Chapter IV
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Chapter IV
Medico, Socio and Legal Implications of Assisted Reproductive Techniques

4.0 Introduction to New Assisted Reproductive Techniques

Reproduction is a biological (physiological) and social phenomenon which covers aspects such as (interpersonal) relationships, the concept of family and structures of society for childcare and child rearing. It also has a political meaning; unequal gender relations and macro level power inequalities at a national and international level are reflected in it. The subject of women and reproduction is highly controversial one. The ability of women to bring children has been seen both as a capacity, a source of power providing status - basically as something positive as well as an incapacity, a source of women’s vulnerability and thus as something negative. Childless individuals and couples see in these technologies a possibility to realize their desire for a child, which they expect to be supported by the providers of the technology and health care facilities. Researchers in human reproduction see it as an opportunity to do fundamental research in the studying process of conception, the beginnings of human life and perhaps to manipulate and have control over these processes. Critics of these technologies are concerned with their repercussions on society and see in these developments the potential far reaching manipulation of the beginning of human life, eugenic selection and increase in the control of women’s bodies and lives. In all ages and throughout the world attempts have been made to control women’s reproduction both by others as well as by women themselves. As pregnancies take place in women’s bodies, control over fertility / reproduction is closely linked to control over women’s sexuality. Various societies have devised techniques different kinds of taboos and laws for this purpose. There is increase in scientific understanding of reproductive processes, which have become more visible and controllable, and interventions in reproduction have become more technological increasingly diverse and precise. Contraceptive technologies make it possible for women to have heterosexual intercourse without becoming pregnant; assisted reproductive techniques assist women to become pregnant without having sex thereby delinking sexuality and reproduction. The struggle for control of women’s body has become more crucial. The increasing use of reproductive techniques and importance given to them in determining reproductive decisions are responsible for bringing reproduction into political domain. Further the
implementations of these technologies have given rise to distinctive medico, socio and legal implications.

4.1 Medical Implications

4.1(i). Assisted Reproductive Techniques

Respect for autonomy is grossly violated. Many times women are not aware of health hazards and the low success rate of the treatment. The nature of treatment is discriminatory. Infertility treatment is costly treatment and made available only to those who can pay for them. Few people cannot avail infertility treatment, e.g, gays, lesbians and older women. Women’s bodies are used as sites of experiment. A wrong may be done to the infertile couple by the physician during IVF treatment thereby amounting to medical negligence. Multiple reductions of pregnancies present threat to the physical and the mental health of the mother. Multiple pregnancies also present a threat to the well being of the offspring. (Discrimination amounting as to which fetus should be aborted.) There are problems associated with low birth weight and with pre term birth. IVF treatment includes early risk of removal of ova for use in later life, thus circumventing the risk of chromosomal abnormality. Over production of embryos is inseparable in treatment of infertility by IVF but it is impossible to guarantee receptive wombs, for those which remain unused in individual cases, and in many cases involving defective embryos.

4.1(ii) In Vitro Fertilization Embryo Transfer (IVF-ET)

The concerns are -

• In vitro fertilization per se does not cure infertility.
• Pressure on women – With the advent of new fertility technologies social pressure to produce biological related children is intensifying. Infertile women are urged to fulfill their full reproductive potential regardless of economic, psychological or bodily cost.
• A serious genetic disorder may be transmitted to the offspring unknowingly.
• Whether IVF access should be funded by health insurance.

4.1(iii) In vitro Maturation of Testicular Sperm (IVMTS)

• Possibility of micromanipulation of sperms leading to chromosomal abnormality.
• Leading to prenatal diagnostic tests and abortions effecting women’s health.
• Genetically defective children would be the consequence of this procedure.
• There is special concern about the reproductive potential of male offspring conceived using ICSI. There are many other unknown risks e.g. – cystic fibrosis and micro deletions in Y chromosomes. In future may lead to multigenerational problems in men.

4.1(iv) Artificial Insemination with Donor Sperm

Donor insemination represents the oldest and simplest form of assisted reproductive technique, from technical and legal perspective. The procedure introduces male donor as a third party. His rights and liabilities must be defined. In this procedure, semen obtained from a donor is injected into the woman, this results in conception in proportion of cases. The husband’s or male partner’s semen may be introduced into the uterus by artificial means, a need which might arise from impotence, from inadequate formation of spermatozoa. When sperm are introduced into a woman’s reproductive tract by means other than coitus, it is called artificial insemination. The sperm can come from a “donor” man who is not the woman’s husband or partner (“artificial insemination donor,” of AID), or the sperm can come from the husband (“artificial insemination husband,” or AIH). In both cases man deposits semen into a vial by masturbating. Several ejaculations, which are collected and frozen, are required to pool enough sperm to be effective.

Donors are classified anonymously, by their physical and personality characteristics and some “sperm banks” screen semen for hereditary diseases and chromosomal abnormalities. Drawbacks of the treatment are—

• However, there is a possibility of transmission of diseases from the donor to the future child and the risk of consanguinity. These drawbacks must be brought to the notice of the patients.
• It is necessary to get the informed consent of both the partners after they are counseled about the possible psychological conflict they may face later their life with the knowledge that one of them is not the biological parent of their child.
• AID is an ethically acceptable procedure provided there is a medical indication and psychological confirmation for its use.
• The normal conditions of anonymity and screening of the donor must be met and only frozen sperm samples that have passed appropriate quarantining for
infectious diseases such as HIV, hepatitis B and C, and syphilis should be used.

4.1(v) *In Vitro Fertilization using Donor Gamete*

When a donor’s ovum or sperm is used in connection with IVF and adequate screening is performed on the donor, the procedure presents a physical risk to the donor.

- Although ova removal technique is viewed as morally troublesome. The woman subjects herself to laparoscopy (for example, the risks of anesthesia and potential infection). When she is doing so to solve her own infertility problem, yet another for a donor to subject herself to the procedure with no equivalent personal benefit. For that reason, some may find it ethically inappropriate to accept donated ova only from women who some other reason to undergo surgery.

- This would include women who are undergoing tubal sterilizations or hysterectomies or who have excess ova removed in the course of laparoscopy for IVF. Particularly in the light of physical risks to the ovum donor, the physician should assure that the woman has not coerced into donating the ovum.

- Like embryo donation, gamete donation also raises the possibility of psychological harm to the participants. One concern is that introducing third parties into creation of the child will damage couples personal bond or that the partner who has infertility problem will feel that the child is less his or her own and may feel resentment toward his or her partner for being able to contribute biologically to the child.

4.1(vi) *Germ-line Therapy*

In this therapy there is insertion of genes into embryos, eggs or sperm so that these genes are inherited. It is likely to do a feasible job in the future. It would be a means for correcting inherited gene defects completely so that future generations would not suffer from the particular disease carried within a family. Ultimately specific gene defects could be permanently eradicated. There are powerful arguments in favor of germ-line gene therapy. It is moral obligation for doctors to offer the best treatment possible. Gene therapy treats the disease before it appears, and ensures that future generations will not suffer from it. It does not involve destroying the human embryo but rather protects its ‘individuality’ or its ‘sanctity’, depending on your point of view. It could also very likely be the most effective treatment of genetic defects.
One limitation of somatic cell gene therapy for diseases such as cystic fibrosis is that by the time gene therapy is started, scar tissue has already formed and there is gross impairment of organ function. So a child with established cystic fibrosis will still be ill, but may not die. He will still suffer from being breathless on exertion, being prone to chest infection, or having retarded growth. Preventing the disease completely, by replacing the defective gene before development, would be medically preferable. Lastly, germ-line therapy will be immensely important for scientific inquiry. There is no doubt that it will enable us to understand much more about how genes enter the embryonic cells and how their expression is controlled.

- The most powerful argument against introducing new genes into human embryos is that the effects of gene insertion are at present unpredictable. If Genes are inserted into cells the basic functions of the cells are disrupted and this would be certainly dangerous. In order for germ-line therapy to work at all, any gene that is therapeutically inserted into the embryo must function normally, providing its usual message to the cell. There is need to ensure that the gene was incorporated into the DNA at the right point, with appropriate DNA sequences ahead of it, and downstream along the DNA string. Failure to do so could have serious and unpredictable effects.

- Next, there must be no risk of causing mutations which might affect the individual. It would, for example, be quite unacceptable to cure cystic fibrosis only to find that the ‘cured’ person has developed leukemia. Nor should there by any genetic side-effects. The cystic fibrosis might be cured, but other genes cease to function or the inserted gene might work for the first year or two of life and then stop expressing. One expensive treatment would lead to another disease. Undoubtedly, in far distant future, many of these problems are likely to be resolved. But given that preimplantation diagnosis is established, it would be safer and more reliable – with all the drawbacks of its complexity – to continue to use it as the tool against genetic disease. Gene insertion in embryos seems a very long way from any possibility of practical application, and it seems more likely that, when it is finally used, it will be used for therapy rather than to manipulate desired traits. However these treatments are cost effective and time consuming treatments. At present Designer babies have arrived in our society amounting to more discrimination and eugenics in society.
4.1(vii) Cryopreservation of Embryos

Cryopreservation is freezing of embryos. This has enabled the sperm to be stored for long periods of time. Donors are screened so as to rule out infections, and donor semen is classified according to the skin color and color of eyes and hair as well as IQ level. In some places religious and educational background are also noted.

The first sperm banks were set up around the end of 1960’s in the US for men who has to be sterilized and for astronauts who were afraid of becoming infertile. Since then commercial sperm banks have been established. In the US there are an estimated 30,000 sperm banks. Customers can choose donors from catalogues specifying height, hair color, eye color religious background, education and IQ Levels. The most famous is the ‘Repository for Germinal Choice’ in Escondido, California established by Robert K Graham in 1980. It is also called the Nobel Sperm bank, because it is said to harbor ‘smart sperm’ – the sperm of several Nobel laureates and young scientists with IQs between 140-190.

Since 1985 the perfection of the technique of freezing and thawing has made it possible for women’s eggs to be stored as well. In the US, catalogues of potential egg donors are also available, now also on the Internet, although most donated eggs come from friends or family members. Until of the middle of 1970’s scientists had no access to human embryos, except after a miscarriage, when the fetus had very little use. However with the development of techniques leading to in vitro fertilization, scientists could recover women’s eggs to fertilize them ex-corporo, in a Petri dish, and witness the first stages of cell development. In order to ensure better chances of success for an IVF procedure doctors attempt to have women super ovulate. They then recover more eggs, some or all of which are all fertilized. If all the eggs are not fertilized, the remaining ones are frozen for subsequent attempt. Embryo research necessitates the collection of large number of eggs. Surplus embryos are also saved by freezing. The method of freezing and thawing embryos was developed by veterinarians in German - In 1978, the first calf ‘Frosti’ was born from a frozen embryo. The second baby to be born after freezing and thawing of an embryo was in The Netherlands at the Dijkzigt Hospital in Rotterdam. In another case non-identical twins were born eight years apart; the latter was from a frozen embryo.

In 1983, Alan Trousan from Australia succeeded in implanting a human embryo which had been frozen for four months but the medical issues pertaining to cryo preservation of embryos are ---
Potential harm to the Embryos

- The main basis for opposition to cryopreservation of embryos, particularly when that risk presents a danger to the resulting child.
- The background radiation of freezing may increase mutation rate, yet the dangers would seem to be relatively small for the short period of time that IVF programs are currently preserving embryos.
- For those who believe that the embryo has moral status of a person, however freezing (in contrast to immediate transfer) may be considered in appropriate since it decreases the likelihood that a particular embryo will be born.
- Some 75% of embryos show cellular damage after freezing. Although some embryos with cellular damage do develop into viable pregnancies, the pregnancy rate after cryopreservation is much less than after immediate transfer.
- Or the embryo is less likely to be given chance to be born once it is frozen, since the couple may decide not to proceed with the implantation of the embryo.
- The child who may be born after cryopreservation may suffer psychological harm as a result of the procedure. The prolonged freezing may rob a thawed and growing life of its genetic progenitors, of its root and support freezing may cause disruption across generations.
- Gestation of embryo after 25 years of cryopreservation may deprive embryo of a chance to meet his or her parents, it may led to unusual situations such as woman gestating embryo that was her own sibling. Because of unusual family relationships cryopreservation might allow potential harm to the resulting child.

Research on Human Embryos - Research in the field of human genetics is progressing very rapidly, although not fast enough of the scientist working in the field. The research may be put to use by pharmaceutical companies for testing various drugs, or for organ banks. The use of embryonic foetal tissue for treating major brain diseases – Alzheimer’s Parkinson’s, congenital abnormalities, perhaps spinal cord injuries – by transplanting the young and supple tissue from aborted human fetuses as organ farms like the living dead in comma being maintained as organ source, is another possibility.
Another issue for consideration is the result of drugs given during the IVF is the health of the resulting fetus and once born – the child, which may be effected as a result of the drugs given during the IVF or freezing and thawing procedures.

It is difficult to answer the long term effects of such technological interventions. However in future if the embryologists learn how to get early embryos to develop outside the womb, while neonatologists learn how to keep less and less developed pre-mature babies alive, the two ends would meet definitely leading to designing of plastic wombs and dispensing with human gestation.

The physician has a legal responsibility to adequately inform the couple about the tests that are available to detect whether they are at risk of passing on a genetic defect. This responsibility – which is identical to that of the physician when the pregnancy is conceived in a more traditional manner – includes letting the couple know whether their race, ethnic background, ages or other factors put them at an increased risk of conceiving a genetically diseased child. The availability of amniocentesis needs to be discussed and, as chronic villi sampling becomes a part of standard medical practice, the couple to be informed about its availability.

4.2 Scientific Concerns

Tremendous scientific progress has been made in the field of assisted reproduction. Important challenges still remain. Three of these challenges are worthy of special mention.

4.2(i). Improving success rates

Success rates have been constantly increasing that is 25% live births per cycle, until the age of 34 years, but then there is steep decline. This success rate sounds good enough. But it also means a failure rate of around 75%, and that is distressing for those who went through the financial and heavy psychological cost of the procedure.

There is room for improving the success rates of assisted reproduction. Success rates have been improved by simply increasing the chances for implantation through transfer of more than one embryo to the uterus.

4.2(ii). Shortage of gametes

ART depends on the availability of an adequate number of healthy gametes to allow successful manipulation. Three approaches are currently being pursued: increasing the production, cryopreservation and donation from a third party. The applicability
and success have been different for female and male gametes. Oocytes are scarce and are more difficult to obtain. But the ovary can be hyper stimulated to yield enough ova. Sperm is normally more than plentiful in fertile men, but can be very scarce in infertile men. There is, however, no way to increase the supply from infertile men, though sperm can now be obtained directly from the epididymis or testis. The relative ease and the success of cryopreservation of sperm and embryos contrast markedly with the problems associated with freezing of oocytes. Sperm donation has been in use for decades. Oocyte donation is possible, but is more difficult and raises different concerns. Shortage of gametes is still a challenge in ART. More research is needed to develop innovative approaches.

4.2(iii). Multiple gestation

Improving success rates and overcoming shortage of gametes are important challenges on which scientists need to work. The pressing problem that challenges scientists is, however, the prevalence of multiple gestations, twins and higher-order births, a result of assisted reproduction.

A world collaborative report on in vitro fertilization (IVF) recorded a multiple birth rate of 29%, the majority of which are twins. The large scale Swedish retrospective cohort study reported a 20-fold increased risk of multiple pregnancies following ART compared with the general population. With increasing resort to and utilization of assisted reproduction, we may soon be facing a public health problem.

Regardless of whether they originate from assisted or non assisted reproduction, multiple gestations is associated with an increased risk of preterm delivery, low birth weight, congenital malformations, fetal and infant deaths and long-term morbidity and mortality as survivors.

