ASSISTED REPRODUCTIVE TECHNOLOGIES: A MULTIFACETED STUDY AND THE WAY AHEAD

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ABSTRACT

"Assisted Reproductive Technology (ART) encompasses a range of fertility treatments, including In-Vitro Fertilization (IVF) and Intracytoplasmic Sperm Injection (ICSI), aimed at aiding conception. Since the first successful IVF birth in India in 1978, ART has become more and more common due to a change in lifestyle, postponed marriage and childbirth, and increasing knowledge of infertility treatments. The goals of the Assisted Reproductive Technology (Regulation) Act, 2021 are to uphold moral behavior, safeguard patient rights, and standardize ART procedures. A strong structure for policing ART clinics and banks supports a range of ART procedures, including gamete intrafallopian transfer, pre-implantation genetic testing, and cryopreservation, in India. Notwithstanding the progress made, ethical issues still exist, especially in relation to the commercialization of surrogacy and the mistreatment of surrogate mothers. Surrogacy has a substantial economic impact, generating revenue and job opportunities while also posing issues with monitoring and regulation. The results of ART could be improved by technological advancements like gene editing and artificial intelligence (AI) in embryo selection. India is becoming a major destination for reproductive tourism, which emphasizes the necessity for extensive infrastructure and qualified personnel. The intricacies of ART are highlighted by the psychological effects on people and families as well as the sensitivity to cultural and religious differences. While India is at the forefront of ART research, developing a humane and sustainable reproductive healthcare system requires a balanced strategy that puts patient welfare, ethical issues, and technology breakthroughs first. With so much promise for the future, ART in India gives millions of couples around the world hope."

Keywords: Assisted Reproductive Technology, Surrogacy, In-Vitro Fertilization, Donor Eggs, and Donor Sperms.

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INTRODUCTION

"A woman (the surrogate) consents to bear and give birth to a child on behalf of another individual or couple (the intended parent(s)) in a process known as surrogacy. A woman who becomes pregnant, carries, and gives birth to a child on behalf of another individual or couple (intended parent(s)) is known as a surrogate, often known as a gestational carrier.[1]"

"According to the American Center for Disease Control (CDC), assisted reproductive technologies (ART) are any fertility-related procedures that involve the manipulation of eggs or embryos. Intrauterine inseminations and other similar procedures that involve the manipulation of only sperm are not covered by this definition. The criteria also do not include treatments where ovarian stimulation is carried out without a strategy for egg retrieval. The use of clinical or laboratory technology on gametes (human eggs or sperm) and/or embryos for the aim of reproduction is known as assisted reproductive technology, or ART.ART encompasses a broad range of technologies. Since simple methods are less intrusive than more complex ones, they are frequently used first."

"In India, assisted reproductive technology, or ART is becoming a more and more common choice for infertile couples. Since the first successful in vitro fertilization (IVF) pregnancy was obtained in 1978, ART treatments have been utilized. IVF, gamete intrafallopian transfer, tubal embryo transfer, zygote intrafallopian transfer, egg-freezing, and preimplantation genetic diagnosis are only a few of the ART techniques that are accessible today. Fertility clinics in India give birth to more than 500 infants each month, which is a major factor in the ART market. The rising use of ART in India can be attributed to a number of factors, such as postponed marriage and childbearing, alterations in lifestyle, and heightened public awareness of infertility treatments."

RESEARCH QUESTIONS

- How Assisted Reproductive Technology work along with its methods and how is it beneficial?
- What is the future scope of Assisted Reproductive Technology and its implications?

[1] "Surrogacy Law" (*Drishti IAS*) https://www.drishtiias.com/daily-updates/daily-news-analysis/surrogacy-law

HISTORICAL DEVELOPMENTS OF ART IN INDIA

"The history of assisted reproductive technology (ART) in India has influenced the nation's fertility treatment environment. The journey started in 1978 when Dr. Subhas Mukherjee successfully completed the first IVF (in vitro fertilization) birth in India. Louise Brown of the UK had the second-most successful IVF delivery globally at that time. Dr. Mukherjee received harsh professional criticism in spite of the groundbreaking accomplishment, and his work went unacknowledged for a long time. The 1980s and 1990s saw the beginning of ART's rise in popularity in India. An important turning point was when Dr. Indira Hinduja opened the first IVF clinic in Mumbai in 1986. Shortly after, Harsha Chawda, India's first test-tube baby, was born."

