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SYNOPSIS

1. INTRODUCTION

Children are integral to family’s prestige, honor and happiness. Children are often cared by multiple extended family members, which makes having children central to family life. Thus couples suffer extreme emotional and psychological stress over infertility. Many families in developing countries depend on children for economic survival. Without children, men and women may starve to death, especially in old age.

Social Consequence of Infertility

Infertility in developing countries extends beyond the loss of human potential and unrealized self. The experience of infertility causes harsh poignant and unique difficulties, economic hardship, social stigma, blame, isolation, alienation, guilt, fear, loss of social status, helplessness and in some cases violence. In some communities infertile people are ostracized to shame, humiliation and sometimes death. Some even choose suicide over the torturous life and mental anguish caused by infertility. Throughout the world, the core prevalence of infertility is about 5% attributable to anatomical, genetic endocrinological and immunological problems. Infertility in developing countries is pervasive and a serious concern.1 According to the WHO definition of health, it could be argued that the emotional and psychological harms associated with infertility are health harms. Denying psychological harm as a serious health problem is classic maneuver that has been the cause of pervasive health care discrimination in most countries. Infertility has the potential to disrupt peace and exacerbate poverty. The harms caused by infertility are pervasive, socially embedded and serious, precisely because infertility interacts with a complex network of social relationships, social expectations and social needs. Therefore there is a need to reevaluate social health care research and treatment priorities to reflect the impact of infertility in societies.

Impact of Infertility on Childless Women

Childless women are generally blamed for their infertility, despite the fact that male factor contributes to at least half of the cases of infertility around the world.1 In

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1 PATH. Feature article; infertility in developing countries. Outlook, 1997, 15; 1-8
developing countries, especially motherhood is often the only way for women to enhance their status within the family and community. For women in developing countries, infertility may occasion life threatening physical as well as psychological violence. In Asia, being childless has more negative social, cultural and emotional repercussions for women, than any other non life threatening condition.

Impact of Infertility on Childless Couples
Couple infertility is used against the afflicted couple, or exclusively against the woman, as a justification for social isolation, abuse violence, indignities, physical and mental torture. Infertility infringes upon the human right to health; it often leads to violation of the most basic moral protection that is intrinsic to humanity itself. Infertility problem transforms from an acute private agony to a harsh public stigma with complex and devastating consequences leading to a serious public concern. Given the pervasiveness of infertility and the seriousness of its harm, infertility is a substantive public health problem.

The World Health Organization 1991 defines health as a state of complete physical, mental and social well being, and merely the absence of disease or infirmity. By this definition infertility is the major cause of diminished health in developing countries. Indeed, few health conditions could more profoundly or pervasively affect a persons well being in many developing countries than infertility. For when someone presents with infertility, he or she is often denied voice or advocacy, he or she does not have recourse to therapy, and moreover, he or she is blamed for infertility.

Causes of Infertility
The increase in demand for medical assistance in conceiving children is due to a variety of factors. Today many couples choose to delay conception, thereby exposing themselves to the increased risks of infertility associated with aging. There appears to be some increase in the number of women encountering iatrogenic fertility problems as a result of difficulties associated with various forms of birth control, such as intra uterine devices (IUDs). More women have entered the work force and as a result, have been exposed to reproductive hazards and pollutants that may adversely affect fertility. Increases in the incidence of sexually transmitted diseases, especially pelvic inflammatory disease, have
also produced a higher incidence of infertility among some subgroups within the general population.

Male infertility is becoming increasingly important for various reasons - low sperm count, poor sperm motility, malformations, clumping (sperm adhering together) or no sperms at all are some of them. The substances that are suspected to be harmful to male reproductive health are lead, dibromochloropropane or DBCP [a now banned soil fumigant], ionizing non ionizing radiation; anaesthetic gasses, the pesticide kopone, heat stress, carbon disulphide and estrogene. The other minor causes of infertility may be environmental or poor nutrition.

Continued infertility can create psychological stress on marriage and at times psychological intervention is also required. If infertility cannot be corrected, adoption becomes the only mean to provide them with a child. Attitudes towards human variability, the desirability of marriage and family, and the importance of biologic kinship between parent and child also play a powerful role in influencing the demand for medical assistance with respect to infertility. There is some evidence that parental expectations concerning pregnancy and reproduction have changed drastically during the past decade.

The British teams of doctors were successful for mixing sperms and eggs in a dish in the laboratory, and a few days, later transferred the resulting embryo carefully prepared uterus of a woman. She successfully delivered a girl child. New technological and scientific development in Assisted Reproductive Technology has exploded public consciousness in July 1978, with the birth of Louis Brown, the world's first successful product of in vitro fertilization and embryo transfer [IVF–ET].

1.1 Assisted Reproductive Techniques

The causes of increased demand for fertility services are confined to physiological factors. Couples who might have considered adoption in earlier decades are now turning in increasing numbers to the medical profession for assistance with respect to conception. There has been dramatic increase in the availability of infertility services and advances in diagnostic techniques such as laparoscopy, hormonal and genetic analysis. These allow

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1 Reproductive Health Outlook [RHO] over review and lessons learned Infertility
www.rho.org/html/infertility-overreview.html
health care professionals to identify with increasing reliability those suffering from impairments in fertility.

Today people’s expectations of fertility treatment are steadily rising, fed no doubt by charismatic doctors, advanced technology and a culture in which everyone is clear about ‘rights’, a little vague about responsibilities and obligations. Moreover, people from all walks of life now bring their infertility problems to infertility clinics; for example — lesbian couples, hitherto regarded as having chosen an inevitably childless partnership, now seek treatment for infertility.

The field of procreation at present has wide application and techniques derived from Assisted Reproductive Techniques interfere in the private sphere of human life, thereby causing great public concern. Specific technologies in the various categories are examined here especially for their implications for women’s health and autonomy. The category of technologies in the field of genetics such as genetic screening, gene therapy and gene manipulation are looked into and discussed with a broader perspective. Reproductive techniques have fragmented the process of procreation; first with the development of contraceptive technologies it became possible to have sex without reproduction. Later with the development of technologies such as artificial insemination and in vitro fertilization, it became possible to have reproduction without sex.

Technological innovation in the field of reproduction is going on at a very rapid pace. These technological developments have received great deal of media attention which can be justified by the fact that they have far reaching implications for the society. The development and use of these technologies have thrown up gender issues, issues of political, philosophical ethical, economic, legal and eugenic nature. These issues are concerned with sociology of technology in general and medical technology in particular.

**Principles of Infertility Treatment**

The first and foremost principle to be considered is the interests of the unborn child. Infertility consultations need to consider preparation for pregnancy, both physical and mental. Since multiple pregnancy can have devastating effects, in terms of both obstetric outcome, life of family, safety of its treatment and its efficacy. For the correction of anovulatory infertility, a single dominant follicle producing a single fetus and a singleton full term baby should be taken into account. In couples in whom assisted infertility
therapy is required, it goes without saying that financial implications should be clearly stated at the outset, the cost and availability of drugs should be explored and stressful nature should be openly acknowledged. The role of counselors and availability of quick efficient communication becomes imperative in such cases. Infertility treatment may further lead to technical problems [e.g.-trauma and penetration of pelvic structures, anesthetic hazards etc, ovarian hyper stimulation, multiple pregnancy and ovarian cancer in the longer run.]

**ART; New Baby Boom Technique**

New technological and scientific development in Assisted Reproductive Technology has exploded public consciousness in July 1978, with the birth of Louis Brown, the world's first test tube baby created by In vitro fertilization and embryo transfer.

Durga was the world's second successful IVF baby born in Calcutta just after a few months after the birth of Louis Brown.

Both these events caused intense public debate, criticism and even social and professional ostracism of those involved in initiating life outside body. Despite such obstacles, the techniques of IVF have survived as a method of choice for treating some types of infertility.

This short history of IVF is filled with repulsive tales. Eggs and embryos have been stolen from women and given to researchers or to others. Fertility drugs have been sold illegally and medical records have gone amiss. Women recruited as surrogate mothers have refused to part with the new born baby that they had conceived to assist couples to bear a child.

Recently, human cloning for reproductive purposes has been banned in many countries, and United Nations has recommended that such activities should not be encouraged. Incidences of misdemeanors, mistakes, negligence and malpractices committed with ART have already raised serious concerns in various segments of our society.

**1.2 Research Problem**

Mushrooming of infertility clinics in India have therefore, been a matter of great concern.