The risks of multiple gestations are often expressed in terms of prenatal and infant morbidity and mortality.

The impact on the woman often takes second place of is completely ignored.

- There are the complications of pregnancy and labor that are more frequently encountered with multiple gestations.
• There is the psychosocial impact (including the impact of multi fetal pregnancy reduction) and the heavy burden on the mother of caring for more than one immature baby.

• Perinatal morbidity and mortality should be appropriately counted as part of the burden of disease on women, rather than on the child, as it is often counted. It is women who have made a major investment of themselves in the pregnancy, and who have the responsibility of caring for a disabled baby.

Controlled ovarian hyper stimulation, intrauterine insemination (IUI) and transferring multiple embryos account for the high incidence of multiple gestations or multiple pregnancies. Transferring multiple embryos is a standard practice to increase the chances of success. Monozygotic twinning has been reported to be higher following assisted reproduction.

4.2(iv) Balance between preventive and curative services
The allocation of resources does not only depend on the magnitude and severity of a health problem. It also depends on the availability of cost-effective interventions. Health services need to balance the utilization of their resources between preventive and curative services. Preventive services may be more cost-effective and benefit more people than expensive curative services.

In a sense, assisted reproduction is not a curative treatment. The couple remains infertile after the success of the procedure. Prevention of infertility, particularly infection-related infertility, should not be ignored in the enthusiasm for assisted reproduction. Prevention of sexually transmitted infections, particularly among adolescents, may save their fertility potential. Sexually active adolescent girls are appropriately advised to use the condom if they want to have a child in the future. It should be recognized, however, that infertility is not always preventable. Preventive services will also not help the many couples who already suffer from the problem.

4.2(v) Professional challenges.
The introduction of assisted as a novel technology poses a number of significant challenges for the health profession as a whole. They are

• The profession is challenged to ensure transparency about the outcome and risks of these new procedures.
The profession is challenged to assume the role of self-regulation and to provide quality control.

The profession has a responsibility to put proper surveillance in place as a follow-up after the introduction of these completely novel technologies.

Last, but not least, the health profession is challenged to partner with consumers, and not to deal with them as passive recipients.

a. Transparency

As with many other novel technologies in medicine, unjustified claims can be made by enthusiasts of new procedures. This does not mean that they may present false data. However, data can be presented in ways that can be misleading to potential clients. Randomized, double-blind, controlled trials are difficult to design in this field except to compare certain modifications or changes in the procedure. One of the professional challenges is to ensure that benefits and risks are presented in an objective and transparent way that allows potential consumers to make informed decisions.

Success of assisted reproduction procedures has variously been reported as a positive beta-hCG test 14 days after treatment, ultrasound diagnosis of a gestation sac, pulsating heart on ultrasound examination, or a take-home baby. Success has been expressed per transfer or per cycle commenced.

A standardized way of presenting results is often advocated, but it can also be misleading if used to compare the performance in different centers without taking into consideration variables that may influence the outcome. The selection of clients influences the success rate. Success can be expected to be higher in younger women. Success is also generally higher in the first cycles, and so may be higher in centers receiving more new clients. The procedure used also influences the success rate. Ovarian hyper stimulation and transfer of more than one embryo carry a higher success rate, but also a higher risk of multiple pregnancies. When results of different centers are complied and published by professional bodies, lack of anonymity may influence centers to project their published results in a more positive light. Anonymity, collective analysis and presentation of the results are alternatives that would still be helpful to potential clients.
b. Self-regulation

Medical and surgical procedures are more difficult to regulate than new drugs or new devices. New drugs and devices are subjected to vigorous testing in animals and in human volunteers before they are finally approved for general medical use, for specific indications and under specific instructions.

The challenge to the profession is to take over this responsibility. The experience with Reproductive Technology Accreditation Committees in Australia has demonstrated that self-regulation can work. Committees accredit practitioners who are qualified to perform the procedures and have adequate facilities to perform them. They also try to ensure that the accredited centers maintain the quality of their services and regularly report their results in an objective, unbiased way.

Benefits of self-regulation include its flexibility. It can respond to new developments in a rapidly advancing field. If the profession does not fulfill this responsibility, it is likely that law-makers or policymakers may be persuaded by the public to impose regulation, which may restrict access and hinder progress.

c. Surveillance

Although scientists, regulatory authorities and service providers all do their best to ensure that drugs and devices are safe for the consumers before they are introduced, post marketing surveillance has become an established practice and a professional responsibility. It is only through surveillance that rare events and distant events can be discovered. Methodologies for surveillance are well established. They include systematic reporting of adverse effects, case-control studies and longitudinal cohort studies in which subjects and matched controls are followed for years. The same principles should apply to new medical procedures. In the field of assisted reproduction, surveillance presents the profession with new and different challenges, in terms of methodology and in terms of targets. The methodology should not be limited to medical surveillance, but has to include psychosocial studies. Also, the follow-up has to be for a long term, and not just for a short term. The targets for surveillance should include not only the child, but also the woman and the family.

- The resultant child

The follow-up of babies is not to be confined to the short-term health consequences of mortality, morbidity and clinically recognizable congenital anomalies.
The further concerns are —.

- Follow-up is needed to provide assurance of psychological and mental development.
- Follow-up is needed to continue for the period of adolescent development.
- Surveillance is still needed to ensure potential future fertility. The direct injection of a single spermatozoon into the mature oocyte eliminates the process of natural sperm selection.
- Of particular concern is the future fertility of babies born to infertile men after this ICSI procedure. The finding that hypospadias is more frequent in ICSI children may be related to paternal sub fertility with a genetic background.

- **Women**

  Controlled ovarian hyper stimulation is a standard component of assisted reproduction, to ensure an adequate supply of oocytes. Women exposed to ovarian hyper stimulation need to be followed up to ensure that they will not be exposed to an increased risk of epithelial ovarian tumors. The surface epithelium of the ovary is subjected to trauma at every occurrence of ovulation. The repair process involves repeated cell division with an increased chance for DNA damage. The protective effect of oral contraceptive would lend support to this hypothesis.

  Bamford and Steele reported the first case of ovarian carcinoma in a patient receiving gonadotrophin therapy. Some studies have shown that infertile women using infertility drugs are three times more at risk for invasive ovarian cancer than women without history of infertility. It may also be noted that assisted reproduction not only involves excessive ovulation, but also repeated minor trauma for ovum pick-up. The jury is still out on the risk of ovarian cancer in women who are super ovulated. Some studies have been reassuring. Large prospective and retrospective studies will be necessary before the risk can be excluded.

- **Families**

  Families need to be followed up for the impact of assisted reproduction, particularly if assisted reproduction involves a third party in the way of gamete or embryo donation. Questions can be raised as to whether parenting in these families is different from parenting in families with natural reproduction. Surveillance should include the quality of parenting, family functioning and child psychological development.
development. Surveillance, particularly its psychosocial component, needs to be carried out in different regions of the world. It is quite possible that the psychosocial outcome of assisted reproduction may be influenced by the cultural context in which the technologies are used.

d. Consumers as partners and not passive recipients
Dealing with consumers as partners and not as passive recipients is not always easy for the medical profession. The medical profession has to adopt new attitudes, and has to abandon a lot of strongly entrenched patronizing attitudes. Partnership between consumers and providers is needed at three levels. At the level of the individual patient – doctor relationship, it means the active participation of the infertile couple in making the decisions about treatment. To make informed decisions, consumers are entitled to factual and objective information about all alternatives. They should know the chances of success, and the risks involved.
At the level of the profession as a group, there is a need for a constructive dialogue with consumer groups in which both sides can listen to each other and talk to each other. Mutual trust is crucial to build. Consumer groups can be represented on appropriate scientific and professional committees.
The WHO Special Programme of Research, Development and Research Training in Human Reproduction realized the need for this dialogue and convened, in collaboration with the International Women’s Health Coalition, a meeting that included both women’s health advocates and scientists. The report of the meeting was published under the title ‘Creating common ground.’ This was followed by a series of regional meetings, and by institutionalizing the participation.
At a third and equally important level, there is power in partnership and this power can be used in advocacy. In the late 1980s, a coalition of consumers and physicians successfully lobbied the Australian federal government for recognition of fertility as a medical condition and for reimbursement for ART treatment.
Assisted reproduction introduced a number of challenges with which society has to cope. Three challenges need to be addressed. The first challenge is rather generic: the public trust in science. The second challenge is limitations on science. The third challenge is that assisted reproduction has brought the issue of gender to the forefront, and society is being challenged to re-think the way it views the role of women.
• Public Trust in Science.
First, scientists need to engage the public in an informed debate. This involves more than just making scientific information freely available. The role of scientists is no longer to preach enlightenment to the ignorant masses. The role of scientists is to present the case objectively to an enlightened citizen jury to allow them to make an informed judgment. Scientists must accept that they are no more qualified than the general public to make value judgments as to the uses to which science shall be put.

• Limitations of science.
Second, scientists should avoid giving the public a perception of being arrogant. Time and again, the limits of science are being exposed. With the recent crisis of the bovine spongiform encephalopathy (mad cow disease), people may feel justified if they question whether they can really trust scientists with their supper.

• Communication of scientific data.
Third, scientists should be careful in communicating scientific data to the public media. The media, in its presentation of science, aims first to engage and entertain, and only second to inform. Scientists should resist the temptation of publicity. Reproduction is by no means equally shared between men and women. Women bear the physical and psychological burden. The incidence of severe ovarian hyperstimulation syndrome has been estimated at 0.2% - 1% of all assisted conception cycles. The burden of assisted reproduction for male infertility falls largely on the woman. It has been reported that 27% of ART in the UK is carried out for severe male infertility. The noble task of reproducing our species has not brought societal awards to women. On the contrary, it has often led to their subordination. Women in society are subject to both pronatalist and paternalist attitudes. The introduction of assisted reproduction is a challenge to societies to re-examine these attitudes.

4.2(vi). Amazing revelations, mitochondrial transfusion and old eggs
There was, just recently, a press report suggesting that American physicians were attempting to make old human eggs young! The poor viability of eggs taken from older women is well documented. Moreover, it is known that the ageing process may be due in part to changes or mutations in DNA of the mitochondria, the organelles in the substance (cytoplasm) of the egg. They announced therefore a ‘break-through’ in helping older women to successful IVF treatment. Once their eggs had been collected, they transfused them with the cytoplasm taken from the eggs of younger
women. By these means, they hoped to give them a kind of royal jelly, or elixir of life. There are several possible responses to such an experiment.

- Firstly, it certainly sounds like quite a good idea. It is quite plausible that the reason why ‘older’ eggs do so badly is because of deterioration in their mitochondrial DNA. There is, after all, no clear evidence of deterioration in the nuclear DNA – and yet ‘old’ eggs do not function nearly as well.

- Misleading information. The second response is highly critical. Indeed, a recent trawl through computer records of all relevant scientific journals on electronic databases revealed no published reports at all of this work, several months after the original article. If it is right and this work has not been properly published first, then this is surely reprehensible. It raises the criticism that these American clinics are using press publicity to advertise treatment, in this case for desperate women, without the slightest evidence it works. Yet, regrettably, this kind of thing happens all the time in the field of human reproduction.

- False advertisements. Advertisements made without proof of published reports.

- But, of course, the real cause for concern about mitochondrial transfusion is that human patients – and potentially human babies, if any are born – are being used as guinea pigs.

- Who knows what the risks of mitochondrial transfusion are? Who knows even if the mitochondria will survive transfusion?

- Who knows whether there may be the chance of an abnormality in a baby born after such an experiment?

The truth is that exhaustive testing should be done in mice eggs first and then probably other species afterwards. A detailed assessment should be made of whether the mitochondria survive and what the risks of damage to the DNA might be. This is not like an experiment on a cancer victim who is surely going to die unless something is rapidly done.

**Misuse of medical technology** - This is misuse of medical technology and it should be a matter of great concern that announcements like these, which happen week after week, are not greeted with more skepticism by the press and with more criticism by those who should be protecting the good name of this controversial and important area of medical practice.
4.2(vii) Effect of Parthenogenesis

It is possible, under some circumstances, to activate a human egg without actually placing a sperm near it. Certain forms of physical injury will do this, as will a small electrical shock. With activation, the egg may start to divide spontaneously and form a structure which, using routine microscopy is indistinguishable from a normal embryo. It is for this reason, that in IVF programmers, eggs are routinely examined at around eighteen hours, to ensure that there is a genuine embryo, and that any subsequent cleavage is not due to parthenogenesis.

It has been suggested that it might be possible, eventually, to produce a complete human being by parthenogenesis.

However, even if the chromosomes were manipulated in some way to that paired chromosomes would be formed, the evidence strongly suggests that lethal genes would prevent further development beyond a few cells.

It seems, therefore, that at least for the time being humans will not reproduce like ants, termites or bees. Sexual reproduction may be complicated, but even without the pleasure it brings to many people, I think that it is here to stay for some time.

4.2(viii) The Artificial Womb

In *Brave New World*, (1932) Adlous Huxley’s wonderfully funny novel, human embryos were kept in vats where they developed into fetuses. Their development could be enhanced by giving them various special food stuffs, so that when they are born they would be most suited to a particular occupation. Embryos could be made identical to each other, so that they could provide a uniform work force. Birth was achieved by a process of decanting.

Adlous Huxley, may have predicted IVF and even cloning – but how likely are his ideas about the artificial womb? It is possible to keep the embryos of a rat outside a uterus for short periods of time. However, the embryos have first to be implanted in the uterus to get early nutrition, before they can be removed. This has been used for an experimental model in some of the study in formation of the placenta, and in studies on the mechanisms of action of certain drugs in pregnancy. However, all remaining embryos rapidly become so big that they cannot survive without a proper placenta which is implanted in their mother’s uterus. The placenta supplies the oxygen nutrients and other essential compounds which dictate satisfactory growth. One unique aspect of the placenta is that it grows and adapts rapidly to the changing
needs of a developing fetus. No man-made machine looks even remotely capable of
achieving such a complex function in the foreseeable future. Doctors have managed
to make very imperfect artificial organs, such as the kidney machine, and a relatively
primitive heart / lung machine. This can keep human patients alive for short periods
of time. But the human placenta is in a sense a heart / lung machine, a kidney
machine, an artificial liver, and an endocrine gland all rolled into one. Moreover, it
grows continuously and its function changes during growth.
There is no doubt that an artificial uterus with an artificial placenta would be of huge
potential benefit in treating a number of human conditions.
First of all, if very premature babies that were miscarried could be rescued by these
means, it would be possible to allow them to grow outside the body until they were
sufficiently viable to breathe in the open air. But also it would be of huge benefit
women who have the most severe diseases in pregnancy, such as extremely high
blood pressure, renal disease and possible to those who develop cancers during
pregnancy.

4.2(ix). Cloning
A clone is simply an individual or group of individuals who are genetically identical
to one another. Cloning can be a natural phenomenon. Identical twins – occurring
when one egg spontaneously splits after fertilization with a single sperm – are natural
clones containing identical genes.

The two types of cloning are:
A. Artificial cloning is centuries-old. Plant cloning was a technique well known to
the ancient Greeks. Macintosh apple trees, for example, are all a clone, having been
produced from a single mutated plant, and all share identical genes.
B. Laboratory cloning was first affected by Dr. Richard Gurdon in 1968. He
transplanted the nucleus of a cell from a tadpole’s intestine, into the egg of another
frog. The egg had been previously prepared by destroying its own nucleus. Once the
new nucleus took over function, the egg divide and grew into a mature frog without
any sperm being involved in fertilization. With the transfer of more nuclei from the
same tadpole into more frogs’ egg, many identical frogs could be produced.
Cloning in mammals turned out to be much more difficult. Initially, experiments were done using embryonic nuclei because it seemed impossible to use the nucleus of a mature mammal for cloning.

