Chapter-II

Conceptual Framework of Infertility and Assisted Reproductive Technology

2.1. Introduction

From the time immemorial women have been considered as a child bearer. The identity of women has always been confined with her ability to have a child. It was as essential as her inability to bear a child is considered as a social stigma. In primitive societies, the women’s inability to conceive a child was called as barrenness. The inability to have a child caused cultural, social and religious pressure upon the married couples compelled them to go to any possible extent to remove this social stigma of barrenness. In India, the sacred duty of a women, enshrined in religious scriptures of Hindus, Muslims, Sikhs and Christians is to bear a child. In ancient India, a husband could tie up his childless wife and burn her.\(^1\) A woman who does not give birth to a child, or is unable to have a child, is automatically relegated to a low status in the family and may also face social ostracism and desertion. Women without children are viewed as inauspicious and excluded from certain religious functions.\(^2\) This chapter provides conceptual framework to infertility, its causes, its consequences and the role of ART in treating infertility, its development, various techniques and procedures also.

2.2. Historical account of Infertility

Historically, hysteria was the earliest reason of barrenness. It was felt that women would develop hysteria which at the time thought to a wondering uterus because of being deprived of sexual relation. Later it was felt that it was God’s will that made women childless, it was up to God only to bless them with children like he did for sarah & other barren women in the Bible. The ancient world looked harshly on women like Rachel. Because fertility remained so closely tied to womanhood, childless women regarded with a mixture of pity and scorn. The Bible paints childless women as tragic and incomplete; ancient Egyptians described them as “mothers of the missing ones”. Frequently, infertile or “barren,” wives were compared with their


\(^2\) Sandhya Srinivasan, *Making Babies: Birth Markets and Assisted Reproductive Technologies in India*, (2010, New Delhi, Zubaan) at XII.
agricultural equivalents: a “field without crops” according to many depictions, or a “tree without leaves.”

For thousands of years and millions of infertile women, therefore, infertility remained a silent and irrevocable curse. Shamed by their condition, childless wives confessed their problem to midwives or shamans or quacks, willing to engage in whatever remedies were thrust upon them. They drank potions of mule urine and rabbit blood and doused themselves with herbs believed to induce pregnancy. They kissed trees, slid on stones, and bathed themselves in brackish water, thought to resemble the blood of childbirth. When all else failed, they prayed, adopted, or, like Rachel, employed another woman to bear her child. This situation was gradually changed in the late seventeenth century, when science described procreation as a physical blending of male and female “semen,” the seeds that were purportedly released by both partners in conception. Now infertility was treated not as an act of God, sin, or malice but rather as a physical condition amenable to scientific remedy.

In the eighteenth and nineteenth centuries, women who suffered from “obstructions” or “female weakness” were regularly advised to get exercise, take cold baths, or confine themselves to bed. By the 19th century, people were turning to physician for treatment of infertility. During World War II the bearing of children was seen as a patriotic duty and it soon became an obsession. During this time, childless couple was seen as socially maladjusted. The post world war was the period of pronatalism. Pronatalist believed that a couple who doesn’t want to have a child is not normal but by bearing children a couple could be seen as normal. It shifted the childlessness as being a medical problem. Thus, the social construction of parenthood has forced the medicalisation of infertility. Now infertility was considered as a fairly straightforward, utterly physical condition. Childlessness which was once seen as a social problem has now become a medical problem.

In a patriarchal society like India where motherhood and child bearing is closely associated with identity of a woman, childlessness and infertility is perceived as a stigma. Infertility can be threaten a women’s identity, status and economic security and consequently, be a major source of anxiety leading to lowered self-esteem and a sense of powerlessness. The infertile women could also be victims of

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3 Supra note 1 at 06.
4 Id at 8.
violence, desertion and social and religious exclusion. In India, a wide of fertility technologies—that can include everything from herbs to homeopathic pills to hormone injections and microsurgery—are easily available and are provided by licensed and unlicensed practitioners.

The patriarchal notion of women being destined to bear children, that too at the “right time” and of the “right gender” is the driving force behind the anxiety that is created around infertility. The socially constructed compulsion to procreate and the extreme forms of ostracism and victimisation that it can take, drive women to fertility clinics. Consequently, the anxiety about fertility is such that women who do not conceive within a few month of marriage often seek help from practitioners of various systems of medicine, and participate in religious rituals, all aimed at enabling them to give birth to a child. Women who approach western or allopathic providers are likely to be subjected to various tests, drugs and procedures. They might be given drugs to induce ovulation, they might undergo artificial insemination, or they may have surgery to open up blocked fallopian tubes.\(^5\)

2.3. Defining Infertility

Essentially, infertility results when a given couple is unable to produce a viable embryo-a sixteen-cell mingling of egg and sperm that will subsequently embed itself in the mother’s womb and evolved into a living child.\(^6\) The American Society for Reproductive Medicine (ASRM) defines infertility as, “a marriage is to be considered barren or infertile when pregnancy has not occurred after a year of coitus without contraception.”\(^7\) Infertility is a worldwide problem affecting 8-12 percent couple (50-80 million) during their reproductive lives.\(^8\) The WHO definition drawn up by the scientific group on epidemiology of infertility has classified infertility into primary and secondary and defined as:

- Infertility can be primary if the couple has never conceived despite cohabition and exposure to pregnancy (not contracepting) for a period of two years; primary infertility is also referred as primary sterility.

\(^5\) Supra note 2 at XII.
\(^6\) Supra note 1 at 14.
\(^7\) Melvin L. Taymor, *Infertility: A Clinician’s Guide to Diagnosis and Treatment*, (1990, New York, Plenum Medical Book Company) at 11, Quoted in supra note 1
Infertility can be secondary if a couple fails to conceive following a previous pregnancy, despite cohabitation and exposure to pregnancy (in absence of contraception, breast feeding or postpartum amenorrhoea) for a period of two years that is also known as secondary sterility.

While WHO defines infertility as failure to conceive despite two years of cohabitation and exposure to pregnancy, many studies adopt their own definitions. Childlessness is defined as the proportion of couples who have not had a live birth by the time of interview, despite at least five years of cohabitation and exposure to pregnancy, and in the absence of contraception, breastfeeding or postpartum amenorrhoea. Unlike a couple with primary infertility, a childless couple also includes those who have successfully conceived but have failed to deliver a live birth. Similarly, secondary sterility to couples having difficulty bearing a second or higher order birth, despite usually five years of exposure, as in the definition above. The five year reference period is typically used, but not necessarily, in demographic surveys.  

A simple definition of infertility may be that a couple have failed to conceive after twelve months of unprotected sexual intercourse or have suffered three or more miscarriages.

### 2.4. Causes of Infertility

The exact cause of infertility is unknown. According to National Institute of Clinical Excellence (NICE) in 27 per cent of cases the medical cause is ovulatory disorders; in 14 percent tubal damages; in 19 per cent low sperm count or quality; and in 30 per cent of cases it is not possible to identify a physical cause. The Human Fertility and Embryology Authority (HFEA) state that in 49 per cent of cases the medical cause of the infertility rest with the man. What is unknown is what causes these problems to arise. There is, no doubt, a plethora of different reasons ranging from obesity; smoking; heavy alcohol use; tight underwear; to delaying the age at which women seek to start a family.  

The three most important risk factors for infertility in both men and women are advancing age, smoking and obesity. In India,

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the exact cause of infertility may be varying. According to WHO multi centric studies in India, 40% women and 73% of men had no demonstrable cause of infertility. 11

It is commonly accepted that infertility affects more than 80 million people worldwide. The Human Fertilisation and Embryology Authority states that in 32 percent of the cases the medical cause of infertility rests with men, 32 percent with the women, and 10 percent with both. 12 In the US, according to the National Survey of Family Growth, 17 per cent of all married women suffered from infertility impaired fecundity in 2002. 13

There is little evidence on the levels and patterns of infertility in India. According to studies conducted by WHO, the extent of primary and secondary infertility in India is 3 and 8 per cent respectively. Recent NEHS data, using childlessness as an indicator, estimates that 3.8 per cent of currently married women between the ages of 40-49 are childless. Based on 1981 Census data, childlessness amongst ever-married women in India is estimated to be about 6 per cent. 14 A range of demographic, behavioral and socio cultural factors have been identified as potential determinants of infertility. Among the recognizable correlates of infertility are:

1. Sexually transmitted diseases which account for an increasing proportion of infertility in developing countries. In particular, previous history of STDs is associated with such conditions as tubal factors in the female partner (in particular tubal occlusion or pelvic adhesions) and obstruction or gland infection in the male partner; the major STDs being gonorrhoea and chlamydia.

2. Maternal health factors such as unhygienic delivery, postpartum infection, and unsafe obstetric and abortion procedures are observed to be linked to sepsis and pelvic infections; severe malnutrition and anemia are also observed to affect infertility; as do such morbidities as tuberculosis. Women's poor health and nutrition status can lead to repeated miscarriages and foetal wastage. The most commonly observed link is that between post-partum or post abortion complication and tubal blockages or pelvic infection that in turn cause infertility.

13 Supra note 1 at 02.
14 Supra note 2 at 08.
3. Age, adolescents are frequently observed to be temporarily in fecund (adolescent sterility); so also, infertility increases among older women who become prematurely menopausal. A woman’s fertility peaks between ages twenty and twenty-four. By age thirty-five, her fertility is only 80 percent of what it was at her peak. By age forty-five, a woman may be 95 percent less fertile than she was at age twenty.\(^{15}\)

4. Lifestyle is sometimes held to be related to infertility -- smoking, alcohol consumption, drug use and even over exercise. Smoking contributes to infertility in women by increasing the rate at which their eggs deteriorate. This leaves fewer ova to mature to ovulation. It also increases a woman’s risk for miscarriage and ectopic pregnancy (when the embryo implants inappropriately in the fallopian tube). The chemical by-products of smoking may keep female fetuses from forming normal amounts of ovarian tissue, so they then have far fewer primordial follicles at birth. Smoking contributes to infertility in men as well. Male smokers have many more misshaped and non motile (not capable of moving) sperm than nonsmokers.\(^{16}\)

5. Side effects of previous contraceptive use: for example large numbers of women with pelvic infections in India had undergone vaginal tubectomy or minilaparotomy.


7. Occupational patterns and exposure to noxious chemicals or pesticides in the work place.

To this list we can add, as background determinants, the availability, accessibility and quality of reproductive health services, including information and referrals on the one hand, and levels of education, household economic status and women’s autonomy on the other. This list is not exhaustive, since determinants of infertility vary widely with culture.

