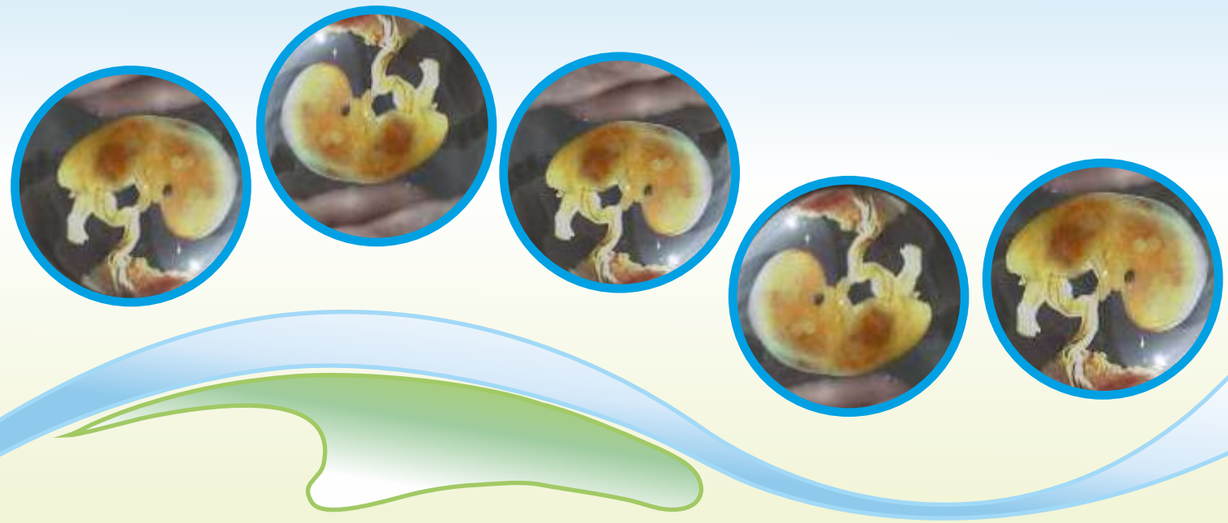
Infertility Updates

By *MSR*

(Maharashtra Chapter of ISAR)

Legal Aspects in Infertility Practice



Dr Sunita Tandulwadkar
Chairperson, *MSR*

Dr Ameet Patki
General Secretary, *MSR*

FROM THE DESK OF CHAIRPERSON MSR

Dr.Sunita Tandulwadkar
Chairperson , MSR (2018 - 2020)

"People who are crazy enough to think they can change the world, are the ones who do."

– Rob Siltanen

Infertility is a significant and common problem; approximately 9% of couples throughout the world are infertile with 56% of couples needing treatment. Reproduction is one of the primal instincts in any living organism, be it in animals, insects, birds, or humans. But the lifestyle that we, humans, are leading today, coupled with the environmental degradation caused by various pollutants, are leading to increasing cases of infertility. Thanks to the advancements in medical science, various techniques are now available to obtain pregnancy by means other than intercourse. The challenges in diagnosis and treatment are both difficult and interesting. Researchers are working on them with enthusiasm, tenacity, and dedication to develop new methods of treatment and provide new solutions to keep up with the ever-changing threats.

The IVF technology has been in India since 1978 but has started gaining popularity only recently. IVF technology, if used properly following the prescribed procedures, is a boon for the modern society. But like any other medical procedure, reckless and irresponsible behaviors can lead to dire consequences. Hence, clearly laid down regulations and laws are required to govern various aspects of ARTs so as to ensure that no evil or malpractice occurs.

Scientific societies around the world, such as the ASRM, ESHRE and IFFS, have drawn up guidelines for the safe and ethical practice of ART. The European Union and the Governments of several countries such as Australia, the UK and the USA have taken steps to accredit and supervise the performance of infertility clinics. At present here are neither strict guidelines nor an enforceable legislation in regard to the practice of ART in India

This booklet intends to provide information and advice on the legality of drugs dispensing, egg donation, and surrogate approaches, which are increasing as older women now are trying desperately to have a child.

Happy reading…

FROM THE DESK OF GENERAL SECRETARY MSR

Dr. Ameet Patki
General Secretary MSR (2018-2020)

With the technology advancing and changing very fast in medical healthcare particularly in Reproductive Healthcare, fertility specialist have to encounter two challenges, one of updating themselves in recent advances and secondly to have a clear view based on sound ethical and legal knowledge on various issues and situations that arise from them. I strongly believe that healthcare ethics and law are two disciplines which need to interact in a virtual learning environment.

Maharashtra ISAR (MSR) has always been ahead of its times in providing its members various educational initiatives . I am glad that under the able leadership of the Chairperson of MSR Dr. Sunita Tandulwadkar we have decided to release focused Updates in Infertility Practice. The first issue on Ethical and Legal issues in Contemporary Infertility Practice has been the brain child of Dr. Manish Machave. It covers all aspects of Ethics and Legal issues including the role of PCPNDT in our practice.

Infertility treatment is not only expensive but also stressful to the couple. Hence as treating physicians I think we should be a clown at heart, a scientist at brain work and a mother at conscience.

I hope you enjoy and treasure these issues as much as we enjoyed bringing it to you.

FROM THE EDITOR'S DESK…

Dr Manish Machave

"Knowing is not enough; we must apply.
Wishing is not enough; we must do."

- Johann Wolfgang Von Goethe

With infertility on the rise thank to erratic life style and late marriages, more and more couples are opting for ART or adopted babies. The safe success rate of ART is 40%. ART today is a 30 billion industry in India with over 3000 clinics across the country. Infertility is the commonest Medical problem in 30-40 years of age group of couples in India. It is heart-warming to know that Govt has all set to make laws for it. This will be the hallmark to resolve the ethical and legal issues related to IVF thereby paving the way for IVF to bloom in India to the hilt.

In the wake of the birth of the first scientifically well documented test tube baby in 1986 in India, the mushrooming IVF clinics emerged across the country without accreditation, supervisory and regulatory body and control of Government, which propelled the Indian Council of Medical Research (ICMR) to develop draft National Guidelines for ART Clinics in India in 2002. Later, the Ministry of Health & Family Welfare examined these guidelines and after slight modifications, published the National Guidelines of Government of India in 2005.

Then, Indian Council of Medical Research (ICMR) developed draft for Assisted Reproductive Technology (Regulation) Bill in 2008 and sent to the Ministry of Health & Family Welfare, which has now been revised by the Ministry of Law & Justice as Assisted Reproductive Technology (Regulation) Bill-2013. Now, the Assisted Reproductive Technology (Regulation) Bill-2014 is before the Cabinet for consideration.The ART (Regulation) Bill proposes to establish National Board, State Boards and National Registry of (ART) in India for accreditation and supervision of ART clinics and ART Banks, ensuring that services provided by these are ethical and that the medical, social and legal rights of all the concerned are protected with maximum benefit to all the stakeholders within a recognized framework of ethics and good medical practices.

The Surrogacy Regulation Bill 2018 is yet to see the light of the day.

This booklet intends to clarify few issues in contemporary infertility practice and corelate it with existing regulations.

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ETHICAL AND LEGAL ISSUES IN CONTEMPORARY INFERTILITY PRACTICE

1. ETHICAL ISSUES IN INFERTILITY PRACTICE

INTRODUCTION-

ART is currently a commonplace technology that has successfully treated millions of infertile couples the world over. However, the explosion of this technology has introduced a myriad of new social, ethical, and legal challenges.

Since 1978, when the world's first in vitro fertilization (IVF) baby Louise Brown was born with the expertise and assistance of Drs. Patrick Steptoe and Robert Edwards, the world has seen a rapidly increasing array of assisted reproductive technologies (ART). In 2001, >270 000 cycles of clinical infertility treatments occurred in Europe alone (ESHRE, 2005). With trends through out the globe toward more women working, later marriages and delayed child bearing, more couples desiring children are discovering that they cannot conceive naturally.

The increasing availability of assisted reproduction technology during the past 20 years has received a lot of public attention because of the ethical implications and thus needs to be scrutinized carefully.

ETHICAL ISSUES IN ART PRACTICE

Debates on IVF are clouded by different ethical value systems and deep prejudices. Decision makers, medical practitioners, scientists, courts, and the public in general are facing new quandaries that involve controversies among profoundly held values.