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Unlike most other medical techniques, success rate using ART is very poor. However, the desire of a child from infertile couples is so great that many infertility clinics with little expertise or reliability has come up all over the country. The services offered by these clinics are questionable. There is neither formal training in this discipline nor any guidelines for practicing ART in our country. Medical practice involving the diagnosis and treatment of infertility is influenced by a variety of factors, ranging from community attitudes to the personal and moral judgment of patients and the health care professionals involved. There are various factors like statutes, judicial decisions, and the right to make procreative decisions, the right to privacy affecting influences upon infertility services. The law shapes the standards by which health care professionals must practice, or render their services to infertile couples. The infertility industry is only one part of any unregulated private health care system which is based on profitability rather than need.

These technologies are offered as a choice. However, in a country such as India, where modern and, or hi-tech infertility treatment depends on the couples woman’s ability to pay, there is not much choice. Moreover due to lack of regulation and laws there are concerns about the lack of professionalism and the safety offered. The total absence of monitoring and self regulation can lead to the misuse of ART and related technologies. The goal of assisted reproductive technology [ART] and genetic services is to restore reproductive confidence for couples facing these types of difficulties. In India legislation is necessary for regulating and monitoring Assisted Reproductive Techniques for safeguarding the best interests of the patients who are at the receiving end. 

A. Objectives of the Research

Reproductive health is of great value for the community. Prevention of infertility should be prior goal of health care, in addition to social measures to counter parental age, abuse of drugs sexually transmitted diseases, obesity and environmental factors. It is thereby observed that if these techniques are safely adopted and practiced by the medical practitioners while assisting infertile couples for procreating children, it will

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Rowland R; Living Laboratories, women and reproductive technologies; Bloomington Indiana University Press; (1992).
aid and assist these couples for having their own biological offspring ultimately rendering happiness to mankind at large. The researchers and medical practitioners should ethically and scientifically adopt these practices. The goal being enhancement of safe motherhood and a healthy child. In India at present there is a need for nation wide guidelines for the practice of Assisted Reproductive Techniques.

**International Standards for Practicing Assisted Reproductive Techniques**

In some countries evidence based guidelines for investigation and management are published by different committees like Royal College of Obstetricians and Gynecologists (RCOG), The European Society of Human Reproduction and Embryology (ESHRE), American Society of Reproductive Medicine (ASRM), International Federation of Fertility Societies (IFFS). These committees have drawn up guide lines for the safe and ethical practice of ART and have forwarded suggestive measures of avoiding errors in the practice of ART. Realizing the shortcomings, countries such as United Kingdom, Australia, Austria, Brazil, Canada, Denmark, Czech Republic, France, Germany, Greece Hungary, Iceland Italy, Japan, Korea, Netherlands, Mexico, Norway, Singapore Israel, Spain, South Africa, Sweden, Switzerland, Saudi Arabia, Taiwan and Turkey and European Union have enacted legislations and taken steps to accredit, and supervise the performance of infertility clinics. In some countries like Finland, Portugal, United States of America there are 'scientific societies'. They have drawn guidelines for practice of ART. In countries such as Argentina, Egypt, United Kingdom, both guidelines and legislation does exist.

**B. Need of the Study**

In the present study the researcher attempts to present the national and international scenario of Assisted Reproductive Techniques. India is known to play host to visiting foreign infertility experts to carry out such procedures that have been banned in home country of the visiting experts. The case of injecting round spermatid into the egg cytoplasm is a good example of such misdemeanor. Sale of eggs and embryos are subtly advertised over the Internet by some IVF clinics in India. Using untested infertility
treatment modalities by capricious teams is not unknown in this discipline of biomedicine, given the intense desire for parenting gullible infertile couple. These unfair practices are adopted and practiced world wide. The New Assisted Reproductive Techniques have created new socio legal issues, complex relations, and ethics and safety standards. The legal rights of the parties, rights of the child, role and responsibilities of the medical profession and scientists, media, policy makers and legislators are determined from time to time.

In India there is a dire need for nation wide guidelines for the practice of ART techniques at present. Accreditation, supervision and licensing of the clinics practicing ART and the regulatory body under which all infertility clinics offering ART services should be placed.

1.3 OBJECTIVES OF THE STUDY

- Study different types of Assisted Reproductive Techniques performed and practiced by medical practitioners for assisting infertile couples in reproduction by medical intervention
- Critically evaluate the socio legal implications of Assisted Reproductive Techniques on consumers [infertile couples], resultant child, and women in general
- Briefly discuss the legislations enacted by different countries for effectively regulating the practices of assisted reproductive practices and discuss the implications of these techniques in the absence of guidelines and legislations
- Elaborately discuss the circumstances of medical negligence on part of doctors while practicing Assisted Reproductive Techniques which may result in deformity of the child born and to analyze the circumstances under which the medical practitioners can be held accountable and liable under Indian Laws
- Critically analyze the practice of surrogacy and related issues, rights of distinct parties with the best interest of the child, and legislations of different countries with regard to surrogacy
To forward suggestions and recommendations for protecting the best interest of infertile couples.

1.4 RESEARCH METHODOLOGY

The study has an exploratory research design. It uses primary and secondary method of data collection.

PRIMARY METHOD OF DATA COLLECTION

Field survey is based on a closed-ended scheduled questionnaire for ascertaining the popularity of the treatment, cost effectiveness and prevalent legal practices in ART. The researcher has attempted to conduct a field survey on 50 clinics practicing ART in Mumbai which indeed was challenging. The scheduled questionnaire was self-administered. The researcher was present with the medical practitioners while they filled in the questionnaire to respond to their query.

SECONDARY METHOD OF DATA COLLECTION

The secondary method of data collection is review of literature based on medical journals, recommendations and suggestions forwarded by various recommendatory committees, study on case laws for judicial interpretation of laws. The sources also include published books on medical law, medical jurisprudence, journals, case study, and parliamentary debates. Various recommendatory reports have been discussed and analyzed like 'The Warnock Committee Report, Draft proposal forwarded by the Indian Council of Medical Research, guidelines forwarded by American society for Reproductive Medicines, or European Society for Human Reproduction and International Federation of Fertility Society for safe practices of ART. Legislations or guidelines are followed in different countries for effective and safe practices of ART. It is thereby observed that if these techniques are scientifically and carefully practiced then definitely it will help human race. Overall with scientific development and advancement it is ultimately for the legislators and executives to implement effective legislations on ART for protecting the best interests of infertile couple [consumers] since services are rendered to them. Ultimately a happy child and a happy family should be seen as success of ART.
1.5 Scope and Limitations of the Study

In field survey, Scheduled printed questionnaire was prepared and given to clinicians practicing ART in Mumbai city. It was difficult for the researcher to have access to these clinics since there is no registry maintaining records of clinics practicing ART. The study aimed at visiting 50 clinics. Given the limitations and nature the study, only 36 doctors responded. Some assisted reproductive techniques like intra uterine insemination, artificial insemination with husband’s semen are commonly offered services to the patients. The data analysis throws insight into popularity of the treatment, cost of the treatment, prevalent legal practices, quality control for clinics, at par with international standards for services such as screening of donors, filling in consent forms, maintaining an equipped laboratory and service equipments. To ascertain the fact that whether legislation is necessary for regulating the practices of ART in India, analysis of data is further presented by tables, designing graphs and pie charts. Some techniques like IUI, AIH are practiced by KEM, Cama hospital and IRR. The government authorities in these hospitals refused to impart information on these techniques. In private clinics after several visits some doctors were kind enough to fill in the questionnaire. However some questions remained unanswered.

1.6 CHAPTER SCHEME

The study consists of 9 Chapters.

Chapter 1 forms introduction of the study outlines the research problem, need of the study, aim and objectives of the study, research methodology and Scope of the Study.

Chapter 2 Religious Attitudes and Cultural Perspectives of Infertility with specific reference to India, Middle East, South Africa and Latin America.

This Chapter elaborately discusses on Non Technological Assisted Reproduction and Technological Assisted Reproduction. It is necessary to understand the cultural and religious background of people and the manner in which Art is being treated in different countries. This Chapter is further subdivided into two parts. Part I discusses on the Religious perspective of Assisted Reproduction under different religions i.e. under Jewish faith, Islam, Christian faith, Hinduism and Buddhist faith. Part II lays insight into
Religious Attitudes, Cultural perspectives of infertility and its alleviation in different countries with specific reference to India, Middle East, South Africa and Latin America. According to Das Gupta, Chen and Krishnan, children in Indian society are looked as a source of labor, income, happiness and security in old age. The perception of women’s role and attitude is shifting in upper middle classes but procreation still remains an important factor in the socio-economic well being traditional societies infertility is often believed to be caused by a curse or evil spirits, therefore, magical rites are often used to propitiate gods and the spirits. Male infertility was less known due to prevalence of custom of levirate in many societies. The theme of infertility plays important role in the Hindu epics Mahabharata and Ramayana.

