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Ethical and Legal aspects of Artificial Reproductive Techniques including surrogacy

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ABSTRACT

There are varied causes of infertility amongst men and women; as a result this makes every case an entity in itself. Treatment to each couple cannot be generalized it varies and so also the success rate which declines with advancing woman's age. The recent advance in ***Assisted Reproductive Technology*** *(especially the media used) has increased the overall success rate from 17% in the past to reach 45% recently. Repeating the attempts results in better success rate which reaches 70-80% in four attempts collectively. Legislation on Reproductive Technologies provides the means for preventing their misuse. However, the implementation of the Acts related to Reproductive Technologies raises several legal, ethical, moral and social issues which have been extensively discussed and debated ever since Edwards and Sharpe (1971) wrote their seminal article. Human experience has shown that mere legislation against undesirable practices, generally does not prevent them; such practices being pushed to the back-alleys. Legislation must be armed and strengthened by measures aimed at bringing about a sea change in societal perceptions of the female child and women in general. One must wait and watch the consequences of the recent legislative measures taken by India.*

Keywords: Artificial insemination, In-Vitro Fertilization, surrogacy, Legitimacy

Introduction

Any reproductive technique that attempts to obtain pregnancy by means other than by intercourse. This may be carried through either **A *rtificial insemination*** i.e. semen deposition into vagina, cervix or uterus by certain instruments, or through ***In-Vitro Fertilization (Test Tube Baby)*** where the sperm and ovum are allowed to incubate outside the human body i.e. in laboratory and the

resulting embryo is then implanted into the uterus. The types of Artificial insemination includes – **(a)** ***Artificial insemination Homologus (AIH)*** *– Semen of husband is normal but he is unable to pour it through intercourse;* ***(b) Artificial insemination Donor (AID) -*** *Semen of husband is defective and hence it is taken from another healthy, suitable individual.*

Broadly speaking AIH raises, least question regarding legal rights, being a product of own parent seeds. In AID fertilization takes place inside women's body for possible variations, thus this child is linked genetically to the male who is outside its own family.

Artificial insemination Homologus Donor (AIHD) was prevalent earlier in which sperm of husband and a donor was mixed so as to hide the conclusive evidence of father of the child to prevent important issue like adultery, and illegitimacy of the child. But now it is happily accepted in our society, so importance of AIHD has gone down.

According to estimates of the **WHO,** 13-19 million couples in India are infertile. Infertility due to reproductive tract infections and genital tuberculosis is preventable and amenable to treatment, and an estimated 8 per cent of infertile couples opt for medical intervention involving the use of advanced Assisted Reproductive Technologies (ART).[1,2,3]

History

The desire of a child in particular male was very natural in the all early society and this was very boldly declared in *VEDAS,* and also by our ancient writers like *YAJNAVALKYA* and *MANU,* and to beget a son various methods were popular and practiced which our ancient laws permit.

AURASA was said to be a legitimate child begotten by man with his own lawfully wedded wife. Other sons were, ***KSHETRAJA*** (Son by another man appointed by husband). ***GUDHAJA*** (Son by another unknown man, brought forth by wife secretly i.e. unknown adultery). ***KANINA*** (Son secretly born by unmarried damsel in her father's house). ***PUTRIKA PUTRA*** (Son of an appointed daughter who was given in the marriage to bridegroom). ***SAHODHAJA*** (Son begotten when a man marries, either knowingly or unknowingly with a pregnant maiden). ***POUNARBHAVA*** (Son begotten by a man on a twice married woman).

SONS BY ADOPTIOPN were ***DATTAK*** (Son of same caste given as a gift to a man). ***KRITA*** (Son sold by its parent to a man). ***KRTRIMA*** (Orphan son being adopted). ***SVAYAMDATTA*** (Abandoned son being adopted). ***APDVIDDHA*** (Deserted son being adopted).