Reporting Regulations-

The widespread use of this technology throughout the world has prompted a desire by the public, governmental bodies, and professional organizations to create mechanisms that evaluate the utilization of ART. Advances in the arena of assisted reproductive technologies (ART) are accompanied by ethical and societal concerns. Legislation and professional societies have attempted to address these concerns for some time. For example, in 1986, the American Fertility Society first published guidelines for the ethical implementation of ART in the United States.

We have ICMR guidelines published in 2005 as a skeleton legislation with The ART Bill 2010 and The Surrogacy Bill 2018 in the pipeline.

The reporting requirements for ART pregnancy results, have also been mandated with legislation in many nations . Furthermore, ART reporting requirements generally include the number of embryos transferred. This measure has been extremely important in correlating the risk of multiple gestations with the transfer of 2 or more embryos. However, in many nations,including India reporting regulations are not accompanied by legislation defining practice patterns.

The success rates-

Success rates of this technique vary with the treatment, patient condition and with respect to other condition. Because of the stress and expense of the procedure, patients became attuned to clinic success rates. This put pressure on clinics to produce encouraging statistics, which they did by selecting their highest rate from among the dozens of possible numerators and denominators.

A criticism beleaguered at some IVF providers is that the clinics are misleading infertile couples by not adequately informing patients of their chances of actually bringing a baby home from the hospital while others shield IVF providers by stating that the success rate in natural conception is not radically different from that achieved by the IVF clinics. Some of this confusion can be accredited to the fact that many clinics report their success rates in terms of pregnancies established, while patients are concerned with live, healthy babies.

Chromosomal and Other Congenital Defects-

Throughout the short history of assisted reproduction there has been concern to monitor the safety of this important technology It is well established that infants conceived following in vitro fertilization (IVF)are more likely to be born preterm, of low birth weight and to be a twin or higher order multiple than spontaneously conceived infants , the evidence relating to the risk of birth defects is less clear.

An increase in chromosomal abnormality in IVF babies due to technical inadequacy has been observed. Numerical abnormalities alone were found in 71.7% of morphologically normal embryos . and in those morphologically abnormal, only 3 out of 14 had a normal chromosomal complement .Congenital malformations include increased neural tube and cardiac defects.

Age limit to offer ART -

There are various questions in for and against of this issue. Some people are saying whether older women can cope with motherhood? What will be the potential health of the child? When the In vitro fertilization is rarely successful in older women then why we are taking a risk? Many such questions need to be answered yet. The chance of successful in vitro fertilization (which itself carries risks) in women aged over 45-50 is remote.

According to data from the Human Fertility and Embryology Authority, UK, in 1992 only one woman over 50 had a baby , in 2002 the number went up to 24. All the 24 woman underwent IVF treatment. In 1992-2,360 babies were born as a result of IVF treatment. In 2002 the number rose to 7,740.

One important concern on use of IVF on older women is based on the welfare of child as the age and health condition of old mothers to be may restrict them from being appropriate parents and this is often seen as infringement of the resultant child's rights

Society may feel entitled to refuse fertility treatment because of cost or because it does not regard infertility as a priority health concern, but it should not feel comfortable justifying such failure of provision in terms of the interests of the potential child.

Religion- social and ethical issues-

Technologies of assisted reproduction such as in vitro fertilization (IVF) have been controversial on religious grounds since their inception, but nonetheless, within Islam, Judaism, Confucianism, Hinduism, and most forms of Christianity, adjustments have been made to facilitate the fertility of their adherents

Catholicism remains the only major world religion that unequivocally condemns the use of ivf. The vatican argues that the research, development, and practice of ivf involve the destruction of embryos, i.e., the ''destruction of human life,'' and by engaging in assisted reproduction, humans are technologically interfering with a process that should remain under god's dominion .

To the catholic church, surrogacy; artificial insemination by husband or donor; and ivf are not allowed, because procreation without sexual union in considered unnatural, and the church has been quite vocal about its criticism. church considers in vitro fertilization wrong because it separates human procreation from conjugal union.

Fetal Reduction:Ethical issues-

Fetal reduction" is usually necessary to protect a live birth.Which fetus to reduce poses an ethical dilemma which remains unsolved academically and legally.

Our judicial system has trailed woefully behind the complex bioethical dilemmas that accompany the rapid advances in biotechnology, biomedicine, and assisted reproductive technologies. Artificial conception raises the possibilities of myriad problems - legal or otherwise, which may need resolution by legislation or national guidelines.

Financial Aspect for ART Treatment-

Perhaps one of the most obvious ethical challenges surrounding ART is the inequitable distribution of access to care. The fact that significant economic barriers to IVF exist in many countries results in the preferential availability of these technologies to couples in a position of financial strength .

The cost of performing ART per live birth varies among countries . The average cost per IVF cycle in the United States is USD 9,266 . However, the cost per live birth for

autologous ART treatment cycles in the United States, Canada, and the United Kingdom ranged from approximately USD 33,000 to 41,000 compared to USD 24,000 to 25,000 in Scandinavia, Japan, and Australia .

The total ART treatment costs as a percentage of total healthcare expenditures in 2003 were 0.06% in the United States, 0.09% in Japan, and 0.25% in Australia .

In India we have variable costs for ART treatment and the ethical and social debate counters such with the process of adoption.

Preimplantation Genetic Testing-

Preimplantation genetic screening (PGS) and diagnosis (PGD) offer the unique ability to characterize the genetic composition of embryos prior to embryo transfer. Given the recent successes of these technologies, the broader implementation of this technology in the future is likely.

In the near future, with refinements in microarray technology and the defining of genetic sequences associated with certain physical characteristics, it is conceivable that specific physical or mental characteristics may be evaluated to guide the decision as to which embryos to transfer. This possibility raises concerns on both ethical and practical levels. Of more concern is the possibility that in the future, technology will permit the manipulation of genetic material within an embryo. Rigorous public and scientific oversight of these technologies is vital to ensure that scientific advances are tempered with the best interests of society in mind.

Fertility Preservation-

Female fertility is well documented to decrease with age . Consequently, much research has been conducted aimed at preserving female fertility before advanced age is realized. Additionally, fertility preservation for individuals afflicted with cancer has important implications as often the chemotherapeutic agents used to treat cancer are toxic to the ovary and result in diminished ovarian reserve and reduced fertility. While techniques for freezing sperm and embryos are well established, techniques for freezing oocytes and ovarian tissue are still considered experimental . Multiple techniques including oocyte cryopreservation and preservation of strips of ovarian cortex with subsequent reimplantation and stimulation have been described, with some pregnancy success . Fertility preservation for cancer patients using in vitro maturation (IVM), oocyte vitrification and the freezing of intact human ovaries with their vascular pedicles have also been reported.

Recently, several laboratories have demonstrated the ability to successfully cryopreserve oocytes following an IVF cycle. These developments have profound implications. As the birth control pill gave women the ability to prevent pregnancy, oocyte cryopreservation may give women the flexibility to preserve their fertility potential, starting at a young age, while postponing childbearing. However, as this technology at the present time in many countries is generally only available to those with financial means. This poses ethical and social issues that will certainly see more attention in the future.

Gamete Donation-

The use of donor gametes, either in the form of donor sperm or donor oocytes, is commonplace in ART. The use of donor sperm can be traced to the 1800's [36]. In the mid 1980s, oocyte donation was introduced . In recent years, issues surrounding the use of donor gametes have become increasingly visible . Women donating oocytes must undergo IVF. Due to the inherent medical risks associated with IVF, including ovarian hyperstimulation syndrome and surgical risks, a central concern of allowing women to be oocyte donors includes adequate informed consent .

Consent, in addition to outlining these medical risks, should include counseling regarding the emotional benefits and risks of donation with an emphasis that long-term data regarding these risks are lacking .

Additionally, it is considered an ethical prerequisite that oocyte donors participate voluntarily and without coercion or undue influence . Some have expressed concern that financial compensation of oocyte donors may lead to exploitation as women may proceed with oocyte donation against their own best interests, given the inherent medical risks involved. The concept of commodification, that any "buying or selling" of human gametes is inherently immoral, is an additional argument used against remunerating women serving as oocyte donors .

Another ethical and legal issue surrounding the use of donated gametes is to what extent the anonymity of the donor should be preserved. The issue of anonymity as it relates to gamete and embryo donation is emotionally charged. Indeed, the ability of human beings to know their genetic roots is universally important, at the core of self identity.

The ethical and legal issues surrounding anonymity and gamete donation are sure to be a centrally debated issues within the field of ART for the foreseeable future.

