF), the number of ART clinics across the country has skyrocketed. In addition to safeguarding the rights of the women undergoing reproductive therapy at these clinics, oversight and control over their operations were vital. Adoption of this Act will greatly enhance ART clinic and ART bank oversight, regulation, licencing, and operational efficiency.

The Act also covers the contentious topic of surrogacy, guaranteeing that surrogate mothers' rights are safeguarded. Furthermore, rigorous adherence to the law will ensure that the therapy is successful within the bounds of law and ethics.

INTRODUCTION

Reproductive medicine has undergone a revolution thanks to in vitro fertilisation (IVF), which has given hope to millions of infertile couples worldwide. It is the most widely used type of assisted reproductive technology, and it helps patients who are having trouble getting pregnant. An extensive synopsis of the historical turning points and recent advancements in IVF technology is given in this study paper. We examine the ethical and scientific difficulties encountered in the past and talk about how improvements in IVF have increased its success rates, accessibility, and ethical implications. The article also sheds light on emerging trends and future prospects in the realm of assisted reproductive technologies.

HISTORICAL DEVELOPMENTS

Research on human reproduction has long been fraught with ethical and scientific issues, which at first hindered the development of treatments for infertility. But in the 1960s and 1970s, breakthroughs in our understanding of the mechanisms behind human oocyte fertilisation allowed for the in vitro (IVF) fertilisation of human oocytes. This insight led to the birth of Louise Brown, the first living "test tube baby," in England in 1978 (Steptoe PC, Edwards RG. Birth after reimplantation of a human embryo. The Lancet. 1978;312:366]. In this sentinel IVF delivery, a single pre-ovulatory oocyte was extracted laparoscopically from the mother's ovary, fertilised in vitro, and then placed into the mother's uterus. The mother's menstrual cycle was regular.

Three years later came the first-ever IVF baby born in the United States and the sixteenth overall. In this case, the mother received daily injections of human menopausal gonadotropin to stimulate the ovary's creation of several follicles rather than the single oocyte that would typically result from this process. Following a laparoscopic extraction, the pre-ovulatory oocytes were fertilised in vitro and transferred into the mother's uterus as day 3 or day 5 embryos.

This procedure is known as controlled ovarian stimulation (COS). A couple who underwent IVF at Washington University and gave birth at what is now Barnes-Jewish Hospital in 1985 had Missouri's first IVF baby . Since that time, the IVF procedure has developed at an amazing rate.

IVF results in thousands of babies born annually in the United States and Europe, as well as millions of births worldwide .National Centre for Health Statistics, Hyattsville, MD, 2014. The National Survey of Family Growth, 1982–2010, provided data on the use of infertility services in the United States. The increasing demand for fertility treatments is driving the development of technologies to enhance IVF regimens and success rates. When pursuing IVF, almost all infertile couples receive counselling in an effort to create a child that shares a similar genetic background. Couples also employ in vitro fertilisation (IVF) to assess the genetic quality of their embryos and reduce the transmission of single-gene variants linked to morbidity. Furthermore, the use of donated sperm and oocytes is expanding, and women who are unable to conceive now have the option of using gestational carriers.

LEGAL DISSECTION

Thanks to Dr. Subhash Mukhopadhyay's successful efforts, Durga became the first IVF baby in Kolkata in 1981. Nevertheless, the government decided not to commemorate this accomplishment for moral and ethical reasons. India's first IVF baby, Harsha, was born in 1986, according to claims made by Drs. T. C. Anand Kumar and Indira Hinduja, with approval from the Indian Council of Medical Research (ICMR).

Since then, especially in the last two decades, ART clinics and banks have proliferated across the nation. The public health system offers very few and inadequate fertility services.

ART clinics are highly commercialised because they are primarily private enterprises. The absence of a mechanism to guarantee adherence to ICMR guidelines has resulted in a mostly unregulated business. There is concern that unethical methods may be applied to infertile couples undergoing infertility therapy. Following the initial physical examination and history taking, a full investigation is conducted on both the male and female spouses. ART treatment includes the retrieval, processing, application, and storage of gametes, embryos, and gonadal tissues. Cryopreservation is used in certain assisted reproduction situations to preserve gametes and embryos.