Today this classification has become a history and rather in our modern society the law has made three distinctions viz – ***legitimate son or daughter*** ; ***Illegitimate son or daughter; Adopted son or daughter*** . Legally legitimate as u/s 112 of IEA 1872, means child born during continuance of valid marriage between the parents or within 280 days of its dissolution, the mother remaining unmarried. Offspring of any void or voidable marriage as u/s 11, 12 of Hindu Marriage Act shall be deemed to be legitimate of their parents not withstanding the decree of nullity.

First therapeutic insemination was performed in London in 1770 by Dr. John hunter in the patient, whose husband had hypospadias.

The **India's first IVF baby, Kanupriya alias Durga,** was born in Calcutta on October 3, 1978, about two months after the **World's first IVF baby, Louise Brown.** Since then, the field of assisted reproduction has developed rapidly. Newer techniques, modifications of existing ones, and new approaches characterise this specialization.[3,4,5]

Legal angle on ART and Need for surrogacy laws

World wide, surrogacy, spins a web of emotional, social and legal issues. Mythological surrogate, mothers are well known. Yashoda played mother to Krishna though Devki and Vasudev were biological parents. Gandhari made Dhritrashtra the proud father of 100 children, though he had no biological relation with them.

In U.K. the medical community has themselves established a voluntary licensing agency (VLA) which ensures that ART is practiced only by persons with adequate qualification and facilities. Regarding statutory laws in U.K. , the first legislation dealing with different aspects of surrogate mother hood was given in 1986, called “the surrogacy arrangements Act”. Subsequently in 1990 the other law was enacted viz – “Human fertilization and embryology Act (HFEA)” and later on was amended in 2000 & 2001.

Voluntary surrogacy is tolerated by society, but the moment the element of commerce – payment to surrogate mother – crop's up, it cries foul.

20 years ago, the famous ‘Baby M' case in New Jersey , **US** made the world sit up and take note of the issue of surrogacy. In US, the first formal agreement between the couple and surrogate mother was signed 1976. Soon brokers entered the scene and commercial exploitation followed. In a case in 1987, Stern Vs Whitefield the superior court and then Supreme Court stripped of parental and visitation rights of Whitefield (the surrogate mother) and allowed stern parents (biological parents) to keep the baby. This case spurred most US states to enact legislation on surrogacy in 1995.

In UK, surrogacy arrangements, not the agreements, are legal. They had shorn of the commercial elements. The UK laws does not recognize surrogate baby's biological father. If British surrogate mother gives birth to a child for a foreign couple, then she alone would be treated as legal mother. If she is married, her husband would be legal father. A foreign couple intending to take legal parent hood of surrogate baby, he must necessarily be domiciled in U.K. If not, then they could take the complication fraught adoption route.

Australia battling with social eruptions over Kirkman sisters case in Victoria , popularly known as ‘My sister baby'. This had sparked much community and legal debate & soon Australia states attempted to settle the legal complication in surrogacy.

Baby Manjhi case of Japanese couple in India has all the twists and turns of suspense filled melodrama. The biggest irony in the story is that the couple has parted away and biological father who wishes to take custody of female surrogate child is unable to do so since Indian law (*Guardianship & wards Act -1980*) does not permit a single male to adopt a girl child. We in **India** do not have any solid legislation to solve such complicated issues. Surrogacy in US, UK and Australia costs between $ 55,000 to $100,000. This makes India a hot destination due to cheep medical and living costs. An American couple recently hired a 23 yr old lady in Mumbai and became a proud parent in total expenditure of $ 40,000. [6,7,8,9,10]

ICMR guidelines on ethical and legal aspects of ART – 2005 (See table)

Code of practice, Ethical consideration and legal issues (chapter-3)[11,12]

[http://www.icmr.nic.in/art/Chapter_3.pdf]

