Chapter VIII
Medical Negligence and Criminal Liability of Medical Practitioners

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Chapter VIII
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8.0. Prenatal screening for Genetic Abnormalities

The importance of genetically dependent diseases has risen as the control of those due to infection has increased. At present, the proportion of childhood deaths attributable wholly or partly to genetic factors runs at about 50%. And it is becoming increasingly clear, as work continues on Human Genome Project to map the genetic code of human species, that a genetic component may operate in many illness and conditions which were previously thought to be controlled by non genetic factors. Assessed from an arm of public health, the role of medical counseling plays important role with practical, ethical and legal problems. Modern genetic counseling involves more than merely quoting risks. The idea is to avoid a directive approach but rather, to concentrate on the psychological circumstances so that couples can be led to make decisions which are right for them. Almost, inevitably, the counselor’s opinion will be sought and how this is reached depends particularly on whether the counseling is retrospective or prospective. Parents are seeking advice because they already have an affected child or is the need for consultation prior to parenting based on information derived from other sources. The social, ethical and legal implications which advance in genetics have expanded and correspondingly today the genetic considerations are studied as a subject in medical jurisprudence. This topic discusses the role of genetic counselor and his liability for negligent failure to diagnose, disclose or treat genetic abnormalities. In order to acknowledge the role and liability of genetic counselor one has to understand and know about the genetic diseases.

8.1. Types of Genetic Diseases

On the basis of knowledge of several types of genetic disorders like chromosomal disorder, Down’s syndrome, hamaoglobinopathies, fragile X syndrome, neural tube defects, phenylketonuria. Geneticists try to predict future health. It is expected that
there is likely to be a greater demand for genetic screening as more and more conditions may be diagnosed prenatally and relatively early in pregnancy.

8.2. Genetic Screening

Genetic Screening is based on the principle that prevention is better than cure. It is now technically possible to carry out genetic screening for a number of disorders such as congenital anatomic defects, congenital hypothyroidism, Down’s syndrome, haemoglobinopathies, fragile X syndrome, neural tube defects, phenylketonuria, hypercholesterolaemia, prostatic cancer, cystic fibrosis and Duchenne muscular dystrophy. (Gezondheidsraad 1944/22).

Genetic screening may be carried out at different stages throughout life and through the use of various techniques. One aspect of genetic screening is preconceptional testing of potential parents by identifying their genetic traits, followed in certain cases by counseling on the risks of commencing a pregnancy. The aim is early detection of heightened risk of giving birth to children with a disorder which is untreatable and which could in (varying degrees) undermine the child’s quality of life and life span, depending on the severity of the condition. The other aspects are preconceptional testing of the embryo in assisted reproduction (IVF), referred to as preimplantation diagnostic (PID) prenatal testing of fetus during pregnancy, referred to prenatal diagnosis (PND) and postnatal screening, either of neonatal or in later life. Many of these tests are based on eugenic bias and on assumptions about the quality of life of people with a handicap.

8.3. Genetic Counseling

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

The role of counselor assumes an entirely different mantle, however if he privy to information of which his client know nothing – perhaps as a result of a confidential discussion with another health professional; the question then arises as to whether and how such information should be imparted. In assisting clients towards a reproductive decision, the counselor can virtually never make a firm statement as to having or not having a further child. He can take extraneous circumstances; e.g. religious or financial status – into consideration, but in the end he is down to speaking about probabilities. In the case of unifactorial disease, he can give accurate figures, e.g. – The chances of an overtly affected child are one in four pregnancies if both the mother and father carry recessive deleterious genes. The position as to chromosomal
disease is more complicated. In the usual circumstance, the condition is due to trisomy, in which three similar chromosomes are present in the cells rather than a pair, this is a chance, occurrence which cannot be predicted mathematically. Males with trisomy -21 or Down’s syndrome are commonly sterile but there is the theoretical risk that half the children of the female sufferer will also have the chromosomal defect; in practice, not only is such a pregnancy unlikely, but also, more than half of any affected fetuses would miscarry naturally. However, rather, 5% of Down’s syndrome patients are not trisomic, but instead, demonstrate a chromosomal abnormality known as translocation -parts of chromosome -21 are exchanged for those of another. This may also occur sporadically but passage to later generation is, thus, possible and its occurrence will be independent of maternal age.

The counselor must therefore, consider each sub-type of chromosomal disorder separately. In the event of a multifactorial condition, the probabilities can only be derived in an empirical fashion. Even then the prospects are subject to interpretation. Thus, presented with a child with spina fida, one can say there is a 10% chance that the couple will have a further child with developmental abnormality. But the choice rests with the couple and this choice is a product of their ability to understand and the skill of the counsellor. However the whole concept of genetic counseling is questionable.

It increasingly involves the systematic selection of fetuses and hence approaches children as consumer objects subject to quality control. The increasing ‘need’ for genetic counseling can be seen as being based on the increasing number of disorders which can be diagnosed and, according to Lippman (1993) “the definition of fetal imperfection will come to mean any condition which can be diagnosed in utero.”

The social and economic pressures on a woman to terminate a pregnancy once an abnormality is discovered in her fetus are such that her autonomous choice is severely prejudiced. These pressures would escalate if cost efficiency of genetic counseling service could be gauged and numbers of abortions were performed.

The House of Commons Science and Technology Committee found that, in Edinburgh, a prenatal test for late onset Huntington’s disease will not be offered to a woman who is herself afflicted unless she agrees to terminate if the test proves positive. The rationale is that the child is otherwise burdened by the knowledge of its early death. Yet, such a policy betrays an underlying attitude towards those affected
by such a condition and ignores the fact that they can enjoy many happy asymptomatic years of life. One thing is, however certain; no woman can be forced to destroy her fetus. The counselor has several advisory options; he can dismiss the risks, he can advise sterilization for either partner, he can put the option of artificial insemination by donor or of ovum donation, or he can arrange for a suitably controlled pregnancy coupled with the alternatives of live birth or abortion as conditions indicate.

8.4. Counseling and Negligence

The parents of an afflicted child may choose to raise an action in negligence against a genetic counselor or doctor who has failed to advise them of the risk of genetic illness in their children or to carry out and interpret correctly, appropriate diagnostic procedures which would have disclosed abnormality in the fetus. The counselors or doctors owes them a duty of care in which he or she has been found wanting; the parents may contend that, as a result they may have been deprived of the opportunity to terminate the pregnancy and they are now burdened with the sick or handicapped child. Such an action, brought by and behalf of parents, is generally known as one for ‘wrongful birth’. Damages may be sought in respect of the distress occasioned by the parents in respect of the existence of the defect in their child and for extra costs which are entailed in bringing up the child.

The Courts in United States which can be seen as pathfinders in this particular area, have had a roller coaster ride on their way to recognize damages for the birth of a handicapped child as a legitimate claim.

*In Becker V, Schwartz (386 NE 2d NY, 178)*

The New York Courts of appeal allowed a parental claim for damages in respect of the cost of the institutional care of a child suffering from a Down’s syndrome. The negligence in question was the failure of the doctor to recommend amniocentesis to a 37 year old mother, who by virtue of her age, had a relatively high risk of bearing a handicapped child.

The important conflicting questions are --;

1. The question of public policy which should in theory favor birth over abortion.

2. The woman’s prerogative to control her own body and the consequent acceptability of abortion is recognized

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

Even so, the causation problem remains. For example --

_Noccah. V. Burger 290 SE 2d 825 (Va, 1982)_

In this case, the Court awarded widely based damages for the birth of an infant with Tay–Sachs disease but costs concerned with child's funeral were disallowed on the grounds that the fatality was the result of hereditary factors rather than defendant’s negligence. The other difficulties relate to the fact that pregnancy has been actually sought in these cases. Should the damages be then awarded for reflecting the full costs of rearing a defective child or should they be limited to the difference in financial burden posed by a normal and handicap infant or should they extend to compensate for emotional distress?

These questions are fairly balanced by American Courts and it should be noted, that they will accept a wrongful birth action in principle in most cases.

Comparable cases have been rare in the United Kingdom but the Courts have shown increased willingness to address the problems in recent years and damages are awarded in respect of negligent counseling; in other words, a wrongful birth action is available in the United Kingdom.

_Salih v Enfield Health Authority (1990) 1Med LR 333; on appeal (1991) 7 BMLR 1, CA_

In this case, it should be noted that the trial judge awarded damages which included the basic costs of maintaining a child, the Court of Appeal, however held that the family had been spared the cost of a normal child and this head of damages was extinguished. The case involving the congenital rubella syndrome is apposite in this that the liability was admitted without question.

_Gregory V Pembroke shire Health Authority (1989) 1Med L R 81._

The trial judge found that the doctor's neglect to inform of the failure of amniocentesis was a breach of duty of care; the action failed however on the grounds of causation, the plaintiff being unable to convince the court that she should have had a second investigation had she offered one.


In this case the father was for the first time awarded damages in respect of alleged negligence of a health board which led to their two sons being born suffering from muscular dystrophy. The pursuers contended that, had they been referred for genetic counseling and testing a genetic disorder carried by his wife would have been
discovered and the couple would have chosen to terminate both pregnancies. The hospital failed to offer or conduct any tests despite the fact the hospital had been informed of a history of X-linked Duchenne muscular dystrophy among the male members of wife’s family. The children’s condition only came to light only when one of the boys injured himself in a fall. After a very comprehensive review of the case law, Lord Nimmo Smith held that there was no good reason to treat the pursuers as having suffered personal injuries in the conventional sense and he accordingly awarded damages under the heads both ‘solatium and parental loss’.

**McClelland v Greater Glasgow Health Board (1990 SC 305, 1999 SLT 543).**

The decision should be noted as to the matter of damages for solatium decided by the Scottish Courts. In this case, the father, was for the first time, awarded damages for the shock and distress he suffered as the result of the birth of a son suffering from Down’s suffering – as in Anderson, the hospital had been made aware of a family history suggestive of genetic disease but failed to offer an amniocentesis.

This ruling is unprecedented because it is normally the mother of the child who will receive damages for pain and suffering.

8.5. Legal action in respect of faulty procedures.

The basis of parental claim may be clear enough, but what is the juristic nature of the claim brought on behalf of the child itself. The status of the fetus in utero is legally established – the fetus has a general right not to be injured by the wrongful act of third party. This right was recognized at common law in Canada and in Australia in two important decisions.