2.4.1. Causes of Male Infertility

Infertility is a widespread problem. For about one in five infertile couples the problem lies solely in the male partner (male infertility). A man may be infertile if he does not produce enough sperm or if many of the sperm he produces are misshaped or non motile. Falling sperm counts are a "serious public health warning", and the trend could be linked to diet, lifestyle and possibly even tight underwear, a major French

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\(^{16}\) Ibid
study has revealed. The study showed that sperm counts and quality have fallen sharply since the start of the 1990s. Between 1989 and 2005, average sperm counts fell by a third in the study of 26,000 men, increasing their risk of infertility. A variety of disorders ranging from hormonal disturbances to physical problems, to psychological problems can cause male infertility.

2.4.1.1. Hormonal Problems:

A small percentage of male infertility is caused by hormonal problems. The hypothalamus-pituitary endocrine system regulates the chain of hormonal events that enables testes to produce and effectively disseminate sperm. The following is a list of hormonal disorders which can disrupt male infertility:

I) Hyperprolactininemia  
II) Hypothyroidism  
III) Congenital Adrenal Hyperplasia  
IV) Hypogonadotropic Hypopituitarism  
V) Panhypopituitism

2.4.1.2. Physical Problems

A variety of physical problems can cause male infertility. These problems either interfere with the sperm production process or disrupt the pathway down which sperm travel from the testes to the tip of the penis. These problems are usually characterized by a low sperm count and/or abnormal sperm morphology. Causes of low sperm production range from serious problems such as pituitary gland dysfunction to genetic disorder. The following is a list of the most common physical problems that cause male infertility:

I) Variocele  
II) Damaged Sperm Ducts  
III) Torsion  
IV) Infection and Disease  
V) Klinefelter’s Syndrome  
VI) Retrograde Ejaculation

2.4.1.3. Psychological/Physical/Behavioral Problems:

Several sexual problems exist that can affect male fertility. These problems are most often both psychological and physical in nature: it is difficult to separate the physiological and physical components.

I) Erectile Disfunction (ED)

II) Premature Ejaculation

III) Ejaculatory Incompetence

2.4.2. Causes of Female Infertility

Ovulatory disorders are one of the most common reasons why women are unable to conceive, and account for 30% of women's infertility. Fortunately, approximately 70% of these cases can be successfully treated by the use of drugs such as Clomiphene and Menogan/Repronex. The causes of failed ovulation can be categorized as follows:

2.4.2.1. Hormonal Problems

These are the most common causes of an ovulation. The process of ovulation depends upon a complex balance of hormones and their interactions to be successful, and any disruption in this process can hinder ovulation. There are three main sources causing this problem:

- Failure to produce mature eggs
- Malfunction of the hypothalamus
- Malfunction of the pituitary gland

2.4.2.2. Scarred Ovaries

Physical damage to the ovaries may result in failed ovulation. For example, extensive, invasive, or multiple surgeries, for repeated ovarian cysts may cause the capsule of the ovary to become damaged or scarred, such that follicles cannot mature properly and ovulation does not occur. Infection may also have this impact.

2.4.2.3. Premature Menopause

This presents a rare and as of yet unexplainable cause of anovulation. Some women cease menstruation and begin menopause before normal age. It is hypothesized that their natural supply of eggs has been depleted or that the majority of cases occur in extremely athletic women with a long history of low body weight and extensive exercise. There is also a genetic possibility for this condition.
2.4.2.4. Follicle Problems

Although currently unexplained, "unruptured follicle syndrome" occurs in women who produce a normal follicle, with an egg inside of it, every month yet the follicle fails to rupture. The egg, therefore, remains inside the ovary and proper ovulation does not occur.

2.4.2.5. Environmental and Occupational Factors:

The ability to conceive may be affected by exposure to various toxins or chemicals in the workplace or the surrounding environment. Substances that can cause mutations, birth defects, abortions, infertility or sterility are called reproductive toxins. Disorders of infertility, reproduction, spontaneous abortion, and teratogenesis are among the top ten work-related diseases and injuries in the U.S. today. Despite the fact that considerable controversy exists regarding the impacts of toxins on fertility, four chemicals are now being regulated based on their documented infringements on conception.

- **Lead**

  Exposure to lead sources has been proven to negatively impact fertility in humans. Lead can produce teratospermias (abnormal sperm) and is thought to be an abortifacient, or substance that causes artificial abortion.

- **Medical Treatments and Materials**

  Repeated exposure to radiation, ranging from simple x-rays to chemotherapy, has been shown to alter sperm production, as well as contribute to a wide array of ovarian problems.

- **Ethylene Oxide**

  A chemical used both in the sterilization of surgical instruments and in the manufacturing of certain pesticides, ethylene oxide may cause birth defects in early pregnancy and has the potential to provoke early miscarriage.

- **Dibromochloropropane (DBCP)**

  Handling the chemicals found in pesticides, such as DBCP, can cause ovarian problems, leading to a variety of health conditions, like early menopause, that may directly impact fertility.

2.5. Consequences of Infertility

Infertility has severe consequences for men and particularly for women's wellbeing. Childlessness has serious demographic, social and health implications. The
ease with which women can be labelled infertile or resist the label, the experiences of childless women and the process of seeking solutions for infertility all go beyond the biological fact of reproductive impairment.\textsuperscript{18} Infertility almost always leads to decreased levels of personal well-being and for many individuals it causes significantly more severe consequences. The "blame" for infertility is unquestioningly placed on the woman. Some of the more commonly expressed consequences of infertility include:

\subsection*{2.5.1 Marital Instability}

A study in Andhra Pradesh, reported that 70\% of women experiencing infertility would be punished with physical violence for their "failure" and nearly 20\% of these women reported that they suffered severe violence at the hands of their husbands as a result of being childless. Some Indian women have reported not being allowed to hold new-born relatives or participate in infant naming ceremonies because of superstitious fears that a new child will die in the arms of an infertile woman. In Andhra Pradesh infertile women reported feeling isolated and ashamed with actual and anticipated rude comments at social functions forcing some women into social reclusion.\textsuperscript{19}

\subsection*{2.5.2 Emotional Harassment}

Harassment comes in many forms: ostracism from family celebrations, taunting and stigmatisation, negative attitudes, as well as beating, withholding of food and health care. One study of gynaecological morbidity in the slums of Baroda has observed in focus group discussions and case studies that emotional harassment is often expressed by infertile women.\textsuperscript{20} As a result of taking responsibility for the emotional impact of the infertility, the woman experiences intense feelings, such as pain, anger, fear, etc., which, combined with the messages that her way of dealing with things is in some way dysfunctional or "crazy", causes her to feel an anxious depression.

\subsection*{2.5.3 Loss of Self-esteem}

Infertility is clearly a major event, and often perceived as a crisis. Studies have highlighted the low self-esteem, security and self-confidence that prevail among the

\textsuperscript{18} Supra note 8 at 132.
\textsuperscript{20} Supra note 8
childless women. The inability to perform their roles as child bearers and rearers, and
the common misconception that infertility is always the shortcoming of the female is
observed to take a huge toll on the woman in terms of loss of self esteem, grief, and
feelings of failure. Incidents reported in India in which the presence of childless
women at joyful occasions is perceived as inauspicious must reinforce feelings of
inferiority. Yet, few of these consequences have been studied in the South Asian
context. 21

2.6 Treatment of Infertility

By the turn of twentieth century, however, matters had begun to change. For
the first time, doctors and scientists started to grapple with the physical cause of
childlessness and with various treatments that actually worked. As these treatments
evolved, they formed the critical supply side of the fertility industry, allowing demand
at last to meet its match. Three developments in particular gave birth to the baby
business. First was the increased understanding of the biology of reproduction.
Second were the discovery of hormones and the development of endocrinology.
Third, and the most spectacular, was the invention of in vitro fertilization, a technique
that shocked the world in 1978 and thrust the business of baby-making into a political
and social maelstrom. 22

Amongst the different stages involved in human reproduction, the process of
fertilization is one of the most important. During sexual intercourse, the sperm of a
man enters the female body's vagina via the cervix. The process of ovulation also has
a very important role to play in human fertilization. It is during ovulation that a
mature ovum is released into the fallopian tube. It is important for an ovum to be
available for the process of fertilization to be initiated. It is the ovum which is
fertilized by the sperm and which results in the formation of the zygote, embryo and
finally the foetus. During the sexual intercourse, millions of sperms are released. But
only one of the sperms is able to fertilize the ovum or the female egg. The process
of human fertilization of the ovum by the sperm takes place in the fallopian tube.
Fertilization involves the fusion of the nuclei of the sperm and the ovum leading to
the formation of the zygote. Once the zygote is formed, it moves towards the uterus.
After numerous transformations, the zygote is transformed into an embryo which

21 Supra note 1 at 17
22 Ibid
remains attached to the inner linings of the uterus. Finally the embryo develops into a foetus and about nine months later childbirth takes place. Assuming the both partners produce normal gametes, timing becomes the key element in conception. An egg and sperm have to merge at just the right time and in just the right place for normal conception to occur.

2.6.1. Hormonal Balance

Technically human reproduction depends on a complex and intimate blend of hormones. The hypothalamus and the pituitary gland together regulate the formation and release of hormones. The process begins in the brain, where tiny hypothalamus gland secretes a substance known as gonadotropin-releasing hormone. This hormone prompts the pituitary gland to produce two other hormones: follicle-stimulating hormone (FSH) and luteinizing hormone (LH). This “push-pull” interplay of messages and responses produces the cyclical hormonal environment in the woman that is designed solely to promote pregnancy. There are two primary sex hormones in the female, estrogen and progesterone. Essentially, estrogen is a substance that launches conception: once the ovarian follicles receive the appropriate hormonal signal, they produce estrogen and release an egg into the fallopian tubes. Progesterone, by contrast, typically ends the cycle, preparing the womb for pregnancy and preventing more eggs from ripening. In men, FSH and LH trigger the production of testosterone and influence the production and maturation of sperm. For conception to occur, all these hormones must be secreted in the right amount and concentrations, at precisely the right time. If any of the hormones is missing or weak or overactive, the entire process stalls and pregnancy becomes virtually impossible. In about 10 to 15 percent of all pregnancies, the embryo fails to implant because the amount of hormones produced and the timing of their release were not perfectly synchronized. These processes became better understood due to scientific experiments, so actual “cures” for infertility suddenly seem possible. Because if the reproductive cycle depended on the interaction of particular hormones and if these hormones could be extracted or synthesised in the laboratory, then treatment became akin, theoretically at

23 Available at http://www.pregnancyxl.com/pregnancy/fertilization-process/ visited on 30/08/2012 at 5:20 P.M.
24 Supra note 15 at 10.
25 Supra note 1 at 20.
least, to normal pharmaceutical procedure of identifying the problem, prescribing the proper medication, dosing to patient and awaiting the result. Such treatments made it possible to re-create the hormones in the laboratory and controlling the amounts also.