1. Clinics should be registered

2. Code of Practice - D eals with all aspects of the treatment provided and the research done at registered clinics.

i) Staff: S ufficiently qualified, using proper equipment and keeping & disposing off the genetic material properly. Failure to comply with the *mandatory code of practice* can lead to his/her removal or suspension of the Clinic's registration.

ii) Facilities: Proper systems for monitoring and assessing practices and procedures are required to be in place in order to optimize the outcome of ART

iii) Confidentiality: Any information about clients and donors must be kept confidential.

iv) Information to patient: All relevant information must be given to the patient before a treatment is started.

v) Consent: No treatment should be given without the written consent of the couple in all stages of that treatment, including the possible freezing of supernumerary embryos.

vi) Counseling: People seeking registered treatment must be given a suitable counseling about the various implications of the treatment.

vii) Use of gametes and embryos: No more than three oocytes or embryos may be placed in a woman in any one cycle, regardless of the procedure/s used, excepting under exceptional circumstances (such as elderly women, poor implantation, adenomiosis, or poor embryo quality) which should be recorded. No woman should be treated with gametes or with embryos derived from more than one man or woman in any one cycle.

viii) Storage and handling of gametes and embryos: The 'highest possible standards' in respect of their security, and their recording & identification, should be followed.

ix) Research: A ccreditation authority must approve all research that involves embryos created *in vitro* . A separate registration should be issued for each research project. Additionally: a) No human embryo may be placed in a non-human animal b) All research projects must be approved by the Institutional Ethics Committee.

x) Complaints: All registered ART clinics should have procedures for acknowledging and investigating complaints, and nominate a person to deal with such complaints.

3. Responsibilities of the Clinic: Clinic should **(** i) G ive **adequate information** explaining the rationale of choosing a particular treatment. (ii) **Maintain, detailed record** in an appropriate proforma, of all donor oocytes, sperm or embryos used, for at least ten years, after which the records must be transferred to ICMR. (iii) Take **DNA fingerprints** of the donor /child /couple/ surrogate mother, if couple agrees. (iv) Keep all information about donors, recipients and couples **confidential and secure** . (v) **Display the charges** suitably or made known to the patient at the beginning of the treatment. (vi) Ensure that **no technique** is used on a patient for which demonstrated expertise does not exist with the staff of the clinic. (vii) B e **totally transparent** in all its operations.

4. Information and Counseling to be given to Patients -

They should be informed about (a) **Basis, limitations and possible outcome** of the treatment proposed, variations in its effectiveness over time, including the success rates. (b) **Side-effects** and

the risks of treatment to the women and the child. (c) Need to **reduce the number of viable foetuses** in order to ensure the survival of at least two foetuses (d) Possible **disruption of the patient's domestic life** during the treatment (e) **Techniques involved,** possible deterioration of gametes or embryos associated with storage, and **possible pain and discomfort** (f) **Cost** (with suitable break-up) to the patient of the treatment proposed and of an alternative treatment (g) **Importance of informing the clinic of the result of the pregnancy** in a pre-paid envelope (h) **Right of the child born** through ART, to seek information about his genetic parent/surrogate mother (including a copy of the DNA fingerprint), on reaching 18 years (i) **Advantages and disadvantages** of continuing treatment after certain attempts.

5. Desirable Practices/Prohibited Scenarios -

There would be **no bar to the use of ART by a single woman** who wishes to have a child, and no ART clinic may refuse to offer its services. The ART clinic must not be a party to any commercial element. A surrogate mother carrying a child biologically unrelated to her **must register as a patient** in her own name. A third-party donor and a surrogate mother must relinquish in writing all parental rights concerning the offspring and vice versa. No ART procedure shall be done without the spouse's consent.

The provision or otherwise of **AIH or ART to an HIV-positive woman** would be governed by the implications of the decision of the Supreme court in the case of X – vs – Hospital 2 (1998) 8 Sec. 269 or any other relevant judgment of the Supreme Court, or law of the country, whichever is the latest.