**Duval V Seguin (1973) 40 DLR (3d) 666 and Watt V Rama ([1972) VR 353.**

Similar recognition is afforded to the fetus by the common law in Scotland and has been held retrospectively to have existed in England prior to Congenital Disabilities (Civil Liability) Act 1976.

The most important aspect of these rights in the present context relates to the responsibilities of the mother to her fetus. The Law Commission considered this question and decided that an action against its mother in respect of damage resulting from her negligence during pregnancy should not be available to a child. It was felt that a claim of this type would comprise the parent–child relationship and might also be used as a weapon in matrimonial disputes. Accordingly, the English legislation
excludes claims by a child against a its mother except as to injuries sustained during traffic accidents, especially on policy grounds and the availability of insurance were held to justify admissibility of such claim. It is difficult to determine the extent to which the mother's duty of care towards her unborn child might be held to limit her freedom of action during pregnancy. In recent years the fetal maternal relationship has been escalated.

A child born with abnormality may urge that some other sort of wrong has been done to it. First, he or she may claim that there was negligence prior to its conception and this negligence has resulted in its being born with certain abnormalities.

*Yeager V Bloomington Obstetric and Gynecology Inc (585 NE 2d 696, Ind, 1992)*

In this case new born suffered from brain damage due to hemolytic disease, this occurred because the hospital negligently failed to treat rhesus immunization of the mother during a previous pregnancy. The Court held it to be reasonably foreseeable that subsequent children would be injured as a result.

Such a claim would be competent under English law provided that, at the time of conception, the parents were not aware of the risk that their child would be born disabled.

The child may also bring a claim in respect of its wrongful life, the basis of claim is that, through the negligence of the defendant, the child's parents were not afforded to terminate pregnancy; as a result the child seeks damages for the impaired existence and he or she is forced to live brutally, he or she would rather never had been born.

The negligence in question may occur either before the child's conception, as for example, genetic counseling or after conception, where doctor fails to detect an abnormality in the fetus. A high proportion of such cases result from laboratory errors which are in general recognized as negligent. The early history of the wrongful life action can be traced through the United State Courts. Suits brought by defective children, however pose difficulties with which the American legal system has been struggling for many years.

*Gleitan V Cosgrove NYS 2d 687 (1967)*

The plaintiff was born deaf, mute and nearly blind as a result of his mother's exposure to German measles during pregnancy. The Supreme Court of New Jersey dismissed the plaintiff's claim for damages against the doctors who were alleged to have told the mother that there was no risk of German measles harming her child. The basis of dismissal was that its acceptance would amount to a statement that it was
better not to be born at all than to be born handicapped; it was logically impossible, the Court, felt, to weigh the value of a handicapped life against non-existence.

A year later, the claim of a child similarly damaged by its mother’s illness was rejected on the grounds that to allow a claim based on failure to abort the plaintiff would be antithesis of the principle of the law of tort, which is directed towards the protection of the plaintiff against the wrongs. The greatest wrong pointed out by the Court was to cause another person’s death. However, action by the parents for emotional shock, expenses incurred in rearing a defective child and the like have been successful.

*Robak Prokanik V Cillo 658 F 2d 471 (1981)*

This was a rare instance of wrongful life action being accepted; a main reason for doing so was that the parents were time barred and could not sue on their own behalf. In the line of common law jurisdictions, the American courts had to allow the neonate a suit for the prenatal injury while denying one for wrongful life.

*Turpin V Sortini 182 Cal Rptr 377*

In this suit the Court accepted the claim to special damages i.e., those incurred as a result of congenital defects but no general damages; the basis for the latter restriction lay in the still insoluble problem of comparing an impaired existence with not being born at all. The movement towards acceptance of the suit, has however been arrested and a definite trend of rejecting such suits began.

*Bruggeman V Schimke 718 P 2d 635 (Kan Rptr, 1986)*

The plaintiff averred that actions for wrongful life were recognized, the Court replied that this was simply not true and that any theory sustaining a legal right to be dead rather than to be alive with deficiencies was one completely contrary to the laws of the state. In practical terms, children are likely to be disadvantaged when an action for wrongful life fails. Since the Courts allow the parents to recover medical expenses in rearing a defective child, the child’s separate claim will apply only to expenses incurred after reaching majority, in most cases defect will be so serious that the damaged child will never reach that age. The United States and states legislatures have expressed their concern for birth over abortion and to this extent not only wrongful life but also wrongful birth actions may be rejected.

*Mckay V Essex Area Health Authority (1982) QB 1166, 2 All ER 771, CA.*

In this case the mother of the handicapped child had been in contact with the virus of German measles and had consulted her doctor. A blood sample was taken but this
was mislaid. A second sample of blood was taken and the mother was duly informed that neither she nor the infant had been infected with rubella; however the infant girl was found to be severely handicapped when she was born.

The plaintiffs alleged that there was negligence on the part of the defendants in that they either failed to carry out the necessary tests on the blood samples or failed to interpret them correctly. A number of claims were made as a result of alleged negligence, including claim by the child for damages in respect of entry into life of distress and suffering. The Court discussed the major issues of legal policy to which this case gave rise in an extensive judgment. The Court did not recognize the infant plaintiff’s claims to damages for wrongful life. The initial analysis was considered in terms of the duty of the doctor. The doctor clearly owed duty to the fetus — no to cause any injury to the fetus which was damaged by some agency for which the doctor could bear no responsibility, in this case by rubella virus. The only duty which court could see would be an alleged duty to abort the fetus and the question then to be considered was whether this could ever be legal. As to ‘wrongful life,’ that an obligation to abort.

Over here it would mean that the life of a handicapped child has less value than a normal child. Or was less valuable that it was not worth preserving; and it would mean that a doctor would be obliged to pay damages to a child infected with rubella birth who was in fact born with some mercifully trivial abnormality. These are the consequences of the basic necessary assumption that a child has a right to be born whole or not at all, not to be born unless it can be born perfect or normal.

Further if the abandoning principle of ‘wrongful life’ in favor of diminished life is compared, whether it is neonate’s current existence and non existence or with normality, but rather at the actual suffering being caused. There would have been no suffering in the event of an abortion as a result of negligence, and it follows that negligence had produced suffering which should be compensated according to its degree. The legal and philosophical arguments in favor of rejecting the wrongful life action are powerful but can be challenged. The apparently insurmountable hurdle on the road to acceptance lies in the more prosaic form of causation — it is undeniable that, save in exceptional circumstances, such as direct injury, no person has caused disabilities. Yet in an age, where compensation for injury is widely acceptable, it is difficult to see why the faulty genetic counselor should be protected and intuition urges that justice is thereby thwarted suffering, if not the cause of suffering has been
created by the negligence and to suffer is to be injured.

_Casse Civb 1, 26 March 1996, Bul Civ, 1996, 1, 156._

A handicapped child was born as a result of negligent failure to interpret correctly a pregnant woman's positive tests for rubella antibodies; had she been correctly counseled, she would certainly terminate her pregnancy.

In an action for breach of contract brought on behalf of the parents, the court of first instance found against physician and laboratory; and it found them to be liable to the child for the loss caused by his handicap.

The cour'd appel then followed precedent and while, confirming the decision in favor of Mme Perruche, overturned in favor of the child on the grounds of causation. The case went through a series of appeal and eventually referred to full Chamber of Cour de cassation who held that causation in child's case was demonstrated by the mother having been prevented from exercising her freedom to proceed to a termination of pregnancy in order to avoid a birth of a handicapped child, the harm resulting to the child from such handicap was caused by that negligence and he could claim compensation from it. The court was in addition, anxious to ensure that the child himself was compensated because that there was no guarantee that his parents would always support him. This unusual case disturbed the accepted medical jurisprudence in this area and caused political uproar in France. At heart, public rejection of the Perruche judgment was based on revulsion at the concept of being compensated for being born. It was attacked from anti abortion lobby by virtue of the stress laid on the woman's right to choose a termination of pregnancy.

Disabled support groups protested that it devalued the lives of the imperfect criticism was especially loud in the case of allied Down's syndrome decisions.

The medical profession rebelled and, indeed, went on strike at the thought of compelled to be 100 % right in their prenatal screening.

8.6. The Legal Position of the Clinician

The procedures involving gamete donation carry the risk that the gametes themselves may be defective. Moreover, all those involved in vitro embryo transfer introduce the additional hazard that the embryos will be damaged either by the hormonal treatment required for super ovulation or during manipulation and that an abnormal fetus will result. Animal experiments indicated that there is no higher incidence of
abnormalities in live born neonates resulting from re implantation than in those which are conceived normally. The HFEA’S Annual Report of 2000 quoted 120 children born as a result of IVF, DI or micro manipulation having developmental defects or syndromes – an occurrence of 1.3 % babies born, which does not indicate any increased risk. The outcome of litigation following such a misfortune depends very largely on proof of causation. However, the grounds rules are very clear. Section 44 of 1990 Act applies the Congenital Disabilities (Civil Liability) Act 1976; s. 1 is applicable to infertility treatment.

If a child resulting from embryo transfer, GIFT, micromanipulation of DI is born disabled and the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of embryo or the gametes used by person answerable to the child, then the child’s disabilities are to be regarded as damage resulting from the wrongful act of that person answerable to the child, and actionable at the suit of the child. This does not apply that if one or both parents knew of the risk of their child being born disabled; particular importance is, therefore, likely to attach to the effectiveness of their consent in respect of the information given. This opens the door to an action for ‘wrongful life’

Under the French law the parents of a child born with a disability which remained undiagnosed during pregnancy due to serious professional fault can claim compensation for harm suffered by them personally but not for costs attributable to the child’ being handicapped, these will be available through social service.

Medical practice involving the diagnosis and treatment of infertility is influenced by a variety of factors, ranging from community attitudes to the personal and moral judgment of patients and the health care professionals involved. There are various factors like statutes, judicial decisions, and the right to make procreative decisions, the right to privacy affecting influences upon infertility services. The law in some shapes the standards by which health care professionals must practice, or render their services to infertile couples.

