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Expanding IVF Treatment in India - Legal Concerns in IVF

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Introduction

The rapid advancements in sciences have revolutionized modern medicine in a number of ways; genetic engineering, Assisted Reproductive Technologies (ART), human cloning, stem cells etc. has opened up the unimagined and promise unquestionable and undreamed benefits to mankind. At the same time, they raise many questions of law and ethical issues relating to public interest, social and religious sentiments and family concern. Although ethical judgments may indeed express personal preferences and may be connected in complicated ways with cultural conventions, ethics itself is a form of rational inquiry that concerns how we should live and what we should do. Some ethical issues are matters of debate.



Having a progeny is an aspiration that is shared universally across the world, though the sensitivities may vary in degree depending on the cultural and personal context. In India, of course, this is a matter of very high sensitivity and an inability can contribute to serious psychological, emotional and social distress to the family, irrespective of economic, educational or religious background. It is, therefore, a matter of great concern and alarm to witness an increasing incidence of infertility cases, much of it owing to changing lifestyles and its consequent effect on physiological and psychological health and also owing to genetic propensity in the case of female.

The good news is that advancement in medical science has achieved much success in the treatment of infertility with an impressive increase in success rate over the years, but it is also a sad reality that the actual beneficiaries are only a very small percentage of the needy owing to issues of awareness, affordability, access and assurance. With a very large and increasing population in child bearing age group and no hope for alleviation in risk factors, it is imperative for the stakeholders of Indian healthcare to address this issue that has serious implications for the individual and the society.

Context - High disease burden of infertility in India

Infertility, the inability to conceive by natural means, is a medical condition with high prevalence affecting nearly 10- 15% of married couples in India. Nearly 27.5 million couples who are actively seeking children suffer from infertility

It is estimated that while female factor accounts for 40-50% of infertility among couples, infertility attributable to male factors is on the rise and constitutes 30-40% of infertility, While there is a rise in the proportion of women in the reproductive age of 20-44years (14% increase estimated between 2010 to 2020) the increase is skewed towards those aged between 30-44 years (20% increase estimated between 2010 to 2020), who typically display lower fertility rates. This shifting demographic trend coupled with increasing contraceptive use and risk factor exposure is likely to drive further rise in the burden of infertility in India

The key risk factors that are leading to high prevalence of infertility include-

- ▶ **Lifestyle factors:** Increasing marital age, increasing number of working women, rising alcohol and tobacco consumption and rising levels of obesity
- ▶ **Clinical factors:** Increasing prevalence of medical conditions such as poly-cystic ovarian syndrome (PCOS), endometrial tuberculosis, and sexually transmitted infections (STIs).



Studies also suggest that South Asian women have a poor ovarian reserve compared to Caucasian women, and are likely to suffer from earlier onset of infertility and poorer outcomes from infertility treatment

Treatment landscape - Highly under-penetrated market with significantly low treatment rates

Assisted reproductive technology (ART), which includes in-vitro fertilisation (IVF), is used primarily for treatment of infertility. In spite of increasing demand for infertility treatment, only 1% of infertile couples in India seek treatment

The low penetration of infertility treatment in India is attributable to:

- 1) High cost of treatment - at INR 150,000 – 200,000 per IVF cycle, which often requires multiple treatment cycles, is largely unaffordable to nearly 80% of the population
- 2) Paucity of skilled IVF specialists and embryologists in India, with only about 3-4% (700-1,000) of the pool of gynaecologists performing IVF procedures. There is an urgent need to address the skill gap and technical expertise required to provide high quality treatment towards improving outcomes and patient safety
- 3) Significant geographical skew in the distribution of infertility centers with ~55% of IVF cycles being performed in the top eight metro cities coupled with a highly fragmented market is affecting access to quality treatment
- 4) Absence of a regulatory framework for quality management of ART centers and patient safety resulting in mushrooming of IVF clinics with poor treatment outcomes and quality of patient care
- 5) Low awareness of fertility problems among couples despite the high need for parenthood and the importance of social status associated with parenthood

It is estimated that the addressable demand in the key metro cities of Delhi, Mumbai and Bangalore is 9 to 12 times higher than the current market for IVF treatment¹

¹ [http://www.ey.com/Publication/vwLUAssets/EY-call-for-action-expanding-ivf-treatment-in-india/\\$FILE/EY-call-for-action-expanding-ivf-treatment-in-india.pdf](http://www.ey.com/Publication/vwLUAssets/EY-call-for-action-expanding-ivf-treatment-in-india/$FILE/EY-call-for-action-expanding-ivf-treatment-in-india.pdf) accessed on 22-11-2016



In-vitro Fertilization

In-vitro fertilization (IVF) is artificially performed fertilization outside the woman's body i.e. 'in test tube'. This procedure involves extraction of a number of eggs from the woman's ovaries and to do this, she is given a drug that enables her to super-ovulate or to produce more eggs in one cycle than she normally does. The eggs are then surgically removed and fertilized outside the body in the laboratory normally with the sperm of the husband but it may be done with sperm from donor. There may be following conditions;

