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Review Research Paper

Assisted Reproductive Techniques Ethical and Legal Issues

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Abstract

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. The Delhi Government has promulgated legislation in this regard which is cited as "The Delhi artificial insemination (Human) Bill 1995. The Indian Council for Medical Research has laid down certain guidelines for clinics practicing of assisted reproductive techniques and handling of surrogates in India. There is a certain element of risk associated with all assisted reproductive procedures. It is, therefore, necessary to ascertain the therapeutic and research value of the AR procedure in each case.

Key Words: Artificial insemination, ART, Surrogate mother, Embryo, Guidelines

Introduction:

The special programmes by WHO on human reproduction has estimated that there are 60 to 80 million infertile couples worldwide; between 6-10% of the couple are infertile. [1] The advent of Assisted Reproductive Technologies (ART) from the late 70s has not only enhanced the possibility of pregnancy but has also made women conceive in situations which would not have been possible decades ago. However, many of these technologies require enormous technical expertise and infrastructure, are expensive and the couple's endurance physically, emotionally, socially and economically. [1]

In order to ensure quality of care, it is imperative that standardised protocols and guidelines should follow for the establishment and accreditation of ART Centres. National guidelines for Accreditation, Supervision and Regulation of ART Clinics have been formulated by ICMR in 2005 [1] to provide optimum benefit of these newer technologies by skilled team of experts, at affordable health and economic cost.

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Equally important are issues related to the conduct of research with material obtained i.e. follicular fluid, oocytes and spare embryos, semen samples, which can be used by researchers in basic or molecular science.

What are Assisted Reproductive Technologies?

Assisted reproductive technologies include any fertilization involving manipulation of gametes/ embryos outside the human body and transfer of gametes/embryos into the body. [1] The new reproductive technologies give great help and offer biomedical parenthood to various infertile couples who have exhausted all other avenues to have a child of their own.

Indication for ART: [2]

- When husband is impotent.
- When husband is infertile.
- When husband is unable to depose semen in female genital i.e. hypospadesis, epispadesis etc.
- When Rh incompatibility between husband and wife.
- When husband is suffering from hereditary diseases.

New Reproductive Techniques: [2]

1. Artificial Insemination
2. In-vitro Fertilization
3. Surrogate Motherhood

Artificial Insemination (AI):

It involves manipulation of fertilization by injecting of a sperm artificially through a needle into the vagina/cervix/uterus/fallopian tubes of the wife directly without sexual intercourse. Success rate of AI is 70 – 75% within three to four months while it is done successively for four five days in each cycle. [2]

Types of Artificial insemination (AI) [2]:

- **Artificial Insemination Homologous/Husband (AIH):**

Where the husband's sperm count is low or because of a disease cannot ejaculate, the artificial insemination is done with the sperm of the husband [AIH].

- **Artificial insemination donor (AID):**

Where the husband is not able to produce sperms, then sperm can be taken from an anonymous donor [AID]. It is normally the first infertility treatment, a couple can try as it is simple to accomplish, involves no pain and less expensive in comparison to other reproductive techniques.

- **Artificial insemination husband donor (AIHD):**

"Pooled donor" the semen of husband is composed with donor's semen where is chance to get fertilization from husband's sperm.

Ethical and Legal Concerns in AIH and AID:

AID raises ethical questions that are not raised by AIH as it takes place between husband and wife. Even though, it is through advanced biomedical techniques and not by natural procedure, most of the people have no moral difficulty to accept it. It maintains the integrity of family and there is continuity between procreation and parenthood.