By performing new techniques, physicians begin to bridge the gap between research and accepted clinical procedures. Some commentators argue that IVF, despite a decade of clinical application, is experimental because its long-term medical, psychological, and social effects have not been determined. A more common viewpoint is that IVF is now an accepted clinical practice rather than an experimental technology. Some of the more recently applied adjuncts to IVF, such as embryo
cryopreservation, preimplantation embryo genetic diagnosis, donation of embryos and oocytes, and in vivo fertilization followed by embryo transfer, are sufficiently novel and untested to be considered research, however clinicians' involvement with embryos can be differentiated from that of researchers who do not intend to transfer the embryo to uterus and whose inquiries go beyond the treatment of infertility. The former usually perform transfers to initiate pregnancy, and so safety to the potential offspring should be a concern to them. A separate provision within the Louisiana statute creates responsibilities for the physician. It provides that "any physician or medical facility who causes in vitro fertilization of a human ovum in vitro will be directly responsible for the in vitro safekeeping of the fertilized ovum." This statute forces physicians and health care institutions to be cautious in introducing new therapies because of the increased statutory responsibilities. The creation of extra liabilities and responsibilities impedes the availability of IVF and its adjuncts. A Kentucky statute allows public medical facilities to conduct IVF "as long as such procedures do not result in the intentional destruction of a human embryo." Thus the laws seem to require medical institutions to donate excess IVF embryos for implantation. An earlier Illinois law created a similar responsibility for physicians performing IVF.

*Smith v Hartigan, 556 FSupp 157 (ND Ill 1983)*

In this case many questions were raised with regard to the duties and liabilities of physicians. A couple who was being treated brought suit against the Illinois Attorney General. In response, the defendants indicated they would not prosecute physicians for all potential risks to the embryo. A physician would be in violation of the law only if he or she willfully harmed the embryo through abuse, mutilation, extermination, or destructive laboratory experimentation. Even these limitations put a chill on IVF programs. Subsequently the law was amended to provide an exception for IVF. Unless cryopreservation is considered to be part of IVF, however, the law may make embryo freezing a criminal offense. Physicians and clinics also face liability for discarding an embryo without the permission of the couple. That right belongs to the couple.

*Del Zio v Manhattan's Columbia Presbyterian Medical Center No -74-3588 (SDNY November 14, 1978)*

In a 1973 case, physicians at Columbia Presbyterian Hospital in New York City attempted IVF of a woman's egg with her husband's sperm. Without consulting
with the physician or the couple, the department chairman removed the culture and destroyed it. The couple sued the department chairman and the hospital’s trustees, charging conversion of personal property and intentional infliction of emotional distress.

The jury rejected the property claim but awarded plaintiffs damages for emotional distress. A couple has the third option with respect to excess embryos, either to sell or donate them to another woman. Sixteen states prohibit a woman from selling an embryo for experimentation; prohibit the donation of embryos or a fetus for research purposes. As embryo transfer after IVF or in vivo fertilization becomes standard clinical practice, these regulations would no longer restrict donation. Although the Louisiana statute prohibits the sale of eggs and embryos produced through IVF, it allows embryo donation. It states, “If the in vitro fertilization patients renounce, by notorial act, their parental rights for in utero implantation, then the in vitro fertilized human ovum shall be available for adoptive implantation in accordance with written procedures of the facility where it is housed or stored. No payment will be made to either party. A further provision prohibits the culture of human ovum fertilized in vitro for research “or any other purposes.” The statute still seems to ban embryo research. Thus it seems that excess embryos may be donated but only for implantation in another woman. Furthermore, the statute does not seem to resolve the ambiguity between research and treatment called into question by the fifth circuit case.

The doctor-patient relationship has changed dramatically over the years. The recent advances in reproduction and genetics in particular have reshaped this important relationship. Arguably, the move from medicine as an art to medicine as a science has colored expectations, raising hope on the one hand and promising despair on the other. In addition, it has raised enormous and weighty ethical problems, which also pose challenges for the law. Many of the dilemmas are confronting law and ethics.

8.7. Informed Consent

The ultimate decision regarding the use of infertility therapies lies with the individual or couple. There is a legal basis for allowing a patient to decide which treatment plan to undergo. Founded both in statutory and case law, the doctrine of informed consent protects the patient’s decision making and right to control her or his body. It is the legal and ethical duty of the physician to communicate with the patient so that the patient fully understands the treatment options. The informed consent doctrine
requires health care professions to provide sufficient information so that patients can make a knowledgeable decision about whether to proceed with a proposed procedure. Studies show that patients benefit both physically and psychologically from having such information. These benefits include furthering self-determination, checking against unnecessary or inappropriate procedures, aiding physician decision making, improving the physician-patient relationship, and speeding recovery. The goal of the communication is to ensure that patients receive relevant information so that they can evaluate the proposed procedure objectively and then apply personal values to reject or accept the recommendation.

Early court decisions on informed consent held physicians liable for operating on patients without their consent. By the late 1950 and early 1960s the courts' notion of informed consent included the requirement that patient must be told about the risk of a proposed procedure to make an informed decision. Current doctrine requires a physician to discuss the patient’s condition; the availability, risks, and alternatives of diagnostic procedures; and the availability, risks, and alternative of treatment procedures. Health care professionals providing infertility therapies should provide extensive information to the couple on the nature and risks as well as the potential success of the proposed procedure. Alternative means of treatment also should be discussed. The couple should be counseled together and individually to assure that one partner is not being pressured to undergo certain therapies. The institution should provide its success rates, because these differ widely for various programs, some programs not yet reporting a pregnancy. Information should be given to patients concerning embryo discard, storage, donation, research, and cost to themselves. The couple should be counseled to prepare a directive for embryo disposition in the event of divorce or death. The information should include which techniques are available; data on the risk of infection, spontaneous abortion, stillbirth, and so forth; an explanation of the psychological risks of participating in the procedures; and the type and purpose of research if it is being conducted. Federal law requires each assisted reproductive technology program to report pregnancy success rates to the U.S. Centers for Disease Control and Prevention (CDC), which shall make the information publicly available. The same law requires the CDC to develop a model program to be carried out by the states for the certification of embryo laboratories. Finally, the discussion should be concluded with solicitation of what the couple wants.

8.7 (l). Considerations of IVF In addition to the general types of information
regarding risks, alternatives, and so forth that must be disclosed about all proposed procedures, each reproductive technique raises special informed consent considerations. For example, the IVF protocol involves stimulation of a woman’s providing as many as 17 or more eggs per laparoscopic procedure. If all eggs were fertilized and re implanted into the woman’s uterus, the risks of multiple pregnancies to her and to the potential offspring would be immense. Usually only three or four embryos are implanted; hence the couple must decide what they want done with the excess embryos. The couple may decide to implant all the embryos (at which point the risks of multiple gestation should be explained, as should the possibility and risks of multi-fetal reduction), freeze the embryos for subsequent implantation, terminate them, donate them to another woman, or donate them for research. Whereas clinics previously limited the couple’s choice to implantation or termination, donation is now common.

8.7(ii). Considerations for Cryopreservation

If the couple is considering cryopreservation, the physician should explain to them the institution’s policies on how long preservation is allowed, the survival rate of embryos after thawing, and any physical or psychological risks to the resulting child that freezing might entail. The couple should also be asked for a written directive regarding the fate of the embryos if they divorce, decide against implantation, or if one or both die. If both die or if they file for divorce without directives about what will be done with the embryos, it is unclear who should make the decision regarding the embryos’ future. The issue of what should be done with the embryos of a couple going through a divorce was addressed by the Supreme Court of Tennessee.

*Davis v Davis, 842 SWD 588 (1992)*

The court held that when the preferences of the couple are unclear or are in dispute and when no prior agreement exists concerning disposition, the interests of the individuals in using the frozen embryos must be weighed. In addition, the court held that the party seeking to avoid procreation should prevail.

In contrast to the approach suggested by Tennessee case law, Louisiana, by appointing the physician as temporary guardian, might make him or her responsible for embryo disposition decisions. If cryopreservation becomes more common, it could be considered negligent for a physician to discard embryo. For example if 5 embryos are produced, 3 are implanted and the other 2 destroyed but the three
implanted embryos do not develop into a pregnancy, the woman might claim that her physician negligently interfered with her chance of producing a child by discarding the additional embryos rather than freezing them. This could especially be critical if eggs are obtained as a result of ‘‘last chance’’ operation (for example; before a woman undergoes radiation therapy or hysterectomy).

8.7(iii). Consideration for Embryo donation. The physician should discuss the risks involved with embryo donation with the donors. There are two types of donors; those who have completed their families and are donating embryos so another woman may have a family and women undergoing infertility treatment who through, therapy procedures have produced excess embryos. Women who have fulfilled their own child bearing needs should be counseled about the physical risks associated with embryo donation, such as infection, permanent scarring and other side effects. In addition to these physical risks, women who undergo infertility therapy must be counseled on psychological risks of donation. At first the physician should make sure that there is no coercion of the woman or couple to donate an embryo, participation in an IVF program should not be limited to women or couples who agree to donate excess embryos. The physician must counsel the woman to consider the emotional risk of donation in case if she herself does not achieve a pregnancy. Donors should also consider the risk of the resulting child’s potential emotional reaction on learning of the existence of a biologic parent with whom he or she will have no contact. These considerations for IVF, cryopreservation and embryo donation arise in addition to the required informed consent disclosures. They point to the increased complexity of decision making in the area of medically assisted reproduction compared with other medical advances, because they involve caretaking decisions for potential or newly created life in addition to the preservation of an existing life.

8.8. Physician Involvement

Physician involvement in artificial insemination by donor (AID) is not medically necessary; nonetheless some statutory enactments require physician supervision. There are 16 related statutes which assume the fact that AID will be performed by or under the supervision of a “licensed physician or certified medical doctor” or person; duly authorized to practice medicine. Because AID is a relatively simple procedure and involves minimal risk, the statute that require medical assistance raise questions whether its performance by someone other than physician (such as husband, lover or donor) will have different legal consequences that prevent the
consenting husband from taking on, and the consenting donor from relinquishing parental rights and responsibilities. The California Artificial Statute states "If under the supervision of licensed physician and with the consent of her husband, a wife is inseminated artificially with the semen donated by a man who is not her husband, the husband is treated in law as if he were the natural father of a child thereby conceived. This type of statutory language raises questions about whether the consenting husband is the legal father when a physician is not involved in the procedure. In that case, however, more general statutory provisions regarding paternity would usually give paternity rights to the husband. [Cal Civil Code; 7005 (a) (West 1983)]. The statutory requirement for physician supervision however can cause problems when AID is performed by a non-physician involving an unmarried woman. Some unmarried women have trouble finding physicians who will agree to perform the procedures for them. Their alternative is to find a donor through a network of friends and acquaintances.