The **accepted age** for a sperm donor shall be between 21- 45 yrs and for the donor woman between 18-35 yrs. **Sex selection** at any stage after fertilization, or abortion of foetus of any particular sex should not be permitted, except to avoid the risk. Collection of gametes from a dying person will only be permitted if **widow** wishes to have a child.

No more than three eggs or embryos should be placed in a woman during any one treatment cycle, regardless of the procedure used, excepting under exceptional circumstances {such as elderly women (above 37 years), poor implantation (more than three previous failures, advanced endometriosis, or poor embryo quality} which should be recorded.

Use of **sperm donated by a relative or a known friend** of either the wife or the husband shall not be permitted. It will be the responsibility of the ART clinic to obtain sperm from appropriate banks; neither the clinic nor the couple shall have the right to know the donor identity and address, but both the clinic and the couple, however, shall have the **right to have the fullest possible information** from the semen bank on the donor such as height, weight, skin colour, educational qualification, profession, family background, freedom from any known diseases or carrier status (such as hepatitis B or AIDS), ethnic origin, and the DNA fingerprint (if possible), before accepting the donor semen. It will be the responsibility of the semen bank and the clinic to ensure that the couple does not come to know the identity of the donor. The ART clinic will be authorized to appropriately charge the couple for the semen provided and the tests done on the donor semen. Same will be applicable for oocytes donation.

Trans-species fertilization involving gametes of two species is prohibited. **Ova derived from foetuses** cannot be used for IVF but may be used for research. Semen from two individuals must **never be mixed** before use, under any circumstance.

The **data** of every accredited ART clinic must be accessible to an appropriate authority of the ICMR at the national level. The **true informed consent** should be made on the consent form, witnessed by a person who is in no way associated with the clinic.

The individual must be free of HIV and hepatitis B and C infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia. Semen or oocyte must be found to be normal according to WHO method manual for semen analysis. **The blood group and the Rh status of the individual** must be determined and placed on record.

7. Sourcing of Sperm and Oocyte Donors and Surrogate Mothers

a. Semen banks: Either an ART clinic or a law firm or any other suitable independent

Organization may set up a semen bank. The bank will ensure that all criteria mentioned above are met and a suitable record of all donors is kept for 10 years after which, or if the bank is wound up during this period, the records shall be transferred to an ICMR. On request for semen by an ART clinic, the bank will provide the clinic with a list of donors (without the name or the address but with a code number) giving all relevant details. The bank shall keep a record of all semen received, stored and supplied, and details of the use of the semen of each donor. This record will be liable to be reviewed by the accreditation authority.

The bank must be run professionally and must have facilities for cryopreservation of semen, following internationally accepted protocols. Semen samples cryopreserved for at least six months before first use must be tested for HIV and hepatitis B and C. The bank must ensure confidentiality in the identity of the semen donor. An appropriate charge may be levied by the bank for the storage. All semen banks will require accreditation.

b. Sourcing of oocytes and surrogate mothers

Law firms and semen banks will be encouraged to obtain (for example, through appropriate advertisement) and maintain information on possible oocytes donors and surrogate mothers. The above organizations may appropriately charge the couple for providing an oocyte or a surrogate mother. The oocyte donor may be compensated suitably (e.g. financially) by the law firm or semen bank when the oocyte is donated.

8. Preservation, Utilization & Destruction of Embryos

Couples must give specific consent to storage and use of their embryos by other couples or for research. The Human Fertilization & Embryology Act, UK (1990), allows a 5-year storage period which India would also follow. Research on embryos shall be restricted to the first fourteen days. No commercial transaction will be allowed for the use of embryos for research.

ICMR guidelines on Surrogacy: General Considerations

1 A child born through surrogacy must be **adopted** by the genetic (biological) parents unless they can establish through DNA fingerprinting (of which the records will be maintained in the clinic) that the child is theirs.