It is simply viewed as a medical technology providing assistance to what could not be accomplished by normal sexual intercourse. Whereas AID introduces a third party into the reproductive matrix**,** therefore, someone who donates sperm, is now contributing genetic material without the intent to parent. Most of the religions also don't accept the impregnation of one's wife by the sperm of third person; it doesn't make the child one's own and is looked down upon as illegitimate. The donation is, however, always made anonymously, so that the father could not be traced by the child, nor can the father elect to make contact with the child. [4]

Recommendations on AI:

The Government of Delhi has promulgated legislation in this regard which is cited as "The Delhi artificial insemination (Human) Bill 1995. [2] The purposes of this bill are as under:

1. To allow the issueless couples to have a child through AI and to give it a legal status.
2. To control spread of HIV through AI.
3. To regulate the donation, sale/storage of human semen//ovum for AI. To control illegal donation/sale/supply of the same.
4. To make obligatory on the part of the medical practitioner –

a. Not to indulge into segregation of the XX or XY chromosomes.
b. Not to disclose the identity of donor/recipient.
c. To prohibit to carry on semen bank without registration.

In-vitro Fertilization: [1, 4]

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 than 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 depose 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 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: [4]

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 in-vitro 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 ethics. 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. [1, 4]

Surrogate Motherhood: [1-3]

Surrogate motherhood involves a woman bearing the child of another woman. Where the woman cannot produce eggs, they enter into a contract with another woman to be artificially inseminated with the husband's sperm and she bears the child for them. Also where the woman can produce eggs but she is unable to carry a child to a term, the embryo is externally formed by in-vitro fertilization of husband's sperm and wife's ova, the embryo is implanted in surrogate mother's womb and she bears the child for them.

This can be done in two ways-either the husband's semen is squirted in the vagina of the surrogate or the fertilization is done externally in the lab by IVF and the embryo is implanted in the uterus of the surrogate mother. The surrogate mother is paid by the married couple for renting her womb. In this case the child would inherit the genetic code of the contracting couple and the sanctity of marriage is maintained. Still the surrogate motherhood is the most controversial of the new reproductive techniques.

Legal and Ethical Concerns in Surrogate Motherhood: [1, 4]

Surrogation involves a contract of sale between the married couple and the surrogate. Certainly, the most serious ethical objection to commercial surrogacy is that it reduces children to objects of barter by putting a price tag in them. Morally, it is no less than selling or trafficking of human beings violating the basic fundamental rights of a human being. Some women could be pressurized into surrogacy by their husbands for money. In India, the surrogate does not enjoy the same rights as in the west.

The Indian medical guidelines allow doctors to implant five embryos into a surrogate, whereas in Britain, the maximum is two and many European countries are moving towards a single embryo implant. Under British laws a surrogate mother who has provided an egg can claim the baby back within two years of child's birth. However in India, she has no right over the child after delivery.

She can cancel the contract only when it is proved that it was not a valid contract according to Section 23 of Indian Contract Act. Ethically also subrogation raises many issues like tempering with the normal process of procreation, undermining the institution of

marriage and family life, treating children as objects of sale etc. Most of the religions also don't approve of the idea of subrogation. There is no law concerning this issue until now.

The Indian Council for Medical Research guidelines for ART clinics and Surrogacy in India: [1]

It is necessary to follow ICMR guidelines in ascertain the therapeutic and research values of the AR procedure.

Informed Consent: After duly counselling the couple/oocyte/semen donor, an informed and written consent should be taken from both the spouses as well as the donor.

They should be explained that:

- The various risks associated with ovarian hyper-stimulation, anaesthetic procedures and invasive procedures like laparoscopy, aspiration of ovum *etc*. in simple language that they can understand.
- The possibility of multiple pregnancies and their risk, ectopic gestation, increased rate of spontaneous abortion, premature births, higher perinatal and infant mortality, growth and developmental problems, possible side effects of the drug used.
- There is no guarantee on the success/failure of the procedure.
- About the cost to the patient of the treatment proposed and of an alternative treatment, if any.
- There may be possible disruption of the patient's domestic life which the treatment an expenses may cause;
- About the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort;
- About the advantages and disadvantages of continuing treatment after a certain number of attempts.
- Informed consent should include information regarding use of spare embryos. It should be made clear whether embryos that are not used for transfer could or could not be used for research purposes or implanted in another woman's womb, or preserved for use at a later date or destroyed.
- Consent may be withdrawn at any time before implantation**.**
- Specific consent must be obtained from couples who have their gametes or embryos frozen, with regard to what should be done with them in case of death, or if any of the parties becomes incapable of varying or revoking her or his consent.
- Abortions should never be encouraged for research purposes.