Embryo Donation-

IVF cycles often result in couples transferring several embryos and cryopreserving other embryos produced by the cycle, presumptively for the purpose future pregnancy. However, in many instances, these surplus embryos are never used by the genetic parents and therefore are stored indefinitely . The number of such embryos stored internationally is surprisingly high. In the United States alone, it is estimated that over 400,000 embryos are currently cryopreserved, many of which will not be used by their genetic parents.

The ethical and moral issues surrounding how to deal with these surplus embryos have been the source of much debate. In general, four possible fates for these embryos exist (1)thawing and discarding,(2)donating to research,(3)indefinite storage,(4)donating the embryos to another couple for the purposes of uterine transfer.
All of these strategies have staunch supporters and detractors.The use of embryos for the purpose of research, specifically as it relates to human stem cells, has also been a source of fierce debate internationally and has resulted in substantial regulation that varies substantially from nation to nation.

Surrogacy-
Another topic of ethical, social, and legal debate surrounds the use of surrogacy/ gestational carriers. A surrogate, involves a couple who undergoes IVF with their genetic gametes and then places the resultant embryo in another woman's uterus, who will carry the pregnancy and relinquish the child to this couple upon delivery
As with donor gametes, surrogates too are subject to significant medical and emotional risks from carrying a pregnancy and undergoing a delivery. As such, extensive counselling and meticulous informed consent are required.
Additionally, the rights of the surrogate to not relinquish the infant following deliver are not well described and is contract dependent.
Another central concern surrounding is the possibility that financial pressures could lead to exploitation and commodification of the service. Due to these financial and legal considerations, international surrogacy has emerged as an emerging industry, especially in developing nations . At the present time, issues surrounding issues of individual rights, commodification, exploitation, citizenship of the offspring of international surrogates, and even fair trade are largely unresolved internationally.

Possible Deleterious Effects of ART-
There are questions that remain outstanding regarding the use of IVF. Conflicting data exists about the risks of IVF on the developing embryo. Multiple studies have failed to find a clinically relevant association between IVF or embryo cryopreservation and adverse maternal or fetal effects. Other studies have suggested that infants of IVF pregnancies may be at a small but statistically significant increased risk for rare epigenetic and other abnormalities .
Despite this controversy, there is a general consensus that IVF confers a small but measurable increased risk for a variety of congenital abnormalities including anatomic abnormalities and imprinting errors as compared to the general population Some maintain, however, that this is secondary to an increased baseline risk for these problems in the population of infertile patients. Regardless of the cause, this small increased risk, while statistically significant with extremely large sample sizes, will likely not be a powerful enough factor to dissuade infertile couples from pursuing parenthood through IVF.

CONCLUSION-
ART has emerged as one of the most widely adopted and successful medical technologies in the last century. While giving hope to millions of couples suffering from infertility, ART also has presented new ethical, legal, and social questions that society must address. Many countries have taken steps to regulate certain aspects of ART. Specifically, what regulations and laws should be in place for ART reporting, social inequities that may arise from financial barriers to ART, genetic testing, emerging laboratory techniques that have improved embryo and gamete survival when cryopreserved, and an individual's right to their genetic offspring in the setting of gamete or embryo donation are aspects of ART which will become increasingly controversial and debated into the future.
However, the lion's share of ethical and legal questions that exist surrounding ART have yet to be resolved. Society must reconcile how to fund ART in a responsible and equitable manner to increase access to care. Additionally, the myriad of unresolved issues surrounding gamete and embryo donation must be addressed in greater detail in future social and legal dialogues.
ART is a field that is dynamic and ever changing. In areas of ART such as preimplantation genetics, new technologies continually change the capabilities of ART. Due to the rapidly evolving nature of the ART, legislation is often unable to keep pace and address all of the ethical and legal issues that are constantly emerging in the field. It is therefore incumbent upon physicians to continually monitor these issues and ensure that ART technologies are offered and delivered in a manner that balances patient care with social and moral responsibility.

2. ICMR GUIDELINES

INTRODUCTION-

The increasing demand for ART has resulted in mushrooming of infertility clinics in India. The Assisted Reproductive Technology (ART) in India is being provided by private sector only. Many of these technologies require enormous technical expertise and infrastructure. However, the success rate is below 30% under the best of circumstances. Moreover, it taxes the couple's endurance physically, emotionally and monetarily.

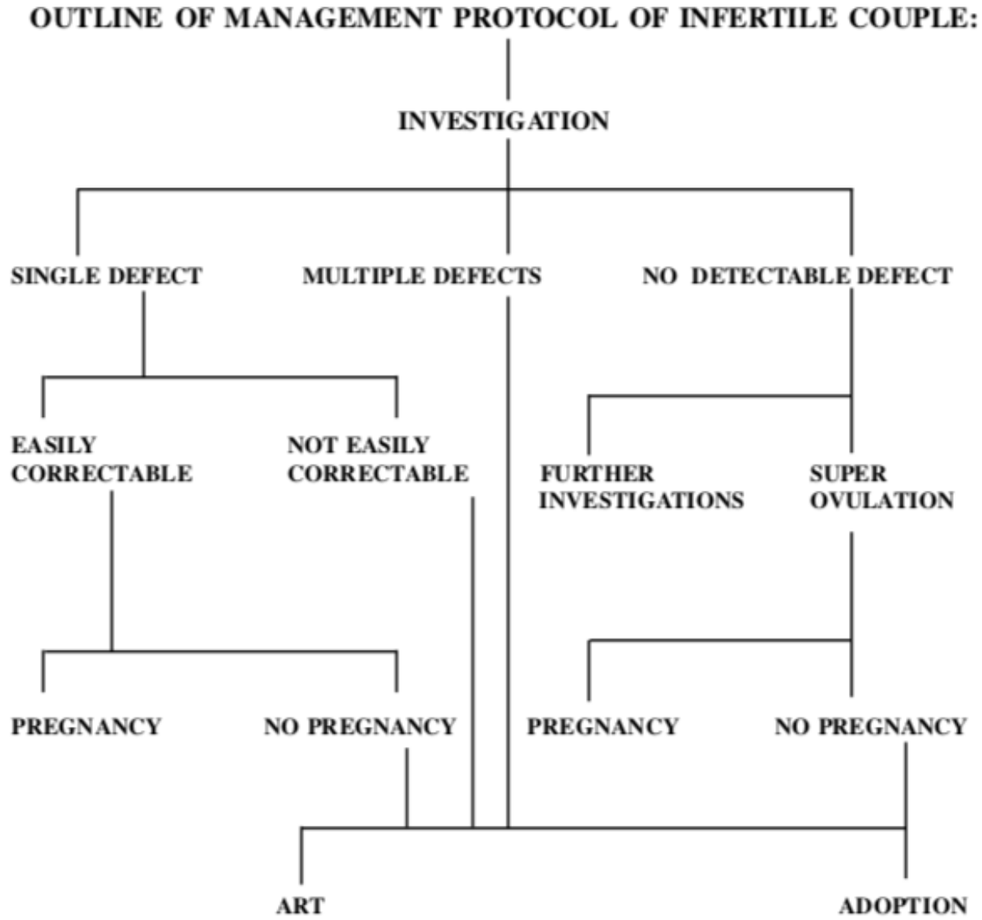
In order to regulate and supervise the ART clinics, the Indian Council of Medical Research (ICMR) and National Academy of Medical Sciences (NAMS) have come out with National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. These Guidelines have been evolved after detailed discussion and debate by experts, practitioners of ART and public.

There are no guidelines for the practice of ART, accreditation of infertility clinics and supervision of their performance in India. This document aims to fill this lacuna and also provide a means of maintaining a national registry of ART clinics in India. The document has been widely publicized, discussed and debated by expert groups of the ICMR and the National Academy of Medical Sciences and then by practitioners of ART and the public in Chennai, Jodhpur, Kolkata, Bangalore, Hyderabad and Mumbai. These discussions involved over 4000 participants including doctors, scientists, bureaucrats, legal experts, infertile couples and the general public. This document was also put on the Council's website and elicited many comments and responses.

We are also grateful to the National Commission for Women and the National Human Rights Commission for their valuable advise.

What it covers

Outline of management protocol of infertile couple



Categorization of ART Clinics

The Guidelines categorize the ART Clinics in Primary (Level1 A), Primary (Level1 B), Secondary (Level 2) and Tertiary (Level 3) Clinics depending upon the facilities and resources that they have within their Clinics.

Ethical Considerations and Legal issues

Code of Practice

This Code of Practice deals with all aspects of the treatment provided and the research done at registered clinics. Those areas which most affect the doctors, scientists and patients and are a part of this code are summarized in a precise manner.