A major breakthrough occurred in 1997 when Dr Ian Wilmot and his colleagues at the Roslyn Institute in Scotland announced that they had used the nucleus taken from the mammary tissue of an adult sheep and transferred it to an enucleate egg. The result was Dolly. This announcement caused a wave of most extraordinary publicity. With it came a huge amount of misinformation, unsubstantiated speculation and simple horror. There was, however, a paucity of rational discussion about the issues involved. The basic concerns were---

- The ability to clone a mammal from an adult cell raised a spectre which still haunts the mind of the public. There was immediate outcry when Wilmot and his colleagues published their work. Even serious journalists argued that it was now just a matter of time before some rich and powerful man – or worse a political dictator – used this technology to reinvent themselves.

- There may be a perfectly understandable objection to making many ‘carbon copies’ of people, but the technology behind cloning is not nearly as threatening as it first appears. Firstly, no individual created by nuclear transfer would be identical to the parent from whom the nucleus was taken. Although nearly all our DNA is held in the nucleus, a much smaller part of it is in the mitochondria – small organelles present in the cytoplasm of the egg. Consequently, the egg as well as the parent nucleus would contribute DNA to that individual. In genetic terms, the individual would be less similar to his or her parent than would identical twins be to each other. Moreover, we are as much a product of our nurture as of our genetic nature.

- But even then there is inadequate evidence that cloning technique is likely to produce a healthy human alone. The human embryos might look normal and might test normally, but there is every reason to believe that cloning attempts would still be likely to produce an abnormal baby. Hundreds of unsuccessful attempts were needed before Dolly the sheep. Since then a few cloned mice and cows have been lucky to survive. In the early experiments with Dolly, for example, a large number of normal looking embryos did not survive. More failed
to implant. With all cloning experiments there have been repeated miscarriages, and a number of more developed fetuses have died in uterus.

- Fetal death at birth has been common and many of the individuals born after cloning have been over weight at birth or have shown abnormalities of their internal organs.

- Moreover, the placenta and the membrane surrounding some of these fetuses have been highly abnormal. These unpredictable abnormalities may be caused because cloning upsets the way certain genes express. It is very likely that the growth factors, which control early development, can not be expressed in normal amounts and consequently there is this loss of life and these abnormalities. These considerations are very sound and for these reasons it would be unwise indeed to consider human cloning and it is believed that very few doctors or scientists would remotely consider trying it. The chances of abnormality would be excessively high, and leaving aside any ethical consideration, the medical legal consequences to them would be severe indeed. And even where cloning has been successful, there will be grave doubts about an individual’s long-term normality.

- Genetic manipulation of this kind could well produce humans who, though externally normal, might suffer from the rapid development of cancer or accelerated diseases.

- Cloning technology might just be used to help men suffering from intractable infertility. Some men cannot produce sperm because their testes are depleted of spermatozoa. It has been suggested that a clone of the father be made and a nucleus placed into the mother’s egg. True, for many married couples, this would be ethically much more justifiable than using donor semen from an anonymous donor. Yet making a cloned person might be too risky and cost effective. But a major refinement of the technology involved could lead to the ability to develop new cells which would effectively replace sperm. Sperm and eggs are different from all other cells in the body in having only one copy of each of the normally paired chromosomes. This state prepares them for fertilization, so that the egg, when it develops, has paired chromosomes with one copy from the father and one from the mother. Using cloning technologies, it may be possible eventually to lose one set of chromosomes. This nucleus could then be injected as a quasi-sperm into a normal egg, which could then develop like any other embryo, with
half its genes derived from the mother and half from the father. Human cloning may pose grave dangers but it would be wrong to be opposed to cloning research. In future is the use of cloning transgenic animals kept for medical purposes – for treatments such as organ transplantation. There has been much recent interest in the possibility of using transgenic pigs for heart transplants because of the acute shortage of spare human hearts and other tissues, such as kidneys, livers and heart valves. Once a pig had been genetically engineered to have the appropriate human genes, cloning technology could also help to preserve and breed endangered species. With the potential lack of availability of animals of both sexes in a particular rare species, cloning could be envisaged. Once initial clones had been obtained of a creature threatened with extinction, they could subsequently be allowed to breed naturally so as to encourage normal genetic diversity, which is an important protective mechanism.

- One serious problem is the lack of genetic diversity in such cloned herds. Given that they would all be genetically similar, they would be susceptible to similar diseases. It is worrying to consider the potential disaster of whole domestic herds being wiped out by being predisposed to a particular infection, or some adverse influence in their environment.

Merits of cloning research are—

Indeed, there is a great amount of valuable information we can learn. It is important to draw a distinction between the use of cloning for reproduction and cloning to treat disease. Whatever cloning, there is no doubt that therapeutic cloning could have enormous benefits for both human and animal health in the next century. There could be immense clinical value in being able to clone human tissues for medical treatments, and these techniques would be valuable for tissue engineering. But the immediate importance of cloning is the information these techniques give to the science of biology. What has been forgotten in all this curious debate is that the practice of cloning animals and animal cells will help the understanding of basic phenomena – for example, the principles of cell regulation? Remarkably, once the adult nucleus is transferred to the egg cell under appropriate conditions, it appears to be totally reprogrammed and effectively starts life from the beginning once again. We have in the nuclei of all our cells, thousands of genes which contribute to the workings of our bodies. Some of these genes are expressed every day in adult life –
for example, as you read this page, your brain makes proteins which send the
messages across its cells which enable your understanding of what you are reading.
You may just have had your supper. Their genes are helping you digest it whilst your
muscles, again gene regulated, turn the pages of this book. But other genes in your
body have only been expressed once. Those are mostly the genes concerned with
development. When you were an embryo, specific growth-controlling and
implantation-controlling genes switched on briefly to allow your successful
development and survival. The cloned adult nucleus, having been expressing adult
genes, suddenly reverts to the beginning of life and starts to ensure that the cloned
embryo survives.
This is an extraordinary reversion. It may give us an insight into how the nucleus and
its genes can be regulated, how different tissues come to grow from cells which are
not differentiated and which have as yet no specific function as bone, muscle or skin,
for example. It may be of immense importance for people studying the development
of cancers and help us to understand what goes wrong with cells as they grow older
and why faults can occur in this process.

4.3 Social Concerns of Assisted Reproductive Techniques
4.3(i). Status of Embryos as a Person?
The status of pre embryo has often been disputed ethically and legally. It is often
questioned that is a pre embryo a person from the moment it has been fertilized?
Clinical text define the embryonic period of human development as a period that
starts with fertilization and ends when the basic organ systems area rudimentarily
established, at about six weeks of gestation. Since the advent of in vitro fertilization
until the onset of primitive streak, this occurs about after 14 days after fertilization.
At that time implantation has been completed, individuation has been established, and
embryonic cells can be differentiated from those of placenta and embryonic
membranes. However four factors must be considered in addressing the moral status
of embryo or pre embryo. First its immaturity; second its presence within or its
dependence on a woman’s body third its species membership; fourth its potential
capacity for member hood.
On the first point, a mature human being is definable as one who has developed the
ability to reproduce offspring. Children, fetuses and embryos are also immature by
this standard. Embryos, pre embryos and fetuses are almost immature by a standard
that measures the ability to survive outside a woman’s body that is viability. The probability of maturation associated with viability increases through the course of development, it is lowest immediately after fertilization, especially in case of embryos or pre embryos. The pre embryo may exist for a time in vitro; they cannot continue their development without transfer to woman’s body. To the extent that transfers of pre embryos involve risk and discomfort to the (potentially) pregnant woman without directly affecting others. The potential father’s wishes are wishes are next in importance because he is generally the most affected by the disposition of embryos.

Regarding species membership, the embryo or pre embryo that develop from human gametes is clearly human, as is the fetus or child that the embryo may eventually become, as humans as are the gametes themselves. Although the question remains whether human embryos are persons or not? This has been debated by theologians and philosophers; their potential for personhood is accepted even by those who deny that they are persons. The potential for personhood also distinguishes human embryos from other human tissues and organs. However several important differences between gametes and embryos are undeniable. The human zygote is a single cell that may naturally develop toward birth and unquestionable personhood without intervention by others. Gametes cannot achieve this natural propensity unless individuals choose to establish through sexual intercourse or assisted fertilization. Further, pre embryos are diploid and embody the total genetic constitution of at least one new human individual. Gametes are haploid and embody only half of the genetic constitution of a new human being. Surely enough these differences between them Human personhood will begin only some weeks after fertilization. (According to Catholic belief) the existence of personhood bars us from abusing or killing a person (fetus), further raising several other socio legal concerns with specific regard to research on embryos and fetuses, donation of embryos and fetal reduction of pregnancy.

4.3(ii). Sub zonal insemination (SUZI) and Intra Cytoplasmic Sperm Injection (ICSI - ICSI or PZD is the most widely accepted choice of treatment for male factor infertility. ICSI can be carried out with fresh or frozen-thawed ejaculated or epididymal / testicular motile or live spermatozoa

- ICSI is expensive technique
- It is more time consuming, requires more equipment and extra skills and in addition to the procedure it does not give better results.
- It does not cure male infertility.
- The resultant offspring in future would suffer from genetic defects and infertility.

4.3(iii). Pre implantation Genetic Diagnosis

- PGD is stigmatized by abortion.
- Sex selection of embryos (male child) is allowed to survive and female child is aborted in many Asian countries.
- Selective Breeding – Selection of embryos as potential neonatal agents.
  This subject has attained great importance in the recent years. The very real possibilities for treating blood dyscrasia, haemoglobinopathies, bone marrow donation or the use of stem cell or the use of totipotent embryonic cell implants for curing genetic diseases has increased. The success of these treatments depends upon genetic compatibility which is sought by sibling donation. Then sibling should be created for express purpose of providing a donor thereby introducing a possible refinement of selecting the best match siblings from number of embryos created by IVF. At fetal stage of multiple pregnancies the procedure of PGD involves selecting the embryo, as a therapeutic tool for the benefit of its sibling.

- Selective destruction of abnormal fetus is justified but whether there would be tort liability in the event of damage to a surviving fetus is arguable.
- The subject opens up the old age question -- of whether it is permissible to use unacceptable means to achieve a desirable end.

4.3(iv). Sex Selection since Old Ages

For thousands of years humans have sought to determine the sex of their offspring. In ancient civilizations males seemed to have been greatly preferred to females. The worst thing that the Pharaoh could think to do to the Hebrews was to issue decrees for the drowning of all their first-born male children in the Nile, so destroying the providers and the potential soldiers. The ancients tended to believe that boys were generated from the right side, and girls from the left. Coital position was therefore considered to be an important factor in determining the sex of the fetus. Other factors which at various times have been thought to have an influence include the timing of intercourse during the menstrual cycle, delaying orgasm, changing the amount of salt in the diet or the acidity of the vagina, or taking up a less stressful life-style. There is
little evidence that any of these methods worked, but the fact that they were widely
used in ancient Egypt, Greece and Rome, and more recently, in many other
civilizations all over the world, is an indication of the importance that was attached to
being able to determine the sex of a child. In many societies today, it is still a matter
of considerable consequence, and in general there has nearly always been a
preference for male children. In some countries with high population growth and low
economic development, boys are preferred because they are more likely to become
the breadwinners. They are potentially capable of supporting their parents when they
are old and infirm. Although the sex ratio between boys and girls is naturally around
106:100 in most parts of the world, in China it is 114:100. There are rumors
suggesting the practice of female infanticide which could account for this difference.
In parts of India and elsewhere in Asia, ultrasound may also be used in attempts to
detect the sex of a baby during pregnancy, and late termination considered if the male
genitalia cannot be seen. The sex of a baby is determined by the sperm fertilizing the
egg. Sperm carrying a Y chromosome produce males. The Y chromosome is
physically smaller than the X chromosome, and there is therefore a minuscule
difference the weight, and possibly size, of male – or female bearing sperm. Some
authors have argued that male sperm swim faster. But in spite of various scientific
papers which are occasionally still published on the subject, there is no convincing
evidence for the agility or increased speed of Y-bearing sperm. A single sperm
weighs less than ten millionths of a gram, and the difference in weight between an X-
carrying sperm and a Y-carrying one is probably no more than about three %. It is
very difficult to measure such a difference accurately, especially when dealing with
such a tiny object.

None the less, some commercially minded doctors and scientists still attempt to
promote methods which claim the successful separation of X – and Y-bearing sperm.
All these methods have the same object of producing enriched sperm samples for
artificial insemination. The most widely used methods of sperm separation usually
involve passing sperm through a high-density fluid, or spinning samples in a
centrifuge to isolate those of a particular weight, or a combination of both these
methods. Several clinics have now been set up to offer a sex selection service,
although there is little independent evidence that their methods actually work. It is
notable that these clinics are most common in America, where 'market forces' drive
so many of the developments in this area of technology.
Currently, the only proved reliable method of human sex selection is pre implantation genetic diagnosis (PGD), when a cell of an embryo can be analyzed for its DNA content. But this is complex, expensive and requires removal of a cell from an embryo – with the possible risk of damage. This is one of the reasons why the HEFA has sanctioned the use of PGD only for those patients at risk of having a baby with a severe disease which is X-linked.

Scientists in Cambridge have enriched sperm samples with X- or Y-bearing sperm by a method known as flow cytometry. This involves placing a fluorescent dye on the X or Y chromosome, after which the sperm can be, sorted by a laser beam. The method has been used with cattle sperm with considerable success. There are some questions as to whether the fluorescent tagging of the sperm might cause genetic damage, but after these safety concerns have been addressed this approach is likely be used in humans.

Incidentally, these safety concerns do not seem to have carried much weight with at least one clinic in the United States. The advertisements on the internet show that they are already proclaiming their use of this method. Flow cytometry requires a complex piece of apparatus which needs calibration with considerable expertise but once the sample has been enriched, only insemination is needed. It is therefore bound to be a much cheaper method of sex selection than pre implantation diagnosis with its reliance on IVF.

Eventually, technology like this raises various socio legal concerns -

- It could change the balance of population, probably increasingly the ratio of boys to girls.
- Sex selection might be likely to increase inequality in society by benefiting the better off families.
- There is a strong possibility that if males predominated, females would become more valuable. Eventually there is pressure societal and natural to restore the balance between both the sexes.
- The valid reason for using sex selection might be to allow family balancing – A male child, for e.g. could be selected in case of family which already had three daughters. This could produce potential harm. In treating child as a commodity in this way, other siblings may be devalued. But family balancing could be of huge benefit encouraging a limit on devastating increase in population
4.3(v). Artificial Insemination with Donor Sperm and related Social Issues

Donors have virtually always been anonymous and it is for the benefit of the donor. Donors do not want any responsibility for unknown offspring. The law requires the donors name to be recorded in confidential records which must be held by the clinic. This is because it was recognized that children born after donation often need to know about genetic fathers. However for the donors, who mostly would not be prepared to donate if they had to identify themselves, there is uncertainty that present law could one day change. The concerns are -

- They may enjoy anonymity now but they could find an unexpected child turning on their doorsteps in future.
- Donors have not always been counseled about the implications of what they are doing. They may not fully recognize how their feelings about donating sperm may change in future or the way or manner in which their partner might react in future, knowing somewhere in the background there may be step-children—some donors long after donation, regret having given semen. Keeping a donor register is of value if recipient families are open about the act of donation. But in many families DI is kept a guarded secret, even from the resulting child.
- A child may possibly discover his true parentage, at the worst possible time, perhaps at puberty during an act of serious rebellion, when one parent breaks the news in anger. The secret may surface if the parents split up, all relationships may be subject to acrimony, and DI is at terrible risk.
- There are other exceptional circumstances when DI children may find that they are not genetically related to their apparent father. A child who is ill with leukemia and whose only hope of recovery is a transplant from a related donor may find it extraordinary that his ‘father’ is of total wrong tissue type.
- If the donor is a close relative or a family friend. This too is fraught with potential problems.
  (a) The donor might see his child under parental guidance which he disapproves.
  (b) He may find himself very possessive towards the child and attempt to interfere with his or her care in later life.
(c) Or an unhealthy bond may develop between the mother and the donor which threatens marital relations. A child may perceive in effect, that he or she has, in effect, three parents. This could interfere with emotional development, and could cause distress if he or she felt dissatisfied with parental decision.