2.6.2 The Test Tube Baby

The third major development in the field of infertility was the announcement by John Rock, in 1944, that he and his research assistant had managed to fertilize four human eggs in vitro. Using egg donated from women undergoing hysterectomies, Rock and his assistant had matched the eggs in a petridish with semen left over from earlier artificial inseminations. After more than a hundred attempts, four of the matches worked, combining to create tiny fertilized ova. The results were greeted, not surprisingly, with a mixture of awe and horror.\textsuperscript{27} Aldous Huxley introduced the term the term “test tube” babies in his 1932 novel “Brave New World”, in which he described a world where children were fertilized and incubated in artificial wombs. The term “test tube” baby refers to fertilization that take place outside of the womb.\textsuperscript{28} In vitro (literally means in glass) fertilization started the science of assisted reproductive technology. On July 25, 1978, Louise Brown the first test tube baby was born in Oldham, England. Only two years after Louise Brown’s birth, doctors in Melbourne, Australia, announced the birth of Candice Elizabeth Reed. Eighteen months later, America’s first test tube child, Elizabeth Jordan Carr, entered the world. By the spring of 1983, roughly one hundred fifty babies have been conceived in vitro.\textsuperscript{29} In India, the first test tube baby was born on August 6, 1986. Three decade have passed since, the first test tube baby was born. Since 1978, IVF has led to the birth of approximately three million infants worldwide. IVF has made it possible for same sex lesbian and gay male couples to have children biologically related to them.

Women in India go through various treatments to avoid the adverse consequences of infertility ranged from traditional methods to modern technologies. The rise of assisted reproduction draws strength and encouragement from concepts deeply rooted in our tradition and culture-patriarchal stereotypes, the notion that motherhood is an essential part of being a woman, and the deep rooted performance for male children. The importance of and desire for having a biological child cuts

\textsuperscript{27} Supra note 1 at 22.
\textsuperscript{28} France Winddance Twine, Outsourcing the Womb: Race, Class, and Gestational Surrogacy in a Global market, (2011, New York and London, Routledge, Taylor & Francis Group), at 4
\textsuperscript{29} Supra note 1 at 28.
across all class, caste and community groups and couples are willing to go to considerable lengths to achieve this.\(^{30}\) In 2004, more than one million Americans underwent some form of fertility treatment, participating in what had become a nearly $3 billion industry.\(^{31}\)

However, the medical profession has hailed ARTs (assisted reproductive technology) as “miracle cures” that “treat” infertility successfully. While underplaying the potentially serious risks and concerns that the use of these technologies poses to the health of the women subjected to them, the medical profession has actually joint hands in the promotion of these technologies. The Godlike status accorded to doctors puts them in a privileged position to use these technologies without much questioning from couples seeking help. And they-the doctors, that is- dismiss these ethical and health concern by claiming that if the couples wish to have this particular treatment, who are the doctors to decide otherwise or deny it to them? After all, they explain, it is the greatest accomplishment to help a women have a baby-to give her the joy of motherhood. When doctors make such statements they are retelling the mythology of motherhood: society’s insistence that a woman is not a woman until she becomes a mother.\(^{32}\)

The United Nations Declaration of Human Rights, 1948 recognizes that, “Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family”.\(^ {33}\) The European Convention on Human Right also guarantees respect for family life and the right to find a family.\(^ {34}\) In all societies reproduction is considered one of the main rationales for marriage. Likewise, the family is the most widely approved social context for having children. The family gives a person a legitimate legal status and social approval for parenthood and reproduction. A family is never complete without a child and infertile couples go for various methods to have a child. The assisted reproductive technologies challenge traditional understandings of family and have thus entered the debate about family with great force.

\(^{30}\) Supra note 15 at 10.

\(^{31}\) Supra note 1 at 3.

\(^{32}\) Supra note 5 at xiv.

\(^{33}\) The UN Declaration of Human Rights, Article 16.1

\(^{34}\) The European Convention on Human Rights, Article 12 said: Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.
For many years, adoption was the only way that an infertile couple could build a family. It was seen as a last resort for an infertile couple. Though not perceived as an acceptable option, very few couple go for it as a last resort. Most of the infertile couples had a negative attitude towards adoption because of strongly rooted desire of biological progeny. While modern Hindu law does not prohibit any such arrangement, Islam and Christianity do. The Islam doesn’t permit mixing of genes and require each child to be related to a known father and mother. Islam does not allow a third party to intrude the marital function of sex and procreation. So, couples may feel that the bond between them is deepened if they have a biological link to the next generation, or they may simply feel shame at the inability to do something as natural as producing a baby. Some people without partners are content to stay single, but want to have their own-not someone else's-children. Whatever the reason, it is clear that people will go to considerable lengths to have children of their own.

Until recently, the treatment for fertility was mainly by medications to correct hormonal deficiency, or by surgery to correct anatomical defects. These treatments were mostly non-controversial from an ethical or religious point of view. Today, there is a vast variety of technologies. The recent advent of medically assisted reproductive technologies (ARTs), however, changed this situation dramatically. These technologies transferred the process of procreation from a private, personal relation between husband and wife, into artificial means in a lab, and, in many instances, involving a third or fourth party in the process. Assisted Reproductive technology is a significant development of medical science for formation of family and parenting. As Debora Spar says in The Baby Business, The science of procreation is new. It is a modern phenomenon, a post industrial miracle that emerged from the high technologies of bio-chemistry, microsurgery, and genetic engineering.” 35

Before the development of in vitro fertilization, infertile couple had few options for treatment. The three most effective procedures were intrauterine insemination, ovulation induction, and controlled ovarian hyper stimulation.36

2.6.3 Intrauterine Insemination (IUI)

In an Intrauterine Insemination cycle, a sample of motile sperm is prepared by the embryologist and placed directly inside the uterus using a very fine catheter. The

35 Supra note 1 at xvii.
36 Supra note 15 at 24.
sperm is deposited before the release of an egg or eggs, in a natural or stimulated cycle. Conception occurs naturally inside the body. IUI can be offered on a natural or stimulated cycle. On a stimulated cycle (super ovulation), the size and number of follicle are measured using ultrasonography; a Human Chorionic Gonadotrophin (HCG) injection is given to mature the eggs when the follicles reach a certain size. IUI is performed 24-36 hours after the administration of the HCG injection. The intrauterine insemination success rate is up to 20% per cycle. It is recommended that at least 3-4 cycles of treatment are attempted before considering other options. 37

Some men have low sperm counts but are potentially fertile if more sperm could reach their spouses' fallopian tubes. The procedure of intrauterine insemination takes all the sperm in an ejaculated specimen, washes out the semen, and concentrates all the sperm in a very small volume of fluid. This fluid is then injected into the uterine cavity of the woman at the time of ovulation. In addition to overcoming some of the sub-fertility associated with low sperm counts, IUI is also used in cases of cervical mucus problem and antisperm antibodies and for non specifically enhancing fertility. Intrauterine insemination (IUI) involves the placement of washed sperm into the uterus under ultrasound guidance to bypass the natural cervical mucus barrier. It is performed as an outpatient procedure with or without COH (Controlled ovarian hyperstimulation). 38 It is designed to bring a high concentration of sperm into close contact with one oocyte after natural ovulation or with multiple oocytes after COH.

2.6.4 Ovulation Induction

Ovulation induction is initially recommended for infertile women who do not ovulate on a regular basis. Oral medication that stimulate the pituitary gland to secrete large amounts of follicle stimulating hormone are prescribed for these women. Ovulation induction is usually combined with IUI to ensure that the large quantities of sperm are available at just and right time to fertilize the egg. Using this combination of treatments, about 8 percent of women get pregnant per cycle of medication. There is a 10 percent increased risk of conceiving twins. 39

39 Supra note 15 at 25.
2.6.5 Controlled Ovarian Hyper Stimulation

It is a procedure where ovaries are stimulated directly by large doses of injected FSH. Women usually ovulate as many as twenty to twenty-five eggs during the same cycle with this treatment. When combined with IUI, about 12 percent of women will conceive per cycle.\(^{40}\) It is a method of assisted reproductive technology consisting of carefully monitored administration of agents designed to induce ovulation by a greater number of ovarian follicles and thus increase the probability of an oocyte being fertilized, also called as controlled ovarian stimulation.\(^{41}\)

2.7 Assisted Reproductive Technology (ART) \(^{42}\)

Baby making, according to Debora L. Spar, in her book *The Baby Business*, is the oldest production known to the humankind, a process that is programmed into the biological fiber of our beings and defines our very survival.\(^{43}\) In the later years of 20\(^{th}\) century infertility has been treated as a medical problem that could be solved with medically assisted reproductive technologies (ART). Assisted Reproductive Technologies are a group of technologies, which assist in conception and pregnancy. It includes a range of techniques for manipulating eggs and sperms in order to overcome infertility. The term assisted reproduction refers to artificial insemination, IVF, GIFT, ZIFT, gestational surrogacy and other reproductive procedures. According to ART (Regulation) Bill 2010, “Assisted Reproductive Technology” (ART), with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or the embryo into the reproductive tract.\(^ {44}\) According to Uniform Parentage Act 2002 "Assisted reproduction" means a method of causing pregnancy other than sexual intercourse. The term includes: i) intrauterine insemination; ii) donation of eggs; iii) donation

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\(^{40}\) Ibid


\(^{42}\) The term generally refers to asexual reproduction-achieving pregnancy and birth without sexual intercourse. According to World Health Organization (WHO) definition, assisted reproductive technology refers to infertility treatments where both eggs (oocytes) and sperm are handled to achieve a live birth.

\(^{43}\) Supra note 1 at 01.

\(^{44}\) Sec.2 (c) of ART (Regulation) Bill 2010,
of embryos; iv) in vitro fertilization and transfer of embryos; and v) intracytoplasmic sperm injection etc.\(^45\)

Although various definitions have been used for ART, the definition used by CDC is based on the 1992 Fertility Clinic Success Rate and Certification Act that requires CDC to publish the annual ART Success Rates Report. According to this definition, ART includes all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman. They do not include treatments in which only sperm are handled or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved.\(^46\) Linda Bickerstaff recommends ART as a primary choice of treatment for a couple if there is the following:\(^47\)

- A female partner over the age of thirty-five
- A female partner with blocked fallopian tubes
- A female partner who does not ovulate
- A male partner who has a low sperm count

Assisted reproductive technologies are meant to address the agonizing problem of infertility and the powerful desire that many people have for children of their own, especially children with whom they have a biological link.\(^48\) The following are the different techniques of ART:

### 2.7.1. Artificial Insemination (AI)\(^49\)

It is the most commonly known method of medically assisted reproduction which has been defined as “the introduction of semen into the vagina other than by coitus.” In majority of the cases, the husband's sperm is used. The sperm is artificially placed into a woman’s cervix (intracervical insemination) or uterus (intrauterine insemination). During artificial insemination treatment, the woman’s menstrual cycle

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\(^{45}\) Sec.160.102 Uniform Parentage Act 2002.