Responsibilities of the ART Clinic

- To give adequate information to the patients (detailed in Section 3.4).
- 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.
- To have all consent forms available in English and local language(s).
- How may Surrogate Mothers and Oocyte Donors be sourced?
- Law firms and semen banks will be encouraged to obtain (for example, through appropriate advertisement) and maintain information on possible oocyte donors and surrogate mothers as per details mentioned elsewhere in this document. 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. However, negotiations between a couple and the surrogate mother must be conducted independently between them.

Helping hand

The sample consent forms as First document amidst the uncertainty to guide the ART practitioners with the kind of documentation that needs to be maintained.

Applicability

These being guidelines are recommendatory in nature are applicable in absence of any law in force.

3. ART Bill

INTRODUCTION-

Most of the new technologies aimed at taking care of infertility, involve handling of the gamete – spermatozoa or the ooctye – outside the body; they also often involve the donation of spermatozoa or oocyte, or the use of a surrogate mother who would be carrying a child with whom she has no biological relationship. These technologies not only require expertise but also open up many avenues for unethical practices which can affect adversely the recipient of the treatment, medically, socially and legally.

The last nearly few years have seen an exponential growth of infertility clinics that use techniques requiring handling of spermatozoa or the oocyte outside the body, or the use of a surrogate mother. As of today, anyone can open infertility or assisted reproductive technology (ART) clinic; no permission is required to do so. There has been, consequently a mushrooming of such clinics around the country.

In view of the above, the ART Bill becomes important to regulate the functioning of such clinics to ensure that the services provided are ethical and that the medical, social and legal rights of all those concerned are protected.

The bill details procedures for accreditation and supervision of infertility clinics (and related organizations such as semen banks) handling spermatozoa or oocytes outside of the body, or dealing with gamete donors and surrogacy, ensuring that the legitimate rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice.

Statement of object

An act to provide for a national framework for the accreditations, regulation and supervision of assisted reproductive technology clinics, for prevention of misuse of assisted reproductive technology, for safe and ethical practice of assisted reproductive technology services and for matters connected therewith or incidental thereto.

What it covers in addition to ICMR Guidelines

Good definitions

- The ART Bill has provided a well thought definitions for several terms which were earlier not defined and could have been vaguely interpreted. The water tight articulation of various aspects through the definitions has helped in reducing the ambiguity and assign a precise meaning to terms such as ART Bank, Commissioning Parents, couple, gamete donor, married couple, unmarried couple, surrogacy, surrogacy agreement and many other.

Sourcing of gametes through ART Bank

- An ART Bank as defined in the Bill is
- "ART bank", means an organisation that is set up to supply sperm / semen, oocytes / oocyte donors and surrogate mothers to assisted reproductive technology clinics or their patients.

- Accordingly the Bill makes it mandatory for the ART Clinics to procure the gamete as well as gamete donors through the ART Bank. However, ICMR has started enrollment or registration of any ART Bank, but there are few organizations which are following the ICMR Guidelines and functioning as ART Banks.

Rights and Duties of Patients

- The Bill states that assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples.
- (2) In case assisted reproductive technology is used by a married or unmarried couple, there must be informed consent from both the parties.
- (3) The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate mother, when and to the extent necessary for the welfare of the child.

Rights and Duties of Donors

- All information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by an order of a court of competent jurisdiction.

- The donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.

- A donor shall relinquish all parental rights over the child which may be conceived from his or her gamete.

- No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained

the consent in writing of his or her spouse, if there, to such procedure.
- The identity of the recipient shall not be made known to the donor.

- The Bill also has narrowed down the rights and duties of surrogates and of the Children born through ART. Also, for the first time in this document Offences and Penalties were laid down for the acts which are not in line with the Bill.

Helping hand
- A detailed Patient Selection Criteria has been covered in the ART Rules which guides the ART practitioners in case of single defect in one partner multiple defects in one or both Partner among others.

Contracts between ART Bank, Clinic etc
- Taking the work done in ICMR Guidelines further, the ART Bill and Rules have gone ahead to draft considerable comprehensive contracts between the Parties such as the Patient, ART Clinic, ART Bank, Oocyte Donor, Semen Donor, Surrogate Mother and the forms in which the records are to be maintained. This specially was a step towards regularizing the documentation throughout the country.

Conclusion
- However, the Bill has not yet seen the light of day to become an Act and accordingly it is not an Act yet. Finally a document as precise, concise, so inclusive and in sync with its object is the need of the hour.

4. SURROGACY & LAW IN INDIA

INTRODUCTION-
The word "surrogate", from Latin "subrogare", means "appointed to act in the place of". The intended parent(s) is the individual or couple who intends to rear the child after its birth.

WHAT DOES SURROGACY ENCOMPASS??
Surrogacy is a well known method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to a contracted party. She may be the child's genetic mother (the more traditional form for surrogacy) or she may be, as a gestational carrier, carry the pregnancy to delivery after having been implanted with an embryo. In some cases surrogacy is the only available option for parents who wish to have a child that is biologically related to them.

TYPES OF SURROGACY-
Before we dive any further to understand the legal stand point in case of surrogacy in India, let us first get familiar with terms such as “gestational surrogacy” and “commercial surrogacy”.
As per the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India drafted jointly by the Indian Council of Medical Research (“ICMR”) and National Academy of Medical Sciences (India) (hereinafter “ICMR Guidelines”) the surrogate mother shall be biologically unrelated to the child and hence “gestational surrogacy” is the type of surrogacy permitted in India.
In "gestational surrogacy" (also know as the Host method) the surrogate becomes pregnant via embryo transfer with a child of which she is not the biological mother. She may have made an arrangement to relinquish it to the biological mother or father to raise, or to a parent who is themselves unrelated to the child (e. g. because the child was conceived using egg donation, germ donation or is the result of a donated embryo). The surrogate mother may be called the gestational carrier.
"Commercial surrogacy" is a form of surrogacy in which a gestational carrier is paid to carry a child to maturity in her womb and is usually resorted to by well off infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. This medical procedure is legal in several countries including in India where due to excellent medical infrastructure, high international demand and ready availability of poor surrogates it is reaching industry proportions.

Intended parents may arrange a surrogate pregnancy because a woman who intends to parent is infertile in such a way that she cannot carry a pregnancy to term. Examples include a woman who has had a hysterectomy, has a uterine malformation, has had recurrent pregnancy loss or has a healthy condition that makes it dangerous for her to be pregnant. Alternatively, the intended parent may be a single male or a male homosexual couple.

SUROGACY LEGISLATIONS-

As on date we have these 3 prominent documents commenting significantly on surrogacy arrangement in India:

- The ICMR Guidelines
- The Assisted Reproductive Technologies (Regulation) Bill – 2010
- The Surrogacy (Regulation) Act, 2016

Now let us understand what these documents have to say and where do they legally stand:

ICMR Guidelines

The ICMR Guidelines are recommendatory in nature and some of the important conditions that a woman must satisfy to become a surrogate mother are:

- A surrogate mother should not be over 45 years of age.
- Before accepting a woman as a possible surrogate for a particular couple's child, the ART clinic must ensure (and put on record) that the woman satisfies all the testable criteria to go through a successful full-term pregnancy.
- A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.
- No woman may act as a surrogate more then thrice in her lifetime.

The Assisted Reproductive Technologies (Regulation) Bill – 2010

- The bill attempts to regulate the functioning of such clinics to ensure that the services provided are ethical and that the medical, social and legal rights of all those concerned in ART procedures are protected.
- The bill details procedures for accreditation and supervision of infertility clinics (and related organizations such as semen banks) handling spermatozoa or oocytes outside of the body, or dealing with gamete donors and surrogacy, ensuring that the legitimate rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice.

Current legal status of the bill:

- The draft ART Bill was formulated in 2008, reviewed and redrafted in 2010 & 2014 but was never passed as law and hence it does not have the binding force.
- You may read the Bill and Rules in the Assisted Reproductive Technologies Section in the Guideline Part of ICMR's website.
- The Surrogacy (Regulation) Act, 2016
- The bill attempts to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

Current legal status of the bill:

- The Bill has not been passed by both the houses of the parliament and hence has no binding force at this point in time.
- You may read the Bill on the official website of Rajya Sabha and Lok Sabha.

CONCLUSION-

Presently in India, we do not have any law regulating the process of surrogacy. However, considering that The Assisted Reproductive Technologies (Regulation) Bill – 2010 and the proposed Surrogacy (Regulation) Act, 2016 are not yet in force, it is appropriate to function under the framework of ICMR Guidelines.

