

ARTIFICIAL INTELLIGENCE IN REPRODUCTIVE TECHNOLOGY: BOON OR BANE?

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Abstract

Motherhood is a joy cherished through natural conception and in some cases of infertility accomplished through substituted reproduction known as Assisted Reproductive Techniques (ART). In the area of reproduction, ART techniques appear as a boon for infertile couples in begetting their genetic child through Intrauterine Insemination, Intrafallopian transfer, Intracytoplasmic sperm injection, In Vitro Fertilization, Surrogacy. These techniques with bare human assistance fail to achieve desired success rates. Instances of repeated implantation failures, multiple pregnancies, ovarian hyperstimulation syndrome, egg-retrieval procedure complications, ectopic pregnancy, premature delivery, and low birth weight make ART techniques a nightmare.

With the advancement of Science and Technology, Artificial Intelligence (AI) has ventured into the personal space of human beings simplifying 'life'. AI is the intelligence displayed by machines based on the data stored into these machines. There are 3 major categories of AI methods widely used in medical applications: Machine Learning (ML), Natural Language Processing (NLP) and Robotic Surgery.

Multiple machine learning techniques have been used to improve the performance of assisted reproductive technology there-by minimizing failures, enhancing pregnancy success rates, and avoiding multiple pregnancies. Through personalizing treatment for individual patient based on his/her medical history clinicians are trying to achieve best results. ML is used for embryo or Oocyte scoring selection through Pre-implantation genetic diagnosis (PGD)¹, Sperm morphology through computer-aided sperm analysis (CASA) systems. This indeed is a boon rather than a bane for couples desiring to have their offspring.

Given this breakthrough in the medical field, laws in India should incorporate this new technology. The half-baked laws on ART and Surrogacy should be passed with immediate effect so that the aggrieved can reap benefit of this technology.

Keywords: Embryos, Assisted Reproductive Technology (ART), Intra Vitro Fertilization (IVF), Surrogacy, Artificial Intelligence.

INTRODUCTION

The term Artificial Intelligence (AI) was first coined by John McCarthy at the Dartmouth Summer Research Project on Artificial Intelligence in 1955. According to him, AI is defined as the ability of machines to learn and display intelligence, which is in stark contrast to the natural intelligence demonstrated by humans and animals. There are 3 major categories of AI methods widely used in medical applications: machine Learning (ML), Natural Language Processing (NLP) and Robotic Surgery².

Global Scientific advancement in the reproductive sector coupled by Machine Learning has paved the way for future sect of Assisted reproductive techniques(ART for brief) such as Intrauterine Insemination, Intrafallopian transfer, Intracytoplasmic sperm injection, In Vitro Fertilization, Surrogacy.

ART AND ITS TYPES³

➤ Intrauterine Insemination (IUI): is an old technique which has low success rate as compared to IVF. This type of method is used in cases where sperm mobility is low or unexplained infertility leading to sterility.

¹. Virtus Health Group based in Australia takes help of AI driven tool 'IVY' which predicts the likelihood of a viable pregnancy from transfer of an individual embryo in a woman undergoing IVF <https://www.ivf.com.au/fertility-treatment/ai-in-ivf>(last visited 10th Sept 2021)

². Renjie Wang, Wei Pan and Shujie Liao, Artificial Intelligence in Reproductive Medicine, <https://www.ncbi.nlm.nih.gov> (last visited on 12th Sept 2021)

³. Point 1.6 titled ART Procedures from the Guidelines framed by the Indian Council of Medical Research to regulate ART clinics (last visited on 17th Sept 2021)

In this method, ovulation cycle of the woman is monitored and timed to inject sperm directly into the female genital track through a catheter and enhance the chance of conception. Advanced and more successful form of IUI is known as IntraUterine TuboPeritoneal Insemination (IUTPL) – L. Mamas method which is painless, cost effective, less hormonal prescription and high success rate up to 40%.