2 Surrogacy by assisted conception should normally be considered only for patients whom it would be **physically or medically impossible to carry a baby to term** .

3 Payments to surrogate mothers should cover all genuine expenses associated with the pregnancy. Documentary evidence of the financial arrangement for surrogacy must be available. The ART centre should not be involved in this monetary aspect.

4 Advertisements regarding surrogacy should not be made by the ART clinic.

5 A surrogate mother **should not be over 45 years** of age.

6 A relative, a known person , as well as a person unknown to the couple may act as a surrogate mother for the couple.

7 A prospective surrogate mother must be tested for **HIV** and shown to be sero-negative for this virus just before embryo transfer. She must also provide a written certificate that (a) she has not had a drug intravenously administered into her through a shared syringe, (b) she has not undergone blood transfusion; and (c) she and her husband (to the best of her/his knowledge) has had no extramarital relationship in the last six months. The prospective surrogate mother must also declare that she will not use drugs intravenously, and not undergo blood transfusion of blood, not obtained from a certified blood bank.

8 No woman may act as a surrogate more then thrice in her lifetime.

General Considerations

1. **Minimum age for ART** in a woman shall be 20 years. Between 20 and 30 years, two years of cohabitation/marriage without the use of a contraceptive, excepting in cases where the man is infertile or the woman cannot physiologically conceive. For a woman over 30 years, one year of cohabitation/marriage without use of contraceptives.

2. **Advertisements** through hoardings and paper advertisements shall be banned. An honest display at appropriate places or publicity of statistics, fee structure, quality of services provided, should be encouraged.

3. No new ART clinic may start operating unless it has obtained a **temporary registration** to do so. This registration would be confirmed only if the clinic obtains **accreditation (permanent registration)** from the Center or State's appropriate accreditation authority within two years of obtaining the temporary registration. The registration must be **renewed every seven years** . Existing ART clinics must obtain a temporary registration within six months of the notification of the accreditation authority, and permanent registration within two years of the notification.

4. Technique of **ICSI** has never undergone critical testing in animal models, but was introduced into the human situation directly. Defects in spermatogenesis and sperm production can be often traced to genetic defects. Such individuals are normally prevented from transmitting these defects to their offspring because of their natural infertility.

5. **Human cloning** for delivering replicas must be banned. Stem cell cloning and research on embryos (less than 15 days old) needs to be encouraged.

6. All the **equipments/machines** should be calibrated regularly.

7. A **State Accreditation Authority** will be set up by the State Governments through its Department of Health and/or Family Welfare to oversee all policy matters relating to Accreditation, Supervision and Regulation of ART Clinics in the States in accordance with the National Guidelines. The State Government may also set up **Appropriate Authorities** for implementation of the

Guidelines for the whole or a part of State having regard to the number of the ART Clinics and delegate powers to impose a fine or a penalty on the center/clinic. In addition to the above, the Ministry of Health and Family Welfare, Govt. of India, will set up a **National Advisory Committee** which will advise the Central Government on policy matters relating to regulation of ART Clinics.

8. Each ART clinic of Levels 1B, 2 and Level 3 must have its own **Ethics**

Committee constituted according to ICMR Guidelines, comprising reputed ART

Practitioners, scientists who are knowledgeable in developmental biology or in Clinical embryology, a social scientist, a member of the judiciary and a person who are well-versed in comparative theology.

9. **Drug companies** must not make exaggerated claims for infertility drugs and market them only to qualified specialists. Infertility drugs must be sold only on prescription by a qualified doctor /ART specialist. Companies dealing with culture media do not give full details of the composition and they keep it as a trade secret. Such companies should be discouraged by ART centers.