5. Laws Governing Storage/ Sale of Drugs By RMP

INTRODUCTION-

The practice of infertility enshrines storage and sale of many drugs and the success depends on the correct protocol individualised for the patient. Can a Registered medical Practitioner store and sell drugs???. This is a question we intend to answer in this chapter as we discuss all laws related to storage and sale of drugs in our country.

Also the drug inspectors are frequent to visit us and we remain clouded about the issues related to storage and sale of drugs.

The Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 is an Act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards. The related Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.

The Drugs Act & Rules do not say anywhere that a doctor (RMP) must take a Drug Licence to run his establishment - a hospital/clinic/nursing home, etc.

Section 18a and 18c is applicable only to those who want to sell medicines and the license is issued in the name of a registered Pharmacist. If a Pharmacist wants to open a medical store, he must obtain a Drug licence.

Rule 123 of the Drug & Cosmetics Rules, 1945 and Schedule K clearly says that RMPs can use all the Drugs available in the market and that they are exempted from all the Sections in Chapter IV of the Drugs Act, 1940. (Kindly read Item 5 in Schedule K.) Section 18 comes under Chapter IV. Kindly note that a right enjoyed by an RMP will not vanish when he is in a place called a hospital, his/her place of work and if there are many doctors.

The Drug Officials are permitted to examine the purchase bills in a private hospital and there ends his duty. He can, of course, take samples of those purchased and sue the seller if found spurious. The RMP is not involved.

"PART XI — EXEMPTIONS

Rule - 123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made there under to the extent and subject to the conditions specified in that Schedule.

SCHEDULE K [See rule 123]"

All that said hereunder is applicable to a doctor & his or her hospital/place of work:

"Class of Drugs:

5. Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner, if it is specially prepared with reference to the condition and for the use of an individual patient, provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules hereunder.

Extent and Conditions of Exemption:

All the provisions of Chapter IV of the Act and the Rules made hereunder, subject to the following conditions: —

(1) The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules and records of such purchases showing the names and quantities of such drugs together with their batch numbers and the names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, make enquiries about purchases of the drugs and may take samples for test.

(2) In the case of medicine containing a substance specified in Schedule G, H or X the following additional conditions shall be complied with:

(a) The medicine shall be labeled with the name and address of the registered medical practitioner by whom it is supplied;

(b) If the medicine is for external application, it shall be labeled with the words "For external use only" or if it is for internal use with the dose;

(c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose;

(d) The entry in the register shall be given a number and that number shall be entered on the label of the container;

(e) The register and the prescription, **if any,** on which the medicines are issued

shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be.
(3) The drug will be stored under proper storage conditions as directed on the label."

Interestingly, the Rule is very different for a Government Hospital:
"Class of Drugs:
5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body.
Extent and Conditions of Exemption:

The provisions of Chapter IV of the Act and the Rules hereunder which require them to be covered by a sale license, subject to the following conditions:—

(1) The dispensing and supply of drugs shall be carried out by or under the supervision of a registered pharmacist;
(2) The premises where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test.
(3) The drugs shall be stored under the proper storage conditions.
(4) The drugs shall be purchased from a manufacturer or a dealer licensed under these rules or received as transferred stocks from hospital stores for distribution. Records of such purchases or receipts shall be maintained."

The Rules are the same for Government & Private Hospitals:
"Class of Drugs:
5B. Whole Human Blood I.P. and/or its components stored for transfusion by a First Referral Unit Community Health Centre, Primary Health Centre and Hospital.[Ins. by G.S.R. 909(E), dated 20.12.2001.]

Extent and Conditions of Exemption:
The provisions of Chapter IV of the Act and the rules made there under which require obtaining of a licence for operation of a blood bank or processing Whole Human Blood and/or its components subject to the following conditions, namely:–
(1) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall be approved by the State/Union Territory Licensing Authority after satisfying the conditions and facilities through inspection."

From a reading of Items 5, 5A & 5B cited it is clear that an RMP (doctor or his/her hospital) is exempted from Chapter IV fully (Item 5). The Drug Officials can inspect the purchase bills.
Out of 33 items in Schedule K, only six items enjoy this vast freedom from Chapter IV. The items are 1, 5, 10, 20, 24 & 30. You may kindly direct your Drugs Controllers to respect those mentioned in Items 5 and 24.

Kindly note that the explanation given under "Class of Drugs" for Item 5 says an RMP can do whatever he wants with the drugs under his disposal. That is, he can dispense it to his patients, or sell or dispense it to the patients of his professional colleagues, and sell it over the counter to anyone "to a degree which render him liable to the provisions of Chapter IV of the Act and the rules hereunder."
Kindly note that the Drugs Act and Rules do not say anywhere the degree or level at which an RMP becomes liable to the provisions of Chapter IV of the Drugs Act, 1940!
On the other hand, a Government hospital is exempted from Chapter IV if a registered Pharmacist is dispensing the medicines. (Item 5A.) The Drug Official can inspect the premises where the drugs are stored.
Finally, Item 5B says that a license is required for all hospitals to run a blood bank.
There are other rules in the Drugs Act & Rules to convince all that a drug license is not required for a hospital or place of work of a doctor, whatever be its name.

"Rule 65. Condition of licenses.— Licenses in Forms 20, 20-A, 20-B, 20-F, and 20-G, 21 and 21-B shall be subject to the conditions stated therein and to the following general conditions —

(5)(1) Subject to the other provisions of these Rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his license number under the Drugs & Cosmetics Act in which the following particulars shall be entered —
(a) Date of sale,

(b) Name, address of the licensee to whom sold and his sale license number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical Practitioner for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner as the case may be,

(c) Name of the drug, the quantity and the batch number,

(d) Name of the manufacturer,
(e) Signature of the competent person under whose supervision the sale was affected.

(9) (A) Substances....
(b) The supply of drugs specified in Schedule H or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years."

Rule 65 (5) (1) (b) clearly says that the drug sellers must supply drugs to Government hospitals, or any hospital, medical institutions and RMPs. If a Drug license is envisaged for private hospitals and RMPs all that the law makers had to do was avoid that sentence. It clearly means that a Drug Licence is not required for all those mentioned in it and hospitals and RMPs are included.

Now let us examine the Conditions stipulated in the Drug Licence certificates the Drug Stores display in the shops –

"FORM 20B"

[See rule 61 (1)]

License to sell, stock or exhibit or offer for sale, or distribute by wholesale, drugs other than those specified in Schedules C, C (I) and X

Conditions of License

1. This license shall be displayed in a prominent place in part of the premises open to public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules hereunder for the time being in force.
3. (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
(ii) No sale of any drug shall be made to a person not holding the requisite license to sell stock or exhibit for sale, or distribute the drug. Provided that this condition shall not apply to the sale of any drug to –
(a) An officer or authority purchasing on behalf of Government, or
(b) A hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or..."

If the Drug Officials had any idea of what they are authorised to do, the raid of hospitals could have been avoided. The definitions in Drug Rules clearly says what is sales and that is copied –

"Rule 2. Definitions. — In these Rules, unless there is anything repugnant in the subject or context—

(f) "Retail sale" means a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person other than a sale by way of wholesale dealing;
(g) "Sale by way of wholesale dealing" means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution; ..."

A registered medical practitioner (RMP) is also well defined in the Drug Rules and the same copied –

"Rule 2. Definitions. – In these Rules, unless there is anything repugnant in the subject or context–
(ee) "Registered medical practitioner" means a person —
(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules

to the Indian Medical Council Act, 1956 (102 of 1956); or
(ii) Registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine excluding the Homoeopathic system of medicine; or..."
It is true that Section 18 (c) in the Drugs Act says a license is required for manufacture and sales of drugs and copied --
"Section 18. Prohibition of manufacture and sale of certain drugs and cosmetics. — From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf–

(c) Manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a license issued for such purpose under this Chapter:
Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:"
Read in the media that your Officers have applied Section 18 (a) also on the hospital and that may be to make the case stronger or tarnish the image of the hospital. However, in that process, they (Drug Officials) have forgotten the fact that RMPs and their institutions are exempted from all the provisions of Chapter IV and kindly note that all punitive actions come under Chapter IV.

The raids conducted by Drugs Control Officers in private hospitals clearly prove that they are grossly ignorant of the Drugs & Cosmetics Act, 1940 and Rules, 1945 and the duties entrusted to them.