- The possibility of “sperm banking” i.e. for use by a woman after her husband’s or partner death when a woman whose partner is in a high risk profession might wish to have this done, while semen be available from ‘banking’ prior to testicular oblation during treatment of malignant disease.

4.3(vi). Embryo donation after in vitro fertilization- When embryo donation is accomplished after IVF, the procedure presents physical risks similar to those of standard IVF. For many this puts IVF followed by transfer of the embryo to the second woman on the moral par as IVF with embryo replacement.

The objections raised by the people are ----

- The introduction of a third party violates the natural structure of human reproduction or adversely affects society by undermining the structure of the nuclear family.

- Furthermore, embryo donation with standard IVF may raise psychological risk that do not exist with standard IVF. The donor may suffer emotionally owing to the relinquishment of the embryo.

- This maybe true in situations where a woman undergoing IVF donates excess embryo to another woman yet does not achieve a pregnancy herself. Steps can be taken to mute the emotional risks. The physician should assure that there is no coercion of the embryo donor toward relinquishment.

Although anonymity may be psychologically soothing to the adults a child born after embryo donation may resent that his or her resenting parent have no information about the biological mother. If artificial insemination is used as a precedent, physicians will try to avoid that possibility by urging couples not to tell the child about his or her unique beginnings. Yet it is questionable whether secrecy provides as great emotional protection to the parties as physician thinks. French researchers Manuel, Chevret and Czyba found that secrecy can be psychologically harmful to the couple (Manuel et al; 1980). Moreover secrecy is difficult to maintain.
Of couples who initially vowed secrecy, 48% eventually disclosed the fact of the artificial insemination to at least one another person (besides the physician).

- The child may be potentially be harmed by the secrecy, since curiosity and learning may be affected if the child thinks there is something that he or she should not know. In addition if the couple is not comfortable with the secrecy, they may let the fact of embryo donation slip in traumatic way. Some children born through artificial insemination have been told of the unique conceptions under punitive conditions or in a frightening way, for example with the husband saying “I am not really your father” Because of the emotional harm unplanned disclosure can cause the child, the possibility of being open should at least be discussed with the couple. Eventually, the participation of the donor of the eggs, sperm or embryos may be revealed to the children as routinely as adoption is now.

The Warnock Committee recommended allowing embryo transfer after IVF as long as anonymity of the donor is maintained, the participants are fully informed; the children are informed about their unique beginnings and the parent and child at maturity about donor’s genetic health.

When a third party (such as donor of sperm, embryo or ovum) assists in procreation, question arises regarding who are the legal parents of the resulting child.

With embryo donation, the recipient mother will presumptively be viewed as the legal mother, even though she is not the genetic mother. This is because the law holds that the woman who gives birth is the legal mother.

- Although there are paternity laws to enable a man to lay claim to a child, there are no maternity laws to create mechanism for embryo donor to assert her rights.

4.3(vii). Social Complications of In Vitro fertilization using Donor Gamete - In addition, donors of sperm ova and embryos and particularly surrogate carriers may have a psychological as well as a physical investment in the children they help to produce. There is evidence that some sperm donors are concerned about the children who have been produced from their sperm. Women who participate in embryo transfer programs may develop an emotional attachment to the embryo they help to create and relinquish it another woman. Furthermore, because of the time spent and the emotional and physical demands they undergo in donating, these women develop emotional bond with the staff as well as other women who are under going this
process. The caring relationship may be helpful for some women, and the termination of those relationships with the end of the program would provide hardships.

- The potential psychological impact on the child needs to be considered. Consideration should be given to whether the child should be told about the donor’s involvement and, if so how this can be done in effective manner.

The American Fertility Society’s ethical statement and the Waller report specify that IVF with donor ovum or sperm should be considered ethically acceptable. The RCOG Report recommends that, as is the case with the sperm donors, ovum donor remain anonymous and not be told whether their gametes produced a pregnancy. The Warnock Committee like wise supports ovum and sperm donation in connection with IVF but recommends against payment. With both sperm and ovum donation, the Warnock Committee recommends that all participants be counseled, that informed consent be obtained, that the child be told about his or her genetic origins, and the couple (and child at maturity) receives information about the donor’s medical history.

**Social Risks with Egg Donation** - The concerns involved with egg donation are in many ways even greater. Unlike sperm donors, egg donors need to undergo a hefty medical process which is not without physical risk to them. They will need to think about the implications of having offspring they will not know. In addition, because nearly all egg donors have already had children, they have to consider whether it matters that those children will have half brothers or half sisters that they will not know.

The risks and complications involved in egg donation are bound to deter many women from donating eggs. They pose social problems to doctors who allow a woman to run them when she can receive no personal benefit.

An alternative source of eggs is to encourage an infertile woman’s friends or relatives to become donors. This also raises some very serious issues. They are —

- We have already seen the emotional and psychological problems that having a related sperm donor can cause a child and its parents later in life.

- Egg donation is likely to pose similar problems. They may be even greater because of the huge commitment. The risks and complications involved in egg donation are bound to deter many women from donating eggs. They pose social problems to doctors who allow a woman to run them when she can receive no personal benefit.
• Even if such an act of donation is done with complete love and consent at the time, feelings between the various people involved may well change later. The indebtedness that such a valuable and extraordinary gift produces may well feel extremely possessive about the child that is genetically hers and take more than a dispassionate interest in his her subsequent well-being.

Some clinics have decided that the only acceptable way of obtaining donor eggs is to collect eggs when women come into hospital for other gynecological procedures. Most women having sterilization or hysterectomy are close to, or over, 40 years old. At this age, the likelihood is that a very large proportion of abnormal eggs will be produced. It is medically unsafe and ethically intolerable to transfer abnormal eggs to infertile couples with all the increased risks entailed.

• An unresolved question is who will take responsibility of the child born to her after egg donation if the mother rejects the child and as to the socio legal implications on donors and recipients?

Legally there may be no doubt that the bearing mother is fully responsible for any child born to her after egg donation, but the emotional implications for both donor and recipient after such an event are clearly very worrying.

• What would be the outcome after egg donation? It is a new field and the oldest child is only thirteen at time of writing. Sperm donation is a poor model because it is so much easier to give sperm than it is to give eggs.

• For various reasons there is severe shortage of egg donors. Because ovarian failure is common, and there are an increasing number of older women in their late 30s and early 40s also requesting egg donation, demand for eggs greatly outstrips supply.

• A frequently used source of donated egg at present is probably young women who are undergoing IVF because they themselves are infertile. This is not at all ideal, and many units will consider using donors of known fertility who are committed to helping infertile woman. However many units find it convenient to use surplus eggs from patients whose IVF treatment has left eggs ‘surplus to requirements’. For e.g., if patient a produced 20 eggs during on IVF cycle, a few of these eggs would be set aside for fertilization by sperm from the male
partner of patient B, who is awaiting egg donation. This means that IVF patient who donates some of her eggs to another woman may find that the recipient of her eggs gets pregnant, but the eggs she retains for her treatment may not fertilize, or if they do may not produce viable embryos. In effect she has gone through demanding and expansive treatment entirely for the benefit of another woman which is devastating. Nonetheless, an IVF patient is a very unsatisfactory source of donated eggs. It is difficult to store eggs safely. Eggs have to be exposed to sperm within few hours of being collected from the ovary.

- When women serve as egg donors, they experience greater health risk and discomfort than the potential father, and when they serve as gestators they serve greater risk and discomfort than either of the potential parents. The variables of specific cases include not only gender differences, i.e. - including those related to life cycle, such as menopause, - other social factors - marital and economic status, cost invasiveness, risk and success rate of different procedures, involvement of third parties as donors or gestators and expectations regarding parental competence of those seeking treatment.

4.3(viii). Reproductive Tourism in Europe

Reproductive or infertility tourism refers to the movement of citizens to another state or jurisdiction to obtain specific types of assistance in reproduction that they cannot receive at home.

R.V. Human Fertilization and Embryology Authority, exp Blood (1997) 2 Au ER 687
Diana Blood, who transferred the sperm of her deceased husband from United Kingdom to Belgium in order to be inseminated, is probably the best known example of this type of medical tourism. Although the media picks up only spectacular cases, but most instances of ‘reproductive tourism are performed by ordinary groups of patients like older woman, donor oocyte recipients or donor sperm recipients.

The Belgian register of assisted reproductive tourism for 1999 indicates that 30% of people receiving in vitro fertilization come from abroad. When oocyte donation is considered separately 60% of all recipients are foreigners. (College of Physicians reproductive medicine and the Belgian register of reproductive tourism.2001). For pre
implantation of genetic diagnosis, half of the couples come from Germany and France as there is legal or practical restriction in these countries.

A country like Belgium which has no law on assisted reproduction and an abundance of high quality fertility centers, attract people from all its neighboring countries and beyond. From Germany patients in need of oocyte donation or who want IVF with donor sperm are coming over. French patients cross the border because they want to increase their chance of success by avoiding the obligatory embryo freezing after oocyte donation or because they do not accept the ‘personalized anonymity’ rule which precludes the use of a known oocyte donor.

Other fairly substantial group from France is lesbian couples and single women who request artificial insemination. From the Netherlands, women over 40, donor sperm recipients and couples who want to use surgically obtained sperm with ICSI visit Belgian clinics. Similar flow of patients exists between other European countries. It is well known for instance that Spain attracts oocyte recipients from all over Europe because of long waiting lists in other countries.

In general the main cause of reproductive tourism can be summarized as follows---

- Treatment is prohibited in the country of origin because the application is considered unethically acceptable (use of donor gametes, sex selection for non medical reasons etc )
- Because the candidate patient possess characteristics that make them unfit for parenthood (post menopausal, lesbian etc).
- The technique is considered medically unsafe. (oocyte freezing, cytoplasmic transfer etc.)
- Treatment is not available because of lack of expertise.( pre implantation of genetic diagnosis)
- The waiting lists are too long (donor oocytes) or the costs, fees are too high.

*For example* – The first stream of patients were from Sweden to neighboring countries for donor sperm after the abolition of donor anonymity. Belgian clinics near the border notice a steady increase of Dutch patients the closer they get to the end of the transition period for anonymous sperm donation. The financial motive for cross border treatment deserves special attention because the classic argument against reproductive tourism is inequality of access. Only ‘well heeled people from well regulated countries go to less well
regulated ones to buy services. The argument is based on the principles of equality; it is discriminatory and unjust when only rich can afford treatment. Firstly it is a strange argument when it is advanced by those who installed the restrictive legislation in the first place. If the prohibitive laws were abolished, neither rich nor poor would need to go abroad. Secondly, this is not an argument against those who have the financial means unless envy is recognized as basis of moral judgment. The first question is whether people should decide about their way of reproducing. Moreover, the cost of infertility treatment may vary considerably from one European country to another. Contrary to the allegations, reproductive tourism may actually reduce social injustice and unfairness by allowing poorer patients from rich countries to obtain the treatment they cannot afford in their home country. Reproductive traveling motivated by costs will probably increase in the future. A brief search on the internet reveals several clinics from Central Europe, Russia and India that actively recruits foreigner patients by emphasizing a cost reduction by 50% or more. This type of tourism can largely be prevented if public health insurance would cover a substantial part of the costs. A worrying aspect of this move towards poorer countries is recruitment of oocyte donors and hiring surrogates from poor countries.

4.3(ix). *Designer babies*

As time goes by, we will be able to screen more and more genetic defects through Pre implantation diagnosis. But PGD is a complex technique which seems unlikely to be widely applicable because of its cost and its uncertainties.

Mankind inevitably wants to explore the potential of going considerably further. Instead of discarding embryos with genetic abnormalities, we may seek to correct those defects by altering our genetic deficiencies. The study of genetics has led to the greater advance in medical understanding in this century. Probably the most valuable of developments in this field has been the ability to introduce genes into animals – to make transgenic.

**Transgenic Technology** So-called transgenic technology is providing information which cannot be derived by other means and it is difficult to under estimate its importance in how it is changing medical knowledge. The insertion of a particular gene of interest into a mouse embryo, for example, helps to evaluate what the gene
does. By producing mice which, alternatively, have a particular gene missing we can evaluate the interaction of other genes. Gene insertion in animals has started to provide the basis for understanding particular genetic diseases. The mouse can become a model, which can then be treated without risking human life or health. Examining transgenic animals has greatly facilitated our understanding of our early development.

It is, for example, playing a key role in learning more about fertility problems and miscarriage. The understanding of the causes of cancer and improvements in therapy are being revolutionized by transgenic work. Coupled with the techniques involved in cloning we may be able produce organs for transplants. But, above all, transgenic technology is the complete model needed to develop gene therapy. This could potentially lead to cures for thousands of genetic disorders and even those diseases which have merely a genetic component.

So far, gene therapy in humans has been limited to inserting genes into somatic cells. Cells in tissues such as liver, muscle, nerve cells and the cells which circulate in the bloodstream. But somatic cell therapy only affects the patient treated and not any offspring because the genes inserted do not enter sperm or egg.

The concerns are

Once parents are offered with these therapies, would they not want also to correct less serious ones? Of course, gene therapy becomes one step away from gene enhancement. There are many characteristics that parents, starting a family, might think desirable for their children. Beauty, height, intelligence strength are few of the most obvious examples. Indeed, we already manipulate all of these in our children and young people in varying ways. To give our children disease resistance, we vaccinate them; for beauty, we send them to orthodontists to straighten unsightly teeth; to give them increased intellectual power we send them to the best schools and universities we can; to give them strength we encourage them to exercise and take part in sports. What is wrong with achieving the same ends more simply, more cheaply and more permanently, by inserting genes and creating ‘designer babies’? Such treatment may produce inherited elite, leading to increased tensions in society. One of the greatest social concerns about all societies is the inequalities which are engendered in them.
• Genetic engineering could create worse divisions than society has ever experienced before; the risk of a **genetic super class** deliberately created would dominate the babies which are born without medical intervention.

• Then there would be a risk of children not meeting the expectations of their parents after genetic manipulation, with the resulting fragmentation of family and society.

• This is already a key issue with regard to screening the fetus during pregnancy. Western society has tended to screen for inherited disorders or handicap. When and abnormality is diagnosed, there is often pressure to terminate pregnancy. Opponents of screening claim that it leads to the devaluation of handicapped people and possibly the same would be true in a society regarding genetic enhancement as desirable.

• Furthermore, parents’ criteria for desirable characteristics are likely to be extremely subjective. Although it may be an advantage in today’s society to be tall and blond, in years to come the ideal might be to be short with less back trouble and dark with less of a predisposition to melanomas. It is, in any case, fairly questionable whether most of the qualities generally considered being desirable could ever be achieved through scientific means. Beauty, intelligence, aggression and so on are not produced by the interaction of one or even a few genes. The genetic component of these traits is extremely complex. To understand just how complex, we can look at the model of disease.