Present Indian scenario

The **Indian scenario** in this field is quite bleak. **Delhi artificial insemination (Human) Act 1995** is the only statutory act prevailing in India . There is no internal regulatory body like VLA in U.K, moreover Indian Infertility specialist have rather opposed the steps towards regulation of practice in this field.[13,14,15]

1. Litigation against doctors – doctors can face few litigations like-

a. Not taking proper informed consent: After duly counseling the couple and / or oocytes / semen donor and informed and written consent should be taken from both the spouses as well as donor. They should be explained various risk factors including risks involve in ovarian hyper stimulation, anaesthetic procedures, invasive procedures like laparoscopy, aspiration of ovum etc. in simple language using the words that they can understand well. They should be explained the possibility of multiple pregnancies, ectopic gestation, increased rate of spontaneous abortion, premature birth, higher perinatal and infant mortality as well as growth related problems.

b. Following the birth of a defective child: To avoid this, the donor's chromosomes must be thoroughly screened for possible genetic defect, and should also inform all the likely possibilities at the time of taking informed consent.

2. Legitimacy - The child born by ART is considered legitimate with all the rights of parentage, support and inheritance, provided he is born during lawful wedlock and with consent of both the spouses. Sperm or oocyte donors shall have no parental rights or duties in relation to the child. A child can be given status of legitimacy also by adoption.

In a case, on the wife's petition for divorce and custody of the child, a question was raised before the court: whether the child, who is born to her consequent to AID, consented to by husband, is legitimate and belongs to mother only? Court held that a child so conceived was not a child born in wedlock and therefore illegitimate. As such it was the child of mother alone and the husband had no rights or interest in the child, not even that of visitation. The husband is not the actual father of the child and, therefore the child is illegitimate.

3. Inheritance of property – Since the child is illegitimate if born out of AID, it cannot inherit the property of his father. Any attempt to conceal this fact by registering the husband, as the father amounts to perjury.

4. Consummation of marriage – Conception of the wife by AI (AIH or AID) does not amount to consummation of marriage, if there is no successful sexual act due to the impotency of husband. The decree of nullity may still be granted in favor of the wife on the ground of impotency of the husband or his willful refusal to consummate the marriage. However, such a decree could be excluded on the grounds of approbation. However in this situation the child will be illegitimate.

5. Rights of an unmarried woman to AID : There is no legal bar on an unmarried woman going for AID. A child born to a single woman through AID would be deemed to be legitimate. However, AID should normally be performed only on a married woman and that too, with the written consent of her husband, as a two-parent family would be always better for the child than a single parent one, and the child's interests must outweigh all other interests.

6. Ground for divorce and judicial separation – Mere AI is not a ground for nullity of marriage and divorce since sterility is not a ground, however if AI is due to impotence of husband, it becomes the ground. AID without husbands consent can be a ground for divorce and judicial separation.

7. Maintenance and custody of child – Under Hindu Adoption and Maintenance Act 1956 the maintenance of the dependents is the responsibility of the parents, whether legitimate or illegitimate, till the son remains minor and daughter is unmarried.

8. Insemination after the death of the husband – This is seen when semen of the husband is cryo-preserved by various methods and the women is inseminated after death of the husband. Such **Posthumous child** is said to be legitimate because the semen is of husband, although the complexity arises since conception is not during the continuance of marriage.

9. Relation between AIH / AID child with subsequent Natural / Adopted child of same family - If the child is born of natural course some times after the birth of the child through AI, the status will remain same for AI child but the natural child born will remain legitimate.

10. Charge of Adultery - AID does not amount to adultery, even if it was done without the consent of husband. For adultery to be committed both parties should be physically present and engage in sexual act and sexual union involving some degree of penetration of the female organ by the male organ should take place. AI is not equivalent to sexual intercourse.

Under section 497 of IPC 1860 , sexual intercourse with a person who is or whom he knows or has reason to believe to be wife of another person without the consent or connivance of that man. For the charge of adultery two things must be proved, sexual intercourse took place with another person's wife and no consent or connivance from another man was granted.