2.1 Practice of Assisted Reproductive Techniques in Ancient Societies

At the beginning of Ramayana, King Dhasratha is unable to impregnate any of his three wives. Ultimately he seeks help of sage, who according to the text, gives Dhasratha some ‘kheer’ [rice pudding probably and euphemism for sperm in the holy book] which he gives to one of his wives to distribute equally among them. All three wives get pregnant and he becomes father of the four sons, one wife having given birth to twins [according to the history she got a double portion.] Could this be seen as one of the earliest known examples of non-medical artificial insemination by donor sperm?

The bible opens with a whole string of infertile [referred as ‘barren’] women – Sarah, Rebecca, Rachel and Hannah – and their agony and desperation over along period of time at not being able to conceive. Only as middle aged women do they succeed in becoming pregnant. Sarah even persuades Abraham to have a child by her maid Hagar. Can we see this early example of non-technological surrogacy?

Often came to help the lady of the manor. These examples show the problem of male infertility has been traditionally dealt with at practical level in different societies.

The Ethics of ART in India, Middle East, Africa and Latin America is influenced by cultures of the peoples and the status of men, women and children in societies. The child is valued as the embodiment of family genes into the future. The woman’s role relates to vital role of ensuring continuation of the family, tribes and race through procreation.
Technologically Assisted Reproduction.
Most of the techniques used in assisted reproduction or artificial reproduction were first used in animals such as cows and sheep. Most reproductive scientists including Robert Edward and Steptoe team, responsible for the world's first IVF baby, Jacques Testart, responsible for the first French IVF baby and Alan Trousan from Australia, to name a few began as animal biologists.
Technologies used to assist reproduction are also referred as contraceptive technologies. They were originally developed to help women with tubal pathologies, or in case of infertility of husband/partner and for [idiopathic] unexplained infertility. These may include such low technologies as Artificial insemination [AI], or In-Vitro Fertilization [IVF], more popular though mistakenly known as ‘test tube’ method, in all its variations. Also techniques such as microscopic tuboplasty are used to help women with tubal pathologies to conceive.*

Cultural Context and Consequences of Infertility

Practice of Assisted Reproductive Techniques in Indian Society

A survey done by WHO on the incidence of infertility in different countries in the world reports the incidence of infertile women in India as 3%. About 10 per cent of couples in India suffer from problems of infertility. ‘Nearly 16 million couples – or 32 million individuals – in the 18 – to 35 year age group, are afflicted by the problem, making infertility one of the most widespread conditions in the country [Katiyaar [1993]
Doctors who have invested large sums of money in expensive medical equipment are keen to recover the capital outlay in a short time as far as possible. With an increasing number of couples desperate for a child and starting on a roller-coaster of various treatments – the two parties usually find their match. Some of the simpler procedures – such as AIH or AID, ovulation cycle study, semen analysis – are performed by gynecologists themselves many of whom have acquired the necessary infrastructure.
However, couples requiring IVF and more complicated services are referred to special infertility clinics which have the latest equipment from abroad.

The economic liberalization policies of government in the 1990s are likely to make imports even easier, and could result in an even larger number of clinics offering more sophisticated services in this field.

Although population control remains India's main objective in the application of human reproductive technologies. IVF is encouraged as treatment for infertility.

However the services in the private sector are mostly market driven. According to an infertility specialist in Delhi, as private specialist invest a lot in acquiring hi-tech equipment, the costs of services are therefore high.

Traditional Practices for treatment of Infertility and ART in SUB-Saharan Africa

Africa has more of the type of infertility that can be solved by ART procedures than any Part of the world.

Traditional therapies for female infertility include; manual trans abdominal massage of the uterine fundus –this practice is common among the Ijaws of Niger Delta area of Nigeria; transvaginal repositioning of the uterus for presumed retroversion; and the application of herbs to the vagina. All these therapies are supposed to aid the outflow of impurities from the uterus Sacrifices of poultry, goats or rams may also be performed to gods/goddess that may be annoyed or to invite their favor so that pregnancy may occur.

At present there is need for ART in SUB-Saharan Africa. However this need for ART far exceeds the availability of facilities and expertise, thereby creating a large gap between need, availability and uptake.

In Nigeria alone there are at least 12 million infertile persons, effected by tubal factors, severe oligospermia and azoospermia account for the majority of the causes of infertility. As of 2000, the total number of IVF cycles performed in Nigeria was less 600 cycles per annum. In Africa, there are more tubal factors, more irreversible oligo – or azoospermia and fewer resources for the management of infertility due to economic, political, capacity – building factors and the severity of disease.
Cultural Practices for treatment on Infertility and Art in Middle East

In middle east there are three major religions, namely Judaism, Christianity and Islam emerged, religion still means a lot and greatly influences behaviors, attitudes, practices and policy-making.

Though ART as an additional line of treatment of infertility would have been expected to be welcomed in the Middle East area, the installment of ART centers in many countries in the area was delayed until the mid-1980s due to cultural and religious factors. There are different modalities available for the treatment of infertility in both the female and the male partners, depending upon the cause of infertility. Some of these modalities have been practiced for hundreds of years and were never of ethical concern, medical therapy, hormonal therapy corrective and reconstructive surgery for female or male infertility. The general ethical principles which govern the medical practices in general, are applicable to all these lines of treatment.

The handling of human gametes in the laboratory and the involvement of a third party in the process of conception created the most bizarre and inconsistent attitudes in many countries all over the world and particularly in the Middle East area. It was not until Fatwa's from Al-Azhar in 1980, the Islamic Fikh Council in Mecca 1984, and the Church from Alexandria in 1989, that the procedure gained popularity and became widely acceptable to the medical profession, patients religious leaders and policy makers in most countries of the area.

These bodies and organization issued guidelines which were adopted by the National Medical Councils and Ministries of Health in various countries and controlled the practices of ART Centers.

The promulgations of these guidelines was just a response to the needs of the community, and the discussions and debates which arose in the area, as well as problems anticipated with the practice of surrogacy with special reference to cultural and religious background.

Socio Cultural Perspective and Practice of ART in Latin American Countries.

Latin America is not a homogenous region; countries are diverse and have a cultural and sociological individuality. Despite their differences, however Latin American countries share certain features; wide gaps between poor and rich people and the high prevalence of
Catholicism. Even though Catholic Church may differ from country to country, religion does have great impact reproductive issues.

In social and cultural context where motherhood is seen as necessary for the personalization of women, the finding of infertility is devastating experience; the infertility is seen as vital crises and a social stigma in Latin American countries. The lack of a law fixing the permissible or the impermissible puts pressure on the providers. They have to decide without and external rule that sets limits. In addition, in societies that are influenced by Catholic Church, what ever minimal intervention falls outside the standard may be easily criticized. Strict adherence to Catholicism goes against the gamut of these techniques. [Whether techniques to be provided to single, lesbians or post menopausal women]

The providers sometimes have to decide what should be done on a case – by – case basis and these decisions are ostensibly difficult. This fosters an attitude of self restraint in the physicians themselves. The providers sometimes have to decide what should be done on a case – by – case basis and these decisions are ostensibly difficult. This fosters an attitude of self restraint in the physicians themselves.

There is widely felt need for regulation. However legislation is not sought because of the fear of very restrictive laws given the prevalence of Catholic lobby. Even if there is no legal regulation, there is a scientific consensus in the region. The consensus on ethical and legal aspects agreed upon by a Latin American network, constituted in 1994 in Chile, [Rennaca] to provide guidance to legislators, health authorities, women’s organizations

Therefore in the present context it is necessary to define distinctive techniques for curing infertility[Assisted Reproductive techniques] .The next Chapter elaborately discusses on the definitions.

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vi Tangwa G.B; Bioethics; African Perspective. Bioethics; (2000)

Chapter 3 Definitions on Infertility Techniques.

'Reproduction' as defined by the Oxford English Dictionary, is the 'action or process of forming, or creating, or bringing into existence again'.