Take, for example, diabetes, height or strength, it has a strong genetic basis. Diabetes is, at one level, a relatively simple disease expression – an inability to regulate sugar levels caused by lack of insulin secretion from cells in the pancreatic gland. This is essentially basic but has invariable mechanism, quite unlike the inherited traits of beauty or intelligence. Yet diabetes is a multigenic disorder: there are at least twenty different genes on several different chromosomes which are likely to predispose a person to developing the disease. Imagine how many different genetic interactions must have taken place for the creation of such poorly defined qualities as beauty or intelligence.

4.4. **Cultural Concerns are** -

No society, primitive or advanced, no culture, no religion, and no legal code have been neutral about reproductive life. Even in societies which do not interfere with fertile individuals making reproductive decisions, infertile couples are often subject to public attention and scrutiny.
In addition, assisted reproduction has brought new issues to the forefront. Societal institutions have been slow to cope with the new developments. Cultural and ethical concerns cannot be lumped all in one basket. First, there is what may be called “moral panic” reaction. On a completely different level, there are concerns based on ideology and religious belief. Third, there are concerns based on utilitarian considerations.

4.4(i). Moral Panic Reaction

The term “moral panic” describes the reaction when traditional moral beliefs about the family and reproduction appear to be threatened by perceived dangers. The reaction is often unjustified or exaggerated. This may be a transient phase before the procedures get accepted. The reaction tends to move from horrified negation to negation without horror, then gradual understanding and finally a slow but final acceptance. Included in this moral panic is the fear of a “slippery path” —if science is not reined in now, it will cross red lines in the future.

4.4(ii). Ideology and Religious Belief

Concerns based on ideology and religious belief include the status of the embryo as a person, with interests and rights, in the Catholic religion. They include also the sanctity of the family’s genetic lineage in Islamic faith. Ideological concerns are entitled to be respected, but cannot be forced on others who do not uphold them.

4.4(iii). Utilitarian Principles

Ethical concerns, based on utilitarian principles, are about what is best for society and what is in the best interests of the child. Different conclusions can be reached through different ethical approaches and are generally tolerated. One example is the concern about donation of human gametes and embryos. People may accept such procedures if there are no commercial transactions involved, or if payment is not considered for a commodity but for a service transaction. In principle, societies have had to cope with two revolutionary concepts in human reproduction: separation of sex from reproduction, and reproduction with involvement of a third party.

4.4(iv). Separation of Sex from Reproduction

The controversy about contraception may now be largely something of the past, but the days are still remembered when there was a moral outrage and strong opposition
on ideological grounds. When Margaret Sanger, her sister Ethel, and a social worker Fania, opened the first contraceptive clinic in Brooklyn, the clinic was soon raided and the three women arrested. Released on bail, they promptly reopened the clinic and were arrested again and charged with maintaining a public nuisance. The Roman Catholic Church still rejects any acts that separate the procreative aspects of human intercourse from the unitive love-making aspects of the sexual act. But contraception has become a way of life. In the world, as a whole, it has been estimated that about 58% of couples in the reproductive age group are currently using contraception, to separate the sex act from the act of procreation, with a range between 55% in less developed regions and 70% in more developed regions.

4.4(v). Reproduction without sex

The other side of the coin, reproduction without sex, is relatively more recent, with the introduction of assisted reproduction. There was less moral outrage probably because it responded to a limited need of infertile couples, it did not contradict pronatalist attitudes, and particularly that it allowed infertile men, and not only women to reproduce. Controversy arose with the expansion of applications that allowed reproduction outside the social frame of a traditionally married man and woman.

4.4(vi) Reproduction with the involvement of a third party

“And she said, ‘Behold my maid Bil-hah, go in unto her, and she shall bear upon my knees, that I may also have children by her’. (Holy Bible: Genesis 30:3(I))”

Gamete and embryo donation raised more ethical and cultural concerns. The act of reproduction is an act of a couple; a third party is considered one too may. Partial surrogacy is mentioned in the Old Testament. Illicit relationships of married partners exist and have been more tolerated than assisted reproduction with donation of gametes.

4.4(vii). Gender issues

Sex is biologically determined; gender is a social construct. Gender is related to how we are perceived and expected to think and act as women and men because of the manner in which society is organized, not because of our biological differences.
Responsibility for infertility is commonly shared by the couple. Analysis of data compiled in a large WHO multinational study showed that a major factor in the female with no demonstrable cause in the male was diagnosed in only 12.8% of cases, and a major factor in the male with no demonstrable cause in the female was diagnosed in only 7.5% if cases for biological and social reasons, however, the burden of infertility is unequally shared.

The psychological and social burden of infertility in most societies is much heavier on the woman. A woman’s status is often identified with her fertility, and failure to have children can be seen as a social disgrace or a cause for divorce. The suffering of the infertile woman can be very real. The noble task of reproducing our species has not brought societal awards to women. On the contrary, it has often led to subordination. Women are subject to both pronatalist and paternalist attitudes. The introduction of assisted reproduction is a challenge to societies to re-examine these attitudes.

4.4(viii). Pronatalist and Paternalist Attitude

Pronatalist attitude- But first we must ask: what is a woman? ‘Tota mulier in utero’, says one, ‘woman is a womb’. (Quoted by Simone de Beauvoir)

Women have been identified with their role as mothers. A woman is reduced to a mobile womb walking on two legs, and with a human face on top. In many societies women are coerced to be mothers. The Declaration of Nicole Ceausescu that the fetus is the socialist property of the whole society, that giving birth is a patriotic duty, determining the fate of the country, and that those who refuse to have children are deserters, escaping the law of natural continuity, may have been an extreme example of coerced motherhood. But coerced motherhood or “compulsory” childbearing, broadly defined, is a major problem in the world today. It does not take place by directly forcing women to be mothers. Women are coerced into childbearing when they are denied the choice, when they are denied the means to avoid unwanted pregnancy, and when society makes children the only goods a woman can deliver and is expected to deliver. In many societies in the world today, women are left with no choice in life except to pursue a reproductive career. It is a valid question to ask whether women resort to assisted reproduction of their own free will, or whether they are being coerced by society to be mothers.

Paternalist attitudes
A woman can claim as her own her head, her hair, her hands, her arms, her upper body, her legs and her feet. She cannot claim the same right to the remaining are of her body, which appears to belong more to certain males of the species, moralists, politicians, lawyers and others, all of whom try to decide on how the area is best utilized. The paternalistic attitude towards women restricts their reproductive freedom in natural reproduction. Women in need of assisted reproduction are even more subject to paternalistic subjective decisions. Decisions, which women can make and should be able to make, are often made on their behalf by others. Because of the subordination of women, societies may see fit to make decisions on who should be mothers and who should not. This does not have a parallel about who should be a father and who should not. Egg donation is treated differently from sperm donation. A postmenopausal woman is treated differently from an elderly man, or a man with a disease which may shorten the lifespan.

The Challenges and the Rewards

The challenges to assisted reproduction cannot be underestimated. But the reward is also great. What reward can be better than a happy mother, a proud father, a healthy child and a harmonious family?

4.4(ix). Health service challenges

The introduction of assisted reproduction in mainstream medical practice poses a number of challenges to health care services, particularly in relatively resource-poor settings. Three such challenges face health administrators and policy-makers for deciding upon;--

a) What resources can be allocated to ART services?

b) Defining who can have access to such services, and

c) Striking the right balance between investment in prevention and in cure.

a. Equitable allocation of resources

Infertility is not a disease. In fact, in many cases of infertility there is no evidence of any disease. Per se, infertility does not threaten life or endanger physical health. Health, as defined in the constitution of the World Health Organization, is not merely the absence of disease or infirmity. It is state of complete physical, mental and social
well-being. Patients do perceive the suffering from infertility as very real. With the population problem on our hands, is it appropriate that we continue to worry about the problem of infertility?

The answer is that we should worry even more. The adoption of a small family norm, through voluntary infertility, which is a desired target at country and at global levels, makes the issue of involuntary infertility more pressing. If couples are urged to postpone and to widely space pregnancies, it is imperative that they should be helped to achieve a pregnancy when they so decide, in the more limited time they have available. Resources are finite. Allocation of relatively scarce resources is difficult.

There is always an opportunity cost. If resources are used for one purpose, the opportunity is lost for using the same resources to deal with another important disease condition. The World Bank attempted to prioritize health problems on the basis of a quantitative assessment of the disability-adjusted life years (Dalys) lost as a result of the health problem. The problem is in the definition of disability. The World Bank study tried to quantify disability from a disease condition by multiplying the expected duration of the condition (to remission or to death) by a severity weight that measured the severity of the disability in comparison with loss of life. Diseases were grouped into six classes of severity of disability. The World Bank report ‘Investing in health’ published tables quantifying the burden of disease in females. In a list of 96 causes, infertility is conspicuous by its absence.

If (Dalys) are substituted with (Qualys) (quality-adjusted life years), the priority ranking of health problems will differ. If ranking is based, not just on the basis of productivity loss but on how people perceive the disability, infertility will rank high on the list. The physical and psychological burdens the infertile couples are willing to go through, and the financial cost couples are willing to pay if they can afford it, attest to the high ranking of infertility as a perceived burden of disease.

b. Access to services

The States Parties to the present Convention recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The States Parties to the present Convention recognize the right of everyone… to enjoy the benefits of scientific progress and its applications.
The Human Rights Treaty, the International Covenant on Economic, Social and Cultural Rights (known as the Economic Covenant) (13), adopted by the United Nations General Assembly in December 1966, and entered into force in January 1976, recognized the right of everyone to enjoy the benefits of scientific progress and its applications, and the right of everyone to enjoy the highest standard of physical and mental health.

In its general comment (14), the United Nations Committee on Economic, Social and Cultural Rights expanded on the right to health, stating that: “The right to health is not to be understood as a right to be healthy. The right to health contains both freedoms and entitlements” Entitlements depend on the availability of resources from public funding.

There is a legitimate need to rationalize the allocation of scarce resource. The important point is that resources are allocated with equity and transparency, with more to those who are more in need. Freedoms in the pursuit of the right to health means that people are not denied access to services.

Socio legal concerns are—

- In the area of assisted reproduction, access to services is often restricted, legally or medically, in one way or another. This raises human rights concerns. Any restrictions on access have to be justifiable and defensible, and have to be shown as not violating people’s human right to health.

- In some countries, access to ART is often limited to certain procedures or to certain consumers. The following procedures are subject to restrictions in certain countries: sperm donation, ovum donation, embryo donation and surrogacy. Restriction may be absolute or related to commercialization of this procedure. Preimplantation genetic manipulation and selection is also subject to certain restrictions.

- Certain consumers are denied access to assisted reproduction for widely different reasons. These include single women, lesbians and homosexual couples. A concept of fitness to parent is sometimes invoked, including no outstanding criminal charges, no history of an offense that was sexual or violent.
in nature, and no disease or disability which could interfere with the capacity to parent. Assisted reproduction has been denied to women with HIV infection, on the basis of concern over the life expectancy of the infected parent and the risk of viral transmission to the offspring. This has recently been challenged; the best interest of the child is often made as an argument. The implication is that it may be in the best interest of the child not to be born at all.

- Because of this the situation invites what may be called “reproductive tourism”. This has been a topic that attracted media attention in Europe.

4.(x) The Relation between Commerce and Medical Science

It is not only individuals but many institutions whose profits are rooted in the exploitation of women’s bodies. Although medical scientists and practitioners say that concern for the infertile is their main concern, making money plays important role. It is not in the interest of medical institutions to seek cures for infertility, but only to deal with its consequences. One may even say that a continuous infertile population is necessary for them to stay on business, to cover the extremely high fixed and operating costs associated with IVF. Conventional infertility treatments often consist of giving women hormones over a period of time to stimulate ovulation. Scientists in Indian Institute of Immunology in New Delhi have found a way to mass produce Hcg – a hormone which is used to make preparation which is used by gynecologist to help women with infertility problems in a species of caterpillars. In the Netherlands an organization ‘Moders voors Moders’ (Mothers for Mothers) call upon young pregnant women to help their less fortunate sisters who have difficulty conceiving naturally. It collects the urine of young pregnant women for 10 weeks between the sixth and sixteenth week of pregnancy. The urine contains hcg – a hormone which until could not be made synthetically. Also the hormone Hmg which is found in the urine of newly menopausal women above 55 year is found usefial. The two hormones hcg and hmg which help the ripening of the egg and ovulation are considered extremely valuable (thus not to be flushed) in infertility treatments, including IVF. The organization which advertises on the radio and through folders, freely distributed in doctors’ surgeries and pharmacies, offer to do a free pregnancy test for women who think they may be pregnant. Some free gifts are offered to women during the weeks they participate in this programme. Writers of ‘Technologie
als wapen' (Technology as weapon by the women against Gene and Reproductive Technology) comment that the Dutch multinational AKZO Pharma and its subsidiaries Oragon and Diosnyth make fertility hormones and hcg pregnancy test kits from this urine. It is clear that women give away free, a natural resource which is at the basis of the product through which AKAZO makes huge profits. IVF specialists are looking for further markets. There is a competition among medical institutions and practitioners; they often argue that if they do not provide the service their clients will go elsewhere. (Which may mean another country too)? Drug and pharmaceutical companies and commercial companies established to sell reproductive technology and genetic engineering have a great stake in the proliferation of these technologies. There is a huge market to combat infertility. Infertility treatment and equipment associated with infertility treatment has now become a lucrative export commodity for some firms, mainly from the West to developing countries. Commercial surrogacy is another lucrative area to make money by exploiting women’s bodies. Trade in eggs and sperm as well as surrogacy is particularly prevalent in US, where several commercial bureaux mediate (through internet) between infertile couples and women who rent their womb. Infertile couples from all over the world including The Netherlands, make use of the services of these agencies, in some cases due to legal restrictions on commerce in these body parts. Clients can choose from detailed catalogues on the basis of information provided, the desired ethnic background, eye color, physical traits educational levels and IQ of the donors. Besides gynecologists, some of these agencies also offer the services of lawyers and psychologists. Some bureaux are also run by erstwhile surrogates. Although commercial surrogacy is banned in some states, there are no federal laws restricting the sale of sperm and eggs.

4.(xi). Women’s Bodies Used as Sites for Experiments

The IVF procedure is still experimental. In its development women’s bodies have been used as the sites for experimentation. Infertile women patients of ‘Edward Hospital’ who were desperate for help and willing to undergo many trials in hope of one day having their own babies’ were asked to cooperate.

At different stages, women were given different dosages of various drugs, so that there efficacy could be tested. (Edward and Steptoe 1980).

The various concerns are ---
• 'The development of IVF, involved in the first place, the use of women’s bodily parts as material for experimentation; ovarian tissue secretions from her reproductive tract as the sites for experiment related to sperm maturation' Several authors including (Gupta 1991) criticizes the medical violence inherent in these technologies.

• IVF is turning women into living laboratories. Scientists who are busy with the dismembering and fragmentation of women into parts - wombs, egg ovaries – body parts disconnected from the women and their lives -have a narrow tunnel vision.

• Eggs and embryos take on lives of their own, become personalized at the expense of women. They can be ‘orphaned’ or ‘parentless’, and ‘good quality or poor quality’ (Rowland 1984). The role of language what Rowland calls plays a very strong part in presenting to the public a very rosy picture of reproductive technology. It is a part of the process that she calls the ‘softening up’ of the attitudes of the public to the work of the technologists

• Multiple births in IVF programmes are used to indicate the programmes are too effective. Failure rates of IVF become success rates which are used as marketing pregnancy successful embryo transfer, as a large number of pregnancies end in spontaneous abortions and clinics often give only pregnancy rates, not live healthy baby rates.