*Jordan C v Mary K, 179 Cal APP 3D 386 222 Cal RPRTR 530, 535 (1986)*

In this case, an unmarried woman privately selected a sperm donor and performed the insemination in her home by herself. The sperm donor was listed as the father on the child's birth certificate. He filed an action to establish paternity and visitation rights. The appellate Court scrutinized the statute, which said, "The donor of semen provided to a licensed physician for use in artificial insemination of a woman other than the doctor’s wife is treated in law as if he were not the natural father of a child thereby conceived. The Court held that because the semen was not provided to the physician, the donor was the legal father of a child thereby conceived and granted him visitation rights. The Court however noted that the fact that physician involvement was necessary for screening of the donor and to obtain his medical history.

8.9. Quality Assurance

8.9 (i). Personnel Qualifications

The patients have relied on traditional tort system to ensure minimum level of quality by bringing a medical malpractice claim. The American Fertility Society (AFS) and the American Association of Tissue Banks (AATB) are professional organizations. They have enumerated guidelines for the performance of reproductive techniques by the physicians and the standard of care that must be met. A Louisiana law codifies such standard by specifically addressing the qualifications of professionals and
standards for facilities performing IVF; the facilities must meet the standards of the American Fertility Society and the American College of Obstetrics and Gynecologists; the director of the facility must be a “medical doctor licensed to practice medicine in this state and possessing specialized training and skill for “in vitro fertilization” and the physician performing such techniques are required to act in conformity with the standards established by the American Fertility Society or The American College of Obstetric and Gynecologists.

8.9 (ii). Screening The statutes that generally address reproductive technology have paid no attention to medical, genetic and psycho logic screening of patients. The development of surrogate motherhood has caused lawmakers to consider the issue and to rethink previous laws on donor insemination. Medical and genetic screening of patients is necessary to protect the health of recipients and the resulting child. A psycho logic assessment may be necessary to determine whether participants are voluntarily and competently entering into alternative reproduction. At least 10 statutes address sperm donor screening. Laws in Idaho and Oregon provide that a person who knows he has genetic defect or venereal disease may not be sperm donor but they provide no requirement that the donors be screened for human immunodeficiency virus (HIV). Under an Ohio law, the donor of fresh semen must undergo a physical examination, give a medical and genetic history, and be tested for blood type and Rh factor. The donor of fresh sperm must undergo appropriate laboratory studies, which may include, but are not limited to venereal disease, Karyotyping, (gonococcus), culture cytomegalovirus, hepatitis, kem-zyme, Tay – Sachs, sickle cell anemia, urea plasma, HTLV-III and Chlamydia. Although few statutory guidelines exist, physicians would face tort liability if they did not undertake proper screening of donors. Failure to do so could leave a physician liable for physical and emotional harm experienced by a recipient on her offspring as a result of transmission of disease.


The surrogate was artificially inseminated with the contracting man’s semen. The surrogate had however, engaged in sexual relations with her husband, and the child to whom she gave birth actually had been fathered by her husband. The child was born with a cytomegalovirus (CMV) infection that resulted in severe birth defects. The surrogate mother brought suit against the attorney arranging the surrogacy procedure, another attorney involved in establishing surrogacy arrangements and the physician
for damages that arose when the child was born from several birth defects. The child’s parents alleged that the mother had contracted CMV infection that was never tested for a sexually transmitted disease, nor was the semen sample tested. The U. S Court of Appeal for the Sixth Circuit considered the matter. The Court held that the duty to protect the surrogate mother from harm may have been breached.

The American Society for Reproductive Medicine (ASRM) and the American Association of Tissue Banks (AATB) have developed extensive screening guidelines. They are - ASRM suggests exclusion of sperm donors who are at the risk for having sexually transmitted diseases. They also suggest re-screening every six months and discontinuing the use of a donor if he has a sexual partner or if there is a break in monogamy or abstinence. The guidelines also recommend rejection of donors with a family history of certain enumerated genetic disorders as well as carriers of those disorders. The AATB Reproductive Council standards recommend selection of donors on the basis of “personal, physical and genetic examination and history”. The guidelines mandate rejection of a sperm donor if he is employed in a job that involves chemical or radiation exposure or if he is an alcohol or drug abuser. Screening for infectious and genetic diseases should be conducted on egg or embryo donors as well.

Federal law requires assisted reproductive technology programs to report annually to the Secretary of Health and Human Services pregnancy of the program with each reproductive technique. The report must also disclose the identity of each laboratory used by the program and whether such laboratory is certified. As a part of certification standards, each lab shall follow a standard program for quality assurance and quality control. The Federal law grants the CDC authority to develop, inspect, and administer the certification program. The CDC has unofficially adopted the ASRM – College of American Pathologists (CAP) Certification program.

8.10. Record Keeping and Confidentiality

Record Keeping

Confidential medical records should be kept so that identity of all parties, their medical and genetic histories of donors and surrogates is provided to the couples or individuals who seek for assisted reproduction. An Ohio law requires substantial but non-identifying disclosure about sperm donors. The physician is required to provide to the recipient and her husband upon their request the medical and genetic history of the donor and the people related to him. Blood type, Rh factor, race, eye and hair color, age, height, weight, educational qualification, religious background and any
other information that he donor has indicated may be disclosed. Efforts at record-keeping of gamete donors have been minimal. Failure to keep adequate records presents the chance of harm to all parties. If a child is conceived with donated egg or sperm and has a medical problem due to a genetic disorder passed on through the donated gamete, without adequate records there is no way of identifying the donor to prevent using him or her for subsequent pregnancies. If the resulting child develops a medical problem that requires donation of genetically compatible organic material (such as a bone marrow), if records are incomplete the child may be prevented from contacting a potential donor. Reluctance by clinicians to keep records may stem from the fear that if the donor could be identified, they might be held financially liable for the child. Physicians may argue that record keeping is burdensome task that diverts resources away from patients. Physician’s duty to keep records may be based on tort principles and code of ethics. A number of states require by statute that physicians keep records about donor insemination. The Ohio Law requires physicians to maintain a file for at least 5 years, separate from any medical chart that includes the written consent information provided to the recipient. Infertility programs must document whether they have in fact achieved a pregnancy and their pregnancy rates. An analysis of such programs provides the data to meet the requirements for informed consent.

In addition to physicians and clinics keeping records about the participants in medically assisted reproduction (including donors and surrogates) and about resulting children, the state might have an interest in keeping information about the extent of use of alternative reproduction, the number of attempts and rates of pregnancy, miscarriage stillbirth, live births and birth defects. Finally state record-keeping could include maintaining a voluntary registry so that if both sides agree biologic children and their siblings or parents can be identified to each other. Some states already have legislation that sets forth record keeping requirements for specific procedures. Three states require physicians to file information on the birth of children conceived through AID (Connecticut, Idaho, and Oregon). The Artificial Insemination statute states of 10 states (Alabama, Colorado, Minnesota, Montana, Nevada, New Jersey, New Mexico, Washington, Wisconsin, Wyoming) require physicians to file with the appropriate state department the dates of all procedures they perform. Pennsylvania has such requirement for IVF but not for AID. Anyone conducting IVF is required to file reports with the Department of Health, including
the names of everyone assisting in the procedure, the location in which the procedure is performed, names and addresses of sponsoring individuals or institutions (except the names of donor recipients of gametes), the number of ova fertilized, the number of embryos discarded or destroyed and the number of women in whom the embryos are implanted.

**Confidentiality**

State laws protect the physician patient relationship by providing the disclosure of confidential information is ground for revocation of the physician’s medical license or a basis for other disciplinary action. An ethical duty exists, founded on Hippocratic oath, or the judicial ethics of the American Medical Association, that is paralleled by a legal duty set out in disciplinary or testimonial privilege statutes in most states. States that mandate filing husband’s consent to AID procedures also protect the confidentiality of such information and the privacy of the individuals. The information generally confidential, may be opened by a Court "for a good cause" shown. The extent and protection of confidentiality varies among jurisdictions. The Ohio law provides that the physician maintaining a file on AID “shall not make this information available for inspection by any person” unless a Court determines that inspection is necessary for or helpful in the medical treatment of a child born as a result of artificial insemination.

### 8.11 India - Misuse of ART in Indian Scenario

Infertility treatment is very stressful for the patient and counseling is of utmost importance. Most clinics do not have pre counseling and post counseling facility for couples during IVF procedures. There are no laws regarding the (misuse) of ART or use of donor eggs and sperm in India. The doctors feel that just assigned contract or a waiver form is enough. They believe that regulation should suit the needs of everyone. Implementing ethical guidelines would mean that the doctors would have to look critically at issues of “informed consent”, screening of donors, legal issues and the quality of services provided.