- Intrafallopian Transfer: In this type of technique, either Gamete gets transferred or Zygote get transferred into the Fallopian tube to aid conception. This technique is preferred by couples who have a religious belief that conception should take place inside a woman's body. Cases where fallopian tubes are damaged or blocked, low sperm mobility or unexplained fertility this method is useful.
- Gamete Intra Fallopian Transfer (GIFT) – In Vivo (internal) fertilization technique is used when a woman has normal and functional Fallopian Tube, sperm count is healthy but still there is an unexplained infertility which is hindering natural conception. Here, ovum is retrieved from the woman's body and mixed with sperm resulting in Gamete. It is then inserted into the normal Fallopian tube through laparoscopy for fertilization process to begin.
- Zygote Intra Fallopian Transfer (ZIFT) – In Vitro (external) fertilization is a method where ovum is procured and merged with sperm and fertilized in the laboratory. After Embryo gets formed it is injected into the Fallopian tube of the woman to further enhance growth.
- Intracytoplasmic Sperm Injection: this method is used when there is a serious issue w.r.t quality and mobility of sperm, DNA damage resulting in frequent miscarriage, decreasing fertility in a man or woman. Eggs are retrieved from the woman's body, cultivated in the laboratory. Mature egg is directly injected with a single live sperm through intracytoplasmic sperm injection and fertilized in the conducive environment. Later the embryo is injected back into the woman's uterus.
- In Vitro Fertilization (IVF): is the most common used technique performed on a woman aged above 35years who has low egg count or damaged fallopian tube, or husband semen count is low or of bad quality or failure in other methods to conceive. After detailed medical examination, IVF process starts with medications to stimulate ovaries to produce quality eggs. Once the eggs get matured enough, they get picked up through transvaginal method and are fertilized with sperm in petri dish outside the woman's body. Once embryo gets formed either in the fresh embryo form or frozen embryo form, it is injected back into the uterus of the woman to achieve success in pregnancy. This method is fondly known by Test-Tube baby method which is used more often in artificial reproduction and surrogacy process.
- Surrogacy: the last option available to an infertile couple when all the above stated fertility treatments fail is the substituted reproduction method called as Surrogacy. An arrangement is designed between the intending couple and another woman (may be a relative or a stranger who agrees to act as a surrogate or substitute) for rendering the uterus to bear the child. The child gets conceptualized with the eggs from the intending mother (not the surrogate egg) and sperm from the intending father or donor eggs or donor sperm in the laboratory. Once embryo gets formed, it is injected into the uterus of the surrogate to carry further pregnancy. Here, the intending couple are the natural and legal parents of the surrogate child and the surrogate must relinquish all her rights on the child post-delivery. In the whole process, there is no presence of physical or sexual activity between the intending father and the surrogate. During this process 'life' gets created in Petri dishes within laboratory outside human body. This is the result of breakthrough in medical science in human reproduction shifting paradigm of conception from natural to artificial.

ROLE OF AI IN ART

Machine Learning under Artificial Intelligence (AI) aims at giving 100% accurate results saving intending mother or surrogate from repetitive & painful IVF procedures, failures. The most complicated job in IVF (In Vitro Fertilization) process is to successfully characterize and identify the most viable Oocytes or Embryos⁴ by human agencies. ML is used for embryo or Oocyte scoring selection through Pre-implantation genetic diagnosis (PGD)⁵, Sperm morphology through computer-aided sperm analysis (CASA) systems.

In the reproductive field, the role of AI is to assist health service providers by assembling inputs on creating a healthy baby by using optimal Surrogate⁶. AI plays a pertinent role in IVF Surrogacy (through Gestational Surrogate/ Carrier) wherein machines imbued with AI screen human micro biome⁷ to design most healthy babies free from gene defect/s. AI has been actively used in western countries by IVF / Fertility treatment Centres to carry out successful implantation of embryo into the Uterus of a Surrogate which sets the ground for