The Drugs Act is a central Act and the framers wanted that to be implemented uniformly all over India and for that purpose they have incorporated Section 7 (1) and that copied –

"7. The Drugs Consultative Committee.—(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act."
To be on the safe side the State Drugs Control Officers should have educated the Central Drugs Control Department under Govt. of India the need to impose Drug License for Private Hospitals and should have amended the relevant rules and then ventured into this exercise, which is totally illegal and against the spirit of the Drugs Act.
Another interesting fact is that a Drug License is issued in the name of a Registered Pharmacist and such a form is copied –

"FORM 21"
[See rule 61 (2)]
Licence to sell, stock or exhibit or offer for sale, or distribute by retail drugs specified in Schedules C and C (1) excluding those specified in Schedule X

1.....is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute by retail the following categories of drugs specified in Schedules C and C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945 and to operate a pharmacy on the premises situated at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.
2. The licence shall be in force from.....to.....
3. Name(s) of registered pharmacists in charge.....
4. Categories of drugs.....

Date..... Licensing Authority
Licence No.....

*Delete if not applicable.

"Conditions of Licence"

Most of the Officials in the Drugs Control Department are pharmacists having some ego clash with the RMPs (doctors). The Pharmacists want to prove they are better or superior than the RMPs. To increase the market value of the Pharmacists, they have invented application of Section 18 (a) and 18 (c) on doctors and hospitals, knowing fully well that no doctor will ever bother to read and study the more than 600 pages in the Drugs Act.
Therefore, by imposing a Drug License on hospitals, a pharmacist will automatically become the master and the doctor will be at his beck & call. That is the ulterior motive behind all these exercises. If a pharmacist is dismissed from a hospital, he can walk away with the license issued in his name or burn it and go away. The doctor must then find out another pharmacist and get a new license to run his pharmacy. How clever are we Indians?

The Pharmacy Act, 1948

42. Dispensing by unregistered persons. —(1) On or after such date as the State Government may by notification in the Official Gazette appoint in this behalf, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner;
Provided that this sub-section shall not apply to dispensing by a medical practitioner of medicine for his own patients, or with the general or special sanction of the State Government, for the patients of another medical practitioner.

From media reports, it is clear that the innocent doctors of those two hospitals are ignorant of the Drugs Act and Pharmacy Act. All they had to tell the media was that the Medical Council of India (MCI) permits them to keep drugs without a Drug License.

"Code of Ethics Regulations, 2002 Medical council Act 1956

6.3 Running an open shop (Dispensing of Drugs and Appliances by Physicians): - A physician should not run an open shop for sale of medicine for dispensing prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. It is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug."
CONCLUSION-
It is very clear from the Drugs Act, 1940 that pharmacists come under Chapter IV of the Act, from which a doctor is fully exempted.
Finally, the word "hospital" is used at 56 places in the Drugs Act and Rules and the question of a Drug Licence is there when they want to import drugs. Otherwise, the Act & Rules are silent on the requirement of a drug license for hospitals. The Drug Rules do not mention about a Form to take Drug License by hospitals.
A close rapport is required between Drugs Department and doctors to help the poor patients.

6. MEDICOLEGAL ASPECTS OF ARTIFICIAL INSEMINATION

INTRODUCTION-

It is estimated that 15 percent of couples around the world are infertile. This implies that infertility is one of the highly prevalent medical problems. The magnitude of the infertility problem also has enormous social implications. Besides the fact that every couple has the right to have a child, in India infertility widely carries with it a social stigma. In the Indian social context specially, children are also a kind of old age insurance.

The rationale behind artificial insemination is increasing the gamete density at the site of fertilization. Since many centuries different pioneers contributed to the history of artificial insemination, not only in humans but even more pronounced in farm animals. The primary reason for using this technique in farm animals was to speed up the rate of genetic improvement by increasing the productivity of food producing animals. This was accomplished by improving the selection differential wherein one highly selected male is mated with thousands of females. The AID industry was born.

For humans the situation is different: artificial insemination was originally developed to help couples to conceive in case of severe male factor subfertility of a physical or psychological nature. Nowadays artificial insemination with homologous semen is most commonly used for unexplained and mild male factor subfertility. In the previous century donor insemination was mainly used for male infertility due to azoospermia or very low sperm count and for inherited genetic diseases linked to the Y-chromosome. Nowadays donor insemination is more commonly used in women with no male partner (lesbians or single women).

MEDICOLEGAL ASPECTS OF IUI-

The moral and social implications of artificial insemination were debated in both the medical and popular press in the United States since 1909, in Europe the debate started in the 1940s. The Catholic Church objected to all forms of artificial insemination, saying that it promoted the vice of onanism and ignored the religious importance of coitus. The main criticism was that artificial insemination with donor semen was a form of adultery promoting the vice of masturbation. Other critics were concerned that AID could encourage eugenic government policies.

Nevertheless, the demand for donor sperm increased tremendously. After the first successful pregnancy from frozen sperm, reported in 1953, the development of a thriving sperm-bank industry starting in the 1970s and the commercialization of AID became unavoidable. The growing number of AID's raised new concerns leading to new regulations. Because of the possible transmission of sexually transmitted diseases, including HIV, when using fresh sperm screening for infections of donors became mandatory. The use of fresh donor semen samples almost disappeared.

Another concern is the possibility to donate semen many times. In order to diminish the chances of unknowing marriage of biological siblings among AID children some government regulations tightly restrict the number of times a single donor's semen may be used and/or restrict the number of children by a given donor.

We in India are governed basically by two sets of regulations in this aspect..The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, by the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences, India, 2005 and The Assisted Reproductive Technology (Regulation) Rules, 2010

Legal aspects related to IUI-

Registration of clinic-

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

Process of Acrreditation-

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.

TYPES OF INFERTILITY CLINICS-

Primary-Level 1

- Preliminary investigations
- Diagnosis of infertility
- Do not require handling of sperm, egg, embryo outside the body
- Consulting room,General hospital
- Responsibilities-…COUNSELING/HISTORY/EXAMINATION/TREATMENT

Secondary-Level 2

- Require registration under ART act
- Facilities of AIH/AID/IUI
- EXCEPT OOCYTES HANDLED OUTSIDE THE BODY
- Responsibilities- SFT/TVS/HYSTEROSCOPY/LAPAROSCOPY
- EXCEPT-Provision for oocyte pick up

Tertiary-Level 3

- Require registration under the act
- All except research on the human embryos.
- In case all facilities not available-should hv access to such at other app accreditated ART BANK OR LAB.
- RESPONSIBILITIES-Cryo preservation of gametes and embryos

ETHICS COMMITTEE

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.

CONSENTS FOR IUI(ART bill, ICMR guidelines)

Consent for Artificial Insemination or Intrauterine Insemination with Husband's Semen / Sperm (See Rule 15.1)

_____ and _____ _____, being husband and wife and both of legal age, authorize Dr._____ to inseminate the wife artificially or intrauterine with the semen / sperm of the husband for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal child. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART Clinic

I / we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Name, address and signature of the Witness from the clinic

Signed: _____ (Husband)

_____(Wife)

Name and signature of the Doctor

Name and address of the ART clinic

Dated:

FORM - F Consent for Artificial Insemination or Intrauterine Insemination with Donor Semen (See Rule 15.1)

We,_____

and _____, being husband and wife and both of legal age, authorize Dr._____ to inseminate the wife artificially or intrauterine with semen / sperm of a donor (ART bank's no._____; obtained from _____ ART bank with valid registration no……) for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

We declare that we shall not attempt to find out the identity of the donor.

I, the husband, also declare that should my wife bear any child or children as a result of such insemination(s), such child or children shall be as my own and shall be my legal heir(s).

The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART Clinic

I/we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Name, address and signature of the Witness from the clinic

Signed :_____(Husband)

_____(Wife)

Name and signature of the Doctor

Name and address of the ART clinic

Dated:

Note: An appropriate modification of this form may be used for Artificial Insemination or Intrauterine Insemination of a single woman with donor semen.

HOW TO PROCURE SPERMS FOR AID???

The collection, screening and storage of semen; and provision of oocyte donor and surrogates, shall be done by an ART bank registered as an independent entity under the provisions of this Act. An ART bank shall operate independently of any assisted reproductive technology clinic.

Semen from males between twenty one years of age and forty five years of age, both inclusive, Examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child. All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period.

An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. An ART bank shall not supply the sperm of a single donor for use more than seventy five times. One sample of semen supplied by an ART bank shall be used by the assisted reproductive technology clinic only once on only one recipient.