11. Incestous relationship – There is high risk of such relationship between naturally born child and child born out of AID of the same parent. What is already known on this topic We already know that the state government of Delhi has enacted the *Delhi Artificial Insemination (Human) Act* in 1995 which, for the first time in India, legalizes the donation of semen and oocytes to infertile couples. Semen banks have been recognized under the supervisory authority of the DHS and the compulsory screening of gamete donors against HIV infection and specifically prohibits the segregation of X and Y chromosome for favouring the conception of a male child through artificial insemination. It is in this context that the National Guidelines for Accreditation, Supervision and

Regulation of ART Clinics in India, by ICMR and the National Academy of Medical Sciences, India, 2005, are significant. What This study adds Being a review article, we have tried to elaborate the present National Guidelines and compare it with various legislations in different countries regarding ART. Infertile women, given the social pressure to reproduce as well as their own intense desire to conceive, are particularly vulnerable to commercial interests and experimentation in the medical field, since desperation might lead them to consent to hazardous techniques in the hope of conceiving. In this perspective we have tried to highlight certain lacunae in the guidelines along with present Indian scenario in surrogacy bazaar. The various recent advances in this technique had also been discussed at length. Suggestions for further development It becomes incumbent upon neutral bodies to ensure that ethical guidelines are adhered to and also to bring to light any violations. For this, well-formulated guidelines drafted with foresight and long-term perspectives are essential.

What is already known on this topic

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What This study adds

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Suggestions for further development

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Challenging Ethical Issues

A. Individual moral constraints on trying for reproduction "at any cost"? [16,17,18,19,20,21]

The concerns like Sex selection; Genetic screening for so-called "defects"; Selective abortion with multiple fetuses; Pregnancies and older women; Surrogate motherhood; Cloning etc are rampant and carrying the headlines these days.

B. Baby factory sells newborns like in Warsaw , Poland of Rs 11,000. It is home to 37 young surrogate mothers. They say, they are offering services since 1.5 million couple in Poland are being childless and they need more peoples.

With infertility on the rise, thank to erratic life style and late marriages and late baby plans, more and more couples an opting for ART or adopted babies. The safe success rate of ART is 40%. ART today is a 30 billion industry in India with more than 300 clinics all over the country. According to Anirudha Malpani “Infertility is the commonest Medical problem in 30-40 yr age group of couples in India ”.

C. P osthumous Artificial insemination due to availability of semen banking, giving rise to problems in connection with the inheritance rights of such a child, born after the death of genetic father.

D. Dehumanizing aspects of procedures - Moral status of the Left-over Embryos, Egg, Sperm, and the Fertilized Egg stored for a married woman who subsequently died.

E . In **Japanese surrogate baby Manjhi case** , a bench said that in commercial surrogacy, a gestational carrier was paid to carry the child to maturity in her womb and was usually resorted to by couples to complete their dream of being parents. “This medical procedure is legal in several countries, including India ” said SC. Similarly a **German couple** is striving hard for the citizenship of their twin surrogate baby, born in India , since German law does not recognize surrogate childrens and Indian law is in very infantile stage to decide such issues, hence SC is in dilemma.

F . An **Israeli gay couple categorical has dislike for Section 377** of the Indian law that makes homosexuality a criminal offence, but they like the `desi' regulation that allowed them to hire a surrogate mother to deliver their child here. " Israel doesn't allow same-sex couples to adopt or have a surrogate mother.

Recent advances

A. Several infertility clinics have, announced a **low cost technique** for test tube baby by certain replacements, like – The egg & sperm are kept in a plastic vial costing Rs 2 instead of using expensive carbon dioxide incubators (costing 7 lakhs). They are using a local hot block costing Rs 15000 to maintain the mixture's temperature at 30 0 C. Alternatively it can be stored in mother-to-be's vagina for two days using female condom to keep it in place. [22,23,24,25,26,27]