⁴. Sec 2 (i), ART Bill 2020

⁵. *ibid* p.1

⁶. Flourish – innovative tech wellness Company takes help of AI driven personal wellness tool 'FLORA' which provides complete analysis of customized food selections specific to the Surrogates. <https://medium.com/uxatcomdes/a-parents-guide-to-ai-driven-gestational-surrogacy-80316867a8fb> (last visited on 4th Feb 2019)

⁷. **Human micro biome** means the full array of microorganisms (the micro biota) that live on and in humans and, more specifically, the collection of microbial genomes that contribute to the broader genetic portrait, or met genome, of a human. <https://www.britannica.com/science/human-microbiome> (last visited on 16th Sept 2021)

critical first stage of a successful pregnancy. Through IVF Surrogacy aided by AI, many childless couples have the joy of having their own genetic child when all sorts of ART treatments/ methods fail to yield result.

Pre-Implantation Genetic Diagnosis (PGD):

A modern technique used to assess the genetic profile of the embryo before it is implanted. This is done to enhance the chance of healthy foetus initially and a healthy baby in the long term. Through this technique, foetus with congenital diseases, heritable genetic or chromosomal defects or diseases are discarded from being implanted into the uterus of the intending mother or Surrogate⁸.

This is an AI embedded technique which screens all 23 chromosomes present in a human body and gives a clarity on the embryo profile. This technique is used in the IVF procedures, where egg and sperm are fused together in a petri dish to form an embryo. This is a boon for aspiring parents who suffer from repeated IVF failures, miscarriages, either of the partner suffering from Thalassemia⁹ or colour blindness¹⁰.

Computer-Aided Sperm Analysis (CASA):

Motility and quality of a sperm¹¹ plays a very crucial role in kick starting fertilisation process. Sperm abnormalities often make the entire conception a failure. To check male fertility - motility and quality of sperm before beginning IVF process, medical practitioners take the aid of AI inbuilt Computer-aided Sperm analysis (CASA) process. CASA is an automated form of semen analysis much more fast, efficient, and accurate when compared to conventional semen analysis method. In CASA, sperm samples are loaded on the microscope slides and computer connected to it with a powerful microscope does the detailed analysis. If the quality of the sperm is assessed as good, then the same shall be used in the IVF procedure to maximise chances of conception. This also reduces the chances of IVF failures, miscarriages, birth defects and pregnancy related complications. Indeed, AI in ART is a boon for intending couples¹² struggling to get their genetic tie.

ART & LAW

India:

In India, laws governing ART procedures or Surrogacy are still in the infant stage. Indian Parliament (Lok Sabha) passed The Surrogacy (Regulation) Bill, 2020, prohibiting commercial Surrogacy as unethical. It created a single channel for couples after the waiting period¹³, to opt for Altruistic Surrogacy through a close relative without any monetary benefit apart from the necessary medical expenses incurred pre-during-post-delivery¹⁴. The ART Bill 2020 has not been made into law to cover ART clinics, ART banks and other medical practitioners into its ambit. They follow guidelines laid down by The Indian Council of Medical Research (ICMR)¹⁵ which are ineffective in handling unethical practices. On the other hand, both reproductive laws fail to legally bind key players in the market such as Intending Couples: IVF Centres: Gestational Surrogates. Bills are silent on liability and accountability issues arising in case of medical negligence/ wrong diagnosis/ data entry error through which AI mechanism's function. Lack of adequate and specific data privacy laws to protect and secure data in digital space is leading to exploitation of the same for commercial purposes. In the benefit of the child to be born, PGT should be made mandatory as preliminary process for all ART techniques. Oocyte donor should be given insurance coverage to cover and protect her family against possible risks caused to her body during egg retrieval. The Bill should lay down strict laws for the ART clinics and banks w.r.t multiple embryo transplantation. Not more than 3 embryos can be transferred in one IVF process to avoid risk of multiple pregnancies¹⁶.