The sociological meaning of human reproduction however, has been broadened to cover reproductive processes – which include sexuality, reproductive pathologies and reproductive technologies. The term 'new reproductive techniques' (NRTS) are designed to intervene in the process of human reproduction. They are – for the prevention of conception and birth (contraceptive technologies) for assisting reproduction (aiding or stimulating conception) for genetic purposes and prenatal diagnosis (including sex pre selection and sex determination). These techniques aim at improving the health and genetic characteristics of fetuses and newborn with the search for 'perfect child'.

Most of the techniques used in assisted reproduction or artificial reproduction were first used in animals such as cow and sheep. Technologies used to assist reproduction are also referred as contraceptive technologies. They were originally developed to help women with tubal pathologies, or in case infertility of husband or partner and for idiopathic unexplained infertility. These include technologies Artificial Insemination (AI), In Vitro fertilization (IVF), Intra Uterine Insemination (IUI) Intra Cytoplasmic Sperm Injection (ICSI), Surrogacy, Cloning etc.

This chapter therefore forwards the definitions on different techniques of ART which are being commonly practiced by the medical practitioners.

Chapter 4 Socio Legal Implications of Assisted Reproductive Techniques

Medically Assisted Technology is running far ahead from morality or legality. The development and growth of these technologies have given rise to distinct socio legal implications. They are being discussed in the third Chapter.

There are medical, legal, cultural, ethical, eugenic and population policy concerns. The increasing use of reproductive techniques and importance given to them in determining reproductive decisions are responsible for bringing reproduction into political domain thereby creating socio legal implications.

Technologies for assisted reproduction have assisted infertile men and women to have their own biological offspring, but on the other hand, they have opened up possibilities
for doctors, lawyer's legislators and the state to intrude into the most private and intimate of experiences – sexuality and procreation

The technologies in this field have led to increase in treating the reproductive organs as commodities generating body products such as sperms, eggs, fetal tissue for sale and wombs for rent. Technology leads to medicalisation of life and reduction of pregnancy to a technological process and it has the potential to create life in the laboratory.

Issues related to human embryo research include the more philosophical aspects as to when life begins. Women’s bodily parts are used as materials for experimentation especially ovarian tissue, secretions from her reproductive tract in relation to sperm maturation. IVF has turned women into living laboratories Scientists are busy with the dismembering and fragmentation of women into body parts – wombs eggs ovaries, embryos. They have become personalized at the expense of women. They can be orphaned or parentless and of good quality or poor quality. The development of IVF involved, in first place, the use of women’s bodily parts as material for experimentation; ovarian tissue, secretions from her reproductive tract as the site for experimentation related to sperm maturation. IVF has turned women into living laboratories Scientists are busy with the dismembering and fragmentation of women into body parts – wombs eggs ovaries. Eggs, embryos takes lives of their own become personalized at the expense of women. They can be orphaned or parentless and of good quality or poor quality. Issues related to human embryo research puts forth philosophical aspect as to when life begins.

The legal implications are – as to ownership of embryos, whose property are they – do they belong to the woman, or the couple, and if the couples are separate later which of them will get the custody and if they both die, could the embryos be gestated by another woman, and the resulting children become heirs to parent’s property

Or the frozen embryos to be treated as orphaned embryos.

Another issue to consider is the health of the resulting fetus and after birth the child may be affected as a result of drugs given during the IVF or freezing and thawing procedures

Assisted Reproductive Technology cannot provide answers with regard to the long term effects of such technological intervention.
Chapter 5 Legislations on Infertility Techniques

This Chapter elaborately discusses about the enacted legislations on assisted reproductive techniques by different countries and guidelines provided by scientific committees. At present the traditional way of making the laws have been especially challenged by biotechnology, because of its rapid development effecting human beings, both present ones and future ones in various ways as they go closer to the center of their physical and mental being, their humanity, than any previous development in biological science.

Medically Assisted Conception - It means conception towards which medical intervention is made at any point between the appearance of gametes in the bodies of women and men and the implantation of fertilized ova [conception], whether the gametes are those of 'intending parents' or not. This includes surrogacy. In the laws of the world various phrases are used for these procedures, and for procedures which include this procedure among others.

The practice of medical assisted conception raises many ethical, social and economic questions, all of which directly concern legislatures and judiciaries. It produces children who may or may not be permitted to know about their genetic father or mother or siblings are; it may either decrease or occasionally, by mistake, increase the number of genetically handicapped children born, its effect on the fertility of children of people who have themselves been generated by this means are still are unknown; and it is expensive. For all these reasons it is universally attended to and usually legislated by national parliaments because of the creation of new and strange relationships between humans, problems of confidentiality, and also on everyday public health grounds and on the grounds of general health economics.

PUBLIC OPINION

The role of public power in the field of biotechnology is expression of public opinion or public will. Elected legislature must take account of public opinion. Public opinion on biotechnology is exceptionally well known in Europe because of two enquiries in 1935 and 1995 and in 1996. This was done for the European Commission by the Institute for Research on Intercultural Cooperation at the Universities of Barb-ant and Tilburg using data from Euro barometer study. People seem to accept some risk as long as there is a
perception of usefulness and no moral concern. Moral doubts act as a veto irrespective of people's views and risk.

**Philosophical and Religious Beliefs**

The religious laws, regulations and judgments made by the religious authorities differ as they follow their convictions while making them. Thus for instance, within monotheism there are differences between Judaism, Christianity and Islam. Within Judaism there are many complex differences. This is also with Christianity, in which there are differences between Roman Catholic, Orthodox and Protestant. Within Western philosophy there are thinkers who favor rights and who favor duties and those who favor ethics of calcui and those who favor ethics of convictions.

Islam is its own world is treated as a different section.

**ISLAMIC LAWS**

Most Muslim countries run two systems of laws concurrently Sharia, the revealed canonical law of Islam, for family and personal relations and for religious practice and a western system for administration and economic activity. The relative of each varies from countries to countries.

In dealing with bioethical issues Islam does not speak with one voice. However it is doubtful, if it anywhere accepts artificial insemination by donor (AID) by any means donor insemination, embryo transfers, surrogacy etc. On the other hand, especially among the richer Muslims of the world who inhibit a moral country of their own, the law is not always closely followed. Medically Assisted Conception as between husband and wife is of course accepted in Islam as elsewhere.

The symposium on Islam and reproduction held in Kuwait in 1982 by the Islamic organization are very clear on AID and AIH.

Islam is in many places still trying to live by God's laws as Christendom did in middle ages, and to Muslims God is still a public power.

**International Organizations.**

All international organizations by definition affect the role of public powers. And those which affect in bioethical field are numerous. They are –
United Nations Educational, Scientific and Cultural Organization [UNESCO]
The World Health Organization [WHO]
The European Union
The Council OF Europe and the
Organization for African Unity [OAU]
There are many international and regional associations of scientific and professional people.

**UNESCO**

In 1993, UNESCO set up the International Bioethics Committee, composed of relevant experts from many of its member States. In 1997, this committee finished work on a Declaration on Human Rights and the Human Genome, which is open to all countries to sign. The text places itself explicitly in the tradition of United Nations Declaration of Human Rights of 1948.

It contains sections on human dignity and the human genome, the rights of the persons concerned, research on human genome, conditions for the exercise of scientific activity, solidarity and international cooperation, promotion of principles set out in the declaration, and implementation of the declaration.\(^{vii}\)

**Chapter 6 Eugenics**

The chapter on eugenics explains or lays insight into the misapplication of science and technology in distinctive and discriminatory manner from ancient ages until today. The phenomenon of man’s inhumanity to man is entirely man made. The science of eugenics (and nuclear fission) has been misapplied in terrible ways. The concept has been with us for more than two thousand years, and even the simplest of techniques such as sterilization, infanticide and euthanasia have been used to commit gross crimes against individual freedoms.

Eugenics as well as sociobiology is used to reinforce sexist, racist and anti handicapped biases. They place the blame for poverty, illness and, ‘abnormal behavior ‘on the genetic background of the individuals rather than society. Politically based eugenics is used as a substitute for social and economic reforms. Eugenics might be formulated as ‘science

applied to qualitative improvement of the set of human genes to be transmitted to the next generation. This definition could be extended to cover methods for regulating population numbers as well as trying to improve the genetic composition of the next generation.