**Sperm Banks—; Donor** semen is becoming increasingly accepted option. In spite of a growing demand for medically assisted reproduction, particularly AID and IVF, there are only a handful of sperm banks in India. WHO guidelines do not support for use of fresh semen especially due to anxieties regarding sexually transmitted diseases including HIV/AIDS. A major problem is to ensure a regular supply of liquid
nitrogen (tanks have to be replaced every 3 – 4 days) without which the extremely low temperature at which the semen has to be stored cannot be maintained. There is some controversy, when the first sperm bank in India was started. Dr. Geeta Pandya claims she started the first one at Jaslok hospital in Mumbai in 1974. The Malpanis, a young husband and wife team who specialize in infertility treatment, started a sperm bank in 1990 and got their first six donors through an advertisement in the newspapers. There are 3 – 4 semen banks in Delhi but they supply fresh semen as they do not have the facilities for storage and preservation. Delhi’s first sperm bank for cryogenically frozen sperm called ‘Cryo –Gene’ was established in 1994. A quarantine period of 180 days for sperm is mandatory, according to Dr. Bhashini Rao, one of its directors. Usually one ejaculate of sperm is used to inseminate a maximum of three women. This measure is practiced in order to prevent incestuous relationship afterwards. In recent years some sperm banks of dubious quality have sprung up due to the huge demand. There is an apparent shortage of good quality sperm, in spite of a handsome payment which is made to donor to defray what the Malpanis call “travel expenses” Donors are generally discouraged by the long battery of laboratory investigations that need to be performed before a donated sample can be declared safe for use. Donors are tested for sexually transmitted diseases (including HIV/AIDS), hepatitis, blood group, genetic disorders, as well as IQ levels standard which has been laid down by the American Fertility Association. Their height, weight, complexion are also recorded. International standards require that only those who have produced two normal children should be accepted as donors. Yuppie donors are considered rather attractive and many specialists believe that their genes might confer a certain advantage on the child. Young medical students are often used as donors. The identity of donors is not revealed as specialists anticipate complications such as paternity suits or blackmail later on. However, not all medical laboratories work according to such high standards or as honestly, so that they maybe able to make quick profits. According to a report some diagnostic laboratories in Delhi are using unsuspecting men as donors for artificial insemination. Those who go to lab for various tests are made to undergo a semen test as well, or if they go for a semen test they are called back on the pretext that additional tests are needed. When a woman comes with a problem of being unable to conceive, the semen of her husband is also taken for examination. If his semen is found to be healthy, his address is noted and whenever there is a demand from a gynecologist for a sperm, he is called back for
further examination and his fresh semen is collected and used for artificial insemination of other women. Another report speaks of a similar malpractice in Bombay. Gynecologists eager to cut costs and effort have found pathology laboratories prepared to supply them with fresh semen, which they would otherwise throw away after the mandatory tests. Gynecologists do not consider setting up sperm banks, where sperm can be frozen up for later use, as cost effective. Besides the success rate with fresh semen is considered higher. Some doctors speak of having ‘cultivated’ their own donors over a period of time. Many doctors use the same donor to inseminate a large number of women and do not match physical characteristics of the donor with the woman’s husband properly. The Malpanis believe that legislation cannot catch up with the extremely lucrative business in infertility, and one has to rely on self regulation and upholding of ethics by people in the business. Women seeking artificial insemination are injected about once a month on the most fertile days of their cycle. Most women have the process repeated every month, for about six months, unless they conceive earlier, and are willing to go on as long as it is required. The costs are about Rs 1,000 per insemination. The success rates vary between 50 – 60 % (At present the rate are Rs 3,000 to Rs 3,500 per insemination). Most doctors are now recommending artificial insemination in place of adoption, as in this way at least one partner is involved in the birth of the child. Also, more men seem open to the idea of their wives being inseminated with donor sperm, as long as this remains a secret. However, some consider it unethical on moral grounds.

**Microscopic Tuboplasty** – Recently there has been a boom in India in the use of microscopic tuboplasty, an operation to surgically reverse tubectomy. The success rate of this surgical operation is claimed 60 -70% higher than achieved by surgery without use of special microscope. This operation can be useful in infertility treatment, or a first trial treatment before starting with IVF, but most doctors carry out this procedure only on women who have undergone tubectomy. The emphasis is on the reversibility of tubectomy, as doctors feel that more women will be encouraged to be tubectomised if they are assured about its reversibility. Therefore, of policy level, preference is given to women who have undergone tubectomy and then desire to have more children. Either because they have unfortunately lost a child, or because they have remarried and want to give their husbands biological
children. Women who are infertile because they have some problems with their tubes, either due to some infection or adhesions, are directed straight to IVF programmes, while the trained doctors wait with their specially imported idle microscope for women who are earlier tubectomised to come for this reversal surgery.

8.12. IVF in India: A Lucrative Growth Industry

India has many infertility clinics however the facilities and the quality provided by these clinics do not match with similar clinics anywhere else in the world, the unfortunate element being is the lack of inadequate facilities and the staff. It is widely known that many clinics, including some of those that have excellent facilities and staff, engage in number of unethical and illegal practices as depicted in examples below. Further lack of a system of supervision and accreditation and supervision of clinics that handle gametes in vitro and practice ART, has the potential of leading to several undesirable situations.

The following examples are:

1. Many instances are known where a patient has only been given intra uterine insemination (IUI) but charged for in vitro fertilization (IVF). Such malpractices become possible in India because 70 % of the country is rural and about half the women of the country (a much larger proportion in the villages are illiterate). The situation is made worse by the fact that the average per capita income in the country is about the lowest in the world, if one takes away the upper creamy layer of the society which, says pays tax and represents a very small proportion (less than 5 %) of the population. Therefore paying for IVF when only IUI has been done on an infertile couple, must cause an immense financial strain on the couple. Often people in villages sell their land and /or other assets to come to an infertility clinic. It would therefore not only be unethical, but even criminal from social point of view for such a couple to be charged for IVF if only IUI has been done.

2. Advertisements:

There have been advertisements in the Indian newspapers by ART clinics saying that their success rate in IVF has been more than three times the average success rate around the world. Such clinics have been clearly misleading the people through such an advertisement to gain advantage over other infertility clinics.

3. There have been advertisements in the recent news papers by infertility clinics by
stating that they can give a couple a child of the desired sex by pre-natal sex selection that is separation of the X and Y spermatozoa, when the fact is that no established technique yet exists which would separate X and Y sperm with hundred percent efficiency.

4. In many infertility clinics in the country today, there is no professional counseling available. There is no codified system to decide as to when the couple must be asked to give up the treatment on ethical grounds, and advised to adopt a child; instead the treatment are prolonged unnecessarily over a large number of cycles in spite of the fact that the gynecologist knows that the expense that the couple would be incurring would be in fructuous.

5. There is no way in the country to prevent such malpractice. Some gynecologists engage in artificial insemination by the husband’s semen (AIH) or by donor semen, when no adequate facility exists with the gynecologist for processing of semen, or for doing appropriate checks in case the semen has been obtained from outside.

6. The above mentioned practices adopted by the medico professionals, with specific reference to ART practices, perhaps incurs in fructuous expenditure of several hundred million rupees by the people of the country, most of whom would have sacrificed a great deal to be able to pay the expense of the treatment at an infertility clinic.

The socio legal issues are –

An important issue in the practice of ART in India is who would be the donor of the semen for AID. In this regard we must remember that a vast majority of population in India, still lives as apart of larger joint family.

Illustration

If a couple is infertile in India, the family lays the blame on the woman even though, about half the diagnosable cases, a male factor is the cause of infertility. The mother–in–law would, however rarely acknowledge in public that her son and not her daughter–in–law is at fault. The son’s infertile status is kept as a secret as far as possible. The daughter–in–law is then coerced by the mother–in–law to be inseminated by the semen of the husband’s brother or a close friend. The daughter–in–law would then undergo psychological stress for the rest of her life, including her pregnancy, on account of knowledge that the biological father of the child she is carrying is some one else and not her husband with whom she has sexual intercourse. In future quarrels between mother–in–law and daughter in law would occur. The
mother – in law may state that her daughter in law has committed adultery and name the person with whom adultery has been committed. DNA finger printing a well established technology in India will play the lead role in establishing the fact that the mother – in – law’s allegations are true and the child is no her son’s child.

As of today, the infertility clinics are not required to keep appropriate records, it will be very difficult for the daughter – in law to establish that she never slept with a man who is the biological father of the child and she was inseminated with the man’s semen with express approval suggestion of the mother in law. The National Commission for women, a statutory organization set up by the Government of India, expresses their opinion with regard to the anonymity of donor of semen in the above mentioned cases. According to the Commission, all sperm donation and egg donation must be anonymous. The next question being raised in the country to the practice of ART pertains to surrogacy. Who may act as the surrogate mother? Usually it is a close relative for example, the mother of the male partner or the sister of the female partner. Thus, in many cases in the country, a woman has given birth to he own grand children without incest. On the other hand, there are advertisements, in the newspapers, or for example, in the magazine –‘Women’s Era’, for surrogate motherhood. It is unethical to have a close relative act as a surrogate mother especially in Indian environment where family ties are very close. In a closely – knit family, the fact that the child was delivered by so and so will always be known to the members of the family and, eventually, to the child when it grows older. Carrying a child in one’s own womb is, in the Indian society, is the epitome of close relationship. Therefore, it would be difficult for a child and the surrogate mother, if they see each other everyday, for such a relationship not to come in the way of the child establishing the expected relationship with the biological mother, without confusion in the child’s mind. The best suggestion is to advertise for a surrogate, strike an appropriate financial arrangement that will adequately compensate the woman who agrees to act as a surrogate mother. Another relevant issue that is exercising the minds of the people in regard to surrogacy is whether or not surrogacy in India should be considered ethical if the reason is only convenience of the couple. There is a view that surrogacy by assisted conception should be considered only for those for whom it would be physically or. medically impossible or undesirable to carry a baby to a term, and for those who are perfectly capable of producing a child in a normal way but desire a surrogate because the woman does not want to go through the pregnancy for
in the sake of inconvenience, or for reasons such as break in professional service, or simply the risk of having one's vital static's affected.

The second major issue faced by ART clinics today in India pertains to donation of oocytes. The question is - As to who should be the oocyte donor. In India till date, it is a close relative from the side of man or woman. The idea of having close relative or friend of the family as donor of the sperm or the egg is that the entire story is kept within the family -family boundary.

**The issues are as follows—**

Do we need to have sperm banks that would also keep track (for example through appropriate advertisement) of possible oocyte donors against monetary compensation?

i) Should we need to encourage the system of egg sharing in which an, indigent infertile couple that needs financial resources for ART agrees to donate oocytes, to an affluent infertile couple wherein the wife can carry the pregnancy through but cannot produce her own oocyte, for in vitro fertilization with the sperm of male partner of the affluent couple, for monetary compensation that would take care of the expenses of an ART procedure. These questions need to be answered.

ii) In the joint family system surrogate mothering (social not biological), is common; widowed family members and older daughters also mother children. The social role fulfillment is stressed rather than the biological process of child birth. What would be the repercussions of renting a womb are likely to be in a society which puts self sacrificing motherhood on a pedestal.

iii) The next concern is about the rights of the child born through donation of a germ cell, to know as to who is his biological father or mother is, when the child attains adulthood, assuming that the sperm or the egg donation has been anonymous. In the Indian environment, it may both impractical and unethical to give the right to the child. Given the closeness of relationships in India, such a right would be psychologically unfair to the child, to the donor and to the couple who have brought up the child; the child of course must continue to have the right to know everything else (except the name and address) about the person who donated the oocyte and the
iv) Today the DNA finger printing is available which establishes the biological parenthood without any doubt. If DNA finger printing is to be done on the child, the child would become aware that the couple who brought up the child does not comprise both the biological parents of the child. This discovery for the child, all of sudden would alienate him from his parents whom he could accuse of deliberately hiding the truth from him. Therefore, there may be no harm in the couple’s telling the child at an appropriate time that he/she was born following anonymous sperm or egg donation.