\(^{46}\) “Assisted reproductive technology” [http://www.cdc.gov/art/](http://www.cdc.gov/art/) visited on 01/02/2012 at 10:54 a.m.

\(^{47}\) Supra note 15 at 28.


\(^{49}\) “Artificial insemination”, means the procedure of artificially transferring semen into the reproductive system of a woman and includes insemination with the husband’s semen or with donor semen;
is closely monitored using ovulation prediction kits (OPK), ultrasounds, and blood tests. The semen to be implanted is “washed” in a laboratory, which increases the chances of fertilization while removing unnecessary, potentially harmful chemicals. The semen is inserted into the woman, and if the procedure is successful, she conceives.\(^{50}\)

According to strict medical definitions, artificial insemination refers to the manipulation of sperm in order for a woman to conceive, a doctor or non-professional places semen into the woman’s vagina or uterus with a syringe, facilitating contact with an egg aiding fertilization. Artificial insemination can be used for many kinds of fertility problems. It’s a popular infertility treatment for men who have very low sperm counts or sperm that aren’t strong enough to swim through the cervix and up into the fallopian tubes. Artificial insemination is also sometimes an option for women who have endometriosis or abnormalities of any of their reproductive organs.\(^{51}\)

Classification of Artificial Insemination according to the Source of the Seeds (Sperm).\(^{52}\)

2.7.1.1. A.I.H. (Artificial Insemination by Husband or Homologous Insemination) –

The sperm comes from the husband. If a man is impotent i.e. unable to have normal sexual intercourse, his sperm may be injected into his wife artificially, known as artificial insemination by husband. \(^{53}\)

Warnock committee report explained artificial insemination by husband as:

> The term artificial insemination is used to refer to the placing of semen inside a woman’s vagina or uterus by means other than sexual intercourse. The principal of this technique has been unknown for centuries in the veterinary context. The simplicity of artificial insemination contrasts sharply with the technical complexity of more recent developments such as in vitro fertilization. It beings with the collection of semen from the husband/partner though masturbation. The semen is either placed in


the upper part of the vagina next to the cervix or injection into the uterus through a fine catheter. Insemination is undertaken near the predicted time of ovulation, the time in women’s menstrual cycle when she has the highest chance of conceiving. The semen used may be fresh or it may have been frozen and thawed before use…\textsuperscript{54}

2.7.1.2. A.I.D. (Artificial Insemination by Donor or Heterologous Insemination) –

This is used where the woman has no partner, or her partner is infertile. It involves the insemination of sperm from a donor into a woman, via her vagina into the cervical canal or into the uterus itself. It is normally used as a last resort.

This involves the woman being impregnated with sperm from another man, as her partner is infertile. The introduction of third party raises the question of their legal status in the arrangements. Although, law could not control any private arrangements of this nature, it does control public arrangements, that is, where services are provided to the public. Control of donors is important because of the possibility of passing on genetic defects or disease.

The Warnock committee Report explained artificial insemination by the donor as:

Artificial insemination by donor (AID) may be used when investigations have shown the husband to be sterile or to have significantly reduced fertility, or it may be used for the avoidance of hereditary disease when these are carried by the male… In this procedure the woman is inseminated with semen from a donor\textsuperscript{55}.

The main advantage of AID is that it enables a couple to achieve pregnancy even though the husband is not the biological father. However, the possible transmission of diseases from the donor to the future child and the risk of consanguinity, constitute some drawbacks that must be brought to the notice of the patients. It is necessary to get the informed consent of both the partners after they are counselled about the possible psychological conflict they may face later in their life with the knowledge that one of them is not the biological parent of their child.\textsuperscript{56} AID is an ethically acceptable procedure provided there is a medical indication and psychological confirmation for its use. Also, the normal conditions of anonymity and screening of the donor must be met and only frozen sperm samples that have passed

\textsuperscript{55} Id at para 4.6
\textsuperscript{56} National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), section 1.6.2.
appropriate quarantining for infectious diseases such as HIV, hepatitis B and C, and syphilis should be used.

**A.I.H.D. (Artificial Insemination Husband Donor or Confused Artificial Insemination)** –

AID raises ethical questions that are not raised by AIH as it takes place between husband and wife. Even though it is through advanced biomedical techniques and not by natural procedure, most of the people have no moral difficulty to accept it. It maintains the integrity of family and there is continuity between procreation and parenthood. Most people agree that there are no morally significant differences between AIH and procreation by intercourse. It is simply viewed as a medical technology providing assistance to what could not be accomplished by normal sexual intercourse. Whereas AID introduces a third party into the reproductive matrix. Someone who donates sperm to be used for AID, is now contributing genetic material without the intent to parent the child that will be produced through the use of his genes. Most of the religions also don't accept the impregnation of one's wife by the sperm of a third person as it doesn't make the child one's own and is looked down upon as illegitimate even in manmade laws. The donation is, however, always made anonymously so that the father could not be traced by the child, nor can the father elect to make contact with the child, potentially disrupting a harmonious family. Still it is redefining the concept of family and turning traditional notions of reproduction upside down.57

Artificial insemination with donor semen (A.I.D.) raises various legal questions which includes whether the resulting child is a legitimate child and who will be responsible for child care. In this respect courts held that the child is a legitimate child and the contesting husband is responsible for child support.58 However in some cases courts held that the child may not be legitimate under the common law.59 In one of the cases court has permitted a sperm donor to obtain a paternity order.60 Many A.I.D. sperm donor seeks to maintain their anonymity. But in some cases it may be

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58 People v. Sorenson, 68 Cal. 2d 280, 437 P.2d 495 (1968)
not possible to maintain anonymity. In a case of California the appellate court of California permitted the parents of a child who has some kidney disease allegedly from the sperm donor to obtain information about the donor in the suit against sperm bank.\textsuperscript{61}

2.7.2. In Vitro Fertilization (IVF)

In vitro fertilization (IVF) started the science of assisted reproductive technology. Louise J. Brown, the first test tube baby was born on July 25, 1978, in Oldham, England. Louise’s parents- Lesley and John Brown was a working class people from Bristol. John worked as a truck driver, Lesley stayed at home. They had been childless for a decade, victims of blocked fallopian tubes that prevented Mrs. Brown from conceiving. Robert Edwards, a reproductive endocrinologist, and Patrick Steptoe, a gynaecologic surgeon, did the first successful IVF procedure and responsible for the birth of Louise. Working together since 1967, Steptoe and Edwards were determined to complete Rock’s mission: fertilize an egg outside a women’s body and transfer it to uterus. To do so, they realised, would involve at least three components, each medically radical in its own right: they would need to remove the women’s eggs at the right time, fertilize them in a medium that could sustain the egg outside the body, and then administer the precise hormones that would convince the woman’s body that conception had occurred. Without this chemical conviction, the womb would reject the fertilized egg in what would become essentially a high-tech miscarriage.\textsuperscript{62} Between 1967 and 1975 Steptoe and Edwards performed at least eighty in vitro procedures without achieving a single pregnancy. When one woman finally became pregnant in 1975, the pregnancy was ectopic and had to be terminated. The two doctor continued to tinker with their methods, at last arriving at the combination of tactics that produced Louise.\textsuperscript{63} Dr. Steptoe harvested a single egg from the ovary of Lesley Brown and placed it in a culture dish. He then placed sperm from the husband, John, into a dish to fertilize the egg. The resulting embryo was transferred into Lesley Brown’s uterus, where it implanted and grew. The result was their daughter, Louise Joy Brown.\textsuperscript{64}

\textsuperscript{61} Johnson v. Superior Court, 80 Cal. App. 4th 1050, 95 Cal. Rptr. 2d 864 (2d Dist. 2000)
\textsuperscript{62} Supra note 1 at 25.
\textsuperscript{63} Ibid
\textsuperscript{64} Supra note 15 at 31.
The technique of IVF that is used today is very similar to that used by doctors Steptoe and Edward. The major difference is that multiple ova, instead of one, are retrieved after a woman undergoes ovarian hyper stimulation. After the eggs are obtained, they are combined with sperm in a laboratory culture dish and placed in an incubator. Three to five days later, the successful embryos are examined under the microscope. Several are selected to be transferred to the woman’s uterus. The remaining embryos are frozen for possible future use. The process of IVF and embryo transfer typically consisting of five main steps:

2.7.2.1. Ovarian Stimulation (super ovulation).

The woman takes ovulation stimulants (fertility drugs) to prompt her ovaries to produce several eggs at once instead of the usual one per month. Standard IVF procedure calls for multiple eggs because often some of them will be defective, and not every embryo may implant or develop properly once transferred to the uterus.

2.7.2.2. Egg Retrieval.

When the eggs are ready, they are extracted from the egg sacs, or follicles, of the ovaries— usually a 30-minute outpatient surgery. In typical egg retrieval, an ultrasound guided needle is inserted into the vagina, through the vaginal wall, and into the ovaries to the egg-bearing follicles. One by one, the eggs are suctioned out through the needle.

2.7.2.3. Intracytoplasmic Sperm Injection (ICSI)

Sometimes the chances of fertilization are greatly increased by a technique known as intracytoplasmic sperm injection (ICSI), in which an egg is pierced and a single sperm cell is injected into it. ICSI is most often used, in conjunction with IVF, for couples in which the male has a very low sperm count. The American Society for Reproductive medicine (ASRM) stated, “ICSI, a form of micromanipulation, involves the injection of a single sperm directly into the cytoplasm of a mature egg using a glass needle. This process increases the likelihood of fertilization when there are abnormalities in the number, quality, or function of the sperm.”

2.7.2.4. Embryo Culture.

After fertilization, the embryos are left to grow in a culture medium. Within 48 hours each one consists of 2 to 4 cells; in three days, 6 to 10 cells. Around the third

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65 Ibid.
66 Id at 32.
day, fertility experts can screen the embryos for genetic diseases using a technique known as preimplantation genetic diagnosis (PGD). Only embryos found to be free of defective genes are selected to be transferred to the uterus.