• IVF is failed technology, as the treatment is still largely unsuccessful. This use of language is only an extension of the terms used to describe women.

• Women’s bodies are treated as defective machines in need of improvement and control, which are constantly blamed for their inability to operate correctly, or on demand they are even ‘stubborn’ after medical intervention.

• Women who do not succeed in bearing a child through IVF they have not only failed themselves and their husbands, but also failed technology (the same was true in case of contraceptives which do not suit certain women).

• Infertility is a painful life crisis. They feel a sense of lack of control which they hope to get through an IVF programme. However few gain that. Many feel used as laboratory animals, as guinea pigs.

• IVF opens a door to host of other procedures such as research on embryos, sex determination, genetic manipulation, use of fetal tissue and so on. Women are
primarily involved because it is women’s bodies on whom the experimentation is taking place and it is their bodies which are needed to carry genetically manipulated embryos to term.

- Most European countries have appointed committees to look into the consequences of NRTs (including gene technology and surrogacy); The Warnock Committee Britain, which published its report in 1985; Gezondheidsraad (The Health Council), The Netherlands, (1984, 1986, 1989, 1994); Benda Committee Germany (1985), Glover Report for the European Commission to consider ethical and social issues raised by the technologies that according to the commission ‘extend our reproductive options’. In this way the public is made to feel that everything is in good hands. However, in these reports there is hardly any mention of the commercial interests of the pharmaceutical industry which thrives on the sale of ovulation induction drugs and doctors who profit from infertility treatments only commercial agencies are prohibited in the proposals. With BOM-moeders and self insemination – self help in this area is difficult to bring under control.

- Except in relation to malpractice law, the State has hardly any place in regulating any field in medicine as ethical committees at individual hospitals are expected to take care of any such issues, It is said that the medical profession will be self regulating – that we can leave it to professional bodies such as ‘Medische Tuchtraad’ (Medical Disciplinary Board in Netherlands), or the Indian Council of Medical Research (ICMR) and one should be able to trust doctors and particularly gynecologists. However, experience shows that ethics and ethical committees are constantly trying to keep up with new developments or breach of ethics. Calls for more and more legislation are raised now, except from scientist involved in this field.

4.5 Legal Concerns

4.5(i). Legal concerns of Artificial Insemination by Donor
The process has specific relevance as to the effect on the child born into a single parent family. It is a simple procedure entailing sperm being deposited in woman’s vagina close to cervix. Many States declare that the donor has no parental right or
obligations to a child conceived with his sperm. These rights and obligations are assigned to the partner of the recipient. Various Courts across the countries in the world have been confronted with the issues involving sperm donors who have sought, and by some courts, received parental status of donor insemination Artificial insemination by donor - introduces two additional concepts into management of infertility.

1) The procedure escapes the confines of a private matter between two persons in a close emotional relationship.

2) In case of male de-privatization inevitably results in production of gross excess of gametes and as a result, to their option and the creation of option for their use.

Legal control of private donor insemination has collateral public importance, regulation is necessary.

Therefore donor insemination is one of the two services permitted only in pursuance of a license.

Ultimately donor insemination and ovum donation depends on the consent of the owner of gametes to their use. Various Courts across the countries have been confronted with the issues involving sperm donors who have sought, and by some courts, received parental status of donor insemination children.

*Anonymous v Anonymous, 41 MISC 2D 886, 246 NYS 2D 835, S CT (1964).*

Husbands in divorce disputes have argued that their children were not entitled to child support because the written consent of a particular State was not adhered to.

*In Wellborn v Doe (VA ct Apps, 1990).*

In New York an untimely unsuccessful challenge to a will was brought on the ground that the two testator’s grandchildren were conceived through donor insemination and therefore arguably not entitled to inherit from their parental grandfather.

A Virginia Court approved a husband’s claim in his twin children conceived through donor insemination despite a private state law that apparently made his parental status clear. The Court found that although the statute, which was similar to that in many states clearly limited the sperm donor’s status it did not thereby protect the husband’s status The State’s legislature has amended the law in question.

The desire for a child is so fundamental and instinctive that we can’t always explain our feelings of failure and loss when it remains unfulfilled. Infertility can be an isolating experience and everyday situation may become difficult to live with.
Society’s attitude to infertility can seem harsh and uncaring, with little to help or support to those who aren’t finding it easy to have a child of their own. The idea of ‘right to a baby’ is firmly rooted only in the minds of the fertile. Infertility is often misunderstood, partly because many people who had to endure it find it too painful to talk about it.

- The process has specific relevance as to the effect on the child born into a single parent family. It could relate to problems in relation to probate and succession. The HFEA (Human Fertilization and Embryology Act 1990) resolves this dilemma. S.286 (b) dearly states that the sperm of a man or embryo the creation of which was brought about with his sperm is used after his death. He is not to be treated as the father of the child. It is to be noted that the process is not prohibited indeed –Sch 3, para 2(2) allows for the relevant consent. The current indications are that a significant proportion of clinics disapprove this process.

- Legal problem would arise with regard to nullity of marriage could be mooted in likely circumstances calling for the use of AIH. Use of the procedure does not however constitute consummation of marriage and a decree of nullity can still be obtained if a woman conceives in this way, children would still be regarded as legitimate on the grounds that the parents were married at the time of conception. The concerns are --.

- Who would be the legal father of a child born after using semen from a male other than the husband?
- If a couple having a child by this method is divorced, is the ex-husband responsible for child support.
- What are inheritance rights of a child conceived by sperm of a man other than its legal father?
- If a child conceived in this manner has a birth defect can the physician be charged with malpractice?
- Should semen be used for selected breeding for certain inherited traits and what are socio / legal implications of selective breeding.

4.5(i). Ownership of Cryopreserved embryos -

The technique of preserving embryos has given rise to number of incidences of legal battle being fought over ownership of frozen embryos between ex (spouses)
a. *In Roe v Wade* (410 U.S 113(1973)

It was upheld that ‘when an embryo conceived naturally is naturally developing within the woman during the first two trimesters, it is clear that the woman’s decision whether or not to terminate will takes precedence over the desires of the man who had provided the sperm’.


The Illinois Attorney General and the District Attorney for the Cook County in their briefs in an Illinois case regarding IVF assumed that the woman’s desire will likewise guide the course.


Maureen and Steven Kass underwent six cycles of IVF but did not achieve pregnancy. When Maureen petitioned for divorce, five embryos has been frozen. The couple had signed two consent agreements. One provided that, in the event of divorce any stored embryos would be included in property settlement as directed by divorce court. The other agreement provided that if the parties could not decide the disposition of the embryos, the embryos would be donated for research. The contested issue in the divorce was possession of the embryos. Maureen wanted to implant the embryos (she wanted to gestate the embryos by herself). Steven wanted to donate the embryos for research.

The New York Supreme Court upheld that the woman had the right to control the future outcome of embryos she produced with her husband. The Court stated that the embryos are not persons and that they are not property. The judge refused to consider dividing the embryos. The possession of the embryos was handed over to the divorcing wife, entrusting her with the right to control their destiny.

d. *Davis v Davis* 842 SW2d 588 (1992)

In this case the couples were divorcing and had undergone IVF with several embryos still frozen at the time of their divorce. The parties disputed as to who should get the custody of the embryos. The judge awarded control over the frozen embryos to the husband, who did not want the embryos to be implanted. After the court awarded custody over frozen embryos to the husband, the embryos were allowed to expire. The Court upheld that when the preferences of the couple are unclear or are in dispute and where no prior agreement exists, concerning disposition, the interest of the individuals in using the frozen embryos must be weighed of the extracorporeal embryo. But it is at least arguable that the man’s desires should have equal weight.
when the embryo’s continued existence need not be balanced against the physical and psychological needs of the woman carrying it.

In August 1998 a British couple caused a furor when they announced they were having their embryos frozen to be implanted later at more convenient time in their career to start a family. The 32 year old woman (herself a banker) found herself in too crucial phase in her career to start a family. However, the couple wanted to freeze their embryos as a sort of ‘fertility insurance’ and to avoid the consequences or reduced fertility or the increased chance of having a baby with Down’s syndrome, due to higher age.

4.5(iii). Laws for Research on Embryos

The research on more than 14 days old embryos is not allowed in most countries which have regulated the research in reproductive technologies including embryo research. For embryos under 14 days scientists have coined the term ‘pre-embryo’. Ethicists and policy makers are particularly concerned with the status and protection of embryo that are not implanted.

The case of the orphan embryo in Australia pointed out the difficulty that can occur when a couple as a unit can no longer direct the fate of an embryo. This may happen when the couple may die, divorce, lose interest in the embryo, or disagree how the embryo should be used.

The Waller report provides that the couple’s consent document must indicate what must happen to the embryo in case of the death of the one or both of its parents or the dissolution of their marriage. If such indication has not been made, the embryo should be removed from storage and allowed to expire.

The Warnock Committee recommends that if one member of the couple dies, the right to use or terminate the embryo should pass on the survivor. If both die then the right should pass on to the storage authority.

The laws in US touch peripherally on the issue of embryo freezing. Laws in seven states that forbid research on fetuses could be used to prosecute physician who participate in embryo freezing. The issues are related to embryo freezing are:

- Various issues arise in this stage, one is the legal aspect about their ownership Whose property are they – do they belong to the woman or the couple; and what if the couple separate later, which of them gets custody; and if they both die, can
they be gestated by another woman and the resulting children become heirs to their parents’ property

- The famous case of the ‘orphaned’ embryo raised some of these questions. In 1980, Elsa and Maria Rios traveled from California to Australia to take part in an IVF programme. Some of the fertilized eggs were implanted in Elsa and the remaining was frozen. The couple later died in an air crash leaving an estate worth US 8 million $. The frozen embryos were in legal limbo. Various groups have suggested placing time limit on storage. The American Fertility Service (1984) recommends that cryo preservation to last only for the reproductive life of the female donor. The Warnock Committee recommends a ten year limit. (Warnock 1984). In UK, embryos are allowed to be frozen for five years after which they must be destroyed. The Bourn Hall clinic (famous for producing the first ‘test—tube’ baby), has about 7,500 embryos in the deep freeze at the moment, 23 from one couple alone. They will be forced to destroy 1,000 of them in 1996 as per legislation which came into force on 1st August 1991.

Dr F Houndius, deputy director of legal affairs for the Council of Europe reported in 1989 that about 200,000 embryos were lying stockpiled in Europe (Raymond 1991) since then 3,000 frozen embryos were destroyed in 1997 after the expiry of five year statutory limit.

Decision making authority over Cryostored embryos. The couple or persons providing the egg and sperm would have primary decision making authority over the embryos that were cryostored at their request. Their right to transfer their decision making authority to others, such as the embryo bank or storage bank is certainly to be recognized. Several questions follow from this initial assignment of property or quasi property rights. One question is the storing the couple’s right to transfer decisional authority over cryostored embryos to others. The joint decision making authority of the gamete providers could be transferred to one of them, to the storage facility, or to others. In general a person who receives authority from the gamete providers or their transferee may exercise the same right of disposition that the gamete providers did concerning continued storage, discard, donation, and research. However the transferee’s right to discard or donate for transfer may be restricted if he or she lacks a reproductive interest in the embryo.

The gamete providers need to specify at the time of storage dispositional alternatives if joint decision making authority is not possible. In case of death, a workable
solution would be to have authority to pass to the survivor with instructions specified about disposition in case of survivor’s death. In case of divorce or separation the parties would specify that the embryo will be discarded or donated to the storage facility.

- An important question arises when their right to designate or transfer decisional authority over the embryo if one or both of them dies. Transfer of decisional authority to the survivor of the couple, or to storage facility if the survivor dies or is unavailable, is workable solution that will be adopted by many couples and programs.

- However some persons may wish to designate another person, for example, to assure that the decedent’s wishes are followed. Law policy or practice should not exclude this possibility.

- A final question is whether the gamete provider’s right to transfer dispositional control of embryos permits them to receive money or other consideration for doing so. Many people object symbolic connotations of “selling embryos,” few laws prohibit directly the receipt of consideration at the present time.

However, official bodies in Australia and Britain have recommended against payment for gametes, embryos and surrogacy and have legislated to that effect. The question of payment is likely to arise when the recipient or transferee of an embryo is asked to pay a fee to cover acquisition and storage costs. Because creation of embryos is expensive (700$ to 1000$ per embryo in many American programs) and cryopreservation charges will arise, it is not necessarily unreasonable to ask the recipient of an embryo donation to share production and storage costs. Recoupment of cost can be distinguished from payment that reflect “profit” or other monetary gain from embryo donation.

4.5(iv). Posthumous Thawing and Embryo Transfer

Cryostorage also raises the possibility of thawing and transfer to a uterus after one or both of the gamete providers have died. Such a disposition may be specified by the gamete provider at the time of storage or in their will or by the survivor of the two, or result from a transferee’s donation of the embryo to an infertile couple.
The posthumous birth of children has occurred to a limited extent. Fathers have died after conception and mothers in child birth but it remains controversial.

For example, the postmortem use of stored sperm has been problematic in France and several other countries. With cryopreservation of human embryos, transfer to the uterus, implantation and birth may not occur until long after gamete source or sources have died. If cryostorage is widely practiced, there will be many more occasions to thaw and transfer embryos posthumously.

- Some persons have questioned the desirability of posthumous transfer because of the feared impact on the offspring being raised by single or elderly parents or by parents who are not genetically related. (as in case of posthumous embryo donation) None of these concerns seem adequate to prevent couples storing embryos from providing from posthumous transfer Reliance on them would be inconsistent with other accepted practices, such as embryo donation itself and elderly men fathering children.

- Moreover a policy that prevents existence altogether hardly protects offspring, when rearing by non genetically related, single or elderly parents does not alone renders a child’s life not worth living.

- However, the inheritance rights of children born posthumously from stored embryos must be clarified for this practice to occur. The ability to transfer thawed embryos to a uterus posthumously means that all biologic heirs may not be in utero or be born at the time of death, the usual requirement for a person to be legal heir of deceased.

- Should embryos “en ventre sa frigidaire” be treated like embryos “ en ventre sa mere”

- There are enormous implications for estate planning and the orderly administration of probate. If people born from frozen embryos are considered heirs, estates could be tied up as long as embryos are cryo stored. Delays in settling estates could be enormous.

- A workable policy to ensure the efficient administration of estates would be that no embryos not in utero at the time of death would qualify under intestacy statutes (which control when there is no will) or under wills that develop property to “heirs, children”, or other designation that could include posthumous offspring from thawed embryos. However, a person’s stated wish to transfer
property to biologic offspring born posthumously has some appeal, particularly when the surviving wife carries the embryo. Thus an exception to proposed inheritance policy might be considered when the testator specifically devises property to offspring "born from embryos stored at time of death." However the risks of long delays in settling estates will still exist unless a time limit for thawing and transfer after death is specified.

4.5(v) Length of Storage

Assuming that indefinite storage of embryos is clinically feasible, the length of storage should be determined in the first instance by the gamete providers and embryo banks. Although most couples will thaw embryos to initiate pregnancy within a few months or years, situations leading to storage for 5, 10 or more years can be easily imagined. Embryo banks may be of two minds concerning indefinite storage. As long as charges are paid, they might have no objection to and even desire lengthy storage. After all, the business of embryo banking is to bank embryos for paying clients. However, IVF programs offering cryo preservation as an adjunct infertility treatment may wish to reduce the administrative burdens of maintaining many embryos and periodically by recontacting the storing parties concerning disposition. It may be administratively easier for some programs to set a time limit of 2 to 5 years, at the end of which storing couple will be contacted and asked to decide about discard or donation to infertile couples or researchers. If the couple is not available, previously given instructions for disposal of remaining embryos will then be followed. With clear instructions concerning disposition at key decisional points, there is no need for law or public policy to specify the maximum limit of storage. Such limit might interfere with the procreative goals of a person who desire longer storage and with the business of banks willing to serve them. Storage limit recommended by various official bodies therefore needs further consideration.