Western Countries:

AI has paved way for revolution in the healthcare sector primarily in reproductive section in western countries like Australia, America giving rise to patient privacy and accountability in case of breach. In European Countries, General Data Protection Regulation (GDPR)¹⁷ permits a patient to delete her/him personal data under special circumstances and entitles her/him to huge compensation in case of breach. Developed countries

⁸. Section 25 of the ART, Bill 2020

⁹. Any of a group of inherited disorders of haemoglobin synthesis (such as Cooley's anaemia) that are marked by mild to severe hypochromic and microcytic anaemia, result from the partial or complete failure in production of one or more globin chains, and tend to occur especially in individuals of Mediterranean, African, or south-eastern Asian ancestry —sometimes used with a prefix (such as alpha-, beta-, or delta-) to indicate the haemoglobin chain affected, <https://www.merriam-webster.com/dictionary/thalassemia> (last visited on 19th Sept 2021)

¹⁰. Color blindness is an abnormal condition characterized by the inability to clearly distinguish different colors of the spectrum. The difficulties can be mild to severe, <https://medical-dictionary.thefreedictionary.com/Colour+blind>

¹¹. Sec 2 (u) of the ART Bill 2020

¹². Section 2(r) Ibid.1 – intending couple means a couple who have been medically certified to be an infertile couple and who intend to become parents through Surrogacy.

¹³. As per the Bill 2020, couples unable to conceive within 1 year of unprotected coitus are only eligible for opting Altruistic Surrogacy as a means of begetting their genetic child.

¹⁴. Section 2(b) of The Surrogacy (Regulation) Bill 2020

¹⁵. Chapter 3 of the ICMR guidelines deals with Code of Practice/ Ethical Consideration & Legal Issues, https://www.icmr.nic.in/sites/default/files/guidelines/Guideline_content.pdf (last visited on 20th Sept 2021)

¹⁶. Point 1.6.8.2 of the ICMR guidelines on ART clinics (last visited on 20th Sept 2021)

¹⁷. Data Subject Rights - Right to be Forgotten under the GDPR, <https://eugdpr.org/> (last visited on 19th Sept 2021)

like UK¹⁸, Australia¹⁹ have their laws in place to deal with human data in digital space. USA²⁰ relies on combination of legislation, statutory regulation, and self-regulation rather than governmental intervention alone.

At present, Europe is the largest market for ART and reproductive tourism with a statutory law in hand²¹.

Table – 01²²

Country	Type of ART governance	New ART legislation since 2009	Type of coverage	Extent of coverage
Belgium	Legislation only	Yes	National health plan and private insurance	Partial
Bulgaria	Legislation only	Yes	National health plan	Partial
Croatia	Legislation only	Yes	National health plan and private insurance	Partial
Czech Republic	Legislation only	Yes	National health plan	Partial
Denmark	Legislation only	Yes	National health plan	Complete
Finland	Legislation only	No	National health plan	Partial
France	Legislation and guidelines	Yes	National health plan	Complete
Greece	Legislation only	No	National health plan	Partial
Russia	Legislation and guidelines	Yes	National health plan	Complete
Slovenia	Legislation only	No	National health plan	Complete
Spain	Legislation and guidelines	No	National health plan and private insurance	Complete
India	Guidelines only	No	No coverage	None
Japan	Guidelines only	No	National health plan	Partial
United States	No	Private insurance	Partial	Partial

¹⁸. Based on the model of EU GDPR, UK has enacted Data Protection Act 2018 focusing more on Data Subject Rights (last visited on 20th Sept 2021)

¹⁹. Privacy Act 1988; Federal privacy Act 1988; Health Privacy Principles; Information privacy Act 2009 (Queens land) (last visited on 15th Sept 2021)

²⁰. Privacy Act 1974; Privacy Protection Act 1980; The Gramm-Leach-Bliley Act 1999; The Health Insurance Portability and Accountability Act 1996; The Fair Credit Reporting Act 2018 (last visited on 10th Sept 2021)