v) Age of donors - What should be the upper limits – upper and lower for germ cell donation or surrogacy, and the number of times one can act as surrogate mother. Another issue is as to what the infertility clinics should do with the spare embryos which would be the main source of totipotent embryonic stem cells. As of today, there is no regulation in the country prescribing what should be done with such embryos.

vi) IVF treatment is extremely expensive, anything from Rs 50,000 – 100,000, (currently approximately US$ 1,500 -3000, although cheap by international standards) depending on the number of attempts necessary. As there is no system of health insurance and government hospitals do not provide the facility, people have to pay for it themselves. Although the first IVF baby was born to a lower middle class couple, who did not have to pay for the treatment as the technique was still in an experimental stage, IVF treatments in India are usually only for the wealthy. However, some people are desperate enough to raise the money required even if they have to sell their valuable assets. Doctors practicing ART should conduct research and survey for successful implementation of these techniques on patients. Sadhana Desai, an infertility expert from Bombay with over 25 years of experience says of the latest options available in the field of assisted reproduction that ‘patients are often confused by the alternatives they have, and so are the doctors’ Their social and working lives are disrupted and forced to revolve around doctors, clinics and hospitals. Sometimes this can take couples to endless maze of infertility clinics and cause considerable emotional strain in the process. But it seems many couples especially women seem to be prepared to pay the high price to be rid of what some
see as their body letting them down and others as the ‘curse’ of infertility, going through up to six cycles of treatment.\textsuperscript{vii}

\textit{A few states have passed law requiring clinics offering infertility services to register themselves, but there is no body which monitors the quality of services provided. The infertility industry is only one part of any unregulated private health care system which is based on profitability rather than need.} As in other nations these health services are capitalizing on cultural demands and people’s poverty, comments Dr Amar Jesani, coordinator of the Center for Enquiry into Health and Allied Themes and editor of the Journal of Medical Ethics. Critics also questions the role of State for its lack of providing health care to its citizens necessitating such incidents where economic pressure drive people to rent or sell their bodies or body parts. These technologies are offered as a choice. However, in a country such as India, where modern and, or hi – tech infertility treatment depends on the couples woman’s ability to pay, there is not much choice. Moreover due to lack of regulation and laws, there are concerns about the lack of professionalism and the safety offered. The total absence of monitoring and self regulation can lead to the misuse of ART and related technologies. India unfortunately, has a history of high female infanticide and sex – selective abortions of female fetuses. The new law against sex –selective technologies now includes technologies like pre implantation diagnosis, but it remains to be seen if it is deterrent. Legal battles regarding ART and surrogate motherhood have been going in the West, but it will not be long before similar problems are faced by the Indian society. A set of rational and consistent policies are required. There should be focus on non – technological solutions such as preventive measures for infertility, adoption of children of all sexes, raising consciousness to reduce the social pressures for biological parenthood and on protesting against perverse use of ART.

8.13. Pre natal Diagnosis in India –

In India, genetics is an underdeveloped field of science. Most of the research is being done in the field of biotechnology – in agriculture, to improve varieties of grains. There is relatively little research in human genetics. Scarcity of funds is one important reason. Genetic detection and counseling is done at some private clinics, but government hospitals, although involved in research do not provide detection and counseling. If a child is born with a handicap it is considered as will of the God by many people. In rural area infanticide is to occur or the child is abandoned. Genetic
counseling may be an important area to develop, particularly for people with a family
history of abnormalities or certain inherited diseases, with a history of recurrent
miscarriages, consanguine marriages, and for women over 35 years of age starting a
pregnancy. Counseling may be used to caution women against the use of medicines
during pregnancy, and warn against measures to be taken in the case of contracting
German measles, hepatitis, mums or malaria during pregnancy. It is estimated 5,000
children are born every year with the thalassaemia trait, who survive on periodic
blood transfusions. The medical cost for a child suffering from this disorder can be
around 10,000 a month. The only cure is bone marrow transplantation which is
extremely costly and few can afford it. There are number of spastic children 60 % of
whom have genetic disorder. In India, barring a few clinics, there is no written
information in the form of brochures provided to the clients giving medical
indications for pre natal diagnosis. In India, however, this test is used by majority of
the masses for determining the sex of the child, for preventing the birth of a female
child. The dangers of ART practices are prevalent. IVF is perpetuating the already
unethical practice of sex- selection abortions of female fetuses through methods such
as pre implantation diagnosis. IVF specialist offers this as a choice to the couple and
do not believe that it amounts to perpetuating male domination and discriminating
against the girl child. One of the most important and disturbing implication of IVF in
the Indian context is the fact that a related technology can be, and is being, misused
for sex – pre selection and the existing law does not deal with it. The first National
Congress on Pre natal Diagnosis and Therapy was held in Bombay from 15th to 17th
December 1990. In India the technologies, originally intended for determining
genetic disorders have been used primarily for sex determination. Obviously there is
greater demand for these tests, so most of the genetic clinics use these techniques for
making quick money.

8.13(i). Sex (Pre) Selection Choosing the Sex of one’s Child
Interest in sex selection is very ancient phenomenon. The Indians, Chinese,
Egyptians and Greek manuscripts are testimony to this. Ideas on how to influence
sex pre conceptually varied from those about the timing of and position during
sexual intercourse and dietary stipulations, to the use of charms and amulets.
Renteln1992 discusses in detail, the use of some of these methods in different cultures historically. In every culture there were ‘old wives’ tales regarding how to influence the sex of the child before conception (sex pre selection) as well as how to find out the sex of the foetus once it is conceived. (Sex selection or sex determination.) A lot of it was based on trial and guesswork. At present there are reliable scientific methods for determining the sex of the child.

8.13(ii). Son Preference

Son preference is a reproductive choice, but not confined to India alone. Cross-cultural studies have shown a marked bias in favor of sons, and the birth of first male child (especially the first born) is announced and received with more exhilaration than what is only ‘a girl’. *Putrayeshthi yajna* (a fire ritual to pray for the birth of a son) in ancient India and the ritual of ‘son praying’ in Korea in the recent past are some of the examples (Williamson, N.E, 1976). Traditionally in most of the societies which are patriarchal; sons were preferred for economic, social and cultural reasons. In patriarchal and patrilineal societies, sons carry on the family name (patronymy), and, perhaps the craft, trade or profession, or profession help to maintain property within the family and are expected to provide for their parents in their old age. In contrast girls were given dowry at the time of their marriages. No payment was necessary for son’s marriage. Certain religious ceremonies in Hindus are to be performed by the males only. According to Hindu scriptures, sons are required to set fire to the funeral pyre of their parents, releasing them from the trammels of this world and ensuring their souls’ entry to heaven. With the birth of a sin the father is released from his debt to his ancestors. In matrilineal societies which were prevalent before the Vedic period and Aryan civilization, remnants of which are still to be found to some extent among the Nair’s in Kerala and certain tribes in different parts of India, women are said to have enjoyed the same rights as men. Son preference is found to have an adverse effect on the Indian Government’s goal to reduce fertility. Couples who have achieved their desired family size may not stop having children if they have not reached their desired number of sons. Although literate women have much lower levels of fertility compared to illiterate women, the influence of son preference is actually higher among literate women. ix

813 (iv). Female Foeticide

A son is considered as an asset, but a daughter is considered as a liability. There
is a proverb ‘Bringing up a girl is like watering a plan in the neighbor’s garden’. Many female children become victims of infanticide. In other cases, female fetuses are destroyed before birth through specific ‘foeticide’ or may be termed as pre –victimization (Janice Raymond 1989). Yet others die in more subtle way, through the consequences of abuse and neglect. This phenomenon of abuse and neglect is common to many cultures. Discrimination in girls occurs mainly in three areas – food, dispensation of medical care and allocation of love and warmth. In civil society neglect would mean denial of or lesser access to other ‘goods’ such as learning opportunities, formal education, and mobility and so on. All this can lead to retarded physical and mental growth, called ‘Deprivation Dwarfism’ (Gardner 1972 quoted in Miller 1981). In general lack of attention and care may lead to morbidity, and reduced mental and physical life chances. It may affect personality development, causing passivity, lack of assertiveness and low self esteem. Child abuse and neglect carried to the extreme may become fatal when this occurs in children less than one year of age it is termed infanticide.

8.14(v). Pre-Conceptional Sex Selection and Sex Determination In Ayurveda (ancient system of indigenous medicines) practiced in India, the sex of the foetus may be determined by the timing of the intercourse or through a special diet, and it can be even be changed in the early months after conception. A child of desired sex may be conceived through timing of sexual intercourse (even dates for male offspring, uneven for female). Another method for conceiving a male child is to crush the root of a plant called (Sveta Kantkari), mix it with milk and apply it to the right nostril of the pregnant woman. Thereafter, a tiny image of gold, silver or iron is burnt and dropped into a pot of milk and the concoction is given to expectant woman to drink. This ritual is called ‘Punasavana Prayog,’ literally Punasavana means conversion into male sex after conception has taken place. Some Ayurvedic specialists maintain that the sex of the foetus can be changed or manipulated up to four weeks after conception (Vaidya .S.S. Kopikkar, pers.com 1993). Based on Ayurvedic principles, For some years ‘Vasu Pharmaceuticals’, in Vadodara, in Gujrat was marketing (until banned) a product for sex selection Select -1 and Select -2 capsules were meant for consumption by a pregnant woman from the 45th day of her last menstruation for a period of two weeks. The manufacturers claimed that it would change the sex of the foetus from female to male or vice versa after conception (Ravindra 1990). It was recommended by
several renowned doctors, although modern medicines warn the use of any medication or drugs in the first trimester, as it can lead to deformities in the fetus. There are various technologies and methods for preconception sex selection and post conceptional sex detection. One such method is the Settles method, which takes into account of the different characteristics of androgenic and gynogenic sperm, which facilitate the desired pairing if carefully linked with the timing of ovulation and a favorable environment in the vagina, produced with an alkaline or acidic douche. (Parikh 1989). Another is to separate the sperm cells into male and female cells and afterwards to inseminate artificially with the sperm of desired choice. One way to achieve the result is by marking the Y – (male chromosome) with a fluorescent color. Thereafter with a laser beam, sperm cells are sorted out one by one in a cell sorter. It is a very expansive method as the apparatus costs around a million Dutch guilders. A more commonly used technique is to spin the sperm through a protein –based gel. This is called the Erickson method after it was discovered by Ronald Erickson, the American reproductive physiologist. Y-Chromosomes bearing sperm cells, are lighter and tend to swim faster to the top; X female chromosomes bearing sperm cells, are heavier, and sink to the bottom. By inseminating women with sperm which has been selected in this manner the conception of a desired child is sought. This procedure is said to improve the chance up to 75% normally it would be 50%. Dr Geeta Pandya of India’s Foundation for Research in Reproduction, is a franchise holder of Erickson technique. It costs about Rs 4, 000 per insemination. Once the sperm has been separated by using one of the methods mentioned above, the woman has to undergo ultra sound to pin point her ovulation timing. After that she is artificially inseminated with the sex –selected sperm of her husband or donor. The entire procedure may be repeated 3 – 4 times for ensuring pregnancy. If a woman conceives there are still 25 % chance that she may have conceived a child of the ‘wrong’ (in most cases, female) sex. Therefore, she would still have to undergo amniocentesis or chronic villi biopsy, and in the event of a ‘mistake’ an abortion or repeated abortions at the cost of her health.