Warnock for example, recommended a maximum of 10 years of storage of embryos after which time decisional authority would pass to storage facility. Other bodies have recommended limits such as five years or not beyond the reproductive life of the storing woman. Indeed, policies limiting the length of storage could unfairly discriminate against women. A time limit based on the woman’s reproductive capacity would prevent continued storage and eventual transfer to surrogate of embryos stored shortly before a woman has to undergo hysterectomy for medical reasons. Yet she still has an important
reproductive interest in the stored embryos despite her inability to gestate as does her spouse or partner. Similarly 5 or 10 years limit might impair the reproductive interest of both men and women.xiii

4.5(vi). Donation of Embryos for Research

Cryopreserved embryos may also be donated for research, if the storing couple no longer wishes them transferred to initiate pregnancy. In most cases embryos donated for research will be discarded after completion of the research. In few cases, transfer to uterus may occur, in effect making it a donation for research and possible transfer.

The question of embryo research has been controversial in Australia, Great Britain and to a lesser extent, USA. To avoid controversy, many researchers are reluctant to conduct studies on human embryos. However, developments in IVF and other fields have drawn researchers to human embryos as vehicles in research in infertility, contraception, genetics, cancer and other fields. Despite the cautious approach taken to embryo research a consensus recognizing the legal acceptability of embryo research can be identified. Official and advisory boards in United States, Great Britain, Canada and Australia have considered embryo research and found it acceptable in well designed studies approved by institutional review boards. Most of these bodies would limit extracorporeal embryo research to 14 days. They would permit transfer to a uterus when there is reasonable ground for thinking that the resulting offspring would be healthy. With the exception of Victoria in Australia, they would even permit research on embryos created solely for that purpose. A few American States have broadly drawn fetal research laws that might appear to prohibit any embryo research. However, unless narrowly interpreted; such laws are vulnerable to constitutional challenge as an interference with first amendment and procreative rights. IVF programs that offer cryo preservation should therefore inform couples storing embryos of their right to donate them for research if they do not wish them thawed and transferred to uterus. This option should be explored at the time of initial storage and when later decisions are made. It will also lessen the need to create embryos solely for research, although it will not eliminate the controversial issue altogether.
4.5(vii). Regulations of Cryopreservation

Today cryopreservation is routinely practiced hence no special regulatory oversight seems needed. Such review is not necessary for IVF or for highly risky procedure such as heart transplants. It would be anomalous to single out cryopreservation for special licensing when accepted medical procedures of greater risk do not require this, for cryopreservation does not appear to impose risks that justify special concern. In the United States IVF programs wishing to cryopreserve human embryos are free to do so, as long as they meet institutional requirements for review of human subjects' research. Some countries might opt for special license requirement for physicians or programs wishing to conduct IVF and variations such as cryopreservation. The Warnock Committee recommended such an approach for Great Britain, and several countries including Australia and Israel now take such an approach.

In most countries the main regulatory mechanism will be professional practice standards and competition for patients rather than direct governmental regulation. The experience with human sperm banking, suggests that the private sector can ensure high quality services and avoid major problems that warrant governmental intervention. IVF programs and embryo banks have strong incentives to comply with professionally determined standards for freezing equipment, counseling patients, record keeping and the like. Given the legal rights of patients storing embryos, they are likely to respect the decisional authority of gamete providers. Although some embryo banks may be unwilling to meet all patient demands, alternative banking facilities are likely to be available. Reliance on private sector assumes that it will develop reasonable standards of practice and ensure that valid patient and societal interest are considered in providing this service. It would be helpful if the professional group is directly involved with infertility. Practice and embryo freezing convened special advisory or ethical committees, with interdisciplinary membership to monitor, developing practices. Future developments in the embryo banking industry may also require monitoring.

In litigious societies like US the threat of lawsuits against IVF programs and embryo banks for negligent destruction of embryos or disregard of decisional authority should ensure compliance with professional standards and patient desires. This solution to the regulatory problem requires that there be a legal remedy for negligent destruction of embryos and mistakes in record keeping. This remedy should
not unduly add to insurance cost or be difficult to pursue by aggrieved parties. However, the legal right to recover for negligent loss of embryos is not yet clearly established.

_**In Del Zio case No. 71-3588 (S.D. N. Y. 1978) [Memorandum decision.]**_

A New York jury awarded 50,000 $ to a couple when a physician deliberately destroyed an embryo to prevent an experimental transfer. However the basis for the award was the intentional infliction of emotional distress, rather than destroying property or quasi property interest in embryos or future offspring. Whether compensation for negligent destruction or misidentification of cryopreserved embryos will be available is unclear. Because there is no way to show that particular embryos would have implanted and gone to term, negligent loss cannot be equated with wrongful death of a child or a fetus.

Moreover, the loss is purely psychological and ordinarily will not occur in the presence of the parent, a situation that the tort system usually does not recognize. The courts will inevitably be drawn into determining whether negligent destruction of embryos seems justified. Legal concepts of tort and property may have to evolve to take care of the situation.

4.5(viii). _Egg Fusion_

In this method, instead of the egg cell and the sperm cell, two egg cells of different individuals are fused; the resulting embryos will always be female. In vitro egg fusion was done by American researcher Pierre Soupart in 1975. These experiments were banned by the state for ethical reasons. Soupart continued his experiments with mouse cells. The result of this research was announced in Nashville, Tennessee in 1978. Through this technique it may be possible for two women to be the genetic parents of a child rather than a woman and a man where eggs and sperm cells are used.

4.5(ix) _In vitro fertilization using donor gamete_

According to Warnock committee’s recommendations, the number of children born from a single donor should be ten. State laws influence that the legal parents would be when an individual calls on the aid of sperm donor, ova donor or surrogate mother. A long line of cases have been held that parties in procreation are not free to decide among themselves who will have legal rights and responsibilities for the child. A person cannot turn over a child to another individual to be raised. Parents are not even free to arrange among themselves the financial responsibilities of the child.
The Court upheld that the mother had no right to waive the child’s right to support from the biological father. In USA these cases occurred as a part of divorce action by the couple who had a child by artificial insemination.

*Ny Dennet, 15 Misc 2d 260, 134 NYS 2d 188 S CT, (1958)*

The wife tried to deny the husband’s visitation rights based on the same rationale. Even though the Courts had some fits and starts in handling the cases (sometimes declaring the child illegitimate), the Courts protected the child financially and emotionally by using an implied contract or equitable estoppel theory to establish that husband should support the child and should have visitation rights. To clarify the paternity of the child conceived through artificial insemination states have adopted laws that provide that the artificial insemination offspring is the legal child of the recipient and her consenting husband. The laws of 15 of the 25 states explicitly provide that the man who donates the sperm to a woman who is not his wife is not the legal father of the child. (Alabama, Alaska, Colorado, Colombia, Florida, Maine, Kentucky, Mississippi, New Mexico, New York)

Although all of these laws were adopted to cover artificial insemination in vivo, they will probably be applied to sperm donation in vitro as well

- To date, no laws have been specifically covering paternity issues, screening service provisions, or reporting in the ovum donation situation, although if such laws are enacted they will probably be based on the artificial insemination model.

- The laws have little to say about how germinal transfers are conducted. Although both the American Fertility Society and the American Association of Tissue Bank have extensive guidelines for the screening of the sperm donor, the state laws have paid little attention to the issue. Three jurisdictions---New York, Oregon and Idaho--prohibit known carriers of genetic diseases and venereal diseases from being sperm donors.

14 of 28 artificial insemination statutes require physicians to file information with the state about their attempts at artificial insemination, and the consent form the husband signed. Like adoption papers, these states file can be opened by a court order “for a good cause”.
4.5(x). Embryo Research (Legislations)

The types of embryo experimentation that are possible are threefold;

- Procedures those are therapeutic to the embryo,
- Procedures those are therapeutic to another individual,
- Procedures that have no immediate therapeutic benefit but could lead societal benefit such as the development of a new drug.

Among the types of research that might be considered therapeutic to the embryo is genetic screening or treatment of a genetic defect.

Experimental procedures benefiting other individuals include innovative treatment to combat infertility such as embryo donation by lavage or to treat other medical problems (such as the use of myocardial tissue from an embryo to repair an individual’s heart vessels). Embryos might also be used to learn whether certain substances are teratogens, to develop contraceptives and to answer questions about genetic and biological development.

Research on embryos in connection with IVF and its variations has been the subject of recommendations by numerous governmental and professional organizations.

In United States the Ethics Advisory Board of the U.S. Department of Health, Education and Welfare suggested that IVF research would be ethically acceptable if the regulations concerning research with human subjects are followed, if research is designed primarily to establish the safety and efficacy of IVF and embryo transfer, the information sought is not obtainable by other means.

Informed consent is obtained from the gamete donors, embryos are not sustained in vitro beyond the stage normally associated with the completion of implantation (defined by the board as 14 days after fertilization), and all parties and the general public are advised if evidence begins to show that the procedure entails the risk of abnormal offspring higher than those associated with natural human reproduction.

The American Fertility Society’s statement seems to envision broader research taking place than that which relates exclusively to the development of IVF. It provides that scientific examination of embryo is ethically acceptable if done within 14 days of fertilization. The Judicial Council of the American Medical Association similarly has adopted guidelines regarding research in connection with IVF, prohibiting such research in embryos that will be implanted in a woman and stipulating that
the research on embryo’s that will not be implanted must comply with the AMA’S fetal research guidelines.

The British Medical Council has also developed guidelines for research related to human fertilization and embryology. These guidelines include the conclusion that scientifically sound research involving IVF with human gametes is ethically acceptable on the condition that the aim of the research is clearly defined and directly related to clinical problems, informed consent is obtained and there is no intent to transfer to uterus any embryo resulting from or used in such experiments. According to the guidelines, human embryos should not be cultured in vitro beyond the implantation stage and should not be stored for unspecified research use, animal studies should not be performed to elucidate the potential risks, and studies on interspecies fertilization should be supported as long as the embryo is not allowed to develop beyond the early cleavage stage. The guidelines of the Medical Council of Australia, like British guidelines, favor research but do not permit the continuation of embryonic development beyond the stage at which implantation would normally occur. The Australian guidelines find cloning to be ethically unacceptable.

The Warnock Committee recommended that research on embryos be permissible until the fourteenth day after fertilization, subject to any restrictions imposed by the licensing body, provided an embryo is not transferred to a woman. The Warnock recommended banning certain types of research—such as placing the human embryo into the uterus of another species or the development of a Trans species hybrid beyond the two cell stage.

In Australia, The Waller Committee similarly imposed a 14-day limit on research. However, it took a more restrictive approach to the timing of the research and the manner in which embryos can be obtained. The use of embryos for research “shall be immediate and in an approved and current project” the only embryos be used for research purposes shall be those that produced by patients in IVF programs. Because of the public interest in embryo research, the Waller Committee suggests that the Health Commission or a recommended body scrutinize all that research. The legal permissibility of the embryo research in United States in some states by fetal research statutes. Twenty five states have statutes restricting experimentation on fetuses eleven specifically define the term fetus to extend from fertilization to birth. Others neglect to define the term fetus, so their statutes may also apply to the embryos For
example—the Maine statute applies to "any live human fetus, whether intrauterine or extra uterine" without defining this.

All 25 fetal research statutes have provisions covering ex utero research on live fetuses, although some may apply only in connection with an abortion. Of the 25 statutes, 15 prohibit non therapeutic research, 6 prohibit any research, and 2 prohibit non therapeutic research unless it imposes no significant risk to the fetus.

Two additional state statutes allow research if the mother has given her consent. The application of these statutes to embryo research will depend on whether the in vitro embryo is considered live. Fourteen states have laws that research on dead fetuses. Six of these prohibit such research expect for pathological examinations, and eight permit research provided the mother has given her consent. xiv (Louisiana, Massachusetts, Michigan, Ohio, Oklahoma Oregon, Pennsylvania)

4.5(xi) Legal Concerns of Reproductive Tourism

Informed consent legislation may be less strict in these countries. Firstly, payment of large amounts may have a deleterious effect on informed consent of the donors. In addition, the general commercial atmosphere surrounding the recruitment of donors and provision of infertility treatment is not conducive to elaborate attention to ethical standards. Clinics in countries without reliable control may be even less scrupulous. Reproductive Tourism is usually presented as a problem. A remarkable finding is that commentators ignore the major cause of reproductive tourism (i.e. restrictive legislation.) when they consider solutions.

The possibility of law evasion has already been used by Swiss Federal Council as an argument to reject a referendum initiative that want to prohibit most forms of in vitro fertilization and the use of donor gametes [Conseil Federal Suisse 2000].

The only consequence of such a law would be the flight of infertile couples to neighboring countries. Other countries react in a coercive repressive manner. Several examples are known of European countries attempting to force their citizens to abide by the law.

One of the ways to do this is by punishing the citizens who violate the law abroad. Around 1990, German border guards forced medical examinations upon women coming back from the Netherlands in search of evidence of extra-territorial abortions. Prosecutors also brought criminal charges against women who obtained abortions in other countries. The European Parliament eventually condemned these practices in 1991. However Articles 59 and 60 of the European Community treaty guarantees free
movement of services, including medical services medical services and thus infertility treatment. It is one thing to introduce rules regarding procreation and family building in one’s society, it is quite another to take every possible measure to force individual citizen to abide by these rules. Such pushed enforcement leads to a frontal clash and may jeopardize social peace. A different attitude towards national legislation is needed. Commentators frequently express disapproval and resentment when talking about reproductive tourism. Reproductive tourists are often seen as disloyal, as circumventing national laws, or evading their domestic constraints or conducting health care shopping -- where the law may be more lax. (Brazier 1999) This attitude may be based on moral convictions; a belief in moral truth a desire to ensure that others observe out standards. This position results in an attempt to make laws that coerce people to abide by the ethical rules However, the purpose of national legislation should not be to prevent those who disagree to perform certain acts or to make use of certain intervention or services. Prohibitive laws can determine which services are available on the territory. Tolerance towards movement by minority members to other countries shows a healthy degree of relativism. The fact that reasonable people in one’s own home state and a majority in other country accept an act or treatment as perfectly legitimate and ethically acceptable should raise a spark of doubt about the unique correctness of one own position. Allowing people to look abroad demonstrates the absolute of minimum respect of their moral autonomy.

a. Legal Harmonization; A wolf in Sheep’s Clothing.

The call for harmonization is often triggered by a particular case of reproductive tourism. The attempts at reproductive cloning undoubtedly gave a major boost to a feeling that international legislation was urgently needed to prevent totally unacceptable practices. Harmonization has nice, positive connotation of people growing towards one another peacefully. However the proponents of legislative harmonization seem to consider harmonization as a one way movement; the others should adopt the same laws we have and they should forbid the same acts we forbid. The direction of the ‘harmonization’ towards more limitation or towards more freedom is crucial.

If the European Convention on Human Rights and Biomedicine is an indication of the future evolution, harmonization moves towards more restrictive legislation. It is easier to move from permission to prohibition when controversial issues are
considered. Most opponents of the reproductive traveling start from the premise that the tougher and more restrictive legislation is also morally superior. One seldom hears a liberal country urge others to demonstrate equal flexibility. Apparently, people are more convinced of the moral correctness of their prohibitions than of the correctness, of their permissions. On the other side there are those people who argue that international legislation should be aligned in a liberal directed.