The ideas of eugenics are not new, as with so many other things the Ancient Greeks were the first. The legacy of Plato and Aristotle will continue to be discussed and debated for centuries to come. Both men held decidedly strong views on eugenics, their aim being to provide the city—state with the most able and effective children for the next generation. Eugenics is a seductive notion, and one that has been debated since antiquity. After all we all want our children to be healthy strong limbed, with clear enquiring voices.

Eugenic is one of those loaded words—taking in philosophy, ethics, sociology, medicine, genetics, biotechnology—that has acquired many ramifications. The worst of these has been picked up by right-wing politicians in America, Germany and Scandinavia in the early part of twentieth century and subsequently applied in grotesque manner. Initially, laws were introduced to prevent those people considered 'undesirable' from having children.

The new eugenics has arisen from the merger of two separate disciplines,

1. First is the new reproductive technology, such as in vitro fertilization, designer babies and cloning
2. The second is the knowledge of genes and how they work. Taking the two together has enormously expanded the scope of eugenics. The major role of legislation will be to curb the over enthusiastic activities of companies and business that promote and sell such eugenic services to the general public. Eugenics emerged as an extension of hereditary factor and thereby claimed to apply genetic principles to the improvement of ‘mankind’.

There are two kinds of eugenics—positive and negative.

Positive eugenics attempts to increase the reproduction of fit individuals, while negative eugenics attempts to reduce the reproduction of ‘unfit’ individuals. This idea of propagating the increase of ‘best’ and limiting the propagation of ‘defectives’ was voiced even by Plato too, but at present it has gained a scientific character and acceptability.

Initially these ideas of eugenics were very popular throughout Europe and North America among scientists, industrialists, government administrators and lay people.
In 1920s 'positive eugenics' were favored in Russia. Soviet geneticists tried to persuade the government to artificially inseminate women with the sperm of superior men in order to 'breed better' children.

In Germany eugenic thinking was propagated under the name of 'racial hygiene' first launched by a physician named 'Alfred Plotz', in 1895 Plotz started the Archive of Race and Sociobiology in 1934 and the following year he formed a Society for Racial Hygiene. Initially he did not concern himself, much with miscegenation, unlike Britain and the USA, where mixture with other races was their main concern.

In Germany the Law for the Prevention of Hereditary Ill Progeny was passed in 1993 and in 1935. The Law for Protection of the genetic health of the German People followed. These laws required premarital medical examinations to detect 'racial damage', and provided that people judged 'damaged' marry only others like themselves after being sterilized.

By 1939, about 300,000 - 400,000 people had been sterilized. It was fulfillment of Hitler's dream as he wrote in 'Mein Kamph', "whoever is not bodily and spiritually healthy and worthy, shall not have the right to pass on his suffering in the body to his children [Glazier 1993].

Actually, preconceptional technologies even go one step further with quality control, beginning with screening of individuals who are themselves healthy to reproduce or not, and whether their gametes [eggs and sperm cells] are 'health' or not to start a pregnancy, if not then egg donation or sperm donation can be alternative for them. The next stages are; 'pre embryo, embryo fetus and so on' - at which the product of conception is at quality control. At present the aim is to control the quality of 'human gene pool' to be further carried out by social control of reproduction.

The procedure of 'designing' babies by enhancement and selection techniques would fall within the original definition of eugenics, which in the early part of twentieth century used selective breeding and sterilization as the only method at its disposal.

The subject is potentially open to all the abuses of discrimination and suppression by authoritarian governments that followed the traits of eugenics field in the first half of the twentieth century.
This has produced widespread revulsion at the very idea that whether the state should interfere with people’s reproductive choices for the purpose of improving the ‘genetic stock’ of the next generation or indeed for any other reason.

The new genetic technology has produced methods a hundred times more powerful than sterilization and abortion to regulate which genes are passed on to the next generation. Genetic screening in future would create a society in which highly educated, better informed will be in a better position to deal with these issues than others. In some cases choice may be available only to those who can afford to pay for the tests.

The right to choose also implies the right to not want to know.

Can people exercise the right not to know?

In future medical technology and its application could be the decisive factors for determining a society and the autonomy of individuals and particularly women will be affected as a consequence of development and application of new technologies in the field of genetics.

In future this will lead to a genetic underclass based on poverty or totalitarian politicians could use these techniques for acquiring control over society.

There is danger of genetic reductionism. This may give rise to thinking in terms of a biological underclass in which problem behavior may be seen as unimprovable. The gap between laypersons and researchers is bound to arise and the most important opposition to research and application of genes technology is based on the fear of return of eugenics. It will lead to coercion on masses for undergoing genetic screening or genetic testing of hereditary disorders and to sterilize or abort afterwards.

When employers and insurers make genetic screening a pre condition for employment or for life or for health insurance, an individual’s right to privacy is eroded. Genetic screening will create a society in future in which the highly educated /better informed will be in a better position to deal with issues than others. The widespread use of information technology has created another fear of violation of confidentiality. With the array of new genetic tests that is available, new legislation will be required to balance the employment rights for individuals at risk of employer’s right.
Genetic colonialism

Besides the wide ranging application of bio technology the further concern is about as to who would control the resources generated by these means. For Instance; Tropical Forests are natural gene banks. However by means of biotechnology, artificial [gene bank of seeds] have been created:

Controversies have arisen over patent rights and the fact that the development of new technologies is nearly, entirely being controlled by transnational enterprises. [By universities and firms who have evolved these techniques.]

These corporations are diversifying into every field of specialty, which use living organisms as a means of production. [Shiva 1993; pg 96] According to Shiva; "Living organisms are central to production processes in biotechnology". The need for ownership rights to living organisms is essential for the next stage of capital accumulation by global corporation. At the core of the business are property rights and patents which guarantee profits excluding others from rights and access to the means of survival". Royalty payments are expected to bring in billions for patent holders.

Blood tissues and hair samples are being taken from ‘endangered’ communities in different parts of the world before they die out and being appropriated by owners of ‘gene banks’

"A new form of ‘first world’ dominance of ‘third world’ is emerging, this time for gene wealth.” [Hynes, 1990. b.132] Shiva [1995.p1] asserts; that Intellectual Property Rights [IPRS] have emerged as the most important trade issue in the recent years, Patents on life relate to politics of knowledge, to bioethics and philosophy of science.

They raise ethical and socio-legal concerns about he integrity and intrinsic worth of species. They raise ecological questions about the manner in which they promote monocultures and destroy bio-diversity.

Last but not the least, the growing interests and profit motives of Pharmaceutical companies. While conducting research and experiments on human beings, animals and plants, they violate their basic freedoms in general. Their solidarity is violated. Balancing of interests is crucial, but priority of interest must be determined.
Chapter 7 Implications of Surrogacy contracts

The concept of surrogacy is not new. It is being practiced since ages in different cultures and in different forms.

Surrogacy is complex in nature as the interest of intended parents; surrogate and the future child may differ. Surrogacy is an acceptable method of assisted reproductive technology of the last resort for specific medical indication, for which only reimbursement of reasonable expenses is allowed. There are medical or physical reasons under which the genetic mother cannot become pregnant. For example severe hypertension, or uterine malformation under such circumstances a surrogate carrier may be asked to gestate a couple’s embryo and then turn the child over to the couple after birth.

There are variations with surrogacy. There is genetic surrogacy and ‘gestational’ surrogacy [full surrogacy]

In the first case the woman is inseminated with the sperm of the commissioning father, while in the latter she receives an embryo from somewhere else.

The classic model of surrogacy is when a surrogate mother is inseminated with the sperm of the husband of the commissioning couple. In this case the egg cells are belonging to her and she provides her uterus.

‘Full surrogacy’ is when the surrogate mother becomes pregnant after egg donation.

Surrogacy is being practiced from ancient time in different countries thereby raising distinct socio legal issues.

There are laws in different countries regulating or governing surrogacy contracts

Legal issues are being judged by the courts of different countries [United Kingdom, USA, India, and Scotland.]

The aspect of ‘womb leasing’ draws special attention – that is, the use of intra-familial surrogates. In this type of surrogacy family relations are seriously disturbed and it also opens door to emotional coercion. This practice should however be made illegal.

At present, the IVF associated surrogacy lies within the framework of the Human Fertilization and Embryology Act. 1990, standard surrogacy does not do so unless it involves artificial insemination that is provided as public service. other than in form of AIH or AIP , That being so, Donor Insemination in the context of surrogacy only if
performed privately or under cover of licensed clinic, as best not best encouraged by HEFA. This leaves an unsatisfactory dichotomy, the solution of which is central to the repute of the process. Many people agree with the minority of the Warnock Committee that it should remain available as treatment option and it must be controlled. Against this background the Brazier Review Team was set up in 1997, intending to ensure that the law continued to meet public concerns.