The delicate procedures used in ART facilities and the challenges encountered by infertile couples make legislation in this emerging area of assisted reproduction critically needed. An important step in the correct path was taken on December 20, 2021, when the Assisted Reproductive Technology (Regulation) Act, 2021, was approved by an act of Parliament[Indian Gazette]. The Ministry of Law and Justice released the Assisted Reproductive Technology (Regulation) Act, 2021 (NO. 42 OF 2021) [Legislative D]. ART clinics who violated ICMR recommendations risked fines from state accrediting agencies prior to the passage of this Act.

There was an urgent need for legislation in this new area of assisted reproduction because of the delicate therapies provided in ART clinics and the struggles infertile couples endured passed by the Parliament . Before this Act was passed, ART facilities who disregarded ICMR guidelines might be fined by state accreditation authorities .

. The rights of infertile couples and surrogate mothers will be protected by this Act as it currently stands. By providing insurance coverage for a year, the statute assures financial security in the donor's favour. The surrogate mother provides her gestational

services up until the baby is born, after which she gives up her parental rights in accordance with the Act's provisions. Surrogacy is prohibited in many European nations, including Austria, France, Italy, Spain, Portugal, and Bulgaria. In order to realise their desire of parenting, infertile couples from various nations travel to India for surrogacy therapy.

ϖ The act is divided into six chapters and forty-six paragraphs. Chapter I of the Act provides definitions for several technical terms to ensure that the intricate ideas and processes involved in assisted reproduction are understood. The operations of banks and ART clinics shall be governed by this Act. In addition, The Act creates criteria for the use of human gametes, embryos, and gonadal tissues for research purposes and addresses the crucial topic of assisted reproduction research. The power and duty bestowed upon the national and state ART and surrogacy bodies will assist in the local implementation of the Act. The registration process has a 60-day window after the national registry is established, as stated in Chapter III. Establishing a national ART registry will contribute to the massive amount of data that can be studied for research purposes, helping to direct policy decisions and current clinical practice for the reproductive health of citizens.Pre-implantation genetic testing and embryo sex selection (detailed in sections 25 and 26 of chapter IV, respectively) are required in order to ensure ethical practise. Obtaining the required data, such as the Aadhar numbers of the surrogate mothers and gamete donors, in order to open a bank account would ensure the targeted and direct distribution of benefits and subsidies.

RISKS WITH IVF

Reprogenetics: As technology and knowledge of scientific genomics advance, it may be possible to retrieve our individual genetic data. This will enable individuals to modify the DNA of embryos prior to implantation into the uterus by taking into account reprogenetics and IVF. Although it might contribute to the prevention of hereditary disorders, it can also lead to prejudice and societal divisiveness.

Financial difficulties: IVF therapy is highly expensive. IVF therapy costs between 1.5 lakhs and 2.5 lakhs in India. Therefore, the price of this procedure can be a deterrent for many couples who would like to choose it. Given that this procedure has a 40% success rate, this should also cover the couple's insurance. However, because insurance only covers illnesses, and fertility therapy is not one of them, many insurance companies choose not to offer insurance for this procedure.

FUTURE OF IVF INDIA

Enter Artificial Intelligence (AI)- While developments like personalized ovarian stimulation and single embryo transfers have improved the IVF industry, a significant gap still exists. This is especially apparent when choosing embryos based on their physical characteristics. Sadly, the evaluation of embryos is subjective, and clinics and operators have different levels of success. AI's accuracy has a huge impact on embryo selection, which is currently done through morphological examination. AI could improve grading by using common imagery or time-lapse recordings, which would improve judgements about embryo transfers. AI may also change how IVF treatment plans are administered. The entire therapy cycle is typically influenced by elements including patient age, medical history, and gamete quality; AI might offer a systematic method to do so. The use of AI could result in a significant transformation of the reproductive landscape, raising expectations and success rates for many. The process

of becoming a parent through IVF may become quicker, more effective, and full of fresh optimism with the inclusion of AI.