"Driven to rising public acceptability and technological breakthroughs, ART services expanded quickly in the 1990s. During this time, the Indian Council of Medical Research (ICMR) also established protocols and guidelines with the goal of standardizing and regulating ART practices. Further technological advances at the turn of the millennium brought hope to cases of male infertility with the advent of ICSI (intracytoplasmic sperm injection). By the early 2000s, fertility tourism had become a major global industry in India, drawing couples from all over the world because of the nation's superior medical knowledge and comparatively lower expenses[2]."

"More regulatory frameworks have been introduced for the ART industry in India in recent years, leading to the Assisted Reproductive Technology (Regulation) Act of 2021. The purpose of this legislation is to control surrogacy agreements, safeguard patient rights, and guarantee ethical practices. India is still leading the way in assisted reproductive technology (ART) today, with a large number of clinics providing a variety of fertility treatments and significantly impacting the ART market globally. The continued developments and legislative actions demonstrate India's dedication to offering ethical and easily accessible reproductive healthcare."

[2] Remah Moustafa Kamel, "Assisted Reproductive Technology after the Birth of Louise Brown" (*PubMed Central (PMC)*, September 1, 2013) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3799275/

TYPES OF ASSISTED REPRODUCTIVE TECHNOLOGY TECHNIQUES IN INDIA

I. IN-VITRO FERTILIZATION:

"One sort of assisted reproduction technology is called in-vitro fertilization (IVF), which is the process of fertilizing an egg in a lab dish with sperm outside of the body. In order to develop numerous eggs, a woman's ovaries are first stimulated with drugs during IVF procedures in India. After that, the eggs are extracted using a minimally invasive technique and mixed with sperm in a lab dish. Before the resultant embryos are placed into the woman's uterus, they are observed for a few days.[3]

IVF was first used to treat women who had fallopian tubes that were broken, obstructed, or missing. IVF is now utilized to treat a variety of infertility-related conditions, including endometriosis, male factor, and infertility that cannot be explained in a pair. Ovarian stimulation, egg retrieval, fertilization, embryo culture, and embryo transfer are the essential processes in an IVF treatment cycle."

II. INTRACYTOPLASMIC SPERM INJECTION (ICSI)

"One treatment used to treat male factor infertility is ICSI. In order to create embryos, a single sperm is injected into an oocyte in a laboratory setting dedicated to embryology. Although the process is similar to "routine" in vitro fertilization (IVF) in that it takes place in a laboratory, the sperm is inserted into the oocyte using tiny surgical devices. Candidates for this surgery include couples experiencing polyspermic fertilization, poor fertilization in the past, or male factor infertility."

III. ASSISTED HATCHING:

"Assisted hatching is a laboratory technique used on three-day-old embryos (not oocytes). The zona pellucida, the glycoprotein shell or coating that envelops the embryo, is artificially opened during this technique. Although assisted hatching is a common practice in ART clinics, some doctors and clinics view it as experimental and there is no proof that it is useful. As decided upon by the Presbyterian Hospital A.R.T.S. team, assisted hatching is not a standard procedure

[3] American Society for Reproductive Medicine, "Assisted Reproductive Technology: A Guide for Patients" (2015) https://www.fertilityanswers.com/wp-content/uploads/2016/04/assisted-reproductive-technologies-booklet.pdf

for in vitro fertilization. This surgery will only be available to couples who have unique treatment programs."

IV. GAMETE INTRAFALLOPIAN TRANSFER (GIFT)

"GIFT was introduced as a more "natural" iteration of IVF. Rather than taking place in a lab culture plate, the woman's eggs are taken out of her ovaries and placed in fine tubing between two layers of sperm. The egg and sperm are then allowed to spontaneously fertilize in one of the woman's fallopian tubes once this tubing has been inserted. These days, GIFT is hardly ever utilized. Couples that choose not to use IVF for religious reasons, however, may still consider it as an option if the woman's fallopian tubes are healthy[4]."