²¹. Präg P., Mills M.C. (2017) Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care. In: Kreyenfeld M., Konietzka D. (eds) Childlessness in Europe: Contexts, Causes, and Consequences. Demographic Research Monographs (A series of the Max Planck Institute for Demographic Research). Springer, Cham. https://doi.org/10.1007/978-3-319-44667-7_14 (last visited on 20th Sept 2021)

²². Ory, S. J., Devroey, P., Banker, M., Brinsden, P., Buster, J., Fiadjoe, M., et al. (2014). IFFS surveillance 2013. Preface and conclusions. Fertility and Sterility, 101, 1582–1583, retrieved from ibid p.22 (last visited on 20th Sept 2021)

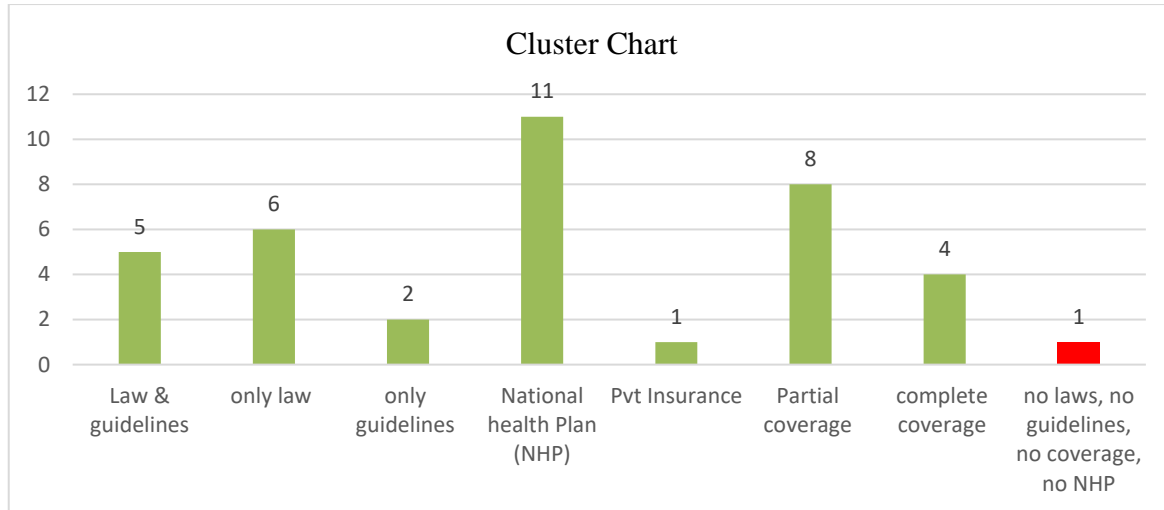


Fig – 01 based on Table - 01

The above figure depicts status of countries where ART laws or guidelines are enacted, insurance coverage under the National Health Plan (NHP) either in the partial mode or complete mode is applied. In a country like India, neither ART laws nor any insurance coverage under NHP scheme is framed (highlighted in red)

AI & Infertility Issues:

AI through machine learning/ data mining and advanced analytics acts as a guide for medical practitioners in the health care sector. It assists Embryologists²³ to analyse embryo quality and can be a useful pre-screening tool to identify viable embryos before implantation saving the cost of Ovarian patients undergoing IVF. It also protects Surrogates from undergoing repeated IVF procedures reducing the risk of intending couples abandoning surrogate child with genetic disorders/ abnormalities. AI inbuilt Pre-implantation of Genetic Diagnosis (PGD)²⁴technic can be used to identify over 1500 inherited single gene disorders and the predictions are 99% accurate, the same can be taken into serious consideration by medical experts.

Through IVF Gestational Surrogacy aided by AI, many couples with implantation failure, advanced maternal age, history of recurrent miscarriages can have the joy of having their own genetic child. AI mechanisms can be used at the basic level to deduct infertility ratios in the couple and the same can be cured through medications solving infertility issues to some extent.