India stands at the cusp of a significant transformation in the field of In Vitro Fertilization (IVF), driven by advancements in medical technology, increasing awareness, and evolving socio-economic dynamics. The future of IVF in India looks promising, with several key trends and developments poised to shape the landscape.

a) Technological Advancements

Technological innovation is a major driving force behind the future of IVF in India. Emerging technologies like Artificial Intelligence (AI) and machine learning are expected to revolutionize embryo selection processes, enhancing success rates by identifying the most viable embryos with greater accuracy. Additionally, advancements in genetic screening techniques, such as Preimplantation Genetic Testing (PGT), will enable the detection of genetic disorders before implantation, ensuring healthier pregnancies.

b) Personalized Medicine

The concept of personalized medicine is gaining traction in the realm of IVF. Customized treatment plans based on an individual's genetic makeup, hormonal profiles, and lifestyle factors will become more prevalent. This personalized approach is anticipated to improve the efficacy of IVF treatments, reduce side effects, and increase the overall success rates, providing a more tailored and patient-centric experience.

c) Cost Reduction and Accessibility

While IVF has traditionally been considered an expensive procedure, efforts are underway to make it more affordable and accessible. Innovations in technology and streamlined processes are expected to reduce the cost of treatments. Government initiatives and public-private partnerships may also play a crucial role in subsidizing costs, making IVF accessible to a broader section of the population, including those in rural and underserved areas.

d) Regulatory Enhancements

The regulatory framework governing IVF and assisted reproductive technologies in India is likely to undergo significant enhancements. The Assisted Reproductive Technology (Regulation) Bill, 2020, aims to establish a robust regulatory mechanism to ensure ethical practices, standardization of procedures, and patient safety. Stricter regulations and oversight will foster greater transparency and accountability, enhancing the credibility of IVF clinics across the country.

e) Medical Tourism

India has already established itself as a hub for medical tourism, and IVF is a significant component of this sector. The future will see an increase in international patients seeking IVF treatments in India, attracted by the combination of advanced medical facilities, skilled professionals, and competitive costs. The influx of medical tourists will not only boost the economy but also promote the exchange of knowledge and best practices, further enhancing the quality of care.

f) Social Acceptance and Awareness

Changing societal attitudes towards infertility and assisted reproductive technologies will play a pivotal role in shaping the future of IVF in India. Increased awareness campaigns and educational initiatives will help destigmatize infertility and promote acceptance of IVF as a viable solution. Support groups and counseling services will

become more prevalent, providing emotional and psychological support to couples undergoing IVF treatments.

g) Research and Development

Investment in research and development will drive continuous improvements in IVF techniques and outcomes. Collaborative efforts between academic institutions, research organizations, and fertility clinics will lead to innovations in treatment protocols, embryo culture methods, and cryopreservation techniques. Ongoing research will also focus on understanding the long-term health outcomes of children born through IVF, ensuring the safety and well-being of future generations.

h) Integration of Holistic Approaches

The future of IVF in India will witness a greater integration of holistic approaches to fertility treatment. Complementary therapies such as acupuncture, yoga, and nutritional counseling will be incorporated into conventional IVF protocols. These holistic practices aim to enhance overall well-being, reduce stress, and improve the chances of successful conception, offering a more comprehensive approach to fertility care.

The future of IVF in India is marked by optimism and innovation. Technological advancements, personalized medicine, cost reductions, regulatory enhancements, and increased social acceptance are poised to transform the landscape of IVF treatments. As India continues to evolve as a global leader in reproductive medicine, the combined efforts of medical professionals, researchers, policymakers, and society at large will ensure that IVF remains a beacon of hope for countless couples striving to realize their dream of parenthood.