V. PRE-IMPLANTATION GENETIC DIAGNOSIS(PGD)

"PGD is primarily used to lower the likelihood that a person or couple would pass on to their offspring a certain genetic, chromosomal, or defect.PGD might also be suitable for women over 38 or for people or couples who have had repeated IVF failures or miscarriages."

VI. CRYOPRESERVATION:

"Any extra embryos could be cryopreserved (frozen) in preparation for another transfer. Because the woman does not need to have her eggs removed or undergo ovarian stimulation, cryopreservation makes subsequent ART cycles easier, less costly, and less invasive than the original IVF cycle. Embryos can be kept for a long time after they are frozen, and reports of live births have been made using embryos that have been frozen for nearly 20 years."

VII. DONOR SPERMS:

"The donor is retested for infectious diseases, such as the human immunodeficiency virus (HIV), and donor sperm is only released for use if all tests are negative. The donor's sperm is frozen and kept in quarantine for six months. Donor sperm can be utilized in an ART cycle or for insemination. In contrast to IUI procedures, the use of frozen sperm in In-vitro fertilization (IVF) cycles does not diminish the likelihood of conceiving a child."

VIII. DONOR EGGS:

[4] DFW Fertility Associates, "ASSISTED REPRODUCTIVE TECHNOLOGY (ART)" https://www.dallasfertility.com/assets/pdf/33-ivfstandardprotocol.pdf

"Women who have a uterus but are unlikely or unable to conceive with their own eggs may choose to use donor eggs. Similar medical and genetic screening is performed on egg donors as it is on sperm donors. Like sperm, eggs could not be frozen or placed in quarantine until recently. However, recent developments in oocyte freezing have made this feasible, and a few businesses and clinics are employing this strategy. The infertile couple or the ART program may select the egg donor. Compared to sperm donors, egg donors bear a greater danger and inconvenience[5]."

IX. SURROGACY/GESTATIONAL CARRIER:

"A pregnancy can be borne by the egg donor (a typical surrogate) or by a gestational carrier, a different woman who is not related to the child genetically. Pregnancy can be obtained via ART or insemination alone if the embryo is intended to be carried by a surrogate. The child and the surrogate will be biologically connected. The eggs are taken out of the infertile woman, fertilized with her partner's sperm, and then placed into the gestational carrier's uterus if the embryo is to be carried by her. There will be no genetic ties between the child and the gestational carrier.

ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021

"On September 14, 2020, the Assisted Reproductive Technology (Regulation) Bill, 2020 was presented to the Lok Sabha. The purpose of the bill was to establish national regulations for services involving assisted reproductive technology. On December 01, 2021, the Lok Sabha approved it, and on December 08, 2021, the Rajya Sabha did the same. On December 18, 2021, the act became operative.

To address issues of reproductive health where assisted reproductive technology is required for becoming a parent or for freezing gametes, embryos, or embryonic tissues for later use due to infertility, disease, or social or medical concerns, as well as for regulating and supervising research and development and for matters related thereto or incidental thereto, the act aims to prevent misuse and to ensure safe and ethical practices in the assisted reproductive technology services industry."

[5] Herve Lucas and Taher Elbarbary, "ASSISTED REPRODUCTIVE TECHNOLOGIES (ART)" https://www.gfmer.ch/Medical_education_En/PGC_RH_2004/Pdf/ART.pdf

The act defines Assisted Reproductive Technology (hereinafter ART) as "all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive system of a woman".[6]

REGULATION OF ART CLINICS AND BANKS –

"According to the Act, all banks and ART clinics must be listed on the National Registry of Banks and Clinics of India. The Act calls for the creation of the National Registry, which will serve as a national database containing information on all ART clinics and banks in the nation. State governments will appoint registration authorities to facilitate the registration process. Only those clinics and banks that meet specific requirements (namely, specialized staff, physical infrastructure, and diagnostic facilities) will be allowed to register. The registration is valid for five years, after which it can be renewed for an additional five. If the entity violates the Act's provisions, registration may be revoked or suspended."

"In accordance with Section 15 of the Surrogacy Act, the act seeks to establish a National Assisted Reproductive Technology and Surrogacy Board. The Surrogacy Act's provisions pertaining to the board's composition, officer terms, meetings, vacancies, disqualifications, temporary associations of individuals, instrument authentication, and eligibility shall all apply mutatis mutandis to ART.