The recommendations of the Brazier Committee's Report are briefly discussed.

AMERICA

The forms of contract drawn up in USA at some of these centers for surrogate parenthood demonstrate -- on paper at least the care that has been taken to protect the interest of all parties. Because the legal validity of such contracts is yet uncertain, even in US, there is often acknowledgement that the rights and liabilities of the parties 'may or may not be honored in a Court of Law should a breach arise' but the rights and liabilities are set out to assist the court in establishing the intention of the parties.

The general terms of the contract provide that the couple pay a fee to the clinic which includes a sum for the host mother and all her reasonable expenses. When the baby is delivered, the semen donor agrees to become legally responsible for its care and support.

The judgment delivered by different courts merely state the facts that surrogacy contracts are controversial and at times justice may not be rightly delivered.

B. The rights of all four parties are disputed

i.e. the right of the surrogate, the commissioning parents and the child who obviously has to accept the decision of the Court.

Commercial surrogacy is the most developed in the U.S. [although it is illegal in some states] also because contract law is more developed there than in Europe. In 1988, 23 agencies were operating in Europe [Klein 1989], many of them were branches of agency founded by lawyer Noel Keane who leads a network of commercial surrogacy agencies in the U.S, who recruits women mainly through newspaper advertisements, tried to establish an administrative office in Frankfurt, Germany in 1987, to allow West German to hire women as surrogates.
Scotland

In Scotland the Children Act of 1975 provides that the parental rights and duties cannot be surrendered or transferred and it is possible that it is criminal offence to receive money in attempt to do so.

The legal situation is complex, unclear unsatisfactory. A decision should be taken, as to contracts for surrogate parenthood should be legally permissible or prohibited. There are certain arguments forwarded by those who claim that such contracts should be valid and enforceable

Commercial surrogacy is not legal in The Netherlands, but it is not explicitly banned either. This is for ethical and practical reasons. The government has taken a realistic stand on this issue. In practice people do enter into surrogacy arrangements but these arrangements do not have legal sanction.

In Netherlands if the surrogate mother decides to keep the child, there is no way she can be legally forced to give to the commissioning parents. The interest of the child is paramount. As long as the risks to the child are not clear surrogacy should not be encouraged.

According to Current Dutch law, the woman who gives birth to the child is the mother of the child; only if the child is given for adoption can the adoptive parents become the legal parents of the child. Thus, the only way surrogacy is possible is through adoption. The Courts decide whether adoption is in the interest of the child or not. Only a married couple or people in long heterosexual relation can adopt a child. Individuals living in other associations – lesbians and homosexual men – cannot adopt, although changes in law to allow them to do so are under consideration. Adoption procedures are every lengthy Also there is an age limit to decide on how old a woman can be if she is allowed to adopt. Many women decide to adopt after several years of inability to conceive and many more years are spent in trying out infertility treatments which may not yield the desired results.

INDIA

30 -year old Nirmala from Chandigarh caused uproar when she announced her decision to bear a child for an infertile couple for Rs 50,000. By acting as a surrogate she hoped to
raise money for the medical bills of her invalid husband, which was otherwise beyond her capacity, her monthly income being only Rs 700. Nirmala expected to conceive through sex with her employer. She openly admitted that she was doing it for money. According to infertility specialist, Dr Parikh, the woman was using her recourses – in this case her womb – to earn money for honorable cause Nirmala was threatened with action under the Suppression of Immoral Traffic Act. Subsequently she filed a lawsuit seeking legal sanction for her action and threatened to commit sati if her husband died of lack of medical help. Surrogacy is still in its infancy in India. Some infertility specialists are hesitant to do commercial surrogacy yet, although they do buy ova. Ova are being bought for Rs 5,000 a piece. The case of Nirmala not only sparked off a controversy but initiated a long – due revision of ethical criteria in medical matters, which were revised after 17 years. A ‘statement of ethical considerations involved in Biomedical Research on Human Subjects’, or the ‘ICMR Code’ was drafted by the Central Ethical Committee on Human Research under the Chairmanship of the former Supreme Court Chief Justice M. N Venkatchalaiah. The ethical guidelines now also encompass developments in the field of human genetics, organ transplant [including fetal tissue transplant] and assisted reproduction technology [ART]

Socio Legal Concerns are ----

• The nature of motherhood has changed with the buying and selling of the babies.

• The market is reshaping social relations although it may make use of non biological ties. Sperm donor unrelated to the family, ova donor surrogate mother. A child may have five parents – a sperm donor, an egg donor, a surrogate mother and two social parents leading to the creation of rights and counter rights.

• Legal problems such as custodial rights to children would arise.

• Inalienable rights are traded as alienable rights. The right of autonomy is an inalienable right that cannot be turned into alienable property and this is precisely what surrogate contract seeks to achieve. The surrogate mother is ‘counseled’ into exercising her autonomy to relinquish her autonomy over the child whom she has acquired by carrying the child in her womb for nine
months. This inalienable right is traded off through a contract as alienable property.

- Surrogate motherhood is a curious and ad hoc compromise of biological and social connection which confirms to no principle whatsoever, but merely serves the interests of whosoever possesses economic and social power to turn generative capacities, technological innovations and economic advantages to their personal use.

Recommendations for practice of surrogacy are put forth by different committees in different countries. The RCOG committee, the Waller Committee and the Warnock Committee have come out against surrogate carriers. The American College of Obstetricians and Gynecologist statement on ethical surrogate motherhood assumes that there will be instances in which physicians are called on to participate in the procedure. Laws in various states affect whether surrogate motherhood may take place and if so, who the legal parents of the child are. No state laws prohibit the use of volunteer surrogate carriers except to the extent that the embryo transfers to an unrelated woman might be considered an unlawful experimentation on the embryo. However paid surrogacy may run afoul of the laws in 24 states that prohibit payment to a mother, beyond certain enumerated medical and legal expenses, in connection with giving a child up for adoption. The 10th statement of the task force on Ethics and Law considers ethical questions to varied surrogacy arrangements.

Chapter 8

Importance of Genetic Counseling, Medical Negligence and Criminal Liability of Medical Practitioners

The importance of genetically dependent diseases has risen as the control of those due to infection has increased. At present, the proportion of childhood deaths attributable wholly or partly to genetic factors runs at about 50%. And it is becoming increasingly clear, as work continues on Human Genome Project to map the genetic code of human species,
that a genetic component may operate in many illness and conditions which were previously thought to be controlled by non genetic factors. The social, ethical and legal implications which advance in genetics have expanded and correspondingly today the genetic considerations are studied as a subject in medical jurisprudence. This topic discusses the role of genetic counselor and his liability for negligent failure to diagnose, disclose or treat genetic abnormalities. Genetic Screening is based on the principle that prevention is better than cure. It is now technically possible to carry out genetic screening for a number of disorders such as ‘congenital anatomic defects, congenital hypothyroidism, Down’s syndrome, hameoglobinopathies, fragile X syndrome, neural tube defects, phenylketonuria, hypercholesterolemia, prostate cancer and cystic fibrosis, Duchene muscular dystrophy. [Gezondheidsraad 1944/22] . Genetic screening may be carried out at different stages throughout life and through the use of various techniques. One aspect of genetic screening is pre conceptional testing of potential parents by identifying their genetic traits, followed in certain cases by counseling on the risks of commencing a pregnancy. The aim is early detection of heightened risk of giving birth to children with a disorder which is untreatable and which could in [varying degrees] undermine the child’s quality of life and life span, depending on the severity of the condition. The other aspects are pre conceptional testing of the embryo in assisted reproduction [IVF], referred to as pre implantation diagnostic [PID] pre natal testing of fetus during pregnancy, referred to pre natal diagnosis [PND] and post natal screening, either of neo natal or in later life. Many of these tests are based on eugenic bias and on assumptions about the quality of life of people with a handicap

Genetic Counseling.

Assessed an arm of public health, the role of medical counseling plays important role with practical ethical and legal problems Modern genetic counseling involves more than merely quoting risks. The idea is to avoid a directive approach but rather, to concentrate on the psychological circumstances so that couples can be led to make decisions which are right for them rather than right for scientists. Almost, inevitably, the counselor’s opinion will be sought and how this is reached depends particularly on whether the
counseling is retrospective or prospective — are parents seeking advice because they already have an affected child or is the need for consultation prior to parenting based on information derived from other sources.