SUGGESTIONS

As IVF and other assisted reproductive technologies (ART) continue to grow in popularity in India, a robust and comprehensive legal framework is essential to ensure ethical practices, protect patients' rights, and maintain high standards of medical care. Here are several key suggestions for strengthening the legal framework of IVF in India:

a) Comprehensive Legislation

India should develop a unified and comprehensive legislation specifically addressing all aspects of ART, including IVF. This legislation should cover ethical practices, patient rights, medical standards, and the regulation of clinics and professionals involved in ART procedures. The Assisted Reproductive Technology (Regulation) Bill, 2020, is a step in the right direction, but it needs to be expanded and refined.

b) Clear Definitions and Scope

The legal framework should clearly define key terms and the scope of ART procedures. Definitions of infertility, ART, IVF, donors, surrogacy, and other relevant terms should be precise to avoid ambiguities and ensure uniform understanding and application across the country.

c) Licensing and Accreditation

Mandatory licensing and accreditation of all ART clinics and practitioners should be implemented. Establishing a centralized regulatory body to oversee the accreditation process, conduct regular inspections, and ensure compliance with established standards is crucial. This body should have the authority to penalize or shut down non-compliant clinics.

d) Ethical Standards and Practices

Strict ethical standards and guidelines should be enforced to prevent exploitation and ensure the welfare of all parties involved. This includes regulations on donor

anonymity, compensation, and the rights of surrogate mothers. Ethical review boards should be established to oversee ART practices and address any ethical concerns.

e) Informed Consent and Counseling

Patients undergoing IVF and other ART procedures should be provided with comprehensive information about the risks, benefits, and alternatives to treatment. Informed consent protocols should be standardized, and pre-treatment counseling should be mandatory to help patients make informed decisions and cope with the emotional and psychological aspects of infertility treatment.

f) Data Privacy and Confidentiality

Robust data privacy and confidentiality measures should be enforced to protect patients' personal and medical information. Clinics must adhere to strict data protection protocols, and any breach of patient confidentiality should be subject to severe penalties.

g) Legal Rights and Protection for Children Born Through ART

The legal framework should explicitly outline the rights and status of children born through ART, ensuring they have the same legal protections as children conceived naturally. This includes provisions for birth registration, inheritance rights, and access to information about their biological origins, if appropriate.

h) Dispute Resolution Mechanisms

Efficient and accessible mechanisms for resolving disputes related to ART procedures should be established. This includes conflicts between patients and clinics, donor-related issues, and disputes involving surrogate mothers. Mediation and arbitration services should be available to provide fair and timely resolutions.

i) Insurance Coverage and Financial Assistance

Policies to promote insurance coverage for infertility treatments, including IVF, should be developed. Government programs and public-private partnerships could be established to provide financial assistance to low-income couples seeking ART services, ensuring broader access to these treatments.

j) Continuous Monitoring and Evaluation

The regulatory framework should include provisions for continuous monitoring, data collection, and evaluation of ART practices. Regular reporting and analysis of treatment outcomes, success rates, and adverse events will help identify areas for improvement and ensure the highest standards of care are maintained.

Strengthening the legal framework for IVF and ART in India is essential to safeguard the interests of patients, ensure ethical practices, and maintain high standards of medical care. By implementing comprehensive legislation, clear definitions, licensing requirements, ethical guidelines, informed consent protocols, data privacy measures, legal protections for children, dispute resolution mechanisms, insurance coverage, and continuous monitoring, India can create a robust and effective regulatory environment for ART. These measures will help build trust in the system, promote the responsible use of ART technologies, and support the aspirations of countless couples seeking to build their families through IVF.

CONCLUSION

Infertility affects 10% of the population, and IVF is a procedure used for parents who are unable to become parents. Since it is legal and a viable option, explicit legislation is required. The Law on Assisted Reproductive Technology Bill should be passed by the government first. This legislation will benefit Indian women's freedom of choice and procreation. We are aware that because each of these ethical, social, and legal issues

relating to IVF adoption is socially unique, we are unable to fully address them. Nevertheless, the law can be seen as an important step towards resolving the IVF-related issue. As a result of the rise in IVF procedures, India will have a clear path to development if an IVF-specific law is created. And rather than condemning the infertile ladies, society ought to offer support so that the couples can receive the appropriate care at the appropriate time. Considering that most causes of infertility are treatable.