Selection of Donor: The semen bank assumes the responsibility in selection of the suitable donor on following terms:

- **Complete physical examination** of the donor should be done; the donor should be healthy with reasonable expectation of good quality eggs or sperms and preferably with proven fertility record.
- **The physical characteristic and mental make-up** of the donor should match as closely as possible to that of the spouse of the recipient, especially with reference to colour, eyes and hair, height and build, religious and ethnic background, and education and ABO blood type.
- **Blood group** of the proposed donor and donee should be tested with respect to Rh compatibility.
- **No donor suffering from any sexually transmitted disease (**e.g. syphilis, gonorrhea, chlamydia, herpes, HIV etc.), infectious disease (e.g. hepatitis B and C, HIV) or genetically transmissible disease. Sexually transmitted diseases should be ruled out within a week of obtaining the seminal fluid.
- **It is essential that donated semen is cryo-preserved and used only after 6 months** as this would enable the centre to retest the donor after 6 months for HIV and eliminate the potential risk of HIV transmission in the 'window' period of HIV infection.
- **Identity of the donor as well as the recipient** should be protected from each other. However, all the records of the donor must be preserved for at least 10 years and should be confidential.
- **Confidentiality of the entire procedure** and its outcome is advisable and therefore, no relative should be accepted as a donor in order to avoid identification and claims of parenthood and inheritance rights.
- **Any information about clients and donors must be kept confidential**. No information about the treatment of couples may be disclosed to anyone other than the accreditation authority or persons covered by the license, except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a court order.
- **Written consent and an undertaking of the donor should be taken towards unrestricted use of sperms** or oocytes for AR and he/she will not attempt to seek the identity of the recipient. In case the donor is

married, the written consent of the spouse should also be taken, if possible.

- **It is also desirable to restrict the use of semen from the same donor to a maximum of 10 pregnancies** to avoid the possibility of an incestuous relationship occurring among the offspring's at a later date.
- In case of the oocyte donor, incurring any health problems related to the process of donation, the costs of the subsequent health care should be borne by the potential recipient couple irrespective of whether they receive oocyte donation as planned or not.
- **In case of unused surplus/ spare embryos**, consent of the concerned couple should be obtained to cryopreserve such embryos for donation to other needy couples. The ownership rights of such embryos rest with the couple concerned.
- **Respect for the embryo's moral status** can be shown by careful regulation of conditions of research, safeguards against commercial exploitation of embryo research, and limiting the time within which research can be done on embryo up to **14 days' growth** i.e. when the **primitive streak** appears.

With Regard to Use of Gametes or Embryo:

- No woman shall be treated with gametes or embryos derived from gametes of more than one man or woman;
- No art clinic shall mix semen from two individuals before use;
- No art clinic shall provide a couple with embryo of desired sex;
- No gametes shall be stored for more than 10 years;
- An embryo shall be stored for not more than five years;
- Sale, transfer or use outside india is prohibited;
- The donor shall relinquish all parental rights over the child which may be conceived from her or his gamete.

Women have a special position as care givers for children with disabilities. Since the bulk of care falls upon the women, she should make the final decision among reproductive options, without coercion from her partner, her doctor, or the law.

Legitimacy of the Child Born through ART: [1]

A child born through AR is presumed to be the legitimate child of the couple having been born within the wedlock and with consent of both the spouses with all the attendant rights of parentage, support and inheritance. Sperm/ oocyte donor should have no parental right or duties in relation to the child and their anonymity should be protected.

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