The chairperson, who will be an officer above the rank of Joint Secretary in the Health Department; the vice-chairperson, who will be an officer above the rank of Joint Director in the Health Department; a distinguished woman representing a women's organization; an officer of the Law Department; and a distinguished registered medical practitioner will be the appropriate authorities, appointed by the federal and state governments.

In furtherance of enforcing standards and overseeing the application of the law, the authority will grant, suspend, or cancel the registration of ART centers, look into complaints of provisional violations, take legal action against the misuse of ART, launch independent investigations, and recommend to the National and State Boards changes to the regulation in light of societal and technological advancements."

[6] Assisted reproductive technology (regulation) act, 2021

CONDITION FOR GAMETE DONATION AND SUPPLY

"Only ART banks that have been registered are authorized to perform the tasks of screening gamete donors, gathering and storing semen, and supplying oocyte donors. Males between the ages of 21 and 55 can donate semen, and females between the ages of 23 and 35 can donate eggs. A woman who has been married for at least three years and has at least one living child is eligible to donate eggs. The woman is limited to one oocyte donation per lifetime and can only have up to seven oocytes extracted from her. Gametes from a single donor cannot be provided by a bank to more than one commissioning couple (couple seeking services).

ART services can only be provided after obtaining the written informed consent of the parties seeking the ART services, as well as the donor. It will be necessary for the commissioning couple to give the oocyte donor insurance coverage from an insurance company to cover specific losses, damage, complications, or the donor's death during the procedure. Before implanting an embryo, ART facilities must screen for genetic disorders; they are not allowed to provide children of a specific gender."

"Additionally, it is illegal to directly or indirectly sell, transfer, or use gametes, zygotes, or embryos or any part of them inside or outside of India, with the exception of personal situations in which people transfer their own embryos and gametes with the National Board's approval."

OFFENSES AND PENALTIES

"The following are considered offenses under the act: (i) abandoning or abusing children born via assisted reproductive technology; (ii) buying, selling, trading, or importing human gametes or embryos; (iii) using middlemen to acquire donors; (iv) abusing a commissioning couple, woman, or gamete donor in any way; and (v) transferring the human embryo into a male or an animal. For the first infraction, these offenses will carry a fine of five to 10 lakh rupees. Subsequent violations will result in a fine of between 10 and 20 lakh rupees in addition to a sentence of eight to twelve years in prison.

Any clinic or bank that advertises or provides sex-selective ART faces a five-to-ten-year prison sentence, a fine of between Rs. 10 lakh and Rs. 25 lakh, or both. Courts will not consider violations of the act unless they receive a complaint from the National or State Board, or from an official designated by the Boards."

ETHICAL CONSIDERATION AND LEGAL DEBATES IN INDIA

"The debate surrounding Assisted Reproductive Technology (ART) in India has intensified, sparking heated discussions and ethical concerns. The country has witnessed a significant surge in the use of ART, including in vitro fertilization (IVF), surrogacy, and gamete donation, giving rise to complex moral dilemmas. One of the primary concerns is the commercialization of human bodies, particularly women's bodies, as they are often exploited as surrogates or egg donors. The Indian Council for Medical Research (ICMR) has expressed concerns about the lack of regulation and oversight in the surrogacy industry, leading to instances of exploitation, harassment, and even human trafficking.

The use of pre-implantation genetic diagnosis (PGD) and sex selection has also sparked debate, with concerns about gender bias and eugenics. Although the Indian Council of Medical Research has banned sex selection for non-medical purposes, there is a fear that this ban is not being effectively enforced. This has led to accusations that ART is being used to perpetuate gender inequality and discriminate against women. Furthermore, there are also concerns about the potential risks and uncertainties associated with ART, including multiple pregnancies, birth defects, and emotional trauma for both intended parents and children born through these technologies."

"Cultural and religious sensitivities surrounding ART are also an issue in India. Different religious groups have varying opinions on the morality and legitimacy of ART, with some viewing it as a Western import that contradicts traditional values. This has led to tensions between religious leaders and medical professionals who advocate for greater access to ART services. Additionally, there is a concern about the lack of informed consent and autonomy for patients undergoing ART procedures, particularly those from lower socioeconomic backgrounds who may be more vulnerable to exploitation.