- Where the wife is able to produce eggs but her husband unable to deposit sperm in her, may be due to oligospermia or low motility of sperm.
- Where the wife is able to produce eggs but unable to carry a child to term. Then wife's egg fertilized in artificial environment in laboratory and the embryo is implanted in wife's uterus.
- Where the wife is not able to produce eggs, another woman is hired to be inseminated with the husband's sperm/fertilized embryo may be implanted in her womb and she carries pregnancy for them to term and then delivered a baby and hand over to that couple. This is called as Surrogate Motherhood
- Where the couple desiring to have children cannot produce any of the sperm or eggs necessary for conception. So, the wife's sister/other woman donates the eggs and husband's brother/donor, donates sperm. Fertilization occurs in vitro and embryo is implanted in the wife's womb, which carries the pregnancy

Ethical & Legal Concerns in IVF

The reproductive revolution has had the ability to separate genetic parenting from gestational parenting and from social parenting and the agent who brings it all about, a biotechnical, will be still another person. Sperm and eggs are being brought and sold and wombs are being rented. The fact, that these techniques have been developed and have a certain success rate does not make them morally acceptable.

Donation of sperms and ova are both contrary to the unity of marriage and the dignity of procreation of human being. Furthermore, these procedures lend themselves to commercialization and exploitation, when people are being paid for sperm, ova and for surrogate motherhood. Some of the ethical issues involved in this technology are:



- Bypassing the natural method of conception,
- Creating life in laboratory
- Fertilizing more embryos than will be needed,
- Discarding excess embryos,
- Expensive technology, not affordable for common man,
- Creating embryos, freezing them and keeping them in limbo,
- Destroying embryos in research,
- Selective termination of embryos etc.

The legal problems that arise from invitro fertilization are that number of persons can assert for parental rights extends to the sperm donor, the egg donor, the surrogate mother, parents who raise the child. Further, if during the time in which the embryos are in storage, the couple divorces, legal complications may arise as to the custody of the embryo. The spare embryos are frozen, discarded, donated or used for experimentation. Since some religions believe that life begins at conception, it may amount to abortion which is contrary to both law and ethics². Expert indentation is also not permissible as science cannot experiment with someone with basic human rights without prior permission.

Donation involves separation of the biological and social roles of parenthood that is significant part of family concept and is equivalent to adoption before birth thereby calling for amendments in adoption laws of most of the countries. When she is carrying more developed embryos, it can endanger her life. The only alternative available to avoid risk to her health and life is to carry out selective termination of one or more of the developing embryos. This not only involves trading of one life or more but the doctor is faced with the decision of which ones to terminate and how to make this decision.

ICMR Regulations

Chapter 3 of the ICMR guidelines enshrines upon Code of Practice, Ethical Considerations and Legal Issues

² <http://medind.nic.in/jal/t12/i4/jalt12i4p350.pdf> accessed on 22-11-2016



Clinics involved in any one of the following activities should be regulated, registered and supervised by the State Accreditation Authority/State Appropriate Authorities

1. Any treatment involving the use of gametes which have been donated or collected or processed in vitro, except for AIH, and for IUI by level 1A clinics who will not process the gametes themselves.
2. Any infertility treatment that involves the use and creation of embryos outside the body.
3. The processing or /and storage of gametes or embryos.
4. Research on human embryo

Responsibilities of the Clinic

- To give adequate information to the patients
- To explain to the patient the rationale of choosing a particular treatment and indicate the choices the patient has (including the cheapest possible course of treatment), with advantages and disadvantages of each choice.
- To help the patient exercise a choice, which may be best for him/her, taking into account the individual's circumstances.
- To maintain records in an appropriate proforma (to be prescribed by the authority) to enable collation by a national body.
- When commercial DNA fingerprinting becomes available, to keep on its record, if the ART clinic desires and couple agrees, DNA fingerprints of the donor, the child, the couple and the surrogate mother should be done.
- To keep all information about donors, recipients and couples confidential and secure. The information about the donor (including a copy of the donor's DNA fingerprint if available, but excluding information on the name and address – that is, the individual's personal identity) should be released by the ART clinic after appropriate identification, only to the offspring and only if asked by him/her after he/she reaches the age of 18 years, or as and when specified and required for legal purposes, and never to the parents (excepting when directed by a court of law).
- To maintain appropriate, detailed record of all donor oocytes, sperm or embryos used, the manner of their use (e.g. the technique in which they are used, and the individual/couple/surrogate mother on whom they are used). These records must be maintained for at least ten years after which the records must be transferred to a



central depository to be maintained by the ICMR. If the ART clinic/centre is wound up during this period, the records must be transferred to the central repository in the ICMR.

- To have the schedule of all its charges suitably displayed in the clinic and made known to the patient at the beginning of the treatment. There must be no extra charges beyond what was intimated to the patient at the beginning of the treatment.
- To ensure that no technique is used on a patient for which demonstrated expertise does not exist with the staff of the clinic.
- To be totally transparent in all its operations. The ART clinics must, therefore, let the patient know what the success rates of the clinic are in regard to the procedures intended to be used on the patient

False claims via hoardings and paper advertisements are a cheap way of attracting a clientele that is vulnerable and, therefore, easily swayed. Such advertisements shall be banned. An honest display at appropriate places or publicity of statistics, fee structure, quality of service and of service provided, will be encouraged, provided the guidelines laid down by the Medical Council of India in this regard, are not violated.



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