An assisted reproductive technology clinic shall never mix semen from two individuals before use. No ART clinic shall obtain or use sperm or oocyte donated by relative or known friend of either of the parties seeking ART treatment or procedures.

An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

Records of such are to be maintained for a period of 10yrs and then sent to ICMR/ART DATBASE.

CONFIDENTIALITY-

Information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate shall be kept confidential. Personal information-personal identification will not be released without the prior informed consent of the genetic parent or parents or surrogate mother.

WHEN WITHELD INFORMATION MAY BE DISCLOSED

In pursuance of an order or decree of a court of competent jurisdiction.

A child may, upon reaching the age of 18, ask for any information, excluding personal

relating to the donor or surrogate mother

Legal guardian, excluding personal, for welfare of the child

Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother.

STATUS OF CHILD BORN OUT OF AID

In case of a married couple and insemination is done with due consent the child born shall have all legal rights as a legitimate child born through sexual intercourse.

In case of unmarried couple and insemination is done with due Consent the child born shall have all legal rights and shall be the legitimate child of both parties.

In case of single man/woman and insemination is done with due Consent the child born shall have all legal rights and shall be the legitimate child of the single man / woman.

In case there is Divorce/ separation of couple after ART but before birth , the child born shall be the legitimate child of couple.

A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.

BIRTH CERTIFICATE AND CITIZENSHIP-

The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.

If a foreigner or a foreign couple seeks sperm or egg donation, or surrogacy, in India, and a child is born as a consequence, the child, even though born in India, shall not be an Indian citizen.

CONCLUSION

While the guidelines attempt to incorporate some issues related to social justice and gender inequality, they still fall short on many fronts. 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 minimised. The guidelines should also keep in mind the unequal gender balance and ensure that the

rights of women users of these technologies are not compromised in any manner.
The very title 'National guidelines for accreditation, supervision and regulation of ART clinics in India' makes it clear that the ICMR, the apex body in India for the formulation, coordination, and promotion of biomedical research, has limited itself to creating red tape on the running of clinics. 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. This role, it seems, is not one that the ICMR is ready to play.

7. MEDICOLEGAL ASPECTS OF IN VITRO FERTILIZATION

INTRODUCTION-

With the enormous advances in medicine and medical technologies, today 85 percent of the cases of infertility can be taken care of through medicines, surgery and/or the new medical technologies such as in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI). It may be recalled that the birth of the first child, Louise Brown in 1978, through the technique of in vitro fertilization by Robert G Edwards and Patrick Steptoe, was a path-breaking step in control of infertility; it is, in retrospect, considered as one of the most important medical advances of the last century.

Most of the new technologies aimed at taking care of infertility, involve handling of the gamete – spermatozoa or the ooctye – outside the body; they also often involve the donation of spermatozoa or oocyte, or the use of a surrogate mother who would be carrying a child with whom she has no biological relationship. These technologies not only require expertise but also open up many avenues for unethical practices which can affect adversely the recipient of the treatment, medically, socially and legally.

MEDICOLEGAL ASPECTS OF IN VITRO FERTILIZATION PRACTICE

Registration of clinic-

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

Process of Acrreditation-

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.

TYPES OF INFERTILITY CLINICS-

Primary-Level 1

Preliminary investigations
Diagnosis of infertility
Do not require handling of sperm, egg, embryo outside the body
Consulting room,General hospital
Responsibilities-…COUNSELING/HISTORY/EXAMINATION/TREATMENT

Secondary-Level 2

Require registration under ART act
Facilities of AIH/AID/IUI
EXCEPT OOCYTES HANDLED OUTSIDE THE BODY
Responsibilities- SFT/TVS/HYSTEROSCOPY/LAPAROSCOPY
EXCEPT-Provision for oocyte pick up

Tertiary-Level 3

Require registration under the act
All except research on the human embryos.
In case all facilities not available-should hv access to such at other app accreditated ART BANK OR LAB.
RESPONSIBILITIES-Cryo preservation of gametes and embryos

ETHICS COMMITTEE

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.

Minimum requirements regarding staff
Mandatory for level 2/3 clinics
Staff can be shared-Embryologist
Gynaecologist-ART/USG/ENDOSCOPY and Andrologist …gen surgery Knowledge/TRAINING
CLINICAL EMBRYOLOGIST graduate/life sciences additional- knowledge/TRAINING
COUNSELOR– social sciences/psychology/medicine
Programme coordinator/director-PR
Directives for Drug companies -
They must not make exaggerated claims for infertility drugs and should market them only to qualified specialists. 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

Minimal physical requirements for ART CLINICS MUST FOR LEVEL2/3-
THE NON STERILE AREA
Reception &waiting room
Examination room with privacy
General purpose clinical laboratory
Store room
Record room
Autoclave room
Steps for vermin proofing
THE STERILE AREA

Semen collection room
Semen processing laboratory
Clean room for IUI
Adjoining embrology area
Changing room
Sterile….footwear
Fresh air with filter system- temp 22-25 degrees
Operation theater-
TVS ovum pick up/emergency resusitative
Room for embryo transfer-

pat can rest post procedure/OT may be used

Few specifications-
Temp/humidity/filtered air/ no of air exchanges/hr
Walls& floors-disinfection
Carpet strict no
List of items-laminar flow,stereo microscope,co2 incubator,hot air oven,refrigerator, freezing embryos, liquid nitrogen etc
Ancilliary laboratory facilities-may be outsourced hormone and other assays microbiology histopathology
Maintainance of laboratory
Quality of consumables used in laboratory
Power supply and back up
Statutary consents-
Consents for treatment/AIH/AID/ET/Oocyte retrieval/ embryo freezing should be taken prior to the said procedure.Such consent can be withdrawn before the actual procedure.

Sample consent-

We have requested the Centre (named above) to provide us with treatment services to help us bear a child. We understand and accept (as applicable) that:
1. The drugs that are used to stimulate the ovaries to raise oocytes have temporary side effects like nausea, headaches and abdominal bloating. Only in a small proportion of cases, a condition called ovarian hyperstimulation occurs, where there is an exaggerated ovarian response. Such cases can be identified ahead of time but only to a limited extent. Further, at times the ovarian response is poor or absent, in spite of using a high dose of drugs. Under these circumstances, the treatment cycle will be cancelled.
2. There is no guarantee that:
   a. The oocytes will be retrieved in all cases.
   b. The oocytes will be fertilized.
   c. Even if there were fertilization, the resulting embryos would be of suitable quality to be transferred.

All these unforeseen situations will result in the cancellation of any treatment.
3. There is no certainty that a pregnancy will result from these procedures even in cases where good quality embryos are replaced
4. Medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal living child.

5. Endorsement by the ART clinic
I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

6. This consent would hold good for all the cycles performed at the clinic.
Name and Signature of the Husband
Name and Signature of the Wife
Name, Address and Signature of the Witness from the clinic
Name and Signature of the Doctor
Dated:

Documentation-
Which records???
donor oocytes, sperm, embryos used,
manner and technique of their use and the individual or couple or surrogate mother, in respect of whom it was used.
Where to store???
Put on line all information available to them in regard to progress of the patient (such as biochemical and clinical pregnancy)
within seven days of the information being available,
withholding the identity of the patient.
Duration of maintaiunance of records
Records shall be maintained for at least a period of ten years, upon the expiry of which the assisted reproductive technology clinic shall transfer the records to a central database.
Closure of ART CLINIC
In the event of the closure of any assisted reproductive technology before the expiry of the period of ten years, the assisted reproductive technology clinic or ART bank shall immediately transfer the records to a central database of a, national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR
ROLE OF ART BANK-
The screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates, shall be done by an ART bank registered as an independent entity under the provisions of this Act.
An ART bank shall operate independently of any assisted reproductive technology clinic. Semen from males between twenty one years of age and forty five years of age, both inclusive,

Examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period.

ART banks shall obtain and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, both inclusive, and examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

How to procure donors??

An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.

Limitation on donations-

An ART bank shall not supply the sperm of a single donor for use more than seventy five times.No woman shall donate oocytes more than six times in her life, with not less than a three-month interval between the oocyte pick-ups.

Sharing of gametes-

Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.

No woman should be treated with gametes or embryos derived from the gametes of more than one man or woman during any one treatment cycle.

One sample of semen supplied by an ART bank shall be used by the assisted reproductive technology clinic only once on only one recipient.

An assisted reproductive technology clinic shall never mix semen from two individuals before use.

Relative or friend as donor-

No ART clinic shall obtain or use sperm or oocyte donated by relative or known friend of either of the parties seeking ART treatment or procedures.