2.7.2.5. Embryo Transfer.

Delivery of embryos to the uterus is generally painless and is performed in the doctor’s office up to six days after egg retrieval. To increase the chances of pregnancy, two or more embryos are usually transferred at once. The embryos, along with the fluid surrounding them, are placed in a long, straw like tube called a transfer catheter. Then the catheter is eased into the vagina and through the cervix, and the embryos are pushed from the tube into the uterus. If all goes well, an embryo implants in the uterine lining.

IVF is also used for infertility caused by endometriosis or male factor infertility. It is sometimes used to treat couples with long-term unexplained infertility who are unable to conceive with other infertility treatments. The woman is given hormones, which stimulate her ovaries up to 30 or more oocyte (ova). These are retrieved by inserting a needle into the ovaries via the vagina with ultrasound guidance. These oocytes are mixed with sperm. The sperm is obtained by masturbation and is usually donated by the husband. If the husband is infertile, however, the sperm may be obtained from another man. If the woman is infertile, similarly, the oocyte may be obtained from another woman whose ovaries have been similarly stimulated. The embryos thus conceived are usually allowed to grow up to the four-to-eight stage over 3 to 4 days, at which time some of the embryos are implanted in the woman's uterus.

The Warnock Committee explained the process of in vitro fertilisation in the following terms:

“The concept of IVF is simple. A ripe human egg is extracted from the ovary, shortly before it would have been released naturally. Next, the egg is mixed with the Semen of the husband or partner, so that fertilisation can occur. The fertilised egg, once it has started to divide, is then transferred back to the mother's uterus. In practice the technique for recovery of the eggs, their culture outside the mother's body, and the transfer of 'the developing embryo to the uterus has to be carried out under very carefully controlled conditions. The development of laparoscopic techniques during the 1960s made the collection of the egg, in cases where the ovaries were accessible, relatively easy. (Another technique for egg recovery based on ultrasound identification has now been developed.) It was not
particularly difficult to fertilise the human egg *in vitro*. The real difficulty related to the implantation of the embryo in the uterus after transfer. A pregnancy achieved in this way must not only survive the normal hazards of implantation of *in vivo* conception, but also the additional problems of IVF and embryo transfer. More is now known about how best to replicate the natural sequence of events, but undoubtedly achieving a successful implantation is still the most uncertain part of the procedure.”  

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, technique of IVF consists of bringing about the fertilization of the oocyte and the spermatozoa in the laboratory instead of in the woman’s fallopian tube. IVF involves induction of ovulation in order to obtain multiple oocytes, thus making available more embryos with which higher pregnancy rates can be achieved. Serial determination of plasma estradiol levels and daily monitoring of ovarian follicular growth by ultrasonography would indicate the response to ovarian stimulation. At the appropriate moment of follicular growth, the follicles are aspirated to obtain the oocytes. The oocytes are mixed with appropriately capacitated spermatozoa from the husband (or the donor, if the medical condition indicates the use of donor sperm) and kept in an incubator for fertilization which is observed microscopically after 16 to 18 hours. Embryos are transferred into the uterine cavity between days 2 and 6 after oocyte aspiration. If implantation ensues, pregnancy can be confirmed by 14 to 16 days after embryo transfer by determining the presence of HCG in a blood or urine sample. Such a test is reliable only when progesterone is used for luteal supplementation instead of HCG. The success rate of IVF is approximately one in every 4-5 women. IVF is the therapeutic option of reproductive medicine with the highest yield per attempt, coming close on many occasions to that achieved by fertile couples conceiving naturally.  

IVF cycles pose health risks for both woman and child. For the woman, the physical demands of the IVF process—the surgery, the monitoring, the waiting—can be uncomfortable, inconvenient, and stressful. The surgery itself comes with a risk, however low, of side effects such as bleeding, infection, and damaged tissue. There is also a chance of complications from taking the fertility drugs that instigate super ovulation, including abdominal pain, memory loss, mood swings, and headaches.

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67 Supra note 54, para 5.2.  
68 Supra note 56, section 1.6.4.
most worrisome among these is a rare but potentially dangerous condition known as ovarian hyper stimulation syndrome, characterized by swollen and painful ovaries. Multiple pregnancies—caused mainly by transferring several embryos at once—increase the chances of high blood pressure, anemia, gestational diabetes, and uterine rupture. For the child, there are concerns that ART techniques may lead to birth defects, low birth weight, and diseases such as cancer.

Multiple pregnancies—a common result of IVF cycles—dramatically raise the risks to children’s life and health. The chances of prenatal and postnatal death are higher than for single pregnancies, and premature birth is much more likely. Prematurity increases the risk of cerebral palsy, blindness, heart defects, serious infection, respiratory distress syndrome, and other grave maladies. Even aside from prematurity, babies born after a multiple pregnancy have an elevated risk of birth defects and low birth weight, the latter being a separate risk factor for many diseases. One way that practitioners try to lower the risks of multiple pregnancy is to use fetal reduction (also known as selective abortion) to eliminate some of the fetuses in uterus. But the procedure itself carries with it a risk of miscarriage.69

Several issues—technological and ethical—arise from the handling of the unused embryos that inevitably result from IVF. The common practice is to freeze, or cryopreserve the extra embryos for possible transfer in the future. Fertility clinics freeze thousands of embryos every year, and hundreds of thousands of them are now in cryostorage. Freezing a woman’s left over embryos give her the option of using them in future IVF cycles rather than going through another arduous (and expensive) round of ovarian stimulation and egg retrieval. By having her embryos frozen, she can also select the timing of embryo transfer to avoid causing or aggravating any health problems in pregnancy. A significant drawback to the process is that cryopreserved embryos are less likely to result in live births than unfrozen embryos are. Another is that many embryos do not live through freezing and thawing. Frozen embryos can remain in cryostorage for years—because the couple divorces, because one or both of them die, because they disagree about what to do with the embryos (for example, if one wants to donate them but the other does not), or because they have changed their minds about getting pregnant. The moral and legal implications of these possibilities are being debated now.

69 Supra note 48.
One alternative is to donate the unused embryos to an infertile couple, which means that the prospective parents will have no genetic connection to the child born to them. Such an arrangement seems unproblematic to some people but is morally or legally questionable to others. Without legal guidance and ethical consensus, fertility clinics must decide what to do with frozen embryos that are unused, unclaimed, or undonated. Often they either donate the embryos for research or destroy them. To those who believe that embryos have a right to life, both of these options are morally impermissible. But even people who don’t believe that embryos are persons may think that embryonic life should not be treated as if it has no moral worth at all.\textsuperscript{70} IVF cycles pose health risks for both woman and child. For the woman, the physical demands of the IVF process—the surgery, the monitoring, the waiting—can be uncomfortable, inconvenient, and stressful.

Since the procedure is so expensive, more embryos than required are fertilized in the lab so that if none of the fertilized eggs are successfully implanted, preimplantation can be done without much additional cost and time. The spare embryos are frozen, discarded, donated or used for experimentation. Freezing is an expensive procedure, it can also kill some of them. These embryos are human lives that, given a chance, would develop into a man or a woman. If they are used for experiment action, it can be fatal for them. Since some religions believe that life begins at conception, it may amount to abortion which is contrary to both law and ethics. Using them for expert indentation is also not permissible as science cannot experiment with someone with basic human rights without prior permission. Donation involves separation of the biological and social roles of parenthood that is significant part of family concept and is equivalent to adoption before birth thereby calling for amendments in adoption laws of most of the countries.

2.7.3. Cryopreservation

Cryopreservation refers to the storage of a living organism at ultra-low temperature such that it can be revived and restored to the same living state as before it was stored. Indefinitely long storage times require that the organism be maintained below the glass transformation temperature of aqueous solutions, approximately -130\textdegree C, and the temperature at which frozen water no longer sublimes and

\textsuperscript{70} Ibid.
recrystallizes. Although ultra-cold freezers may stabilize some living cells for weeks or even years, liquid nitrogen is required for longer storage times.\textsuperscript{71}

Cryobanks for human semen were first proposed in 1866, but it was not until 1953 that a successful and practical cryopreservation (freezing) technique was introduced. The establishment of the first semen bank in the United States was based primarily on the expectation that millions of men would elect to store their semen prior to undergoing vasectomies for fertility insurance, an expectation largely unrealized to date. Current cryobanking includes timed multiple inseminations for AIH and AID, storage pooling, concentration of sperm for AIH, retention of fertilizing capacity in absence, death, or hazard exposure of the husband. Embryo freezing is offered as a service to IVF patients as part of their in vitro fertilization treatment cycle and is offered for three reasons:

1. To reduce the expense, time, and physical discomfort associated with repeated IVF treatment cycles. Embryos from a treatment cycle, which were not transferred, can be frozen for later use.

2. To reduce the risk of multiple pregnancies by transferring a limited number of embryos at a woman's first in vitro fertilization transfer (ET) and freezing the remaining embryos.

3. To take full advantage of all eggs available during the woman's first egg recovery by attempting to fertilize all available eggs.

The first pregnancy from a frozen/thawed human embryo was reported in 1983, and a birth from this source occurred the following year. Of 99,629 cases of Assisted Reproductive Technology in the United States in 2000, about 16\% of cases (16,194) used frozen/thawed embryos. In 2000, live birth rates per thaw cycle were 18.3\% versus 26.6\% from fresh embryo transfer. At GRS, the ongoing pregnancy rate for IVF using frozen/thawed embryos is currently 52\%.\textsuperscript{72}

Egg retrieval under ultrasound guidance and subsequent fertilization and embryo culture are carried out according to our current procedures. If there happens to be a surplus of embryos following selection for fresh transfer (usually between one to four embryos are transferred to the uterus), then embryos of sufficient quality may be considered for cryostorage. While embryos can be frozen at any preimplantation stage


\textsuperscript{72} Available at http://www.ivf.com/cryo.html visited on 24 March 2012.
between one-cell (one day old) to the blastocyst stage (5-6 days old), in an attempt to minimize the freezing of excessive numbers of "spare" embryos and to help pre-select the most potentially viable embryos, we generally choose to cryopreserve only at the blastocyst stage. In certain cases where all embryos need to be frozen without a fresh transfer (e.g., when a woman may be at risk from ovarian hyper stimulation that might be complicated by pregnancy), we generally freeze all embryos the day after egg collection at the one-cell stage.\(^{73}\)

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, facilities for cryopreservation are an essential component of an ART clinic as they are to be used under a variety of conditions such as those described below. Men, who are likely to suffer from psychological stress at the time of ovum pick-up or those who cannot be present at the time of ovum pick-up, are recommended to have their semen frozen for use at the appropriate time. One of the important reasons for freezing semen from donors is that any donor semen has to be quarantined for six months. The safety of using frozen sperm has been abundantly proven, both by experimental work and the actual results in humans. Matters of concern are the donor’s health and the necessity to avoid donors who are infected with venereal diseases, hepatitis B or C, or HIV. One of the drawbacks of sperm freezing is an approximate 20% loss in motility after thawing. Donors whose semen is frozen for future use are required to report to the semen bank six months after donation to be checked for HIV, HBV or HCV infection/disease status.\(^{74}\)

2.7.3.1. Freezing Embryos

Embryos are routinely cryopreserved to enable storage of supernumerary embryos, as upto a maximum of only three embryos is allowed for transfer to avoid the risk of multiple pregnancies. Embryo freezing is a widespread routine procedure to increase cumulative pregnancy rates.