SUGGESTIONS/ RECOMMENDATIONS

1. Best ways to implement AI is to introduce it in clinical work from the initial stages to provide best results.
2. Performance of ML is based on quantity and quality of data input. Small datasets can result in poor performance and wrong predictions. Hence care must be taken in this regard.
3. Scope of AI is limited to screening of embryos, sperm cells and outcome of ART. Issues such as early disease prediction and diagnosis, treatment and prognosis evaluation are relatively inadequate. These should also get covered under AI area.
4. Every human body is different from each other, and a uniform method cannot work out. Therefore, Clinicians should also use their experience and due sense in handling such matters. They cannot blindly follow the predictions of ML models.
5. ART clinics are the main source of embryonic stem cells through which inter-country sale of embryos and stem cells take place. Hence to regulate and prevent this trafficking ART bill 2020 must be passed with immediate effect.
6. Artificial intelligence technology can be a big boon for primary health care centres (PHC) situated in remote areas/ rural areas. Government should take steps to accommodate the same. Digital space can act as a bridge between PHC and medical practitioners in urban areas to solve complex maternity related issues.

²³. ICMR Guidelines on ART Clinics (last visited on 15th July 2021)

²⁴. The use of genetic analysis in the course of vitro fertilization to ensure that a baby does not possess a known genetic defect of either parent <https://medical-dictionary.thefreedictionary.com/preimplantation+genetic+diagnosis>(last visited on 1st Sept 2021)

7. Encourage R & D in AI related public healthcare sector at the National level on the model of IBM – Watson and Manipal Hospitals²⁵.
8. Frame Intellectual Property/civil/ criminal liability issues with respect to privacy, data access, data security, confidentiality, ownership, and informed consent in case of breach by machine technology.
9. Set up Special Courts to address technical issues related to AI and ART with judges who are well versed with technology.
10. Create awareness on PGD to intending couples suffering from chromosomal/ genetic defects which could pass on to their offspring.
11. Lay down regulatory mechanisms to promote end-to-end human monitoring on machine learning to avoid biased data input resulting in biased decision by the system.
12. Applications of AI in reproductive medicine are relatively limited and mostly semi-automatic (we need automatic AI-assisted reproduction). Government should make it mandatory for all ART clinics to have fully automated machines to get license.
13. ICMR guidelines on ART clinics should be made mandatory and punitive in case of violation.
14. Frame National Health Plans (NHP) like western countries and provide coverage to patients seeking ART services. Example: in Denmark since 2012 under the private sector free ART treatment is given to the patient if she/he is referred by the General Practitioner; under the public sector up to 3 cycles of ART free of cost to those who doesn't meet the eligibility criteria. If the patient wants to go for an additional cycle, he/she need to pay for the cost²⁶.

CONCLUSION

*We always overestimate the change that will occur in the next two years and underestimate the change that will occur in the next ten*²⁷

AI in reproductive healthcare is really a boon rather than a bane. Keeping in mind alarming infertility ratio and emerging forms of assisted reproductive techniques, it is advisable to rely on this Machine Deep Learning in solving problems of childless couples. Intending Couples who are trying to conceive can be saved from unsuccessful, recurrent IVF cycles, financial, physical, and even emotional pressure. As and when the Society moves towards technology, laws need to be updated to stand as a strong fort to safeguard people from its misuse or pave the way for benefits to the deserving class.

²⁵. Manipal Hospitals has partnered with IBM for utilizing 'Watson' software at its Oncology department. The Machine assists doctors in diagnosing and providing treatment to cancer patients. <https://watsononcology.manipalhospitals.com/> (last visited on 19th June 2021)

²⁶. Assisted Reproduction in Denmark, Rothmar Herrmann, Janne, Assisted Reproduction in Denmark (June 19, 2018). Available at SSRN: <https://ssrn.com/abstract=3198538> or <http://dx.doi.org/10.2139/ssrn.3198538> (last visited on 20th Sept 2021)

²⁷. Bill Gates (1996) <https://www.internationalsos.com/client-magazines/in-this-issue-3/how-ai-is-transforming-the-future-of-healthcare> (last visited on 20th June 2021)