Patient — clients who know that genetic disease might affect their family come, in the main, with a degree of preparedness and an appreciation of their future options.

The role of counselor assumes an entirely different mantle, however if he adopts the practice of privacy to information of which his client know nothing — perhaps as a result of a confidential discussion with another health professional; the question then arises as to whether and how such information should be imparted.

In assisting clients towards a reproductive decision, the counselor can virtually never make a firm statement as to having or not having a further child. He can take extraneous circumstances; e.g. religious or financial status — into consideration, but in the end he is down to speaking about probabilities.

The socio legal implications of prenatal diagnostic techniques are —

Basically pregnancy is a natural process and unless there are complications, one may ask it would not be better for a successful pregnancy and women should have her own strength to continue with her pregnancy. These techniques should be offered only when there is family history of genetic disorder or woman’s own obstetric history, or it is advisable to subject pregnant woman to medical interventions. By offering prenatal diagnostic techniques doctors play upon the anxieties /uncertainties of pregnant woman who learns to trust the technology more than herself. The technology changes the experiences of women. By making the foetus visible it allows some women to have a closer bonding with the child and at the same time, it calls into being new images /concepts of motherhood, new guidelines are drawn in pregnancy, particularly her relation to her foetus. The proliferation of PND technologies in the management of pregnancy has resulted in their indiscriminate use and loss of traditional way of looking at pregnancy, particularly her relation to the foetus. Instead every pregnancy is seen as suspect, or as a disease, which needs high tech management. The new technology in the hands of doctors destroys the old knowledge in the hands of women and midwives. Ultra-sound scanning has become quite a routine part of ante-natal care in Europe and the USA, which is referred as ‘‘a new pregnancy ritual’’. This
technique has gained world wide importance. Technologies expand medical control and intervention at a time when women are extremely vulnerable because they want the best for their future child. At present should such disposal run parallel with an increasing pre natal diagnostic capability when, as a result, more parents may reject what will be regarded as imperfect children?

PND offers the promise of 'perfect babies ' it creates a social climate where the birth of a handicapped child is seen as 'missed prevention. It creates a tension between individual needs and needs of society. In this sense the right to choose has become restrictive and it is imposed choice. It is a relative right of freedom. The only choice available to woman is to abort in the medical world pregnancy at present is being treated as a disease. PND poses a new problem since the 1980s of 'women's rights v foetal right within women's right to abortion'. At present these tests should be used for useful purposes and they should be weighed against the disadvantages, including health risks. Technologies such as IVF and pre natal diagnosis techniques give embryos and foetus a new sense of identity. The foetus has come a long way from Biblical 'seed' and mystical 'homunculus' to an individual with medical problems that can be diagnosed and treated, like a patient. [Harrison 1982, p.23, quoted in Rowland 1985].

Counseling and Negligence.
The parents of an afflicted child may choose to raise an action in negligence against a genetic counselor or doctor who has failed to advise them of the risk of genetic illness in their children or to carry out and interpret correctly, appropriate diagnostic procedures which would have disclosed abnormality in the fetus. The counselors or doctors owes them a duty of care in which he or she has been found wanting; the parents may contend that, as a result they may have been deprived of the opportunity to terminate the pregnancy and they are now burdened with the sick or handicapped child. Such an action, brought by and behalf of parents, is generally known as one for 'wrongful birth'. Damages may be sought in respect of the distress occasioned by the parents in respect of the existence of the defect in their child and for extra costs which are entailed in bringing
up the child. The Courts in United States, which can be seen as pathfinders in this particular area, have had a roller coaster ride on their way to recognize damages for the birth of a handicapped child as a legitimate claim.

In Becker v. Schwartz [386 NE 2d [NY, 178]

The New York Courts of appeal allowed a parental claim for damages in respect of the cost of the institutional care of a child suffering from a Down's syndrome.

The negligence in question was the failure of the doctor to recommend amniocentesis to a 37-year-old mother, who by virtue of her age, had a relatively high risk of bearing a handicapped child.

The important conflicting questions are:

- The question of public policy which should in theory favor birth over abortion.
- The woman's prerogative to control her own body and the consequent acceptability of abortion is recognized.

The general rule which seems to have emerged is that, while wrongful life actions will fail, the corresponding claim for wrongful birth will succeed.

Even so, the causation problem remains. For example;

- In Nocash v. Burger 290 SE 2d 825 [Va, 1982] widely based damages were awarded for the birth of an infant with Tay-Sachs disease but costs concerned with child's funeral were disallowed on the grounds that the fatality was the result of hereditary factors rather than defendant's negligence.

- The other difficulties relate to the fact that pregnancy has been actually sought in these cases.
- Should damages awarded then reflect the full costs of rearing a defective child or should they be limited to the difference in financial burden posed by a normal and handicap infant.
- Should they extend to compensate for emotional distress?

These questions are fairly balanced by American Courts and it should be noted, that they will accept a wrongful birth action in principle in most cases.
Comparable cases have been rare in the United Kingdom but the Courts have shown increased willingness to address the problems in recent years and damages are awarded in respect of negligent counseling; in other words, a wrongful birth action is available in the United Kingdom. In Salih v Enfield Health Authority [1990] 1 Med LR 333; on appeal [1991] 7 BMLR 1, CA.

In this case it should be noted that the trial judge awarded damages which included the basic costs of maintaining a child, the Court of Appeal, however held that the family had been spared the cost of a normal child and this head of damages was extinguished.

The case involving the congenital rubella syndrome is apposite in this that the liability was admitted without question.

Diminished or wrongful life actions
The basis of parental claim may be clear enough, but what is the juristic nature of the claim brought on behalf of the child itself. The status of the fetus in utero is legally established – the fetus has a general right not to be injured by the wrongful act of third party. This right was recognized at common law in Canada and in Australia in two important decisions, Duval V Seguin [1973] 40 DLR [3d] 666 and Watt V Rama [1972] VR 353. Similar recognition is afforded to the fetus by the common law in Scotland and has been held retrospectively to have existed in England prior to Congenital Disabilities [Civil Liability] Act 1976. The most important aspect of these rights in the present context relates to the responsibilities of the mother to her fetus. The Law Commission considered this question and decided that an action against its mother in respect of damage resulting from her negligence during pregnancy should not be available to a child. It was felt that a claim of this type would comprise the parent – child relationship and might also be used as a weapon in matrimonial disputes. Accordingly, the English legislation excludes claims by a child against its mother except as to injuries sustained during traffic accidents, especially on policy grounds and the availability of insurance were held to justify admissibility of such claim. It is difficult to determine the extent to which the mother's duty of care towards her unborn child might be held to limit her freedom of action during pregnancy. In recent years the fetal maternal relationship has been escalated. A child born with abnormality may urge that some other sort of wrong
has been done to it. First, he or she may claim that there was negligence prior to its conception and this negligence has resulted in its being born with certain abnormalities. The child may also bring a claim in respect of its wrongful life, the basis of claim is that, through the negligence of the defendant, the child's parents were not afforded to terminate pregnancy; as a result the child seeks damages for the impaired existence and he or she is forced to live brutally, he or she would rather never had been born. The negligence in question may occur either before the child's conception, as for example - genetic counseling or after conception --- where doctor fails to detects an abnormality in the fetus. A high proportion of such cases result from laboratory errors which are in general recognized as negligent. The early history of the wrongful life action can be traced through the United State Courts. Suits brought by defective children, however pose difficulties with which the American legal system has been struggling for many years.