Surrogate can be relative or known but has to be from same generation.

How many oocytes/ embryos can I harvest and transfer????

Assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations of the National Board or concerned State Board or any rule as may be prescribed under this Act. No ART procedure if woman is less than 21 yrs of age.

number of oocytes or embryos that may be placed in a woman in any one cycle shall be according to the rules and regulations provided.

Max 3(Exceptions)

What I should do with extra gametes????

All unused oocytes/embryos-stored for 5yrs then allowed to perish or use for research. If Commissioning parent/ spouse dies gametes shall be handed over to living spouse or used for research.

An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

Records of such to be kept for 10yrs then send to ICMR/ART DATBASE.

Can I buy / cell gametes??

ICMR- Indigent to Affluent persons

ART bill-1) sale of gametes/ zygotes/ embryos out side India- prohibited.

2) zygotes/ embryos in India-prohibited

3) gametes can be sold for ART to ART clinic for treatment of infertility in India.

Confidentiality of information

Information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate shall be confidential. Personal information-personal identification will not be released without the prior informed consent of the genetic parent or parents or surrogate mother

Withheld information is to be disclosed in pursuance of an order or decree of a court of competent jurisdiction or a child may, upon reaching the age of 18, ask for any information, excluding personal relating to the donor or surrogate mother or Legal guardian, excluding personal, for welfare of the child.

Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother.

Sex selection

No assisted reproductive technology clinic shall offer to provide a couple with a child of a pre-determined sex.

It shall be a criminal offence and it is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology.

No person shall knowingly provide, prescribe or administer any thing that would ensure or increase the probability that an embryo shall be of a particular sex, or that

would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.
No assisted reproductive technology clinic will carry out any assisted reproductive technology procedure to separate, or yield fractions enriched in sperm of X or Y variations.

Preimplantation Genetic Diagnosis
Pre-implantation Genetic Diagnosis shall be used only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority. Destruction or donation (with the approval of the patient) to an approved research laboratory for research purposes, of an embryo after Pre-implantation Genetic Diagnosis, shall be done only when the embryo suffers from pre-existing, heritable, life-threatening or genetic diseases The State Board may lay down such other conditions as it deems fit in the interests of Pre-implantation Genetic Diagnosis.

LEGITIMACY ISSUES- REFER CHAPTER ON ML issues in Donor insemination
COMMERCIAL ASPECT
The ART clinic must not be a party to any commercial element. ART clinic must display the charges suitably or made known to the patient at the beginning of the treatment.
Cost (with suitable break-up)has to be given to the patient of the treatment proposed and of an alternative treatment and the clinic is expected to be totally transparent in all its operations

ADVERTISEMENTS-
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.
OFFENCES AND PENALTIES-
Medical geneticist, Gynaecologist, RMP, any person who owns or operates, employed, renders services is liable for penalties for-
1) Advertisement Pcpndt and contravention-5yrs RI + Fine
2)Contravenes any provision-2ys + Fine susequent-5yrs + Fine
+ State medical council-suspension of registration 2yrs(first) and permanently(susequent)
3) Contravention of PCPNDT ACT-3yrs(First) 5yrs(subsequent) + Fine
Presumption is that the women was forced by husband/relatives
4)Transfer of human embryo into male/animal-3yrs + Fine
5)Sale of human embryo for research-3yrs + Fine
6)Brokers/intermediaries for donors/surrogates-3yrs + Fine
When no specific punishment is provided-3ys + Fine and additional Fine for continuing contravention

CONCLUSION-
Infertility clinics in India are able to provide requisite technology and personal care at a much lower rate than those provided outside the country. However, all these treatments come under the legal gamete of the Indian Council of Medical Research (ICMR). According to ICMR, legitimate fertility clinics must fulfill the following criteria:
Registration for all fertility clinics dealing with infertility treatments and involved in the use and creation of embryos outside of the body
A code of practice to identify the qualification of the personnel
Couple's written consent; otherwise no treatment can take place
Patients must be given counseling and information about the treatment before and during the process
Human embryo cannot be placed in a non-human body and all research projects must be approved by the Institutional Ethics Committee

8. Assisted Reproductive Technology practice and The PCPNDT, Act 1994

INTRODUCTION-

The PC-PNDT Act was enacted on 20 September 1994 with the intent to prohibit prenatal diagnostic techniques for determination of the sex of the fetus leading to female feticide. That is to say the preliminary object was to put a check on female feticide. No doubt the bare perusal of the Act indicates that it is a draconic act from the point of its effect on radiologists/sonologists. The Act does not offer any escape to the erring radiologist/sonologist.

But at the same time it is very simple to fulfill and abide by the requisitions of the Act. The few basic requirements of the Act are:

1. Registration under Section (18) of the PC-PNDT Act.
2. Written consent of the pregnant woman and prohibition of communicating the sex of fetus under Section 5 of the Act.
3. Maintenance of records as provided under Section 29 of the Act.
4. Creating awareness among the public at large by placing the board of prohibition on sex determination.

A look at the basic requirement of the Act shows the simplicity of the Act, but non-compliance of the Act in any manner, be it the smallest of an error brings wrath upon the errant. The Act penalizes all the errants, either involved in sex determination or non-maintenance of records.

The Act is legislated in a manner that it should be a deterrent for those indulging in sex determination. The unfortunate decline in the male-female sex ratio has brought in stringent measures, there is suspension of registration, filing of criminal cases and sealing of machines. Besides, criminal prosecution will also bring in suspension and cancellation of registration granted by the State Medical Council.

Remedies are also provided–like filing an appeal before the appellate authority and getting the machine released from the court of law, but all these remedial measures are time-consuming and bring the career of an individual to a standstill.

ART AND PCPNDT-

Assisted Reproductive Technologies with In Vitro Fertilization Clinics are at a boom. The governing regulation functional at present are the ICMR guidelines with the ART Bill and Surrogacy Bill in the pipeline.

The implementation Of The PCPNDT act 1994 is an issue which remains controversial to the core.

There was a Gazetted Notification under The PCPNDT act 1994 on 9 Oct 2014 notification which said that all ART centres have to register under PCPNDT ACT AS

1. Genetic counselling center
2. Genetic clinic
3. Genetic laboratory

In accordance with which prenatal diagnostic technique(test/ procedure) is carried out at the center example-

PND PROCEDURE-(selection of sex)USG/embryo/tissue/fluid/man/woman

PND TEST-USG/Other tests on pregnant woman/conceptus

PND TECNIQUES-Both of above.

The notification also said that there was no need for any new form.

F form was to be filled-

- A-for all diagnostic procedures/tests
- B-for non invasive procedure/tests
- C-for invasive procedures/tests 21(v)-any other
- D- declaration of patient/ doctor
- FORM G-form of consent(for invasive techniques)

COMPLIANCE-

The following table shall clarify the compliance ART practitioner has to do under the PCPNDT Act 1994

Procedure	Forms Yes/no	Section/rule	Records	Section/rule
Follicular study	NO	-	NA	-
Oocyte retrival	Yes-G	Rule10	G/D as per the case	Rule 10,9(2)
Embryo Transfer	Yes	Rule10	D/E/G	Rule 10,9(2)(3)
IUI SCAN	N0	-	NA	-
IVF	Yes	Rule 10	D/E/G	Rule 10,9(2)(3)
Surrogacy	Yes	Rule4(3),9(4),10	F/G	Rule4(3),9(4),10
ICSI	Yes	Rule 10	E/G	Rule 9(3),10
Semen Analysis	NO	-	NA	-
PGS	Yes	Rule10	D/E/G	Rule 9(2),(3),10
PGD	Yes	Rule 10	D/E/G	Rule 9(2),(3),10
Infertile male patients	NO	-	NA	-
Testicular Biopsy	NO	NA	-	NA
Body fluids	Exempted	-	-	-
NIPT	Yes	Rule 4(3),9(4),10(1A)	F	Rule 4(3),9(4),10(1A)

CONCLUSION-

The ART Bill 2010 very clearly states that no assisted reproductive technology clinic shall offer to provide a couple with a child of a pre-determined sex. It shall be a criminal offence and it is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology.

No person shall knowingly provide, prescribe or administer any thing that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.

Never the less the mandatory statutory compliance under thr PCPNDT Act 1994 has to be kept.

In this era of skewed interpretation of statutes, it is absolutely essential to stick to standard compliance procedures. No disrepute shall be thumped upon the subject , its knowledge or the healthcare provider for want of correct documentation.

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