Thus the argument that sex – pre selection is entirely non – invasive and non violent does not hold (Gupte and Duggal 1986). Further some gynecologists state that they were doing only ‘sex planning’(through diet, timing of intercourse within the menstrual cycle etc) especially after the government ban on sex
determination tests. Electronics has made sex selection easier. A new important gadget called CHISBO-FA-001 was introduced in summer of 1996 in South Delhi by 'Reach Marketing and Information Services' without much publicity. They claimed that it had been successfully tried out in China and had government approval there. In appearance like high tech digital alarm clock, it is based on regulating the time of intercourse with 'identifiable' points in the menstrual cycle, it is said to indicate with 98 per cent accuracy the chances of conceiving a boy or a girl on a given date. The CHISBO was based on the hypothesis that X and Y - chromosomes carrying the sperm have a different life span and motility. If coitus occurs at time of ovulation when the ovum is waiting for fertilization, the chances for conceiving a boy are greater as the Y -chromosome carrying the sperm would reach the ovum first. The use or marketing of such a gadget is not punishable under The Pre natal Diagnostic Techniques (Regulation and Prevention of Misuse Act). Women's rights organizations have called for amendment of the Act to cover such devices and also punish those who sell it under Magic Remedies Act. The distributors argue that such devices obviate the need for foeticide and saves considerable expenses by way of post conceptual diagnostic test and procedures. If people are able to choose the sex of the future child they may decide on a birth order, which has the consequences of psychological development of children; it can affect personality and life sciences. A large body of research exists which shows the firstborns are more enterprising, intelligent, achievement oriented, successful, and independent and have a higher sense of self esteem (Rowland 1984; Steinbacher 1981). Therefore people will choose males first; and girls will likely become younger sisters. In this manner sexism and male dominance will become institutionalized in birth order if parents preference for first born becomes a reality. The alternative method of detecting the sex of the foetus is Chorionic Villi Biopsy (CVB) enables sex determination in the third month of pregnancy. Sonography or ultrasound is also being routinely used for 'monitoring pregnancies and for sex determination. Some doctors are trying to sell this technique as a simple, accurate and safe method for finding out the sex of the fetus in the first trimester. Although there are spontaneous abortions, and scars on bodies of children born after amniocentesis; but many people undergo this risk for getting rid of 'unwanted daughters'.
8.15. A Girl or a Boy – Choice of the Woman

A survey of 71 medical geneticists in four developing countries, and 611 in 15 developed countries, found widespread willingness to use prenatal diagnosis for sex selection purpose. Sex determination is being justified by some thinkers not only for health reasons but as a matter of choice, which entitles parents to choose on their individual preferences. For many people who are against sex selection do not see anything wrong in eliminating male fetuses with sex-linked diseases. The degree of sex pre-determination through the use of sex selective abortion (and eventually sex-selective fertilization and implantation) depends on demand, supply and social influences such as eugenic ideology and policy. In the West, with changes in nuclear families there is increase in number of children being born outside marriage, patrronymy is giving way to more liberal legislation where a child on attaining a certain age may be able to choose between its mother’s or father’s last name. A law to this effect was passed in the Netherlands.

8.16. Amniocentesis Tests; Sex selective Abortions of Female Fetuses;

Abuse and Misuse of Technology - Amniocentesis was first introduced in India in 1974 at the All India Institute of Medical Sciences (AIIMS) in New Delhi to detect foetal abnormalities. By 1977, the test became popular for conducting sex selective abortions. The AIIMS stopped performing the tests in 1979, when the Government of India banned the misuse of medical technology for sex determination in all government institutions. Reports came from Mumbai and Amritsar of private gynecologists offering these tests. This marked the beginning of privatization and commercialization of the technology. Dr Bhandari of the New Bhandari Hospital in Amritsar announced his unique saving scheme in a handbill with a tempting slogan; ‘Spend Rs 500 now and save Rs 50,000 later’ which meant that a small amount could be spent now and huge amount of dowry will be saved later. This was called as sex selective abortions. The advertisement referred to daughters as ‘liability’ for the family and a ‘threat to the nation’ while coercing women to avail themselves of the services of the clinic to escape this danger. Prenatal diagnosis has grown into a thriving business of sex detection for the purpose of selective abortion of female fetuses in society where there is governmental pressure (family planning) on people to have not more than two children and preference for male children is very strong. Clinics providing
diagnostic facilities including amniocentesis and ultrasound scan mushroomed even in the remote corners of India. The techniques appear to become household words, even in rural India where people are illiterate and there is lack of basic amenities like clean drinking water and electricity. In rural India the age of woman’s average marriage and her first child is approximately 18 years and child bearing age ends by mid thirties. Unless there is family history of hereditary diseases is it really necessary for women to undergo amniocentesis tests. Often the conditions under which such tests are conducted are unhygienic. It could further lead to reproductary tract infections, thus bringing additional health risks. The rate of error could be high as 40% of unqualified medical staff (Chaterjee 1986, in Parikh 1989, p26). Most people are unaware that these tests are meant to diagnose birth defects but they know them as ‘sex tests or boy or girl tests’ New Bhandari Hospital made an error in detecting the sex of the foetus in 1982. In this case the lady was wife of an influential government officer. She was informed that she was carrying a female foetus, she was aborted, later it was discovered that the foetus was a male. The duped father informed the medial and the evil practice of sex determination. The matter came into limelight. In 1988, the State Government of Maharashtra banned these tests for the purpose of sex determination and in 1994 the tests were banned at a national level by the Government of India through an Act of Parliament. Dr Loomba, earlier working at the hospital in Amritsar, cashing in on the demand for sex determination tests, started his own genetic laboratory in Delhi. All leading newspapers carried the advertisement of his clinic with these wording ‘ Normal boy or Girl’ almost for several years particularly in Northern and North Western States – Uttar- Pradesh, Rajasthan, Haryana, Madhya – Pradesh, Punjab, Gujarat and Maharashtra (these States where preference of male child is higher). Courier services were used to send samples of amniotic fluid from rural clinics (not possessing the facilities for chromosomal analysis) to genetic laboratories in big towns and cities. In the last decade, several micro-level studies have been carried out in different parts of the country, where the practice of female foeticide is known, to determine the extent of proliferation, the profile of women couples who practice it and their attitude to it. Few significant data is quoted here. According to this data that is from 1978 to 1982, about 78,000 female fetuses were aborted after sex determination tests, a number of them were even in the second trimester (18 – 19)
weeks of pregnancy (Patel 1984). Another article in The times of India in 1986 revealed that almost 100 per cent of 15,914 abortions during 1984-1985 by a well known abortion centre in Bombay was undertaken after sex determinations tests. A survey done by Women's Centre Bombay, in six city hospitals revealed that at least 10 women went for these tests per day and of the total 8,0000 abortions, 7,999 were that of females. Between 1982—1986 the number of clinics offering sex determination tests in Maharashtra rose from 10 to 500-600 (This figure is quoted from the report of technical sub committee of the committee of experts appointed by the State Government of Maharashtra to study this issue). In 1985, 30,000 to 40,000 female fetuses were aborted in Bombay alone (Ravindra 1987, p 490). A study was conducted by Dr. Kulkarni (1986) a gynecologist at the Foundation of Research in Community Health (FRCH) in Bombay, at the initiative of State Government of Maharashtra revealed that 64.3% of gynecologist interviewed were performing amniocentesis solely for sex determination purposes. These 42 doctors together performed on an average 271 sex determination tests per month. Less then 10 percent of cases tests were conducted for detection of genetic defects. The majority of doctors stated that their clients came from the upper middle class, and a very small number from the lower class. In majority of the cases the women who came for the tests had two or three daughters, only about 10 per cent of women had one or sons (Kulkarni 1986). In 1991, about 100,000 female fetuses were aborted after sex determination tests. A memorandum submitted to the Prime Minister by the Women's Cultural Association of Ahmedabad in the state of Gujarat reported that out of 35,000 sex determination tests conducted about, 18,000 were followed by abortion. Some of the fetuses were sold to and exported to Europe for research and cell transplants (Kimbrell 1993). Studies were conducted to find out the background of women and couples opting for or showing an interest in sex selection and the fact is that women and men belonging to upper middle classes, and those having a better education, and that more than women men were keenly interested in these techniques and were willing to use them. A survey (with respect to occupation, socio economic status etc) was conducted in the city of Delhi regarding the social and moral aspects of female foeticide showed that a significantly higher percentage of female respondents (a total of 150) expressed a positive opinion of female foeticide. (Shah and Taneja 1991). This showed that
education alone cannot bring about changes in deep rooted patriarchal biases. A majority of doctors who offered sex determination tests claim that they were offering these tests as service to mankind (especially women) who did not want daughters. Dr D.N. Pai an influential figure in the Indian Family establishment strongly advocated the use of sex determination tests within India's family programme. In 1974 in Stockholm, Dr Pai, described amniocentesis followed by abortion of the female foetus as a possible 'solution' population growth 'problem' (Balasubrahmanyan 1986, p. 69). Amniocentesis is advocated as a method to so-called 'balanced family' this concept of a balanced family has a clear sexist bias. Sex determination tests do not guarantee the birth of a male child. Therefore, a woman is likely to have more abortions, not for medical or social reasons but to achieve so-called 'balanced family' The new slogan of the reproductive programme, NRR 1 (New Reproductive Rate of 1), not more than one daughter per couple with the logic that fewer women means less reproduction, is likely to exacerbate this practice. An important consequence of the use of such techniques for sex determination and preconceptional sex selection can create imbalance in female male sex ratios, especially in societies where a preference of a male child exists India has an already low and almost steadily decreasing female - male sex ratio in contrast to most developed countries 972; 1000 in 1901, 927; 1000 in 1991 (GOI 1991 Census figures). These practices of sex selection, and sex selective abortions of female fetuses, female infanticides are likely to have serious demographic repercussions in terms of tilting the sex ratio further against females.