To address these concerns, there is a need for greater regulation and standardization of ART practices in India. While the ICMR[7] has issued guidelines for ART centers, enforcement remains patchy. There is a need for greater transparency around pricing, advertising, and treatment options to ensure that patients are well-informed and protected. Moreover, there is a need for more research into the psychological and social impacts of ART on families and children born through these technologies. As India continues to grapple with these complex

[7] "Indian Council of Medical Research | Government of India" https://main.icmr.nic.in/

issues, it is essential that policymakers, medical professionals, and society at large engage in open and nuanced discussions about the ethical considerations surrounding ART in India."

PSYCHOLOGICAL IMPLICATIONS OF SURROGACY IN INDIA

"The widespread use of Assisted Reproductive Technology (ART) in India has significant psychological implications for individuals and families seeking to build their families through these methods. One of the most pressing concerns is the emotional toll of the ART process, which can lead to feelings of anxiety, disappointment, and stress. In India's culturally conservative society, where traditional family values and social expectations around childbearing are highly valued, these feelings can be intensified. Women, in particular, may experience feelings of shame, guilt, and self-blame if they are unable to conceive naturally, leading to a sense of failure and inadequacy that can have long-term effects on their mental health.

The high failure rates of ART cycles can also result in feelings of frustration and disappointment among individuals and couples who invest significant emotional and financial resources in the process. The emotional toll of repeated failed attempts at conception can be overwhelming, leading to feelings of hopelessness and despair. Furthermore, the commercialization of gametes and the creation of "snowflake" babies through donor conception raises questions about identity, belonging, and sense of self, particularly among children born through these technologies. Children born through donor conception may struggle with issues related to their biological origins and may feel disconnected from their biological parents, leading to feelings of uncertainty and confusion about their identity and place in the world."

"The growing trend of surrogacy in India also raises concerns about the exploitation of surrogate mothers and the psychological impact on them. Surrogate mothers often experience feelings of loss and grief when they surrender their children to commissioning parents, which can have long-term effects on their mental health. It is essential to recognize the psychological complexities surrounding ART in India and provide support services and counseling to individuals and families navigating these complex technologies. This includes providing emotional support to those who experience disappointment or failure, as well as counseling for those who may struggle with issues related to identity and belonging.

To create a more compassionate and supportive environment for individuals and families seeking to build their families through ART, policymakers and healthcare providers must prioritize the welfare of surrogate mothers and ensure that they receive adequate support and care during the surrogacy process. By acknowledging the psychological complexities surrounding ART in India, we can work towards creating a more empathetic society that recognizes the emotional needs of all individuals involved in this process."

ECONOMIC ASPECTS OF SURROGACY IN INDIA

"India's assisted reproductive technology (ART) industry has emerged as a significant economic sector, driven by the country's large pool of willing surrogates and relatively low cost of IVF treatment. With costs ranging from $15,000 to $30,000, inclusive of medical expenses, accommodation, and food, India has become a popular destination for international surrogacy. This affordability has attracted couples from developed countries seeking affordable options. The economic benefits of surrogacy in India extend beyond foreign clients, creating employment opportunities for thousands of women in rural and semi-urban areas who earn a decent income as surrogates. Additionally, the industry has generated employment for medical professionals, nursing staff, and support staff in hospitals and clinics.

However, the economic benefits of surrogacy in India come with challenges. The lack of regulation and oversight in the industry raises concerns about the exploitation of surrogates, who are often illiterate and unaware of their rights. Many surrogates are forced to undergo multiple pregnancies and abortions, which can have serious health consequences. Furthermore, some commercial surrogacy agencies charge exorbitant fees from clients and exploit surrogates. To address these concerns, the Indian government has introduced regulations to ensure that surrogacy is carried out ethically and with consent. The Assisted Reproductive Technology (Regulation) Bill, 2020 aims to regulate the ART industry and ensure transparency and consent."

"While the industry generates revenue and employment opportunities, it also raises concerns about exploitation and lack of regulation. To ensure that surrogacy is carried out ethically and with consent, it is crucial to strengthen regulations and oversight mechanisms. The Indian government's efforts to regulate the ART industry are a step towards ensuring that surrogacy respects the rights and dignity of all parties involved."