Human embryos can be successfully cryopreserved at any stage from zygote to blastocyst, using 1, 2 propanediol (PROH) or dimethylsulfoxide (DMSO) for zygotes and cleaved embryos and glycerol for blastocysts. The formation of ice crystals is of concern during embryo freezing. Using programmed, slow freezers

\(^{73}\) Ibid
\(^{74}\) Supra note 56 at section 1.6.8.
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reduces this problem considerably, and slow cooling is the most widely employed method. Human embryos are known to survive a simple ultra-rapid procedure of fast cooling but there is not much data on the efficacy of these techniques when used routinely. Straws or ampoules used for freezing embryos should be carefully and permanently labeled for identification purpose. Patients should be fully informed before the treatment cycle on the procedure of cryopreservation, the risks and, particularly, what is to be done with their embryos if they do not use them. They should sign a consent form concerning the agreement for embryo freezing as well as for the future use of the embryos. When a serum supplementation is used in the preparation of freezing and thawing solutions, one must carefully avoid any risk of viral transmission to the embryo through the serum.75

2.7.3.2. Oocyte Cryopreservation

This procedure has been successfully used in cases where a large number of immature oocytes have been retrieved during ovum-pick-up. The oocyte can be thawed at a later date, matured in vitro and used for oocyte donation or similar procedures either on the person from whom the oocytes were retrieved or on other prospective recipients. However, the success rates in terms of fertilization, pregnancy and live births with the use of cryopreserved oocytes are not very encouraging. Much remains to be learnt on identifying the optimal stage of oocyte development when cryopreservation would be of value.76

2.7.3.3. In Vitro Culture Media

There has been a spurt of new media introduced for in vitro culture of gametes and embryos. If one takes a close look at these media, they are products that have evolved over the years. However, some manufacturers do not give the exact composition of their media but merely state that for reasons of patent protection or as trade secret they are constrained to give full details of the composition of their media.

This is an undesirable situation. Infertility clinics that deal with human embryos and the future life of the products they create in the laboratory must be privy to the knowledge about the media they use, if need be by signing an appropriate confidentiality agreement which would prohibit the clinic from using or passing on

75 Id
76 Supra note 56 at section 1.6.8.3.
the proprietary information provided by the manufactures of the media to any other
organization that may commercially exploit this information.

2.7.4. Gamete Intrafallopian Transfer (GIFT)

The procedure is most often recommended for couples with unexplained infertility with the female partner having at least one open fallopian tube. It may also be recommended for patients whose infertility is due to cervical or immunological factors, mild endometriosis, or selected cases of male infertility. GIFT is considered a variation of in vitro fertilization (IVF), with one significant difference. With the GIFT procedure, fertilization is intended to occur naturally within the woman's body instead of in a laboratory. For this reason, GIFT is sometimes described as an alternative for patients whose religious beliefs prohibit conception outside the body.\(^\text{77}\)

GIFT involves three steps. The first step is ovarian stimulation and monitoring. Medications are used to stimulate the woman to produce more than one follicle and ovum and to aid in stimulating the follicles to release the ova. During this time, the woman's response to the medication and the development of her ova are watched and assessed. The second stage begins with a laparoscopy performed under general anesthesia to retrieve the ova. The ova are then examined under a microscope to determine maturity. Semen is obtained and processed in a centrifuge, where it is washed and then placed in a test tube so that the active sperm can swim to the top. The third step consists in transfer of the ova and sperm into the woman's body. Ova and sperm are placed in a catheter, and the catheter is inserted directly into the woman's fallopian tube through a surgical procedure using a laparoscope. The ova and sperm are then injected into the fallopian tube with the intent of fertilization occurring in its normal environment within the woman's body. If fertilization does occur, the developing embryo(s) will remain in the fallopian tube and then move to the uterus for implantation.

2.7.5. Intra-cytoplasmic Sperm Injection (ICSI) & Sub Zonal Insemination (SUZI)

Intracytoplasmic sperm injection (ICSI) is a form of ART involving the injection of a single sperm into the cytoplasm of an oocyte to achieve fertilization. It is indicated for the treatment of couples with male factor infertility and those with

poor fertilization with conventional IVF, although some have recommended its broad use as first-line ART treatment. ICSI is the only treatment option for couples with severe male factor infertility. It can be performed with ejaculated or surgically retrieved sperm. In this method procedure is same way as IVF in which oocytes are examined after 16 hours for fertilization, and viable embryos are transferred to the women uterus after 1 to 3 days later. ICSI particularly useful where the sperm cannot naturally penetrate the egg or where it is of poor mobility.

2.7.6. Collaborative Reproduction (Third Party Reproduction)

The term ‘collaborative reproduction’ is used to describe situations in which a third party (who will have no parenting role once the child is born) assists in the production of child. It refers to reproductive procedures using sperm donation, egg donation, and surrogacy.

2.7.6.1. Egg/Germete Donation

Women may donate their oocytes to enable another woman to have a child. The oocyte donor normally undergoes a cycle of controlled ovarian hyperstimulation, then, following collection of the oocytes, donates the oocytes to a recipient – normally for fertilization by the sperm of the recipient’s partner and replacement of the resulting embryo in the uterus of the recipient. This may be performed either when the recipient has no oocytes of her own – due to age, premature menopause or treatment with chemotherapy – or where the recipient’s own oocytes have proved to be unsatisfactory for treatment with IVF.

This procedure may help those women who cannot themselves produce an egg. It may also help those who would be candidates for IVF except that in their case egg collection is impossible because their ovaries are inaccessible. About 5% of infertile couples might benefit from this technique. A mature egg is recovered from a fertile woman donor, for example during sterilization, and is fertilized in-vitro, using the semen of the husband of the infertile woman. The resulting embryo is then transferred to the patient's uterus. If it implants she may then carry the pregnancy to term. There are other situations where eggs might be donated. When a woman is

herself undergoing infertility treatment and several eggs have been recovered from her, she may be prepared to donate one or more eggs to another woman whose infertility can be treated only by egg donation.\textsuperscript{80}

There are many complex ethical issues associated with the use of donated oocytes, particularly the need for free and properly informed consent on the part of the donor as well as the use of donated oocytes in women at advanced age.

2.7.6.2 Sperm Donation

Men may donate their sperm for use by another man to achieve a pregnancy in his partner. Donated sperm may be used in cases where no usable sperm can be obtained from the testis or the couple may choose to have artificial insemination with donated sperm in preference to subjecting the female partner to controlled ovarian hyper stimulation and oocyte recovery. Donated sperm may also be used to achieve a pregnancy in women without a male partner.

2.7.6.3 Embryo Donation

\textit{Warnock Committee} explains the term as follows:

Embryo donation would help the same groups of women who might benefit from egg donation and, more particularly, the even smaller number whose husbands are also infertile. Embryo donation may take two forms. One involves the donation of both egg and semen. The donated egg is fertilised \textit{in vitro} with donated semen and the resulting embryo transferred to a woman who is unable to produce an egg herself and whose husband is infertile. The second method, known as lavage, does not involve removing the egg by surgical intervention. Instead the egg is released naturally from the ovary at the normal time in the donor's menstrual cycle. At the predicted time of ovulation she is artificially inseminated with semen from the husband of the infertile woman (or from a donor if the husband is also infertile). Some three to four days later, before the start of implantation, the donor's uterus is "washed out" and any embryo retrieved is then transferred to the uterus of the infertile woman. If the embryo implants successfully the recipient carries the pregnancy to term. Embryo donation by lavage is, according to its advocates, much safer for the donor as it does not require general anaesthesia, and a simple and safer procedure is involved; moreover, for the embryo, there is the advantage of a shorter interval \textit{in vitro} during which time it might

\textsuperscript{80} Supra note 54.
deteriorate. When semen from the husband is used, the child is genetically his though not his wife's.  

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, oocyte donation would necessitate using the husband’s semen for fertilization and transferring the resultant embryo to the infertile female partner. Embryo donation would obviate the necessity of using the husband’s semen. The choice of oocytes and embryos for oocyte or embryo donation would depend entirely on the circumstances prevalent at the time the infertile couple comes for treatment, and the access of the infertility clinic to frozen oocytes or embryos. 

Donors should be healthy (as determined by medical and psychological examination, screening for STDs, and absence of HIV antibodies) women in the age group of 18-35 years. Oocytes may be obtained for donation, mostly by surgical intervention from women participating in an IVF program, or those undergoing elective sterilization or surgery. The recipient should be a healthy woman (determined by medical and psychological examination) having normal genitalia (as determined by physical examination) and uterine cavity (as determined by hysterosalpingography). In case of OD, the semen characteristics of the husband must be determined to see if they are in conformity with those associated with normal fertility. The blood group of the donor should be noted; the donor should also be tested for antibodies to rubella, HIV, hepatitis, CMV, gonorrhea, syphilis, chlamydia, mycoplasma and trichomonas. 

Ovum/embryo donation can be carried out in menopausal women with no surviving child and desiring to have a child. The endometrium of menopausal women has the ability to respond to sex hormones and provide a receptive environment for the implantation of an embryo. Various protocols are now available to prepare the endometrium of the recipient for OD or ED with estrogens and progestogens until the placenta takes over the function of maintaining the gestation. 

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81 Supra note 54.
82 Id section 1.6.7.
83 Supra note 56 at section 1.6.7.1.
84 Ibid.
2.7.6.2. Surrogacy\textsuperscript{85}

The word “surrogate” derives from the Latin word “subrogate”, which means “appointed to act in the place of”. Surrogacy is defined as one woman, referred to as the mother, having intercourse or medical treatment in order to achieve pregnancy for the purpose of another woman. Surrogacy was defined in the Warnock Report as “the practice whereby one woman carries a child for another with the intention that the child should be handed over after birth.”\textsuperscript{86} It went on to say, “The use of artificial insemination and the recent development of in vitro fertilisation have eliminated the necessity for sexual intercourse in order to establish a surrogate pregnancy.”\textsuperscript{87} The Courts also performed their unique job in defining the term surrogacy. \textsuperscript{88} In English law, the only statutory definition of surrogacy is contained in the Surrogacy Arrangement Act, 1985.\textsuperscript{89}

\textit{Law Commission of India in its 228\textsuperscript{th} report\textsuperscript{90} defines surrogacy as:}

“The word ‘surrogate’ has its origin in Latin ‘surrogates’, past participle of ‘surrogate’, meaning a substitute, that is, a person appointed to act in the place of another. Thus a surrogate mother is a woman who bears a child on behalf of another woman, either from her own egg or from the implantation in her womb of a fertilized egg from other woman.”