The Legal Position of the Clinician

The procedures involving gamete donation carry the risk that the gametes themselves may be defective. Moreover, all those involved in vitro embryo transfer introduce the additional hazard that the embryos will be damaged either by the hormonal treatment required for super ovulation or during manipulation and that an abnormal fetus will result. Animal experiments indicated that there is no higher incidence of abnormalities in live born neonates resulting from re implantation than in those which are conceived normally. The HFEA'S Annual Report of 2000 quoted 120 children born as a result of IVF, DI or micro manipulation having developmental defects or syndromes – an occurrence of 1.3 per cent of babies born, which does not indicate any increased risk. The outcome of litigation following such a misfortune depends very largely on proof of causation. However, the grounds rules are very clear. Section 44 of 1990 Act applies the Congenital Disabilities [Civil Liability] Act 1976; s. 1 is applicable to infertility treatment. If a child resulting from embryo transfer, GIFT, micromanipulation of DI is born disabled and the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of embryo or the gametes used by person answerable to the child, then the child's disabilities are to be regarded as damage resulting from the wrongful act of that person answerable to the child, and actionable at
the suit of the child. This does not apply that if one or both parents knew of the risk of their child being born disabled; particular importance is, therefore, likely to attach to the effectiveness of their consent in respect of the information given. This opens the door to an action for ‘wrongful life’. Under the French law the parents of a child born with a disability which remained undiagnosed during pregnancy due to serious professional fault can claim compensation for harm suffered by them personally but not for costs attributable to the child being Handicapped – these will be available through social service. Health care professionals providing infertility therapies should provide extensive information to the couple on the nature and risks as well as the potential success of the proposed procedure. Alternative means of treatment also should be discussed. The couple should be counseled together and individually to assure that one partner is not being pressured to undergo certain therapies. The institution should provide its success for various programs, some programs not yet reporting a pregnancy. Information should be given to patients concerning embryo discard, storage, donation, research, and cost to themselves. The couple should be counseled to prepare a directive for embryo disposition in the event of divorce or death. The information should include which techniques are available; data on the risk of infection, spontaneous abortion, stillbirth, and so forth; an explanation of the psychological risks of participating in the procedures; and the type and purpose of research if it is being conducted. Federal law requires each assisted reproductive technology program to report pregnancy success rates to the U.S. Centers for Disease Control and Prevention (CDC), which shall make the information publicly available. The same law requires the CDC to develop a model program to be carried out by the states for the certification of embryo laboratories the embryos for subsequent implantation, terminate them, donate them to another woman, or donate them for research. Whereas clinics previously limited the couple’s choice to implantation or termination, donation is now common.

The American Fertility Society [AFS] and the American Association of Tissue Banks [AATB] are professional organizations. They have enumerated guidelines for the performance of reproductive techniques by the physicians and the standard of care that must be met.

A Louisiana law codifies such standard by specifically addressing the qualifications of
professionals and standards for facilities performing IVF; the facilities must meet the
standards of the American Fertility Society and the American College of Obstetrics and
Gynecologists; the director of the facility must be a "medical doctor licensed to
practice medicine in this state and possessing specialized training and skill in in vitro
fertilization", and the physician performing such techniques are required to act "in
conformity with the standards established by the American Fertility Society or The
American College of Obstetric and Gynecologists.
The American Society for Reproductive Medicine [ASRM] and the [American
Association of Tissue Banks [AATB] have developed extensive screening guidelines.
They are -- ASRM suggests exclusion of sperm donors who are at the risk for having
sexually transmitted diseases. They also suggest re screening every six months and
discontinuing the use of a donor if he has a sexual partner or if there is break in
monogamy or abstinence. The guidelines also recommend rejection of donors with a
family history of certain enumerated genetic disorders as well as carriers of those
disorders. The AATB Reproductive Council standards recommend selection of donors on
the basis of "personal, physical and genetic examination and history". The guidelines
mandate rejection of a sperm donor if he is employed in a job that involves chemical or
radiation exposure or if he is an alcohol or drug abuser. Screening for infectious and
genetic diseases should be conducted on egg or embryo donors as well. Federal law
requires assisted reproductive technology programs to report annually to the Secretary of
Health and Human Services pregnancy of the program with each reproductive technique.
The report must also disclose the identity of each laboratory used by the program and
whether such laboratory is certified. As a part of certification standards, each lab shall
follow a standard program for quality assurance and quality control. In India infertility
treatment is very stressful for the patients and counseling is important. Most clinics do
not have a counseling facility for couples before and during IVF procedures. There are
no laws regarding the [misuse] of ART or use of donor eggs and sperm in India. And
the doctors feel that just assigned contract or a waiver form is enough. They believe that
regulation should suit the needs of everyone. Implementing ethical guidelines would
mean that the doctors would have to look critically at issues of "informed consent",
screening of donors, legal issues and the quality of services provided.
India has many infertility clinics however the facilities and the quality provided by these clinics do not match with similar clinics anywhere else in the world, the unfortunate element being is the lack of inadequate facilities and the staff.

It is widely known that many clinics, including some of those that have excellent facilities and staff, engage in number of unethical and illegal practices. Further lack of a system of supervision and accreditation and supervision of clinics that handle gametes in vitro and practice ART, has the potential of leading to several undesirable situations.

India unfortunately has a history of female infanticide and sex – selective abortions of female fetuses. The new law against sex –selective technologies now includes technologies like pre implantation diagnosis, but it remains to be seen if it is deterrent. Legal battles regarding ART and surrogate motherhood have been going in the West, but it will not be long before similar problems are faced by the Indian society. A set of rational and consistent policies are required. There should be focus on non – technological solutions such as preventive measures for infertility, adoption of children of all sexes, raising consciousness to reduce the social pressures for biological parenthood and on protesting against perverse use of ART.

Amniocentesis is advocated as a method to so – called ‘balanced family’ this concept of a balanced family has a clear sexist bias. Sex determination tests do not guarantee the birth of a male child Therefore, a woman is likely to have more abortions, not for medical or social reasons but to achieve so called ‘balanced family’. India has an already low and almost steadily decreasing female – male sex ratio in contrast to most developed countries 972; 1000 in 1901, 927;1000 in 1991 [GOI 1991 Census figures. ] These practices of sex` selection, and sex selective abortions of female fetuses, female infanticide is likely to have serious demographic repercussions in terms of tilting the sex ratio further against females. In October 1985, The Forum against Sex determination and Sex Pre Selection Techniques [FASDSP] was formed. It was heterogeneous group of men and women with varied interests and backgrounds; feminists, women’s health activists, lawyers, doctors, people involved in human rights, movement the People’s Science Movement and so on. A campaign was launched by holding a workshop on 8th April 1986, in Bombay where the technical, social, legal and social aspects were discussed. A counter – advertisement campaign in Bombay’s local trains was mounted
against the blatant advertising of tests on bill boards in public places. This forum raised issues on several planes—on equality of sexes, health, human rights, democracy and issues concerning decision making on vital issues like technology use, and in particular reproductive technologies. They raised issues at an ideological level, with regard to health of women. A private member’s bill was introduced in the Maharashtra State Legislative Assembly to demand a ban on Sex.

Determination Practice.

Sex determination tests were banned in State of Maharashtra on 10 May 1988 under the Maharashtra Regulation of Use of Pre NATAL Diagnostic Techniques Act. This Act provided for regulation of genetic counseling centers, genetic laboratories and genetic clinics. Pre natal diagnosis was to be conducted only for specified and under certain conditions offending the law would be punishable by imprisonment, fines, and punishment by the State Medical Council. Finally on 26th July 1994 the Indian Parliament finally passed legislation for all—India ban on these tests. The Indian Council of Medical Research provides guidelines for Accreditation, Supervision and Regulation of ART clinics in India.

CHAPTER 9  SUGGESTIONS AND RECOMMENDATIONS.

On the basis of survey and data analysis the researcher would state that ART is the need of the day. It provides assistance to infertile couple for their ray of hope and happiness is a healthy child and healthy family. But the advent of these technologies has led to several socio legal concerns as they interfere with the private lives of individuals. The practice of Assisted Reproductive Technique no wonder is misused in different forms.

- Eggs and embryos given to another woman or to researchers.
- Medical records missing
- Surrogate mothers refuse to impart with their new born babies.
- Fertility drugs sold illegally.
In India it is thereby strongly recommended that if the interests of the infertile couples are to be protected then effective legislation is the need of the day. There should be licensing and accreditation of ART centers for regulating and ensuring ethical practices in Art clinics and cryo banks. To fix charges for gamete donation and surrogacy. Central repository to be maintained by ICMR. To facilitate dialogue with various IVF centers. Further to develop National ART Registries and National ART surveillance programs. There should be linkage between Art registries and national health registries. To generate national database on pregnancy and neonatal outcome, birth rate singleton/multiple births, complications of pregnancy and fetal reductions. Further treatment should be provided to lower income groups. Legislations for holding medical practitioners practicing ART to be accountable and liable for negligence. It is for the state to protect and balance the best interests of infertile couples for happy family with a healthy child. This is necessary for development of any State.\(^\text{16}\)

\(^{16}\) Indian Council Of Medical Research; National Guidelines for Accreditation, Supervision and Regulation of ART clinics in India. (2002).