McGleenan predicted after studying the Blood case that the jurisprudence of the European Court of Justice on article 59 of the European Community Treaty would generate a structural downward pressure so that any regulation would gravitate towards the most permissive laws (Mc Gleenan 1999). To prevent this community wide policy on assisted reproductive technology should impose a minimal degree of respect.

b. Need for Harmonization for general consideration /safety standards.

There are two suggestions to avoid the problems of harmonization until a minimal common legislation is introduced. The first solution is to limit European legislation to broad ethical principles

There are number of common normative values that transcend cultural and jurisdictional differences. They are -- the inherent dignity of the human person, the security of human genetic material, the quality of services and the inviolability and the inalienability of the human person. The same values are expressed in the Charter of Fundamental Rights of European Union relating to technological innovation (European Union 2000). However the consensus is fake. As soon as the general principle or value is applied in concrete cases it becomes clear that the agreement was based on mistaken belief that the parties were talking about the same thing. Respect for human dignity is for some the right to decide when one’s life is no longer worth living, while others believe that human dignity is best protected by not allowing people to decide when they wish to die. Another proposal is to avoid substantive moral issues in legislation and to concentrate on safety issues and quality issues. Patients all over Europe have the right to be protected against incompetence, negligence and recklessness against practitioners. Quality standards regarding donor screening, cryopreservation, success rates complication rates etc should be guaranteed.
The legal framework should only focus on licensing and controlling centers of assisted reproduction for ensuring homogenous and adequate standards.

For countries with little or no control on what happens in infertility clinics, it is difficult to verify the information and the standards are always not respected in countries where infertility clinics are ill regulated and ill controlled.

The most important point is to prevent unsuspicous patients from being lured into low cost clinics. It is education about general rules for evaluating certain information, like the need to take into account the multiple pregnancy rates when comparing the success rate of the clinics.

The awareness of the risks for mother and children of multiple pregnancies may also counterbalance the possibly increased request of couples who look for treatment abroad to replace more than one embryo. However, the preference to replace several embryos exist in all patients who know that they can have one or limited cycles.

Treatment abroad in this respect is probably not worse than expansive treatment than home. Although safety and quality standards are important and patients should be informed about the performance of the clinics, regulation on safety should be carefully screened to prevent trespassing on ethics.

There are two reasons for caution –

- Firstly, safety is primarily a moral and not a technical issue. It concerns the balance between benefit and harm and is expressed in principles like ‘responsible parenthood’ good clinical practice and the best interest of the child. Amoral standard is needed to evaluate the medico technical data. The choice of a standard is decisive for acceptability of treatment of options; some people accept no risk while others take a more lenient position. This is illustrated in the discussion on the prohibition of ICSI with surgically obtained sperm in the Netherlands or in the debate on the use of cryopreserved oocytes in the United Kingdom.

This directive is explicitly presented as a way to guarantee the safety and quality of human cells and tissues used for transplantation and therapeutic purposes, to safeguard public health and to avoid transmission of infectious disease.

Article 12 states that member states shall endeavor to ensure voluntary and unpaid donation of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences to donation.

- Payment has little to do with safety and quality; it is almost indirectly linked to safety of the tissues. Remuneration is a moral principle that should be discussed openly and should not be forced sneakily upon the member states.

- The European Council on Ethics also pointed out in its opinion on stem cells, although the European Union has no legislative competence to regulate research, some directives alludes to the issue of embryo research and use. For instance, the directive 98/97/EC on in vitro diagnostic medical devices provides that the removal, collection and use of tissues and substances of human origin shall be governed by principles laid down in the Convention.

- In this way member states have not ratified the convention, are indirectly forced to follow its principles.

4.5(xii). European Convention on Human Rights and Biomedicine

The European Convention on Human Rights and Biomedicine is an attempt to create uniformity of legislation on medicine across European countries. The convention has been widely criticized for its methodological and ethical deficiencies and political bias. (Mori and Neri 2001, Sass 2001) Moreover, the usefulness of a minimal European legislation that expresses consensus is unclear. If there is agreement on the prohibition of a certain treatment or on acceptability of a technique the individual member states can incorporate this point in their national legislation.

- Take sex selection for non medical reasons. In the Belgium law on research on embryo in vivo of 28th May 2003, an article stipulates that this application is prohibited. Article 14 of the convention does not add anything on this point.

The Convention contains a series of articles which are not acceptable for Belgium. If Belgium would want to ratify the convention now, it would have to make reservations for Article 13 and 18 of the convention.

Since no prohibition on the germ line therapy it is included in the Belgian law, and thereby the creation of embryos for research.
Instead of arguing that the member states should adopt the convention and make reservations about specific articles and provisions, it would be logical not to ratify, to introduce the points one accepts into one’s national legislation. This would also permit countries to change their minds. The present evolution is one directional; National states can grant a wider measure of protection than the convention, but after legislation be more permissive. If the competence of the member states regarding ethical issues is taken seriously, national law should take precedence over the Convention whenever it is voted.

The Italian law clearly illustrates that the convention is no protection against very prohibitive initiatives in particular countries, as some claim.

4.5(xiii). Political Apathy

People do not identify with Europe. A major problem for all European elections is to motivate people to vote. Every step that increases the distance between the citizens and the level of political decision making risks to political apathy. By lifting ethical issues to the European level, the citizens will feel that they have the competence to decide about deeply felt moral issues, that touch upon very private aspects of a person’s life and which are being taken away from them.

There is no unified culture and no core of substantive common values. However, this diversity should be valued not regretted. The wish to obtain homogeneity not only denies the richness of cultural, political and ethical differences, it also impedes progress towards a better regulation. The presence of other ethical codes and legislations in Europe renders it impossible to present a law self evident. When Sweden broke unanimity regarding sperm donor anonymity, in 1985, the other countries were forced to justify their laws on this issue.

The confrontation stimulates progress and public debate. Each country can learn something from the other, but with big difference that possible alterations in national legislation are based on persuasion and not on coercion. Moreover, each country constitutes a ‘natural experiment’ on a limited scale from which the others may collect useful information for their own legislation. The Council of Europe and other European institutions can play a beneficial role in stimulating discussion among national legislators and in disseminating information about alternative legal solutions.
4.5 (xiv). Registration of Birth

The law requires that all births must be registered and the willful making of false statement to the registrar when so registering a birth is an offence under s. 4 of the Perjury Act 1911 (under English Law). In most cases where a child is born as a result of AID, the mother in law, should not state that her husband is the father. In practice however, such a false statement is frequently made. The law commission agreed with the widely held view that it is unsatisfactory that married couples should be put into a position where they are strongly tempted to make a false declaration and commit perjury on registering the birth. Accordingly they recommended that a child conceived by AID with the husband’s consent should be registered as the husband’s child.

The concerns are -

- Many people regard this as unfortunate that society should be deceived by secrecy and deceit in concealing the true facts surrounding the birth;
- It is not in the interests of the child and the family to do so.
- Thus there is certainly a case for annotating the birth certificate to indicate the nature of child’s origin.

4.6 Infertility treatment; Creation of Rights and Duties and Obligations

The right to have ones biologically related child may not be absolute or positive, it is surely a negative right which entails responsibilities on part of others not to interfere with its expression. Justification for non interference is often articulated as privacy claims, as are many practices involving sexuality and reproduction. In general, these claims have their limits, but they represent prima facie obligations for others. The fact that an individual cannot have his or her own biological children without participation of another, who has the right to refuse, shows the fact that this right is not absolute.

The different roles played by male and female partners in infertility treatment suggest different rights and responsibilities on the part of each. The impact of gender socialization makes it even more difficult to determine whether women fully exercise their autonomy when they contend to procedures intended to facilitate reproduction. The clinicians are bound to ensure that consent to treatment is fully informed and free. Despite the possible pressure from others, it
is possible for individual women to disagree with others, including their partners and others in their choices for and against specific procedures that may be used in medically assisted reproduction. For some women, however, autonomy may be manifestly compromised.

The social and ethical challenge for the clinician is to maximize respect for the autonomy of the persons most affected by intervention.

The clinician should offer or provide a specific procedure to a couple or individual which may depend on many factors that may be irrelevant to the decision making of individual or couple. Some caregivers may be morally or religiously opposed to some methods of assisted reproduction; providing such assistance would be betrayal to their own moral values or beliefs. Some clinicians would have developed expertise with one technique but only limited expertise with another; they may be obliged to refer individual to another clinician if optimal treatment requires other’s expertise.

The responsibilities of clinicians and researchers are distinct. Researchers are primarily committed to obtain knowledge that may be useful for future patients. Clinicians are committed to the individual patient with whom they establish a relationship. Reproductive endocrinologists who are researchers as well as clinicians often face the conflict between the values of scientific knowledge, along with its potential benefits to future patients and the need or desires of particular patients or couples. The clinical obligations to current patient supersede the obligations of the researcher as, reflecting a priority of health over knowledge of immediate therapeutic impact over potential therapeutic effectiveness.

The people responsible for public policy have distinct responsibility than clinicians and researchers. If health is the goal in the world, infertility treatment of individuals or couples is probably not as important a need as detection and correction of environmental causes of infertility, which affect other areas of human health and well-being. Indeed, it may be argued that advances in reproductive technologies that facilitate and encourage an increase in world’s population, with little corresponding effort with regard to population control or restraint, ultimately
leading to further constraints on future generations as to quality of life which would be inferior in future.

Infertility treatment involves the participation of third parties as providers of gametes or gestation another role is added to the mix – another right may then be asserted – the right to have a child for another right to sell ones genetic material to another. These rights are negative imposing.

**Co relative Duties**

- Duty to disclose any known health risk that one’s gametes or gestational role might entail for the potential offspring.
- Contractual agreements are used to ensure that both rights and duties and duties are observed by all participants.
- However for some as a result of these arrangements, it is comparable to baby-selling.

**CONCLUDING REMARKS**

These technologies are socially controlled and they lead in principle for multiple choices in women, on the other hand these techniques are controlled by others including the State, religious leaders, the medical profession and men. The new reproductive techniques have a potential to reduce women’s role in procreation, and they make procreation or production of human life away from women’s bodies’ altogether. These techniques have redefined reproduction and have placed before us new dilemmas. They are responsible for change in our reproductive consciousness. There is a belief that conception can be perfectly controlled. NRTS techniques are controversial not only among feminists but among a wider public because they crystallize issues at the heart of society – contemporary controversies over sexuality, parenthood, reproduction and family, philosophical question of beginning of human life and so on. These techniques are being practiced at national and international levels by various groups like population control organizations, national governments the multinational drug industry, public and privately funded international bodies, medical researchers and health workers for promoting population policies, creating significant impact on the health and autonomy of women.
Reproduction has an individual and social dimensions. The individual dimension is based on the fact that pregnancies take place in women's bodies and on women's desire for control over their sexuality and fertility. However, the social dimension of reproduction is based on the fact that women are human beings and the reproduction fulfills the needs of the society. Obviously, there will be tension between individual needs and rights and society's need. Further, rights of women are to be determined individually and to be determined collectively as a group. Women's choices are made within a micro level framework of the specific conditions in which they live as they are based on several factors — gender relations, one's own income, adequate housing facilities, childcare information, or information regarding contraceptive methods and accessibility, affordability, and availability of services for the same. Their choices are made on a macro level framework of patriarchal structures which determine gender relations. Population control and Eugenics State policies. Therefore, political, cultural, social, and economic differences exercise a greater degree of control on women's lives. The influence of national and international population policies, health care infrastructure, the political climate in a particular country, the role of religion/religious leaders and culturally determined ideas about women and motherhood are significant factors. The different factors at micro and macro level which play a role are—

CULTURE

- Patriarchal ideologies have tried to control over women's sexuality, their reproductive labor power, property and other economic resources and control over women's mobility.
- Relation between man and woman culturally determined.
• Need for many children as labor power, economic earners, and financial security in old age, for acquiring social and emotional reasons.

• Role of religious institutions and their leaders e.g.; in allowing use of contraceptives and abortion or technology in field of reproduction.

• Family and motherhood ideology.

• Images and representation of women and their roles as prevalent in society and as projected by media.

SOCIO ECONOMIC CONDITIONS

• Within societies in the process of transformation and modernization, access to literacy, education and vocational training for women and their income are important factors. Lack of these means remain limited, mainly restricted to motherhood. Increase in fertility levels is seen to be generally followed by a decrease in fertility level.

• Access to health care which includes access to comprehensive reproductive health services (availability of methods for fertility and infertility management), and quality of care are crucial factors. High infant and child mortality rates discourage use of contraceptives.

• Childcare facilities, either at the level of the extended family or paid child minders and crèches.

POLITICAL FACTORS

• People’s participation in democratic processes are at different level. This includes women’s role in decision making at different levels. All these factors are interlinked and therefore must be considered for practice of reproductive techniques.
• The active and dominant group creating its impact on new reproductive techniques are –

• The State National governments of various countries make funds available for research on contraceptive methods and other reproductive technologies to organizations such as WHO, particularly its Special Programme for Research Development and Research Training on Human Development (WHO – Hrp), the Population Council and Family Health International Ministers of Health, Social Welfare and Justice, and the House of Parliament (In India and Netherlands) and Department of Family Welfare within the Ministry of within the Ministry of Health (in India) are various organs through which the State exerts influence.

• Conservative groups such as pro-lifers, Commercial firm’s particularly pharmaceutical companies.

• Religious leaders, --- Particularly the Roman Catholic Church, and Islamic Leaders – have considerable influence.

• Research organizations and research scientists.

• Print and broadcasting media – newspapers, magazines and specialized journals, television radio and internet. Women’s interest groups, particularly women’s health and (reproductive) rights advocates, and the feminist groups at local, national and international level. At the international level Women’s Health Coalition (WHC), Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) and The Women’s Global Network for Reproductive Rights (WGNRR) are among the networks which are active in this field and have a wide outreach and influence.

• Population controllers and develop mentalists who devise State -led anti and pro-natalist policies. These include a network of intergovernmental population control
agencies and semi public institutions such as World Bank and IMF etc which work at a macro level. These institutions are also financed by the national governments of different governments. In the field of population, their main objective is the reduction of population growth in ‘The Third World’. Women are seen as instruments to achieve these goals. These organizations finance large-scale projects in developing countries and exert a great deal of influence through financial pressures and regulations.

- While reproductive technologies can help women to achieve self determination and control over their bodies they can easily become an instrument of those in power to exercise control when used either within patriarchal ideologies of population control, based on women’s sexuality and fertility. Women become instruments of the interests and agenda population controllers, experiments by researchers and profit making manufacturers and providers of New Reproductive Techniques.
Footnotes


iii Olivennes F. Avoiding multiple pregnancies in ART Double Trouble; yes a twin pregnancy is an adverse outcome. *Human reproduction* 15; 1663 –1665 (2005)


ix Holy Bible; genesis 1; 28; 30; 1


xii Trounsan A; Preservation of Human Eggs and Embryos; Fertil Ster 46; 1, (1986) John A Robertson Baker and Bots Professor of Law; *Ethical and Legal issues in cryopreservation of Human Embryos The University of Texas, School Of Law, Austin, Texas*. (1986).


xvi Mc Gleenan T. *Reproductive Technology and the slippery slope argument; a message in Blood.*

xvii Guido Pennings. *Analysis Legal Harmonization and Reproductive Tourism in Europe.* (Reproductive Health matters 13 [25]; 120-128 (2005)