B. Test Tube babies offer hope to **HIV–discordant couples** , especially when carried through ICSI (Intra cytoplasmic Sperm infection). Two Medical Journals, Lancet and New England Journal of Medicine carried exhaustive studies highlighting for over 5 years back, establishing a treatment protocol for HIV–discordant couple. HIV affected man's sperms are put through a “wash” for IVF treatment. The density gradient sperm wash, which is conducted in a centrifuge machine, continues for almost 60 min and separate the sperms from the other cells and waste in the semen. The live sperms are again tested for HIV, before being transferred to woman in a procedure called Intra–uterine transfer. However to be extra cautious we use a technique called ICSI. In fact, a peer reviewed medical journals, AIDS 2007, recently advocated a wider use of IVF technique for HIV discordant couple.

C . The **world first birth through oocyte freezing and thawing** was pioneered by Prof. Christopher Chen in Australia , 1986. Recently the first pregnancy and birth in **India** after the transfer of embryo generated from frozen-thawed oocytes (Cook oocyte freezing media) accomplished by Dr Priya selvaraj and her team. Birth of a male was accomplished for the first time in India by newer technique of frozen egg **(freezing by vitrification)** in Ahemdabad by Dr. Himanshu and Falguni Bhavishish recently.

D. A gene was found (SMAD-3) by a team from Virginia Commonwealth University whose absence caused infertility.

Conclusion

ICMR guidelines although had defined certain issues very meticulously but has certain controversial views. Researches permitted are those which are in public interest, but it fails to define "public interest". It has redefined legitimacy of Indian Evidence Act 1872 that limits legitimacy of a child born to only within 280 days after dissolution of marriage (by death or divorce). [28,29]

The guidelines ***should ideally encourage adoption and foster parenthood,*** *and avoid statements such as: "Infertility, though not life threatening, causes intense mental agony and trauma that can only be best described by infertile couples themselves". It should not accept the social stigma attached to infertility as a norm.*

Guidelines should be ***broad and flexible in the commercial transfer*** *of embryonic material, stem cells, etc. Chapter 3, talks only about written consent, but fails to make* ***informed consent*** *mandatory.*

There are no clear guidelines for the groups other than married couples, who want to bear child like, ***homosexuals, divorced or single*** *. Recently* ***CARA*** *(Central adoption resource agency) has sought to ban gay and lesbian couples from adopting childrens, in its newly framed guidelines. As now section 377 have been made more liberal and decriminalized, this issue should now be raised and hence accordingly the words "husband" and "wife" must be substituted by "male partner" and "female partner".*

Off-spring should not be allowed ***to know the donor*** *even after 18 years just like adopted children.*

Use of sperm / oocyte donated by a relative or a known friend *of couple should be permitted, as these are the commonest sources of donor in IVF clinics all over the world today, and this will decrease the cost of treatment. Relative or a known person may act as a surrogate to discourage commercial surrogacy. The Doctors should discuss their charges with the patient and* ***not display*** *it. Requirements to have* ***13 separate rooms to run ART clinics*** *is a big concern since the cost of IVF would go up drastically. Small space can be used for good results.*

The guidelines are more or less like the one followed in the UK , which should not be the case considering the ***Indian mindset and scenario*** *.*

The ethical ***guidelines should go beyond technicalities*** *and build effective safeguards so that the unequal power relationship between the providers and users of new technology is minimized. It is critical to envision future trends and lay down an ethical framework for* ***biomedical research*** *, especially in the new frontier of human reproduction that could change the very face of humanity.*

What ever shape this guideline takes when it comes out of the parliament in the form of an act the ***doctors should make it a practice to absorb certain precautions*** *, so as to prevent various ethical social and legal issues which may arise pre and post delivery like- Should obtain signed request from wife & husband; Written informed consent from both and also from donor and his wife; Detail clinical records to be well preserved; Details of donor should be kept secret in AID; Female attainder nurse should be present at the time of insemination. The agreement made with the donor is that if the child birth resulted, donor would have parental rights and obligation associated with child.*

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