Assisted Reproductive Technology (Regulation) Bill, 2010\textsuperscript{91} defines surrogacy

\textsuperscript{85} In Oxford English Dictionary the term surrogate defined as “A person appointed by authority to act in place of another, a deputy, A person or thing taking the place of another, a substitute.”, Oxford English Dictionary. Page no.3123, volume 2., In Encyclopedia Americana the word ‘Surrogate’ means,”A person appointed to act in place of another.” Encyclopedia Americana. Page no.70, volume 26., According to the Black’s Law Dictionary: surrogacy means “the process of carrying and delivering a child for another person.” Black’s Law Dictionary, P.9.

\textsuperscript{86} Supra note 54, para 8.1.

\textsuperscript{87} ibid

\textsuperscript{88} “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.”, Manji Yamada v. Union of India and Anr. (2008), 13 SCC 518.

\textsuperscript{89} Section 1(2) of the Act says: A surrogate mother means a women who carries a child in pursuance of an arrangement: a. Made before she began to carry the child; and b. Made with a view to any child carried in pursuance of it being handed over to, and the parental right being exercised (so far as practicable) by, another person or other persons.

Section 1(3) of the Act defines surrogacy arrangement as; An arrangement is a surrogacy arrangement if, were a women to whom the arrangement relates to carry a child in pursuance of it, she would be a surrogate mother.

\textsuperscript{90} Submitted on 5 august 2009

\textsuperscript{91} Assisted Reproductive Technology (Regulation) Bill, 2008, Sec.2(t)
as follows “surrogacy”, means an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belong to her or her husband, with the intention to carry it to term and hand over the child to the person or persons for whom she is acting as a surrogate;

Surrogacy is not so new as far as assisted reproductive technologies are concerned, and it is often noted that the practice dates back to Biblical times. The Old Testament gives the example of Abraham’s infertile wife, Sarah, who “commissions” her maid Hagar to bear her a child by persuading Abraham to sleep with her. Another example in the book of Genesis is Rachel, who is infertile, commands her husband to consort with her maid, “Behold my maid, Bilhah,” she cries, “Go in unto her, and that she may bear upon my knees, and I also obtain children by her.”, Bilhah gives birth to two sons whom Rachel names and considers her children. This is the earliest biblical example of what could be called surrogate mothers. Hindu mythology also gives instances of surrogacy and reflects the secrecy that still surrounds surrogacy practice. In the Bhagvata Purana, Vishnu heard Vasudev’s prayers beseeching Kansa not to kill all sons being born. Vishnu heard these prayers and had an embryo from Devaki’s womb transferred to the womb of Rohini, another wife of Vasudev. Rohini gave birth to the baby, Balaram, brother of Krishna, and secretly raised the child while Vasudev and Devaki told Kansa the child was born dead.

In Biblical surrogacy, therefore, as in many contemporary surrogacy arrangements, the child was genetically related to the father who would raise him. The birth mother, by contrast, was neither a pure volunteer nor a paid provider. She was a servant in most cases, or sometimes a second wife or concubine of the father.

Another form of surrogacy arose in the Middle Ages, when wealthy women regularly turned their newborns over to wet nurses: nursing mothers who, for a fee, would assume the care and feeding of an additional child. Typically, child would live with the wet nurse during the first five year of life, with the natural mother making only occasional visits. In many respects, this relationship is the closest antecedent to modern day commercial surrogacy. The surrogate generally has no long-term

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93 Supra note 1 at 73
Involvement with the child; she is employed for a specific task and paid a nontrivial fee.  

In the later decade of the twentieth century, though, surrogacy underwent a significant revival. In the past, the only way for surrogate mothers to produce children was to engage in sexual relations with the prospective father- a messy business under any circumstances and the one that held little appeal for the wives of the husband involved. With artificial insemination however, conception was removed from sex, making it possible for a man to impregnate a surrogate without even necessarily meeting her. Artificial insemination also made surrogacy more feasible, allowing infertile couples to procure sperm and eggs outside, unrelated sources. By the mid 1980s, new technology for conception had supplanted the traditional model of surrogacy, creating a substitute with far greater commercial potential. This substitute of course was gestational surrogacy.  

A woman may opt for gestational surrogacy because she has an abnormal uterus or no uterus (because of hysterectomy or congenital defect) or because she suffers from health problems that make pregnancy dangerous, such as cystic fibrosis and serious forms of diabetes and heart disease. A couple may turn to a traditional surrogate for many of the same reasons. In both kinds of surrogacy, the intended parents generally want more than just a child— they want a biologically related child. For them, then, adoption may be less attractive. The different types of surrogacy are discussed as follows:-  

2.7.6.2.1. Traditional Surrogacy  
The birth mother is both the “gestational” surrogate and the biological mother (contributed the genetic material-the ovum). Like a gestational surrogate she is selling her reproductive labour, that is, renting her womb out for a fee. In contrast to gestational surrogates she has a genetic tie to the child she is carrying. In traditional surrogacy, the surrogate mother is artificially inseminated with the sperm of the intended father or sperm donor. The surrogate's own egg will be used, thus she will be the genetic mother of the resulting child. What made the traditional surrogacy

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94 Ibid  
95 Id  at 75  
96 Id  at 78  
97 Supra note 48.  
98 Supra note 92.
complicated was the surrogate mother was also the genetic mother of the child she bore. Like Rachel’s maid, the surrogate was indeed giving her child to another woman, who has no genetic tie to the child.

### 2.7.6.2.2. Gestational Surrogacy

This is the most common form of commercial surrogacy today. A woman who gestates a fetus (allow herself to be impregnated and carries the pregnancy to term) but has no genetic tie to the child she births. She is not the intended parent but is a paid labourer working on a nine-month commercial contract. There is an embryo transfer and she carries a child of which she is not the biological mother.\(^99\) Eggs are extracted from the intended mother or egg donor and mixed with sperm from the intended father or sperm donor in vitro. The embryos are then transferred into the surrogate's uterus. Embryos which are not transferred may be frozen and used for transfer at a later time if the first transfer does not result in pregnancy.\(^100\)

#### 2.7.6.2.2 Altruistic Surrogacy

It is a kind of surrogacy in which surrogate receives no financial reward for her pregnancy although usually all expenses such as medical expenses, maternity clothing, and other related expenses related to the pregnancy and birth are paid by the intended parents.\(^101\)

### 2.7.6.2.3. Commercial Surrogacy

Commercial surrogacy\(^102\) 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 higher income infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. This procedure is legal in several countries including in India where due to high international demand and easy availability of poor surrogates it is reaching to a level of industry. For the society, commercial surrogacy is questionable because it defines a baby as a commodity, up for sale at the prevailing market price. It is a form of surrogacy in which surrogates are paid for carrying a child to maturity in her womb and is usually resorted to by

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\(^{99}\) Supra note 28 at 11

\(^{100}\) Ibid.


\(^{102}\) Also known as Compensated Surrogacy or Paid Surrogacy or Womb for Rent or Out sourced Pregnancies or Baby Farms).
higher income infertile couples or people who save and borrow in order to complete their dream of being parents.\textsuperscript{103}

Surrogacy has received more adverse criticism than any of the other ‘new’ reproductive technology. The true incidence of surrogacy is unknown, though it seems likely that the amount of emotion expended upon it is out of all proportion to the extent to which people would and do resort to it in order to have children. But surrogacy, together with abortion, raises in perhaps starkest form the questions of the extent to which women should be free to exploit and control their reproductive capacity, even when they have no wish to raise a child themselves, and the degree to which other should be able to call upon that reproductive capacity to fulfil their own needs.\textsuperscript{104}

Some confusion surrounds the definition of surrogate arrangements. The carrying women may or may not be the genetic mother. In partial surrogacy she provides the ovum, and the commissioning father provides sperm. But in full surrogacy (also called as renting the womb) the commissioning mother provides the ovum, which is fertilised in vitro with her husband’s sperm, then gestated in the surrogate’s uterus. Here carrying woman is not genetically related to the child she carries. The Warnock Committee noted that surrogacy could theoretically be used for ‘convenience’, where the commissioning mother is physically able to bear a child, but wishes to avoid doing so, perhaps in order not to interrupt her career, or not to affect her appearance. Surrogacy could also be utilised by lesbian women, and by single men and male homosexuals who want to bring up children.\textsuperscript{105}

Third party reproduction, and specially surrogacy, is the most controversial issue in ART. Because, both the sperm and egg donors are paid, and surrogates may receive a considerable amount of money. Many feel that third party reproduction smacks of “baby buying”.\textsuperscript{106} Defenders of surrogacy deny that it constitutes babyselling, claiming instead that a surrogate is simply relinquishing her right as a parent to have a relationship with the child.

\textsuperscript{103} Supra note 101.
\textsuperscript{104} Supra note 78 at 389
\textsuperscript{105} Id at 390
\textsuperscript{106} Supra note 15 at 45.
2.7.7 Posthumous Procreation

Posthumous conception has been defined as the beginning of human gestational process after the death of one or both biological parents. Posthumous births have been recognized since antiquity when a husband or male partner died from illness, from accident, or in war after conception and pregnancy had been achieved, but before the resulting birth has occurred. Legally and socially, the ensuing child has been usually considered the rightful heir of the deceased father.