The social consequences for girls and women of this unfavorable sex ratio are bound to be serious. Research studies on societies with adverse female sex ratios have indicated the presence of customs like polyandry (which in reality means being used by more men) abduction and purchase of women. Adverse sex ratios in future are bound to increase the incidence of rape, prostitution and violence against women (Mies1986; Lingam, 1989). In October 1985, The Forum against Sex determination and Sex Pre Selection Techniques (FASDSP) was formed. It was heterogeneous group of men and women with varied interests and backgrounds; feminists, women's health activists, lawyers, doctors, people involved in human rights, movement the People's Science Movement and so on. A campaign was launched by holding a workshop on 8th April 1986, in Bombay
where the technical, social, legal and social aspects were discussed. A counter-
advertisement campaign in Bombay’s local trains was mounted against the blatant
advertising of tests on bill boards in public places. This forum raised issues on
several planes – is on equality of sexes, health, human rights, democracy and
issues concerning decision making on vital issues like technology use, and in
particular reproductive technologies. They raised issues at an ideological level,
with regard to health of women. A private member’s bill was introduced in the
Maharashtra State Legislative Assembly to demand a ban on Sex Determination
Practice. The State Government set up an Expert committee on sex determination
and female feticide. The Secretary of the Department of Public Health also asked
The Foundation of Research Community Health to conduct a survey of sex
determination in Bombay. Campaign groups were set up in other parts of the
country as well, as demanding nation wide law. In April 1987, he set up an expert
committee to look into the issue. The FASDSP asked for a ban on the misuse of
sex determination techniques, while demanding proper use of these technologies
for detection of genetic abnormalities.

As a result of this campaign, sex determination tests were banned in State of
Maharashtra on 10 May 1988 under the Maharashtra Regulation of Use of Pre
Natal Diagnostic Techniques Act. This Act provided for regulation of genetic
counseling centers, genetic laboratories and genetic clinics. Pre-natal diagnosis
was to be conducted only for specified and under certain conditions. Offending
the law would be punishable by imprisonment, fines, and punishment by the State
Medical Council. This ban did not stop the lucrative business of sex determination
tests, it made it more expansive. Although a vigilance committee was formed, its
members (no member of the FASDSP was appointed) were ‘too busy’ to keep
any check on the practice. A forum against Sex Determination was formed in
Gujarat as well in which after a long drawn struggle, succeeded in getting an
improved version of the Maharashtra Act passed in Gujarat.

Finally on 26th July 1994 the Indian Parliament finally passed legislation for all-
India ban on these tests. Medical practitioners or laboratories performing the tests
for sex selection will lose their license to practice if found guilty. It makes the
woman asking for a sex determination test and her husband and relatives co-
offenders. The legislation has several drawbacks and loopholes – How will those who misuse the technology (both clients and providers) to be tracked down and convicted.

8.17 Medical Negligence and Criminal Liability of doctors in India.

It is estimated that 98,000 people die every year in the United States because of mistakes committed by medical professionals.

One can well imagine the figures in India. However, the law does not aim to punish all acts of a doctor that caused injury to a patient. It is concerned only with negligent acts. Medical negligence arises from an act or omission by a medical practitioner, which no reasonably competent and careful practitioner would have committed. What is expected of a medical practitioner is 'reasonably skilful behavior' adopting the 'ordinary skills' and practices of the profession with 'ordinary care'.

There is, however, room for ambiguity, and judicial interpretation as what is 'reasonable' and 'ordinary' is a question of fact. Essentially, doctors are generally bound to exercise an ordinary degree of care and not the highest possible degree of care. If a medical practitioner has taken reasonable care, then he cannot be held liable. A mere difference in opinion is not a ground for fastening liability on doctor.

Doctors' duties to their patients are clear. They must decide whether or not to undertake the case; they must decide what treatment to give, and they must take care in the administration of that treatment. A breach of any of these duties gives the patient a right to action for negligence.

8.17(i) Liability under the Consumer Protection Act

*Indian Medical Association v. V P Shantha AIR (1995) 6 SCC 651*

The Supreme Court in this case brought the medical profession within the ambit of a 'service' as defined in the Consumer Protection Act, 1986, by defining the relationship between patients and medical professionals as contractual. Patients who had sustained injuries in the course of treatment could now sue doctors in 'procedure-free' Consumer Protection courts for compensation. The Court held that even though services rendered by medical practitioners are of a personal nature they cannot be treated as contracts of personal service (which are excluded from the Consumer Protection Act). They are contracts for service, under which a doctor could be sued under Consumer Protection Act. A 'contract for service'
implies a contract whereby one party undertakes to render services (such as professional or technical services) to another, in which the service provider is not subjected to a detailed direction and control. The provider exercises professional or technical skill and uses his or her own knowledge and discretion. A 'contract of service' implies a relationship of master and servant and involves an obligation to obey orders in the work to be performed and as to its mode and manner of performance. The 'contract of service' is beyond the ambit of the Consumer Protection Act, 1986, under Section 2(1) (o) of the Act. The Consumer Protection Act will not come to the rescue of patients if the service is rendered free of charge, or if they have paid only a nominal registration fee. However, if patients' charges are waived because of their incapacity to pay, they are considered to be consumers and can sue under the Consumer Protection Act.

8.17(ii) Liability under the Tort Law

Under civil laws, at a point where the Consumer Protection Act ends, the law of torts takes over and protects the interests of patients. This applies even if medical professionals provide free services. In cases where the services offered by the doctor or hospital do not fall in the ambit of 'service' as defined in the Consumer Protection Act, patients can take recourse to the law relating to negligence under the law of torts and successfully claim compensation. The onus is on the patient to prove that the doctor was negligent and that the injury was a consequence of the doctor's negligence.

Such cases of negligence may include--

i) Transfusion of blood of incorrect blood groups.

ii) Leaving a mop in the patient's abdomen after operating.

iii) Unsuccessful sterilization resulting in the birth of a child.

iv) Removal of organs without taking consent.

v) Operating on a patient without giving anesthesia.

vi) Administering wrong medicine resulting in injury.

8.17 (iii) Liability under the Criminal laws

In certain cases, negligence is so blatant that it invites criminal proceedings. A doctor can be punished under Section 304A of the Indian Penal Code (IPC) for causing death by a rash or negligent act, say in a case where death of a patient is caused during operation by a doctor not qualified to operate.

_In Suresh Gupta (Dr) v. Govt. of NCT of Delhi (2004) 6 SCC 422_
The Supreme Court decided upon, the standard of negligence required to be proved against a doctor in cases of criminal negligence (especially that under Section 304A of the IPC) should be so high that it can be described as 'gross negligence' or 'recklessness', not merely lack of necessary care. Criminal liability will not be attracted if the patient dies due to error in judgment or accident. Every civil negligence is not criminal negligence, and for civil negligence to become criminal it should be of such a nature that it could be treated as gross negligence. Very rarely can a doctor be prosecuted for murder or attempt to murder as doctors never intend to kill their patients, and hence do not possess the required level of guilty intention. When doctors administer a treatment involving the risk of death, they do so in good faith and for the patient's benefit. A doctor can also be punished for causing hurt or grievous hurt under the IPC. However, Sections 87, 88, 89 and 92 of the IPC provide immunity from criminal prosecutions to doctors who act in good faith and for the patient's benefit. But the defense must prove that the doctor acted in good faith and for the patient's benefit. For example, a doctor who consciously or knowingly did not use sterilized equipment for an operation cannot be said to have acted in good faith. Doctors rendering infertility treatment to patients could be held responsible of criminal negligence.

Conclusion
The very nature of the medical profession makes it vulnerable to civil and criminal suits. Many suits are filed to harass doctors, or are filed to evade the payment of bills. In the post V P Shantha era it is difficult for doctors to shun responsibility. It is also easier for people to force negligent doctors to Consumer Protection Forums. It is important to punish guilty doctors. It is also important to protect doctors who act in good faith from harassment. The courts must strike a perfect balance.

**Paramananda Katara v. Union of India (1989) 4 SCC 286**
The Supreme Court observed that the doctor's job is to protect life and the courts should assist in this cause as far as possible. It is also the duty of the courts to see that doctors are not harassed in the course of performance of such duty. If a child resulting from embryo transfer, GIFT, micromanipulation of DI is born disabled and the disability results from an act or omission in the course of the
selection, or the keeping or use outside the body, of embryo or the gametes used by person answerable to the child, then the child’s disabilities are to be regarded as damage resulting from the wrongful act of that person answerable to the child, and actionable at the suit of the child. This does not apply that if one or both parents knew of the risk of their child being born disabled; particular importance is, therefore, likely to attach to the effectiveness of their consent in respect of the information given. This opens the door to an action for ‘wrongful life.’

The informed consent doctrine requires health care professions to provide sufficient information so that patients can make a knowledgeable decision about whether to proceed with a proposed procedure. Studies show that patients benefit both physically and psychologically from having such information. These benefits include furthering self-determination, checking against unnecessary or inappropriate procedures, aiding physician decision making, improving the physician-patient relationship, and speeding recovery. The goal of the communication is to ensure that patients receive relevant information so that they can evaluate the proposed procedure objectively and then apply personal values to reject or accept the recommendation. Negligence, recklessness on part of doctors to provide proper services to his patients would ultimately hold them liable under Consumer

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i Nuffield Council On Bioethics and Genetic Screening; Ethical Issues. (1993)
iii Robertson J; Embryos, Families and procreative liberty; The legal structure of the new reproduction. So Cal rev 59; 939, (1986).
vi American Fertility Society; Guidelines for Gamaete Donation. Fertility Steril 59 (Supp 1);


viii Ramola Talwar and Nancy P Corea, The plus point of pre natal tests, The Indian Express, Bombay 5/9/90

ix National Family Health Survey Bulletin; (1992-1993)

x Ravidra R. P (1990), traces the history of proliferation of sex determination tests and the campaign launched by FASDSP in India until the banning of tests in the State of Maharashttra and the further demand of all – India Ban. (He was member of the expert committee set on the issue by Government of India.)

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