TECHNOLOGICAL ADVANCEMENTS AND FUTURE DIRECTIONS IN INDIA

"India has emerged as a leader in the field of Assisted Reproductive Technology (ART), with significant advancements made in recent years. The country has established itself as a hub for infertility treatment, with many Indian hospitals and clinics offering cutting-edge treatments such as In-Vitro Fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI), and Embryo Transfer (ET). The government's "Make in India" campaign has also played a crucial role in promoting the growth of the ART industry.

Looking ahead, technological innovations such as the adoption of robotics and artificial intelligence (AI) are expected to shape the future of ART in India. For instance, robotic-assisted laparoscopic surgery can enhance the success rates of IVF procedures by allowing for more precise and minimally invasive surgeries. AI-powered embryo selection tools can also help identify the most viable embryos for transfer, reducing the risk of multiple pregnancies and improving overall pregnancy outcomes."

"Gene editing technologies, such as CRISPR-Cas9, hold immense potential for treating genetic disorders and improving fertility treatments. Indian researchers are already exploring the application of gene editing in the context of infertility, with a focus on treating genetic defects that cause infertility. Additionally, there is an increasing trend towards cryopreservation technologies, which enable the freezing of eggs, sperm, and embryos for future use. This trend is expected to become more prominent in the future, particularly among working women who may require fertility preservation options due to career commitments or medical conditions.

India is also witnessing a growing demand for reproductive tourism, with many international patients traveling to India for affordable and high-quality ART treatments. To cater to this demand, Indian hospitals and clinics are investing in infrastructure development and hiring specialized personnel. The Indian government has also taken steps to regulate the industry by establishing guidelines and standards for ART clinics and embryologists."

"With its strong research capabilities, skilled medical professionals, and favorable regulatory environment, India is poised to play a significant role in shaping the future directions of ART globally. As technology continues to evolve, India is likely to remain at the forefront of ART innovation, offering new hope to millions of couples struggling with infertility worldwide."

CONCLUSION

"The field of reproductive procedures in India has seen substantial changes as a result of the development of aided reproductive technology (ART). India has advanced remarkably in assisted reproductive technology (ART) since the first successful IVF birth occurred there in 1978, becoming a global center for infertility treatments. A number of variables, including changing lifestyles, postponing marriage and childbirth, and increased awareness of infertility treatments, have contributed to the growing popularity of ART in India. India provides complete solutions for infertile couples with a variety of treatments available, such as IVF, Intracytoplasmic sperm injection (ICSI), egg freezing, and preimplantation genetic diagnosis (PGD).

The Assisted Reproductive Technology (Regulation) Act, 2021 is a crucial step toward regulating surrogacy agreements, protecting patient rights, and guaranteeing ethical practices. This legislation seeks to standardize ART procedures, improving the caliber and accessibility of reproductive therapies, in conjunction with the creation of the National Registry of Banks and Clinics of India. But there are still discussions and ethical issues surrounding surrogacy, especially when it comes to the commercialization of the practice, the mistreatment of surrogate mothers, and the psychological effects on all parties."

"The economic aspects of surrogacy in India present a dual narrative. Even while the sector creates a lot of money and job prospects, there are worries about surrogate exploitation and the need for strict regulations. Technology-driven innovations like gene editing and AI-powered embryo selection have the potential to transform ART by increasing success rates and opening up new treatment options for hereditary illnesses. Furthermore, the increasing popularity of India as a reproductive tourism destination highlights the necessity of having a strong infrastructure and skilled staff to serve patients from other countries.

In summary, India is leading the way in ART innovation thanks to its dedication to ethical norms, legal frameworks, and technological breakthroughs. There is a great deal of promise for the future of ART in India since continued study and development might give millions of couples worldwide fresh hope. A balanced strategy that puts patient welfare, ethical considerations, and technological advancements first will be essential in forming a long-lasting and compassionate reproductive healthcare system as the nation continues to traverse the difficulties of ART."

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Statute:

- Assisted Reproductive Technology (Regulation) Act, 2021
- The Surrogacy (regulation) Act, 2021