Posthumous reproduction, on the other hand, became possible only after semen could be frozen and used for artificial insemination after the donor was deceased. The legal and social status of a child born from these origins has been ambiguous, even if the insemination and pregnancy occur with the wife of the dead man. With the advent of assisted reproduction, insemination with a dead husband’s sperm might be requested by the widow to achieve a pregnancy and bear a child even if her husband died before. This could be achieved by traditional conception, and they had the foresight to collect and freeze a semen sample before death. Alternatively, requests have been made to collect sperm from the terminally ill or newly deceased male for the same purpose. Such techniques as stimulated ejaculation, Microsurgical Epididymal Sperm Aspiration (MESA), or testicular sperm extraction (TSE) might be employed. In addition, specimens frozen and stored in a sperm bank for donation under usual circumstances might be used for anonymous insemination after the donor has died, in which case issues of assigning legitimacy and inheritance are different than in a husband–wife relationship. In some of the above illustrations, the technology may involve only the cryopreservation of the sperm and insemination, but the social issues are complex. The advent of in vitro fertilization and the potential for cryopreservation of ova may extend the options for posthumous reproduction to the use of the cryopreserved ovum, much as for using sperm for posthumous conception, but with the added requirement of a “surrogate” uterus for gestation to achieve a pregnancy. There is an option to obtain and store undamaged sperm from men who undergo radiation or chemotherapy for cancer, should they wish to have children in the future, and it is possible that this will be available in the future for the protection of ova as well. In the event that the man does not recover from his cancer, his germ cells would be stored and available for posthumous reproduction should his partner request this.
In contrast to the ancient phenomenon of posthumous birth, the recent possibility of posthumous reproduction raises more ethical, practical, and legal questions for physicians practicing reproductive medicine and the public concerning the interests and rights of the donor(s), the gestating woman, the prospective rearing parent(s), and any children that may result.¹⁰⁷

Section 28(6) (b) of the HFEA 1990 provided that, where sperm was used after a man’s death, the man was not to be treated as the father of the child. In 1993, a California appellate court permits the deceased’s girlfriend to use semen that he had willed to her.¹⁰⁸ In 2004, a federal appellate court ruled that twins conceived from frozen semen after their father’s death was eligible for Social Security.¹⁰⁹

2.7.7. Cloning

Reproductive cloning is also a kind of ART but presently it is illegal. Cloning is the process of making a genetically identical organism through nonsexual means. It has been used for many years to produce plants. Animal cloning has been the subject of scientific experiments for years, but garnered little attention until the birth of the first cloned mammal in 1997, a sheep named Dolly. Since Dolly, several scientists have cloned other animals, including cows and mice. The recent success in cloning animals has sparked fierce debates among scientists, politicians and the general public about the use and morality of cloning plants, animals and possibly humans.

Cloning is the creation of almost genetically identical organisms. For ordinary purposes, clones can be treated as genetically identical to the organisms from which the nuclear DNA is taken. In fact there is a small difference, because the egg also contains a small amount of DNA in mitochondria, small bodies in the main part of the egg. Like organisms produced by sexual reproduction, the clone inherits this DNA only from its mother, not from the nucleus donor.¹¹⁰

2.7.7.1. Reproductive Cloning

Reproductive cloning is the production of a genetic duplicate of an existing organism. A human clone would be a genetic copy of an existing person. Somatic cell
nuclear transfer (SCNT) is the most common cloning technique. SCNT involves putting the nucleus of a body cell into an egg from which the nucleus has been removed. This produces a clonal embryo, which is triggered to begin developing with chemicals or electricity. Placing this cloned embryo into the uterus of a female animal and bringing it to term creates a clone, with genes identical to those of the animal from which the original body cell was taken.\textsuperscript{111}

2.7.7.2. Therapeutic Cloning

Therapeutic cloning is cloning which is performed for the purpose of medical treatment. For example, it could theoretically be used to grow a replacement organ, to generate skin for a burn victim, or to create nerve cells for someone suffering from brain damage or a neurological condition. Therapeutic cloning is closely related to reproductive cloning, in which a copy of an organism is produced, but the two have very different end goals.

Formally, this type of cloning is called somatic cell nuclear transfer. It involves extracting the nucleus of a cell, and putting the nucleus into an egg which has been denuded. Then, the egg is allowed to divide and grow. In therapeutic cloning, the growing egg is used as a source of stem cells, which are undifferentiated cells which can grow into a wide variety of different types of cells. In reproductive cloning, the egg is allowed to grow into a baby.\textsuperscript{112}

In UK, The Human Fertilization and Embryology Act 2008, permit the licensing of some form of human cloning, but only for the purpose of research. India allows experimentation with stem cell research. In India medical termination of pregnancy is permitted under the MTP Act of 1971.\textsuperscript{113} The resulting fetal tissues that are freely available from the MTP Clinics and hospitals can be utilized for research purposes. Termination of pregnancy for obtaining fetus for stem cell research or for transplantation is not permitted. The main source of embryonic cells will be from the ART/IVF clinics dealing with the infertility treatment where spare or supernumery embryos will be available for the purposes. However, no embryos can be created for the sole purpose of obtaining stem cells.

\textsuperscript{111} Supra note 24.  
\textsuperscript{112} “What is Therapeutic Cloning?” Available at http://www.wisegeek.com/what-is-therapeutic-cloning.htm, visited on 11 April 2011.  
\textsuperscript{113} Medical Termination of Pregnancy Act, 1971 (Act No. 34 of 1971).
Institutional ethics committee should keep in view the ethical, legal and social issues and should adhere to the “Ethical Guidelines for biomedical research on human subjects” issued by the Indian Council of Medical Research (ICMR) in October 2000. In India, only the research programmes and not the therapeutic transplantations are permitted at present.

2.7.8. In Vitro Maturation (IVM)

This is a new form of treatment which has only been used occasionally in England. In vitro maturation (IVM) was first developed in the early 1990’s to provide a safer and cheaper alternative to in vitro fertilization (IVF). With in vitro maturation (IVM) eggs are removed from the ovaries and are collected when they are still immature. They are then matured in the laboratory before being fertilised. The difference between IVM and conventional in-vitro fertilization (IVF) is that the eggs are immature when they are collected. This means that the woman does not need to take as many drugs before the eggs can be collected as she might if using conventional IVF, when mature eggs are collected. The procedure for IVM is as follows:

Step 1. As in conventional IVF, eggs are collected, but at an earlier stage, when they are immature. This means that you do not need to take as many ovary-stimulating hormones before your eggs are collected.

Step 2. The eggs are matured in a dish placed in an incubator in the laboratory for one to two days.

Step 3. When the eggs are mature, they are fertilised with your partner’s, or donor’s sperm. Embryos are cultured then transferred to your womb, just as they would be with conventional IVF treatment.

As with all fertility treatments, IVM is not considered appropriate for all women. Women who typically benefit the most from IVM include:

- Women who are at higher risk for ovarian hyper stimulation syndrome (OHSS), including women with polycystic ovarian syndrome (PCOS).
- Women who are younger and have normal menstrual cycles.

The advantage of IVM is that, it can also be used with regular IVF cycles when the stimulation protocol allows for many immature eggs to be obtained as well.

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IVM is less expensive because it does not involve costly gonadotropin injections and requires less monitoring. On average, an IVM cycle costs about $5,000 to $7,000 compared to $15,000 to $20,000 for traditional IVF. The disadvantage is, IVM is still relatively new, and the overall success rates and long-term outcomes of IVM are unclear. Because the eggs collected via IVM are extremely sensitive, they need to be handled very carefully in the lab or risk losing them. Also, the outer part of these eggs can become tough for sperm to penetrate making ICSI required.  

2.8. Recently Developed Techniques

Preimplantation genetic diagnosis (PGD) and microsorting are the two techniques that allow the sex of a child to be selected, are among the issue most hotly debated.

2.8.1. Preimplantation Genetic Diagnosis (PGD)

Reproductive endocrinologists developed Preimplantation genetic diagnosis in England in the mid-1980. It was initially developed to identify genetic defects in embryo of women undergoing IVF. Preimplantation genetic diagnosis, also called Preimplantation Genetic Testing (PGT), is a procedure used prior to implantation to help identify genetic defects within embryos created through in vitro fertilization to prevent certain diseases or disorders from being passed on to the child. The preimplantation genetic diagnosis begins with the normal process of in vitro fertilization that includes: ovary stimulation through medication, egg retrieval, and fertilization in a laboratory. Over the next three days the embryo will divide into 8 cells. The preimplantation genetic diagnosis involves the following steps:

1. First, a one or two cells are removed from the embryo.
2. Next, DNA is retrieved from the cell and copied through a process known as polymerase chain reaction (PCR).
3. Finally, by molecular analysis, the DNA sequence code is evaluated to determine if the inheritance of a problematic gene is present.

Once the PGD procedure has been performed and embryos free of genetic problems have been identified, implantation will be attempted through embryo transfer, intracytoplasmic sperm injection (ICSI), or zygote intrafallopian transfer.

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116 Available at http://www.fertilityauthority.com/treatment/vitro-maturation-ivm visited on 3/9/2012 at 5:08 P.M.
Examples of disorders that can occur because of genetic defects include hemophilia, thalassemia, muscular dystrophy, cystic fibrosis, and Down’s syndrome. Infertile couples that use PGD have fewer children with genetic disorders than those who do not use PGD. Nevertheless, many people believe that the use of PGD is morally wrong. They believe that life begins when a sperm fertilizes an egg and that discarding genetically defective embryos is a type of murder. Others object to PGD because it allows for gender selection.

2.8.2. Micro Sorting

Microsorting was originally developed to help couples avoid passing sex-linked genetic disorders to their children. A sex-linked genetic disorder is one caused by defective genes attached to either the X chromosome or the Y chromosome. Hemophilia, for instance, is a sex-linked blood disorder that mainly affects males and is caused by genetic abnormalities on the Y chromosome.

The ethics committee of the American Society for Reproductive Medicine (ASRM) believes that the nonmedical use of preconception gender selection by microsorting or preimplantation genetic diagnosis should be reserved for families who already have at least one child and want to have a child of the opposite sex for family balancing. This issue is still quite controversial.

2.9. Conclusion

The problem of infertility is the grave concern for human beings as millions of people worldwide are suffering from it. The people suffering from infertility are living a life of harassment and stigma. So they may go to any possible extent to overcome this problem of infertility. Fertility treatments have brought millions of babies to the infertile couples, and genetic engineering and pre-natal treatment together with sperm and egg donation make it possible to produce a child of their own choice. ART industry has transformed the character of fertility technology in India. Although ARTs are miracle cure for the infertile couple, there are many complex legal and other issues involved with the use of these technologies. This rapidly developing ART industry has been unregulated at national as well as international level. There is a lack of ethical and legal regulation by both sides; the government as

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117 Available at http://www.americanpregnancy.org/infertility/preimplantationgeneticdiagnosis.html visited on 31/08/2012 at 5:32 P.M.
118 Supra note 15 at 37
119 Ibid.
well as the medical scientists. Infertility is an approximately $3-4$ billion-per-year business. By passing the natural method of conception, fertilizing more embryos than needed, discarding excess embryos, unnatural environment for embryos, freezing them and destroying them in research are the issues involved in misuse of technology. National and international regulation may have a great impact to ART. So, there is a strong need to regulate this complex issue through law. The next chapter will try to discuss about the need for legal regulation and also examine the present legal response towards ART.